Food and Drug Regulations

C.R.C., c. 870

FOOD AND DRUGS ACT

Regulations Respecting Food and Drugs

# PART A

# ADMINISTRATION

## General

A.01.001. These Regulations may be cited as the Food and Drug Regulations.

A.01.002. These Regulations, where applicable, prescribe the standards of composition, strength, potency, purity, quality or other property of the article of food or drug to which they refer.

A.01.003. [Repealed, SOR/94-289, s. 1]

## Interpretation

A.01.010. In these Regulations,

“acceptable method” means a method of analysis or examination designated by the Director as acceptable for use in the administration of the Act and these Regulations; (méthode acceptable)

“Act” means the Food and Drugs Act, except in Parts G and J; (Loi)

“common-law partner”, in relation to an individual, means a person who is cohabiting with the individual in a conjugal relationship, having so cohabited for a period of at least one year; (conjoint de fait)

“cubic centimetre” and its abbreviation “cc.” shall be deemed to be interchangeable with the term “millilitre” and its abbreviation “ml.”; (centimètre cube)

“Director” means the Assistant Deputy Minister, Health Products and Food Branch, of the Department of Health; (Directeur)

“inner label” means the label on or affixed to an immediate container of a food or drug; (étiquette intérieure)

“Lot number” means any combination of letters, figures, or both, by which any food or drug can be traced in manufacture and identified in distribution; (numéro de lot)

“manufacturer”[Repealed, SOR/97-12, s. 1]

“manufacturer” or “distributor” means a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug; (fabricant*or*distributeur)

“official method” means a method of analysis or examination designated as such by the Director for use in the administration of the Act and these Regulations; (méthode officielle)

“outer label” means the label on or affixed to the outside of a package of a food or drug; (étiquette extérieure)

“principal display panel” has the same meaning as in the Consumer Packaging and Labelling Regulations; (espace principal)

“security package” means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase. (emballage de sécurité)

SOR/84-300, s. 1(F); SOR/85-141, s. 1; SOR/89-455, s. 1; SOR/97-12, s. 1; SOR/2000-353, s. 1; SOR/2001-272, s. 5; SOR/2003-135, s. 1.

A.01.011. The Director shall, upon request, furnish copies of official methods.

A.01.012. The Director shall, upon request, indicate that a method is acceptable or otherwise upon its submission to him for a ruling.

A.01.013. Where a food, drug, vitamin or cosmetic has more than one name, whether proper or common, a reference in these Regulations to the food, drug, vitamin or cosmetic by any of its names is deemed to be a reference to the food, drug or vitamin by all of its names.

A.01.014. When a lot number is required by these Regulations to appear on any article, container, package or label it shall be preceded by one of the following designations:

(*a*) “Lot number”;

(*b*) “Lot No.”;

(*c*) “Lot”; or

(*d*) “(L)”.

A.01.015. (1) Subject to subsection (2), any statement, information or declaration that is required by these Regulations to appear on the label of any drug shall be in either the French or the English language in addition to any other language.

(2) The adequate directions for use required to be shown on the inner and outer labels of a drug pursuant to subparagraph C.01.004(1)(*c*)(iii) shall be in both the French and English languages if the drug is available for sale without prescription in an open self-selection area.

SOR/85-140, s. 1.

A.01.016. All information required by these Regulations to appear on a label of a food or drug shall be

(*a*) clearly and prominently displayed on the label; and

(*b*) readily discernible to the purchaser or consumer under the customary conditions of purchase and use.

# Analysts; Inspectors

A.01.020. and A.01.021. [Repealed, SOR/81-935, s. 1]

A.01.022. An inspector shall perform the functions and duties and carry out the responsibilities in respect of foods and drugs prescribed by the Act, and these Regulations.

A.01.023. The authority of an inspector extends to and includes the whole of Canada.

A.01.024. The certificate of designation required pursuant to subsection 22(2) of the Act shall

(*a*) certify that the person named therein is an inspector for the purpose of the Act; and

(*b*) be signed by

(i) the Director and the person named in the certificate, in the case of an inspector on the staff of the Department, or

(ii) [Repealed, SOR/2000-184, s. 60]

SOR/80-500, s. 1; SOR/92-626, s. 1; SOR/95-548, s. 5; SOR/2000-184, s. 60.

A.01.025. Where authorized by a regulation made pursuant to the Broadcasting Act, inspectors shall act as representatives of the Canadian Radio-television and Telecommunications Commission for the purpose of enforcing the provisions of regulations made by the Canadian Radio-Television and Telecommunications Commission concerning the advertising of any article to which the Proprietary or Patent Medicine Act or the Food and Drugs Act applies, or concerning recommendations for the prevention, treatment or cure of a disease or ailment.

A.01.026. An inspector may, for the proper administration of the Act or these Regulations, take photographs of

(*a*) any article that is referred to in subsection 23(2) of the Act;

(*b*) any place where, on reasonable grounds, he believes any article referred to in paragraph (*a*) is manufactured, prepared, preserved, packaged or stored; and

(*c*) anything that, on reasonable grounds, he believes is used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any article referred to in paragraph (*a*).

SOR/90-814, s. 1.

# Importations

A.01.040. Subject to section A.01.044, no person shall import into Canada for sale a food or drug the sale of which in Canada would constitute a violation of the Act or these Regulations.

SOR/92-626, s. 2(F).

A.01.041. An inspector may examine and take samples of any food or drug sought to be imported into Canada.

A.01.042. Where an inspector examines or takes a sample of a food or drug pursuant to section A.01.041, he may submit the food or drug or sample to an analyst for analysis or examination.

A.01.043. Where an inspector, upon examination of a food or drug or sample thereof or on receipt of a report of an analyst of the result of an analysis or examination of the food or drug or sample, is of the opinion that the sale of the food or drug in Canada would constitute a violation of the Act or these Regulations, the inspector shall so notify in writing the collector of customs concerned and the importer.

SOR/84-300, s. 2(E).

A.01.044. (1) Where a person seeks to import a food or drug into Canada for sale and the sale would constitute a violation of the Act or these Regulations, that person may, if the sale of the food or drug would be in conformity with the Act and these Regulations after its relabelling or modification, import it into Canada on condition that

(*a*) the person gives to an inspector notice of the proposed importation; and

(*b*) the food or drug will be relabelled or modified as may be necessary to enable its sale to be lawful in Canada.

(2) No person shall sell a food or drug that has been imported into Canada under subsection (1) unless the food or drug has been relabelled or modified within three months after the importation or within such longer period as may be specified by

(*a*) in the case of a drug, the Director; or

(*b*) in the case of food, the Director or the President of the Canadian Food Inspection Agency.

SOR/92-626, s. 3; SOR/95-548, s. 5; SOR/2000-184, s. 61; SOR/2000-317, s. 18.

# Exports

A.01.045. A certificate referred to in section 37 of the Act shall be signed and issued by the exporter in the form set out in Appendix III.

SOR/80-318, s. 1; SOR/90-814, s. 2.

# Sampling

A.01.050. When taking a sample of an article pursuant to paragraph 23(1)(*a*) of the Act, an inspector shall inform the owner thereof or the person from whom the sample is being obtained of the inspector’s intention to submit the sample or a part thereof to an analyst for analysis or examination, and

(*a*) where, in the opinion of the inspector, division of the procured quantity would not interfere with analysis or examination

(i) divide the quantity into three parts,

(ii) identify the three parts as the owner's portion, the sample, and the duplicate sample and where only one part bears the label, that part shall be identified as the sample,

(iii) seal each part in such a manner that it cannot be opened without breaking the seal, and

(iv) deliver the part identified as the owner's portion to the owner or the person from whom the sample was obtained and forward the sample and the duplicate sample to an analyst for analysis or examination; or

(*b*) where, in the opinion of the inspector, division of the procured quantity would interfere with analysis or examination

(i) identify the entire quantity as the sample,

(ii) seal the sample in such a manner that it cannot be opened without breaking the seal, and

(iii) forward the sample to an analyst for analysis or examination.

SOR/90-814, s. 3.

A.01.051. Where the owner or the person from whom the sample was obtained objects to the procedure followed by an inspector under section A.01.050 at the time the sample was obtained, the inspector shall follow both procedures set out in that section if the owner or the person from whom the sample was obtained supplies him with a sufficient quantity of the article.

# Tariff of Fees

A.01.060. The cost of analysing a sample other than for the purpose of the Act, for a department of the Government of Canada for the purpose of legal action is $15.

# Labelling of Food and Drugs in Pressurized Containers

A.01.060.1. In sections A.01.061 and A.01.062,

"flame projection" means the ability of the pressurized contents of an aerosol container to ignite and the length of that ignition, when tested in accordance with official method DO-30, Determination of Flame Projection, dated October 15, 1981; (projection de flamme)

"flashback" means that part of the flame projection that extends from its point of ignition back to the aerosol container when tested in accordance with official method DO-30, Determination of Flame Projection, dated October 15, 1981; (retour de flamme)

"principal display panel"[Repealed, SOR/2000-353, s. 2]

SOR/92-15, s. 1; SOR/2000-353, s. 2; SOR/2001-272, s. 6.

A.01.061. (1) Subject to section A.01.063, in the case of a food or a drug packaged in a disposable metal container designed to release pressurized contents by use of a manually operated valve that forms an integral part of the container, the principal display panel of the inner and outer labels of the food or drug shall display, in accordance with sections 15 to 18 of the Consumer Chemicals and Containers Regulations, as they read on September 30, 2001, the following information:

(*a*) the hazard symbol set out in Column II of item 10 of Schedule II to those Regulations, accompanied by the signal word “CAUTION / ATTENTION”; and

(*b*) the primary hazard statement “CONTAINER MAY EXPLODE IF HEATED. / CE CONTENANT PEUT EXPLOSER S’IL EST CHAUFFÉ.”.

(2) Subject to section A.01.063, one panel of the inner and outer labels of a food or drug referred to in subsection (1) shall display, in the size required by paragraph 19(1)(*b*) of the Consumer Chemicals and Containers Regulations, as they read on September 30, 2001, the following additional hazard statement:

“Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store at temperatures over 50°C.

Contenu sous pression. Ne pas mettre dans l’eau chaude ni près des radiateurs, poêles ou autres sources de chaleur. Ne pas percer le contenant, ni le jeter au feu, ni le conserver à des températures dépassant 50 °C.”

(3) The requirements of subsections (1) and (2) do not apply where

(*a*) in relation to a drug or cosmetic, in the opinion of the Director, or

(*b*) in relation to a food, in the opinion of the Minister of Consumer and Corporate Affairs,

the design of the container, the materials used in its construction or the incorporation of a safety device eliminate the potential hazard therein.

SOR/81-616, s. 1; SOR/85-1023, s. 1; SOR/92-15, s. 2; SOR/2001-272, s. 7.

A.01.062. (1) Subject to section A.01.063, if a food or drug is packaged in a container described in subsection A.01.061(1) and has a flame projection of a length set out in column I of any of items 1 to 3 of the table to this subsection or a flashback as set out in column I of item 4 of that table, as determined by official method DO-30, Determination of Flame Projection, dated October 15, 1981, the principal display panel of the inner and outer labels of the food or drug shall display, in accordance with sections 15 to 18 of the Consumer Chemicals and Containers Regulations, as they read on September 30, 2001, the following information:

(*a*) the hazard symbol set out in Column II of the same item;

(*b*) in both official languages, the signal word set out in Column III of the same item; and

(*c*) in both official languages, the primary hazard statement set out in Column IV of the same item.

TABLE IS NOT DISPLAYED, SEE SOR/81-616, S. 2; SOR/92-15, S. 3

(2) In addition to the requirements of subsection (1), one panel of the inner label and outer labels of a food or drug referred to in that subsection shall display, in the size required by paragraph 19(1)(*b*) of the Consumer Chemicals and Containers Regulations, as they read on September 30, 2001, the following additional hazard statement:

“Do not use in presence of open flame or spark.

Ne pas utiliser en présence d’une flamme nue ou d’étincelles.”

SOR/81-616, s. 2; SOR/82-429, s. 1; SOR/85-1023, s. 2; SOR/92-15, s. 3; SOR/2001-272, s. 8.

A.01.063. (1) Where the labelled net contents of a container of a food or drug described in subsection A.01.061(1) or A.01.062(1) does not exceed 60 millilitres or 60 grams, the inner label may show only the information described in paragraph A.01.061(1)(*a*) or paragraphs A.01.062(1)(*a*) and (*b*), as the case may be.

(2) Where the labelled net contents of a container of a food or drug described in subsection A.01.061(1) or A.01.062(1) exceeds 60 millilitres or 60 grams but does not exceed 120 millilitres or 120 grams, the inner label may show only the information described in subsection A.01.061(1) or subsection A.01.062(1), as the case may be.

(3) Where the labelled net quantity, in a container, of a food or drug referred to in subsection A.01.061(1) or A.01.062(1) is less than 30 mL or 30 g, the hazard symbol shall be of such size as to be capable of being circumscribed by a circle with a diameter of at least 6 mm.

(4) Where a container of a food or drug, described in subsection (1) or (2) is sold in a package, the outer label may show only the information described in subsection A.01.061(2) and, where applicable, subsection A.01.062(2).

SOR/81-616, s. 2; SOR/92-15, s. 4.

A.01.064. [Repealed, SOR/93-243, s. 2]

# Security Packaging

A.01.065 (1) In this section, “drug for human use” means a drug that is intended for human use, whether the drug is

(*a*) a mouthwash;

(*b*) to be inhaled, ingested or inserted into the body; or

(*c*) for ophthalmic use.

(2) Subject to subsection (3), no person shall sell or import a drug for human use that is packaged and available to the general public in a self-service display, unless the drug is contained in a security package.

(3) Subsection (2) does not apply to lozenges.

(4) Subject to subsection (5), a statement or illustration that draws attention to the security feature of the security package referred to in subsection (2) shall be carried

(*a*) on the inner label of the package; and

(*b*) if the security feature is a part of the outer package, on the outer label.

(5) Subsection (4) does not apply if the security feature of a security package is self-evident and is an integral part of the immediate product container.

SOR/85-141, s. 2; SOR/88-323, s. 1; SOR/92-664, s. 1.

# Exemptions

## Application

A.01.066. Sections A.01.067 and A.01.068 do not apply to

(*a*) a drug included in Schedule I, II, III, IV or V to the Controlled Drugs and Substances Act; or

(*b*) a drug that is listed or described in Schedule F, other than a drug that is listed or described in Part II of that Schedule and that is

(i) in a form not suitable for human use, or

(ii) labelled in the manner prescribed by paragraph C.01.046(*b*).

SOR/2007-288, s. 1.

## Advertising

A.01.067. A drug is exempt from subsection 3(1) of the Act with respect to its advertisement to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

SOR/2007-288, s. 1.

## Sale

A.01.068. A drug is exempt from subsection 3(2) of the Act with respect to its sale by a person where the drug is represented by label or is advertised by that person to the general public as a preventative, but not as a treatment or cure, for any of the diseases, disorders or abnormal physical states referred to in Schedule A to the Act.

SOR/2007-288, s. 1.

# PART B

# FOODS

# Division 1

## General

B.01.001. (1) In this Part,

“agricultural chemical” means any substance that is used, or represented for use, in or on a food during its production, storage or transport, and whose use results, or may reasonably be expected to result, in a residue, component or derivative of that substance in or on a food and includes any pest control product as defined in subsection 2(1) of the Pest Control Products Act, plant growth regulator, fertilizer or any adjuvant or carrier used with that substance. This definition does not include any

(*a*) food additive that is listed in, and used in accordance with, the tables to section B.16.100,

(*b*) nutritive substance that is used, recognized or commonly sold as food or as an ingredient of food,

(*c*) vitamin, mineral nutrient or amino acid,

(*d*) essential oil, flavouring preparation, natural extractive, oleoresin, seasoning or spice,

(*e*) food packaging material or any substance of which that material is composed, or

(*f*) drug recommended for administration to animals that may be consumed as food; (produit chimique agricole)

“available display surface”, in respect of a prepackaged product, means

(*a*) the bottom of an ornamental container or the total surface area of both sides of a tag attached to the ornamental container, whichever is greater,

(*b*) the total surface area of both sides of a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, and

(*c*) the total surface area of any other package, excluding the bottom if the contents of the package leak out or are damaged when the package is turned over,

but does not include

(*d*) any area of a package on which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase,

(*e*) any part of a package that is intended to be destroyed when it is opened, other than a package of a food that is intended to be consumed by one person at a single eating occasion, or

(*f*) the area occupied by the universal product code; (surface exposée disponible)

“close proximity” means, with reference to the common name, immediately adjacent to the common name without any intervening printed, written or graphic matter; (à proximité)

“common name” means, with reference to a food,

(*a*) the name of the food printed in boldface type in these Regulations,

(*b*) the name prescribed by any other regulation, or

(*c*) if the name of the food is not so printed or prescribed, the name by which the food is generally known; (nom usuel)

“component” means an individual unit of food that is combined as an individual unit of food with one or more other individual units of food to form an ingredient; (constituant)

“daily value” means

(*a*) in respect of a vitamin or mineral nutrient referred to in the definition "recommended daily intake", the recommended daily intake for that vitamin or mineral nutrient, and

(*b*) in respect of a nutrient referred to in the definition "reference standard", the reference standard for that nutrient; (valeur quotidienne)

"durable life" means the period, commencing on the day on which a prepackaged product is packaged for retail sale, during which the product, when it is stored under conditions appropriate to that product, will retain, without any appreciable deterioration, its normal wholesomeness, palatability, nutritional value and any other qualities claimed for it by the manufacturer; (durée de conservation)

"durable life date" means the date on which the durable life of a prepackaged product ends; (date limite de conservation)

"energy value" means, in respect of a food, the amount of energy made available to a person's body when the chemical constituents of the food, including protein, fat, carbohydrate and alcohol, are metabolized following ingestion of the food by the person; (valeur énergétique)

"extended meat product" means a meat product to which a meat product extender has been added; (produit de viande avec allongeur)

"extended poultry product" means a poultry product to which a poultry product extender has been added; (produit de volaille avec allongeur)

"fish product" means fish or prepared fish; (produit de poisson)

"flavouring preparation" includes any food for which a standard is provided in Division 10; (préparation aromatisante)

"food additive" means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include

(*a*) any nutritive material that is used, recognized or commonly sold as an article or ingredient of food;

(*b*) vitamins, mineral nutrients and amino acids, other than those listed in the tables to Division 16,

(*c*) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives;

(*d*) agricultural chemicals, other than those listed in the tables to Division 16,

(*e*) food packaging materials and components thereof; and

(*f*) drugs recommended for administration to animals that may be consumed as food; (additif alimentaire)

"food colour" means those colours permitted for use in or upon food by Division 6; (colorant alimentaire)

"gelling agent" means gelatin, agar and carrageenan; (agent gélatinisant)

“ingredient” means an individual unit of food that is combined as an individual unit of food with one or more other individual units of food to form an integral unit of food that is sold as a prepackaged product; (ingrédient)

“meal replacement” means a formulated food that, by itself, can replace one or more daily meals; (substitut de repas)

“meat product” means meat, meat by-product, prepared meat or prepared meat by-product; (produit de viande)

“meat product extender” means a food that is a source of protein and that is represented as being for the purpose of extending meat products; (allongeur de produit de viande)

“monounsaturated fatty acids”, “monounsaturated fat”, “monounsaturates” or “monounsaturated” means *cis*-monounsaturated fatty acids; (acides gras monoinsaturés, graisses monoinsaturées, gras monoinsaturés, lipides monoinsaturés*ou*monoinsaturés)

“nutritional supplement” means a food sold or represented as a supplement to a diet that may be inadequate in energy and essential nutrients; (supplément nutritif)

“nutrition facts table” means the nutrition facts table that is required by subsection B.01.401(1) to be carried on the label of a prepackaged product; (tableau de la valeur nutritive)

“omega-3 polyunsaturated fatty acids”, “omega-3 polyunsaturated fat”, “omega-3 polyunsaturates”, “omega-3 polyunsaturated” or “omega-3” means

(*a*) 9-*cis*, 12-*cis*, 15-*cis* octadecatrienoic acid or α-linolenic acid,

(*b*) 8-*cis*, 11-*cis*, 14-*cis*, 17-*cis* eicosatetraenoic acid,

(*c*) 5-*cis*, 8-*cis*, 11-*cis*, 14-*cis*, 17-*cis* eicosapentaenoic acid or EPA,

(*d*) 7-*cis*, 10-*cis*, 13-*cis*, 16-*cis*, 19-*cis* docosapentaenoic acid, or

(*e*) 4-*cis*, 7-*cis*, 10-*cis*, 13-*cis*, 16-*cis*, 19-*cis* docosahexaenoic acid or DHA; (acides gras polyinsaturés oméga-3, graisses polyinsaturées oméga-3, gras polyinsaturés oméga-3, lipides polyinsaturés oméga-3, polyinsaturés oméga-3*ou*oméga-3)

“omega-6 polyunsaturated fatty acids”, “omega-6 polyunsaturated fat”, “omega-6 polyunsaturates”, “omega-6 polyunsaturated” or “omega-6” means

(*a*) 9-*cis*, 12-*cis* octadecadienoic acid or linoleic acid,

(*b*) 6-*cis*, 9-*cis*, 12-*cis* octadecatrienoic acid,

(*c*) 8-*cis*, 11-*cis*, 14-*cis* eicosatrienoic acid or di-homo-γ-linolenic acid,

(*d*) 5-*cis*, 8-*cis*, 11-*cis*, 14-*cis* eicosatetraenoic acid or arachidonic acid,

(*e*) 7-*cis*, 10-*cis*, 13-*cis*, 16-*cis* docosatetraenoic acid, or

(*f*) 4-*cis*, 7-*cis*, 10-*cis*, 13-*cis*, 16-*cis* docosapentaenoic acid; (acides gras polyinsaturés oméga-6, graisses polyinsaturées oméga-6, gras polyinsaturés oméga-6, lipides polyinsaturés oméga-6, polyinsaturés oméga-6*ou*oméga-6)

“ornamental container” means a container that, except on the bottom, does not have any promotional or advertising material thereon, other than a trade mark or common name and that, because of any design appearing on its surface or because of its shape or texture, appears to be a decorative ornament and is sold as a decorative ornament in addition to being sold as the container of a product; (emballage décoratif)

“overage” means the amount of a vitamin or mineral nutrient that is, within the limits of good manufacturing practice, added to a food in excess of the amount declared on the label, in order to ensure that the amount of the vitamin or mineral nutrient declared on the label is maintained throughout the durable life of the food; (surtitrage)

“parts per million”[Repealed, SOR/2010-94, s. 1]

“parts per million” or “p.p.m.” means parts per million by weight unless otherwise stated; (parties par million*ou*p.p.m.)

“per cent” or “%” means per cent by weight, unless otherwise stated; (pour cent)

“polyunsaturated fatty acids”, “polyunsaturated fat”, “polyunsaturates” or “polyunsaturated” means *cis*-methylene interrupted polyunsaturated fatty acids; (acides gras polyinsaturés, graisses polyinsaturées, gras polyinsaturés, lipides polyinsaturés*ou*polyinsaturés)

“poultry product” means poultry meat, prepared poultry meat, poultry meat by-product or prepared poultry meat by-product; (produit de volaille)

“poultry product extender” means a food that is a source of protein and that is represented as being for the purpose of extending poultry products; (allongeur de produit de volaille)

“prepackaged meal” means a prepackaged selection of foods for one individual that requires no preparation other than heating and that contains at least one serving, as described in Canada’s Food Guide to Healthy Eating, published in 1992 by the Department of Supply and Services by authority of the Minister of National Health and Welfare, of

(*a*) meat, fish, poultry, legumes, nuts, seeds, eggs or milk or milk products other than butter, cream, sour cream, ice-cream, ice milk and sherbet; and

(*b*) vegetables, fruit or grain products; (repas préemballé)

“prepackaged product” means any food that is contained in a package in the manner in which it is ordinarily sold to or used or purchased by a person; (produit préemballé)

“principal display panel” means, despite the meaning assigned to that term in section A.01.010,

(*a*) in the case of a label applied to a prepackaged product that is subject to the Consumer Packaging and Labelling Act the principal display panel as defined in the Consumer Packaging and Labelling Regulations,

(*b*) in the case of a label applied to a prepackaged product that is not subject to the Consumer Packaging and Labelling Act, that part of the label applied to all or part of the side or surface of the container that is displayed or visible under normal or customary conditions of sale or use, and where the container does not have such a side or surface, that part of the label applied to any part of the container, except the bottom, if any, and

(*c*) in the case of a label applied to a food that is not a prepackaged product, that part of the label applied to all or part of the side or surface of the food that is displayed or visible under normal or customary conditions of sale or use; (espace principal)

“reasonable daily intake”, in respect of a food set out in Column I of an item of Schedule K, means the amount of that food set out in Column II of that item; (ration quotidienne raisonnable)

“recommended daily intake”, in respect of a vitamin or mineral nutrient set out in column I of Table I to Division 1 of Part D or in column I of Table I to Division 2 of Part D, means

(*a*) in the case of a prepackaged product intended solely for children under two years of age, the quantity set out in column III, and

(*b*) in any other case, the quantity set out in column II; (apport quotidien recommandé)

“reference amount”, in respect of a food set out in column 1 of Schedule M, means the amount of that food set out in column 2; (quantité de référence)

“reference standard”, in respect of a nutrient set out in column 1 of the table to section B.01.001.1, means the amount set out in column 2; (norme de référence)

“saturated fatty acids”, “saturated fat”, “saturates” or “saturated” means all fatty acids that contain no double bonds; (acides gras saturés, graisses saturées, gras saturés, lipides saturés*ou*saturés)

“simulated meat product” means any food that does not contain any meat product, poultry product or fish product but that has the appearance of a meat product; (simili-produit de viande)

“simulated poultry product” means any food that does not contain any poultry product, meat product or fish product but that has the appearance of a poultry product; (simili-produit de volaille)

“sugars” means all monosaccharides and disaccharides; (sucres)

“sweetener” means any food additive listed as a sweetener in Table IX to section B.16.100; (édulcorant)

“sweetening agent” includes any food for which a standard is provided in Division 18, but does not include those food additives listed in the tables to Division 16; (agent édulcorant)

“trans fatty acids”, “trans fat” or “trans” means unsaturated fatty acids that contain one or more isolated or non-conjugated double bonds in a *trans*-configuration; (acides gras trans, graisses trans, gras trans, lipides trans*ou*trans)

“unstandardized food” means any food for which a standard is not prescribed in this Part; (aliment non normalisé)

“weighted recommended nutrient intake”, in respect of a vitamin or mineral nutrient set out in column I of Table II to Division 1 of Part D or in column I of Table II to Division 2 of Part D, means the amount set out in column III; (apport nutritionnel recommandé pondéré)

“yolk-replaced egg” means a food that

(*a*) does not contain egg yolk but contains fluid, dried or frozen egg albumen or mixtures thereof,

(*b*) is intended as a substitute for whole egg, and

(*c*) meets the requirements of section B.22.032. (oeuf à jaune substitué)

(2) The definitions in this subsection apply for the purposes of the Act.

“agricultural chemical” has the same meaning as in subsection (1). (produit chimique agricole)

“food additive” has the same meaning as in subsection (1). (additif alimentaire)

SOR/78-403, s. 1(F); SOR/79-23, s. 1; SOR/81-83, s. 1; SOR/81-617, s. 1; SOR/88-336, s. 1; SOR/88-559, s. 1; SOR/89-175, s. 1; SOR/91-124, s. 1; SOR/91-527, s. 1; SOR/93-276, s. 1; SOR/95-474, s. 1; SOR/98-580, s. 1(F); SOR/2000-353, s. 3; SOR/2003-11, s. 1; err.(E), Vol. 137, No. 5; SOR/2005-98, s. 1; SOR/2008-181, s. 1; SOR/2008-182, s. 1; SOR/2010-94, s. 1.

Previous Version

B.01.001.1 (1) In this section, “fat” means all fatty acids expressed as triglycerides.

(2) The reference standard for a nutrient set out in column 1 of the table to this section is the amount set out in column 2.

TABLE

REFERENCE STANDARDS

| | Column 1 | Column 2 |
|---|---|---|
| Item | Nutrient | Amount |
| 1. | Fat | 65 g |
| 2. | The sum of saturated fatty acids and *trans* fatty acids | 20 g |
| 3. | Cholesterol | 300 mg |
| 4. | Carbohydrate | 300 g |
| 5. | Fibre | 25 g |
| 6. | Sodium | 2400 mg |
| 7. | Potassium | 3500 mg |

SOR/2003-11, s. 2.

B.01.002. Each provision in this Part in which the symbol **[S]** appears between the provision number and the name of the food described in that provision prescribes the standard of composition, strength, potency, purity, quality or other property of that food and a provision in which the symbol does not appear does not prescribe a standard for a food.

SOR/79-752, s. 1.

B.01.002A. (1) For the purposes of this Part, a serving of stated size of a food shall be

(*a*) based on the food as offered for sale; and

(*b*) expressed

(i) in grams, if

(A) the net quantity of the food is declared on the label by weight or by count, or

(B) the food is set out in column 1 of item 78, 149 or 150 of Schedule M, and

(ii) in millilitres, if the net quantity of the food is declared on the label by volume, except in the case of a food referred to in clause (i)(B).

(2) A serving of stated size shall be the net quantity of the food in the package if

(*a*) the quantity of food can reasonably be consumed by one person at a single eating occasion;

(*b*) the reference amount of the food is less than 100 g or 100 mL and the package contains less than 200% of that reference amount; or

(*c*) the reference amount of the food is 100 g or 100 mL or more and the package contains 150% or less of that reference amount.

SOR/88-559, s. 2; SOR/2003-11, s. 3.

B.01.003. (1) The following foods shall carry a label when offered for sale:

(*a*) all prepackaged products other than

(i) prepackaged confections, commonly known as one bite confections, that are sold individually, and

(ii) prepackaged products consisting of fresh fruits or fresh vegetables that are packaged in a wrapper or confining band of less than 1/2 inch in width;

(*b*) meat and meat by-products that are barbecued, roasted or broiled on the retail premises;

(*c*) poultry, poultry meat or poultry meat by-products that are barbecued, roasted or broiled on the retail premises;

(*d*) horse-meat or horse-meat by-product;

(*e*) any substance or mixture of substances for use as a food additive or food additive preparation; and

(*f*) flour and whole wheat flour that has been treated with gamma radiation from Cobalt 60 Source.

(2) [Repealed, SOR/79-23, s. 2]

SOR/79-23, s. 2.

B.01.004. (1) All or part of the label referred to in section B.01.003 shall be applied

(*a*) in the case of a prepackaged product, to the container in which the prepackaged product is sold; and

(*b*) in the case of a food that is not a prepackaged product, to the food itself.

(2) The label shall be applied in such a manner that the container of the prepackaged product or the food, as the case may be, will bear the label at the time it is sold.

SOR/84-300, s. 3.

B.01.005. (1) Subject to subsections (2) to (5), the information required to be shown on a label shall not be shown on that part of the label, if any, that is applied to the bottom of a food or container.

(2) The information required to be shown on a label may be shown on that part of the label, if any, that is applied to the bottom of a food or to the bottom of a container if such information is also shown in those parts of the label that are not applied to the bottom of the food or container.

(3) Notwithstanding subsection (2), where the container of a prepackaged product is an ornamental container and the label is applied to the bottom of the container, the information required to be shown may be shown on the label that is applied to the bottom of the container.

(4) Notwithstanding subsection (2), the information required by subparagraph B.01.007(1.1)(*b*)(i) or paragraph B.24.103(*g*) or B.25.057(1)(*f*) or (2)(*f*) may be shown on that part of the label that is applied to the bottom of the package if a clear indication of the location of the required information appears elsewhere on the label.

(5) Notwithstanding subsection (2), the nutrition facts table may be shown on that part of the label that is applied to the bottom of the food or container if the available display surface includes the bottom.

SOR/79-529, s. 1; SOR/92-626, s. 4; SOR/2003-11, s. 4.

B.01.006. (1) The common name of the food shall be shown on the principal display panel.

(2) Notwithstanding subsection (1), the common name of a fresh fruit or fresh vegetable that is prepackaged in such a manner that the fruit or vegetable is visible and identifiable in the package is not required to be shown on the label.

SOR/79-23, s. 3; SOR/92-626, s. 5.

B.01.007. (1) In this section, “packaging date” means

(*a*) the date on which a food is placed for the first time in a package in which it will be offered for sale to a consumer; or

(*b*) the date on which a prepackaged product is weighed by a retailer in a package in which it will be offered for sale for the first time to a consumer.

(1.1) The following information shall be shown on any part of the label:

(*a*) the identity and principal place of business of the person by or for whom the food was manufactured or produced;

(*b*) where a prepackaged product having a durable life of 90 days or less is packaged at a place other than the retail premises from which it is to be sold,

(i) the durable life date, and

(ii) instructions for the proper storage of the prepackaged product if it requires storage conditions that differ from normal room temperature; and

(*c*) where a prepackaged product having a durable life of 90 days or less is packaged on the retail premises from which it is to be sold,

(i) the packaging date, and

(ii) the durable life of the food, except when the durable life appears on a poster next to the food.

(1.2) The packaging date referred to in paragraph (1.1)(*c*) shall be shown in the form and manner prescribed for the durable life date by subsections (4) and (5) and the terms "best before" and "meilleur avant" on the label shall be replaced by the terms "packaged on" and "empaqueté le".

(2) Paragraph (1.1)(*a*) does not apply to fresh fruits or fresh vegetables that are prepackaged on retail premises in such a manner that the fruits or vegetables are visible and identifiable in the package.

(3) Paragraphs (1.1)(*b*) and (*c*) do not apply to

(*a*) prepackaged products consisting of fresh fruits or fresh vegetables;

(*b*) prepackaged individual portions of food that are served by a restaurant or other commercial enterprise with meals or snacks;

(*c*) prepackaged individual servings of food that are prepared by a commissary and sold by automatic vending machines or mobile canteens; or

(*d*) prepackaged donuts.

(4) The durable life date shall be shown in the following manner:

(*a*) the words "best before" and "meilleur avant" shall be shown grouped together with the durable life date unless a clear explanation of the significance of the durable life date appears elsewhere on the label;

(*b*) where, for the sake of clarity, it is necessary to show the year in which the durable life date occurs, the year shall be shown first and shall be expressed by at least the last two numbers of the year;

(*c*) the month shall be shown in words after the year, if the year is shown, and may be abbreviated as prescribed by subsection (5); and

(*d*) the day of the month shall be shown after the month and shall be expressed in numbers.

(5) The month of the durable life date, when abbreviated, shall be abbreviated as follows and only one such abbreviation shall be used for the English language and the French language:

| | | | |
|---|---|---|---|
| JA | for JANUARY | JL | for JULY |
| FE | for FEBRUARY | AU | for AUGUST |
| MR | for MARCH | SE | for SEPTEMBER |
| AL | for APRIL | OC | for OCTOBER |

MA for MAY NO for NOVEMBER
JN for JUNE DE for DECEMBER

(6) Except as otherwise provided in these Regulations, no person shall use a durable life date marking system on the label of a prepackaged product or in advertising a prepackaged product other than the marking system set out in this section.

(7) Paragraph (1.1)(*b*) does not apply to prepackaged fresh yeast, if

(*a*) the date on which it is estimated that the product has lost its effectiveness is shown on the label in the form and manner prescribed for the durable life date by subsections (4) and (5); and

(*b*) the terms “best before” and “meilleur avant” are replaced by the terms “use by” and “employez avant”.

SOR/79-23, s. 4; SOR/79-529, s. 2; SOR/88-291, s. 1; SOR/92-626, s. 6.

B.01.008. (1) The following information shall be shown grouped together on any part of the label:

(*a*) any information required by these Regulations, other than the information required to appear on the principal display panel or the nutrition facts table and the information required by sections B.01.007, B.01.301, B.01.305, B.01.311, B.01.503, B.01.513 and B.01.601; and

(*b*) where a prepackaged product consists of more than one ingredient, a list of all ingredients, including, subject to section B.01.009, components, if any.

(2) Paragraph (1)(*b*) does not apply to

(*a*) prepackaged products packaged from bulk on retail premises, except prepackaged products that are a mixture of nuts;

(*b*) prepackaged individual portions of food that are served by a restaurant or other commercial enterprise with meals or snacks;

(*c*) prepackaged individual servings of food that are prepared by a commissary and sold by automatic vending machines or mobile canteens;

(*d*) prepackaged meat and meat by-products that are barbecued, roasted or broiled on the retail premises;

(*e*) prepackaged poultry, poultry meat or poultry meat by-products that are barbecued, roasted or broiled on the retail premises;

(*f*) Bourbon whisky and prepackaged products subject to compositional standards in Division 2; or

(*g*) prepackaged products subject to compositional standards in Division 19.

(3) Ingredients shall be shown in descending order of their proportion of the prepackaged product or as a percentage of the prepackaged product and the order or percentage shall be the order or percentage of the ingredients before they are combined to form the prepackaged product.

(4) Notwithstanding subsection (3), the following ingredients may be shown at the end of the list of ingredients in any order:

(*a*) spices, seasonings and herbs, except salt;

(*b*) natural and artificial flavours;

(*c*) flavour enhancers;

(*d*) food additives, except ingredients of food additive preparations or mixtures of substances for use as a food additive;

(*e*) vitamins;

(*f*) salts or derivatives of vitamins;

(*g*) mineral nutrients; and

(*h*) salts of mineral nutrients.

(5) Components shall be shown

(*a*) immediately after the ingredient of which they are components in such a manner as to indicate that they are components of that ingredient; and

(*b*) in descending order of their proportion of the ingredient.

(6) Notwithstanding paragraph (1)(*b*) and subsection (5), but subject to section B.01.009, where one or more components of an ingredient are required by these Regulations to be shown in the list of ingredients on the label of a prepackaged product, the ingredient that contains the components is not required to be shown in the list if all components of that ingredient are listed by their common names with the other ingredients of the product

(*a*) in descending order of their proportion of the product, or

(*b*) as a percentage of the product,

the order or percentage, as the case may be, being based

(*c*) in the case of components, on the total amount of each of the components before they are combined to form ingredients in the product; and

(*d*) in the case of ingredients, on the amount of each of the ingredients before they are combined to form the product.

(7) Notwithstanding paragraph (1)(*b*), wax coating compounds and their components are not required to be shown on the label of a prepackaged fresh fruit or fresh vegetable as an ingredient or component thereof.

(8) Notwithstanding paragraph (1)(*b*), sausage casings are not required to be shown on the label of prepackaged sausages as an ingredient or component thereof.

(9) Notwithstanding paragraph (1)(*b*), hydrogen, when used for hydrogenation purposes, is not required to be shown on the label of any prepackaged product as an ingredient or component thereof.

(10) Notwithstanding paragraph (1)(*b*), components of ingredients of a sandwich made with bread are not required to be shown in the list of ingredients on the label of the sandwich.

SOR/79-23, s. 5; SOR/88-559, s. 3; SOR/92-626, s. 7; SOR/93-145, s. 1; SOR/2003-11, s. 5.

B.01.009. (1) Components of ingredients or of classes of ingredients set out in the following table are not required to be shown on a label:

TABLE

| Item | Ingredient |
|---|---|
| 1. | butter |
| 2. | margarine |
| 3. | shortening |
| 4. | lard |
| 5. | leaf lard |
| 6. | monoglycerides |
| 7. | diglycerides |
| 8. | rice |
| 9. | starches or modified starches |
| 10. | breads subject to compositional standards in sections B.13.021 to B.13.029 |
| 11. | flour |
| 12. | soy flour |
| 13. | graham flour |
| 14. | whole wheat flour |
| 15. | baking powder |
| 16. | milks subject to compositional standards in sections B.08.003 to B.08.027 |
| 17. | chewing gumbase |
| 18. | sweetening agents subject to compositional standards in sections B.18.001 to B.18.018 |
| 19. | cocoa, low-fat cocoa |
| 20. | salt |
| 21. | vinegars subject to compositional standards in sections B.19.003 to B.19.007 |
| 22. | Bourbon whisky and alcoholic beverages subject to compositional standards in sections B.02.001 to B.02.134 |
| 23. | cheese for which a standard is prescribed in Division 8, if the total amount of cheese in a prepackaged product is less than 10 per cent of that packaged product |
| 24. | jams, marmalades and jellies subject to compositional standards in sections B.11.201 to B.11.241 when the total amount of those ingredients is less than 5 per cent of a prepackaged product |
| 25. | olives, pickles, relish and horse-radish when the total amount of those ingredients is less than 10 per cent of a prepackaged product |
| 26. | one or more vegetable or animal fats or oils for which a standard is prescribed in Division 9, and hydrogenated, modified or interesterified vegetable or animal fats or oils, if the total of those fats and oils as are contained in a prepackaged product is less than 15 per cent of that prepackaged product |
| 27. | prepared or preserved meat, fish, poultry meat, meat by-product or poultry by-product |

| Item | Ingredient |
|---|---|
| | when the total amount of those ingredients is less than 10 per cent of a prepackaged product that consists of an unstandardized food |
| 28. | alimentary paste that does not contain egg in any form or any flour other than wheat flour |
| 29. | bacterial culture |
| 30. | hydrolysed plant protein |
| 31. | carbonated water |
| 32. | whey, whey powder, concentrated whey, whey butter and whey butter oil |
| 33. | mould culture |
| 34. | chlorinated water and fluorinated water |
| 35. | gelatin |
| 36. | toasted wheat crumbs used in or as a binder, filler or breading in or on a food product |

(2) Subject to subsection (3), where a preparation or mixture set out in the table to this subsection is added to a food, the ingredients and components of the preparation or mixture are not required to be shown on the label of that food.

TABLE

| Item | Preparation/Mixture |
|---|---|
| 1. | food colour preparations |
| 2. | flavouring preparations |
| 3. | artificial flavouring preparations |
| 4. | spice mixtures |
| 5. | seasoning or herb mixtures |
| 6. | vitamin preparations |
| 7. | mineral preparations |
| 8. | food additive preparations |
| 9. | rennet preparations |
| 10. | food flavour-enhancer preparations |
| 11. | compressed, dry, active or instant yeast preparations |

(3) Where a preparation or mixture set out in the table to subsection (2) is added to a food, and the preparation or mixture contains one or more of the following ingredients or components, those ingredients or components shall be shown by their common names in the list of the ingredients of the food to which they are added as if they were ingredients of that food:

(*a*) salt;

(*b*) glutamic acid or its salts;

(*c*) hydrolysed plant protein;

(*d*) aspartame;

(*e*) potassium chloride; and

(*f*) any ingredient or component that performs a function in, or has any effect on, that food.

(4) Notwithstanding subsections (1) and (2), where any of the following components is contained in an ingredient set out in the tables to those subsections, that component shall be shown in the list of ingredients:

(*a*) peanut oil;

(*b*) hydrogenated or partially hydrogenated peanut oil; and

(*c*) modified peanut oil.

(5) Notwithstanding subsection B.01.008(10) and item 23 of the table to subsection (1), if lysozyme from egg-white is added to a food described in section B.08.033 or B.08.034, the label of the food shall show “lysozyme from egg-white" in the list of ingredients in the same manner that is required in subsection B.01.008(4) or (5), as applicable.

SOR/78-728, s. 1; SOR/79-23, s. 6; SOR/79-662, s. 1; SOR/88-559, s. 4; SOR/92-626, s. 8; SOR/93-145, s. 2; SOR/93-465, s. 1; SOR/95-548, s. 5(F); SOR/97-263, s. 1; SOR/2000-417, s. 1; SOR/2010-143, s. 39(E).

Previous Version

B.01.010. (1) In this section, “common name” includes a name set out in Column II of the tables to subsection (3).

(2) An ingredient or component shall be shown in the list of ingredients by its common name.

(3) For the purposes of subsection (2),

(*a*) the ingredient or component set out in Column I of an item of the following table shall be shown in the list of ingredients by the common name set out in Column II of that item:

TABLE

| | Column I | Column II |
|---|---|---|
| Item | Ingredient or Component | Common Name |
| 1. | any oil, fat or tallow described in section B.09.002 of Division 9, except lard, leaf or suet | the name of the meat from which the oil, fat or tallow is obtained plus oil, fat or tallow |
| 2. | shortening or margarine containing fats or oils, except shortening or margarine containing coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter | shortening or margarine modified by vegetable oil or marine oil or by the common name of the vegetable, animal or marine oil or fat used |
| 3. | shortening or margarine containing coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter | shortening or margarine modified by the common name of the vegetable oil or fat used |
| 4. | meat | the name of the meat |
| 5. | poultry meat | the name of the poultry |
| 6. | fish | the name of the fish |
| 7. | plant protein product | the name of the plant plus protein product |
| 8. | hydrolyzed plant protein produced by the | hydrolyzed plus the name of the plant |

| | Column I | Column II |
|---|---|---|
| Item | Ingredient or Component | Common Name |
| | enzymatic process | plus protein |
| 9. | any protein isolate | the name of the source of the protein plus protein or the common name of the protein isolate |
| 10. | any meat by-product described in section B.14.003, other than gelatin | the name of the meat plus by-product or the name of the meat plus the name of the meat by-product |
| 11. | any poultry meat by-product described in section B.22.003 | the name of the poultry plus by-product or the name of the poultry plus the name of the poultry meat by-product |
| 12. | any oil or fat referred to in section B.09.002 that has been hydrogenated or partially hydrogenated, including tallow, but not including lard | "hydrogenated" *plus the name of the meat from which the oil, fat or tallow is obtained, plus* oil, fat or tallow |
| 13. | any oil or fat referred to in section B.09.002 of Division 9, including tallow, that has been modified by the complete or partial removal of a fatty acid | modified plus the name of the meat from which the oil, fat or tallow is obtained, plus oil, fat or tallow |
| 14. | one or more vegetable fats or oils, except coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter, that have been hydrogenated or partially hydrogenated | hydrogenated vegetable oil or hydrogenated vegetable fat or hydrogenated plus the specific name of the oil or fat |
| 15. | coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter that has been hydrogenated or partially hydrogenated | hydrogenated plus the specific name of the oil or fat |
| 16. | one or more marine fats or oils that have been hydrogenated or partially hydrogenated | hydrogenated marine oil or hydrogenated marine fat or hydrogenated plus the specific name of the oil or fat |
| 17. | one or more vegetable fats or oils, except coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter, that have been modified by the complete or partial removal of a fatty acid | modified vegetable oil or modified vegetable fat or modified plus the specific name of the oil or fat |
| 18. | coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter that has been modified by the complete or partial removal of a fatty acid | modified plus the specific name of the oil or fat |
| 19. | one or more marine fats or oils that have been modified by the complete or partial removal of a fatty acid | modified marine oil or modified plus the specific name of the oil or fat |

(*b*) except when one of the ingredients or components set out in column I of the table to this paragraph is shown separately in the list of ingredients by its common name, all of the ingredients or components present in a food set out in column I of an item of that table may be shown collectively in the list of ingredients by the common name set out in column II of that item:

TABLE

| Item | Column I<br>Ingredient or Component | Column II<br>Common Name |
|---|---|---|
| 1. | one or more vegetable fats or oils, except coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter | vegetable oil or vegetable fat |
| 2. | one or more marine fats or oils | marine oil |
| 3. | one or more of the colours listed in Table III of Division 16, except annatto where used in accordance with paragraph B.14.031(*i*) or subparagraph B.14.032(*d*)(xvi) | colour |
| 4. | one or more substances prepared for their flavouring properties and produced from animal or vegetable raw materials or from food constituents derived solely from animal or vegetable raw materials | flavour |
| 5. | one or more substances prepared for their flavouring properties and derived in whole or in part from components obtained by chemical synthesis | artificial flavour, imitation flavour or simulated flavour |
| 6. | one or more spices, seasonings or herbs except salt | spices, seasonings or herbs |
| 7. | any of the following in liquid, concentrated, dry, frozen or reconstituted form, namely, butter, buttermilk, butter oil, milk fat, cream, milk, partly skimmed milk, skim milk and any other component of milk the chemical composition of which has not been altered and that exists in the food in the same chemical state in which it is found in milk | milk ingredients |
| 7.1 | any of the following in liquid, concentrated, dry, frozen or reconstituted form, namely, calcium-reduced skim milk (obtained by the ion-exchange process), casein, caseinates, cultured milk products, milk serum proteins, ultrafiltered milk, whey, whey butter, whey cream and any other component of milk the chemical state of which has been altered from that in which it is found in milk | modified milk ingredients |
| 7.2 | one or more ingredients or components set out in item 7 combined with any one or more ingredients or components set out in item 7.1 | modified milk ingredients |
| 8. | any combination of disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate | sodium phosphate or sodium phosphates |
| 9. | one or more species of bacteria | bacterial culture |
| 10. | one or more species of mould | mold culture or mould culture |
| 11. | preparation containing rennin | rennet |
| 12. | milk coagulating enzymes from *Aspergillus oryzae* RET-1 (pBoel777), *Endothia parasitica, Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson))or *Mucor pusillus Lindt* | microbial enzyme |
| 13. | one or more substances the function of which is to impart flavour | the name of the plant |

| Item | Column I<br>Ingredient or Component | Column II<br>Common Name |
|---|---|---|
| | and that are obtained solely from the plant or animal source after which the flavour is named | or animal source plus the word “flavour” |
| 14. | toasted wheat crumbs made by cooking a dough prepared with flour and water, which may be unleavened or chemically or yeast leavened, and which otherwise complies with the standard prescribed by section B.13.021 or B.13.022 | toasted wheat crumbs |
| 15. | that portion of chewing gum, other than the coating, that does not impart sweetness, flavour or colour | gum base |
| 16. | sugar, liquid sugar, invert sugar or liquid invert sugar, singly or in combination | sugar |
| 17. | glucose syrups and isomerized glucose syrups, singly or in combination, where the fructose fraction does not exceed 60 per cent of the sweetener on a dry basis | glucose-fructose |
| 18. | glucose syrups and isomerized glucose syrups, singly or in combination, where the fructose fraction exceeds 60 per cent of the sweetener on a dry basis | fructose syrup |
| 19. | sugar or glucose-fructose, singly or in combination | sugar/glucose-fructose |
| 20. | water to which carbon dioxide is added | carbonated water |
| 21. | one or more of the following food additives, namely, potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium metabisulphite, sodium sulphite, sodium dithionite, sulphurous acid and sulphur dioxide | sulphiting agents or sulphites |
| 22. | demineralized water or water otherwise treated to remove hardness or impurities, or fluoridated or chlorinated water | water |
| 23. | wine vinegar, spirit vinegar, alcohol vinegar, white vinegar, grain vinegar, malt vinegar, cider vinegar or apple vinegar, singly or in combination | vinegar |

(4) Notwithstanding subsection (2) and subsection B.01.008(5), where a food contains ingredients of the same class, those ingredients may be shown by a class name if

(*a*) they consist of more than one component and are not listed in the table to subsection B.01.009(1); and

(*b*) their components are shown

(i) immediately after the class name of the ingredients of which they are components, in such a manner as to indicate that they are components of the ingredients, and

(ii) in descending order of their collective proportion of those ingredients.

SOR/79-23, ss. 7, 8(F); SOR/79-529, s. 3; SOR/80-632, s. 1; SOR/84-300, ss. 4(E), 5(F); SOR/91-124, s. 2; SOR/92-626, s. 9; SOR/92-725, s. 1; SOR/93-243, s. 2(F); SOR/93-465, s. 2; SOR/95-548, s. 5(F); SOR/97-516, s. 1; SOR/98-458, ss. 1, 7(F); SOR/2005-98, s. 7; SOR/2007-302, s. 4(F).

Previous Version

B.01.011. (1) Where it is an acceptable manufacturing practice for a manufacturer to

(*a*) omit from his prepackaged product any food that is ordinarily an ingredient or component, or

(*b*) substitute in whole or in part in his prepackaged product any other food for a food that is ordinarily an ingredient or component,

the list of ingredients for the 12-month period commencing from the time the label is applied to the prepackaged product may show as ingredients or components the foods that may be omitted and the foods that may be used as substitutes if

(*c*) all the foods that may be used as ingredients or components throughout the 12-month period are shown in the list of ingredients;

(*d*) it is clearly stated as part of the list of ingredients that the food shown as an ingredient or component may not be present or that another food may be substituted for a food shown as an ingredient or component; and

(*e*) the foods that may be omitted or substituted are grouped with the same class of foods that are used as ingredients or components and the foods within each such group are listed in descending order of the proportion in which they will probably be used during the 12-month period.

(2) Where it is an acceptable manufacturing practice for a manufacturer to vary the proportions of ingredients or components of his prepackaged product, the list of ingredients for the 12-month period commencing from the time the label is applied to the prepackaged product may show the ingredients or components in the same proportions throughout the 12-month period if

(*a*) it is clearly stated as part of the list of ingredients that the proportions indicated are subject to change; and

(*b*) the ingredients or components are listed in descending order of the proportion in which they will probably be used during the 12-month period.

B.01.012. (1) In this section,

“local government unit” means a city, metropolitan government area, town, village, municipality or other area of local government but does not include any local government unit situated within a bilingual district established under the Official Languages Act; (collectivité locale)

“local food” means a food that is manufactured, processed, produced or packaged in a local government unit and sold only in

(*a*) the local government unit in which it is manufactured, processed or packaged,

(*b*) one or more local government units that are immediately adjacent to the one in which it is manufactured, processed, produced or packaged, or

(*c*) the local government unit in which it is manufactured, processed, produced or packaged and in one or more local government units that are immediately adjacent to the one in which it is manufactured, processed, produced or packaged; (produit alimentaire local)

“mother tongue” means the language first learned in childhood by persons in any area of Canada and still understood by them as ascertained by the decennial census taken immediately preceding the date on which the food referred to in subsection (3) is sold to the consumer; (langue maternelle)

“official languages” means the English language and the French language; (langues officielles)

“specialty food” means a food that

(*a*) has special religious significance and is used in religious ceremonies; or

(*b*) is an imported food

(i) that is not widely used by the population as a whole in Canada, and

(ii) for which there is no readily available substitute that is manufactured, processed, produced or packaged in Canada and that is generally accepted as being a comparable substitute; (aliment spécial)

“test market food” means a food that, prior to the date of the notice of intention respecting that food referred to in subsection (5), was not sold in Canada in that form and that differs substantially from any other food sold in Canada with respect to its composition, function, state or packaging form and includes a food referred to in section B.01.054. (produit alimentaire d’essai)

(2) Subject to subsections (9), (10) and (11), all information required by these Regulations to be shown on the label of a food shall be shown in both official languages.

(3) Subject to subsections (4) to (6), subsection (2) does not apply to a local food or test market food if

(*a*) it is sold in a local government unit in which one of the official languages is the mother tongue of less than 10 per cent of the total number of persons residing in the local government unit; and

(*b*) the information required by these Regulations to be shown on the label of a food is shown in the official language that is the mother tongue of at least 10 per cent of the total number of persons residing in the local government unit.

(4) Where one of the official languages is the mother tongue of less than 10 per cent of the total number of persons residing in a local government unit and the other official language is the mother tongue of less than 10 per cent of the total number of persons residing in the same local government unit, subsection (3) does not apply.

(5) Subsection (3) does not apply to a test market food unless the person who intends to conduct the test marketing of the food has, six weeks prior to conducting the test marketing, filed with the President of the Canadian Food Inspection Agency a notice of intention in a form acceptable to the President.

(6) A test market food shall, for the purposes of subsection (3), cease to be a test market food upon the expiration of 12 cumulative months after the date on which it was first offered for sale as a test market food but any test market food that was acquired for resale by a person, other than the person who filed the notice of intention referred to in subsection (5), before the

expiration of those 12 cumulative months, shall continue to be a test market food for the purposes of subsection (3) until it is sold.

(7) Subsection (2) does not apply to a specialty food if the information required by these Regulations to be shown on the label thereon is shown in one of the official languages.

(8) Where there are one or more surfaces on the label of a food that are of at least the same size and prominence as the principal display panel, the information required by these Regulations to be shown on the principal display panel may be shown in one official language if such information is shown in the other official language on one of those other surfaces.

(9) Subsection (2) does not apply to the identity and principal place of business of the person by or for whom the food was manufactured, processed, produced or packaged for resale if this information is shown in one of the official languages.

(10) Subsection (2) does not apply to the following common names if the common name appears on the principal display panel in the following manner:

| | |
|---|---|
| Scotch Whisky | Akvavit |
| Irish Whisky | Aquavit |
| Highland Whisky | Armagnac |
| Dry Gin | Marc |
| Bourbon | Grappa |
| Tennessee Whisky | Calvados |
| Tequila | Poire William |
| Mezcal | Crème de Bleuets |
| Rye Whisky | Curaçao Orange |
| Crème de Menthe | Liqueur de Fraise |
| Crème de Cacao | Mandarinette |
| Crème de Cassis | Prunelle de Bourgogne |
| Crème de Banane | Chartreuse |
| Triple Sec | Pastis |
| Anisette | Fior d’Alpe |
| Crème de Noyau | Strega |
| Brandy | Campari |
| Sake or Saki | Americano |
| Advocaat or Advokaat | Apricot Brandy Liqueur |
| Kirsch | Peach Brandy Liqueur |
| Slivovitz | Sloe Gin |
| Ouzo | Manhattan |
| Cherry Brandy Liqueur | Martini |
| Kummel | |

(11) Subsection (2) does not apply to the label of a shipping container destined to a commercial or industrial enterprise or institution, if

(*a*) the shipping container and its contents are not resold as a one unit prepackaged product to a consumer at the retail level; and

(*b*) all information required by these Regulations to be shown on a label of a food is shown in one of the official languages.

SOR/79-23, s. 9; SOR/79-529, s. 4; SOR/84-300, s. 6; SOR/93-603, s. 1; SOR/95-548, s. 5; SOR/2000-184, s. 62.

B.01.013. (1) Unless specifically required by the Act or these Regulations, no reference, direct or indirect, to the Act or to these Regulations shall be made on any label of, or in any advertisement for, a food.

(2) Notwithstanding subsection (1), where a food complies with a standard established by these Regulations and the manufacturer of the food has substantiated, by means of the results of tests carried out before the statement is made or by other evidence that exists before the statement is made, that the food so complies, a statement that the food "complies with the standard for (naming the common name of the food in respect of which the claim is made) in the Food and Drug Regulations" may be made on the label of, or in an advertisement for, the food.

SOR/92-626, s. 10; SOR/95-548, s. 5(F).

B.01.014. The label of a food, other than a sweetener, that contains aspartame shall carry the following information:

(*a*) subject to paragraph (*b*), a statement on the principal display panel to the effect that the food contains aspartame or is sweetened with aspartame, in letters of at least the same size and prominence as the letters used in the numerical portion of the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*b*) in the case where other sweeteners are used in conjunction with aspartame, a statement on the principal display panel to the effect that the food

(i) contains aspartame and (naming the other sweeteners), or

(ii) is sweetened with aspartame and (naming the other sweeteners),

in letters of at least the same size and prominence as the letters used in the numerical portion of the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*c*) a statement on any part of the label to the effect that aspartame contains phenylalanine; and

(*d*) a statement setting out the aspartame content expressed in milligrams per serving of stated size.

SOR/81-617, s. 2; SOR/88-559, s. 5; SOR/2003-11, s. 6.

B.01.015. (1) The label of a food that is a sweetener that contains aspartame shall carry the following information:

(*a*) a statement on the principal display panel to the effect that the food contains aspartame or is sweetened with aspartame, in letters of at least the same size and prominence as the letters used in the numerical portion of the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*b*) a statement on any part of the label to the effect that aspartame contains phenylalanine;

(*c*) a statement on any part of the label of the sweetness per serving expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness; and

(*d*) a statement setting out the aspartame content expressed in milligrams per serving of stated size.

(2) [Repealed, SOR/2007-176, s. 1]

SOR/81-617, s. 2; SOR/88-559, s. 6; SOR/2003-11, s. 7; SOR/2007-176, s. 1.

Previous Version

B.01.016. The label of a food, other than a table-top sweetener, that contains sucralose shall carry the following information:

(*a*) subject to paragraph (*b*), a statement on the principal display panel to the effect that the food contains sucralose or is sweetened with sucralose, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*b*) where sucralose is used in conjunction with another sweetener or a sweetening agent or both, the names thereof shown in a statement on the principal display panel to the effect that the food contains, or is sweetened with, sucralose and the other sweetener or the sweetening agent or both, as the case may be, in letters as described in paragraph (*a*); and

(*c*) a statement setting out the sucralose content expressed in milligrams per serving of stated size.

SOR/91-527, s. 2; SOR/94-625, s. 1; SOR/2003-11, s. 8.

B.01.017. (1) The label of a food that is a table-top sweetener that contains sucralose shall carry the following information:

(*a*) a statement on the principal display panel to the effect that the food contains sucralose or is sweetened with sucralose, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*b*) a statement on any part of the label setting out the sweetness per serving expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness; and

(*c*) a statement setting out the sucralose content expressed in milligrams per serving of stated size.

(2) [Repealed, SOR/2007-176, s. 2]

SOR/91-527, s. 2; SOR/94-625, s. 2; SOR/2003-11, s. 9; SOR/2007-176, s. 2.

Previous Version

B.01.018. The label of a food that contains polydextrose shall indicate the amount of polydextrose expressed in grams per serving of stated size.

SOR/93-276, s. 2; SOR/94-779, s. 1; SOR/97-512, s. 1; SOR/2003-11, s. 10.

B.01.019. The label of a food, other than a table-top sweetener, that contains acesulfame-potassium shall carry the following information:

(*a*) subject to paragraph (*b*), a statement on the principal display panel to the effect that the food contains acesulfame-potassium or is sweetened with acesulfame-potassium, in letters of at least the same size and prominence as the characters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*b*) where acesulfame-potassium is used in conjunction with another sweetener or a sweetening agent or both, the names thereof shown in a statement on the principal display panel to the effect that the food contains, or is sweetened with, acesulfame-potassium and the other sweetener or the sweetening agent or both, as the case may be, in letters as described in paragraph (*a*); and

(*c*) a statement setting out the acesulfame-potassium content expressed in milligrams per serving of stated size.

SOR/94-625, s. 3; SOR/2003-11, s. 11.

B.01.020. (1) The label of a food that is a table-top sweetener that contains acesulfame-potassium shall carry the following information:

(*a*) a statement, on the principal display panel, to the effect that the food contains acesulfame-potassium or is sweetened with acesulfame-potassium, in letters of at least the same size and prominence as the characters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*b*) a statement, on any part of the label, setting out the sweetness per serving, expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness; and

(*c*) a statement setting out the acesulfame-potassium content expressed in milligrams per serving of stated size.

(2) [Repealed, SOR/2007-176, s. 3]

SOR/94-625, s. 3; SOR/2003-11, s. 12; SOR/2007-176, s. 3.

Previous Version

B.01.021. (1) The label of a food that contains erythritol shall carry a statement indicating the amount of erythritol expressed in grams per serving of stated size unless the label carries a nutrition facts table.

(2) The statement of the amount of erythritol shall be grouped together with the statement of the amount of any other sugar alcohols and the amount of polydextrose.

SOR/2004-261, s. 1.

B.01.022. The label of a food, other than a table-top sweetener, that contains neotame shall carry the following information:

(*a*) subject to paragraph (*b*), a statement on the principal display panel to the effect that the food contains neotame or is sweetened with neotame, in letters of at least the same size and

prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*b*) in the case where other sweeteners or sweetening agents are used in conjunction with neotame, a statement on the principal display panel, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations, to the effect that the food

(i) contains neotame and (naming the other sweeteners and the sweetening agents), or

(ii) is sweetened with neotame and (naming the other sweeteners and the sweetening agents);

(*c*) if the label of the food carries a nutrition facts table, a statement setting out the neotame content expressed in milligrams per serving of stated size; and

(*d*) if the label of the food does not carry a nutrition facts table, a statement setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence on any part of the label:

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the neotame content, expressed in milligrams.

SOR/2007-176, s. 4.

B.01.023. The label of a food that is a table-top sweetener that contains neotame shall carry the following information:

(*a*) a statement on the principal display panel to the effect that the food contains neotame or is sweetened with neotame, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the Consumer Packaging and Labelling Regulations;

(*b*) a statement on any part of the label of the sweetness per serving expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness;

(*c*) if the label of the food carries a nutrition facts table, a statement setting out the neotame content expressed in milligrams per serving of stated size; and

(*d*) if the label of the food does not carry a nutrition facts table, a statement setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence on any part of the label:

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the neotame content, expressed in milligrams.

SOR/2007-176, s. 4.

B.01.033. (1) Except in the case of infant formula or a formulated liquid diet, no person shall sell a food represented in any manner as containing hydrolyzed or partially hydrolyzed collagen, hydrolyzed or partially hydrolyzed gelatin or hydrolyzed or partially hydrolyzed casein unless the label carries the following statement on the principal display panel in the same size type used for the common name:

“CAUTION, DO NOT USE AS SOLE SOURCE OF NUTRITION”.

(2) In this section, “formulated liquid diet” means a food that meets the requirements of sections B.24.101 to B.24.103.

SOR/78-65, s. 1.

B.01.034. [Repealed, SOR/88-559, s. 7]

B.01.035. (1) Subject to subsection (8), where an irradiated food referred to in Column I of the table to Division 26 is offered for sale as a prepackaged product, the principal display panel of the label applied to the package shall carry the symbol described in subsection (5).

(2) Where an irradiated food referred to in Column I of the table to Division 26 is not a prepackaged product and is offered for sale, a sign that carries the symbol described in subsection (5) shall be displayed immediately next to the food.

(3) The symbol required pursuant to subsection (1) or (2) shall appear in close proximity on the principal display panel referred to in subsection (1) or on the sign referred to in subsection (2) to one of the following statements or a written statement that has the same meaning:

(*a*) “treated with radiation”;

(*b*) “treated by irradiation”; or

(*c*) “irradiated”.

(4) No person shall sell a food referred to in Column I of the table to Division 26 that has been irradiated in the manner set out in subsection B.26.003(2) unless the requirements of subsections (1) to (3) are met.

(5) For the purposes of subsections (1) to (3), the symbol that indicates the irradiated food shall

(*a*) have an outer diameter

(i) in the case referred to in subsection (1), equal to or greater than the height of the numerical quantity prescribed by section 14 of the Consumer Packaging and Labelling Regulations for the declaration of net quantity of the package, and

(ii) in the case referred to in subsection (2), not less than 5 cm; and

(*b*) be in the following form:

GRAPHIC IS NOT DISPLAYED, SEE SOR/89-172, S. 1

(6) Notwithstanding subsection B.01.009(1), any food referred to in Column I of the table to Division 26 that is an ingredient or component of a prepackaged product and that has been

irradiated shall, if the food constitutes 10 per cent or more of the prepackaged product, be included in the list of ingredients and preceded by the statement “irradiated”.

(7) The label attached to a shipping container containing any food referred to in Column I of the table to Division 26 that has been subjected to the maximum permitted absorbed dose set out in Column IV of that table shall carry the statement required by subsection (3) and the statement “Do not irradiate again”.

(8) Where a shipping container constitutes the package of the prepackaged product, the label attached to the shipping container shall carry the statement required by subsection (7) but need not carry the symbol required by subsection (5).

(9) Any advertising of an irradiated food referred to in Column I of the table to Division 26 shall identify the food as having been irradiated.

(10) The statements referred to in subsections (3) and (6) to (8) shall be in both official languages in accordance with subsection B.01.012(2).

SOR/89-172, s. 1.

B.01.037. [Repealed, SOR/88-559, s. 8]

B.01.040. [Repealed, SOR/88-559, s. 9]

B.01.042. Where a standard for a food is prescribed in this **Part**,

(*a*) the food shall contain only the ingredients included in the standard for the food;

(*b*) each ingredient shall be incorporated in the food in a quantity within any limits prescribed for that ingredient; and

(*c*) if the standard includes an ingredient to be used as a food additive for a specified purpose, that ingredient shall be a food additive set out in one of the tables to section B.16.100 for use as an additive to that food for that purpose.

B.01.043. Subject to section B.25.062, where a standard for a food is not prescribed in this Part,

(*a*) the food shall not contain any food additives except food additives set out in a table to section B.16.100 for use as additives to that food for the purpose set out in that table; and

(*b*) each such food additive shall be incorporated in the food in a quantity within any limits prescribed for that food and food additive in that table.

SOR/87-640, s. 1.

B.01.044. Where the limit prescribed for a food additive in a table to section B.16.100 is stated to be “Good Manufacturing Practice”, the amount of the food additive added to a food in manufacturing and processing shall not exceed the amount required to accomplish the purpose for which that additive is permitted to be added to that food.

B.01.045. A food additive shall,

(*a*) where specifications are set out in this Part for that additive, meet those specifications;

(*b*) where no specifications are set out in this Part for that additive but specifications are set out for it in the Food Chemicals Codex, Fourth Edition, 1996, published by the National Academy of Sciences, Washington, D.C., United States, as amended from time to time, meet those specifications;

(*c*) in the case of lactitol and maltitol, meet the specifications established by the Joint FAO/WHO Expert Committee on Food Additives as set out in the Specifications for identity and purity of certain food additives — FAO Food and Nutrition Paper 38, published in 1988 by the Food and Agriculture Organization of the United Nations, Rome;

(*d*) [Repealed, SOR/2010-142, s. 1]

(*e*) [Repealed, SOR/97-512, s. 2]

(*f*) in the case of isomalt, meet the specifications established by the Joint FAO/WHO Expert Committee on Food Additives as set out in the Compendium of food additive specifications, Addendum 4 — FAO Food and Nutrition Paper 52, published in 1996 by the Food and Agriculture Organization of the United Nations, Rome.

(*g*) [Repealed, SOR/97-512, s. 2]

SOR/82-383, s. 1; SOR/91-527, s. 3; SOR/92-93, s. 1; SOR/92-551, s. 1; SOR/93-276, s. 3; SOR/94-625, s. 4; SOR/94-779, s. 2; SOR/95-172, s. 2; SOR/97-512, s. 2; SOR/2010-142, s. 1.

Previous Version

B.01.046. (1) A food is adulterated if any of the following substances or classes of substances are present therein or have been added thereto:

(*a*) mineral oil, paraffin wax or petrolatum or any preparation thereof;

(*b*) coumarin, an extract of tonka beans, the seed of *Dipteryx odorata* Willd. or *Dipteryx oppositifolia* Willd.;

(*c*) non-nutritive sweetening agents;

(*d*) cottonseed flour that contains more than 450 parts per million of free gossypol;

(*e*) fatty acids and their salts containing chick-edema factor or other toxic factors;

(*f*) dihydrosafrole;

(*g*) isosafrole;

(*h*) oil of American sassafras from *Sassafras albidum* (Nutt). Nees;

(*i*) oil of Brazilian sassafras from *Ocotea cymbarum* H.B.K.;

(*j*) oil of camphor sassafrassy from *Cinnamomum camphorum* Sieb.;

(*k*) oil of micranthum from *Cinnamomum micranthum* Hayata;

(*l*) safrole;

(*m*) oil, extract or root of calamus from *Acorus calamus* L.;

(*n*) nut and nut products that contain more than 15 parts per billion of aflatoxin;

(*o*) ethylene thiourea;

(*p*) chlorinated dibenzo-*p*-dioxins; or

(*q*) cinnamyl anthranilate.

(2) For the purpose of paragraph (1)(*n*), the aflatoxin content of a nut or nut product shall be calculated on the basis of the nut meat portion.

SOR/79-358, s. 1; SOR/80-501, s. 1; SOR/82-1071, s. 1; SOR/83-857, s. 1; SOR/84-300, s. 7; SOR/88-534, s. 1.

B.01.047. Notwithstanding section B.01.046

(*a*) a food, other than sausage casing, is not adulterated by reason only that it contains 0.3 per cent or less mineral oil, if good manufacturing practice requires the use of mineral oil;

(*b*) chewing gum is not adulterated by reason only that it contains a paraffin wax base;

(*c*) fresh fruits and vegetables, except turnips, are not adulterated by reason only that they are coated with not more than 0.3 per cent paraffin wax and petrolatum, if good manufacturing practices require the use of such coating;

(*d*) turnips and cheese are not adulterated by reason only that they are coated with paraffin wax in accordance with good manufacturing practice;

(*e*) sausage casing is not adulterated by reason only that it contains five per cent or less mineral oil by weight, if good manufacturing practice requires the use of mineral oil;

(*f*) fish is not adulterated by reason only that it contains 20 parts per trillion or less of 2,3,7,8-tetrachlorodibenzoparadioxin;

(*g*) bakery products and confectionery are not adulterated by reason only that they contain 0.15 per cent or less petrolatum, if good manufacturing practice requires the use of petrolatum;

(*h*) a salt substitute is not adulterated by reason only that it contains 0.6 per cent or less mineral oil, if good manufacturing practice requires the use of mineral oil; and

(*i*) fruits, vegetables and cereals are not adulterated by reason only that they contain 0.05 parts per million or less of ethylene thiourea.

SOR/81-934, s. 1; SOR/82-122, s. 1; SOR/82-1071, s. 2; SOR/83-932, s. 1; SOR/84-17, s. 1; SOR/92-76, s. 1.

B.01.047.1 (1) The following definitions apply in this section.

“BSE” means Bovine Spongiform Encephalopathy. (ESB)

“specified risk material” means

(*a*) the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older; and

(*b*) the distal ileum of cattle of all ages. (matériel à risque spécifié)

(2) No person shall sell or import for sale food that contains specified risk material.

(3) Subsection (2) does not apply in respect of food that originates from a country that is designated as being free from BSE in accordance with section 7 of the Health of Animals Regulations.

(4) Subsection (2) does not apply in respect of food that is packaged for sale or imported for sale before the day on which this subsection comes into force.

SOR/2003-265, s. 1.

B.01.048. (1) No person shall sell

(*a*) any animal intended for consumption as food if any product containing any drug listed in subsection (2) has been administered to the animal;

(*b*) any meat, meat by-products, eggs or milk intended for consumption as food and derived from an animal if any product containing any drug listed in subsection (2) has been administered to that animal; or

(*c*) any meat, meat by-products, eggs or milk that contains any residue of any drug listed in subsection (2).

(2) The drugs referred to in subsection (1) are

(*a*) chloramphenicol and its salts and derivatives;

(*b*) a 5-nitrofuran compound;

(*c*) clenbuterol and its salts and derivatives;

(*d*) a 5-nitroimidazole compound; and

(*e*) diethylstilbestrol and other stilbene compounds.

SOR/85-685, s. 1; SOR/87-626, s. 1; SOR/94-568, s. 1; SOR/97-510, s. 1; SOR/2003-292, s. 1.

B.01.049. No person shall use, in labelling, packaging, advertising or selling a food that does not meet the requirements of the kashruth applicable to it, the word “kosher” or any letters of the Hebrew alphabet or any other word, expression, depiction, sign, symbol, mark, device or other representation that indicates or that is likely to create an impression that the food is kosher.

SOR/84-300, s. 8.

B.01.053. No person shall sell a product represented as a ready breakfast or instant breakfast or by any similar designation unless each serving of stated size of the product contains

(*a*) not less than 4.0 mg. iron;

(*b*) Vitamin A, thiamine, riboflavin, niacin or niacinamide and Vitamin C;

(*c*) a good dietary source of protein; and

(*d*) where consumed as directed, not less than 300 calories.

SOR/2003-11, s. 13.

B.01.054. (1) In order to generate information in support of an amendment to the Regulations, the Director may issue to the manufacturer or distributor of a food, where the food or the packaging, labelling or advertising of the food does not comply with the requirements of these Regulations, a Temporary Marketing Authorization Letter that authorizes the sale of the food described therein or the packaging, labelling or advertising of the food described therein for a specified period of time, within a designated area and in a specified quantity, in the manner specified in the Letter if

(*a*) the manufacturer or distributor of the food has supplied to the Director the following information:

(i) the purpose for which the temporary marketing authorization of the food is required,

(ii) a description of the food including a sample and proposed label,

(iii) a description of any proposed variation from the requirements of these Regulations,

(iv) adequate data to show that the use of the food will not be detrimental to the health of the purchaser or user,

(v) the proposed quantity of the food to be sold,

(vi) the proposed period of time required for such sale,

(vii) the proposed area designated for such sale, and

(viii) such other data as the Director may require; and

(*b*) the manufacturer or distributor of the food has agreed to

(i) describe the food on a label or in an advertisement in a manner that is not false, misleading or deceptive,

(ii) use such marks or statements on the label or in any advertisement as the Director may require,

(iii) on request, submit to the Director results of the temporary marketing, and

(iv) on request, withdraw the product from sale where the Director is of the opinion that it is in the public interest to do so.

(2) The Director shall, in any Temporary Marketing Authorization Letter issued pursuant to subsection (1), set out

(*a*) the common name and description of the food to be sold;

(*b*) the name and address of the manufacturer or distributor of the food;

(*c*) the purpose for which the temporary marketing of the food is authorized;

(*d*) the quantity of the food that is authorized for sale;

(*d.1*) the type of packaging, labelling or advertising authorized in respect of the food where the Letter is intended to authorize a variation from a requirement of any provision of the Regulations respecting packaging, labelling or advertising;

(*e*) the period of time during which the food may be sold; and

(*f*) the designated area within which the food may be sold.

SOR/81-566, s. 1; SOR/85-275, s. 1.

B.01.055. (1) A manufacturer or distributor named in a Temporary Marketing Authorization Letter issued pursuant to subsection B.01.054(1) may, for the purpose set out in the Letter, sell the food in the manner authorized in the Letter and package, label or advertise that food in the manner authorized in the Letter for the period of time, within the designated area and in the quantity set out in the Letter.

(2) No provision of these Regulations made pursuant to paragraph 30(1)(*b*) of the Act applies in respect of a food or the packaging, labelling or advertising of a food for which a Temporary Marketing Authorization Letter has been issued pursuant to subsection B.01.054(1) to the extent that the food, or the packaging, labelling or advertising of the food, as authorized in the Letter, does not comply with that provision.

SOR/81-566, s. 1; SOR/85-275, s. 2; SOR/90-814, s. 4.

B.01.056. (1) This section applies in respect of interim marketing authorizations that the Minister may issue under subsection 30.2(1) of the Act.

(2) In this section, “food for special dietary use” has the same meaning as in section B.24.001.

(3) The manufacturer of a food or of an agricultural chemical, veterinary drug, food additive, vitamin, mineral nutrient or amino acid present in or on a food may submit an application in writing to the Minister for the issuance of an interim marketing authorization in respect of the food that provides for any matter referred to in subsection 30.2(2) of the Act.

(4) The application shall be accompanied by the following information:

(*a*) the common name and description of the food;

(*b*) the reasons for which the interim marketing authorization is requested;

(*c*) a description of every exemption requested in respect of the food from the application, in whole or in part, of sections 5 to 6.1 of the Act and the applicable requirements of these Regulations;

(*d*) adequate data, including results of tests and scientific analysis, that demonstrate that the food would not be harmful to the health of the purchaser or consumer;

(*e*) if the application relates to the addition of vitamins, mineral nutrients or amino acids to the food, a statement, with supporting documentation, indicating that the proposed addition is for one or more of the following purposes:

(i) to restore the levels of vitamins or mineral nutrients to the levels that were present in the food before processing or, in the case of amino acids, to provide protein of a nutritional quality that is equivalent to that which was present in the food before processing,

(ii) to make the food that is intended to be sold as a substitute for another food nutritionally equivalent to the food that it is intended to replace in the diet in respect of

(A) the levels of added vitamins or mineral nutrients, or

(B) the quality of protein provided through the addition of amino acids,

(iii) to prevent or correct a deficiency of vitamins or mineral nutrients in the population or specific population groups, or

(iv) to modify the levels of vitamins, mineral nutrients or amino acids in the food for special dietary use; and

(*f*) if the application relates to the use of a food additive in or on the food, the information described in section B.16.002.

(5) In addition to the matters that may be provided for in accordance with subsections 30.2(2) and (4) of the Act, an interim marketing authorization shall set out

(*a*) the common name and description of the food;

(*b*) the reasons for which the interim marketing authorization is issued; and

(*c*) the provisions of the Act and of these Regulations in respect of which the food is exempted.

(6) An interim marketing authorization may be cancelled by the Minister if the Minister determines, after reviewing any additional information that comes to his or her attention, that the food for which the authorization was issued is or may be harmful to the health of the purchaser or consumer.

SOR/97-313, s. 1; SOR/2008-181, s. 2.

Previous Version

B.01.060. to B.01.066. [Repealed, SOR/88-559, s. 10]

B.01.070. **[S].** Mixed nuts or a mixture of nuts shall consist of a mixture of nuts in which not less than five per cent by weight of each type of nuts is present in the mixture.

B.01.071. Where a prepackaged product is a mixture of nuts, the percentage and common name of the nut that is present in the product in the greatest amount by weight shall be applied to the principal display panel of the package in close proximity to the common name of the product.

SOR/88-336, s. 3; SOR/92-626, s. 11.

B.01.072. Notwithstanding any requirement prescribed in Part B, a food product that has been subjected to heat in the presence of a vaporized liquid solution of smoke derived from hardwood, hardwood sawdust or corn cobs may be described as “smoked”.

SOR/92-626, s. 11.

B.01.080. (1) In this section, “frozen” means preserved by freezing temperature and does not include any surface freezing that may occur during holding and transportation.

(2) Where meat, meat by-products, poultry meat, poultry by-products or fish, or meat of any marine or fresh water animal, that has been frozen is thawed prior to sale, the words “previously frozen” shall be shown

(*a*) on the principal display panel in close proximity to the common name of the food and in letters at least as legible and conspicuous as those used in the common name;

(*b*) anywhere on the principal display panel in letters of not less than 1/4 of an inch (6.4 millimetres) in height; or

(*c*) on a sign displayed adjacent to the food in letters that are legible and conspicuous to a prospective purchaser.

(3) Where part of a food referred to in subsection (2) has been frozen and thawed prior to sale, the words “Made from fresh and frozen portions” or “Made from fresh and frozen (naming the food)” shall be shown in the manner described in paragraph (2)(*a*), (*b*) or (*c*).

SOR/88-336, s. 3.

B.01.090. (1) No person shall offer for sale at retail any solid cut meat or solid cut poultry meat to which phosphate salts or water has been added, unless that meat or poultry meat is contained in a package and carries a label.

(2) The label referred to in subsection (1) shall contain a statement of the minimum percentage of meat protein as part of the common name of the product on the principal display panel of the package in type that is as legible and conspicuous as any other type on that display panel, and in letters that are at least one half of the size of the letters used in the common name of the product but that are not less than 1.6 mm in height.

SOR/94-262, s. 1.

B.01.091. The label of any solid cut meat or solid cut poultry meat that has had phosphate salts or water added to it, that is not cured and that is prepackaged at retail shall contain a statement of the ingredients contained in the food in accordance with subsections B.01.008(3) to (5).

SOR/94-262, s. 1; SOR/2003-11, s. 14.

B.01.092. Sections B.01.090 and B.01.091 do not apply in respect of side bacon, Wiltshire bacon, pork jowls, salt pork or salt beef.

SOR/94-262, s. 1.

B.01.100. (1) The common name of a simulated meat product or simulated poultry product shall be the common name of the meat product or poultry product that is simulated, modified by the word “simulated”.

(2) The word “simulated” in the common name of a simulated meat product or simulated poultry product shall be shown in letters of at least the same size and prominence as those used in the remainder of the common name of that product.

(3) Where a simulated meat product or a simulated poultry product is not a prepackaged product, the common name of the product and the other information required by this section to be shown on the label of a simulated meat product or simulated poultry product shall be

shown on a sign displayed on or adjacent to the product in letters that are legible and conspicuous to a prospective purchaser.

(4) The words

(*a*) “contains no meat”, in the case of a simulated meat product, and

(*b*) “contains no poultry”, in the case of a simulated poultry product,

shall be shown on the principal display panel of the label of a simulated meat product or simulated poultry product in close proximity to the common name and in letters of at least the same size and prominence as those shown in the common name.

(5) to (7) [Repealed, SOR/88-559, s. 11]

SOR/88-336, s. 3; SOR/88-559, s. 11.

B.01.101. (1) For the purposes of this section and section B.01.102, “source of protein” means any food that contains protein, but does not include spices, seasonings, flavours, artificial flavours, flavour enhancers, food additives and similar foods that contain only small amounts of protein.

(2) The common name of a meat product extender shall be the common name of each food in the meat product extender that is a source of protein, plus

(*a*) the word “meat”, or the common name of the meat product that is to be extended, plus the word “extender”; or

(*b*) the words “extender for” plus the common name of the meat product that is to be extended.

(3) The common name of a poultry product extender shall be the common name of each food in the poultry product extender that is a source of protein, plus

(*a*) the word “poultry”, or the common name of the poultry product that is to be extended plus the word “extender”; or

(*b*) the words “extender for” plus the common name of the poultry product that is to be extended.

(4) Foods that are a source of protein in the meat product extender or poultry product extender shall be shown by their common names in the common name of that meat product extender or poultry product extender

(*a*) in descending order of their proportion of the meat product extender or poultry product extender; and

(*b*) in letters of at least the same size and prominence as those used in the remainder of the common name of the meat product extender or poultry product extender.

(5) and (6) [Repealed, SOR/88-559, s. 12]

SOR/88-559, s. 12.

B.01.102. (1) The common name of an extended meat product or an extended poultry product shall be the common name of the meat product or poultry product that is extended, modified by the common name of each of the foods that are sources of protein in the extended meat product or extended poultry product.

(2) Notwithstanding subsection (1),

(*a*) the word or words “meat”, “meat product”, “poultry”, “poultry meat” or “poultry meat by-product” as the case may be, may be used in the common name of an extended meat product or extended poultry product as the common name of the food therein that is a source of protein derived from a meat product or poultry product; and

(*b*) where it is an acceptable manufacturing practice for a manufacturer to omit from his meat product extender or poultry product extender any source of protein derived from a plant that is ordinarily an ingredient of that meat product extender or poultry product extender, or to substitute in whole or in part in his meat product extender or poultry product extender any source of protein derived from a plant for a source of protein that is ordinarily an ingredient of that meat product extender or poultry product extender, the word “plant” may be used in the common name of an extended meat product or extended poultry product as the common name of the food therein that is a source of protein derived from a plant.

(3) Foods that are a source of protein in an extended meat product or extended poultry product shall be shown by their common names in the common name of that product

(*a*) in descending order of their proportion of that product; and

(*b*) in letters of at least the same size and prominence as those used in the remainder of the common name of that product.

(4) Where an extended meat product or extended poultry product is not a prepackaged product, the common name of that product and the information required by this section to be shown on the label of an extended meat product or extended poultry product shall be shown on a sign displayed on or adjacent to that product in letters that are legible and conspicuous to a prospective purchaser.

(5) to (7) [Repealed, SOR/88-559, s. 13]

SOR/84-300, s. 9; SOR/88-559, s. 13.

B.01.103. (1) The common name of a yolk-replaced egg shall be “yolk-replaced egg”.

(2) to (4) [Repealed, SOR/88-559, s. 14]

SOR/88-559, s. 14.

B.01.300. [Repealed, SOR/2003-11, s. 15]

B.01.301. (1) No person shall, on the label of or in any advertisement for a food, other than in the nutrition facts table, if any, include a declaration of the food’s energy value or the amount of a nutrient contained in the food unless it is declared in the following manner, per serving of stated size:

(*a*) in the case of the energy value, in Calories;

(*b*) in the case of a vitamin set out in column I of Table I to Division 1 of Part D or a mineral nutrient set out in column I of Table I to Division 2 of Part D, in the units specified in that column;

(*c*) in the case of sodium, potassium or cholesterol, in milligrams;

(*d*) in the case of the mineral ion content of prepackaged water or ice, in parts per million; and

(*e*) in any other case, in grams.

(2) Despite subsection (1), a person may, on the label of a food or in any advertisement for a food, other than in the nutrition facts table, if any, include a declaration of the percentage of the daily value of a nutrient contained in the food if

(*a*) the nutrient is listed in column 1 of the table to section B.01.401 or the table to section B.01.402;

(*b*) the percentage of the daily value of the nutrient is required or permitted to be declared in the nutrition facts table; and

(*c*) the percentage of the daily value of the nutrient is declared per serving of stated size.

(3) A declaration referred to in subsection (1) or (2) that appears on the label of a food shall be

(*a*) in English and French; or

(*b*) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

SOR/88-559, s. 15; SOR/2003-11, s. 16.

B.01.302. to B.01.304. [Repealed, SOR/2003-11, s. 17]

B.01.305. (1) No person shall, on the label of or in any advertisement for a food, make a representation, express or implied, respecting a protein unless the food meets the conditions set out in column 2 of item 8 of the table following section B.01.513 for the subject “source of protein” set out in column 1.

(2) No person shall, on the label of or in any advertisement for a food, make a representation, express or implied, respecting an amino acid unless

(*a*) the food meets the conditions set out in column 2 of item 8 of the table following section B.01.513 for the subject “source of protein” set out in column 1; and

(*b*) the label or advertisement includes a declaration of the amount of histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan and valine contained in the food, expressed in grams per serving of stated size.

(3) Subsections (1) and (2) do not apply in respect of

(*a*) a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute;

(*b*) foods represented for use in gluten-free diets, protein restricted diets, low (naming the amino acid) diets and (naming the amino acid) free diets;

(*c*) the word “protein” when used as part of the common name of an ingredient in the list of ingredients;

(*d*) the declaration of amino acids in the list of ingredients;

(*e*) the common names set out in column II of items 7 to 9 of the table to paragraph B.01.010(3)(*a*), when shown in the list of ingredients in accordance with that paragraph;

(*f*) the common name of a single amino acid preparation that may be sold as a food;

(*g*) the statements required by paragraphs B.01.014(*c*) and B.01.015(1)(*b*);

(*h*) a statement or claim set out in column 4 of item 7 of the table following section B.01.513 respecting the subject “low in protein” set out in column 1;

(*i*) a declaration of the amount of protein in the nutrition facts table;

(*j*) a statement of the protein content of a food as required by paragraph B.24.103(*c*), subparagraph B.24.202(*a*)(ii), paragraph B.24.304(*b*) or B.25.057(1)(*a*) or subparagraph B.25.057(2)(*c*)(i) or (*d*)(i); or

(*k*) a statement that a food is not a source of protein.

(4) A representation referred to in subsection (1) or (2) that appears on the label of a food shall be

(*a*) in English and French; or

(*b*) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

SOR/88-559, s. 15; SOR/90-830, s. 3(F); SOR/2003-11, s. 18.

B.01.306. to B.01.310. [Repealed, SOR/2003-11, s. 19]

B.01.311. (1) Subject to subsections (2) and (3), no person shall, on the label of or in any advertisement for a food, make a representation, express or implied, concerning the action or effect of the food’s energy value or of a nutrient contained in the food.

(2) The label of or advertisement for a food may carry a statement or claim set out in column 1 of the table following section B.01.603.

(3) Subject to section B.01.312, the label of or advertisement for a food may carry a statement or claim to the effect that the food’s energy value or a nutrient contained in the food is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

(4) If a statement or claim described in subsection (3) concerns a nutrient not listed in column 1 of the tables to sections B.01.401 and B.01.402, the amount of the nutrient contained in the food must be expressed on any part of the label in grams per serving of stated size.

(5) A statement or claim referred to in subsection (2) or (3) that appears on the label of a food shall be

(*a*) in English and French; or

(*b*) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

SOR/88-559, s. 15; SOR/2003-11, s. 20.

B.01.312. (1) If a statement or claim described in subsection B.01.311(3) is made on the label of or in an advertisement for a food that is not a prepackaged product or in an advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include a declaration, per serving of stated size, of

(*a*) the energy value, if the energy value is the subject of the statement or claim; or

(*b*) the amount of the nutrient, if a nutrient is the subject of the statement or claim.

(2) If the statement or claim is made in an advertisement other than a radio or television advertisement, the declaration referred to in subsection (1) shall be

(*a*) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and

(*b*) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

(3) If the statement or claim is made in a radio advertisement or in the audio portion of a television advertisement, the declaration referred to in subsection (1) shall immediately precede or follow the statement or claim.

(4) If the statement or claim is made in a television advertisement, the declaration referred to in subsection (1) shall be communicated

(*a*) in the audio mode, if the statement or claim is made only in the audio portion of the advertisement or in both the audio and visual portions; or

(*b*) in the audio or visual mode, if the statement or claim is made only in the visual portion of the advertisement.

(5) If the declaration referred to in subsection (1) is communicated in the visual mode of a television advertisement, it shall

(*a*) appear concurrently with and for at least the same amount of time as the statement or claim;

(*b*) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and

(*c*) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

SOR/2003-11, s. 20.

## Interpretation

B.01.400. The following definitions apply in sections B.01.401 to B.01.603.

“fat” means all fatty acids expressed as triglycerides. (lipides)

“point” means a unit of measurement for type size that is known as an Anglo-American point and is equal to 0.3514598 mm. (point)

SOR/2003-11, s. 20.

## Nutrition Labelling

### Core Information

B.01.401. (1) Except as otherwise provided in this section and sections B.01.402 to B.01.406 and B.01.467, the label of a prepackaged product shall carry a nutrition facts table that contains only the information set out in column 1 of the table to this section expressed using a description set out in column 2, in the unit set out in column 3 and in the manner set out in column 4.

(2) Subsection (1) does not apply to a prepackaged product if

(*a*) all the information set out in column 1 of the table to this section, other than in respect of item 1 (“Serving of stated size”), may be expressed as “0” in the nutrition facts table in accordance with this section;

(*b*) the product is

(i) a beverage with an alcohol content of more than 0.5%,

(ii) a fresh vegetable or fruit or any combination of fresh vegetables or fruits without any added ingredients, an orange with added food colour or a fresh vegetable or fruit coated with paraffin wax or petrolatum,

(iii) a raw single ingredient meat, meat by-product, poultry meat or poultry meat by-product,

(iv) a raw single ingredient marine or fresh water animal product,

(v) sold only in the retail establishment where the product is prepared and processed from its ingredients, including from a pre-mix if an ingredient other than water is added to the pre-mix during the preparation and processing of the product,

(vi) sold only at a road-side stand, craft show, flea market, fair, farmers’ market or sugar bush by the individual who prepared and processed the product,

(vii) an individual serving that is sold for immediate consumption and that has not been subjected to a process to extend its durable life, including special packaging, or

(viii) sold only in the retail establishment where the product is packaged, if the product is labelled by means of a sticker and has an available display surface of less than 200 $cm^2$; or

(*c*) the product is

(i) a prepackaged confection, commonly known as a one bite confection, that is sold individually,

(ii) a prepackaged individual portion of food that is solely intended to be served by a restaurant or other commercial enterprise with meals or snacks, or

(iii) milk, partly skimmed milk, skim milk, goat's milk, partly skimmed goat's milk, skimmed goat's milk, (naming the flavour) milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk or cream sold in a refillable glass container.

(3) Despite paragraphs (2)(*a*) and (*b*), subsection (1) applies to a prepackaged product if

(*a*) the product contains an added vitamin or mineral nutrient;

(*b*) a vitamin or mineral nutrient is declared as a component of one of the product's ingredients other than flour;

(*c*) the product contains added acesulfame-potassium, aspartame, neotame or sucralose;

(*d*) the product is a meat, meat by-product, poultry meat or poultry meat by-product that is ground; or

(*e*) the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product, contains

(i) a reference to the energy value, a nutrient set out in column 1 of the table to this section or in column 1 of the table to section B.01.402 or a constituent of such a nutrient, other than information required by Division 12 or a reference to the common name of an ingredient in the list of ingredients for the product,

(ii) a representation that expressly or implicitly indicates that the product has particular nutritional or health-related properties, including any statement or claim set out in column 4 of the table following section B.01.513 or column 1 of the table following section B.01.603 or referred to in section B.01.311, D.01.006 or D.02.004,

(iii) a health-related name, statement, logo, symbol, seal of approval or mark, or

(iv) the phrase "nutrition facts", "valeur nutritive" or "valeurs nutritives".

(4) Subsection (1) does not apply to a formulated liquid diet, a human milk substitute, a food represented as containing a human milk substitute, a meal replacement, a nutritional supplement or a food represented for use in a very low energy diet.

(5) The label of or advertisement for a formulated liquid diet, a human milk substitute, a food represented as containing a human milk substitute, a meal replacement, a nutritional supplement or a food represented for use in a very low energy diet shall not contain a nutrition facts table or the phrase "nutrition facts", "valeur nutritive" or "valeurs nutritives".

(6) If, for a prepackaged product other than one intended solely for children under two years of age, the information in respect of seven or more of the energy value and nutrients referred

to in column 1 of items 2 to 5 and 7 to 13 of the table to this section may be expressed as “0” in the nutrition facts table in accordance with this section, the nutrition facts table need only include the following information:

(*a*) the serving of stated size;

(*b*) the energy value;

(*c*) the amount of fat;

(*d*) the amount of carbohydrate;

(*e*) the amount of protein;

(*f*) the amount of any nutrient that is the subject of a representation referred to in subparagraph (3)(*e*)(ii);

(*g*) the amount of any sugar alcohol, vitamin or mineral nutrient added to the prepackaged product, other than iodide added to salt for table or general household use or fluoride added to prepackaged water or ice;

(*h*) the amount of any vitamin or mineral nutrient that is declared as a component of one of the prepackaged product’s ingredients other than flour;

(*i*) the amount of any nutrient referred to in column 1 of item 4, 5, 7, 8, 10, 11 or 13 of the table to this section that may not be expressed as “0” in the nutrition facts table; and

(*j*) the statement “Not a significant source of (naming each nutrient that is omitted from the nutrition facts table in accordance with this subsection)” or, if the prepackaged product meets the condition specified in subsection B.01.455(3), the statement “Not a significant source of other nutrients”.

(7) Subsection (1) does not apply to a prepackaged product

(*a*) that is intended solely for use as an ingredient in the manufacture of other prepackaged products intended for sale to a consumer at the retail level or as an ingredient in the preparation of food by a commercial or industrial enterprise or institution; or

(*b*) that is a multiple-serving ready-to-serve prepackaged product intended solely to be served in a commercial or industrial enterprise or institution.

TABLE

CORE INFORMATION

| | Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|---|
| Item | Information | Description | Unit | Manner of expression |
| 1. | Serving of stated size | “Serving Size (naming the serving size)”, “Serving (naming the serving size)” or “Per (naming the serving size)” | (1) The size is expressed in one of the following units:<br>(*a*) in the case of a food that is usually divided into pieces before being consumed (such as | (1) The size when expressed in metric units is rounded off<br>(*a*) if it is less than 10 g or 10 mL, to the nearest multiple of 0.1 g or 0.1 mL; and |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | | cake, pie and pizza), a fraction of the entire food; | |
| | | | (*b*) in the case of a food described in subsection B.01.002A(2), the entire container; and | (*b*) if it is 10 g or more or 10 mL or more, to the nearest multiple of 1 g or 1 mL. |
| | | | (*c*) in all other cases, in a commonly used unit in respect of which the quantity is visibly measurable, such as millilitres, cups, tablespoons or "(naming the unit of food)". | (2) The size when expressed as a fraction is represented by a numerator and a denominator separated by a line. |
| | | | (2) The size expressed in accordance with subitem (1) is followed by the size expressed in grams or millilitres, as specified by paragraph B.01.002A(1)(*b*). | (3) The size shall include the word "assorted" if the information in the nutrition facts table of a prepackaged product that contains an assortment of foods is set out as a composite value. |
| 2. | Energy value | | | The value is rounded off<br>(*a*) if it is less than 5 Calories |
| | | "Calories", "Total Calories" or "Calories, Total" | The value is expressed in Calories per serving of stated size. | (i) if the product meets the conditions set out in column 2 of item 1 of the table following section B.01.513 for the subject" free of energy" set out in column 1, to "0" Calorie, and |
| | | | | (ii) in all other cases, to the nearest multiple of 1 Calorie; |
| | | | | (*b*) if it is 5 Calories or more but not more than 50 Calories, to the nearest multiple of 5 Calories; and |
| | | | | (*c*) if it is more than 50 Calories, to the nearest |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | | | multiple of 10 Calories. |
| 3. | Amount of fat | “Fat”, “Total Fat” or “Fat, Total” | The amount is expressed<br>(*a*) in grams per serving of stated size; and | (1) The amount is rounded off<br>(*a*) if it is less than 0.5 g<br>(i) if the product meets the conditions set out in column 2 of item 11 of the table following section B.01.513 for the subject “free of fat” set out in column 1 and the amounts of saturated fatty acids and *trans* fatty acids are declared as “0 g” in the nutrition facts table or are omitted from that table in accordance with subsection B.01.401(6) and no other fatty acids are declared in an amount greater than 0 g, to “0 g”, and<br>(ii) in all other cases, to the nearest multiple of 0.1 g;<br>(*b*) if it is 0.5 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and<br>(*c*) if it is more than 5 g, to the nearest multiple of 1 g.<br>(2) The percentage is rounded off<br>(*a*) if the amount is declared as “0 g”, to “0%“; and<br>(*b*) in all other cases, to the nearest multiple of 1%. |
| | | | (*b*) as a percentage of the daily value per serving of stated size. | |
| 4. | Amount of saturated fatty acids | “Saturated Fat”, “Saturated Fatty Acids”, “Saturated” | The amount is expressed in grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 0.5 g |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | or “Saturates” | | (i) if the product meets the conditions set out in column 2 of item 18 of the table following section B.01.513 for the subject “free of saturated fatty acids” set out in column 1, to “0 g”, and<br><br>(ii) in all other cases, to the nearest multiple of 0.1 g; |
| 5. | | “Trans Fat”, “Trans Fatty Acids” or “Trans” | The amount is expressed in grams per serving of stated size. | The amount is rounded off<br><br>(*a*) if it is less than 0.5 g<br><br>(i) if the product meets the conditions set out in column 2 of item 22 of the table following section B.01.513 for the subject “free of *trans* fatty acids” set out in column 1, to “0 g”, and<br><br>(ii) in all other cases, to the nearest multiple of 0.1 g;<br><br>(*b*) if it is 0.5 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and<br><br>(*c*) if it is more than 5 g, to the nearest multiple of 1 g. |
| | Amount of *trans* fatty acids | | | |
| 6. | The sum of saturated fatty acids and *trans* fatty acids | “Saturated Fat + Trans Fat”, “Saturated Fatty Acids + Trans Fatty Acids”, “Saturated + Trans” or “Saturates | The sum is expressed as a percentage of the daily value per serving of stated size. | The percentage is rounded off<br><br>(*a*) if the amounts of saturated fatty acids and *trans* fatty acids are |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | + Trans” | | declared as “0 g”, to “0%”; and<br>(*b*) in all other cases, to the nearest multiple of 1%. |
| 7. | Amount of cholesterol | “Cholesterol” | The amount is expressed in milligrams per serving of stated size and may also be expressed as a percentage of the daily value per serving of stated size. | (1) The amount is rounded off<br>(*a*) if the product meets the conditions set out in column 2 of item 27 of the table following section B.01.513 for the subject “free of cholesterol” set out in column 1, to “0 mg”; and<br>(*b*) in all other cases, to the nearest multiple of 5 mg.<br>(2) The percentage is rounded off<br>(*a*) if the amount is declared as “0 mg” to “0%”; and<br>(*b*) in all other cases, to the nearest multiple of 1%. |
| 8. | Amount of sodium | “Sodium” | The amount is expressed<br>(*a*) in milligrams per serving of stated size; and<br>(*b*) as a percentage of the daily value per serving of stated size. | (1) The amount is rounded off<br>(*a*) if it is less than 5 mg<br>(i) if the product meets the conditions set out in column 2 of item 31 of the table following section B.01.513 for the subject “free of sodium or salt” set out in column 1, to “0 mg”, and<br>(ii) in all other cases, to the nearest multiple of 1 mg;<br>(*b*) if it is 5 mg or more |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | | | but not more than 140 mg, to the nearest multiple of 5 mg; and<br>(*c*) if it is more than 140 mg, to the nearest multiple of 10 mg.<br>(2) The percentage is rounded off<br>(*a*) if the amount is declared as “0 mg”, to “0%”; and<br>(*b*) in all other cases, to the nearest multiple of 1%. |
| 9. | Amount of carbohydrate | “Carbohydrate”, “Total Carbohydrate” or “Carbohydrate, Total” | The amount is expressed<br>(*a*) in grams per serving of stated size; and<br>(*b*) as a percentage of the daily value per serving of stated size. | (1) The amount is rounded off<br>(*a*) if it is less than 0.5 g, to “0 g”; and<br>(*b*) if it is 0.5 g or more, to the nearest multiple of 1 g.<br>(2) The percentage is rounded off<br>(*a*) if the amount is declared as “0 g”, to “0%”; and<br>(*b*) in all other cases, to the nearest multiple of 1%. |
| 10. | Amount of fibre | “Fibre”, “Fiber”, “Dietary Fibre” or “Dietary Fiber” | The amount is expressed<br>(*a*) in grams per serving of stated size; and<br>(*b*) as a percentage of the daily value per serving of stated size. | (1) The amount is rounded off<br>(*a*) if it is less than 0.5 g, to “0 g”; and<br>(*b*) if it is 0.5 g or more, to the nearest multiple of 1 g.<br>(2) The percentage is rounded off<br>(*a*) if the amount is declared as “0 g”, to “0%”; and<br>(*b*) in all other cases, to the nearest multiple of 1%. |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| 11. | Amount of sugars | “Sugars” | The amount is expressed in grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 0.5 g, to “0 g”; and<br>(*b*) if it is 0.5 g or more, to the nearest multiple of 1 g. |
| 12. | Amount of protein | “Protein” | The amount is expressed in grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 0.5 g, to the nearest multiple of 0.1 g; and<br>(*b*) if it is 0.5 g or more, to the nearest multiple of 1 g. |
| 13. | Amount of | | The amount is expressed as a percentage of the daily value per serving of stated size. | The percentage is rounded off |
| | (*a*) vitamin A | (*a*) “Vitamin A” or “Vit A” | | (*a*) if it is less than 2% |
| | (*b*) vitamin C | (*b*) “Vitamin C” or “Vit C” | | (i) if the product contains less than 1% of the daily value per reference amount and per serving of stated size, to “0 %”, and |
| | (*c*) calcium | (*c*) “Calcium” | | (ii) in all other cases, to “2%”; |
| | (*d*) iron | (*d*) “Iron” | | (*b*) if it is 2% or more but not more than 10%, to the nearest multiple of 2%;<br>(*c*) if it is more than 10% but not more than 50%, to the nearest multiple of 5%; and<br>(*d*) if it is more than 50%, to the nearest multiple of 10%. |

SOR/2003-11, s. 20; SOR/2007-176, s. 5.

Previous Version

**Additional Information**

B.01.402. (1) The nutrition facts table may also contain information set out in column 1 of the table to this section.

(2) If information set out in column 1 of the table to this section is included in the nutrition facts table, it shall be expressed using a description set out in column 2, in the unit set out in column 3 and in the manner set out in column 4.

(3) The amount of omega-6 polyunsaturated fatty acids, omega-3 polyunsaturated fatty acids and monounsaturated fatty acids shall be in the nutrition facts table if

(*a*) the amount of any of those groups of fatty acids or the amount of polyunsaturated fatty acids is in the nutrition facts table or is shown on the label of the prepackaged product or in any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product; or

(*b*) the amount of any specific fatty acid is shown on the label of the prepackaged product or in any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product.

(4) If the label of a prepackaged product, or any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product, contains a representation, express or implied, that includes information that is set out in column 1 of the table to this section, that information shall also be in the nutrition facts table.

(5) The amount of potassium shall be in the nutrition facts table if the prepackaged product contains added potassium salts and the label of the product or any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product contains a statement or claim referred to in column 4 of any of items 31 to 36 of the table following section B.01.513 for the subject “free of sodium or salt”, “low in sodium or salt”, “reduced in sodium or salt”, “lower in sodium or salt”, “no added sodium or salt” or “lightly salted” set out in column 1.

(6) The nutrition facts table shall show the amount of any sugar alcohol, vitamin or mineral nutrient added to the prepackaged product, except in the case of iodide added to salt for table or general household use or fluoride added to prepackaged water or ice.

(7) The nutrition facts table shall show the amount of any vitamin or mineral nutrient that is declared as a component of one of the prepackaged product’s ingredients other than flour.

(8) Despite subsection (1) and item 1 of the table to this section, the nutrition facts table shall not include information on servings per container if the serving of stated size is expressed in cups or tablespoons.

(9) If information set out in column 1 of the table to this section is included in the nutrition facts table, it shall be shown

(*a*) in English and French; or

(*b*) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the product may be shown in that language only and is shown on the label in that language.

TABLE

ADDITIONAL INFORMATION

| | Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|---|
| Item | Information | Description | Unit | Manner of expression |
| 1. | Servings per container | “Servings Per Container” or “(number of units) Per | The quantity is expressed in | (1) The quantity is rounded off |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | Container” | number of servings. | (*a*) if it is less than 2, to the nearest multiple of 1;<br>(*b*) if it is between 2 and 5, to the nearest multiple of 0.5; and<br>(*c*) if it is more than 5, to the nearest multiple of 1.<br>(2) If a quantity is rounded off, it shall be preceded by the word “about”.<br>(3) If the product is of a random weight, the quantity may be declared as “varied”. |
| 2. | Energy value | “kilojoules” or “kJ” | The value is expressed in kilojoules per serving of stated size. | The value is rounded off to the nearest multiple of 10 kilojoules. |
| 3. | | | | The value is rounded off |
| | Energy value from fat | “Calories from Fat” or “Calories from Total Fat” | The value is expressed in Calories per serving of stated size. | (*a*) if it is less than 5 Calories<br>(i) if the amount of fat is declared as “0 g” in the nutrition facts table, to “0” Calorie, and<br>(ii) in all other cases, to the nearest multiple of 1 Calorie;<br>(*b*) if it is 5 Calories or more but not more than 50 Calories, to the nearest multiple of 5 Calories; and<br>(*c*) if it is more than 50 Calories, to the nearest multiple of 10 Calories. |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| 4. | Energy value from the sum of saturated and *trans* fatty acids | "Calories from Saturated + Trans Fat", "Calories from Saturated + Trans Fatty Acids", "Calories from Saturated + Trans" or "Calories from Saturates + Trans" | The value is expressed in Calories per serving of stated size. | The value is rounded off<br>(*a*) if it is less than 5 Calories<br>(i) if the amounts of saturated fatty acids and *trans* fatty acids are declared as "0 g" in the nutrition facts table, to "0" Calorie, and<br>(ii) in all other cases, to the nearest multiple of Calorie;<br>(*b*) if it is 5 Calories or more but not more than 50 Calories, to the nearest multiple of 5 Calories; and<br>(*c*) if it is more than 50 Calories, to the nearest multiple of 10 Calories. |
| 5. | Amount of polyunsaturated fatty acids | "Polyunsaturated Fat", "Polyunsaturated Fatty Acids", "Polyunsaturated" or "Polyunsaturates" | The amount is expressed in grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 1 g, to the nearest multiple of 0.1 g;<br>(*b*) if it is 1 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and<br>(*c*) if it is more than 5 g, to the nearest multiple of 1 g. |
| 6. | Amount of omega-6 polyunsaturated fatty acids | (1) If the nutrition facts table includes the amount of polyunsaturated fatty acids: "Omega-6", "Omega-6 Polyunsaturated Fat", "Omega-6 Polyunsaturated Fatty Acids", "Omega-6 Polyunsaturates" or "Omega-6 Polyunsaturated" | The amount is expressed in grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 1 g, to the nearest multiple of 0.1 g;<br>(*b*) if it is 1 g or more but not more than 5 g, to the nearest |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | | | multiple of 0.5 g; and<br>(*c*) if it is more than 5 g, to the nearest multiple of 1 g. |
| | | (2) In all other cases: "Omega-6 Polyunsaturated Fat", "Omega-6 Polyunsaturated Fatty Acids", "Omega-6 Polyunsaturates" or "Omega-6 Polyunsaturated" | | |
| 7. | Amount of omega-3 polyunsaturated fatty acids | (1) If the nutrition facts table includes the amount of polyunsaturated fatty acids: "Omega-3", "Omega-3 Polyunsaturated Fat", "Omega-3 Polyunsaturated Fatty Acids", "Omega-3 Polyunsaturates" or "Omega-3 Polyunsaturated" | The amount is expressed in grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 1 g, to the nearest multiple of 0.1 g;<br>(*b*) if it is 1 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and<br>(*c*) if it is more than 5 g, to the nearest multiple of 1 g. |
| | | (2) In all other cases: "Omega-3 Polyunsaturated Fat", "Omega-3 Polyunsaturated Fatty Acids", "Omega-3 Polyunsaturates" or "Omega-3 Polyunsaturated" | | |
| 8. | Amount of monounsaturated fatty acids | "Monounsaturated Fat", "Monounsaturated Fatty Acids", "Monounsaturates" or "Monounsaturated" | The amount is expressed in grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 1 g, to the nearest multiple of 0.1 g;<br>(*b*) if it is 1 g or more but not more than 5 g, to the nearest multiple of 0.5 g; and<br>(*c*) if it is more than 5 g, to the nearest multiple of 1 g. |
| 9. | Amount of potassium | "Potassium" | The amount is expressed<br>(*a*) in milligrams per serving of stated size; and | (1) The amount is rounded off<br>(*a*) if it is less than 5 mg |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | | (*b*) as a percentage of the daily value per serving of stated size. | (i) if the product contains less than 5 mg of potassium per reference amount and per serving of stated size, to “0 mg”, and<br>(ii) in all other cases, to the nearest multiple of 1 mg;<br>(*b*) if it is 5 mg or more but not more than 140 mg, to the nearest multiple of 5 mg; and<br>(*c*) if it is more than 140 mg, to the nearest multiple of 10 mg.<br>(2) The percentage is rounded off<br>(*a*) if the amount is declared as “0 mg”, to “0%”; or<br>(*b*) in all other cases, to the nearest multiple of 1%. |
| 10. | Amount of soluble fibre | “Soluble Fibre” or “Soluble Fiber” | The amount is expressed as grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 0.5 g, to “0 g”; and<br>(*b*) if it is 0.5 g or more, to the nearest multiple of 1 g. |
| 11. | Amount of insoluble fibre | “Insoluble Fibre” or “Insoluble Fiber” | The amount is expressed as grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 0.5 g, to “0 g”; and<br>(*b*) if it is 0.5 g or more, to the nearest multiple of 1 g. |
| 12. | Amount of sugar alcohol | (1) If the food contains only one type of sugar alcohol: “Sugar Alcohol”, “Polyol” or | The amount is expressed as grams per | The amount is rounded off<br>(*a*) if it is less than |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | | "(naming the sugar alcohol)" | serving of stated size. | 0.5 g, to "0 g"; and<br>(*b*) if it is 0.5 g or more, to the nearest multiple of 1 g. |
| | | (2) In all other cases: "Sugar Alcohols" or "Polyols" | | |
| 13. | Amount of starch | "Starch" | The amount is expressed as grams per serving of stated size. | The amount is rounded off<br>(*a*) if it is less than 0.5 g, to "0 g"; and<br>(*b*) if it is 0.5 g or more, to the nearest multiple of 1 g. |
| 14. | Amount of | | The amount is expressed as a percentage of the daily value per serving of stated size. | The percentage is rounded off<br>(*a*) if it is less than 2%<br>(i) if the product contains less than 1% of the daily value per reference amount and per serving of stated size, to "0%", and<br>(ii) in all other cases, to the nearest multiple of 2%;<br>(*b*) if it is 2% or more but not more than 10%, to the nearest multiple of 2%;<br>(*c*) if it is more than 10% but not more than 50%, to the nearest multiple of 5%; and<br>(*d*) if it is more than 50%, to the nearest multiple of 10%. |
| | (*a*) vitamin D | (*a*) "Vitamin D" or "Vit D" | | |
| | (*b*) vitamin E | (*b*) "Vitamin E" or "Vit E" | | |
| | (*c*) vitamin K | (*c*) "Vitamin K" or "Vit K" | | |
| | (*d*) thiamine | (*d*) "Thiamine", "Thiamin", "Thiamine (Vitamin $B_1$)", "Thiamine (Vit $B_1$)", "Thiamin (Vitamin $B_1$)" or "Thiamin (Vit $B_1$)" | | |
| | (*e*) riboflavin | (*e*) "Riboflavin", "Riboflavin (Vitamin $B_2$)" or "Riboflavin (Vit $B_2$)" | | |
| | (*f*) niacin | (*f*) "Niacin" | | |
| | (*g*) vitamin $B_6$ | (*g*) "Vitamin $B_6$" or "Vit $B_6$" | | |
| | (*h*) folate | (*h*) "Folate" | | |
| | (*i*) vitamin $B_{12}$ | (*i*) "Vitamin $B_{12}$" or "Vit $B_{12}$" | | |
| | (*j*) biotin | (*j*) "Biotin" | | |
| | (*k*) pantothenic | (*k*) "Pantothenic Acid" or | | |

| Item | Column 1<br>Information | Column 2<br>Description | Column 3<br>Unit | Column 4<br>Manner of expression |
|---|---|---|---|---|
| | acid | “Pantothenate” | | |
| | (*l*) phosphorus | (*l*) “Phosphorus” | | |
| | (*m*) iodide | (*m*) “Iodide” or “Iodine” | | |
| | (*n*) magnesium | (*n*) “Magnesium” | | |
| | (*o*) zinc | (*o*) “Zinc” | | |
| | (*p*) selenium | (*p*) “Selenium” | | |
| | (*q*) copper | (*q*) “Copper” | | |
| | (*r*) manganese | (*r*) “Manganese” | | |
| | (*s*) chromium | (*s*) “Chromium” | | |
| | (*t*) molybdenum | (*t*) “Molybdenum” | | |
| | (*u*) chloride | (*u*) “Chloride” | | |
| 15. | Basis of the percent daily values | One of the four footnotes to the subheading “% Daily Value” set out in Figures 18.1(E) and (F) of Schedule L | | In the version of the footnote that refers to nutrients,<br>(*a*) the daily value for potassium is included only if the amount of potassium is declared in the nutrition facts table; and<br>(*b*) the daily value for cholesterol is included only if the amount of cholesterol is declared in the nutrition facts table as a percentage of the daily value per serving of stated size. |
| 16. | Energy conversion factors | “Calories per gram:”, “Fat 9”, “Carbohydrate 4” and “Protein 4” | | |

SOR/2003-11, s. 20; err., Vol. 137, No. 5; SOR/2005-98, s. 2(F).

**Foods for Children under Two Years of Age**

B.01.403. (1) This section applies in respect of a prepackaged product intended solely for children under two years of age.

(2) The nutrition facts table of the product shall not contain

(*a*) the percentage of the daily value of fat, cholesterol, sodium, potassium, carbohydrate or fibre or of the sum of saturated fatty acids and *trans* fatty acids;

(*b*) the energy value from fat or from the sum of saturated fatty acids and *trans* fatty acids; or

(*c*) any of the footnotes to the subheading “% Daily Value” set out in Figures 18.1(E) and (F) in Schedule L.

(3) The nutrition facts table of the product may omit the amount of saturated fatty acids, *trans* fatty acids and cholesterol.

(4) Despite subsection (3), if the amount of cholesterol is in the nutrition facts table, the amounts of saturated fatty acids and *trans* fatty acids shall also be in the nutrition facts table.

(5) If the information in respect of six or more of the energy value and nutrients referred to in column 1 of items 2, 3 and 8 to 13 of the table to section B.01.401 may be expressed as “0” in the nutrition facts table of the product in accordance with that section, the nutrition facts table need only include the following information:

(*a*) the serving of stated size;

(*b*) the energy value;

(*c*) the amount of fat;

(*d*) the amount of carbohydrate;

(*e*) the amount of protein;

(*f*) the amount of any nutrient that is the subject of a representation referred to in subparagraph B.01.401(3)(*e*)(ii);

(*g*) the amount of any sugar alcohol, vitamin or mineral nutrient added to the product, other than fluoride added to prepackaged water or ice;

(*h*) the amount of any vitamin or mineral nutrient that is declared as a component of one of the product’s ingredients other than flour;

(*i*) the amount of any nutrient referred to in column 1 of item 8, 10, 11 or 13 of the table to section B.01.401 that may not be expressed as “0” in the nutrition facts table;

(*j*) except in the case described in paragraph (*k*), the statement “Not a significant source of (naming each nutrient that is omitted from the nutrition facts table in accordance with this subsection)”, but such a statement may be omitted in respect of saturated fatty acids, *trans* fatty acids and cholesterol; and

(*k*) if the product meets the condition specified in subsection B.01.462(3), the statement “Not a significant source of other nutrients” or the statement referred to in paragraph (*j*).

SOR/2003-11, s. 20.

**Food for Use in Manufacturing other Foods**

B.01.404. (1) This section applies to a prepackaged product that is intended solely for use as an ingredient in the manufacture of other prepackaged products intended for sale to a consumer at the retail level or as an ingredient in the preparation of food by a commercial or industrial enterprise or institution.

(2) No person shall sell the product unless written nutrition information concerning the product accompanies the product when it is delivered to the purchaser.

(3) The nutrition information

(*a*) shall include the information that would, but for subsection B.01.401(7), be required by sections B.01.401 and B.01.402 to be included in a nutrition facts table for the product;

(*b*) may include other information that is permitted by section B.01.402 to be included in that nutrition facts table; and

(*c*) shall be expressed in accordance with sections B.01.401 and B.01.402, subject to the following modifications, namely,

(i) information for vitamins set out in column I of Table I to Division 1 of Part D and mineral nutrients set out in column I of Table I to Division 2 of that Part shall be expressed in the applicable units referred to in that column,

(A) per gram or 100 grams of the food, if the net quantity of the food is declared on the label by weight or by count, or

(B) per millilitre or 100 millilitres of the food, if the net quantity of the food is declared on the label by volume,

(ii) information for other nutrients and the energy value set out in column 1 of the table to section B.01.401 or in column 1 of the table to section B.01.402 shall be expressed in the units referred to in column 3,

(A) per gram or 100 grams of the food, if the net quantity of the food is declared on the label by weight or by count, or

(B) per millilitre or 100 millilitres of the food, if the net quantity of the food is declared on the label by volume,

(iii) percentages of daily values and information on servings of stated size may be omitted, and

(iv) the nutrition information shall be stated with a degree of precision that corresponds to the accuracy of the analytical methodology used to produce the information.

SOR/2003-11, s. 20.

**Foods for Enterprise or Institution**

B.01.405. (1) This section applies to a prepackaged product that is a multiple-serving ready-to-serve prepackaged product intended solely to be served in a commercial or industrial enterprise or institution.

(2) No person shall sell the product unless written nutrition information concerning the product accompanies the product when it is delivered to the purchaser.

(3) The nutrition information

(*a*) shall include the information that would, but for subsection B.01.401(7), be required by sections B.01.401 and B.01.402 to be included in a nutrition facts table for the product;

(*b*) may include other information that is permitted by section B.01.402 to be included in that nutrition facts table; and

(*c*) shall be expressed in accordance with sections B.01.401 and B.01.402.

SOR/2003-11, s. 20.

**Basis of Information**

B.01.406. (1) Subject to subsections (2) to (8), the information in the nutrition facts table shall be set out only on the basis of the prepackaged product as offered for sale.

(2) If a prepackaged product contains separately packaged ingredients or foods that are intended to be consumed together, the information in the nutrition facts table shall be set out for each ingredient or food or for the entire product.

(3) If a prepackaged product contains an assortment of foods of the same type and the typical serving consists of only one of those foods, the information in the nutrition facts table shall be set out

(*a*) on the basis of each of the foods contained in the product, if the nutrition information set out in column 1 of the table to section B.01.401 for each of those foods is different; or

(*b*) on the basis of one of the foods contained in the product, if the nutrition information set out in column 1 of the table to section B.01.401 for each of those foods is the same.

(4) If a prepackaged product contains an assortment of foods of the same type and the typical serving consists of more than one of those foods, the information in the nutrition facts table shall be set out for each of the foods contained in the product or as a composite value.

(5) If a prepackaged product contains a food that is to be prepared in accordance with directions provided in or on the package or that is commonly combined with other ingredients or another food or cooked before being consumed, the nutrition facts table may also set out information for the food as prepared, in which case

(*a*) the nutrition facts table shall set out the following information for the food as prepared, namely,

(i) except in the case described in subparagraph (ii), the amount of the food expressed in a unit specified in column 3 of paragraph 1(1)(*a*) or (*c*) of the table to section B.01.401 as “about (naming the serving size)” or “about (naming the serving size) prepared” and, if applicable, in the manner specified in column 4 of subitems 1(1) and (2),

(ii) if the food is commonly served combined with another food, the amount of the other food expressed in a unit specified in column 3 of paragraph 1(1)(*c*) of the table to section B.01.401 and, if applicable, in the manner specified in column 4 of subitem 1(1),

(iii) the energy value, expressed using a description set out in column 2 of item 2 of the table to section B.01.401, in the unit set out in column 3 and in the manner set out in column 4,

(iv) if it is declared in the nutrition facts table for the food as sold, the energy value from fat, expressed using a description set out in column 2 of item 3 of the table to section B.01.402, in the unit set out in column 3 and in the manner set out in column 4, and

(v) the information set out in column 1 of items 3, 6 to 10 and 13 of the table to section B.01.401 and in column 1 of items 9 and 14 of the table to section B.01.402 that is declared as a percentage of the daily value in the nutrition facts table for the food as sold, expressed using

a description set out in column 2, as a percentage of the daily value per serving of stated size and in the manner specified in column 4; and

(*b*) the nutrition facts table may also set out the following information for the added ingredients or the other food, if it is declared in the nutrition facts table for the food as sold, namely,

(i) the information set out in column 1 of items 3 to 5 and 7 to 12 of the table to section B.01.401, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of items 7 and 8 and in grams for the information set out in column 1 of items 3 to 5 and 9 to 12 and in the manner specified in column 4, and

(ii) the information set out in column 1 of items 5 to 13 of the table to section B.01.402, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of item 9 and in grams for the information set out in column 1 of items 5 to 8 and 10 to 13 and in the manner specified in column 4.

(6) Subsection (5) does not apply in respect of a prepackaged product that is intended solely for children under two years of age.

(7) Subject to subsection (8), the information in the nutrition facts table may also be set out on the basis of other amounts of a food that reflect different uses or different units of measurement of a food, in which case

(*a*) the nutrition facts table shall set out the following information for each of the other amounts of food, namely,

(i) the amount of the food expressed in a unit specified in column 3 of subitem 1(1) of the table to section B.01.401 and, if applicable, in the manner specified in column 4 of subitems 1(1) and (2),

(ii) the energy value, expressed using a description set out in column 2 of item 2 of the table to section B.01.401, in the unit set out in column 3 and in the manner set out in column 4,

(iii) if it is declared in the nutrition facts table for the first amount of food for which information is declared, the energy value from fat, expressed using a description set out in column 2 of item 3 of the table to section B.01.402, in the unit set out in column 3 and in the manner set out in column 4, and

(iv) the information set out in column 1 of items 3, 6 to 10 and 13 of the table to section B.01.401 and in column 1 of items 9 and 14 of the table to section B.01.402 that is declared as a percentage of the daily value in the nutrition facts table for the first amount of food for which information is declared, expressed using a description set out in column 2, as a percentage of the daily value per serving of stated size and in the manner specified in column 4;

(*b*) if the nutrition facts table is set out in a version of the dual format specified in section B.01.458, it may also set out the amount of each of the other amounts of food expressed in the unit specified in column 3 of subitem 1(2) of the table to section B.01.401 and in the manner specified in column 4 of subitem 1(1), if that information is declared in the nutrition facts table for the first amount of food for which information is declared; and

(*c*) if the nutrition facts table is set out in a version of the aggregate format specified in section B.01.459 or B.01.464, it shall also set out the following information for each of the other

amounts of food, if that information is declared in the nutrition facts table for the first amount of food for which information is declared, namely,

(i) the amount of the food expressed in the unit specified in column 3 of subitem 1(2) of the table to section B.01.401 and in the manner specified in column 4 of subitem 1(1),

(ii) the information set out in column 1 of items 3 to 5 and 7 to 12 of the table to section B.01.401, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of items 7 and 8 and in grams for the information set out in column 1 of items 3 to 5 and 9 to 12 and in the manner specified in column 4, and

(iii) the information set out in column 1 of items 5 to 13 of the table to section B.01.402, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of item 9 and in grams for the information set out in column 1 of items 5 to 8 and 10 to 13 and in the manner specified in column 4.

(8) If the nutrition facts table of a prepackaged product that is intended solely for children under two years of age sets out information in accordance with subsection (7), it shall set out the information referred to in paragraphs (7)(*a*) and (*c*).

SOR/2003-11, s. 20.

**[B.01.407 to B.01.449 reserved]**

**Presentation of Nutrition Facts Table**

B.01.450. (1) Subject to subsections (2) to (6), the nutrition facts table shall be presented in accordance with the format specified in the applicable figure in Schedule L, having regard to matters such as order of presentation, dimensions, spacing and the use of upper and lower case letters and bold type.

(2) The characters and rules in the nutrition facts table shall be displayed in a single colour that is a visual equivalent of 100% solid black type on a white background or on a uniform neutral background with a maximum 5% tint of colour.

(3) The characters in the nutrition facts table

(*a*) shall be displayed in a single standard sans serif font that is not decorative and in such a manner that the characters never touch each other or the rules; and

(*b*) may be displayed with larger dimensions than those specified in the applicable figure in Schedule L if all the characters in the table are enlarged in a uniform manner.

(4) A rule that is specified in the applicable figure in Schedule L as being a 1 point rule or a 2 point rule may be displayed with larger dimensions in the nutrition facts table.

(5) The information in the nutrition facts table shall be in accordance with sections B.01.400 to B.01.403 and B.01.406.

(6) In a nutrition facts table consisting of a table in both English and French, the order of languages may be reversed from the order shown in the applicable figure in Schedule L.

SOR/2003-11, s. 20.

**Location of Nutrition Facts Table**

B.01.451. (1) Subject to subsection (2), the nutrition facts table shall be displayed on the label of the prepackaged product

(*a*) in a table in English and a table in French on the same continuous surface of the available display surface;

(*b*) in a table in both English and French on a continuous surface of the available display surface; or

(*c*) in a table in English on a continuous surface of the available display surface and a table in French on another continuous surface of the available display surface that is of the same size and prominence as the first surface.

(2) If in accordance with subsection B.01.012(3) or (7) the information required by these Regulations may be shown on the label of a prepackaged product in English only or in French only and is shown in that language, the nutrition facts table may be displayed on the label of the prepackaged product in a table in that language only on a continuous surface of the available display surface.

SOR/2003-11, s. 20.

**Orientation of Nutrition Facts Table**

B.01.452. (1) Subject to subsection (2), the nutrition facts table shall be oriented in the same manner as other information appearing on the label of the prepackaged product.

(2) If a version of a nutrition facts table cannot be oriented in the same manner as other information appearing on the label of the prepackaged product, it shall be oriented in another manner if there is sufficient space to do so and the food contained in the package does not leak out and is not damaged when the package is turned over.

(3) Subsection (1) does not apply in respect of a nutrition facts table that is set out on the top or bottom of a prepackaged product.

SOR/2003-11, s. 20.

**Application**

B.01.453. (1) Sections B.01.454 to B.01.460 apply to prepackaged products other than those that are intended solely for children under two years of age.

(2) Sections B.01.461 to B.01.465 apply to prepackaged products that are intended solely for children under two years of age.

SOR/2003-11, s. 20.

**Standard and Horizontal Formats**

B.01.454. (1) This section applies to a prepackaged product unless any of sections B.01.455 to B.01.459 applies to the product.

(2) Subject to subsection (3), the nutrition facts table of the prepackaged product shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(3) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(*a*) the bilingual standard format in accordance with Figure 3.5(B), 3.6(B) or 3.7(B) of Schedule L;

(*b*) the bilingual horizontal format in accordance with Figure 4.3(B), 4.4(B) or 4.5(B) of Schedule L;

(*c*) the linear format in accordance with Figures 16.1(E) and (F) or 16.2(E) and (F) of Schedule L;

(*d*) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table; or

(*e*) a manner described in section B.01.466.

(4) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included in that table.

(5) Despite subsections (2) and (3), if the prepackaged product is sold only in the retail establishment where the product is packaged, is labelled by means of a sticker and has an available display surface of 200 $cm^2$ or more, its nutrition facts table shall be set out in a version that is listed in column 1 of items 1 to 3 of Parts 1 to 3 of the table to this section, without regard to any condition specified in column 2.

(6) Despite subsections (2) and (3), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (3)(*a*), (*b*) or (*c*) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

# TABLE

# PART 1

# STANDARD FORMAT

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 1.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 1.2(E) and (F) | The version in item 1 cannot be displayed in accordance with |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| | (7 point type with 11 point leading) | these Regulations on 15% or less of the available display surface. |
| 3. | 1.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 1.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 1.5(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 1.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# NARROW STANDARD FORMAT

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 2.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 2.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 2.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 2.4(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 3

# BILINGUAL STANDARD FORMAT

| | Column 1 | Column 2 |
|---|---|---|

| Item | Figure in Schedule L (Version) | Condition of use |
|---|---|---|
| 1. | 3.1(B) (8 point type with 12 point leading) | |
| 2. | 3.2(B) (7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 3.3(B) (7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 3.4(B) (6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 4

# BILINGUAL HORIZONTAL FORMAT

| | Column 1 | Column 2 |
|---|---|---|
| Item | Figure in Schedule L (Version) | Condition of use |
| 1. | 4.1(B) (7 point condensed type with 11 point leading) | The versions in Parts 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 2. | 4.2(B) (6 point condensed type with 10 point leading) | The versions in Parts 1 to 3 and in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Simplified Formats**

B.01.455. (1) This section applies to a prepackaged product if it satisfies the condition set out in subsection B.01.401(6) and its nutrition facts table includes only the information referred to in paragraphs B.01.401(6)(*a*) to (*j*).

(2) Subject to subsection (3), the nutrition facts table of the prepackaged product shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(3) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table containing only the information referred to in paragraphs B.01.401(6)(*a*) to (*j*) in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(*a*) the bilingual simplified standard format in accordance with Figure 6.5(B) or 6.6(B) of Schedule L;

(*b*) the bilingual simplified horizontal format in accordance with Figure 7.3(B) or 7.4(B) of Schedule L;

(*c*) the simplified linear format in accordance with Figures 17.1(E) and (F) or 17.2(E) and (F) of Schedule L;

(*d*) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table; or

(*e*) a manner described in section B.01.466.

(4) Despite subsections (2) and (3), if the prepackaged product is sold only in the retail establishment where the product is packaged, is labelled by means of a sticker and has an available display surface of 200 $cm^2$ or more, its nutrition facts table shall be set out in a version that is listed in column 1 of items 1 to 3 of Parts 1 and 2 of the table to this section, without regard to any condition specified in column 2.

(5) Despite subsections (2) and (3), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (3)(*a*), (*b*) or (*c*) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

# TABLE

# PART 1

# SIMPLIFIED STANDARD FORMAT

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 5.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 5.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 5.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 5.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 5.5(E) and (F)<br>(6 point condensed type | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| | with 10 point leading) | |
| 6. | 5.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# BILINGUAL SIMPLIFIED STANDARD FORMAT

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 6.1(B)<br>(8 point type with 12 point leading) | |
| 2. | 6.2(B)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 6.3(B)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 6.4(B)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 3

# BILINGUAL SIMPLIFIED HORIZONTAL FORMAT

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 7.1(B)<br>(7 point condensed type with 11 point leading) | The versions in Parts 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 2. | 7.2(B)<br>(6 point condensed type | The versions in Parts 1 and 2 and in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| | with 10 point leading) | |

SOR/2003-11, s. 20.

**Dual Format — Foods Requiring Preparation**

B.01.456. (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product includes information referred to in subsection B.01.406(5), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(*a*) the bilingual dual format in accordance with Figure 9.5(B) or 9.6(B) of Schedule L; or

(*b*) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included in the table, together with the information referred to in subsection B.01.406(5).

(4) Despite subsections (1) and (2), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (2)(*a*) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

# TABLE

# PART 1

# DUAL FORMAT — FOODS REQUIRING PREPARATION

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 8.1(E) and (F)<br>(8 point type with | |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| | 12 point leading) | |
| 2. | 8.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 8.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 8.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 8.5(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 8.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# BILINGUAL DUAL FORMAT — FOODS REQUIRING PREPARATION

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 9.1(B)<br>(8 point type with 12 point leading) | |
| 2. | 9.2(B)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 9.3(B)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 9.4(B)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Aggregate Format — Different Kinds of Foods**

B.01.457. (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product includes separate information for each food or ingredient as provided in subsection B.01.406(2), paragraph B.01.406(3)(*a*) or subsection B.01.406(4), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out

(*a*) in the case of a product described in subsection B.01.406(2) or (4), in

(i) the bilingual aggregate format in accordance with Figure 11.5(B) or 11.6(B) of Schedule L, or

(ii) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table, or

(*b*) in the case of a product described in paragraph B.01.406(3)(*a*), in

(i) the bilingual aggregate format in accordance with Figure 11.5(B) or 11.6(B) of Schedule L,

(ii) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table, or

(iii) a manner described in section B.01.466.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each food or ingredient for which separate information is set out in the table.

(4) Despite subsections (1) and (2), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in subparagraph (2)(*a*)(i) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

# TABLE

# PART 1

# AGGREGATE FORMAT — DIFFERENT KINDS OF FOODS

| Column 1 | Column 2 |
| --- | --- |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 10.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 10.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 10.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 10.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 10.5(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 10.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# BILINGUAL AGGREGATE FORMAT — DIFFERENT KINDS OF FOODS

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 11.1(B)<br>(8 point type with 12 point leading) | |
| 2. | 11.2(B)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 11.3(B)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 11.4(B)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Dual Format — Different Amounts of Food**

B.01.458. (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product includes separate information for different amounts of the food as provided in paragraph B.01.406(7)(*a*) without including the information referred to in paragraph B.01.406(7)(*c*), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(*a*) the bilingual dual format in accordance with Figure 13.5(B) or 13.6(B) of Schedule L; or

(*b*) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each amount of the food for which separate information is set out in the table.

(4) Despite subsections (1) and (2), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (2)(*a*) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

# TABLE

# PART 1

# DUAL FORMAT — DIFFERENT AMOUNTS OF FOOD

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 12.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 12.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 12.3(E) and (F)<br>(7 point condensed type | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| | with 11 point leading) | |
| 4. | 12.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 12.5(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 12.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# BILINGUAL DUAL FORMAT — DIFFERENT AMOUNTS OF FOOD

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 13.1(B)<br>(8 point type with 12 point leading) | |
| 2. | 13.2(B)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 13.3(B)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 13.4(B)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Aggregate Format — Different Amounts of Food**

B.01.459. (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product includes separate information for different amounts of the food as provided in paragraphs B.01.406(7)(*a*) and (*c*), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(*a*) the bilingual aggregate format in accordance with Figure 15.5(B) or 15.6(B) of Schedule L; or

(*b*) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each amount of the food for which separate information is set out in the table.

(4) Despite subsections (1) and (2), if the nutrition facts table of the prepackaged product is set out on a tag attached to an ornamental container or a tag attached to a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase, it shall be set out in a version that is described in paragraph (2)(*a*) or that is listed in column 1 of the table to this section, without regard to any condition specified in column 2.

# TABLE

# PART 1

# AGGREGATE FORMAT — DIFFERENT AMOUNTS OF FOOD

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 14.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 14.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 14.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4, | 14.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 5. | 14.5(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 14.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# BILINGUAL AGGREGATE FORMAT — DIFFERENT AMOUNTS OF FOOD

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 15.1(B)<br>(8 point type with 12 point leading) | |
| 2. | 15.2(B)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 15.3(B)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 15.4(B)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Presentation of Additional Information**

B.01.460. (1) If information referred to in column 1 of the table to section B.01.402 is included in a nutrition facts table that is set out in a version consisting of a table in English and a table in French or a table in English or French, that information shall be displayed

(*a*) in accordance with the order of presentation, the use of indents and the presentation of footnotes illustrated in Figures 18.1(E) and (F) of Schedule L; and

(*b*) in respect of matters other than those referred to in paragraph (*a*), in accordance with the format that is specified in the applicable figure in Schedule L.

(2) If information referred to in column 1 of the table to section B.01.402 is included in a nutrition facts table that is set out in a version consisting of a table in both English and French, that information shall be displayed

(*a*) in accordance with the order of presentation, the use of indents and the presentation of footnotes illustrated in Figure 19.1(B) of Schedule L; and

(*b*) in respect of matters other than those referred to in paragraph (*a*), in accordance with the format that is specified in the applicable figure in Schedule L.

(3) Despite paragraph (1)(*a*), the use of indents illustrated in Figures 18.1(E) and (F) of Schedule L is not applicable if information referred to in column 1 of the table to section B.01.402 is set out in the linear format referred to in paragraph B.01.454(3)(*c*) or the simplified linear format referred to in paragraph B.01.455(3)(*c*).

SOR/2003-11, s. 20.

**Standard and Horizontal Formats — Children under Two Years of Age**

[SOR/2003-11, s. 20; err.(E), Vol. 137, No. 5]

B.01.461. (1) This section applies to a prepackaged product that is intended solely for children under two years of age unless section B.01.462, B.01.463 or B.01.464 applies to the product.

(2) Subject to subsection (3), the nutrition facts table of the prepackaged product shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(3) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(*a*) the bilingual standard format in accordance with Figure 22.5(B), 22.6(B) or 22.7(B) of Schedule L;

(*b*) the bilingual horizontal format in accordance with Figure 23.3(B) or 23.4(B) of Schedule L;

(*c*) the linear format in accordance with Figures 31.1(E) and (F) or 31.2(E) and (F) of Schedule L;

(*d*) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table; or

(*e*) a manner described in section B.01.466.

(4) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included in that table.

# TABLE

# PART 1

# STANDARD FORMAT — CHILDREN UNDER TWO YEARS OF AGE

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 20.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 20.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 20.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 20.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 20.5(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 20.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# NARROW STANDARD FORMAT — CHILDREN UNDER TWO YEARS OF AGE

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 21.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 21.2(E) and (F)<br>(7 point type with | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| | 11 point leading) | surface. |
| 3. | 21.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 21.4(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 3

# BILINGUAL STANDARD FORMAT — CHILDREN UNDER TWO YEARS OF AGE

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 22.1(B)<br>(8 point type with 12 point leading) | |
| 2. | 22.2(B)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 22.3(B)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 22.4(B)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 4

# BILINGUAL HORIZONTAL FORMAT — CHILDREN UNDER TWO YEARS OF AGE

| Column 1 | Column 2 |
|---|---|

| Item | Figure in Schedule L (Version) | Condition of use |
|---|---|---|
| 1. | 23.1(B) (7 point condensed type with 11 point leading) | The versions in Parts 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 2. | 23.2(B) (6 point condensed type with 10 point leading) | The versions in Parts 1 to 3 and in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Simplified Formats — Children under Two Years of Age**

B.01.462. (1) This section applies to a prepackaged product that is intended solely for children under two years of age if it satisfies the condition set out in subsection B.01.403(5) and its nutrition facts table includes only the information referred to in paragraphs B.01.403(5)(*a*) to (*k*).

(2) Subject to subsection (3), the nutrition facts table of the prepackaged product shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(3) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table containing only the information referred to in paragraphs B.01.403(5)(*a*) to (*k*) in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(*a*) the bilingual simplified standard format in accordance with Figure 25.5(B) or 25.6(B) of Schedule L;

(*b*) the bilingual simplified horizontal format in accordance with Figure 26.3(B) or 26.4(B) of Schedule L;

(*c*) the simplified linear format in accordance with Figures 32.1(E) and (F) or 32.2(E) and (F) of Schedule L;

(*d*) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table; or

(*e*) a manner described in section B.01.466.

# TABLE

# PART 1

# SIMPLIFIED STANDARD FORMAT — CHILDREN UNDER TWO YEARS OF AGE

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 24.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 24.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 24.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 24.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 24.5(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 24.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# BILINGUAL SIMPLIFIED STANDARD FORMAT — CHILDREN UNDER TWO YEARS OF AGE

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 25.1(B)<br>(8 point type with 12 point leading) | |
| 2. | 25.2(B)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 25.3(B)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 25.4(B)<br>(6 point condensed type | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| | with 10 point leading) | |

# PART 3

# BILINGUAL SIMPLIFIED HORIZONTAL FORMAT — CHILDREN UNDER TWO YEARS OF AGE

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 26.1(B)<br>(7 point condensed type with 11 point leading) | The versions in Parts 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 2. | 26.2(B)<br>(6 point condensed type with 10 point leading) | The versions in Parts 1 and 2 and in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Aggregate Format — Different Kinds of Foods — Children under Two Years of Age**

B.01.463. (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product that is intended solely for children under two years of age includes separate information for each food or ingredient as provided in subsection B.01.406(2), paragraph B.01.406(3)(*a*) or subsection B.01.406(4), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out

(*a*) in the case of a product described in subsection B.01.406(2) or (4), in

(i) the bilingual aggregate format in accordance with Figure 28.5(B) or 28.6(B) of Schedule L, or

(ii) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table, or

(*b*) in the case of a product described in paragraph B.01.406(3)(*a*), in

(i) the bilingual aggregate format in accordance with Figure 28.5(B) or 28.6(B) of Schedule L,

(ii) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table, or

(iii) a manner described in section B.01.466.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each food or ingredient for which separate information is set out in the table.

# TABLE

# PART 1

# AGGREGATE FORMAT — DIFFERENT KINDS OF FOODS — CHILDREN UNDER TWO YEARS OF AGE

| | Column 1 | Column 2 |
|---|---|---|
| Item | Figure in Schedule L (Version) | Condition of use |
| 1. | 27.1(E) and (F) (8 point type with 12 point leading) | |
| 2. | 27.2(E) and (F) (7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 27.3(E) and (F) (7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 27.4(E) and (F) (7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 27.5(E) and (F) (6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 27.6(E) and (F) (6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# BILINGUAL AGGREGATE FORMAT — DIFFERENT KINDS OF FOODS — CHILDREN UNDER TWO YEARS OF AGE

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 28.1(B)<br>(8 point type with 12 point leading) | |
| 2. | 28.2(B)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 28.3(B)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 28.4(B)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Aggregate Format — Different Amounts of Food — Children under Two Years of Age**

B.01.464. (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product that is intended solely for children under two years of age includes separate information for different amounts of the food as provided in subsection B.01.406(8), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

(2) If it is not possible to display, in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, a nutrition facts table in any of the versions that is listed in column 1 of the table to this section, the nutrition facts table shall be set out in

(*a*) the bilingual aggregate format in accordance with Figure 30.5(B) or 30.6(B) of Schedule L; or

(*b*) a version that is listed in column 1 of the table to this section, even though more than 15% of the available display surface would be required to display the nutrition facts table.

(3) For the purpose of this section, in determining whether a version of a nutrition facts table cannot be displayed in accordance with these Regulations on 15% or less of the available display surface of the prepackaged product, the nutrition facts table shall include only the information that is required by these Regulations to be included for each amount of the food for which separate information is set out in the table.

# TABLE

# PART 1

# AGGREGATE FORMAT — DIFFERENT AMOUNTS OF FOOD — CHILDREN UNDER TWO YEARS OF AGE

| Item | Column 1<br>Figure in Schedule L (Version) | Column 2<br>Condition of use |
|---|---|---|
| 1. | 29.1(E) and (F)<br>(8 point type with 12 point leading) | |
| 2. | 29.2(E) and (F)<br>(7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 29.3(E) and (F)<br>(7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 29.4(E) and (F)<br>(7 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 5. | 29.5(E) and (F)<br>(6 point condensed type with 10 point leading) | The versions in items 1 to 4 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 6. | 29.6(E) and (F)<br>(6 point condensed type with 9 point leading) | The versions in items 1 to 5 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

# PART 2

# BILINGUAL AGGREGATE FORMAT — DIFFERENT AMOUNTS OF FOOD — CHILDREN UNDER TWO YEARS OF AGE

| Column 1 | Column 2 |
|---|---|

| Item | Figure in Schedule L (Version) | Condition of use |
|---|---|---|
| 1. | 30.1(B) (8 point type with 12 point leading) | |
| 2. | 30.2(B) (7 point type with 11 point leading) | The version in item 1 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 3. | 30.3(B) (7 point condensed type with 11 point leading) | The versions in items 1 and 2 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |
| 4. | 30.4(B) (6 point condensed type with 10 point leading) | The versions in items 1 to 3 cannot be displayed in accordance with these Regulations on 15% or less of the available display surface. |

SOR/2003-11, s. 20.

**Presentation of Additional Information — Children under Two Years of Age**

B.01.465. (1) This section applies to a prepackaged product that is intended solely for children under two years of age.

(2) If information referred to in column 1 of the table to section B.01.402 is included in a nutrition facts table that is set out in a version consisting of a table in English and a table in French or a table in English or French, that information shall be displayed

(*a*) in accordance with the order of presentation and the use of indents illustrated in Figures 33.1(E) and (F) of Schedule L; and

(*b*) in respect of matters other than those referred to in paragraph (*a*), in accordance with the format that is specified in the applicable figure in Schedule L.

(3) If information referred to in column 1 of the table to section B.01.402 is included in a nutrition facts table that is set out in a version consisting of a table in both English and French, that information shall be displayed

(*a*) in accordance with the order of presentation and the use of indents illustrated in Figure 34.1(B) of Schedule L; and

(*b*) in respect of matters other than those referred to in paragraph (*a*), in accordance with the format that is specified in the applicable figure in Schedule L.

(4) Despite paragraph (2)(*a*), the use of indents illustrated in Figures 33.1(E) and (F) of Schedule L is not applicable if information referred to in column 1 of the table to section B.01.402 is set out in the linear format referred to in paragraph B.01.461(3)(*c*) or the simplified linear format referred to in paragraph B.01.462(3)(*c*).

SOR/2003-11, s. 20.

**Alternative Methods of Presentation**

B.01.466. (1) Despite section A.01.016, the nutrition facts table of a prepackaged product that meets the condition specified in subsection B.01.454(3) or B.01.455(3), paragraph B.01.457(2)(*b*), subsection B.01.461(3) or B.01.462(3) or paragraph B.01.463(2)(*b*) may be set out on

(*a*) a tag attached to the package;

(*b*) a package insert;

(*c*) the inner side of a label;

(*d*) a fold-out label; or

(*e*) an outer sleeve, overwrap or collar.

(2) If the nutrition facts table is set out in a manner described in paragraph (1)(*b*) or (*c*), the outer side of the label of the package shall indicate in a type size of not less than 8 points where the nutrition facts table is located.

(3) If the nutrition facts table is set out in a manner described in subsection (1), it shall be set out

(*a*) in the case of a product described in subsection B.01.454(3), in a version that is described in paragraph B.01.454(3)(*a*), (*b*) or (*c*) or that is listed in column 1 of the table to section B.01.454;

(*b*) in the case of a product described in subsection B.01.455(3), in a version that is described in paragraph B.01.455(3)(*a*), (*b*) or (*c*) or that is listed in column 1 of the table to section B.01.455;

(*c*) in the case of a product described in paragraph B.01.457(2)(*b*), in a version that is described in subparagraph B.01.457(2)(*b*)(i) or that is listed in column 1 of the table to section B.01.457;

(*d*) in the case of a product described in subsection B.01.461(3), in a version that is described in paragraph B.01.461(3)(*a*), (*b*) or (*c*) or that is listed in column 1 of the table to section B.01.461;

(*e*) in the case of a product described in subsection B.01.462(3), in a version that is described in paragraph B.01.462(3)(*a*), (*b*) or (*c*) or that is listed in column 1 of the table to section B.01.462; and

(*f*) in the case of a product described in paragraph B.01.463(2)(*b*), in a version that is described in subparagraph B.01.463(2)(*b*)(i) or that is listed in column 1 of the table to section B.01.463.

SOR/2003-11, s. 20.

**Small Packages**

B.01.467. (1) Despite section A.01.016 and subject to subsection (2), if the available display surface of a prepackaged product is less than 100 $cm^2$, the label of the product need not carry a nutrition facts table if the outer side of the label contains an indication of how a purchaser or consumer may obtain the nutrition information that would otherwise be required to be set out in a nutrition facts table on the label of the product.

(2) Subsection (1) does not apply to a prepackaged product that is

(*a*) described in paragraph B.01.401(3)(*a*), (*b*), (*c*) or (*e*); or

(*b*) contained in a package to which a label cannot be physically applied or on which information cannot be legibly set out and easily viewed by the purchaser or consumer under the customary conditions of purchase.

(3) An indication referred to in subsection (1)

(*a*) shall be set out in a type size of not less than 8 points;

(*b*) shall include a postal address or a toll-free telephone number; and

(*c*) shall be

(i) in English and French, or

(ii) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the product may be shown in that language only and is shown on the label in that language.

(4) The manufacturer of the prepackaged product shall provide the information referred to in subsection (1) to a purchaser or consumer on request

(*a*) without charge;

(*b*) in the following manner, namely,

(i) in the official language in which the information is requested or, if specified by the purchaser or consumer, in both official languages, or

(ii) in one of the official languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the product may be shown in that language only and is shown on the label in that language; and

(*c*) in the form of a nutrition facts table that is set out

(i) in a format, other than a horizontal format, that is specified in any of sections B.01.454 to B.01.459 or B.01.461 to B.01.464 and that would otherwise be carried on the label of the product in accordance with these Regulations, and

(ii) in a version of that format that is listed in column 1 of item 1 of any Part of the table to the applicable section referred to in subparagraph (i).

(5) In this section, “official languages” means the English language and the French language.

SOR/2003-11, s. 20.

**[B.01.468 to B.01.499 reserved]**

## Nutrient Content Claims

### Interpretation

B.01.500. (1) The following definitions apply in this section and in the table following section B.01.513.

“combination foods” means the category of food to which belong foods that contain as ingredients foods from more than one food group, or foods from one or more food groups mixed with foods from the category of other foods, such as pizza or lasagna. (aliments composés)

“food group” means one of the following categories of foods:

(*a*) milk products, and milk product alternatives such as fortified plant-based beverages;

(*b*) meat, poultry and fish, and alternatives such as legumes, eggs, tofu or peanut butter;

(*c*) bread and grain products; or

(*d*) vegetables and fruit. (groupe alimentaire)

“other foods” means the category of food to which belong foods that are not part of any food group, including

(*a*) foods that are mostly fats, such as butter, margarine, oil or lard;

(*b*) foods that are mostly sugars, such as jam, honey, syrup or confectionery;

(*c*) snack foods, such as potato chips or pretzels;

(*d*) beverages, such as water, tea, coffee or soft drinks; and

(*e*) herbs, spices and condiments, such as pickles, mustard or ketchup. (autres aliments)

“reference food of the same food group” means a food that can be substituted in the diet for the food to which it is compared and that belongs to

(*a*) the same food group as the food to which it is compared, such as cheese as a reference food for milk, or chicken as a reference food for tofu;

(*b*) the category of other foods, if the food to which it is compared also belongs to that category, such as pretzels as a reference food for potato chips; or

(*c*) the category of combination foods, if the food to which it is compared also belongs to that category, such as pizza as a reference food for lasagna. (aliment de référence du même groupe alimentaire)

“similar reference food” means a food of the same type as the food to which it is compared and that has not been processed, formulated, reformulated or otherwise modified in a manner that increases or decreases the energy value or the amount of a nutrient that is the subject of the comparison, such as whole milk as a similar reference food for partly skimmed milk or regular chocolate chip cookies as a similar reference food for fat-reduced chocolate chip cookies. (aliment de référence similaire)

(2) The similar reference food referred to in column 3 of item 45 of the table following section B.01.513, with respect to the subject “light in energy or fat” set out in column 1, shall have a nutrient value that is representative of foods of that type that have not been processed,

formulated, reformulated or otherwise modified in a manner that increases the energy value or the amount of fat.

SOR/2003-11, s. 20; SOR/2007-302, s. 4(F).

Previous Version

**Languages**

B.01.501. The representations provided for in sections B.01.503 to B.01.513 that appear on the label of a food shall be

(*a*) in English and French; or

(*b*) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

SOR/2003-11, s. 20.

**Statements or Claims**

B.01.502. (1) No person shall, on the label of or in any advertisement for a food, make a representation, express or implied, that characterizes the energy value of the food or the amount of a nutrient contained in the food.

(2) Subsection (1) does not apply to

(*a*) a representation otherwise provided for in these Regulations;

(*b*) a representation provided for by section 35 of the Processed Products Regulations;

(*c*) a representation provided for by subsection 94(4) of the Meat Inspection Regulations, 1990;

(*d*) a representation that characterizes the amount of lactose in a food;

(*e*) a representation that characterizes the addition of salt to a food, other than any statement or claim set out in column 4 of the table following section B.01.513;

(*f*) a representation that characterizes the addition of sugars to a food, other than any statement or claim set out in column 4 of the table following section B.01.513;

(*g*) a representation that characterizes the amount of starch in a food, if the food is intended solely for children under two years of age;

(*h*) the representations “defatted (naming the food)”, “demineralized (naming the food)” and “high (naming the monosaccharide or disaccharide) (naming the syrup)”;

(*i*) a representation that characterizes the amount of a fatty acid in a vegetable oil and forms part of its common name;

(*j*) a representation that characterizes the amount of alcohol in beverages that contain more than 0.5% alcohol;

(*k*) the representation “light salted” with respect to fish; or

(*l*) the English representation “lean” with respect to a prepackaged meal represented for use in a weight reduction diet or a weight maintenance diet.

SOR/2003-11, s. 20.

B.01.503. (1) A person may, on the label of or in any advertisement for a food, make a statement or claim set out in column 4 of the table following section B.01.513, with respect to a subject set out in column 1, if

(*a*) the food meets the applicable conditions set out in column 2;

(*b*) the label or advertisement meets the conditions, if any, set out in column 3, in accordance with sections B.01.504 to B.01.506; and

(*c*) in the case of a food that is not a prepackaged product, or a prepackaged product for which an advertisement is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement includes, per serving of stated size, and in accordance with section B.01.505 or B.01.506 if applicable,

(i) the declaration of the energy value, if the energy value is the subject of the statement or claim, or

(ii) the amount of the nutrient, if a nutrient is the subject of the statement or claim.

(2) Despite subsection (1), no person shall, on the label of or in any advertisement for a food that is intended solely for children under two years of age, make a statement or claim set out in column 4 of the table following section B.01.513, unless it is a statement or claim respecting one of the following subjects set out in column 1:

(*a*) “source of protein”, set out in item 8;

(*b*) “excellent source of protein”, set out in item 9;

(*c*) “more protein”, set out in item 10;

(*d*) “no added sodium or salt”, set out in item 35; or

(*e*) “no added sugars”, set out in item 40.

(3) If a statement or claim set out in column 4 of the table following section B.01.513 is made on the label of or in any advertisement for a food, all the words, numbers, signs or symbols that constitute the statement or claim shall be of the same size and prominence.

(4) In the English version of the statements or claims, the word “fibre” may be spelled as “fiber”.

SOR/2003-11, s. 20.

B.01.504. If a statement or claim set out in column 4 of the table following section B.01.513 is made on the label of a food, the information required under the conditions set out in column 3 shall be

(*a*) adjacent to, without any intervening printed, written or graphic material,

(i) the statement or claim, if the statement or claim is made only once, or

(ii) the most prominent statement or claim on the principal display panel or, if none appears there, the most prominent statement or claim elsewhere on the label, if the statement or claim is made more than once; and

(*b*) shown in letters of at least the same size and prominence as

(i) those of the statement or claim, if the statement or claim is made only once, or

(ii) those of the most prominent statement or claim on the principal display panel or, if none appears there, the most prominent statement or claim elsewhere on the label, if the statement or claim is made more than once.

SOR/2003-11, s. 20.

B.01.505. If a statement or claim set out in column 4 of the table following section B.01.513 is made in an advertisement for a food, other than a radio or television advertisement, the information required under the conditions set out in column 3 and, if applicable, the information required by paragraph B.01.503(1)(*c*), shall be

(*a*) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and

(*b*) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

SOR/2003-11, s. 20.

B.01.506. (1) If a statement or claim set out in column 4 of the table following section B.01.513 is made in a radio or television advertisement, the information required under the conditions set out in column 3 and, if applicable, the information required by paragraph B.01.503(1)(*c*), shall be provided in the advertisement, except for the information required under the condition set out in paragraph (*a*) of column 3, in respect of the following subjects set out in column 1, which may be on the label:

(*a*) “reduced in energy”, set out in item 3;

(*b*) “reduced in fat”, set out in item 13;

(*c*) “reduced in saturated fatty acids”, set out in item 20;

(*d*) “reduced in *trans* fatty acids”, set out in item 23;

(*e*) “reduced in cholesterol”, set out in item 29;

(*f*) “reduced in sodium or salt”, set out in item 33;

(*g*) “lightly salted”, set out in item 36;

(*h*) “reduced in sugars”, set out in item 38; and

(*i*) “light in energy or fat”, set out in item 45.

(2) Despite subsection (1), if the statement or claim is made in a radio or television advertisement that is not made or placed by or on the direction of the manufacturer of the food, the information required under the condition set out in paragraph (*a*) of column 3 of the table following section B.01.513, in respect of the subjects set out in paragraphs (1)(*a*) to (*i*), shall be provided in the advertisement.

(3) If the information required under the conditions set out in column 3 of the table following section B.01.513 and the information required by paragraph B.01.503(1)(*c*) is provided in a radio advertisement or in the audio portion of a television advertisement, that information shall immediately precede or follow the statement or claim.

(4) In the case of a television advertisement, the information required under the conditions set out in column 3 of the table following section B.01.513 and, if applicable, the information required by paragraph B.01.503(1)(*c*), shall be communicated

(*a*) in the audio mode, if the statement or claim is made only in the audio portion of the advertisement or in both the audio and visual portions; or

(*b*) in the audio or visual mode, if the statement or claim is made only in the visual portion of the advertisement.

(5) If the information required under the conditions set out in column 3 of the table following section B.01.513 and the information required by paragraph B.01.503(1)(*c*) is communicated in the visual mode of a television advertisement, it shall

(*a*) appear concurrently with and for at least the same amount of time as the statement or claim;

(*b*) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and

(*c*) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

SOR/2003-11, s. 20.

B.01.507. A person may, on the label of or in any advertisement for a food, make a representation, express or implied, that the food is for use in an energy-reduced diet, if a statement or claim set out in column 4 of the table following section B.01.513, in respect of any of the following subjects set out in column 1, is made on the label of or in the advertisement for the food, in accordance with section B.01.503:

(*a*) “free of energy”, set out in item 1;

(*b*) “low in energy”, set out in item 2;

(*c*) “reduced in energy”, set out in item 3;

(*d*) “lower in energy”, set out in item 4; or

(*e*) “free of sugars”, set out in item 37.

SOR/2003-11, s. 20.

B.01.508. A person may, on the label of or in any advertisement for a food, make a representation, express or implied, that the food is for use in a sodium-restricted diet, if a statement or claim set out in column 4 of the table following section B.01.513, in respect of any of the following subjects set out in column 1, is made on the label of or in the advertisement for the food, in accordance with section B.01.503:

(*a*) “free of sodium or salt”, set out in item 31;

(*b*) “low in sodium or salt”, set out in item 32;

(*c*) “reduced in sodium or salt”, set out in item 33; or

(*d*) “lower in sodium or salt”, set out in item 34.

SOR/2003-11, s. 20.

B.01.509. A person may, on the label of or in any advertisement for a food, make the statement or claim that the food is “unsweetened” if the food meets the conditions set out in column 2 of item 40 of the table following section B.01.513 for the subject “no added sugars” set out in column 1 and the food does not contain a sweetener set out in column I of Table IX to section B.16.100.

SOR/2003-11, s. 20.

B.01.510. A statement or claim set out in column 4 of the table following section B.01.513, respecting the following subjects set out in column 1, that is made on the label of or in an advertisement for a breakfast cereal with milk, shall be accompanied by an indication that it refers to 30 g of the breakfast cereal combined with 125 mL of milk:

(*a*) “source of protein”, set out in item 8;

(*b*) “excellent source of protein”, set out in item 9; and

(*c*) “more protein”, set out in item 10.

SOR/2003-11, s. 20.

B.01.511. (1) For greater certainty and subject to subsections (2) to (4), a statement or claim set out in column 4 of the table following section B.01.513 that is made on the label of or in any advertisement for a food may be preceded or followed by other words, numbers, signs or symbols, but none of those shall be interposed between the words, numbers, signs or symbols of the statement or claim.

(2) The words “very”, “ultra” and “extra”, and all other words, numbers, signs or symbols that modify the nature of a statement or claim, shall not precede or follow the statement or claim.

(3) A statement or claim that is made on the label of or in any advertisement for a food that has not been processed, formulated, reformulated or otherwise modified to meet the conditions set out in column 2 of the table following section B.01.513 shall not be accompanied by the brand name of the food.

(4) Any words, numbers, signs or symbols preceding or following the statement or claim referred to in subsection (3) shall accompany the statement or claim in such a manner that the statement or claim characterizes all foods of that type, and not only the specific food.

SOR/2003-11, s. 20.

B.01.512. If a food meets the conditions set out in column 2 of the table following section B.01.513 for more than one of the subjects set out in column 1, it is not necessary to repeat the common element of the statements or claims set out in column 4 that are used on the label of or in the advertisement for the food, and the remaining elements may be joined by means of a conjunction or punctuation, as appropriate.

SOR/2003-11, s. 20.

**Sensory Characteristic**

B.01.513. (1) No person shall, on the label of or in any advertisement for a food, make the statement or claim “light” or “léger” — including any phonetic rendering of that statement or claim — respecting a sensory characteristic of the food unless the following conditions are met:

(*a*) if the statement or claim “light” or “léger” is made on the label of a food, the sensory characteristic shall be

(i) adjacent to, without any intervening printed, written or graphic material,

(A) the statement or claim, if the statement or claim is made only once, or

(B) the most prominent statement or claim on the principal display panel or, if none appears there, the most prominent statement or claim elsewhere on the label, if the statement or claim is made more than once, and

(ii) shown in letters of at least the same size and prominence as

(A) those of the statement or claim, if the statement or claim is made only once, or

(B) those of the most prominent statement or claim on the principal display panel or, if none appears there, the most prominent statement or claim elsewhere on the label, if the statement or claim is made more than once;

(*b*) if the statement or claim “light” or “léger” is made in an advertisement for a food, other than a radio or television advertisement, the sensory characteristic shall be

(i) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and

(ii) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once;

(*c*) if the statement or claim “light” or “léger” is made in a radio advertisement or in the audio portion of a television advertisement, the sensory characteristic shall immediately precede or follow the statement or claim; and

(*d*) if the statement or claim “light” or “léger” is made in the visual portion of a television advertisement, the sensory characteristic shall

(i) appear concurrently with and for the same amount of time as the statement or claim,

(ii) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and

(iii) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

(2) Subsection (1) does not apply to

(*a*) the English statement or claim "light" when used in accordance with subsection 12(1) of the Maple Products Regulations; or

(*b*) the statement or claim "light" or "léger" when used with respect to rum.

TABLE

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| 1. | Free of energy | The food provides less than 5 Calories or 21 kilojoules per reference amount and serving of stated size. | | "energy-free", "free of energy", "no energy", "0 energy", "zero energy", "without energy", "contains no energy", "Calorie-free", "free of Calories", "no Calories", "0 Calories", "zero Calories", "without Calories" or "contains no Calories" |
| 2. | Low in energy | The food provides<br>(*a*) 40 Calories or 167 kilojoules or less per reference amount and serving of stated size and, in the case of a food other than a table-top sweetener, if the reference amount is 30 g or 30 mL or less, per 50 g; or<br>(*b*) 120 Calories or 500 kilojoules or less per 100 g, if the food is a prepackaged meal. | | "low energy", "low in energy", "low source of energy", "little energy", "low Calorie", "low in Calories", "low source of Calories", "contains only (number) Calories per serving", "contains less than (number) Calories per serving" or "few Calories" |
| 3. | Reduced in energy | (1) The food is processed, formulated, reformulated or otherwise modified so | The following are identified: | "reduced energy", "reduced in energy", "energy-reduced", "less energy", "lower energy", |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | that it provides at least 25% less energy<br><br>(*a*) per reference amount of the food, than the reference amount of the similar reference food; or<br><br>(*b*) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal.<br><br>(2) The similar reference food does not meet the conditions set out in column 2 of item 2 for the subject “low in energy” set out in column 1. | (*a*) the similar reference food;<br><br>(*b*) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and<br><br>(*c*) the difference in energy value compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in Calories. | “lower in energy”, “reduced Calorie”, “reduced in Calories”, “Calorie-reduced”, “less Calories”, “lower Calories”, “lower in Calories” or “fewer Calories” |
| 4. | Lower in energy | (1) The food provides at least 25% less energy<br><br>(*a*) per reference amount of the food, than the reference amount of the reference food of the same food group; or<br><br>(*b*) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal.<br><br>(2) The reference food of the same food group does not meet the conditions set out in column 2 of item 2 for the subject “low in | The following are identified:<br><br>(*a*) the reference food of the same food group;<br><br>(*b*) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and<br><br>(*c*) the difference in energy value compared to the reference food of the same food group, per serving | “less energy”, “lower energy”, “lower in energy”, “less Calories”, “lower Calorie”, “lower in Calories” or “fewer Calories” |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | energy” set out in column 1. | of stated size, expressed as a percentage or fraction or in Calories. | |
| 5. | Source of energy | The food provides at least 100 Calories or 420 kilojoules per reference amount and serving of stated size. | | “source of energy”, “contains energy”, “provides energy”, “source of Calories”, “contains Calories” or “provides Calories” |
| 6. | More energy | The food provides at least 25% more energy, totalling at least 100 more Calories or 420 more kilojoules | The following are identified: | “more Calories”, “contains more Calories”, “higher Calories” or “higher in Calories” |
| | | (*a*) per reference amount of the food, than the reference amount of the reference food of the same food group or the similar reference food; or | (*a*) the reference food of the same food group or the similar reference food; | |
| | | (*b*) per 100 g, than 100 g of the reference food of the same food group or the similar reference food, if the food is a prepackaged meal. | (*b*) the amounts of the food and the reference food of the same food group or the similar reference food being compared, if those amounts are not equal; and | |
| | | | (*c*) the difference in energy value compared to the reference food of the same food group or the similar reference food, per serving of stated size, expressed as a percentage or fraction or in Calories. | |
| 7. | Low in protein | The food contains no more than 1 g of protein | | “low protein”, “low in protein”, “low source of |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | per 100 g of the food. | | protein", "contains only (number) g of protein per serving" or "contains less than (number) g of protein per serving" |
| 8. | Source of protein | The food has a protein rating of 20 or more, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981,<br>(*a*) per reasonable daily intake; or<br>(*b*) per 30 g combined with 125 mL of milk, if the food is a breakfast cereal. | | "source of protein", "contains protein", "good source of protein", "high protein", "high in protein" or "provides protein" |
| 9. | Excellent source of protein | The food has a protein rating of 40 or more, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981,<br>(*a*) per reasonable daily intake; or<br>(*b*) per 30 g combined with 125 mL of milk, if the food is a breakfast cereal. | | "excellent source of protein", "very high protein", "very high in protein" or "rich in protein" |
| 10. | More protein | The food | The following are identified: | |
| | | (*a*) has a protein rating of 20 or more, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981, | (*a*) the reference food of the same food group or the similar reference food; | "more protein", "higher protein" or "higher in protein" |
| | | (i) per reasonable daily intake, or | (*b*) the amounts of the food and the reference food of the same food group or the similar | |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | | reference food being compared, if those amounts are not equal; and | |
| | | | (*c*) the difference in protein compared to the reference food of the same food group or the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams. | |
| | | (ii) per 30 g combined with 125 mL of milk, if the food is a breakfast cereal; and | | |
| | | (*b*) contains at least 25% more protein, totalling at least 7 g more, per reasonable daily intake than the reference food of the same food group or the similar reference food. | | |
| 11. | Free of fat | The food contains<br>(*a*) less than 0.5 g of fat per reference amount and serving of stated size; or<br>(*b*) less than 0.5 g of fat per serving of stated size, if the food is a prepackaged meal. | | “fat-free”, “free of fat”, “no fat”, “0 fat”, “zero fat”, “without fat”, “contains no fat” or “non-fat” |
| 12. | Low in fat | The food contains<br>(*a*) 3 g or less of fat per reference amount and serving of stated size and, if the reference amount is 30 g or 30 mL or less, per 50 g; or<br>(*b*) 3 g or less of fat per 100 g with 30% or less of the energy from fat, if the food is a prepackaged meal. | | “low fat”, “low in fat”, “low source of fat”, “little fat”, “contains only (number) g of fat per serving” or “contains less than (number) g of fat per serving” |
| 13. | Reduced in fat | (1) The food is processed, formulated, | The following are identified: | “reduced fat”, “reduced in fat”, “fat-reduced”, “less |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | reformulated or otherwise modified so that it contains at least 25% less fat | | fat", "lower fat" or "lower in fat" |
| | | (*a*) per reference amount of the food, than the reference amount of the similar reference food; or | (*a*) the similar reference food; | |
| | | (*b*) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. | (*b*) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and | |
| | | (2) The similar reference food does not meet the conditions set out in column 2 of item 12 for the subject "low in fat" set out in column 1. | (*c*) the difference in fat compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams. | |
| 14. | Lower in fat | (1) The food contains at least 25% less fat | The following are identified: | "less fat", "lower fat" or "lower in fat" |
| | | (*a*) per reference amount of the food, than the reference amount of the reference food of the same food group; or | (*a*) the reference food of the same food group; | |
| | | (*b*) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. | (*b*) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and | |
| | | (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 12 for the subject "low in fat" set out in column 1. | (*c*) the difference in fat compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or | |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | | fraction or in grams. | |
| 15. | 100% fat-free | The food<br>(*a*) contains less than 0.5 g of fat per 100 g;<br>(*b*) contains no added fat; and<br>(*c*) meets the conditions set out in column 2 of item 11 for the subject “free of fat” set out in column 1. | | “100% fat-free” or “100% free of fat” |
| 16. | (Percentage) fat-free | The food meets the conditions set out in column 2 of item 12 for the subject “low in fat” set out in column 1. | One of the following statements or claims is stated: “low fat” or “low in fat”. | “(percentage) fat-free” or “(percentage) free of fat” |
| 17. | No added fat | (1) The food contains no added fats or oils set out in Division 9, or added butter or ghee, or ingredients that contain added fats or oils, or butter or ghee.<br>(2) The similar reference food contains added fats or oils set out in Division 9, or added butter or ghee. | | “no fat added”, “no added fat” or “without added fat” |
| 18. | Free of saturated fatty acids | The food contains<br>(*a*) less than 0.2 g saturated fatty acids and less than 0.2 g *trans* fatty acids per reference amount and serving of stated size; or<br>(*b*) less than 0.2 g saturated fatty acids and less than 0.2 g *trans* fatty acids per serving of stated size, if the food is a prepackaged meal. | | “saturated fatty acids-free”, “free of saturated fatty acids”, “no saturated fatty acids”, “0 saturated fatty acids”, “zero saturated fatty acids”, “without saturated fatty acids”, “saturated fat-free”, “free of saturated fat”, “no saturated fat”, “0 saturated fat”, “zero saturated fat”, “without saturated fat”, “saturates-free”, “free of saturates”, “no saturates”, “0 saturates”, “zero saturates” or “without |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | | | saturates” |
| 19. | Low in saturated fatty acids | (1) The food contains 2 g or less of saturated fatty acids and *trans* fatty acids combined<br>(*a*) per reference amount and serving of stated size; or<br>(*b*) per 100 g, if the food is a prepackaged meal.<br><br>(2) The food provides 15% or less energy from the sum of saturated fatty acids and *trans* fatty acids. | | “low saturated fatty acids”, “low in saturated fatty acids”, “low source of saturated fatty acids”, “little saturated fatty acids”, “contains only (number) g of saturated fatty acids per serving”, “contains less than (number) g of saturated fatty acids per serving”, “low saturated fat”, “low in saturated fat”, “low source of saturated fat”, “little saturated fat”, “contains only (number) g of saturated fat per serving”, “contains less than (number) g of saturated fat per serving”, “low saturates”, “low in saturates”, “low source of saturates”, “little saturates”, “contains only (number) g of saturates per serving” or “contains less than (number) g of saturates per serving” |
| 20. | Reduced in saturated fatty acids | (1) The food is processed, formulated, reformulated or otherwise modified, without increasing the content of *trans* fatty acids, so that it contains at least 25% less saturated fatty acids<br>(*a*) per reference amount of the food, than the reference amount of the similar reference food; or<br>(*b*) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. | The following are identified:<br><br>(*a*) the similar reference food;<br><br>(*b*) the amounts of the food and the similar reference food being | “reduced saturated fatty acids”, “reduced in saturated fatty acids”, “saturated fatty acids-reduced”, “less saturated fatty acids”, “lower saturated fatty acids”, “lower in saturated fatty acids”, “fewer saturated fatty acids”, “reduced saturated fat”, “reduced in saturated fat”, “saturated fat-reduced”, “less saturated fat”, “lower saturated fat”, “lower in saturated fat”, “reduced saturates”, “reduced in |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | | compared, if those amounts are not equal; and | saturates", "saturates-reduced", "less saturates", "lower saturates", "lower in saturates" or "fewer saturates" |
| | | (2) The similar reference food does not meet the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1. | (*c*) the difference in saturated fatty acids compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams. | |
| 21. | Lower in saturated fatty acids | (1) The food contains at least 25% less saturated fatty acids and the content of *trans* fatty acids is not higher<br>(*a*) per reference amount of the food, than the reference amount of the reference food of the same food group; or<br>(*b*) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. | The following are identified:<br>(*a*) the reference food of the same food group;<br>(*b*) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and | "less saturated fatty acids", "lower saturated fatty acids", "lower in saturated fatty acids", "fewer saturated fatty acids", "less saturated fat", "lower saturated fat", "lower in saturated fat", "less saturates", "lower saturates", "lower in saturates" or "fewer saturates" |
| | | (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1. | (*c*) the difference in saturated fatty acids compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in grams. | |
| 22. | Free of *trans* fatty acids | The food<br>(*a*) contains less than 0.2 g of *trans* fatty acids | | "trans fatty acids-free", "free of trans fatty acids", "no trans fatty acids", "0 |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | (i) per reference amount and serving of stated size, or<br><br>(ii) per serving of stated size, if the food is a prepackaged meal; and<br><br>(*b*) meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1. | | trans fatty acids", "zero trans fatty acids", "without trans fatty acids", "contains no trans fatty acids", "trans fat-free", "free of trans fat", "no trans fat", "0 trans fat", "zero trans fat", "without trans fat", "contains no trans fat", "trans-free", "free of trans", "no trans", "0 trans", "zero trans" or "without trans" |
| 23. | Reduced in *trans* fatty acids | (1) The food is processed, formulated, reformulated or otherwise modified, without increasing the content of saturated fatty acids, so that it contains at least 25% less *trans* fatty acids<br><br>(*a*) per reference amount of the food, than the reference amount of the similar reference food; or<br><br>(*b*) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal.<br><br>(2) The similar reference food does not meet the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1. | The following are identified:<br><br>(*a*) the similar reference food;<br><br>(*b*) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and<br><br>(*c*) the difference in *trans* fatty acids compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams. | "reduced trans", "reduced in trans", "trans-reduced", "reduced trans fatty acids", "reduced in trans fatty acids", "trans fatty acids-reduced", "less trans fatty acids", "lower trans fatty acids", "lower in trans fatty acids", "fewer trans fatty acids", "reduced trans fat", "reduced in trans fat", "trans fat-reduced", "less trans fat", "lower trans fat" or "lower in trans fat" |
| 24. | Lower in *trans* fatty acids | (1) The food contains at least 25% less *trans* fatty acids and the content of | The following are identified: | "less trans fatty acids", "lower trans fatty acids", "lower in trans fatty |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | saturated fatty acids is not higher<br>(*a*) per reference amount of the food, than the reference amount of the reference food of the same food group; or<br>(*b*) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal.<br>(2) The reference food of the same food group does not meet the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1. | (*a*) the reference food of the same food group;<br>(*b*) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and<br>(*c*) the difference in *trans* fatty acids compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in grams. | acids", "fewer trans fatty acids", "less trans fat", "lower trans fat", "lower in trans fat", "less trans", "lower trans" or "lower in trans" |
| 25. | Source of omega-3 poly-unsaturated fatty acids | The food contains<br>(*a*) 0.3 g or more of omega-3 polyunsaturated fatty acids per reference amount and serving of stated size; or<br>(*b*) 0.3 g or more of omega-3 polyunsaturated fatty acids per 100 g, if the food is a prepackaged meal. | | "source of omega-3 polyunsaturated fatty acids", "contains omega-3 polyunsaturated fatty acids", "provides omega-3 polyunsaturated fatty acids", "source of omega-3 polyunsaturated fat", "contains omega-3 polyunsaturated fat", "provides omega-3 polyunsaturated fat", "source of omega-3 polyunsaturates", "contains omega-3 polyunsaturates" or "provides omega-3 polyunsaturates" |
| 26. | Source of omega-6 poly- | The food contains<br>(*a*) 2 g or more of omega-6 polyunsaturated | | "source of omega-6 polyunsaturated fatty acids", "contains omega-6 |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | unsaturated fatty acids | fatty acids per reference amount and serving of stated size; or<br><br>(*b*) 2 g or more of omega-6 polyunsaturated fatty acids per 100 g, if the food is a prepackaged meal. | | polyunsaturated fatty acids", "provides omega-6 polyunsaturated fatty acids", "source of omega-6 polyunsaturated fat", "contains omega-6 polyunsaturated fat", "provides omega-6 polyunsaturated fat", "source of omega-6 polyunsaturates", "contains omega-6 polyunsaturates" or "provides omega-6 polyunsaturates" |
| 27. | Free of cholesterol | The food<br><br>(*a*) contains less than 2 mg of cholesterol<br><br>(i) per reference amount and serving of stated size, or<br><br>(ii) per serving of stated size, if the food is a prepackaged meal; and<br><br>(*b*) meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1. | | "cholesterol-free", "free of cholesterol", "no cholesterol", "0 cholesterol", "zero cholesterol", "without cholesterol" or "contains no cholesterol" |
| 28. | Low in cholesterol | The food<br><br>(*a*) contains 20 mg or less of cholesterol per<br><br>(i) reference amount and serving of stated size and, if the reference amount is 30 g or 30 mL or less, per 50 g, or<br><br>(ii) per 100 g, if the food is a prepackaged meal; | | "low cholesterol", "low in cholesterol", "low source of cholesterol", "little cholesterol", "contains only (number) mg of cholesterol per serving" or "contains less than (number) mg of cholesterol per serving" |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | and<br>(*b*) meets the conditions set out in column 2 of item 19 for the subject “low in saturated fatty acids” set out in column 1. | | |
| 29. | Reduced in cholesterol | (1) The food is processed, formulated, reformulated or otherwise modified so that it contains at least 25% less cholesterol<br>(*a*) per reference amount of the food, than the reference amount of the similar reference food; or<br>(*b*) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal.<br>(2) The similar reference food does not meet the conditions set out in column 2 of item 28 for the subject “low in cholesterol” set out in column 1.<br>(3) The food meets the conditions set out in column 2 of item 19 for the subject “low in saturated fatty acids” set out in column 1. | The following are identified:<br>(*a*) the similar reference food;<br>(*b*) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and<br>(*c*) the difference in cholesterol compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in milligrams. | “reduced cholesterol”, “reduced in cholesterol”, “cholesterol-reduced”, “less cholesterol”, “lower cholesterol” or “lower in cholesterol” |
| 30. | Lower in cholesterol | (1) The food contains at least 25% less cholesterol<br>(*a*) per reference amount | The following are identified:<br>(*a*) the reference | “less cholesterol”, “lower cholesterol” or “lower in cholesterol” |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | of the food, than the reference amount of the reference food of the same food group; or<br><br>(*b*) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal.<br><br>(2) The reference food of the same food group does not meet the conditions set out in column 2 of item 28 for the subject "low in cholesterol" set out in column 1.<br><br>(3) The food meets the conditions set out in column 2 of item 19 for the subject "low in saturated fatty acids" set out in column 1. | food of the same food group;<br><br>(*b*) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and<br><br>(*c*) the difference in cholesterol compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in milligrams. | |
| 31. | Free of sodium or salt | The food contains<br><br>(*a*) less than 5 mg of sodium per reference amount and serving of stated size; or<br><br>(*b*) less than 5 mg of sodium per serving of stated size, if the food is a prepackaged meal. | | "sodium-free", "free of sodium", "no sodium", "0 sodium", "zero sodium", "without sodium", "contains no sodium", "salt-free", "free of salt", "no salt", "0 salt", "zero salt", "without salt" or "contains no salt" |
| 32. | Low in sodium or salt | The food contains<br><br>(*a*) 140 mg or less of sodium per reference amount and serving of | | "low sodium", "low in sodium", "low source of sodium", "little sodium", "contains only (number) mg of sodium per serving", "contains less |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | stated size and, if the reference amount is 30 g or 30 mL or less, per 50 g; or<br><br>(*b*) 140 mg or less of sodium per 100 g, if the food is a prepackaged meal. | | than (number) mg of sodium per serving", "low salt", "low in salt", "low source of salt", "little salt", "contains only (number) mg of salt per serving" or "contains less than (number) mg salt per serving" |
| 33. | Reduced in sodium or salt | (1) The food is processed, formulated, reformulated or otherwise modified so that it contains at least 25% less sodium<br><br>(*a*) per reference amount of the food, than the reference amount of the similar reference food; or<br><br>(*b*) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal.<br><br>(2) The similar reference food does not meet the conditions set out in column 2 of item 32 for the subject "low in sodium or salt" set out in column 1. | The following are identified:<br><br>(*a*) the similar reference food;<br><br>(*b*) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and<br><br>(*c*) the difference in sodium content compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in milligrams. | "reduced sodium", "reduced in sodium", "sodium-reduced", "less sodium", "lower sodium", "lower in sodium", "reduced salt", "reduced in salt", "salt-reduced", "less salt", "lower salt" or "lower in salt" |
| 34. | Lower in sodium or salt | (1) The food contains at least 25% less sodium<br><br>(*a*) per reference amount of the food, than the reference amount of the reference food of the same food group; or<br><br>(*b*) per 100 g, than 100 g | The following are identified:<br><br>(*a*) the reference food of the same food group;<br><br>(*b*) the amounts of | "less sodium", "lower sodium", "lower in sodium", "less salt", "lower salt" or "lower in salt" |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | of the reference food of the same food group, if the food is a prepackaged meal. | the food and the reference food of the same food group being compared, if those amounts are not equal; and | |
| | | (2) The reference food of the same food group does not meet the conditions set out in column 2 of item 32 for the subject “low in sodium or salt” set out in column 1. | (*c*) the difference in sodium content compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in milligrams. | |
| 35. | No added sodium or salt | (1) The food contains no added salt, other sodium salts or ingredients that contain sodium that functionally substitute for added salt. | | “unsalted”, “without added salt”, “no salt added”, “no added salt”, “without added sodium”, “no sodium added” or “no added sodium” |
| | | (2) The similar reference food does not meet the conditions set out in column 2 of item 32 for the subject “low in sodium or salt” set out in column 1 and contains added salt or other sodium salts. | | |
| 36. | Lightly salted | (1) The food contains at least 50% less added sodium than the sodium added to the similar reference food. | The following are identified: | “lightly salted” or “salted lightly” |
| | | (2) The similar reference food does not meet the conditions set out in column 2 of item 32 for the subject “low in sodium or salt” set out in column 1. | (*a*) the similar reference food;<br>(*b*) the amounts of the food and the similar reference food being compared, if those amounts are not | |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | | equal; and<br>(*c*) the difference in sodium content compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in milligrams. | |
| 37. | Free of sugars | The food<br>(*a*) contains less than 0.5 g of sugars per reference amount and serving of stated size; and<br>(*b*) with the exception of chewing gum, meets the conditions set out in column 2 of item 1 for the subject “free of energy” set out in column 1. | | “sugar-free”, “free of sugar”, “no sugar”, “0 sugar”, “zero sugar”, “without sugar”, “contains no sugar” or “sugarless” |
| 38. | Reduced in sugars | The food is processed, formulated, reformulated or otherwise modified so that it contains at least 25% less sugars, totalling at least 5 g less,<br>(*a*) per reference amount of the food, than the reference amount of the similar reference food; or<br>(*b*) per 100 g, than 100 g of the similar reference food, if the food is a prepackaged meal. | The following are identified:<br>(*a*) the similar reference food;<br>(*b*) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and<br>(*c*) the difference in sugars compared to the similar reference | “reduced sugar”, “reduced in sugar”, “sugar-reduced”, “less sugar”, “lower sugar” or “lower in sugar” |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | | food, per serving of stated size, expressed as a percentage or fraction or in grams. | |
| 39. | Lower in sugars | The food contains at least 25% less sugars, totalling at least 5 g less,<br>(*a*) per reference amount of the food, than the reference amount of the reference food of the same food group; or<br>(*b*) per 100 g, than 100 g of the reference food of the same food group, if the food is a prepackaged meal. | The following are identified:<br>(*a*) the reference food of the same food group;<br>(*b*) the amounts of the food and the reference food of the same food group being compared, if those amounts are not equal; and<br>(*c*) the difference in sugars compared to the reference food of the same food group, per serving of stated size, expressed as a percentage or fraction or in grams. | “lower sugar”, “lower in sugar” or “less sugar” |
| 40. | No added sugars | (1) The food contains no added sugars, no ingredients containing added sugars or ingredients that contain sugars that functionally substitute for added sugars.<br>(2) The sugars content is not increased through some other means except if the functional effect is not to increase the sugars content of the food.<br>(3) The similar reference food contains added | | “no sugar added”, “no added sugar” or “without added sugar” |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | sugars. | | |
| 41. | Source of fibre | (1) The food contains 2 g or more<br>(*a*) of fibre per reference amount and serving of stated size, if no fibre or fibre source is identified in the statement or claim; or<br>(*b*) of each identified fibre or fibre from an identified fibre source per reference amount and serving of stated size, if a fibre or fibre source is identified in the statement or claim.<br>(2) The food contains at least one ingredient that meets one of the conditions set out in subsection (1), if the food is a prepackaged meal. | | “source of fibre”, “contains fibre”, “provides fibre”, “made with fibre”, “source of (naming the fibre)”, “contains (naming the fibre)”, “provides (naming the fibre)”, “made with (naming the fibre)”, “source of (naming the fibre source)”, “contains (naming the fibre source)”, “provides (naming the fibre source)”, “made with (naming the fibre source)”, “source of dietary fibre”, “contains dietary fibre”, “provides dietary fibre” or “made with dietary fibre” |
| 42. | High source of fibre | (1) The food contains 4 g or more<br>(*a*) of fibre per reference amount and serving of stated size, if no fibre or fibre source is identified in the statement or claim; or<br>(*b*) of each identified fibre or fibre from an identified fibre source per reference amount and serving of stated size, if a fibre or fibre source is identified in the statement or claim.<br>(2) The food contains at least one ingredient that meets one of the conditions set out in subsection (1), if the | | “high source of fibre”, “high fibre”, “high in fibre”, “high source of (naming the fibre)”, “high (naming the fibre)”, “high in (naming the fibre)”, “high source of (naming the fibre source)”, “high (naming the fibre source)”, “high in (naming the fibre source)”, “high source of dietary fibre”, “high dietary fibre” or “high in dietary fibre” |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | food is a prepackaged meal. | | |
| 43. | Very high source of fibre | (1) The food contains 6 g or more<br>(*a*) of fibre per reference amount and serving of stated size, if no fibre or fibre source is identified in the statement or claim; or<br>(*b*) of each identified fibre or fibre from an identified fibre source per reference amount and serving of stated size, if a fibre or fibre source is identified in the statement or claim.<br>(2) The food contains at least one ingredient that meets one of the conditions set out in subsection (1), if the food is a prepackaged meal. | | "very high source of fibre", "very high fibre", "very high in fibre", "fibre rich", "rich in fibre", "very high source of (naming the fibre)", "very high (naming the fibre)", "very high in (naming the fibre)", "(naming the fibre) rich", "rich in (naming the fibre)", "very high source of (naming the fibre source)", "very high (naming the fibre source)", "very high in (naming the fibre source)", "(naming the fibre source) rich", "rich in (naming the fibre source)", "very high source of dietary fibre", "very high dietary fibre", "very high in dietary fibre", "dietary fibre rich" or "rich in dietary fibre" |
| 44. | More fibre | (1) The food contains at least 25% more fibre, totalling at least 1 g more, if no fibre or fibre source is identified in the statement or claim, or at least 25% more of an identified fibre or fibre from an identified fibre source, totalling at least 1 g more, if a fibre or fibre source is identified in the statement or claim<br>(*a*) per reference amount of the food, than the reference amount of the reference food of the same food group or the similar reference food; or<br>(*b*) per 100 g, than 100 g | The following are identified:<br>(*a*) the reference food of the same food group or the similar reference food;<br>(*b*) the amounts of | "more fibre", "higher fibre", "higher in fibre", "more (naming the fibre)", "higher (naming the fibre)", "higher in (naming the fibre)", "more (naming the fibre source)", "higher (naming the fibre source)", "higher in (naming the fibre source)", "more dietary fibre", "higher dietary fibre" or "higher in dietary fibre" |

| Item | Column 1<br>Subject | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement | Column 4<br>Statement or Claim |
|---|---|---|---|---|
| | | of the reference food of the same food group or the similar reference food, if the food is a prepackaged meal. | the food and the reference food of the same food group or the similar reference food being compared, if those amounts are not equal; and | |
| | | (2) The food contains<br>(*a*) at least 2 g of fibre per reference amount and serving of stated size if no fibre or fibre source is identified in the statement or claim, or at least 2 g of identified fibre or fibre from an identified fibre source per reference amount and serving of stated size if a fibre or fibre source is identified in the statement or claim; or<br>(*b*) at least one ingredient that meets the conditions set out in column 2 of item 41 for the subject “source of fibre” set out in column 1, if the food is a prepackaged meal. | (*c*) the difference in fibre compared to the reference food of the same food group or the similar reference food, per serving of stated size, expressed as a percentage or fraction or in grams. | |
| 45. | Light in energy or fat | The food meets the conditions set out in column 2<br>(*a*) of item 3 for the subject “reduced in energy” set out in column 1; or<br>(*b*) of item 13 for the subject “reduced in fat” set out in column 1. | The following are identified:<br>(*a*) the similar reference food;<br>(*b*) the amounts of the food and the similar reference food being compared, if those amounts are not equal; and<br>(*c*) the difference in | “light” or “lite” |

| | Column 1 | Column 2 | Column 3 | Column 4 |
|---|---|---|---|---|
| Item | Subject | Conditions — Food | Conditions — Label or Advertisement | Statement or Claim |
| | | | energy or fat value compared to the similar reference food, per serving of stated size, expressed as a percentage or fraction or in Calories or grams. | |
| 46. | Lean | The food<br>(*a*) is meat or poultry that has not been ground, a marine or fresh water animal or a product of any of these; and<br>(*b*) contains 10% or less fat. | | “lean” |
| 47. | Extra lean | The food<br>(*a*) is meat or poultry that has not been ground, a marine or fresh water animal or a product of any of these; and<br>(*b*) contains 7.5% or less fat. | | “extra lean” |

SOR/2003-11, s. 20; err.(F), Vol. 137, No. 5; SOR/2007-176, s. 6.

Previous Version

**[B.01.514 to B.01.599 reserved]**

## Health Claims

### Languages

B.01.600. A statement or claim set out in column 1 of the table following section B.01.603 that appears on the label of a food shall be

(*a*) in English and French; or

(*b*) in one of those languages, if in accordance with subsection B.01.012(3) or (7) the information that is required by these Regulations to be shown on the label of the food may be shown in that language only and is shown on the label in that language.

SOR/2003-11, s. 20.

### Statements or Claims

B.01.601. (1) A food with a label or advertisement that carries a statement or claim set out in column 1 of the table following section B.01.603 is exempt from the provisions of the Act and its Regulations with respect to drugs, and from subsections 3(1) and (2) of the Act, if

(*a*) the food meets the applicable conditions set out in column 2;

(*b*) the label of or the advertisement for the food meets the applicable conditions set out in column 3; and

(*c*) the food is not

(i) intended solely for children under two years of age, or

(ii) a food represented for use in a very low energy diet.

(2) Subsection (1) does not apply to a food that comes within the definition of "drug" as defined in section 2 of the Act for a reason other than the fact that its label or advertisement carries a statement or claim referred to in that subsection.

(3) Subsection (1) applies even if the word "graisses" in the French version of the statement or claim is replaced by the word "lipides".

SOR/2003-11, s. 20.

B.01.602. (1) The information required under the conditions set out in column 3 of the table following section B.01.603 that appears in an advertisement for a food that is not a prepackaged product, or in an advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, shall,

(*a*) in the case of an advertisement, other than a radio or television advertisement, be

(i) adjacent to, without any intervening printed, written or graphic material, the statement or claim set out in column 1, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and

(ii) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once;

(*b*) in the case of a radio advertisement or the audio portion of a television advertisement, immediately precede or follow the statement or claim set out in column 1; or

(*c*) in the case of a television advertisement, be communicated

(i) in the audio mode, if the statement or claim set out in column 1 is made only in the audio portion of the advertisement or in both the audio and visual portions, or

(ii) in the audio or visual mode, if the statement or claim set out in column 1 is made only in the visual portion of the advertisement.

(2) The information that is communicated in the visual mode of a television advertisement in accordance with subparagraph (1)(*c*)(ii) shall

(*a*) appear concurrently with and for at least the same amount of time as the statement or claim;

(*b*) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and

(*c*) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

SOR/2003-11, s. 20.

B.01.603. For greater certainty, a statement or claim set out in column 1 of the table following this section that is made on the label of or in any advertisement for a food may be preceded or followed by other words, numbers, signs or symbols, but none of those shall be interposed between the words, numbers, signs or symbols of the statement or claim.

TABLE

| | Column 1 | Column 2 | Column 3 |
|---|---|---|---|
| Item | Statement or Claim | Conditions — Food | Conditions — Label or Advertisement |
| 1. | (1) “A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is sodium-free.”<br><br>(2) “A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is low in sodium.”<br><br>(3) “A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is a good source of potassium and is | The food<br><br>(*a*) other than a vegetable or fruit, does not meet the conditions set out in column 2 of item 2 of the table following section B.01.513 for the subject “low in energy” set out in column 1;<br><br>(*b*) contains at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient<br><br>(i) per reference amount and per serving of stated size, or<br><br>(ii) per serving of stated size, if the food is a prepackaged meal;<br><br>(*c*) meets the conditions set out in column 2 of item 19 of the table following section B.01.513 for the subject “low in saturated fatty acids” set out in column 1;<br><br>(*d*) contains 0.5% or less alcohol;<br><br>(*e*) meets the conditions set out in column 2 of item 31 of the table following section B.01.513 for the subject “free of sodium or salt” set out in column 1, if the | (1) If the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the nutrition facts table shall include the amount of potassium, in accordance with subsection B.01.402(2).<br><br>(2) If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of sodium and potassium per serving of stated size, in accordance with section B.01.602 if applicable. |

| Item | Column 1<br>Statement or Claim | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement |
|---|---|---|---|
| | sodium-free.”<br><br>(4) “A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is a good source of potassium and is low in sodium.”<br><br>(5) “A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is high in potassium and is sodium-free.”<br><br>(6) “A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. (Naming the food) is high in potassium and is low in sodium.” | label of or advertisement for the food carries statement or claim (1), (3) or (5) set out in column 1 of this item;<br><br>(*f*) meets the conditions set out in column 2 of item 32 of the table following section B.01.513 for the subject “low in sodium or salt” set out in column 1, if the label of or advertisement for the food carries statement or claim (2), (4) or (6) set out in column 1 of this item; and<br><br>(*g*) contains 350 mg or more of potassium, if the label of or advertisement for the food carries statement or claim (3), (4), (5) or (6) set out in column 1 of this item,<br><br>(i) per reference amount and per serving of stated size, or | |

| Item | Column 1<br>Statement or Claim | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement |
|---|---|---|---|
| | | (ii) per serving of stated size, if the food is a prepackaged meal. | |
| 2. | (1) “A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is a good source of calcium.”<br><br>(2) “A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is high in calcium.”<br><br>(3) “A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is an excellent source of calcium.”<br><br>(4) “A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is | The food<br><br>(*a*) other than a vegetable or fruit, does not meet the conditions set out in column 2 of item 2 of the table following section B.01.513 for the subject “low in energy” set out in column 1;<br><br>(*b*) contains no more phosphorus, excluding that provided by phytate, than calcium;<br><br>(*c*) contains 0.5% or less alcohol;<br><br>(*d*) contains, if the label of or advertisement for the food carries statement or claim (1) or (2) set out in column 1 of this item,<br><br>(i) 200 mg or more of calcium per reference amount and per serving of stated size, or<br><br>(ii) 300 mg or more of calcium per serving of stated size, if the food is a prepackaged meal;<br><br>(*e*) contains, if the label of or advertisement for the food carries statement or claim (3), (4), (5) or (6) set out in column 1 of this item,<br><br>(i) 275 mg or more of calcium per reference amount and per serving of stated size, or<br><br>(ii) 400 mg or more of calcium per serving of stated size, if the food is a prepackaged meal; and | (1) If the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the nutrition facts table shall include the amount of vitamin D and phosphorus, in accordance with subsection B.01.402(2).<br><br>(2) If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of vitamin D, calcium and phosphorus per serving of stated size, in accordance with section B.01.602 if applicable. |

| Item | Column 1<br>Statement or Claim | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement |
|---|---|---|---|
| | very high in calcium.”<br><br>(5) “A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is an excellent source of calcium and vitamin D.” | | |
| | (6) “A healthy diet with adequate calcium and vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis. (Naming the food) is very high in calcium and vitamin D.” | (*f*) contains 1.25 µg or more of vitamin D, if the label of or advertisement for the food carries statement or claim (5) or (6) set out in column 1 of this item,<br><br>(i) per reference amount and per serving of stated size, or<br><br>(ii) per serving of stated size, if the food is a prepackaged meal. | |
| 3. | (1) “A healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Naming the food) is free of saturated and trans fats.”<br><br>(2) “A healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Naming the food) is low in saturated and trans fats.” | The food<br><br>(*a*) other than a vegetable or fruit, does not meet the conditions set out in column 2 of item 2 of the table following section B.01.513 for the subject “low in energy” set out in column 1;<br><br>(*b*) contains at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient<br><br>(i) per reference amount and per serving of stated size, or<br><br>(ii) per serving of stated size, if the food is a prepackaged meal;<br><br>(*c*) contains 100 mg or less of | If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of saturated fatty acids and *trans* fatty acids per serving of stated size, in accordance with section B.01.602 if applicable. |

| Column 1<br>Item | Statement or Claim | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement |
|---|---|---|---|
| | | cholesterol per 100 g of food;<br><br>(*d*) contains 0.5% or less alcohol;<br><br>(*e*) if it is a fat or an oil, meets the conditions set out in<br><br>(i) column 2 of item 25 of the table following section B.01.513 for the subject “source of omega-3 polyunsaturated fatty acids” set out in column 1,<br><br>(ii) column 2 of item 26 of the table following section B.01.513 for the subject “source of omega-6 polyunsaturated fatty acids” set out in column 1, or<br><br>(iii) subparagraphs (i) and (ii);<br><br>(*f*) contains<br><br>(i) 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or<br><br>(ii) 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal;<br><br>(*g*) meets the conditions set out in column 2 of item 18 of the table following section B.01.513 for the subject “free of saturated fatty acids” set out in column 1, if the label of or advertisement for the food carries statement or claim (1) set out in column 1 of this item; and<br><br>(*h*) meets the conditions set out in column 2 of item 19 of the table following section B.01.513 for the subject “low in saturated fatty acids” set out in column 1, if the | |

| Item | Column 1<br>Statement or Claim | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement |
|---|---|---|---|
| 4. | “A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer.” | label of or advertisement for the food carries statement or claim (2) set out in column 1 of this item.<br><br>The food<br><br>(*a*) is one of the following vegetables, fruit, or juice, and may contain only sweetening agents, food additives as permitted by these Regulations, salt, herbs, spices, seasonings or water:<br><br>(i) a fresh, frozen, canned or dried vegetable,<br><br>(ii) a fresh, frozen, canned or dried fruit,<br><br>(iii) a vegetable or fruit juice, or<br><br>(iv) a combination of the foods set out in subparagraphs (i) to (iii);<br><br>(*b*) is not one of the following:<br><br>(i) potatoes, yams, cassava, plantain, corn, mushrooms, mature legumes and their juices,<br><br>(ii) vegetables or fruit used as condiments, garnishes or flavourings, including maraschino cherries, glacé fruit, candied fruit and onion flakes,<br><br>(iii) jams or jam-type spreads, marmalades, preserves and jellies,<br><br>(iv) olives, or<br><br>(v) powdered vegetables or fruit; and<br><br>(*c*) contains 0.5% or less alcohol. | |

| Item | Column 1<br>Statement or Claim | Column 2<br>Conditions — Food | Column 3<br>Conditions — Label or Advertisement |
|---|---|---|---|
| 5. | (1) “Won’t cause cavities.”<br>(2) “Does not promote tooth decay.”<br>(3) “Does not promote dental caries.”<br>(4) “Non-cariogenic.” | The food is a chewing gum, hard candy or breath freshener product that<br>(*a*) contains 0.25% or less starch, dextrins, mono-, di- and oligosaccharides or other fermentable carbohydrates combined; or<br>(*b*) does not, if it contains more than 0.25% fermentable carbohydrates, lower plaque pH below 5.7 by bacterial fermentation during 30 minutes after consumption as measured by the indwelling plaque pH test, referred to in “Identification of Low Caries Risk Dietary Components” by T.N. Imfeld, Volume 11, Monographs in Oral Science, 1983. | If the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the nutrition facts table shall include the amount of sugar alcohols, if present, in accordance with subsection B.01.402(2). |

SOR/2003-11, s. 20; err.(F), Vol. 137, No. 5; SOR/2010-142, s. 2.

Previous Version

# Division 2

# Alcoholic Beverages

B.02.001. The foods referred to in this Division are included in the term *alcoholic beverage*.

SOR/93-145, s. 3(F).

B.02.002. In this Division,

“absolute alcohol” means alcohol of a strength of 100 per cent; (alcool absolu)

“age” means the period during which an alcoholic beverage is kept under such conditions of storage as may be necessary to develop its characteristic flavour and bouquet; (âge)

“alcohol” means ethyl alcohol; (alcool)

“flavouring” means, in respect of a spirit, any other spirit or wine, domestic or imported, added as a flavouring to that spirit as authorized under the Excise Act; (substance aromatique)

“grain spirit” means an alcoholic distillate, obtained from a mash of cereal grain or cereal grain products saccharified by the diastase of malt or by other enzymes and fermented by the

action of yeast or a mixture of yeast and other micro-organisms, and from which all or nearly all of the naturally occurring substances other than alcohol and water have been removed; (esprit de grain)

“malt spirit” means an alcoholic distillate, obtained by pot-still distillation from a mash of cereal grain or cereal grain products saccharified by the diastase of malt and fermented by the action of yeast or a mixture of yeast and other micro-organisms; (esprit de malt)

“molasses spirit” means an alcoholic distillate, obtained from sugar-cane or sugar-cane products fermented by the action of yeast or a mixture of yeast and other micro-organisms, from which all or nearly all of the naturally occurring substances other than alcohol and water have been removed; (esprit de mélasse)

“small wood” means wood casks or barrels of not greater than 700 L capacity; (petit fût)

“sweetening agent” means glucose-fructose, fructose syrup or any food for which a standard is provided in Division 18, or any combination thereof. (agent édulcorant)

SOR/84-300, s. 10; SOR/93-145, s. 4.

B.02.003. Where an alcoholic beverage contains 1.1 per cent or more alcohol by volume, the percentage by volume of alcohol present in the alcoholic beverage shall be shown on the principal display panel followed by the words “alcohol by volume” or the abbreviation “alc./vol.”.

SOR/88-418, s. 1; SOR/93-145, s. 5(F).

## Whisky

B.02.010. **[S]. Whisky** or **Whiskey**, other than Malt Whisky, Scotch Whisky, Irish Whisky, Canadian Whisky, Canadian Rye Whisky, Rye Whisky, Highland Whisky, Bourbon Whisky and Tennessee Whisky,

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained from a mash of cereal grain or cereal grain products saccharified by the diastase of malt or by other enzymes and fermented by the action of yeast or a mixture of yeast and other micro-organisms; and

(*b*) may contain caramel and flavouring.

SOR/93-145, s. 6; SOR/93-603, s. 2.

B.02.011. and B.02.012. [Repealed, SOR/93-145, s. 7]

B.02.013. **[S]. Malt Whisky**

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of a mash of malted grain fermented by the action of yeast or a mixture of yeast and other micro-organisms;

(*b*) shall possess the aroma, taste and character generally attributed to malt whisky; and

(*c*) may contain caramel and flavouring.

SOR/93-145, s. 8.

B.02.014. and B.02.015. [Repealed, SOR/93-145, s. 9]

B.02.016. **[S]. Scotch Whisky** shall be whisky distilled in Scotland as Scotch whisky for domestic consumption in accordance with the laws of the United Kingdom.

B.02.017. No person shall blend or modify in any manner any Scotch whisky that is imported in bulk for the purpose of bottling and sale in Canada as Scotch whisky except by

(*a*) blending with other Scotch whisky,

(*b*) the addition of distilled or otherwise purified water to adjust to a required strength, or

(*c*) the addition of caramel.

B.02.018. **[S]. Irish Whisky** shall be whisky distilled in Northern Ireland or in the Republic of Ireland as Irish whisky for domestic consumption in accordance with the laws of Northern Ireland or the Republic of Ireland.

B.02.019. No person shall blend or modify in any manner any Irish whisky that is imported in bulk for the purpose of bottling and sale in Canada as Irish whisky except by

(*a*) blending with other Irish whisky,

(*b*) the addition of distilled or otherwise purified water to adjust to a required strength, or

(*c*) the addition of caramel.

B.02.020. **[S].** (1) **Canadian Whisky, Canadian Rye Whisky** or **Rye Whisky**

(*a*) shall

(i) be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained from a mash of cereal grain or cereal grain products saccharified by the diastase of malt or by other enzymes and fermented by the action of yeast or a mixture of yeast and other micro-organisms,

(ii) be aged in small wood for not less than three years,

(iii) possess the aroma, taste and character generally attributed to Canadian whisky,

(iv) be manufactured in accordance with the requirements of the Excise Act and the regulations made thereunder,

(v) be mashed, distilled and aged in Canada, and

(vi) contain not less than 40 per cent alcohol by volume; and

(*b*) may contain caramel and flavouring.

(2) Subject to subsection (3), no person shall make any claim with respect to the age of Canadian whisky, other than for the period during which the whisky has been held in small wood.

(3) Where Canadian whisky has been aged in small wood for a period of at least three years, any period not exceeding six months during which that whisky was held in other containers may be claimed as age.

SOR/93-145, s. 10; SOR/2000-51, s. 1.

B.02.021. **[S]. Highland Whisky**

(*a*) shall be a potable alcoholic beverage blended in Canada from

(i) not less than 25 per cent malt whisky calculated on an absolute alcohol basis, distilled in Canada or Scotland, and

(ii) whisky; and

(*b*) may, if it contains 51 per cent or more malt whisky distilled in Scotland, be labelled or advertised as containing malt whisky distilled in Scotland.

SOR/93-145, s. 10.

B.02.022. (1) Subject to subsection (2), no person shall label, package, sell or advertise any food as **Bourbon Whisky**, or in such a manner that it is likely to be mistaken for Bourbon whisky unless it is whisky manufactured in the United States as Bourbon whisky in accordance with the laws of the United States applicable in respect of Bourbon whisky for consumption in the United States.

(2) A person may modify Bourbon whisky that is imported for the purpose of bottling and sale in Canada as Bourbon whisky by the addition of distilled or otherwise purified water to adjust the Bourbon whisky to a required strength.

SOR/89-59, s. 2; SOR/93-145, s. 11(F).

B.02.022.1. (1) Subject to subsection (2), no person shall label, package, sell or advertise any food as **Tennessee Whisky**, or in such a manner that it is likely to be mistaken for Tennessee whisky unless it is a straight Bourbon whisky produced in the State of Tennessee and manufactured in the United States as Tennessee whisky in accordance with the laws of the United States applicable in respect of Tennessee whisky for consumption in the United States.

(2) A person may modify Tennessee whisky that is imported for the purpose of bottling and sale in Canada as Tennessee whisky by the addition of distilled or otherwise purified water to adjust the Tennessee whisky to a required strength.

SOR/93-603, s. 3.

B.02.023. (1) Subject to sections B.02.022 and B.02.022.1, no person shall sell for consumption in Canada any whisky that has not been aged for a period of at least three years in small wood.

(2) Nothing in subsection (1) applies in respect of flavouring contained in whisky, but no person shall sell for consumption in Canada whisky containing any flavouring, other than wine, that has not been aged for a period of at least two years in small wood.

SOR/93-145, s. 12; SOR/93-603, s. 4.

## Rum

B.02.030. **[S]. Rum**

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained from sugar-cane or sugar-cane products fermented by the action of yeast or a mixture of yeast and other micro-organisms; and

(*b*) may contain

(i) caramel,

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations.

SOR/93-145, s. 13.

B.02.031. (1) No person shall sell for consumption in Canada any rum that has not been aged for a period of at least one year in small wood.

(2) Nothing in subsection (1) applies in respect of flavouring contained in rum, but no person shall sell for consumption in Canada rum containing any flavouring, other than wine, that has not been aged for a period of at least one year in small wood.

SOR/84-657, s. 1; SOR/93-145, s. 13.

B.02.032. [Repealed, SOR/93-145, s. 14]

B.02.033. No person shall blend or modify in any manner any rum that is imported in bulk for the purpose of bottling and sale in Canada as imported rum except by

(*a*) blending with other imported rum,

(*b*) adding distilled or otherwise purified water to adjust the rum to the strength stated on the label applied to the container; or

(*c*) the addition of caramel.

SOR/89-127, s. 1.

B.02.034. (1) Notwithstanding section B.02.033, no person shall blend or modify in any manner any rum made from sugar cane products of a Commonwealth Caribbean country that has been distilled and fermented in a Commonwealth Caribbean country and imported in bulk from a Commonwealth Caribbean Country for bottling and sale in Canada as Caribbean rum except by

(*a*) blending with other rum of a Commonwealth Caribbean country;

(*b*) blending with Canadian rum in proportions that result in one to 1.5 per cent Canadian rum by volume in the final product;

(*c*) adding distilled or otherwise purified water to adjust the rum to the strength stated on the label applied to the container; or

(*d*) adding caramel.

(2) In this section, “Commonwealth Caribbean country” means Anguilla, Antigua and Barbuda, Barbados, the Bahamas, Belize, Bermuda, the British Virgin Islands, the Caymen Islands, Dominica, Grenada, Guyana, Jamaica, Montserrat, St. Christopher and Nevis, Saint

Lucia, St. Vincent and the Grenadines, Trinidad and Tobago and the Turks and Caicos Islands.

SOR/89-127, s. 2.

## Gin

B.02.040. **[S]. Hollands, Hollands Gin, Geneva, Geneva Gin, Genever, Genever Gin** or **Dutch-type Gin**

(*a*) shall be a potable alcoholic beverage obtained

(i) by the redistillation of malt spirit with or over juniper berries, or by a mixture of the products of more than one such redistillation,

(ii) by the redistillation of a combination of malt spirit and not more than four times its volume on an absolute alcohol basis of grain spirit with or over juniper berries, or by a mixture of the products of more than one such redistillation, or

(iii) by the blending of malt spirit, redistilled with or over juniper berries, with not more than four times its volume on an absolute alcohol basis of grain spirit or molasses spirit, or by a mixture of the products of more than one such blending;

(*b*) may contain

(i) other aromatic botanical substances, added during the redistillation process, and

(ii) caramel;

(*c*) shall not contain more than two per cent sweetening agent;

(*d*) may be labelled or advertised as being distilled, where subparagraph (*a*)(i) or (ii) is complied with; and

(*e*) shall be described on the principal display panel of its label and in any advertisements as blended gin, where subparagraph (*a*)(iii) is complied with.

SOR/93-145, s. 15.

B.02.041. **[S]. Gin,** other than Hollands, Hollands Gin, Geneva, Geneva Gin, Genever, Genever Gin or Dutch-type Gin,

(*a*) shall be a potable alcoholic beverage obtained

(i) by the redistillation of alcohol from food sources with or over juniper berries, or by a mixture of the products of more than one such redistillation, or

(ii) by the blending of alcohol from food sources, redistilled with or over juniper berries, with alcohol from food sources or by a mixture of the products of more than one such blending;

(*b*) may contain

(i) other aromatic botanical substances, added during the redistillation process,

(ii) a sweetening agent, and

(iii) a flavouring preparation for the purpose of maintaining a uniform flavour profile; and

(*c*) may be labelled or advertised as Dry Gin or London Dry Gin if sweetening agents have not been added.

SOR/93-145, s. 15.

B.02.042. [Repealed, SOR/93-145, s. 15]

B.02.043. No person shall make any claim for age for gin but gin that has been held in suitable containers may bear a label declaration to that effect.

## Brandy

B.02.050. **[S]. Brandy**, other than Armagnac Brandy or Armagnac, Canadian Brandy, Cognac Brandy or Cognac, Dried Fruit Brandy, Fruit Brandy, Grappa, Lees Brandy and Pomace or Marc,

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of wine; and

(*b*) may contain

(i) caramel,

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations.

SOR/84-300, s. 12; SOR/93-145, s. 16.

B.02.051. **[S]. Armagnac Brandy** or **Armagnac** shall be brandy manufactured in the Armagnac district of France in accordance with the laws of the French Republic for consumption in that country.

SOR/93-145, s. 16.

B.02.052. **[S]. Canadian Brandy**

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of wine that has been fermented in Canada; and

(*b*) may contain

(i) caramel,

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations.

SOR/93-145, s. 16.

B.02.053. **[S]. Cognac Brandy** or **Cognac** shall be brandy manufactured in the Cognac district of France in accordance with the laws of the French Republic for consumption in that country.

SOR/93-145, s. 16.

B.02.054. **[S]. Dried Fruit Brandy**

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained from sound dried fruit; and

(*b*) may contain

(i) caramel,

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations.

SOR/93-145, s. 16.

B.02.055. **[S]. Fruit Brandy**

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of

(i) fruit wine or a mixture of fruit wines, or

(ii) a fermented mash of sound ripe fruit other than grapes, or a mixture of sound ripe fruits other than grapes;

(*b*) may contain

(i) caramel,

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations; and

(*c*) may be described on its label as "(*naming the fruit*) brandy" if all of the fruit or fruit wine used to make the brandy originates from the named fruit.

SOR/93-145, s. 16.

B.02.056. **[S]. Grappa**

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of the pomace from sound ripe grapes after the removal of the juice or wine; and

(*b*) may contain

(i) caramel

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations.

SOR/93-145, s. 16.

B.02.057. **[S]. Lees Brandy**

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of the lees of wine or fruit wine;

(*b*) may contain

(i) caramel,

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations; and

(*c*) may be described on its label as "(*naming the fruit*) Lees Brandy" if all of the lees used to make the brandy originate from the named fruit.

SOR/93-145, s. 16.

B.02.058. **[S]. Pomace** or **Marc**

(*a*) shall be a potable alcoholic distillate, or a mixture of potable alcoholic distillates, obtained by the distillation of the skin and pulp of sound ripe fruit after the removal of the fruit juice, wine or fruit wine;

(*b*) may contain

(i) caramel,

(ii) fruit and other botanical substances, and

(iii) flavouring and flavouring preparations; and

(*c*) may be described on its label as "(*naming the fruit*) Pomace" or "(*naming the fruit*) Marc" if all of the skin and pulp used to make the brandy originate from the named fruit.

SOR/93-145, s. 16.

B.02.059. No person shall blend or modify in any manner any brandy that is imported in bulk for the purpose of bottling and sale in Canada as imported brandy, except by

(*a*) blending with other imported brandy;

(*b*) the addition of caramel; and

(*c*) the addition of distilled or otherwise purified water to adjust the brandy to a required strength.

SOR/93-145, s. 16.

B.02.060. Where brandy is wholly distilled in a country other than Canada, the label shall indicate the country of origin.

SOR/84-300, s. 13(F); SOR/93-145, s. 16.

B.02.061. (1) No person shall sell any brandy that has not been aged for a period of at least one year in wooden containers or at least six months in small wood.

(2) Nothing in subsection (1) applies in respect of flavouring contained in brandy, but no person shall sell brandy containing any flavouring, other than wine, that has not been aged for a period of at least one year in wooden containers or at least six months in small wood.

(3) Nothing in subsection (1) or (2) applies in respect of brandy that meets the standards prescribed by any of sections B.02.051 to B.02.058.

(4) No person shall make any claim with respect to the age of brandy other than for the period during which the brandy has been held in wooden containers or in small wood.

SOR/93-145, s. 16.

## Liqueurs and Spirituous Cordials

B.02.070. **[S]. Liqueur** or **Spirituous Cordial**

(*a*) shall be a product obtained by the mixing or distillation of alcohol from food sources with or over fruits, flowers, leaves or other botanical substances or their juices or with extracts derived by the infusion, percolation or maceration of those botanical substances;

(*b*) shall have added, during the course of manufacture, a sweetening agent in an amount that is not less than 2.5 per cent of the finished product;

(*c*) shall contain not less than 23 per cent absolute alcohol by volume; and

(*d*) may contain

(i) natural and artificial flavouring preparations, and

(ii) colour.

SOR/93-145, s. 16.

## Vodka

B.02.080. **[S]. Vodka** shall be a potable alcoholic beverage obtained by the treatment of grain spirit or potato spirit with charcoal so as to render the product without distinctive character, aroma or taste.

SOR/93-145, s. 16.

## Tequila

B.02.090. (1) Subject to subsection (2), no person shall label, package, sell or advertise any food as **Tequila**, or in such a manner that it is likely to be mistaken for Tequila unless it is Tequila manufactured in Mexico as Tequila in accordance with the laws of Mexico applicable in respect of Tequila for consumption in Mexico.

(2) A person may modify Tequila that is imported for the purpose of bottling and sale in Canada as Tequila by the addition of distilled or otherwise purified water to adjust the Tequila to a required strength.

SOR/93-603, s. 5.

## Mezcal

B.02.091. (1) Subject to subsection (2), no person shall label, package, sell or advertise any food as **Mezcal**, or in such a manner that it is likely to be mistaken for Mezcal unless it is Mezcal manufactured in Mexico as Mezcal in accordance with the laws of Mexico applicable in respect of Mezcal for consumption in Mexico.

(2) A person may modify Mezcal that is imported for the purpose of bottling and sale in Canada as Mezcal by the addition of distilled or otherwise purified water to adjust the Mezcal to a required strength.

SOR/93-603, s. 6.

## Wine

B.02.100. **[S]. Wine**

(*a*) shall be an alcoholic beverage that is produced by the complete or partial alcoholic fermentation of fresh grapes, grape must, products derived solely from fresh grapes, or any combination of them;

(*b*) may have added to it during the course of the manufacture

(i) yeast,

(ii) concentrated grape juice,

(iii) dextrose, fructose, glucose or glucose solids, invert sugar, sugar, or aqueous solutions of any of them, (iv) yeast foods, in accordance with Table XIV to section B.16.100,

(iv) yeast foods, in accordance with Table XIV to section B.16.100,

(v) calcium sulphate in such quantity that the content of soluble sulphates in the finished wine shall not exceed 0.2 per cent weight by volume calculated as potassium sulphate,

(vi) calcium carbonate in such quantity that the content of tartaric acid in the finished wine shall not be less than 0.15 per cent weight by volume,

(vii) sulphurous acid, including salts thereof, in such quantity that its content in the finished wine shall not exceed

(A) 70 parts per million in the free state, or

(B) 350 parts per million in the combined state, calculated as sulphur dioxide,

(viii) any of the following substances:

(A) citric acid, fumaric acid, lactic acid, malic acid, potassium bicarbonate, potassium carbonate, potassium citrate and tartaric acid, at a maximum level of use consistent with good manufacturing practice,

(B) metatartaric acid at a maximum level of use of 0.01 per cent, and

(C) potassium acid tartrate at a maximum level of use of 0.42 per cent,

(ix) amylase and pectinase at a maximum level of use consistent with good manufacturing practice,

(x) ascorbic acid or erythorbic acid, or their salts, at a maximum level of use consistent with good manufacturing practice,

(xi) antifoaming agents, in accordance with Table VIII to section B.16.100,

(xii) any of the following fining agents:

(A) activated carbon, albumen, casein, clay, diatomaceous earth, egg-white, isinglass, polyvinylpolypyrrolidone and silicon dioxide,

(B) acacia gum, agar, gelatin and potassium ferrocyanide, at a maximum level of use consistent with good manufacturing practice,

(C) tannic acid at a maximum level of use of 200 parts per million, and

(D) polyvinylpyrrolidone in an amount that does not exceed 2 parts per million in the finished product,

(xiii) caramel at a maximum level of use consistent with good manufacturing practice,

(xiv) brandy, fruit spirit or alcohol derived from the alcoholic fermentation of a food source distilled to not less than 94 per cent alcohol by volume,

(xv) any of the following substances:

(A) carbon dioxide and ozone at a maximum level of use consistent with good manufacturing practice, and

(B) oxygen,

(xvi) sorbic acid or salts thereof, not exceeding 500 parts per million calculated as sorbic acid,

(xvii) malolactic bacteria from the genera *Lactobacillus*, *Leuconostoc* and *Pediococcus*,

(xviii) copper sulphate in such a quantity that the content of copper in the finished product shall not exceed 0.0001 per cent,

(xix) nitrogen, and

(xx) oak chips and particles; and

(*c*) prior to final filtration may be treated with

(i) a strongly acid cation exchange resin in the sodium ion form, or

(ii) a weakly basic anion exchange resin in the hydroxyl ion form.

SOR/78-402, s. 1; SOR/81-565, s. 1; SOR/84-300, ss. 14(F), 15(E); SOR/2006-91, s. 1; SOR/2008-142, s. 1(F); SOR/2010-143, s. 39(E).

Previous Version

B.02.101. No person shall sell wine that contains more than 0.24 per cent weight by volume of volatile acidity calculated as acetic acid, as determined by official method FO-2, Determination of Volatile Acidity of Wine, Cider and Champagne Cider, October 15, 1981.

SOR/82-768, s. 2; SOR/2006-91, s. 2.

Previous Version

B.02.102. **[S]. Fruit spirit** shall be an alcoholic distillate obtained from wine, fruit wine, grape pomace or fruit pomace.

B.02.103. **[S]. Fruit Wine,** or **(naming the fruit) Wine** shall be the product of the alcoholic fermentation of the juice of sound ripe fruit other than grape, and in all other respects shall meet the requirements of the standard for wine as prescribed by section B.02.100.

B.02.104. **[S]. Vermouth** shall be wine to which has been added bitters, aromatics or other botanical substances or a flavouring preparation, and shall contain not more than 20 per cent absolute alcohol by volume.

SOR/93-145, s. 17(F).

B.02.105. **[S]. Flavoured Wine, Wine Cocktail, Aperitif Wine** shall be wine to which has been added herbs, spices, other botanical substances, fruit juices or a flavouring preparation, and shall contain not more than 20 per cent absolute alcohol by volume.

B.02.105A. **[S]. Flavoured (naming the fruit) Wine, (naming the fruit) Wine Cocktail,** or **Aperitif (naming the fruit) Wine** shall be fruit wine, a mixture of fruit wines, or a mixture of fruit wine and wine to which has been added herbs, spices, other botanical substances, fruit juices or a flavouring preparation, and shall contain not more than 20 per cent absolute alcohol by volume.

B.02.106. **[S]. Honey Wine**

(*a*) shall be the product of the alcoholic fermentation of an aqueous solution of honey; and

(*b*) may have added to it during the course of manufacture any of the following substances:

(i) yeast;

(ii) yeast foods;

(iii) sulphurous acid, including salts thereof, in such quantity that its content in the finished wine shall not exceed

(A) 70 p.p.m. in the free state, or

(B) 350 p.p.m. in the combined state, calculated as sulphur dioxide;

(iv) tartaric or citric acid;

(v) potassium acid tartrate;

(vi) natural botanical flavours;

(vii) fruit spirit or alcohol derived from the alcoholic fermentation of a food source distilled to not less than 94 per cent alcohol by volume;

(viii) caramel;

(ix) carbon dioxide;

(x) activated carbon, clay or tannic acid as fining agents; or

(xi) sorbic acid, and any salts thereof, calculated as sorbic acid, in a quantity such that the content of sorbic acid and its salts in the finished wine does not exceed 500 parts per million.

SOR/96-241, s. 1; SOR/2010-94, s. 9(E).

Previous Version

B.02.107. **[S]. May Wine** shall be wine to which has been added artificial woodruff flavouring preparation.

B.02.108. A clear indication of the country of origin shall be shown on the principal display panel of a wine.

SOR/84-300, s. 16(E).

## Cider

B.02.120. **[S]. Cider**

(*a*) shall

(i) be the product of the alcoholic fermentation of apple juice, and

(ii) contain not less than 2.5 per cent and not more than 13.0 per cent absolute alcohol by volume; and

(*b*) may have added to it during the course of manufacture

(i) yeast,

(ii) concentrated apple juice,

(iii) sugar, dextrose, invert sugar, glucose, glucose solids, or aqueous solutions thereof,

(iv) yeast foods,

(v) sulphurous acid, including salts thereof, in such quantity that its content in the finished cider shall not exceed

(A) 70 parts per million in the free state, or

(B) 350 parts per million in the combined state, calculated as sulphur dioxide,

(vi) tartaric acid and potassium tartrate,

(vii) citric acid,

(viii) lactic acid,

(ix) pectinase and amylase,

(x) ascorbic or erythorbic acid, or salts thereof,

(xi) any of the following fining agents:

(A) activated carbon,

(B) clay,

(C) diatomaceous earth,

(D) gelatin,

(E) albumen,

(F) sodium chloride,

(G) silica gel,

(H) casein,

(I) tannic acid not exceeding 200 parts per million, or

(J) polyvinylpyrrolidone not exceeding two parts per million in the finished product,

(xii) caramel,

(xiii) brandy, fruit spirit or alcohol derived from the alcoholic fermentation of a food source distilled to not less than 94 per cent alcohol by volume,

(xiv) carbon dioxide,

(xv) oxygen,

(xvi) ozone, or

(xvii) sorbic acid or salts thereof, not exceeding 500 parts per million, calculated as sorbic acid.

SOR/81-565, s. 2; SOR/84-300, s. 17(E).

B.02.122. **[S]. Champagne Cider** shall be cider that is impregnated with carbon dioxide under pressure by

(*a*) conducting the afterpart of the fermentation in closed vessels, or

(*b*) secondary fermentation in closed vessels with or without the addition of sugar, dextrose, invert sugar, glucose or glucose solids or aqueous solutions thereof,

and shall contain not less than seven per cent absolute alcohol by volume.

SOR/84-300, s. 18.

B.02.123. No person shall sell cider or champagne cider that has more than 0.2 per cent weight by volume of volatile acidity calculated as acetic acid, as determined by official method FO-2, Determination of Volatile Acidity of Wine, Cider and Champagne Cider, October 15, 1981.

SOR/82-768, s. 3.

## Beer

B.02.130. **[S]. Beer**

(*a*) shall be the product of the alcoholic fermentation by yeast of an infusion of barley or wheat malt and hops or hop extract in potable water and shall be brewed in such a manner as to possess the aroma, taste and character commonly attributed to beer; and

(*b*) may have added to it during the course of manufacture any of the following ingredients:

(i) cereal grain,

(ii) carbohydrate matter,

(iii) salt,

(iv) hop oil,

(v) hop extract, if the hop extract is added to the wort before or during cooking,

(vi) pre-isomerized hop extract,

(vi.1) reduced isomerized hop extract,

(vii) Irish moss seaweed of the species *Chondrus crispus*,

(viii) carbon dioxide,

(ix) caramel,

(x) dextrin,

(xi) food enzymes,

(xii) stabilizing agents,

(xiii) pH adjusting and water correcting agents,

(xiv) Class I preservatives,

(xv) Class II preservatives,

(xvi) sequestering agent,

(xvii) yeast foods,

(xviii) any of the following fining agents: acacia gum, activated carbon, aluminum silicate, bentonite, calcium silicate, cellulose, China clay, diatomaceous earth, gelatin, isinglass, magnesium silicate, Nylon 66, polyvinylpolypyrrolidone, silica gel and wood shavings derived from beech, cherry, hazelnut and oak wood,

(xix) polyvinylpyrrolidone,

(xx) ammonium persulphate,

(xxi) in the case of wort, dimethylpolysiloxane, and

(xxii) in the case of mash, hydrogen peroxide.

SOR/88-418, s. 2; SOR/92-92, s. 1; SOR/96-483, s. 1; SOR/2006-91, s. 3.

Previous Version

B.02.131. **[S]. Ale, Stout, Porter** or **Malt Liquor**

(*a*) shall be the product of the alcoholic fermentation by yeast of an infusion of barley or wheat malt and hops or hop extract in potable water and shall be brewed in such a manner as to possess the aroma, taste and character commonly attributed to ale, stout, porter, or malt liquor, respectively; and

(*b*) may have added to it during the course of manufacture any of the ingredients referred to in paragraph B.02.130(*b*).

SOR/88-418, s. 2.

B.02.132. Where a beer, ale, stout, porter or malt liquor contains the percentage of alcohol by volume set out in Column I of an item of the table, the qualified common name or common name set out in Column II of that item shall be used in any advertisement of and on the label of the beer, ale, stout, porter or malt liquor.

TABLE

| | Column I | Column II |
|---|---|---|
| Item | Percentage alcohol by volume | Qualified common name or Common name |
| 1. | 1.1 to 2.5 | Extra Light Beer, Extra Light Ale, Extra Light Stout, Extra Light Porter |
| 2. | 2.6 to 4.0 | Light Beer, Light Ale, Light Stout, Light Porter |
| 3. | 4.1 to 5.5 | Beer, Ale, Stout, Porter |
| 4. | 5.6 to 8.5 | Strong Beer, Strong Ale, Strong Stout, Strong Porter, Malt Liquor |
| 5. | 8.6 or more | Extra Strong Beer, Extra Strong Ale, Extra Strong Stout, Extra Strong Porter, Strong Malt Liquor |

SOR/88-418, s. 2.

B.02.133. **[S].** In this Division, “hop extract” means an extract derived from hops by a process employing the solvent

(*a*) hexane, methanol, or methylene chloride in such a manner that the hop extract does not contain more than 2.2 per cent of the solvent used; or

(*b*) carbon dioxide or ethyl alcohol in an amount consistent with good manufacturing practice.

SOR/86-89, s. 1; SOR/88-418, s. 3.

B.02.134. **[S].** (1) In this Division, “pre-isomerized hop extract” means an extract derived from hops by

(*a*) the use of one of the following solvents:

(i) hexane,

(ii) carbon dioxide, or

(iii) ethanol; and

(*b*) the subsequent isolation of the alpha acids and their conversion to isomerized alpha acids by means of diluted alkali and heat.

(2) For the purposes of paragraph (1)(*b*), the residues of hexane shall not exceed 1.5 parts per million per per cent iso-alpha acid content of the pre-isomerized hop extract.

SOR/88-418, s. 4.

B.02.135. **[S].** In this Division, “reduced isomerized hop extract” means

(*a*) tetrahydroisohumulones derived from hops

(i) by isomerization and reduction of humulones (alpha-acids) by means of hydrogen and a catalyst, or

(ii) by reduction of lupulones (beta-acids) by means of hydrogen and a catalyst, followed by oxidation and isomerization;

(*b*) hexahydroisohumulones derived from hops by reduction of tetrahydroisohumulones by means of sodium borohydride; and

(*c*) dihydroisohumulones derived from hops by reduction of isoalpha acids by means of sodium borohydride.

SOR/96-483, s. 2; SOR/2000-352, s. 1.

# Division 3

# Baking Powder

B.03.001. In this Division, “acid-reacting material” means one or any combination of

(*a*) lactic acid or its salts;

(*b*) tartaric acid or its salts;

(*c*) acid salts of phosphoric acid; and

(*d*) acid compounds of aluminum.

B.03.002. **[S]. Baking Powder** shall be a combination of sodium or potassium bicarbonate, an acid-reacting material, starch or other neutral material, may contain an anticaking agent and shall yield not less than 10 per cent of its weight of carbon dioxide, as determined by official method FO-3, Determination of Carbon Dioxide in Baking Powder, October 15, 1981.

SOR/82-768, s. 4; SOR/92-626, s. 12.

# Division 4

# Cocoa And Chocolate Products

B.04.001. The definitions in this section apply in this Division.

“chocolate product” means a product derived from one or more cocoa products and includes chocolate, bittersweet chocolate, semi-sweet chocolate, dark chocolate, sweet chocolate, milk chocolate and white chocolate. (produit de chocolat)

“cocoa product” means a product derived from cocoa beans and includes cocoa nibs, cocoa liquor, cocoa mass, unsweetened chocolate, bitter chocolate, chocolate liquor, cocoa, low fat cocoa, cocoa powder and low fat cocoa powder. (produit du cacao)

“milk ingredient” means one or any combination of

(*a*) the following products for which a standard is prescribed in this Part, namely,

(i) milk or whole milk,

(ii) skim milk,

(iii) partly skimmed milk or partially skimmed milk,

(iv) sterilized milk,

(v) condensed milk or sweetened condensed milk,

(vi) evaporated milk,

(vii) evaporated skim milk or concentrated skim milk,

(viii) evaporated partly skimmed milk or concentrated partly skimmed milk,

(ix) milk powder or whole milk powder or dry whole milk or powdered whole milk,

(x) skim milk powder or dry skim milk,

(xi) skim milk with added milk solids,

(xii) partly skimmed milk with added milk solids or partially skimmed milk with added milk solids,

(xiii) malted milk or malted milk powder,

(xiv) butter, and

(xv) cream; and

(*b*) the following products for which a standard is not prescribed by this Part, namely

(i) reconstituted milk or whole milk,

(ii) reconstituted skim milk,

(iii) reconstitued partly skimmed milk,

(iv) partly skimmed milk powder,

(v) buttermilk,

(vi) butter oil, and

(vii) reconstituted cream. (ingrédient laitier)

“sweetening ingredient” means any one or any combination of sweetening agents, except for icing sugar. (ingrédient édulcorant)

SOR/97-263, s. 2.

B.04.002. **[S]. Cocoa Beans** shall be the seeds of *Theobroma cacao L.* or a closely related species.

SOR/97-263, s. 2.

B.04.003. **[S]. Cocoa Nibs** shall be the product prepared by removing the shell from cleaned cocoa beans, of which the residual shell content may not exceed 1.75 per cent by mass, calculated to an alkali free basis if the nibs or the cocoa beans from which the nibs were prepared have been processed with alkali, as determined by the method prescribed in the Official Methods of Analysis of the Association of Official Analytical Chemists, 12th Ed. (1975), sections 13.010 to 13.014, under the heading “Shell in Cacao Nibs—Official Final Action”, published by the Association of Official Analytical Chemists, in Washington.

SOR/97-263, s. 2.

B.04.004. **[S]. Cocoa Liquor, Cocoa Mass, Unsweetened Chocolate, Bitter Chocolate** or **Chocolate Liquor** shall

(*a*) be the product obtained from the mechanical disintegration of the cocoa nib with or without removal or addition of any of its constituents; and

(*b*) contain not less than 50 per cent cocoa butter.

SOR/97-263, s. 2.

B.04.005. (1) Cocoa products may be processed with one or more of the following pH-adjusting or alkalizing agents:

(*a*) hydroxides of ammonia, carbonates of ammonia, bicarbonates of ammonia, hydroxides of sodium, carbonates of sodium, bicarbonates of sodium, hydroxides of potassium, carbonates of potassium or bicarbonates of potassium;

(*b*) carbonates of magnesium or hydroxides of magnesium; and

(*c*) carbonates of calcium.

(2) The quantity of any one pH-adjusting agent referred to in paragraphs (1)(*a*) to (*c*) shall not exceed the maximum level of use for that agent set out in column III of an item of Table X to section B.16.100.

(3) The total mass of the pH-adjusting agents referred to in paragraphs (1)(*a*) to (*c*) shall not be greater in neutralizing value, calculated from the respective masses of those agents, than the neutralizing value of five parts by mass of anhydrous potassium carbonate for each 100 parts by mass of cocoa product, calculated on a fat-free basis.

(4) Cocoa products may be processed with one or more of the following pH-adjusting or neutralizing agents, added as such or in aqueous solution:

(*a*) phosphoric acid;

(*b*) citric acid; and

(*c*) L-tartaric acid.

(5) The total mass of pH-adjusting agents referred to in subsection (4) shall not exceed in neutralizing value, calculated from the respective masses of those agents, the appropriate maximum levels of use set out in column III of Table X to section B.16.100.

(6) For the purpose of subsection (5),

(*a*) the total quantity of phosphoric acid shall not be greater than 0.5 part by mass, expressed as $P_2O_5$, for each 100 parts by mass of cocoa product, calculated on a fat-free basis; and

(*b*) the total quantity, singly or in combination, of citric acid and L-tartaric acid shall not be greater than 1.0 part by mass for each 100 parts by mass of cocoa product, calculated on a fat-free basis.

SOR/97-263, s. 2.

B.04.006. **[S]. Chocolate, Bittersweet Chocolate, Semi-sweet Chocolate** or **Dark Chocolate**

(*a*) shall be one or more of the following combined with a sweetening ingredient, namely,

(i) cocoa liquor,

(ii) cocoa liquor and cocoa butter, and

(iii) cocoa butter and cocoa powder;

(*b*) shall contain not less than 35 per cent total cocoa solids, of which

(i) not less than 18 per cent is cocoa butter, and

(ii) not less than 14 per cent is fat-free cocoa solids; and

(*c*) may contain

(i) less than 5 per cent total milk solids from milk ingredients,

(ii) spices,

(iii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,

(iv) salt, and

(v) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of chocolate product, namely,

(A) mono-glycerides and mono- and diglycerides,

(B) lecithin and hydroxylated lecithin,

(C) ammonium salts of phosphorylated glycerides,

(D) polyglycerol esters of interesterified castor oil fatty acids, and

(E) sorbitan monostearate.

SOR/79-664, s. 2; SOR/97-263, s. 2.

B.04.007. **[S]. Sweet Chocolate**

(*a*) shall be one or more of the following combined with a sweetening ingredient, namely,

(i) cocoa liquor,

(ii) cocoa liquor and cocoa butter, and

(iii) cocoa butter and cocoa powder;

(*b*) shall contain not less than 30 per cent total cocoa solids, of which

(i) 18 per cent is cocoa butter, and

(ii) 12 per cent is fat-free cocoa solids; and

(*c*) may contain

(i) less than 12 per cent total milk solids from milk ingredients,

(ii) spices,

(iii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,

(iv) salt, and

(v) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of chocolate product, namely,

(A) mono-glycerides and mono- and diglycerides,

(B) lecithin and hydroxylated lecithin,

(C) ammonium salts of phosphorylated glycerides,

(D) polyglycerol esters of interesterified castor oil fatty acids, and

(E) sorbitan monostearate.

SOR/97-263, s. 2.

B.04.008. **[S]. Milk Chocolate**

(*a*) shall be one or more of the following combined with a sweetening ingredient, namely,

(i) cocoa liquor,

(ii) cocoa liquor and cocoa butter, and

(iii) cocoa butter and cocoa powder;

(*b*) shall contain not less than

(i) 25 per cent total cocoa solids, of which

(A) not less than 15 per cent is cocoa butter, and

(B) not less than 2.5 per cent is fat-free cocoa solids,

(ii) 12 per cent total milk solids from milk ingredients, and

(iii) 3.39 per cent milk fat; and

(*c*) may contain

(i) less than 5 per cent whey or whey products,

(ii) spices,

(iii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,

(iv) salt, and

(v) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of chocolate product, namely,

(A) mono-glycerides and mono- and diglycerides,

(B) lecithin and hydroxylated lecithin,

(C) ammonium salts of phosphorylated glycerides,

(D) polyglycerol esters of interesterified castor oil fatty acids, and

(E) sorbitan monostearate.

SOR/97-263, s. 2

B.04.009. **[S]. White Chocolate**

(*a*) shall contain the following combined together, namely,

(i) not less than 20 per cent cocoa butter,

(ii) not less than 14 per cent total milk solids from milk ingredients, and

(iii) not less than 3.5 per cent milk fat; and

(*b*) may contain

(i) less than 5 per cent whey or whey products,

(ii) spices,

(iii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,

(iv) salt, and

(v) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of chocolate product, namely,

(A) mono-glycerides and mono- and diglycerides,

(B) lecithin and hydroxylated lecithin,

(C) ammonium salts of phosphorylated glycerides,

(D) polyglycerol esters of interesterified castor oil fatty acids, and

(E) sorbitan monostearate.

SOR/97-263, s. 2.

B.04.010. **[S]. Cocoa** or **Cocoa Powder**

(*a*) shall be the product that

(i) is obtained by pulverising the remaining material from partially defatted cocoa liquor by mechanical means, and

(ii) contains not less than 10 per cent cocoa butter; and

(*b*) may contain

(i) spices,

(ii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,

(iii) salt, and

(iv) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of cocoa product, namely,

(A) mono-glycerides and mono- and diglycerides,

(B) lecithin and hydroxylated lecithin, and

(C) ammonium salts of phosphorylated glycerides.

SOR/82-768, s. 5; SOR/97-263, s. 2.

B.04.011. **[S]. Low Fat Cocoa** or **Low Fat Cocoa Powder**

(*a*) shall be the product that:

(i) is obtained by pulverising the remaining material from partially defatted cocoa liquor by mechanical means, and

(ii) contains less than 10 per cent cocoa butter; and

(*b*) may contain

(i) spices,

(ii) flavouring preparations, other than those that imitate the flavour of chocolate or milk, to balance flavour,

(iii) salt, and

(iv) any of the following emulsifying agents, which singly shall not exceed the maximum level of use set out in column III of Table IV to section B.16.100, and in combination shall not exceed 1.5 per cent by mass of cocoa product, namely,

(A) mono-glycerides and mono- and diglycerides,

(B) lecithin and hydroxylated lecithin, and

(C) ammonium salts of phosphorylated glycerides.

SOR/82-768, s. 6; SOR/97-263, s. 2.

B.04.012. No person shall sell a cocoa product or a chocolate product unless it is free from bacteria of the genus *Salmonella* as determined by official method MFO-11, Microbiological Examination of Cocoa and Chocolate, November 30, 1981.

SOR/97-263, s. 2.

# Division 5

# Coffee

B.05.001. **[S]. Green Coffee, Raw Coffee** or **Unroasted Coffee** shall be the seed of *Coffee arabica L., C. liberica Hiern*, or *C. robusta Chev*., freed from all but a small portion of its spermoderm.

B.05.002. **[S]. Roasted Coffee** or **Coffee** shall be roasted green coffee, and shall contain not less than 10 per cent fat, and may contain not more than six per cent total ash.

B.05.003. **[S]. Decaffeinated (indicating the type of coffee)**

(*a*) shall be coffee of the type indicated, from which caffeine has been removed and that, as a result of the removal, contains not more than

(i) 0.1 per cent caffeine, in the case of decaffeinated raw coffee and decaffeinated coffee, or

(ii) 0.3 per cent caffeine, in the case of decaffeinated instant coffee; and

(*b*) may have been decaffeinated by means of extraction solvents set out in Table XV to Division 16.

SOR/90-443, s. 1.

# Division 6

## Food Colours

B.06.001. In this Division,

“diluent” means any substance other than a synthetic colour present in a colour mixture or preparation; (diluant)

“dye” means the principal dye and associated subsidiary and isomeric dyes contained in a synthetic colour; (pigment)

“mixture” means a mixture of two or more synthetic colours or a mixture of one or more synthetic colours with one or more diluents; (mélange)

“official method FO-7” means official method FO-7, Determination of Dye Content of Synthetic Food Colours, March 15, 1984; ((méthode officielle FO-7))

“official method FO-8” means official method FO-8, Determination of Water Insoluble Matter in Synthetic Food Colours, March 15, 1984; ((méthode officielle FO-8))

“official method FO-9” means official method FO-9, Determination of Combined Ether Extracts in Synthetic Food Colours, March 15, 1984; ((méthode officielle FO-9))

“official method FO-10” means official method FO-10, Determination of Subsidiary Dyes in Synthetic Food Colours, March 15, 1984; ((méthode officielle FO-1003))

“official method FO-11” means official method FO-11, Determination of Intermediates in Synthetic Food Colours, March 15, 1984; ((méthode officielle FO-11))

“official method FO-12” means official method FO-12, Determination of Volatile Matter in Citrus Red No. 2, March 15, 1984; ((méthode officielle FO-12))

“official method FO-13” means official method FO-13, Determination of Sulphated Ash in Citrus Red No. 2, March 15, 1984; ((méthode officielle FO-13))

“official method FO-14” means official method FO-14, Determination of Water Soluble Matter in Citrus Red No. 2, March 15, 1984; ((méthode officielle FO-14))

“official method FO-15” means offical method FO-15, Determination of Carbon Tetrachloride Insoluble Matter in Citrus Red No. 2, March 15, 1984; ((méthode officielle))

“preparation” means a preparation of one or more synthetic colours containing less than three per cent dye and sold for household use; (préparation)

“synthetic colour” means any organic colour, other than caramel, that is produced by chemical synthesis and has no counterpart in nature and for which a standard is prescribed in sections B.06.041 to B.06.053. (colorant synthétique)

SOR/80-500, s. 2; SOR/84-440, s. 1.

B.06.002. No person shall sell a food, other than a synthetic colour, mixture, preparation or flavouring preparation, that contains, when prepared for consumption according to label directions, more than

(*a*) 300 parts per million of Allura Red, Amaranth, Erythrosine, Indigotine, Sunset Yellow FCF or Tartrazine or any combination of those colours unless a higher maximum level of use is specified in column III of item 3 of Table III to section B.16.100;

(*b*) 100 parts per million of Fast Green FCF or Brilliant Blue FCF or any combination of those colours;

(*c*) 300 parts per million of any combination of the synthetic colours named in paragraphs (*a*) and (*b*) within the limits set by those paragraphs; or

(*d*) 150 parts per million of Ponceau SX.

SOR/80-500, s. 2; SOR/84-440, s. 2; SOR/86-178, s. 1(F); SOR/2007-75, s. 1.

Previous Version

B.06.003. No person shall sell a colour for use in or upon food that contains more than

(*a*) three parts per million of arsenic, calculated as arsenic, as determined by official method FO-4, Determination of Arsenic in Food Colours, October 15, 1981;

(*b*) 10 parts per million of lead, calculated as lead, as determined by official method FO-5, Determination of Lead in Food Colours, October 15, 1981; or

(*c*) 40 parts per million of heavy metals, except in the case of iron oxide, titanium dioxide, aluminum metal and silver metal.

SOR/80-500, s. 2; SOR/82-768, s. 7.

B.06.004. No person shall sell a synthetic colour for use in or upon food unless

(*a*) the label carries the lot number and common name of the synthetic colour and the words “Food Colour”;

(*b*) the Director, or an agency acceptable to the Director, has certified that each lot meets the requirements of section B.06.003 and the standard for such colour as prescribed in sections B.06.041 to B.06.053; and

(*c*) where the synthetic colour is certified by an agency, a copy of the certificate has been submitted to and accepted by the Director.

SOR/80-500, s. 2.

B.06.005. No person shall import a synthetic colour for use in or upon food unless

(*a*) the Director, or an agency acceptable to the Director, has certified that each lot meets the requirements of section B.06.003 and the standard for such colour as prescribed in sections B.06.041 to B.06.053; and

(*b*) where the synthetic colour is certified by an agency, a copy of the certificate has been submitted to and accepted by the Director.

SOR/80-500, s. 2.

B.06.006. No person shall sell a mixture for use in or upon food unless the label carries the lot number of the mixture and the words “Food Colour”.

SOR/80-500, s. 2.

B.06.007. No person shall sell a preparation for use in or upon food unless

(*a*) the label carries the words “Food Colour Preparation” on its principal display panel; and

(*b*) in the case of a liquid preparation, the container has a capacity of 60 ml or less and will permit dropwise discharge only.

SOR/80-500, s. 2.

B.06.008. No person shall import or sell a mixture or preparation for use in or upon food unless

(*a*) the Director, or an agency acceptable to the Director, has certified that any synthetic colour contained therein meets the requirements of section B.06.003 and the standard for such colour as prescribed in sections B.06.041 to B.06.053; or

(*b*) any synthetic colour contained therein has been previously certified and the certificate has been accepted as required by sections B.06.004 and B.06.005.

SOR/80-500, s. 2.

B.06.009. to B.06.013. [Repealed, SOR/80-500, s. 2]

## Natural Colours

B.06.021. **[S]. Oil-soluble Annatto, Annatto Butter Colour,** or **Annatto Margarine Colour**

(*a*) shall be the extractives of *Bixa orellana* seeds

(i) dissolved in vegetable oil, castor oil, monoglycerides and diglycerides, propylene glycol or propylene glycol monoesters and diesters of fat-forming fatty acids, with or without one per cent potassium hydroxide, or

(ii) suspended upon sugar, lactose, starch or hydrated calcium silicate, with or without calcium phosphate, potassium aluminum sulphate, sodium bicarbonate or salt; and

(*b*) shall contain not less than 0.30 per cent total pigments calculated as natural (*cis*-) bixin, which pigments shall consist of not less than 40 per cent natural (*cis*-) bixin.

B.06.022. **[S]. ß-Carotene** shall be the food colour chemically known as ß-carotene that is manufactured synthetically and shall conform to the following specifications:

(*a*) one per cent solution in chloroform .....clear;

(*b*) loss of weight on drying .....not more than 0.2 per cent;

(*c*) residue on ignition .....not more than 0.2 per cent; and

(*d*) assay (spectrophotometric) .....96 to 101 per cent.

B.06.023. **[S]. ß-Apo-8′-Carotenal** shall be the food colour chemically known as ß-apo-8′-carotenal and shall conform to the following specifications:

(*a*) one per cent solution in chloroform .....clear;

(*b*) melting point (decomposition) .....136°C. to 140°C (corrected);

(*c*) loss of weight on drying .....not more than 0.2 per cent;

(*d*) residue on ignition .....not more than 0.2 per cent; and

(*e*) assay (spectrophotometric) .....96 to 101 per cent.

B.06.024. **[S]. Canthaxanthin** shall be the food colour chemically known as canthaxanthin and shall conform to the following specifications:

(*a*) one per cent solution in chloroform .....clear;

(*b*) loss of weight on drying .....not more than 0.2 per cent;

(*c*) assay (spectrophotometric) .....96 to 101 per cent.

B.06.025. **[S]. Ethyl ß-apo-8′-carotenoate** shall be the food colour chemically known as ethyl ß-apo-8′-carotenoate and shall conform to the following specifications:

(*a*) one per cent solution in chloroform .....clear

(*b*) loss of weight on drying .....not more than 0.2 per cent, and

(*c*) assay (spectrophotometric) .....96 to 101 per cent.

SOR/84-300, s. 19(F).

## Inorganic Colours

B.06.031. **[S]. Carbon black** shall be carbon prepared from natural gas by the “channel” or “impingement” process and shall contain no higher aromatic hydrocarbons or tarry materials as determined by official method FO-6, Determination of Higher Aromatic Hydrocarbons or Tarry Materials in Carbon Black and Charcoal, October 15, 1981.

SOR/82-768, s. 8.

B.06.032. **[S]. Charcoal** shall be carbon prepared by the incomplete combustion of vegetable matter and shall contain no higher aromatic hydrocarbons or tarry materials as determined by official method FO-6, Determination of Higher Aromatic Hydrocarbons or Tarry Materials in Carbon Black and Charcoal, October 15, 1981.

SOR/82-768, s. 8.

B.06.033. **[S]. Titanium Dioxide** shall be the chemical substance known as titanium dioxide and shall contain not less than 99 per cent titanium dioxide, and notwithstanding section B.06.006, shall contain not more than 50 parts per million of total antimony expressed as the metal and as determined by an acceptable method.

## Synthetic Colours

B.06.041. **[S]. Amaranth** shall be the trisodium salt of 1-(4-sulpho-1-naphthylazo)-2-naphthol-3,6-disulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.2 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 4.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 0.5 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 9; SOR/84-440, s. 3.

B.06.042. **[S]. Erythrosine** shall be the disodium salt of 2,4,5,7-tetraiodofluorescein, shall contain not less than 85 per cent dye calculated as the monohydrate, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.2 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 5.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 0.5 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 9; SOR/84-440, s. 3.

B.06.043. **[S]. Ponceau SX** shall be the disodium salt of 2-(5-sulpho-2,4-xylylazo)-1-naphthol-4-sulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.2 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 1.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 0.5 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 9; SOR/84-440, s. 3.

B.06.044. **[S]. Allura Red** shall be the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulphophenyl)azo]-2-naphthalene sulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.2 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 4.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 0.5 per cent intermediates, as determined by official method FO-11.

SOR/84-440, s. 3.

B.06.045. **[S]. Tartrazine** shall be the trisodium salt of 3-carboxy-5-hydroxy-1-p-sulphophenyl-4-p-sulphophenyl-azopyrazole, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.2 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 1.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 0.5 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 10; SOR/84-440, s. 3.

B.06.046. **[S]. Sunset Yellow FCF** shall be the disodium salt of 1-p-sulphophenylazo-2-naphthol-6-sulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.2 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 5.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 0.5 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 10; SOR/84-440, s. 3.

B.06.049. **[S]. Fast Green FCF** shall be the disodium salt of 4,4′-di(N-ethyl-m-sulphobenzylamino)-2″-sulpho-4″-hydroxytriphenylmethanol anhydride, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.4 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 5.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 1.0 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 11; SOR/84-440, s. 3.

B.06.050. **[S]. Indigotine** shall be the disodium salt of indigotine-5,5′-disulphonic acid, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.4 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 1.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 0.5 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 11; SOR/84-440, s. 3.

B.06.051. **[S]. Brilliant Blue FCF** shall be the disodium salt of 4,4′-di (N-ethyl-m-sulphobenzylamino)-2″-sulphotriphenylmethanol anhydride, shall contain not less than 85 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.2 per cent water insoluble matter, as determined by official method FO-8;

(*b*) 0.4 per cent combined ether extracts, as determined by official method FO-9;

(*c*) 5.0 per cent subsidiary dyes, as determined by official method FO-10; and

(*d*) 2.0 per cent intermediates, as determined by official method FO-11.

SOR/82-768, s. 11; SOR/84-440, s. 3.

B.06.053. **[S]. Citrus Red. No. 2** shall be 1-(2,5-dimethoxyphenylazo)-2-naphthol, shall contain not less than 98 per cent dye, as determined by official method FO-7, and may contain not more than

(*a*) 0.5 per cent volatile matter (at 100°C), as determined by official method FO-12;

(*b*) 0.3 per cent sulphated ash, as determined by official method FO-13;

(*c*) 0.3 per cent water soluble matter, as determined by official method FO-14;

(*d*) 0.5 per cent carbon tetrachloride insoluble matter, as determined by official method FO-15;

(*e*) 0.05 per cent uncombined intermediates; and

(*f*) 2.0 per cent subsidiary dyes.

SOR/82-768, s. 12; SOR/84-440, s. 3.

B.06.061. The lake of any water soluble synthetic colour for which a standard is provided in sections B.06.041, B.06.042, B.06.043, B.06.044, B.06.045, B.06.046, B.06.049, B.06.050 or B.06.051 shall be the calcium or aluminum salt of the respective colour extended on alumina.

SOR/82-1071, s. 3; SOR/84-300, s. 20; SOR/87-640, s. 2.

B.06.062. [Repealed, SOR/82-768, s. 13]

# Division 7

# Spices, Dressings And Seasonings

B.07.001. **[S]. Allspice** or **Pimento**, whole or ground, shall be the dried, full but unripe whole berries of *Pimenta dioica (L) Merr.* and shall contain

(*a*) not more than

(i) 25 per cent crude fibre,

(ii) 5.5 per cent total ash,

(iii) 0.4 per cent ash insoluble in hydrochloric acid, and

(iv) 12 per cent moisture; and

(*b*) not less than 2.5 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.002. **[S]. Anise** or **Anise Seed**, whole or ground, shall be the dried fruit of *Pimpinella anisum L.* and shall contain

(*a*) not more than

(i) nine per cent total ash,

(ii) one per cent ash insoluble in hydrochloric acid, and

(iii) 10 per cent moisture; and

(*b*) not less than two millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.003. **[S]. Basil** or **Sweet Basil**, whole or ground, shall be the dried leaves of *Ocimum basilicum L.* and shall contain

(*a*) not more than

(i) 15 per cent total ash,

(ii) two per cent ash insoluble in hydrochloric acid, and

(iii) nine per cent moisture; and

(*b*) not less than 0.2 millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.004. **[S]. Bay Leaves** or **Laurel Leaves**, whole or ground, shall be the dried leaves of *Laurus nobilis L.* and shall contain

(*a*) not more than

(i) 4.5 per cent total ash,

(ii) 0.5 per cent ash insoluble in hydrochloric acid, and

(iii) seven per cent moisture; and

(*b*) not less than one millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.005. **[S]. Caraway** or **Caraway Seed**, whole or ground, shall be the dried fruit of the caraway plant, *Carum carvi L.* and shall contain

(*a*) not more than

(i) eight per cent total ash,

(ii) one per cent ash insoluble in hydrochloric acid, and

(iii) 11.5 per cent moisture; and

(*b*) not less than two millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.006. **[S]. Cardamom** or **Cardamom Seed**, bleached or green, whole or ground, shall be the dried ripe fruit of *Elettaria cardamomum Maton* and shall contain

(*a*) not more than

(i) eight per cent total ash,

(ii) three per cent ash insoluble in hydrochloric acid, and

(iii) 13 per cent moisture; and

(*b*) not less than three millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.007. **[S]. Cayenne Pepper** or **Cayenne**, whole or ground,

(*a*) shall be the dried ripe fruit of *Capsicum frutescens L.*, *Capsicum baccatum L.*, or other small-fruited species of Capsicum and shall contain not more than

(i) 1.5 per cent starch,

(ii) 28 per cent crude fibre,

(iii) 10 per cent total ash,

(iv) 1.5 per cent ash insoluble in hydrochloric acid, and

(v) 10 per cent moisture; and

(*b*) may contain silicon dioxide as an anti-caking agent in an amount not exceeding 2.0 per cent.

SOR/79-659, s. 1; SOR/84-17, s. 2.

B.07.008. **[S]. Celery Salt**

(*a*) shall be a combination of

(i) ground celery seed or ground dehydrated celery, and

(ii) salt in an amount not exceeding 75 per cent; and

(*b*) may contain silicon dioxide as an anticaking agent in an amount not exceeding 0.5 per cent.

SOR/79-659, s. 1.

B.07.009. **[S]. Celery Seed**, whole or ground, shall be the dried ripe fruit of *Apium graveolens L.* and shall contain

(*a*) not more than

(i) 12 per cent total ash,

(ii) two per cent ash insoluble in hydrochloric acid, and

(iii) 10 per cent moisture; and

(*b*) not less than 1.5 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.010. **[S]. Celery Pepper**

(*a*) shall be a combination of

(i) ground celery seed or ground dehydrated celery, and

(ii) ground black pepper in an amount not exceeding 70 per cent; and

(*b*) may contain silicon dioxide as an anticaking agent in an amount not exceeding 0.5 per cent.

SOR/79-659, s. 1.

B.07.011. **[S]. Cinnamon** or **Cassia**, whole or ground, shall be the dried bark of trees of the genus *Cinnamomum* of Species *C. burmanni Blume*, *C. loureirii Nees* or *C. Cassia Blume* and shall contain

(*a*) not more than

(i) six per cent total ash,

(ii) two per cent ash insoluble in hydrochloric acid, and

(iii) 13 per cent moisture; and

(*b*) not less than 1.2 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.012. **[S]. Ceylon Cinnamon**, whole or ground, shall be cinnamon obtained exclusively from *Cinnamomum zeylanicum Nees*.

SOR/79-659, s. 1.

B.07.013. **[S]. Cloves**, whole or ground, shall be the dried unopened flower buds of *Eugenia caryophyllus (Spreng)* and shall contain

(*a*) not more than

(i) five per cent clove stems,

(ii) six per cent total ash,

(iii) 0.5 per cent ash insoluble in hydrochloric acid,

(iv) 10 per cent crude fibre, and

(v) eight per cent moisture; and

(*b*) not less than 13 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.014. **[S]. Coriander** or **Coriander Seed**, whole or ground, shall be the dried fruit of *Coriandrum sativum L.* and shall contain

(*a*) not more than

(i) seven per cent total ash,

(ii) one per cent ash insoluble in hydrochloric acid, and

(iii) nine per cent moisture; and

(*b*) not less than 0.3 millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.015. **[S]. Cumin** or **Cumin Seed**, whole or ground, shall be the dried seeds of *Cuminum cyminum L.* and shall contain

(*a*) not more than

(i) 9.5 per cent total ash,

(ii) 1.5 per cent ash insoluble in hydrochloric acid, and

(iii) nine per cent moisture; and

(*b*) not less than 2.5 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.016. **[S]. Curry Powder** shall be any combination of

(*a*) turmeric with spices and seasoning; and

(*b*) salt in an amount not exceeding five per cent.

SOR/79-659, s. 1.

B.07.017. **[S]. Dill Seed**, whole or ground, shall be the dried fruit of *Anethum graveolens L.*, or *Anethum sowa D.C.* and shall contain

(*a*) not more than

(i) 10 per cent total ash,

(ii) two per cent ash insoluble in hydrochloric acid, and

(iii) nine per cent moisture; and

(*b*) not less than two millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.018. **[S]. Fennel** or **Fennel Seed**, whole or ground, shall be the dried ripe fruit of *Foeniculum vulgare Mill*. and shall contain

(*a*) not more than

(i) 10 per cent total ash,

(ii) one per cent ash insoluble in hydrochloric acid, and

(iii) 10 per cent moisture; and

(*b*) not less than one millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.019. **[S]. Fenugreek**, whole or ground, shall be the dried ripe fruit of *Trigonella foenumgraecum L.* and shall contain not more than

(*a*) five per cent total ash;

(*b*) one per cent ash insoluble in hydrochloric acid; and

(*c*) 10 per cent moisture.

SOR/79-659, s. 1.

B.07.020. **[S]. Garlic Salt**

(*a*) shall be a combination of

(i) powdered dehydrated garlic, and

(ii) salt in an amount not exceeding 75 per cent; and

(*b*) may contain one or more of the following anticaking agents in a total amount not exceeding two per cent:

calcium aluminum silicate, calcium phosphate tribasic, calcium silicate, calcium stearate, magnesium carbonate, magnesium silicate, magnesium stearate, silicone dioxide in an amount not exceeding one per cent and sodium aluminum silicate.

SOR/79-659, s. 1.

B.07.021. **[S]. Ginger** whole or ground, shall be the washed and dried or decorticated rhizome of *Zingiber officinale Roscoe* and shall contain

(*a*) not more than

(i) seven per cent total ash,

(ii) one per cent ash insoluble in hydrochloric acid, and

(iii) 12.5 per cent moisture; and

(*b*) not less than 1.5 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.022. **[S]. Mace**, whole or ground, shall be the dried arillus of *Myristica fragrans Houttyn* and shall contain

(*a*) not more than

(i) 3.5 per cent total ash,

(ii) 0.5 per cent ash insoluble in hydrochloric acid, and

(iii) eight per cent moisture, and

(*b*) not less than 11 millilitres volatile oil per 100 grams of spice,

and the total non-volatile extracts obtainable therefrom by

(*c*) ethyl ether, shall not be less than 20 per cent nor more than 35 per cent, and

(*d*) ethyl ether, after preliminary extraction with petroleum ether, shall not exceed five per cent.

SOR/79-659, s. 1.

B.07.023. **[S]. Marjoram**, whole or ground, shall be the dried leaves, with or without a small proportion of the flowering tops, of *Marjorana hortensis Moench* and shall contain

(*a*) not more than

(i) 10 per cent stems and foreign material of plant origin,

(ii) 13.5 per cent total ash,

(iii) 4.5 per cent ash insoluble in hydrochloric acid, and

(iv) 10 per cent moisture; and

(*b*) not less than 0.7 millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.024. **[S]. Mustard Seed** shall be the seed of *Sinapis alba, Brassica hirta Moench, Brassica juncea (L) Cosson* or *Brassica nigra* and shall contain

(*a*) not more than

(i) seven per cent total ash,

(ii) one per cent ash insoluble in hydrochloric acid, and

(iii) 11 per cent moisture; and

(*b*) not less than 25 per cent non-volatile ether extract.

SOR/79-659, s. 1.

B.07.025. **[S]. Mustard, Mustard Flour** or **Ground Mustard** shall be powdered mustard seed

(*a*) made from mustard seed from which

(i) most of the hulls have been removed, and

(ii) a portion of the fixed oil may have been removed; and

(*b*) that contains not more than

(i) 1.5 per cent starch, and

(ii) eight per cent total ash, on an oil-free basis.

SOR/79-659, s. 1; SOR/2010-142, s. 3(F).

Previous Version

B.07.026. **[S]. Nutmeg**, whole or ground, shall be the dried seed of *Myristica fragrans Houttyn* and may, prior to grinding, have a thin coating of lime and shall contain

(*a*) not more than

(i) three per cent total ash,

(ii) 0.5 per cent ash insoluble in hydrochloric acid, and

(iii) eight per cent moisture; and

(*b*) not less than

(i) 25 per cent non-volatile ether extract, and

(ii) 6.5 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.027. **[S]. Onion Salt**

(*a*) shall be a combination of

(i) powdered dehydrated onion, and

(ii) salt in an amount not exceeding 75 per cent; and

(*b*) may contain one or more of the following anticaking agents in a total amount not exceeding two per cent:

calcium aluminum silicate, calcium phosphate tribasic, calcium silicate, calcium stearate, magnesium carbonate, magnesium silicate, magnesium stearate, silicon dioxide in an amount not exceeding one per cent and sodium aluminum silicate.

SOR/79-659, s. 1.

B.07.028. **[S]. Oregano**, whole or ground, shall be the dried leaves of *Origanum vulgar L.* or *Origanum Spp.* and shall contain

(*a*) not more than

(i) 10 per cent total ash,

(ii) two per cent ash insoluble in hydrochloric acid, and

(iii) 10 per cent moisture; and

(*b*) not less than 2.5 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.029. **[S]. Paprika** shall be the dried, ground ripe fruit of *Capsicum annuum L.* and

(*a*) shall contain not more than

(i) 23 per cent crude fibre,

(ii) 8.5 per cent total ash,

(iii) one per cent ash insoluble in hydrochloric acid, and

(iv) 12 per cent moisture; and

(*b*) may contain silicon dioxide as an anti-caking agent in an amount not exceeding 2.0 per cent.

SOR/79-659, s. 1; SOR/84-17, s. 3.

B.07.030. **[S]. Black Pepper** or **Peppercorn**, whole or ground, shall be the dried, immature berry of *Piper nigrum L.* and shall contain

(*a*) not more than

(i) seven per cent total ash,

(ii) one per cent ash insoluble in hydrochloric acid, and

(iii) 12 per cent moisture;

(*b*) not less than

(i) six per cent non-volatile methylene chloride extract,

(ii) 30 per cent pepper starch, and

(iii) 2.0 millilitres volatile oil per 100 grams of spice; and

(*c*) when ground, all the parts of the berry in their normal proportions.

SOR/79-659, s. 1.

B.07.031. **[S]. White Pepper**, whole or ground, shall be the dried, mature berry of *Piper nigrum L.*, from which the outer coating is and the inner coating may be removed and shall contain

(*a*) not more than

(i) five per cent crude fibre,

(ii) 2.5 per cent total ash,

(iii) 0.3 per cent ash insoluble in hydrochloric acid, and

(iv) 15 per cent moisture; and

(*b*) not less than

(i) six per cent non-volatile methylene chloride extract,

(ii) 52 per cent pepper starch, and

(iii) one millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.032. **[S]. Poppy seed** shall be the dried seed of *Papaver somniferum L.* and shall contain

(*a*) not more than

(i) seven per cent total ash, and

(ii) one per cent ash insoluble in hydrochloric acid; and

(*b*) not less than 40 per cent non-volatile ether extract.

SOR/79-659, s. 1.

B.07.033. **[S]. Rosemary**, whole or ground, shall be the dried leaves of *Rosemarinus officinalis L.* and shall contain

(*a*) not more than

(i) 7.5 per cent total ash,

(ii) one per cent ash insoluble in hydrochloric acid, and

(iii) nine per cent moisture; and

(*b*) not less than 1.2 millilitres volatile oil per 100 grams of spice.

SOR/78-637, s. 1; SOR/79-659, s. 1.

B.07.034. **[S]. Sage**, whole or ground, shall be the dried leaves of the sage plant *Salvia officinalis L., Salvia triloba L.* or *Salvia lavandulaefolia Vahl*. and shall contain

(*a*) not more than

(i) 12 per cent stems excluding petioles and foreign material of plant origin,

(ii) 10 per cent total ash,

(iii) one per cent ash insoluble in hydrochloric acid, and

(iv) 10 per cent moisture; and

(*b*) not less than one millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.035. **[S]. Savory**, whole or ground, shall be the dried leaves and flowering tops of *Satureja hortensis L.* or *Satureja montana L.* and shall contain

(*a*) not more than

(i) 11 per cent total ash,

(ii) two per cent ash insoluble in hydrochloric acid, and

(iii) 14 per cent moisture; and

(*b*) not less than 0.8 millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.036. **[S]. Sesame Seed** shall be the dried hulled seed of *Sesamum indicum L.* and shall contain

(*a*) not more than eight per cent moisture; and

(*b*) not less than 50 per cent non-volatile ether extract.

SOR/79-659, s. 1; SOR/2010-142, s. 4(F).

Previous Version

B.07.037. **[S]. Tarragon**, whole or ground, shall be the dried leaves and flowering tops of *Artemisia dracunculus L.* and shall contain

(*a*) not more than

(i) 15 per cent total ash,

(ii) 1.5 per cent ash insoluble in hydrochloric acid, and

(iii) 10 per cent moisture; and

(*b*) not less than 0.3 millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.038. **[S]. Thyme**, whole or ground, shall be the dried leaves and flowering tops of the thyme plant *Thymus vulgaris L.* or *Thymus zygis L.* and shall contain

(*a*) not more than

(i) 12 per cent total ash,

(ii) five per cent ash insoluble in hydrochloric acid, and

(iii) nine per cent moisture; and

(*b*) not less than 0.9 millilitre volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.039. **[S]. Turmeric**, whole or ground, shall be the dried rhizome of *Curcuma longa L.* and shall contain

(*a*) not more than

(i) seven per cent total ash,

(ii) 1.5 per cent ash insoluble in hydrochloric acid, and

(iii) 10 per cent moisture; and

(*b*) not less than 3.5 millilitres volatile oil per 100 grams of spice.

SOR/79-659, s. 1.

B.07.040. **[S]. Mayonnaise, Mayonnaise Dressing** or **Mayonnaise Salad Dressing**

(*a*) shall be a combination of

(i) vegetable oil,

(ii) whole egg or egg yolk, in liquid, frozen or dried form, and

(iii) vinegar or lemon juice;

(*b*) may contain

(i) water,

(ii) salt,

(iii) a sweetening agent,

(iv) spice or other seasoning except turmeric or saffron,

(v) citric, tartaric or lactic acid, and

(vi) a sequestering agent; and

(*c*) shall contain not less than 65 per cent vegetable oil.

SOR/79-659, s. 1.

B.07.041. **[S]. French Dressing**

(*a*) shall be a combination of

(i) vegetable oil, and

(ii) vinegar or lemon juice;

(*b*) may contain

(i) water,

(ii) salt,

(iii) a sweetening agent,

(iv) spice, tomato or other seasoning,

(v) an emulsifying agent,

(vi) whole egg or egg yolk, in liquid, frozen or dried form,

(vii) citric, tartaric or lactic acid, and

(viii) a sequestering agent; and

(*c*) shall contain not less than 35 per cent vegetable oil.

SOR/79-659, s. 1.

B.07.042. **[S]. Salad Dressing**

(*a*) shall be a combination of

(i) vegetable oil,

(ii) whole egg or egg yolk, in liquid, frozen or dried form,

(iii) vinegar or lemon juice, and

(iv) starch, flour, rye flour or tapioca flour or any combination thereof;

(*b*) may contain

(i) water,

(ii) salt,

(iii) a sweetening agent,

(iv) spice or other seasoning,

(v) an emulsifying agent,

(vi) citric, tartaric or lactic acid, and

(vii) a sequestering agent; and

(*c*) shall contain not less than 35 per cent vegetable oil.

SOR/79-659, s. 1.

B.07.043. No person shall sell a dressing that contains more than five per cent $C_{22}$ Monoenoic Fatty Acids calculated as a proportion of the total fatty acids contained in the dressing.

SOR/79-659, s. 1.

# Division 8

# Dairy Products

B.08.001. The foods referred to in this Division are *dairy products*.

B.08.001.1 The following definitions apply in this Division.

“milk product” means

(*a*) with respect to butter or whey butter, any of the following products, namely,

(i) partly skimmed milk, skim milk, cream, buttermilk and whey cream, and

(ii) milk in concentrated, dried or reconstituted form and any product referred to in subparagraph (i) in concentrated, dried or reconstituted form;

(*b*) with respect to cheese, any of the following products, namely,

(i) partly skimmed milk, skim milk, cream, buttermilk, whey and whey cream,

(ii) milk in concentrated, dried, frozen or reconstituted form and any product referred to in subparagraph (i) in concentrated, dried, frozen or reconstituted form,

(iii) butter, butter oil and whey butter,

(iv) any constituent of milk — other than water — singly or in combination with other constituents of milk, and

(v) whey protein concentrate;

(*c*) with respect to cold-pack cheese food, cold-pack cheese food with (naming the added ingredients), cream cheese spread, cream cheese spread with (naming the added ingredients), processed cheese food, processed cheese food with (naming the added ingredients), processed cheese spread or processed cheese spread with (naming the added ingredients), any of the following products, namely,

(i) butter, whey butter and whey,

(ii) whey protein concentrate, and

(iii) any product referred to in subparagraph (i) in concentrated or dried form; and

(*d*) with respect to ice milk mix, ice cream mix or sherbet, any of the products referred to in subparagraph (*a*)(i) or (ii) or (*c*)(i) or (ii). (produit du lait)

“ultrafiltered”, in relation to milk, partly skimmed milk or skim milk, means that the milk, partly skimmed milk or skim milk has been subjected to a process in which it is passed over one or more semi-permeable membranes to partially remove water, lactose, minerals and water-soluble vitamins without altering the whey protein to casein ratio and that results in a liquid product. (ultrafiltré)

SOR/92-400, s. 1. SOR/97-543, s. 1(F); SOR/98-580, s. 1(F); SOR/2007-302, s. 1; SOR/2010-94, s. 2.

Previous Version

B.08.002. Except as provided in these Regulations, a dairy product that contains a fat other than milk fat is adulterated.

B.08.002.1. Sections B.08.003 to B.08.028 do not apply to a lacteal secretion obtained from the mammary gland of any animal other than a cow, genus *Bos*, or a product or derivative of such secretion.

SOR/85-623, s. 1.

B.08.002.2 (1) Subject to subsection (2), no person shall sell the normal lacteal secretion obtained from the mammary gland of the cow, genus *Bos*, or of any other animal, or sell a dairy product made with any such secretion, unless the secretion or dairy product has been pasteurized by being held at a temperature and for a period that ensure the reduction of the alkaline phosphatase activity so as to meet the tolerances specified in official method MFO-3, Determination of Phosphatase Activity in Dairy Products, dated November 30, 1981.

(2) Subsection (1) does not apply to

(*a*) cheese; or

(*b*) any food that is sold for further manufacturing or processing in order to pasteurize it in the manner described in subsection (1).

SOR/91-549, s. 1; SOR/95-499, s. 1.

## Milk

B.08.003. **[S]. Milk** or **Whole Milk**

(*a*) shall be the normal lacteal secretion obtained from the mammary gland of the cow, genus *Bos*; and

(*b*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

SOR/95-499, s. 2.

B.08.004. **[S]. Skim Milk**

(*a*) shall be milk that contains not more than 0.3 per cent milk fat;

(*b*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A; and

(*c*) shall contain vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

SOR/78-656, s. 1.

B.08.005. **[S]. Partly Skimmed Milk** or **Partially Skimmed Milk**

(*a*) shall be derived from milk that has had its fat content reduced by mechanical separation or adjusted by the addition of cream, milk, partly skimmed milk or skim milk, either singly or in combination;

(*b*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A; and

(*c*) shall contain vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

SOR/78-656, s. 2.

B.08.006. **[S]. Milk Fat** or **Butter Fat** shall be the fat of cow’s milk, and shall have

(*a*) a specific gravity of not less than 0.905 at a temperature of 40°,

(*b*) a tocopherol content not greater than 50 micrograms per gram, as determined by official method FO-16, Determination of Tocopherol in Milk Fat or Butter Fat, October 15, 1981,

(*c*) a Reichert-Meissl number not less than 24, and

(*d*) a Polenske number not exceeding 10 per cent of the Reichert-Meissl number and in no case shall the Polenske number exceed 3.5, and

where the tocopherol content is greater than 50 micrograms per gram or the Polenske number exceeds 10 per cent of the Reichert-Meissl number, there shall be deemed to have been an addition to the milk fat of fat other than that of cow's milk.

SOR/82-768, s. 14.

B.08.007. **[S]. Sterilized Milk**

(*a*) and (*b*) [Repealed, SOR/97-148, s. 1]

(*c*) shall contain not less than

(i) 11.75 per cent milk solids, and

(ii) 3.25 per cent milk fat; and

(*d*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

SOR/97-148, s. 1.

B.08.008. The percentage of milk fat contained in

(*a*) partly skimmed milk or partially skimmed milk,

(*b*) partly skimmed milk with added milk solids or partially skimmed milk with added milk solids, or

(*c*) evaporated partly skimmed milk or concentrated partly skimmed milk

shall be shown on the principal display panel followed by the words "milk fat" or the abbreviation "B.F." or "M.F.".

B.08.009. **[S]. Condensed Milk** or **Sweetened Condensed Milk** shall be milk from which water has been evaporated and to which has been added sugar, dextrose, glucose, glucose solids or lactose, or any combination thereof, may contain added vitamin D and shall contain not less than

(*a*) 28 per cent milk solids; and

(*b*) eight per cent milk fat.

B.08.010. **[S]. Evaporated Milk**

(*a*) shall be milk from which water has been evaporated;

(*b*) shall contain not less than

(i) 25.0 per cent milk solids, and

(ii) 7.5 per cent milk fat;

(*c*) shall, notwithstanding sections D.01.009 to D.01.011, contain added vitamin C in such an amount that a reasonable daily intake of the milk contains not less than 60 milligrams and not more than 75 milligrams of vitamin C;

(*d*) shall contain vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

(*e*) may contain

(i) added disodium phosphate or sodium citrate, or both, and

(ii) an emulsifying agent.

SOR/78-656, s. 3; SOR/92-400, s. 2.

B.08.011. **[S]. Evaporated Skim Milk** or **Concentrated Skim Milk**

(*a*) shall be milk that has been concentrated to at least one-half of its original volume by the removal of water;

(*b*) shall contain

(i) not more than 0.3 per cent milk fat, and

(ii) not less than 17.0 per cent milk solids other than fat;

(*c*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A;

(*d*) shall, notwithstanding sections D.01.009 to D.01.011, contain added vitamin C in such an amount that a reasonable daily intake of the milk contains not less than 60 milligrams and not more than 75 milligrams of vitamin C;

(*e*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

(*f*) may contain added disodium phosphate or sodium citrate, or both.

B.08.012. **[S]. Evaporated Partly Skimmed Milk** or **Concentrated Partly Skimmed Milk**

(*a*) shall be milk from which part of the milk fat has been removed;

(*b*) shall be concentrated to at least one-half its original volume by the removal of water;

(*c*) shall contain not less than 17.0 per cent milk solids other than fat; and

(*d*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A;

(*e*) shall, notwithstanding sections D.01.009 to D.01.011, contain added vitamin C in such an amount that a reasonable daily intake of the milk contains not less than 60 milligrams and not more than 75 milligrams of vitamin C;

(*f*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

(*g*) may contain

(i) an emulsifying agent, and

(ii) added disodium phosphate or sodium citrate, or both.

B.08.013. **[S]. Milk Powder, Whole Milk Powder, Dry Whole Milk,** or **Powdered Whole Milk**

(*a*) shall be dried milk;

(*b*) shall contain not less than

(i) 95 per cent milk solids, and

(ii) 26 per cent milk fat;

(*c*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

(*d*) may contain the emulsifying agent lecithin in an amount not exceeding 0.5 per cent.

SOR/78-656, s. 4; SOR/83-932, s. 2.

B.08.014. **[S]. Skim Milk Powder or Dry Skim Milk**

(*a*) shall be dried skim milk;

(*b*) shall contain not less than 95 per cent milk solids; and

(*c*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A;

(*d*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

(*e*) may contain an anti-foaming agent.

SOR/78-656, s. 5; SOR/80-501, s. 2(F).

B.08.014A. No person shall sell milk powder, whole milk powder, dry whole milk, powdered whole milk, skim milk powder or dry skim milk unless it is free from bacteria of the genus *Salmonella*, as determined by official method MFO-12, Microbiological Examination of Milk Powder, November 30, 1981.

SOR/78-656, s. 6; SOR/82-768, s. 15.

B.08.015. No person shall sell milk, skim milk, partly skimmed milk, (naming the flavour) milk, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, skim milk

with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, condensed milk, evaporated milk, evaporated skim milk, evaporated partly skimmed milk, milk powder or skim milk powder, in which the vitamin content has been increased by either irradiation or addition unless

(*a*) in the case of the addition of vitamin D, the menstruum containing the vitamin D contributes not more than 0.01 per cent fat foreign to milk; and

(*b*) in cases where the vitamin D content is increased by irradiation, the principal display panel of the label carries the statement “Vitamin D Increased” immediately preceding or following the name of the food, without intervening written, printed or graphic matter.

SOR/88-336, s. 3.

B.08.016. **[S]. (naming the flavour) Milk**

(*a*) shall be the product made from

(i) milk, milk powder, skim milk, skim milk powder, partly skimmed milk, evaporated milk, evaporated partly skimmed milk, evaporated skim milk or cream or any combination thereof,

(ii) a flavouring preparation, and

(iii) a sweetening agent;

(*b*) shall contain not less than three per cent milk fat;

(*c*) shall contain added vitamin D in such an amount that a reasonable intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D;

(*d*) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch; and

(*e*) may contain not more than 50,000 total aerobic bacteria per cubic centimetre, as determined by official method MFO-7, Microbiological Examination of Milk, November 30, 1981.

SOR/78-656, s. 7; SOR/82-768, s. 16; SOR/84-762, s. 1.

B.08.017. **[S]. (naming the flavour) Skim Milk**

(*a*) shall be the product made from

(i) skim milk, skim milk powder or evaporated skim milk or any combination thereof,

(ii) a flavouring preparation, and

(iii) a sweetening agent;

(*b*) shall contain not more than 0.3 per cent milk fat;

(*c*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A;

(*d*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

(*e*) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch.

SOR/78-656, s. 8; SOR/84-762, s. 2.

B.08.018. **[S]. (naming the flavour) Partly (Partially) Skimmed Milk**

(*a*) shall be the product made from

(i) milk, milk powder, skim milk, skim milk powder, partly skimmed milk, evaporated milk, evaporated partly skimmed milk, evaporated skim milk or cream or any combination thereof,

(ii) a flavouring preparation, and

(iii) a sweetening agent;

(*b*) shall contain more than 0.3 per cent and less than 3.0 per cent milk fat;

(*c*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A;

(*d*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D;

(*e*) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch; and

(*f*) may contain not more than 50,000 total aerobic bacteria per cubic centimetre, as determined by official method MFO-7, Microbiological Examination of Milk, November 30, 1981.

SOR/78-656, s. 9; SOR/82-768, s. 17; SOR/84-762, s. 3.

B.08.019. **[S]. Skim Milk with Added Milk Solids**

(*a*) shall be skim milk to which has been added skim milk powder or evaporated skim milk or both;

(*b*) shall contain not less than 10 per cent milk solids;

(*c*) shall contain not more than 0.3 per cent milk fat;

(*d*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the dairy product contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A; and

(*e*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

SOR/78-656, s. 10.

B.08.020. **[S]. Partly Skimmed Milk with Added Milk Solids** or **Partially Skimmed Milk with Added Milk Solids**

(*a*) shall be partly skimmed milk to which has been added skim milk powder, milk powder, evaporated milk, evaporated partly skimmed milk or evaporated skim milk or any combination thereof;

(*b*) shall contain not less than 10 per cent milk solids not including fat; and

(*c*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A; and

(*d*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D.

B.08.021. **[S]. Malted Milk** or **Malted Milk Powder**

(*a*) shall be the product made by combining milk with the liquid separated from a mash of ground barley malt and meal;

(*b*) may have added to it, in such manner as to secure the full enzyme action of the malt extract, salt and sodium bicarbonate or potassium bicarbonate;

(*c*) may have water removed from it; and

(*d*) shall contain

(i) not less than 7.5 per cent milk fat, and

(ii) not more than 3.5 per cent moisture.

B.08.022. **[S]. (naming the flavour) Malted Milk** or **(naming the flavour) Malted Milk Powder**

(*a*) shall be malted milk or malted milk powder containing a flavouring preparation; and

(*b*) may contain lactase.

SOR/84-762, s. 4.

B.08.023. **[S]. (naming the flavour) Skim Milk with Added Milk Solids**

(*a*) shall be the product made from

(i) skim milk, skim milk powder, or evaporated skim milk or any combination thereof,

(ii) a flavouring preparation, and

(iii) a sweetening agent;

(*b*) shall contain not less than 10 per cent milk solids not including fat;

(*c*) shall contain not more than 0.3 per cent milk fat;

(*d*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A;

(*e*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D; and

(*f*) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch.

SOR/78-656, s. 11; SOR/84-762, s. 5.

B.08.024. No person shall sell milk for manufacture into dairy products if it contains more than

(*a*) two million total aerobic bacteria per millilitre, as determined by official method MFO-7, Microbiological Examination of Milk, November 30, 1981; or

(*b*) two milligrams of sediment per 16 fluid ounces, as determined by official method MFO-8, Determination of Sediment in Milk, November 30, 1981.

SOR/82-768, s. 18.

B.08.025. No manufacturer shall purchase milk for manufacture or manufacture milk into other dairy products if he has reason to believe it does not meet the requirements of section B.08.024.

B.08.026. **[S]. (naming the flavour) Partly (Partially) Skimmed Milk with Added Milk Solids**

(*a*) shall be the product made from

(i) milk, milk powder, skim milk, skim milk powder, partly skimmed milk, evaporated milk, evaporated partly skimmed milk, evaporated skim milk or cream or any combination thereof,

(ii) a flavouring preparation, and

(iii) a sweetening agent;

(*b*) shall contain not less than 10 per cent milk solids not including fat;

(*c*) shall contain more than 0.3 per cent and less than 3.0 per cent milk fat;

(*d*) shall, notwithstanding sections D.01.009 and D.01.010, contain added vitamin A in such an amount that a reasonable daily intake of the milk contains not less than 1,200 International Units and not more than 2,500 International Units of vitamin A;

(*e*) shall contain added vitamin D in such an amount that a reasonable daily intake of the milk contains not less than 300 International Units and not more than 400 International Units of vitamin D;

(*f*) may contain salt, food colour, lactase, stabilizing agent and not more than 0.5 per cent starch; and

(*g*) may contain not more than 50,000 total aerobic bacteria per cubic centimetre, as determined by official method MFO-7, Microbiological Examination of Milk, November 30, 1981.

SOR/78-656, s. 12; SOR/82-768, s. 19; SOR/84-300, s. 21(F); SOR/84-762, s. 6.

B.08.027. Notwithstanding anything contained in these Regulations, the following dairy products that are used in or sold for the manufacture of other foods are not required to contain added vitamins: milk; partly skimmed milk; partially skimmed milk; skim milk; sterilized milk; evaporated milk; evaporated skim milk; concentrated skim milk; evaporated partly skimmed milk; concentrated partly skimmed milk; milk powder; dry whole milk; powdered whole milk; skim milk powder; dry skim milk; partly skimmed milk powder; partially skimmed milk powder; skim milk with added milk solids; partly skimmed milk with added milk solids; and partially skimmed milk with added milk solids.

SOR/78-656, s. 13.

B.08.028. (1) The percentage of milk fat contained in

(*a*) (naming the flavour) milk,

(*b*) (naming the flavour) partly (partially) skimmed milk,

(*c*) (naming the flavour) partly (partially) skimmed milk with added milk solids,

(*d*) cream, and

(*e*) sour cream,

shall be shown on the principal display panel followed by the words “milk fat” or the abbreviation “B.F.” or “M.F.”.

(2) In addition to the statement referred to in subsection (1), a person may, on the label of a food referred to in that subsection, make a declaration of the fat content of the food, expressed in grams per serving of stated size.

SOR/79-23, s. 10; SOR/88-559, s. 16; SOR/2010-94, s. 3(F).

Previous Version

## Goat’s Milk

B.08.028.1. A lacteal secretion obtained from themammary gland of any animal other than a cow, genus Bos, and a product or derivative of such secretion shall be labelled so as to identify that animal.

SOR/85-623, s. 2.

B.08.029. (1) Notwithstanding sections D.01.009 to D.01.011, no person shall sell goat’s milk or goat’s milk powder to which vitamin D has been added unless the goat’s milk or goat’s milk powder contains not less than 35 International Units and not more than 45 International Units of vitamin D per 100 mL of the food when ready-to-serve.

(2) Notwithstanding sections D.01.009 to D.01.011, no person shall sell partly skimmed goat’s milk, skimmed goat’s milk, partly skimmed goat’s milk powder or skimmed goat’s milk powder to which vitamins have been added unless the product contains not less than 35

International Units of vitamin D and 140 International Units of vitamin A and not more than 45 International Units of vitamin D and 300 International Units of vitamin A per 100 mL of food when ready-to-serve.

(3) Notwithstanding sections D.01.009 to D.01.011, no person shall sell evaporated goat's milk to which vitamins have been added unless 100 mL of the evaporated goat's milk, when reconstituted according to directions for use, contains not less than seven milligrams of vitamin C, 35 International Units of vitamin D and 10 micrograms of folic acid and not more than nine milligrams of vitamin C, 45 International Units of vitamin D and 20 micrograms of folic acid.

(4) Notwithstanding sections D.01.009 to D.01.011, no person shall sell evaporated partly skimmed goat's milk or evaporated skimmed goat's milk to which vitamins have been added unless 100 mL of the evaporated partly skimmed goat's milk or the evaporated skimmed goat's milk, when reconstituted according to directions for use, contains not less than 140 International Units of vitamin A, seven milligrams of vitamin C, 35 International Units of vitamin D and 10 micrograms of folic acid and not more than 300 International Units of vitamin A, nine milligrams of vitamin C, 45 International Units of vitamin D and 20 micrograms of folic acid.

SOR/85-623, s. 2.

## Cheese

B.08.030. (1) In this Division, when used with respect to cheese,

"pasteurized source" means milk, skim milk, cream, reconstituted milk powder, reconstituted skim milk powder or any combination thereof that has been pasteurized by being held at a temperature of not less than 61.6°C for a period of not less than 30 minutes, or for a time and a temperature that is equivalent thereto in phosphatase destruction, as determined by official method MFO-3, Determination of Phosphatase Activity in Dairy Products, November 30, 1981; (matière première pasteurisée)

"pickles and relishes" means foods that meet the standard prescribed in section B.11.051; (cornichons et achards)

"stored" means to have been kept or held at a temperature of 2°C or more for a period of 60 days or more from the date of the beginning of the manufacturing process; (entreposé)

"whole" means of the original size and shape as manufactured. (entier)

(2) The word "process" may be used in the place of the word "processed" in the following common names: processed (naming the variety) cheese, processed (naming the variety) cheese with (naming the added ingredients), processed cheese food, processed cheese food with (naming the added ingredients), processed cheese spread, and processed cheese spread with (naming the added ingredients).

SOR/79-752, s. 2; SOR/82-768, s. 20; SOR/92-400, s. 3.

B.08.031. A cheese made from milk that is the normal lacteal secretion of the mammary gland of animals other than the cow, genus *Bos*, shall

(*a*) conform to all requirements in this Division applicable to the variety; and

(*b*) be labelled to show the source of the milk on the principal display panel.

SOR/79-752, s. 2.

B.08.032. (1) Each of the following foods for which a standard is prescribed, namely,

(*a*) (naming the variety) cheese,

(*b*) cheddar cheese,

(*c*) cream cheese,

(*d*) whey cheese,

(*e*) (naming the variety) whey cheese,

(*f*) cream cheese with (naming the added ingredients),

(*g*) cream cheese spread,

(*h*) cream cheese spread with (naming the added ingredients),

(*i*) processed (naming the variety) cheese,

(*j*) processed (naming the variety) cheese with (naming the added ingredients),

(*k*) processed cheese food,

(*l*) processed cheese food with (naming the added ingredients),

(*m*) processed cheese spread,

(*n*) processed cheese spread with (naming the added ingredients),

(*o*) cold-pack (naming the variety) cheese,

(*p*) cold-pack (naming the variety) cheese with (naming the added ingredients),

(*q*) cold-pack cheese food, and

(*r*) cold-pack cheese food with (naming the added ingredients),

shall be labelled to show on the principal display panel a statement of the percentage of milk fat in the food followed by the words “milk fat” or the abbreviation “B.F.” or “M.F.”, and the percentage of moisture in the food followed by the word “moisture” or “water”.

(2) Subject to subsection (3), no person shall make any direct or indirect reference on the label of a food referred to in subsection (1) to the milk fat content or moisture content of the food except as required by subsection (1).

(3) In addition to the statements referred to in subsection (1), a person may, on the label of a food referred to in that subsection, make a declaration of the fat content of the food, expressed in grams per serving of a stated size.

SOR/79-752, s. 2; SOR/88-559, s. 17; SOR/94-689, s. 2(E); SOR/2010-94, s. 8(E).

Previous Version

B.08.033. (1) **[S]. (Naming the variety) Cheese**, other than cheddar cheese, cream cheese, whey cheese, cream cheese with (naming the added ingredients), cream cheese spread, cream cheese spread with (naming the added ingredients), processed (naming the variety) cheese, processed (naming the variety) cheese with (naming the added ingredients), processed cheese food, processed cheese food with (naming the added ingredients), processed cheese spread, processed cheese spread with (naming the added ingredients), cold-pack (naming the variety) cheese, cold-pack (naming the variety) cheese with (naming the added ingredients), cold-pack cheese food, cold-pack cheese food with (naming the added ingredients), cottage cheese and creamed cottage cheese,

(*a*) shall

(i) be the product made by coagulating milk, milk products or a combination thereof with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey,

(i.1) except for feta cheese, have a casein content that is derived from milk or from ultrafiltered milk, partly skimmed milk, ultrafiltered partly skimmed milk, skim milk, ultrafiltered skim milk or cream, rather than from other milk products,that is at least the following percentage of the total protein content of the cheese, namely,

(A) 63 per cent in the case of Pizza Mozzarella cheese and Part Skim Pizza Mozzarella cheese,

(B) 83 per cent, in the case of Brick cheese, Canadian Style Brick cheese, Canadian Style Munster cheese, Colby cheese, Farmer’s cheese, Jack cheese, Monterey (Monterey Jack) cheese, Mozzarella (Scamorza) cheese, Part Skim Mozzarella (Part Skim Scamorza) cheese, Part Skim Pizza cheese, Pizza cheese, Skim milk cheese and any other variety of cheese not referred to in clause (A) or (C), and

(C) 95 per cent, in the case of any other variety of cheese named in the table to this section,

(i.2) have a whey protein to casein ratio that does not exceed the whey protein to casein ratio of milk,

(ii) possess the physical, chemical and organoleptic properties typical for the variety,

(iii) where it is a cheese of variety named in the table to this section, contain no more than the maximum percentage of moisture shown in Column II thereof for that variety,

(iv) where it is a cheese of a variety named in Part I of the table to this section, contain no less than the minimum percentage of milk fat shown in Column III for that variety, and

(v) where it is cheese of a variety named in Part II of the table to this section, contain no more than the maximum percentage of milk fat shown in Column III for that variety; and

(*b*) may contain

(i) salt, seasonings, condiments and spices,

(ii) flavouring preparations other than cheese flavouring,

(iii) micro-organisms to aid further ripening,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin or turmeric,

(B) in an amount not exceeding 35 parts per million, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate or a combination thereof, and

(C) in an amount not exceeding 0.10 parts per million, brilliant blue FCF in feta cheese only,

(v) calcium chloride as a firming agent in an amount not exceeding 0.02 per cent of the milk and milk products used,

(vi) paraffin wax as a coating in an amount consistent with good manufacturing practice,

(vii) where potassium nitrate, sodium nitrate or a combination thereof are used for the purpose and in the manner described in subsection (2), residues of potassium nitrate, sodium nitrate or a combination thereof in an amount not exceeding 50 parts per million,

(viii) wood smoke as a preservative in an amount consistent with good manufacturing practice,

(ix) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid,

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively, or

(D) natamycin applied to the surface of the cheese in an amount that does not exceed 20 parts per million or, if the cheese is grated or shredded, 10 parts per million,

(x) in the case of grated or shredded cheese, calcium silicate, microcrystalline cellulose or cellulose, or a combination of them, as an anticaking agent, the total amount not to exceed 2.0 per cent, and

(xi) carbon dioxide as a pH adjusting agent in milk for cheese production, in an amount consistent with good manufacturing practice.

(1.1) A cheese of a variety set out in column I of Part I of the table to this section may contain more than the maximum percentage of moisture set out in column II and less than the minimum percentage of milk fat set out in column III if

(*a*) a statement or claim set out in column 4 of any of items 12 to 14, 16, 20, 21 and 45 of the table following section B.01.513 is shown on the label of the product as part of the common name; and

(*b*) the cheese has the characteristic flavour and texture of the named variety of cheese.

(1.2) The reference to "83 per cent" in clause (1)(*a*)(i.1)(B) shall be read as "78 per cent", and the reference to "95 per cent" in clause (1)(*a*)(i.1)(C) shall be read as "90 per cent", with respect to the named variety of cheese if

(*a*) a statement or claim set out in column 4 of any of items 12 to 14, 16, 20, 21 and 45 of the table following section B.01.513 is shown on the label of the product as part of the common name; and

(*b*) the cheese has the characteristic flavour and texture of the named variety of cheese.

(2) Potassium nitrate, sodium nitrate or a combination thereof may be used as a preservative in cheese providing the following requirements are met:

(*a*) the amount of the salt or combination of salts does not exceed 200 parts per million of the milk and milk products used to make the cheese;

(*b*) the cheese in which the preservative is used is

(i) mold ripened cheese packed in a hermetically sealed container, or

(ii) ripened cheese

(A) that contains not more than 68 per cent moisture on a fat free basis, and

(B) during the manufacture of which the lactic acid fermentation and salting was completed more than 12 hours after coagulation of the curd by enzymes; and

(*c*) the salting is, in the case of the cheese described in subparagraph (*b*)(ii), applied externally as a dry salt or in the form of a brine.

(3) No person shall use an enzyme other than

(*a*) aminopeptidase derived from *Lactococcus lactis*, bovine rennet derived from aqueous extracts from the fourth stomach of adult bovine animals, sheep and goats, chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), lipase derived from Animal pancreatic tissue; *Aspergillus niger* var.; *Aspergillus oryzae* var.; Edible forestomach tissue of calves, kids or lambs; *Rhizopus oryzae* var. or from *Aspergillus oryzae* (MLT-2) (pRML 787) (p3SR2); *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (*Cooney and Emerson*)); *Rhizopus niveus*, milk coagulating enzyme derived from *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)), from *Mucor pusillus Lindt* by pure culture fermentation process or from *Aspergillus oryzae* RET-1 (pBoel777), pepsin derived from glandular layer of porcine stomach, phospholipase derived from *Aspergillus oryzae* (pPFJo142), protease derived from *Micrococcus caseolyticus* var. or rennet derived from aqueous extracts from the fourth stomach of calves, kids or lambs, in the manufacture of any cheese to which subsection (1) applies;

(*b*) [Repealed, SOR/2010-143, s. 1]

(*c*) a milk coagulating enzyme derived from *Endothia parasitica* and enzymes described in paragraph (*a*), in the manufacture of Emmentaler (Emmental, Swiss) cheese, Mozzarella (Scamorza) cheese and Part Skim Mozzarella (Part Skim Scamorza) cheese;

(*d*) a milk coagulating enzyme derived from *Endothia parasitica* and enzymes described in paragraph (*a*), in the manufacture of Parmesan cheese and Romano cheese;

(*e*) protease derived from *Aspergillus oryzae* var., *Aspergillus niger* var. or *Bacillus subtilis* var., in the manufacture of Colby cheese; and

(*f*) lysozyme derived from egg-white.

(3.1) No person shall use an enzyme referred to in subsection (3) at a level of use above that consistent with good manufacturing practice.

(4) Where a flavouring preparation, other than a flavouring preparation that has been traditionally used in the variety, is added to a cheese as permitted in subsection (1), the words "with (naming the flavouring preparation)" shall be added to the common name on any label.

(5) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term "smoked" on a label.

(6) Where a cheese is labelled as permitted in subsection (5), the word "smoked" shall be shown on the principal display panel.

# TABLE

PART I

| | Column I | Column II | Column III |
|---|---|---|---|
| Item | Variety of Cheese | Maximum percentage of moisture | Minimum percentage of milk fat |
| 1. | Asiago | 40.0 | 30.0 |
| 2. | Baby Edam | 47.0 | 21.0 |
| 3. | Baby Gouda | 45.0 | 26.0 |
| 4. | Blue | 47.0 | 27.0 |
| 5. | Butter (Butterkäse) | 46.0 | 27.0 |
| 6. | Bra | 36.0 | 26.0 |
| 7. | Brick | 42.0 | 29.0 |
| 8. | Brie | 54.0 | 23.0 |
| 9. | Caciocavallo | 45.0 | 24.0 |
| 10. | Camembert (Carré de l'est) | 56.0 | 22.0 |
| 11. | Canadian Style Brick | 42.0 | 29.0 |
| 12. | Canadian Style Munster | 46.0 | 27.0 |
| 13. | Colby | 42.0 | 29.0 |
| 14. | Danbo | 46.0 | 25.0 |
| 15. | Edam | 46.0 | 22.0 |
| 16. | Elbo | 46.0 | 25.0 |
| 17. | Emmentaler (Emmental, Swiss) | 40.0 | 27.0 |
| 18. | Esrom | 50.0 | 23.0 |
| 19. | Farmer's | 44.0 | 27.0 |
| 20. | Feta | 55.0 | 22.0 |
| 21. | Fontina | 46.0 | 27.0 |
| 22. | Fynbo | 46.0 | 25.0 |

| Item | Column I<br>Variety of Cheese | Column II<br>Maximum percentage of moisture | Column III<br>Minimum percentage of milk fat |
|---|---|---|---|
| 23. | Gouda | 43.0 | 28.0 |
| 24. | Gournay | 55.0 | 33.0 |
| 25. | Gruyère | 38.0 | 28.0 |
| 26. | Havarti | 50.0 | 23.0 |
| 27. | Jack | 50.0 | 25.0 |
| 28. | Kasseri | 44.0 | 25.0 |
| 29. | Limburger | 50.0 | 25.0 |
| 30. | Maribo | 43.0 | 26.0 |
| 31. | Montasio | 40.0 | 28.0 |
| 32. | Monterey (Monterey Jack) | 44.0 | 28.0 |
| 33. | Mozzarella (Scamorza) | 52.0 | 20.0 |
| 34. | Muenster (Munster) | 50.0 | 25.0 |
| 35. | Neufchâtel | 60.0 | 20.0 |
| 36. | Parmesan | 32.0 | 22.0 |
| 37. | Part Skim Mozzarella (Part Skim Scamorza) | 52.0 | 15.0 |
| 38. | Part Skim Pizza | 48.0 | 15.0 |
| 38.1 | Part Skim Pizza Mozzarella | 61.0 | 11.0 |
| 39. | Pizza | 48.0 | 20.0 |
| 39.1 | Pizza Mozzarella | 58.0 | 15.0 |
| 40. | Provolone | 45.0 | 24.0 |
| 41. | Romano (Sardo) | 34.0 | 25.0 |
| 42. | St. Jorge | 40.0 | 27.0 |
| 43. | Saint-Paulin | 50.0 | 25.0 |
| 44. | Samsoë | 44.0 | 26.0 |
| 45. | Tilsiter (Tilsit) | 45.0 | 25.0 |
| 46. | Tybo | 46.0 | 25.0 |

PART II

| Item | Column I<br>Variety of Cheese | Column II<br>Maximum percentage of moisture | Column III<br>Maximum percentage of milk fat |
|---|---|---|---|
| 1. | Harzkase (Harzer Käse, Mainzer Käse) | 55.0 | 3.0 |
| 2. | Skim Milk | 55.0 | 7.0 |

SOR/79-752, s. 2; SOR/80-632, s. 2; SOR/82-383, ss. 2,3; SOR/82-566, s. 1; SOR/84-302, s. 1; SOR/86-89, s. 2; SOR/87-640, s. 3; SOR/88-534, s. 2; SOR/89-198, s. 1; SOR/90-469, s. 1; SOR/91-88, s. 1; SOR/92-197, s. 1; SOR/92-400, s. 4; SOR/93-477, s. 1; SOR/94-212, s. 1; SOR/94-417, s. 1; SOR/95-183, s. 1; SOR/97-191, s. 1; SOR/98-458, s. 2; SOR/2000-336, s.

1; SOR/2000-353, s. 4; SOR/2000-417, s. 2; SOR/2001-94, s. 1; SOR/2005-98, s. 7; SOR/2007-302, ss. 2, 4(F); SOR/2010-94, s. 8(E); SOR/2010-143, ss. 1, 39(E).

Previous Version

B.08.034. (1) **[S]. Cheddar Cheese**

(*a*) shall

(i) be the product that is made by coagulating milk, milk products or a combination of those things with the aid of bacteria to form a curd and subjecting the curd to the cheddar process or any process other than the cheddar process that produces a cheese having the same physical, chemical and organoleptic properties as those of cheese produced by the cheddar process,

(i.1) have a casein content that is derived from milk or from ultrafiltered milk, partly skimmed milk, ultrafiltered partly skimmed milk, skim milk, ultrafiltered skim milk or cream, rather than from other milk products, that is at least 83 per cent of the total protein content of the cheese,

(i.2) have a whey protein to casein ratio that does not exceed the whey protein to casein ratio of milk, and

(ii) contain

(A) not more than 39 per cent moisture, and

(B) not less than 31 per cent milk fat;

(*b*) may contain

(i) salt,

(ii) flavouring preparations other than cheese flavouring,

(iii) bacterial cultures to aid further ripening,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8’-carotenal, ethyl beta-apo-8’-carotenoate,

(v) calcium chloride as a firming agent in an amount not exceeding 0.02 per cent of the milk and milk products used,

(vi) wood smoke as a preservative in an amount consistent with good manufacturing practice,

(vii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or a combination thereof in an amount not exceeding 2,000 parts per million calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate or a combination thereof in an amount not exceeding 3,000 parts per million calculated as sorbic acid,

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million calculated as propionic acid and sorbic acid respectively, or

(D) natamycin applied to the surface of the cheese in an amount that does not exceed 20 parts per million or, if the cheese is grated or shredded, 10 parts per million, and

(viii) in the case of grated or shredded cheddar cheese, calcium silicate, microcrystalline cellulose or cellulose, or a combination of them, as an anticaking agent, the total amount not to exceed 2.0 per cent; and

(*c*) shall not be labelled or advertised as cheddar cheese that has been aged unless

(i) it is made solely with milk, ultrafiltered milk, partly skimmed milk, ultrafiltered partly skimmed milk, skim milk, ultrafiltered skim milk or cream or a combination of those things, and

(ii) it has been aged for at least nine months and the period for which it has been aged is specified on the principal display panel of that label or in that advertising.

(1.1) Cheddar cheese may contain more than the maximum percentage of moisture set out in clause (1)(*a*)(ii)(A) and less than the minimum percentage of milk fat set out in clause (1)(*a*)(ii)(B) if

(*a*) a statement or claim set out in column 4 of any of items 12 to 14, 16, 20, 21 and 45 of the table following section B.01.513 is shown on the label of the product as part of the common name; and

(*b*) the cheese has the characteristic flavour and texture of cheddar cheese.

(1.2) The reference to “83 per cent” in subparagraph (1)(*a*)(i.1) shall be read as “78 per cent” if

(*a*) a statement or claim set out in column 4 of any of items 12 to 14, 16, 20, 21 and 45 of the table following section B.01.513 is shown on the label of the product as part of the common name; and

(*b*) the cheese has the characteristic flavour and texture of cheddar cheese.

(2) No person shall, in the manufacture of the cheddar cheese, use any enzyme other than

(*a*) aminopeptidase derived from *Lactococcus lactis*, chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), lipase derived from Animal pancreatic tissue; *Aspergillus niger* var.; *Aspergillus oryzae* var.; Edible forestomach tissue of calves, kids or lambs; *Rhizopus oryzae* var. or from *Aspergillus oryzae* (MLT-2) (pRML 787) (p3SR2); *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (*Cooney and Emerson*)); *Rhizopus niveus*, milk coagulating enzyme derived from *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)), from *Mucor pusillus Lindt* by pure culture fermentation process or from *Aspergillus oryzae* RET-1 (pBoel777), pepsin derived from glandular layer of porcine stomach, phospholipase derived from *Aspergillus oryzae* (pPFJo142) or rennet derived from aqueous extracts from the fourth stomach of calves, kids or lambs;

(*b*) protease derived from *Aspergillus oryzae*; and

(*c*) lysozyme derived from egg-white.

(2.1) No person shall use an enzyme referred to in subsection (2) at a level of use above that consistent with good manufacturing practice.

(3) Where a flavouring preparation is added to a cheese as permitted in subsection (1), the words “with (naming the flavouring preparation)” shall be added to the common name in any label.

(4) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(5) Where a cheese is labelled as permitted in subsection (4), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/82-383, s. 4; SOR/83-617, s. 1; SOR/84-302, s. 2; SOR/84-762, s. 7; SOR/88-534, s. 3; SOR/89-244, s. 1; SOR/90-469, s. 2; SOR/91-88, s. 2; SOR/92-197, s. 2; SOR/93-477, s. 2; SOR/94-212, s. 2; SOR/95-183, s. 2; SOR/97-191, s. 2; SOR/98-458, s. 3; SOR/2000-336, s. 2; SOR/2000-417, s. 3; SOR/2005-98, s. 7; SOR/2007-302, ss. 3, 4(F); SOR/2010-143, ss. 2, 39(E).

Previous Version

B.08.035. (1) **[S]. Cream Cheese**

(*a*) shall

(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey, and

(ii) contain

(A) not more than 55 per cent moisture, and

(B) not less than 30 per cent milk fat; and

(*b*) may contain

(i) cream added to adjust the milk fat content,

(ii) salt,

(iii) nitrogen to improve spreadability in an amount consistent with good manufacturing practice,

(iv) the following emulsifying, gelling, stabilizing and thickening agents:

ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or any combination thereof in an amount not exceeding 0.5 per cent, and

(v) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) No person shall use any enzyme

(*a*) other than chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS 105), pepsin derived from glandular layer of porcine stomach or rennet derived from aqueous extracts from the fourth stomach of calves, kids or lambs, in the manufacture of cream cheese; and

(*b*) at a level of use above that consistent with good manufacturing practice.

SOR/79-752, s. 2; SOR/92-197, s. 3; SOR/94-212, s. 3; SOR/95-183, s. 3; SOR/2010-143, s. 3.

Previous Version

B.08.036. (1) **[S]. Whey Cheese or (naming the variety) Whey Cheese**

(*a*) shall be the product made by coagulating whey or concentrated whey with the aid of heat to form a curd and shaping the curd; and

(*b*) may contain

(i) micro-organisms to aid further ripening,

(ii) added milk and milk products, and

(iii) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, sodium hydroxide and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice.

(2) No person shall use, to aid coagulation of whey in the manufacture of whey cheese, a substance other than vinegar or sour whey.

SOR/79-752, s. 2; SOR/2007-302, s. 4(F); SOR/2010-142, s. 5.

Previous Version

B.08.037. (1) **[S]. Cream Cheese with (naming the added ingredients)**

(*a*) shall

(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey, and

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from cream cheese but not in amounts so large as to change the basic nature of the product:

(A) cheese other than cream cheese,

(B) seasonings, spices, flavouring preparations, condiments or chocolate,

(C) fruits, vegetables, pickles, relishes or nuts,

(D) prepared or preserved meat, or

(E) prepared or preserved fish, and

(iii) contain

(A) not more than 60 per cent moisture, and

(B) not less than 26 per cent milk fat; and

(*b*) may contain

(i) cream added to adjust the milk fat content,

(ii) salt,

(iii) nitrogen to improve spreadability in an amount consistent with good manufacturing practice,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or any combination thereof in an amount not exceeding 0.5 per cent, and

(vi) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) No person shall use any enzyme

(*a*) other than chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from

*Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS 105), pepsin derived from glandular layer of porcine stomach or rennet derived from aqueous extracts from the fourth stomach of calves, kids or lambs, in the manufacture of a product to which subsection (1) applies; and

(*b*) at a level of use above that consistent with good manufacturing practice.

SOR/79-752, s. 2; SOR/92-197, s. 4; SOR/94-212, s. 4; SOR/95-183, s. 4; SOR/2010-143, s. 4.

Previous Version

B.08.038. (1) **[S]. Cream Cheese Spread**

(*a*) shall

(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey, and

(ii) contain

(A) added milk and milk products,

(B) not less than 51 per cent cream cheese,

(C) not more than 60 per cent moisture, and

(D) not less than 24 per cent milk fat; and

(*b*) may contain

(i) cream added to adjust the milk fat content,

(ii) salt, vinegar and sweetening agents,

(iii) nitrogen to improve spreadability in an amount consistent with good manufacturing practice,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

(A) ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent, and

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium

gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice, and

(vii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) No person shall use any enzyme

(*a*) other than chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS 105), pepsin derived from glandular layer of porcine stomach or rennet derived from aqueous extracts from the fourth stomach of calves, kids or lambs, in the manufacture of a product to which subsection (1) applies; and

(*b*) at a level of use above that consistent with good manufacturing practice.

SOR/79-752, s. 2; SOR/92-197, s. 5; SOR/94-212, s. 5; SOR/95-183, s. 5; SOR/2007-302, s. 4(F); SOR/2010-143, s. 5.

Previous Version

B.08.039. (1) **[S]. Cream Cheese Spread with (naming the added ingredients)**

(*a*) shall

(i) be the product made by coagulating cream with the aid of bacteria to form a curd and forming the curd into a homogeneous mass after draining the whey,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from cream cheese spread but not in amounts so large as to change the basic nature of the product:

(A) cheese other than cream cheese,

(B) seasonings, spices, flavouring preparation, condiments or chocolate,

(C) fruits, vegetables, pickles, relishes or nuts,

(D) prepared or preserved meat, or

(E) prepared or preserved fish, and

(iii) contain

(A) added milk and milk products,

(B) not more than 60 per cent moisture, and

(C) not less than 24 per cent milk fat; and

(*b*) may contain

(i) cream added to adjust the milk fat content,

(ii) salt, vinegar and sweetening agents,

(iii) nitrogen to improve spreadability in an amount consistent with good manufacturing practice,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

(A) ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent, and

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice, and

(vii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) No person shall use any enzyme

(*a*) other than chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS 105), pepsin derived from glandular layer of porcine stomach or rennet derived from aqueous extracts from the fourth stomach of calves, kids or lambs, in the manufacture of a product to which subsection (1) applies; and

(*b*) at a level of use above that consistent with good manufacturing practice.

SOR/79-752, s. 2; SOR/92-197, s. 6; SOR/94-212, s. 6; SOR/95-183, s. 6; SOR/2007-302, s. 4(F); SOR/2010-143, s. 6.

Previous Version

B.08.040. (1) **[S]. Processed (naming the variety) Cheese**

(*a*) shall

(i) subject to subparagraph (ii), be the product made by comminuting and mixing the named variety or varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat,

(ii) in the case of processed cheddar cheese, be the product made by comminuting and mixing one or more of the following:

(A) cheddar cheese,

(B) stirred curd cheese,

(C) granular curd cheese, or

(D) washed curd cheese

into a homogeneous mass with the aid of heat,

(iii) have, where it is made from

(A) one variety of cheese, in which the maximum amount of moisture permitted is less than 40 per cent, or

(B) two or more varieties of cheese, in which the average maximum amount of moisture permitted is less than 40 per cent,

a moisture content that does not exceed, by more than five per cent, the amount referred to in clause (A) or (B), as the case may be, and a milk fat content that is not less, by more than three per cent, than the minimum milk fat content or average minimum milk fat content permitted for that variety or those varieties, as the case may be,

(iv) subject to subparagraph (v), have, where it is made from

(A) one variety of cheese, in which the maximum amount of moisture permitted is 40 per cent or more, or

(B) more than one variety of cheese, in which the average maximum amount of moisture permitted is 40 per cent or more,

a moisture content that does not exceed, by more than three per cent, the amount referred to in clause (A) or (B), as the case may be, and a milk fat content that is not less, by more than two per cent, than the minimum milk fat content or average minimum milk fat content permitted for that variety or those varieties, as the case may be, and

(v) in the case of processed skim milk cheese, contain not more than

(A) 55 per cent moisture, and

(B) seven per cent milk fat; and

(*b*) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) in the case of processed skim milk cheese, added skim milk powder, buttermilk powder and whey powder,

(iv) salt, vinegar and sweetening agents,

(v) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(vi) the following emulsifying, gelling, stabilizing and thickening agents:

(A) sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate) in an amount not exceeding 0.5 per cent,

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(C) lecithin in an amount not exceeding 0.2 per cent, and

(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

(vi.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vii) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(viii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(ix) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/91-409, s. 1.

B.08.041. (1) **[S]. Processed (naming the variety) Cheese with (naming the added ingredients)**

(*a*) shall

(i) be the product made by comminuting and mixing the named variety or varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from processed (naming the variety) cheese but not in amounts so large as to change the basic nature of the product:

(iii) have, where it is made from

(A) one variety of cheese, in which the maximum amount of moisture permitted is less than 40 per cent, or

(B) more than one variety of cheese, in which the average maximum amount of moisture permitted is less than 40 per cent,

a moisture content that does not exceed by more than five per cent, the amount referred to in clause (A) or (B), as the case may be, and a milk fat content that is not less, by more than three per cent, than the minimum milk fat content or average minimum milk fat content permitted for that variety or those varieties, as the case may be, and

(iv) have, where it is made from

(A) one variety of cheese, in which the maximum amount of moisture permitted is 40 per cent or more, or

(B) more than one variety of cheese, in which the average maximum amount of moisture permitted is 40 per cent or more,

a moisture content that does not exceed, by more than three per cent, the amount referred to in clause (A) or (B), as the case may be, and a milk fat content that is not less, by more than two per cent, than the minimum milk fat content or average minimum milk fat content permitted for that variety or those varieties, as the case may be; and

(*b*) may contain

(i) water added to adjust moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

(A) sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate) in an amount not exceeding 0.5 per cent,

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(C) lecithin in an amount not exceeding 0.2 per cent, and

(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

(v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/91-409, s. 2; SOR/92-400, s. 5; SOR/2010-94, s. 4(E).

Previous Version

B.08.041.1. (1) **[S]. Processed Cheese Food**

(*a*) shall

(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat, and

(ii) contain

(A) added milk or milk products,

(B) not less than 51 per cent cheese,

(C) not more than 46 per cent moisture, and

(D) not less than 23 per cent milk fat; and

(*b*) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

(A) sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate) in an amount not exceeding 0.5 per cent,

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium

gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(C) lecithin in an amount not exceeding 0.2 per cent, and

(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

(v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/91-409, s. 3; SOR/92-400, s. 6; SOR/2007-302, s. 4(F).

Previous Version

B.08.041.2. (1) **[S]. Processed Cheese Food with (naming the added ingredients)**

(*a*) shall

(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from processed cheese food but not in amounts so large as to change the basic nature of the product:

(A) seasonings, spices, flavouring preparations, condiments or chocolate,

(B) fruits, vegetables, pickles, relishes or nuts,

(C) prepared or preserved meat, or

(D) prepared or preserved fish, and

(iii) contain

(A) added milk or milk products,

(B) not more than 46 per cent moisture, and

(C) not less than 22 per cent milk fat; and

(*b*) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8'-carotenal, ethyl beta-apo-8'-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

(A) sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate) in an amount not exceeding 0.5 per cent,

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(C) lecithin in an amount not exceeding 0.2 per cent, and

(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

(v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/91-409, s. 4; SOR/92-400, s. 7; SOR/2007-302, s. 4(F).

Previous Version

B.08.041.3. (1) **[S]. Processed Cheese Spread**

(*a*) shall

(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat, and

(ii) contain

(A) added milk or milk products,

(B) not less than 51 per cent cheese,

(C) not more than 60 per cent moisture, and

(D) not less than 20 per cent milk fat;

(*b*) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8’-carotenal, ethyl beta-apo-8’-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

(A) ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol

alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(C) lecithin in an amount not exceeding 0.2 per cent, and

(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

(v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/82-1071, s. 4; SOR/91-409, s. 5; SOR/2007-302, s. 4(F).

Previous Version

B.08.041.4. (1) **[S]. Processed Cheese Spread with (naming the added ingredients)**

(*a*) shall

(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass with the aid of heat,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from processed cheese spread but not in amounts so large as to change the basic nature of the product:

(A) seasonings, spices, flavouring preparations, condiments or chocolate,

(B) fruits, vegetables, pickles, relishes or nuts,

(C) prepared or preserved meat, or

(D) prepared or preserved fish, and

(iii) contain

(A) added milk or milk products,

(B) not more than 60 per cent moisture, and

(C) not less than 20 per cent milk fat; and

(*b*) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

(A) ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,

(B) calcium phosphate dibasic, potassium phosphate dibasic, sodium acid pyrophosphate, sodium aluminum phosphate, sodium hexametaphosphate, sodium phosphate dibasic, sodium phosphate monobasic, sodium phosphate tribasic, sodium pyrophosphate tetrabasic, calcium citrate, potassium citrate, sodium citrate, sodium potassium tartrate, sodium tartrate, sodium gluconate or any combination thereof in an amount, when calculated as anhydrous salts, not exceeding 3.5 per cent in the case of phosphate salts and 4.0 per cent in total,

(C) lecithin in an amount not exceeding 0.2 per cent, and

(D) monoglycerides, mono- and diglycerides or any combination thereof in an amount not exceeding 0.5 per cent,

(v.1) calcium phosphate tribasic as an agent to improve colour, texture, consistency and spreadability, in an amount not exceeding 1 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/82-1071, s. 5; SOR/91-409, s. 6; SOR/2007-302, s. 4(F).

Previous Version

B.08.041.5. (1) **[S]. Cold-Pack (naming the variety) Cheese**

(*a*) shall

(i) subject to subparagraph (ii), be the product made by comminuting and mixing the named variety or varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass without the aid of heat,

(ii) in the case of cold-pack cheddar cheese, be the product made by comminuting and mixing one or more of the following:

(A) cheddar cheese,

(B) stirred curd cheese,

(C) granular curd cheese, or

(D) washed curd cheese

into a homogeneous mass without the aid of heat,

(iii) contain, where it is made from

(A) one variety of cheese, not more moisture and not less milk fat than the maximum moisture content and minimum fat content permitted for that variety, or

(B) more than one variety of cheese, not more moisture and not less milk fat than the average maximum moisture content and the average minimum fat content permitted for those varieties; and

(*b*) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vi) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(vii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/92-400, s. 8.

B.08.041.6. (1) **[S]. Cold-Pack (naming the variety) Cheese with (naming the added ingredients)**

(*a*) shall

(i) be the product made by comminuting and mixing the named variety or varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass without the aid of heat,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from cold-pack (naming the variety) cheese but not in amounts so large as to change the basic nature of the product:

(iii) contain, where it is made from

(A) one variety of cheese, not more moisture and not less milk fat than the maximum moisture content and one per cent less than the minimum milk fat content permitted for that variety, or

(B) more than one variety of cheese, not more moisture and not less milk fat than the average maximum moisture content and one per cent less than the average minimum milk fat content permitted for those varieties; and

(*b*) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/92-400, s. 9; SOR/2010-94, s. 5(E).

Previous Version

B.08.041.7. (1) **[S]. Cold-Pack Cheese Food**

(*a*) shall

(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass without the aid of heat,

(ii) contain

(A) added milk or milk products,

(B) not less than 51 per cent cheese,

(C) not more than 46 per cent moisture, and

(D) not less than 23 per cent milk fat; and

(*b*) may contain

(i) water added to adjust the moisture content,

(ii) added milk fat,

(iii) salt, vinegar and sweetening agents,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/2007-302, s. 4(F).

Previous Version

B.08.041.8. (1) **[S]. Cold-Pack Cheese Food with (naming the added ingredients)**

(*a*) shall

(i) be the product made by comminuting and mixing one or more varieties of cheese, other than cream cheese, cottage cheese or whey cheese, into a homogeneous mass without the aid of heat,

(ii) contain the named added ingredients which shall be one or more of the following ingredients in amounts sufficient to differentiate the product from cold-pack cheese food but not in amounts so large as to change the basic nature of the product:

(A) seasonings, spices, flavouring preparations, condiments or chocolate,

(B) fruits, vegetables, pickles, relishes or nuts,

(C) prepared or preserved meat, or

(D) prepared or preserved fish, and

(iii) contain

(A) added milk or milk products,

(B) not more than 46 per cent moisture, and

(C) not less than 22 per cent milk fat; and

(*b*) may contain

(i) water added to adjust moisture content,

(ii) added milk fat,

(iii) sweetening agents, salt and vinegar,

(iv) one or more of the following colouring agents:

(A) in an amount consistent with good manufacturing practice, annatto, beta-carotene, chlorophyll, paprika, riboflavin, turmeric, and

(B) in an amount not exceeding 35 parts per million, either singly or in combination thereof, beta-apo-8′-carotenal, ethyl beta-apo-8′-carotenoate,

(v) the following emulsifying, gelling, stabilizing and thickening agents:

ammonium carrageenan, calcium carrageenan, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, Irish Moss Gelose, potassium carrageenan, propylene glycol alginate, sodium carboxymethyl cellulose (carboxymethyl cellulose, cellulose gum, sodium cellulose glycolate), sodium carrageenan, tragacanth gum, xanthan gum or a combination thereof in an amount not exceeding 0.5 per cent,

(vi) acetic acid, calcium carbonate, citric acid, lactic acid, malic acid, phosphoric acid, potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate and tartaric acid as pH adjusting agents in an amount consistent with good manufacturing practice,

(vii) wood smoke as a preservative in an amount consistent with good manufacturing practice, and

(viii) the following preservatives:

(A) propionic acid, calcium propionate, sodium propionate or any combination thereof in an amount not exceeding 2,000 parts per million, calculated as propionic acid,

(B) sorbic acid, calcium sorbate, potassium sorbate, sodium sorbate, or any combination thereof in an amount not exceeding 3,000 parts per million, calculated as sorbic acid, or

(C) any combination of the preservatives named in clauses (A) and (B) in an amount not exceeding 3,000 parts per million, calculated as propionic acid and sorbic acid respectively.

(2) Only a cheese to which wood smoke has been added as permitted in subsection (1) may be described by the term “smoked” on a label.

(3) Where a cheese is labelled as permitted in subsection (2), the word “smoked” shall be shown on the principal display panel.

SOR/79-752, s. 2; SOR/2007-302, s. 4(F).

Previous Version

B.08.042. No manufacturer shall sell whole cheese that is not made from a pasteurized source unless the date of the beginning of the manufacturing process is

(*a*) marked or branded thereon within three days thereof; or

(*b*) marked on the label at the time of packaging, if the cheese is such that, because of its texture, consistency, or physical structure, such date cannot be effectively branded or marked on the cheese.

B.08.043. No manufacturer shall sell any cheese that is not made from a pasteurized source if it has been cut into smaller portions, unless

(*a*) it has been duly stored; or

(*b*) each portion of cut cheese is marked, branded or labelled with the date of the beginning of the manufacturing process.

B.08.044. (1) Subject to subsection (2), no person shall sell cheese, including cheese curd, that is not made from a pasteurized source unless it has been stored.

(2) Cheese, including cheese curd, that is not made from a pasteurized source may be used as an ingredient in any food providing such food is manufactured or processed so as to pasteurize the cheese in the manner described in the definition “pasteurized source” in section B.08.030(1).

SOR/78-405, s. 1; SOR/79-752, s. 3.

B.08.045. Notwithstanding B.08.044, cheese that has not been manufactured from a pasteurized source and has not been stored but is marked or branded with the date of the beginning of the manufacturing process, may be sold to

(*a*) a wholesaler;

(*b*) a jobber; or

(*c*) in quantities of not less than 900 pounds, to a retailer.

B.08.046. No person shall sell any whole cheese that has not been made from a pasteurized source unless there is stamped thereon the date of the beginning of the manufacturing process.

B.08.047. Every manufacturer, wholesaler, or jobber who sells cheese not made from a pasteurized source and which has not been stored shall keep a record of

(*a*) the registered number of the cheese factory,

(*b*) the date of manufacture of the cheese,

(*c*) the vat number or vat numbers,

(*d*) the name and address of the person to whom the cheese is sold, and

(*e*) the weight sold from each vat,

for each lot of cheese sold.

B.08.048. (1) Subject to section B.08.054, no person shall sell cheese, including cheese curd, made from a pasteurized source if the cheese contains more than

(*a*) 100 *Escherichia coli*, or

(*b*) 100 *Staphylococcus aureus*

per gram, as determined by official method MFO-14, Microbiological Examination of Cheese, November 30, 1983.

(2) No person shall sell cheese, made from an unpasteurized source if the cheese contains more than

(*a*) 500 *Escherichia coli*, or

(*b*) 1,000 *Staphylococcus aureus*

per gram, as determined by official method MFO-14, Microbiological Examination of Cheese, November 30, 1983.

SOR/78-405, s. 2; SOR/82-768, s. 21; SOR/84-17, s. 4.

B.08.049. **[S]. Whey**

(*a*) shall be the product remaining after the curd has been removed from milk in the process of making cheese; and

(*b*) may contain

(i) catalase, in the case of liquid whey that has been treated with hydrogen peroxide,

(ii) lactase,

(iii) hydrogen peroxide, in the case of liquid whey destined for the manufacture of dried whey products,

(iv) benzoyl peroxide and calcium phosphate tribasic, as a carrier of the benzoyl peroxide, in the case of liquid whey destined for the manufacture of dried whey products other than those for use in infant formula, and

(v) sodium hexametaphosphate, in the case of liquid whey destined for the manufacture of concentrated or dried whey products.

SOR/79-752, s. 4; SOR/89-555, s. 1; SOR/2010-40, s. 1.

Previous Version

B.08.050. [Repealed, SOR/95-281, s. 1]

B.08.051. **[S]. Cottage Cheese**

(*a*) shall be the product, in the form of discrete curd particles, prepared from skim milk, evaporated skim milk or skim milk powder and harmless acid-producing bacterial cultures;

(*b*) shall contain not more than 80 per cent moisture;

(*c*) may contain not more than 0.5 per cent stabilizing agent; and

(*d*) may contain

(i) milk,

(ii) cream,

(iii) milk powder,

(iv) rennet derived from aqueous extracts from the fourth stomach of calves, kids or lambs,

(v) a milk coagulating enzyme derived from *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)), from *Mucor pusillus Lindt* by pure culture fermentation process or from *Aspergillus oryzae* RET-1 (pBoel777), in an amount consistent with good manufacturing practice,

(vi) chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), in an amount consistent with good manufacturing practice,

(vi.1) chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), in an amount consistent with good manufacturing practice,

(vi.2) pepsin derived from glandular layer of porcine stomach,

(vii) salt,

(viii) calcium chloride,

(ix) added lactose,

(x) pH adjusting agents,

(xi) relishes,

(xii) fruits,

(xiii) vegetables, and

(xiv) carbon dioxide.

SOR/81-60, s. 4; SOR/92-197, s. 7; SOR/94-212, s. 7; SOR/95-183, s. 7; SOR/98-458, s. 4; SOR/2001-94, s. 2; SOR/2005-98, s. 7; SOR/2010-143, ss. 7, 39(E).

Previous Version

B.08.052. **[S]. Creamed Cottage Cheese** shall be cottage cheese containing cream or a mixture of cream with milk or skim milk, or both, in such quantity that the final product shall contain

(*a*) not less than four per cent milk fat; and

(*b*) not more than 80 per cent moisture and may contain emulsifying, gelling, stabilizing and thickening agents.

B.08.053. All dairy products used in the preparation of cottage cheese shall be from a pasteurized source.

B.08.054. No person shall sell cottage cheese or creamed cottage cheese that contains more than 10 coliform bacteria per gram, as determined by official method MFO-4, Microbiological Examination of Cottage Cheese, November 30, 1981.

SOR/82-768, s. 22.

## Butter

B.08.056. **[S]. Butter**

(*a*) shall

(i) be the food prepared in accordance with good manufacturing practices from milk or milk products, and

(ii) contain not less than 80 per cent milk fat; and

(*b*) may contain

(i) milk solids,

(ii) bacterial culture,

(iii) salt, and

(iv) food colour.

SOR/92-400, s. 10.

B.08.057. **[S]. Whey Butter** shall be butter made from whey cream.

SOR/92-400, s. 10.

## Ice Cream

B.08.061. **[S]. Ice Cream Mix**

(*a*) shall be the unfrozen, pasteurized combination of cream, milk or other milk products, sweetened with sugar, liquid sugar, invert sugar, honey, dextrose, glucose, corn syrup, corn syrup solids or any combination of such sweeteners;

(*b*) may contain

(i) egg,

(ii) a flavouring preparation,

(iii) cocoa or chocolate syrup,

(iv) a food colour,

(v) pH adjusting agents,

(vi) microcrystalline cellulose or a stabilizing agent or both in an amount that will not exceed 0.5 per cent of the ice cream made from the mix,

(vii) a sequestering agent,

(viii) salt,

(ix) not more than one per cent added edible casein or edible caseinates; and

(x) propylene glycol mono fatty acid esters in an amount that will not exceed 0.35 per cent of the ice cream made from the mix and sorbitan tristearate in an amount that will not exceed 0.035 per cent of the ice cream made from the mix; and

(*c*) shall contain not less than

(i) 36 per cent solids, and

(ii) 10 per cent milk fat or, where cocoa or chocolate syrup has been added, eight per cent milk fat.

SOR/92-400, s. 11; SOR/97-543, s. 2(F); SOR/2007-75, s. 2; SOR/2007-302, s. 4(F); SOR/2010-142, s. 6(F).

Previous Version

B.08.062. **[S]. Ice Cream**

(*a*) shall be the frozen food obtained by freezing an ice cream mix, with or without the incorporation of air;

(*b*) may contain cocoa or chocolate syrup, fruit, nuts or confections;

(*c*) shall contain not less than

(i) 36 per cent solids,

(ii) 10 per cent milk fat, or, where cocoa or chocolate syrup, fruit, nuts, or confections have been added, eight per cent milk fat, and

(iii) 180 grams of solids per litre of which amount not less than 50 grams shall be milk fat, or, where cocoa or chocolate syrup, fruit, nuts or confections have been added, 180 grams of solids per litre of which amount not less than 40 grams shall be milk fat; and

(*d*) shall contain not more than

(i) 100,000 bacteria per gram, and

(ii) 10 coliform organisms per gram,

as determined by official method MFO-2, Microbiological Examination of Ice Cream or Ice Milk, November 30, 1981.

SOR/82-768, s. 23; SOR/92-400, s. 12.

## Sherbet

[SOR/98-580, s. 1(F)]

B.08.063. **[S]. Sherbet**

(*a*) shall be the frozen food, other than ice cream or ice milk, made from a milk product;

(*b*) may contain

(i) water,

(ii) a sweetening agent,

(iii) fruit or fruit juice,

(iv) citric or tartaric acid,

(v) a flavouring preparation,

(vi) a food colour,

(vii) not more than 0.75 per cent stabilizing agent,

(viii) a sequestering agent,

(ix) lactose,

(x) not more than 0.5 per cent microcrystalline cellulose, and

(xi) not more than one per cent added edible casein or edible caseinates; and

(*c*) shall contain

(i) not more than five per cent milk solids, including milk fat, and

(ii) not less than 0.35 per cent acid determined by titration and expressed as lactic acid.

SOR/92-400, s. 13; SOR/97-543, s. 3(F); SOR/98-580, s. 1(F); SOR/2007-302, s. 4(F).

Previous Version

## Ice Milk

B.08.071. **[S]. Ice Milk Mix**

(*a*) shall be the unfrozen, pasteurized combination of cream, milk or other milk products, sweetened with sugar, liquid sugar, invert sugar, honey, dextrose, glucose, corn syrup, corn syrup solids or any combination of such sweeteners;

(*b*) may contain

(i) egg,

(ii) a flavouring preparation,

(iii) cocoa or chocolate syrup,

(iv) a food colour,

(v) a pH adjusting agent,

(vi) a stabilizing agent, in an amount that will not result in more than 0.5 per cent stabilizing agent in the ice milk,

(vii) a sequestering agent,

(viii) added lactose, and

(ix) not more than 1.5 per cent microcrystalline cellulose,

(x) salt, and

(xi) not more than one per cent added edible casein or edible caseinates; and

(*c*) shall contain

(i) not less than 33 per cent solids, and

(ii) not less than three per cent and not more than five per cent milk fat.

SOR/92-400, s. 14; SOR/97-543, s. 4(F); SOR/2007-302, s. 4(F).

Previous Version

B.08.072. **[S]. Ice Milk**

(*a*) shall be the frozen food obtained by freezing an ice milk mix, with or without the incorporation of air;

(*b*) may contain cocoa or chocolate syrup, fruit, nuts or confections;

(*c*) shall contain

(i) not less than 33 per cent solids,

(ii) not less than three per cent and not more than five per cent milk fat, and

(iii) not less than 160 grams of solids per litre of which amount not less than 14 grams shall be milk fat; and

(*d*) shall contain not more than

(i) 100,000 bacteria per gram, and

(ii) 10 coliform organisms per gram,

as determined by official method MFO-2, Microbiological Examination of Ice Cream or Ice Milk, November 30, 1981.

SOR/82-768, s. 24; SOR/92-400, s. 15.

B.08.073. [Repealed, SOR/92-626, s. 13]

B.08.074. (1) The percentage of milk fat contained in

(*a*) yogurt,

(*b*) cottage cheese, and

(*c*) creamed cottage cheese,

shall be shown on the principal display panel followed by the words “milk fat” or the abbreviation “B.F.” or “M.F.”.

(2) In addition to the statement referred to in subsection (1), a person may, on the label of a food referred to in subsection (1), make a declaration of the fat content of the food, expressed in grams per serving of stated size.

SOR/88-559, s. 18.

## Cream

B.08.075. **[S]. Cream**

(*a*) shall be the fatty liquid prepared from milk by separating the milk constituents in such a manner as to increase the milk fat content; and

(*b*) may contain

(i) a pH adjusting agent,

(ii) a stabilizing agent,

(iii) in the case of cream for whipping that has been heat-treated above 100°C, the following ingredients and food additives:

(A) skim milk powder in an amount not exceeding 0.25 per cent,

(B) glucose solids in an amount not exceeding 0.1 per cent,

(C) calcium sulphate in an amount not exceeding 0.005 per cent, and

(D) xanthan gum in an amount not exceeding 0.02 per cent, and

(E) [Repealed, SOR/2010-142, s. 7]

(iv) in the case of cream for whipping, microcrystalline cellulose in an amount not exceeding 0.2 per cent.

SOR/79-662, s. 2; SOR/82-1071, s. 6; SOR/88-419, s. 1; SOR/2010-142, s. 7.

Previous Version

B.08.076. (1) The percentage of milk fat contained in canned cream shall be shown on the principal display panel followed by the words “milk fat” or the abbreviation “B.F.” or “M.F.”.

(2) In addition to the statement referred to in subsection (1), a person may, on the label of canned cream, make a declaration of the fat content of the cream, expressed in grams per serving of stated size.

SOR/88-559, s. 19.

B.08.077. **[S]. Sour Cream**

(*a*) shall be the product prepared by the souring of pasteurized cream with acid-producing bacterial culture and shall contain not less than 14 per cent milk fat; and

(*b*) may contain

(i) milk solids,

(ii) whey solids,

(iii) buttermilk,

(iv) starch in an amount not exceeding one per cent,

(v) salt,

(vi) rennet derived from aqueous extracts from the fourth stomach of calves, kids or lambs, in an amount consistent with good manufacturing practice,

(vii) the following emulsifying, gelling, stabilizing and thickening agents:

(A) algin, carob bean gum (locust bean gum), carrageenan, gelatin, guar gum, pectin or propylene glycol alginate or any combination thereof in an amount not exceeding 0.5 per cent,

(B) monoglycerides, mono- and diglycerides, or any combination thereof, in an amount not exceeding 0.3 per cent, and

(C) sodium phosphate dibasic in an amount not exceeding 0.05 per cent,

(viii) sodium citrate as a flavour precursor in an amount not exceeding 0.1 per cent,

(ix) a milk coagulating enzyme derived from *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)), from *Mucor pusillus Lindt* by pure culture fermentation process or from *Aspergillus oryzae* RET-1 (pBoel777), in an amount consistent with good manufacturing practice,

(x) chymosin A derived from *Escherichia coli* K-12, GE81 (pPFZ87A), in an amount consistent with good manufacturing practice, and

(xi) chymosin B derived from *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR) or from *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105), in an amount consistent with good manufacturing practice.

SOR/78-876, s. 1; SOR/80-500, s. 3; SOR/81-60, s. 5; SOR/92-197, s. 8; SOR/94-212, s. 8; SOR/95-183, s. 8; SOR/98-458, s. 5; SOR/2005-98, s. 7; SOR/2010-143, ss. 8, 39(E).

Previous Version

# Division 9

# Fats And Oils

B.09.001. **[S]. Vegetable fats and oils** shall be fats and oils obtained entirely from the botanical source after which they are named, shall be dry and sweet in flavour and odour and, with the exception of olive oil, may contain emulsifying agents, Class IV preservatives, an antifoaming agent, and B-carotene in a quantity sufficient to replace that lost during processing, if such an addition is declared on the label.

SOR/85-179, s. 1.

B.09.002. **[S]. Animal fats and oils** shall be fats and oils obtained entirely from animals healthy at the time of slaughter, shall be dry and sweet in flavour and odour and may contain

(*a*) with the exception of milk fat and suet, Class IV preservatives; and

(*b*) with the exception of lard, milk fat and suet, an antifoaming agent.

B.09.003. **[S]. Olive Oil** or **Sweet Oil**

(*a*) shall be the oil obtained from the fruit of the olive tree (*Olea europaea L*);

(*b*) shall have a fatty acid content that is

(i) not less than 56.0 and not more than 83.0 per cent oleic acid,

(ii) not less than 7.5 and not more than 20.0 per cent palmitic acid,

(iii) not less than 3.5 and not more than 20.0 per cent linoleic acid,

(iv) not less than 0.5 and not more than 3.5 per cent stearic acid,

(v) not less than 0.3 and not more than 3.5 per cent palmitoleic acid,

(vi) not more than 1.5 per cent linolenic acid, and

(vii) not more than 0.05 per cent myristic acid, calculated as methyl esters;

(*c*) shall not contain more than minute amounts of arachidic acid, behenic acid, gadoleic acid or lignoceric acid;

(*d*) shall have

(i) a relative density of not less than 0.910 and not more than 0.916, calculated with the oil at 20°C and water at 20°C (20°C/water at 20°C),

(ii) a refractive index of not less than 1.4677 and not more than 1.4705, calculated using the sodium D-line as the light source and with the oil at 20°C ($n_D$20°C),

(iii) an iodine value of not less than 75 and not more than 94, calculated using the Wijs test,

(iv) a saponification value of not less than 184 and not more than 196, expressed as milligrams of potassium hydroxide per gram of oil,

(v) an acid value of not more than 6.6 milligrams potassium hydroxide per gram of oil,

(vi) a free acidity of not more than 3.3 per cent expressed as oleic acid,

(vii) a peroxide value of not more than 20 milliequivalents peroxide oxygen per kilogram of oil,

(viii) an unsaponifiable matter content of not more than 15 grams per kilogram, and

(ix) a Bellier index of not more than 17;

(*e*) shall show negative results when tested for semi-siccative oil, olive-residue oil, cotton-seed oil, tea-seed oil or sesame seed oil; and

(*f*) notwithstanding section B.09.001, may contain alpha-tocopherol in a quantity sufficient to replace that lost during refining, if such an addition is declared on the label.

SOR/78-655, s. 1.

B.09.004. **[S]. Cotton Seed Oil**

(*a*) shall be the oil of seeds of cultivated *Gossypium spp.*;

(*b*) shall have

(i) a relative density (20°C/water at 20°C) of not less than 0.918 and not more than 0.926,

(ii) a refractive index ($n_D$40°C) of not less than 1.458 and not more than 1.466,

(iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 189 and not more than 198,

(iv) an iodine value (Wijs) of not less than 99 and not more than 119,

(v) an unsaponifiable matter content of not more than 15 grams per kilogram,

(vi) a positive Halphen test,

(vii) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and

(viii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil; and

(*c*) may contain oxystearin.

B.09.005. **[S]. Cocoa Butter** shall be the fat from cocoa nibs, obtained either before or after roasting, or cocoa liquor, and shall have

(*a*) a refractive index (40°C) of not less than 1.453 and not more than 1.458;

(*b*) a saponification value of not less than 188 and not more than 202;

(*c*) an iodine value (Hanus) of not less than 32 and not more than 41; and

(*d*) an acid value of not more than five.

SOR/97-263, s. 3.

B.09.006. **[S]. Corn Oil** or **Maize Oil**

(*a*) shall be the oil of the germ or embryo of *Zea mays L.*; and

(*b*) shall have

(i) a relative density of (20°C/water at 20°C) of not less than 0.917 and not more than 0.925,

(ii) a refractive index ($n_D$40°C) of not less than 1.465 and not more than 1.468,

(iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 187 and not more than 195,

(iv) an iodine value (Wijs) of not less than 103 and not more than 128,

(v) an unsaponifiable matter content of not more than 28 grams per kilogram,

(vi) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and

(vii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil.

B.09.007. **[S]. Peanut Oil** or **Arachis Oil**

(*a*) shall be the oil of the seeds of *Arachis hypogaea L.*;

(*b*) shall have

(i) a relative density of (20°C/water at 20°C) of not less than 0.914 and not more than 0.917,

(ii) a refractive index ($n_D$40°C) of not less than 1.460 and not more than 1.465,

(iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 187 and not more than 196,

(iv) an iodine value (Wijs) of not less than 80 and not more than 106,

(v) an unsaponifiable matter content of not more than 10 grams per kilogram,

(vi) an arachidic and higher fatty acids content of not less than 48 grams per kilogram,

(vii) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and

(viii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil; and

(*c*) not contain oxystearin.

SOR/84-300, s. 22(E).

B.09.008. **[S]. Soybean Oil, Soya Bean Oil, Soja Oil** or **Soya Oil**

(*a*) shall be the oil of the seeds of *Glycine max (L.) Merr.*;

(*b*) shall have

(i) a relative density of (20°C/water at 20°C) of not less than 0.919 and not more than 0.925,

(ii) a refractive index ($n_D$40°C) of not less than 1.466 and not more than 1.470,

(iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 189 and not more than 195,

(iv) an iodine value (Wijs) of not less than 120 and not more than 143,

(v) an unsaponifiable matter content of not more than 15 grams per kilogram,

(vi) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and

(vii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil; and

(*c*) may contain oxystearin.

SOR/84-300, s. 23(E).

B.09.009. **[S]. Sunflowerseed Oil** or **Sunflower Oil**

(*a*) shall be the oil of the seeds of *Helianthus annuus L.*; and

(*b*) shall have

(i) a relative density of (20°C/water at 20°C) of not less than 0.918 and not more than 0.923,

(ii) a refractive index ($n_D$40°C) of not less than 1.467 and not more than 1.469,

(iii) an iodine value (Wijs) of not less than 110 and not more than 143,

(iv) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 188 and not more than 194,

(v) an unsaponifiable matter content of not more than 15 grams per kilogram,

(vi) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and

(vii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil.

B.09.009A. **[S]. Safflowerseed Oil** or **Safflower Oil**

(*a*) shall be the oil of the seeds of *Carthamus tinctorius L.*;

(*b*) shall have

(i) a relative density of (20°C/water at 20°C) of not less than 0.922 and not more than 0.927,

(ii) a refractive index ($n_D$40°C) of not less than 1.467 and not more than 1.470,

(iii) a saponification value (milligrams potassium hydroxide per gram of oil) of not less than 186 and not more than 198,

(iv) an iodine value (Wijs) of not less than 135 and not more than 150,

(v) an unsaponifiable matter content of not more than 15 grams per kilogram,

(vi) an acid value of not more than 0.6 milligram potassium hydroxide per gram of oil, and

(vii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of oil.

B.09.010. Notwithstanding item 1 of the table to paragraph B.01.010(3)(*b*), where a vegetable fat or oil is an ingredient of any cooking oil, salad oil or table oil, the fat or oil shall be shown in the list of ingredients by its common name.

SOR/98-458, s. 7(F).

B.09.011. **[S]. Shortening,** other than butter or lard, shall be the semi-solid food prepared from fats, oils or a combination of fats and oils, may be processed by hydrogenation and may contain

(*a*) Class IV preservatives,

(*b*) an antifoaming agent,

(*c*) stearyl monoglyceridyl citrate,

(*d*) monoglycerides or a combination of monoglycerides and diglycerides of fat forming fatty acids, the weight of the monoglycerides being not more than 10 per cent and the total weight of monoglycerides and diglycerides being not more than 20 per cent of the weight of the shortening,

(*e*) lactylated monoglycerides, or a combination of lactylated monoglycerides and diglycerides of fat forming fatty acids, the total weight being not more than eight per cent of the weight of the shortening, and

(*f*) sorbitan tristearate,

except that the total weight of the ingredients permitted under paragraphs (*d*) and (*e*) shall not be greater than 20 per cent of the weight of the shortening.

B.09.012. [Repealed, SOR/97-148, s. 2]

B.09.013. **[S]. Lard**

(*a*) shall be the rendered fat from hogs;

(*b*) shall have

(i) a relative density of not less than 0.894 and not more than 0.906, calculated with the lard at 40°C and water at 20°C (40°C/water at 20°C),

(ii) a refractive index of not less than 1.448 and not more than 1.461, calculated using the sodium D-line as the light source and with the lard at 40°C ($n_D$40°C),

(iii) a titre of not less than 32°C and not more than 45°C,

(iv) a saponification value of not less than 192 and not more than 203, expressed as milligrams potassium hydroxide per gram of fat,

(v) an iodine value of not less than 45 and not more than 70, calculated using the Wijs test,

(vi) an unsaponifiable matter content of not more than 12 grams per kilogram,

(vii) an acid value of not more than 2.5 milligrams potassium hydroxide per gram of fat, and

(viii) a peroxide value of not more than 16 milliequivalents peroxide oxygen per kilogram of fat; and

(*c*) may contain

(i) lard stearine or hydrogenated lard,

(ii) a Class IV preservative, and

(iii) not more than one per cent of substances resulting from the rendering process, other than fatty acids and fat.

SOR/78-401, s. 1(F); SOR/84-300, s. 25(F).

B.09.014. **[S]. Leaf Lard** shall be lard that has been rendered at a moderately high temperature from the internal fat of the abdomen of the hog, excluding that adhering to the intestines, and shall have an iodine value (Hanus) of not more than 65.

B.09.015. **[S]. Suet**

(*a*) shall be the fat taken from the region of the kidney or loin or caul fat of a beef carcass;

(*b*) shall have

(i) a relative density of not less than 0.893 and not more than 0.898, calculated with the suet at 40°C and water at 20°C (40°C/water at 20°C),

(ii) a refractive index of not less than 1.448 and not more than 1.460, calculated using the sodium D-line as the light source and with the suet at 40°C ($n_D$40°C),

(iii) a titre of not less than 42.5°C and not more than 47°C,

(iv) a saponification value of not less than 190 and not more than 200, expressed as milligrams of potassium hydroxide per gram of fat,

(v) an iodine value of not less than 32 and not more than 47, calculated using the Wijs test,

(vi) an unsaponifiable matter content of not more than 10 grams per kilogram,

(vii) an acid value of not more than 2.0 milligrams potassium hydroxide per gram of fat, and

(viii) a peroxide value of not more than 10 milliequivalents peroxide oxygen per kilogram of fat; and

(*c*) where sold in comminuted form, shall contain not more than three per cent cereal and one per cent salt.

SOR/78-655, s. 2(F).

B.09.016. **[S]. Margarine**

(*a*) shall be a plastic or fluid emulsion of water in fats, oil or fats and oil that are not derived from milk and may have been subjected to hydrogenation;

(*b*) shall contain

(i) not less than 80 per cent fat, oil or fat and oil calculated as fat, and

(ii) notwithstanding section D.01.009, not less than

(A) 3,300 International Units of vitamin A, and

(B) 530 International Units of vitamin D

per 100 grams; and

(*c*) may contain

(i) skim milk powder, buttermilk powder or liquid buttermilk,

(ii) whey solids or modified whey solids,

(iii) protein,

(iv) water,

(v) vitamin E, if added in such an amount as will result in the finished product containing not less than 0.6 International Unit of alphatocopherol per gram of linoleic acid present in the margarine,

(vi) a flavouring agent,

(vii) a sweetening agent,

(viii) potassium chloride and sodium chloride,

(ix) the following colouring agents: annatto, ß-apo-8′- carotenal, canthaxanthin, carotene, ethyl ß-apo-8′-carotenoate and turmeric, as set out in Table III to section B.16.100,

(x) the following emulsifying agents: lecithin, mono- and di-glycerides, mono-glycerides and sorbitan tristearate, as set out in Table IV to section B.16.100,

(xi) the following pH adjusting agents: citric acid, lactic acid, potassium bicarbonate, sodium bicarbonate, potassium carbonate, sodium carbonate, sodium citrate, sodium lactate, potassium citrate, potassium hydroxide, sodium hydroxide, potassium lactate, sodium potassium tartrate and tartaric acid, as set out in Table X to section B.16.100,

(xii) the following preservatives: ascorbyl palmitate, ascorbyl stearate, benzoic acid, butylated hydroxyanisole, butylated hydroxytoluene, calcium sorbate, monoglyceride citrate, monoisopropyl citrate, potassium benzoate, potassium sorbate, propyl gallate, sodium benzoate, sodium sorbate and sorbic acid, as set out in Table XI to section B.16.100, and

(xiii) the following sequestering agents: calcium disodium ethylenediaminetetraacetate and stearyl citrate, as set out in Table XII to section B.16.100.

SOR/81-60, s. 6; SOR/84-300, s. 26(F); SOR/93-466, s. 1.

B.09.017. **[S]. Calorie-Reduced Margarine**

(*a*) shall conform to the standard for margarine except it shall contain not more than

(i) 40 per cent fat, oil or fat and oil calculated as fat, and

(ii) 50 per cent of the calories that would be normally present in the product if it were not calorie-reduced;

(*b*) subject to paragraph (*c*), may contain, either singly or in combination, in an amount not exceeding 0.5 per cent,

(i) acacia gum,

(ii) agar,

(iii) algin,

(iv) carob bean gum,

(v) carrageenan,

(vi) furcelleran,

(vii) gellan gum,

(viii) guar gum,

(ix) karaya gum,

(x) propylene glycol alginate,

(xi) tragacanth gum, and

(xii) xanthan gum;

(*c*) may

(i) if it contains none of the ingredients mentioned in paragraph (*b*), contain polyglycerol esters of fatty acids in an amount not exceeding 0.2 per cent, or

(ii) if it contains a combination of one or more of the ingredients mentioned in paragraph (*b*) and polyglycerol esters of fatty acids, contain such esters in an amount not exceeding 0.2 per cent, provided that the total combination of such esters and ingredients does not exceed an amount of 0.5 per cent;

(*d*) notwithstanding subparagraph B.09.016(*c*)(x), may contain lecithin in an amount not exceeding 0.5 per cent; and

(*e*) may contain

(i) vegetable starch,

(ii) modified vegetable starch, and

(iii) maltodextrin.

SOR/94-38, s. 1; SOR/95-350, s. 1; SOR/96-160, s. 1.

B.09.020. and B.09.021. [Repealed, SOR/88-559, s. 20]

B.09.022. No person shall sell cooking oil, margarine, salad oil, simulated dairy product, shortening or food that resembles margarine or shortening, if the product contains more than five per cent $C_{22}$ Monoenoic Fatty Acids calculated as a proportion of the total fatty acids contained in the product.

# Division 10

# Flavouring Preparations

B.10.003. **[S]. (naming the flavour) Extract** or **(naming the flavour) Essence** shall be a solution in ethyl alcohol, glycerol, propylene glycol or any combination of these, of sapid or odorous principles, or both, derived from the plant after which the flavouring extract or essence is named, and may contain water, a sweetening agent, food colour and a Class II preservative or Class IV preservative.

B.10.004. **[S]. Artificial (naming the flavour) Extract, Artificial (naming the flavour) Essence, Imitation (naming the flavour) Extract** or **Imitation (naming the flavour) Essence** shall be a flavouring extract or essence except that the flavouring principles shall be derived in whole, or in part, from sources other than the aromatic plant after which it is named, and if such extract or essence is defined in these Regulations, the flavouring strength of the artificial or imitation extract or essence shall be not less than that of the extract or essence.

B.10.005. **[S]. (naming the flavour) Flavour**

(*a*) shall be a preparation, other than a flavouring preparation described in section B.10.003, of sapid or odorous principles, or both, derived from the aromatic plant after which the flavour is named;

(*b*) may contain a sweetening agent, food colour, Class II preservative, thaumatin, Class IV preservative or emulsifying agent; and

(*c*) may have added to it the following liquids only:

(i) water,

(ii) any of, or any combination of, the following: benzyl alcohol; 1, 3-butylene glycol, ethyl acetate, ethyl alcohol, glycerol, glyceryl diacetate, glyceryl triacetate, glyceryl tributyrate, isopropyl alcohol, monoglycerides and diglycerides; 1, 2-propylene glycol or triethylcitrate,

(iii) edible vegetable oil, and

(iv) brominated vegetable oil, sucrose acetate isobutyrate or mixtures thereof, when such flavour is used in beverages containing citrus or spruce oils.

SOR/84-300, s. 27(E); SOR/86-1112, s. 1; SOR/2010-142, s. 8.

Previous Version

B.10.006. **[S]. Artificial (naming the flavour) Flavour** or **Imitation (naming the flavour) Flavour** shall be a flavour except that the flavouring principles may be derived in whole or in part from sources other than the aromatic plant after which it is named, and if such flavour is defined in these Regulations, the flavouring strength of the artificial or imitation flavour shall be not less than that of the flavour.

B.10.007. **[S].** Notwithstanding sections B.10.003 and B.10.005, a **(naming the fruit) Extract Naturally Fortified, (naming the fruit) Essence Naturally Fortified** or **(naming the fruit) Flavour Naturally Fortified** shall be an extract, essence or flavour derived from the named fruit to which other natural extractives have been added and 51 per cent of the flavouring strength shall be derived from the named fruit.

B.10.008. On any label of or in any advertisement for an artificial or imitation flavouring preparation, the word “artificial”, or “imitation” shall be an integral part of the name of such flavouring preparation and shall be set out in identical type and identically displayed with such name.

SOR/84-300, s. 28.

B.10.009. **[S]. Almond Essence, Almond Extract** or **Almond Flavour** shall be the essence, extract or flavour derived from the kernels of the bitter almond, apricot or peach and shall contain not less than one per cent by volume of hydrocyanic acid-free volatile oil obtained therefrom.

B.10.010. **[S]. Anise Essence, Anise Extract** or **Anise Flavour** shall be the essence, extract or flavour derived from natural or terpeneless oil of anise and shall correspond in flavouring strength to an alcoholic solution containing not less than three per cent by volume of oil of anise, the volatile oil obtained from the fruit of *Pimpinella anisum* L. or *Illicium verum* Hook.

B.10.011. **[S]. Celery Seed Essence, Celery Seed Extract** or **Celery Seed Flavour** shall be the essence, extract or flavour derived from celery seed, or oil of celery seed, or terpeneless

oil of celery seed and shall correspond in flavouring strength to an alcoholic solution containing not less than 0.3 per cent by volume of volatile oil of celery seed.

B.10.012. **[S]. Cassia Essence, Cassia Extract, Cassia Cinnamon Essence, Cassia Cinnamon Extract, Cassia Flavour** or **Cassia Cinnamon Flavour** shall be the essence, extract or flavour derived from natural or terpeneless oil, obtained from leaves and twigs of *Cinnamomum cassia* L. containing not less than 80 per cent cinnamic aldehyde, and shall correspond in flavouring strength to an alcoholic solution containing not less than two per cent by volume of volatile oil of cassia cinnamon.

B.10.013. **[S]. Ceylon Cinnamon Essence, Ceylon Cinnamon Extract** or **Ceylon Cinnamon Flavour** shall be the essence, extract or flavour derived from the volatile oil obtained from the bark of *Cinnamomum zeylanicum* Nees, and shall contain

(*a*) not less than two per cent by volume of oil of Ceylon cinnamon;

(*b*) not less than 65 per cent cinnamic aldehyde; and

(*c*) not more than 10 per cent eugenol.

B.10.014. **[S]. Clove Essence, Clove Extract** or **Clove Flavour** shall be the essence, extract or flavour derived from the volatile oil obtained from clove buds, and shall contain not less than two per cent by volume of oil of clove.

B.10.015. **[S]. Ginger Essence, Ginger Extract** or **Ginger Flavour** shall be the essence, extract or flavour derived from ginger and shall contain in 100 millilitres the alcohol-soluble matter from not less than 20 grams of ginger.

B.10.016. **[S]. Lemon Essence, Lemon Extract** or **Lemon Flavour** shall be the essence, extract or flavour prepared from natural or terpeneless oil of lemon or from lemon peel and shall contain not less than 0.2 per cent citral derived from oil of lemon.

B.10.017. **[S]. Nutmeg Essence, Nutmeg Extract** or **Nutmeg Flavour** shall be the essence, extract or flavour prepared from natural or terpeneless oil of nutmeg and shall correspond in flavouring strength to an alcoholic solution containing not less than two per cent by volume of oil of nutmeg.

B.10.018. **[S]. Orange Essence, Orange Extract** or **Orange Flavour** shall be the essence, extract or flavour prepared from sweet orange peel, oil of sweet orange or terpeneless oil of sweet orange, and shall correspond in flavouring strength to an alcoholic solution containing five per cent by volume of oil of sweet orange, the volatile oil obtained from the fresh peel of *Citrus aurantium* L., that shall have an optical rotation, at a temperature of 25°C, of not less than +95° using a tube 100 millimetres in length.

B.10.019. **[S]. Peppermint Essence, Peppermint Extract** or **Peppermint Flavour** shall be the essence, extract or flavour prepared from peppermint or oil of peppermint, obtained from the leaves and flowering tops of *Mentha piperita* L., or of *Mentha arvensis* De.C., var. *piperascens* Holmes, and shall correspond in flavouring strength to an alcoholic solution of not less than three per cent by volume of oil of peppermint, containing not less than 50 per cent free and combined menthol.

B.10.020. **[S]. Rose Essence, Rose Extract** or **Rose Flavour** shall be the essence, extract or flavour prepared from the volatile oil obtained from the petals of *Rosa damascena* Mill., *R.*

*centajolia* L., or *R. moschata* Herrm, and shall contain not less than 0.4 per cent by volume of attar of rose.

B.10.021. **[S]. Savory Essence, Savory Extract** or **Savory Flavour** shall be the essence, extract or flavour prepared from savory or oil of savory and shall contain not less than 0.35 per cent by volume oil of savory.

B.10.022. **[S]. Spearmint Essence, Spearmint Extract** or **Spearmint Flavour** shall be the essence, extract or flavour prepared from spearmint or from oil of spearmint, obtained from the leaves and flowering tops of *Mentha spicata* L. and shall contain not less than three per cent by volume of oil of spearmint.

B.10.023. **[S]. Sweet Basil Essence, Sweet Basil Extract** or **Sweet Basil Flavour** shall be the essence, extract or flavour prepared from sweet basil or from oil of sweet basil, obtained from the leaves and tops of *Ocymum basilicum* L. and shall contain not less than 0.1 per cent by volume of oil of sweet basil.

B.10.024. **[S]. Sweet Marjoram Essence, Sweet Marjoram Extract, Marjoram Essence, Marjoram Extract, Sweet Marjoram Flavour** or **Marjoram Flavour** shall be the essence, extract or flavour prepared from marjoram or from oil of marjoram and shall contain not less than one per cent by volume of oil of marjoram.

B.10.025. **[S]. Thyme Essence, Thyme Extract** or **Thyme Flavour** shall be the essence, extract or flavour prepared from thyme or from oil of thyme and shall contain not less than 0.2 per cent by volume of oil of thyme.

B.10.026. **[S]. Vanilla Extract, Vanilla Essence** or **Vanilla Flavour**

(*a*) shall be the essence, extract or flavour prepared from the vanilla bean, the dried, cured fruit of *Vanilla planifolia*, Andrews, or *Vanilla tahitensia*, J. W. Moore;

(*b*) shall contain in 100 ml, regardless of the method of extraction, at least the quantity of soluble substances in their natural proportions that are extractable, according to official method FO-17, Extraction of Soluble Substances from Vanilla Beans, dated September 15, 1989, from

(i) not less than 10 g of vanilla beans, where the beans contain 25 per cent or less moisture, and

(ii) not less than 7.5 g of vanilla beans on the moisture-free basis, where the beans contain more than 25 per cent moisture; and

(*c*) notwithstanding sections B.10.003 and B.10.005, shall not contain added colour.

SOR/82-768, s. 25; SOR/84-300, s. 29(F); SOR/91-149, s. 1.

B.10.027. **[S]. Wintergreen Essence, Wintergreen Extract** or **Wintergreen Flavour** shall be the essence, extract or flavour prepared from oil of wintergreen, the volatile oil distilled from the leaves of *Gaultheria procumbens* L. or from *Betula lenta* L. and shall contain not less than three per cent by volume of oil of wintergreen.

# Division 11

# Fruits, Vegetables, Their Products And Substitutes

[SOR/78-478, s. 1]

B.11.001. In this Division,

“acid ingredient” means

(*a*) citric, malic or tartaric acid,

(*b*) lemon or lime juice, or

(*c*) vinegar; (ingrédient acide)

“fruit juice” means the unfermented liquid expressed from sound ripe fresh fruit, and includes any such liquid that is heat treated and chilled; (jus de fruit)

“sweetening ingredient” means sugar, invert sugar, honey, dextrose, glucose or glucose solids or any combination thereof in dry or liquid form. (ingrédient édulcorant)

B.11.001.1. No person shall sell any fresh fruit or vegetable that is intended to be consumed raw, except grapes, if sulphurous acid or any salt thereof has been added thereto.

SOR/87-374, s. 1.

## Vegetables

B.11.002. **[S].** Canned **(naming the vegetable)**

(*a*) shall be the product obtained by heat processing the named fresh vegetable after it has been properly prepared;

(*b*) shall be packed in hermetically sealed containers;

(*c*) may contain

(i) a sweetening ingredient,

(ii) salt,

(iii) water, and

(iv) a firming agent; and

(*d*) may contain

(i) in the case of canned green beans and canned wax beans, pieces of green peppers, red peppers and tomato in an amount not exceeding 15 per cent of the final product, and dill seasonings and vinegar,

(ii) in the case of canned peas, garnishes composed of one or more of lettuce, onions, carrots, and pieces of green or red peppers in an amount not exceeding 15 per cent of the total drained vegetable ingredient, aromatic herbs, spices and seasonings, stock or juice of vegetables and aromatic herbs, calcium hydroxide in an amount not exceeding 0.01 per cent of the final product and magnesium hydroxide in an amount not exceeding 0.05 per cent of the final product,

(iii) in the case of

(A) canned asparagus, acetic acid, citric acid, malic acid and tartaric acid at levels consistent with good manufacturing practice,

(B) canned white asparagus, acetic acid, citric acid, malic acid, tartaric acid and ascorbic acid at levels consistent with good manufacturing practice, and

(C) canned chili peppers, citric acid at a level consistent with good manufacturing practice,

(iv) in the case of asparagus packed in glass containers or fully lined (lacquered) cans, stannous chloride in an amount not exceeding 25 parts per million, calculated as tin,

(v) in the case of canned artichokes, canned bean sprouts and canned onions, citric acid at levels consistent with good manufacturing practice, to be used as a pH adjusting agent,

(vi) in the case of canned ripe lima beans (butter beans) and canned pinto beans, calcium disodium ethylenediaminetetraacetate in an amount not exceeding 130 parts per million,

(vi.1) in the case of canned fava beans, calcium disodium ethylenediaminetetraacetate in an amount not exceeding 365 parts per million,

(vii) in the case of canned red kidney beans, canned chick peas (garbanzo beans) and canned black-eye peas, disodium ethylenediaminetetraacetate in an amount not exceeding 150 parts per million, and

(viii) in the case of canned asparagus, canned green beans, canned wax beans and canned peas

(A) butter or other edible animal or vegetable fats or oils, but if butter is added it shall be not less than three per cent of the final product,

(B) natural or enzymatically or physically modified starches when used with butter or other edible animal or vegetable fats and oils,

(C) acacia gum, algin, carrageenan, furcelleran, guar gum and propylene glycol alginate used with butter or other edible animal or vegetable fats or oils in an amount not exceeding one per cent, singly or in any combination, of the final product, and

(D) characterizing sauces, seasonings or flavouring agents if it is included in the common name of the product.

SOR/79-660, s. 1; SOR/84-300, s. 30; SOR/95-435, s. 1; SOR/97-561, s. 1.

B.11.003. **[S].** Canned **Mushrooms**

(*a*) shall be the product obtained by heat-processing properly prepared mushrooms of the cultivated type;

(*b*) shall be packed in hermetically sealed containers; and

(*c*) may contain ascorbic acid, citric acid and salt.

SOR/84-300, s. 31.

B.11.003A. **[S]. Frozen Mushrooms**

(*a*) shall be the product obtained by freezing properly prepared mushrooms of the cultivated type; and

(*b*) may contain sodium metabisulphite, sodium phosphate dibasic, sodium sulphate and salt.

B.11.004. **[S]. Frozen (naming the vegetable)** shall be the product obtained by freezing the named fresh vegetable after it has been properly prepared and subjected to a blanching treatment and may contain added salt.

B.11.005. **[S]. Tomatoes** or **Canned Tomatoes**

(*a*) shall be the product made by heat processing properly prepared fresh ripe tomatoes;

(*b*) may contain

(i) a sweetening ingredient in dry form,

(ii) salt,

(iii) a firming agent,

(iv) citric acid, and

(v) spice or other seasoning; and

(*c*) shall contain not less than 50 per cent drained tomato solids, as determined by official method FO-18, Determination of Drained Tomato Solids, October 15, 1981.

SOR/82-768, s. 26.

B.11.007. **[S]. Tomato Juice** shall be the unconcentrated, pasteurized liquid containing a substantial portion of fine tomato pulp extracted from sound, ripe, whole tomatoes from which all stems and objectionable portions have been removed by any method that does not add water to the liquid and may contain salt and a sweetening ingredient in dry form.

B.11.009. **[S]. Tomato Paste** shall be the product made by evaporating a portion of the water from tomatoes or sound tomato trimmings, may contain salt and Class II preservatives and shall contain not less than 20 per cent tomato solids, as determined by official method FO-19, Determination of Tomato Solids, October 15, 1981.

SOR/82-768, s. 27.

B.11.010. **[S]. Concentrated Tomato Paste** shall be tomato paste containing not less than 30 per cent tomato solids, as determined by official method FO-19, Determination of Tomato Solids, October 15, 1981.

SOR/82-768, s. 27.

B.11.011. **[S]. Tomato Pulp** shall be the heat processed product made from whole, ripe tomatoes or sound tomato trimmings concentrated to yield a product with a specific gravity of not less than 1.050 (20°C/20°C) and may contain salt and a Class II preservative.

B.11.012. **[S]. Tomato Puree** shall be the heat processed product made from whole, ripe tomatoes, with the skins and seeds removed, concentrated to yield a product with a specific gravity of not less than 1.050 (20°C/20°C) and may contain salt and a Class II preservative.

B.11.014. **[S]. Tomato Catsup, Catsup** or products whose common names are variants of the word Catsup

(*a*) shall be the heat processed product made from the juice of red-ripe tomatoes or sound tomato trimmings from which skins and seeds have been removed;

(*b*) shall contain

(i) vinegar,

(ii) salt,

(iii) seasoning, and

(iv) a sweetening ingredient; and

(*c*) may contain

(i) a Class II preservative, and

(ii) food colour.

B.11.015. [Repealed, SOR/97-151, s. 19]

B.11.016. No person shall sell canned tomatoes, tomato juice or vegetable juice that contains mould filaments in more than 25 per cent of the microscopic fields, when examined by official method MFO-5, Examination of Canned Tomatoes, Tomato Juice and Vegetable Juice, Tomato Puree, Tomato Paste, Tomato Pulp and Tomato Catsup for Mould Filaments, November 30, 1981.

SOR/82-768, s. 28.

B.11.017. No person shall sell tomato puree, tomato paste, tomato pulp or tomato catsup that contains mould filaments in more than 50 per cent of the microscopic fields, when examined by official method MFO-5, Examination of Canned Tomatoes, Tomato Juice and Vegetable Juice, Tomato Puree, Tomato Paste, Tomato Pulp and Tomato Catsup for Mould Filaments, November 30, 1981.

SOR/82-768, s. 28.

B.11.025. No person shall sell potatoes, sweet potatoes or yams that have been artificially coloured.

B.11.040. **[S]. Beans with Pork** or **Beans and Pork** shall be the food prepared from dried beans and pork, may contain sauce, seasoning, spices and a sweetening agent and shall contain not less than 60 per cent drained solids, as determined by official method FO-20, Determination of Drained Solids of Beans with Pork or Beans and Pork and Beans or Vegetarian Beans, October 15, 1981.

SOR/82-768, s. 29.

B.11.041. **[S]. Beans** or **Vegetarian Beans** shall be the food prepared from dried beans, may contain sauce, seasoning, spices and a sweetening agent and shall contain not less than 60 per cent drained solids, as determined by official method FO-20, Determination of Drained Solids of Beans with Pork or Beans and Pork and Beans or Vegetarian Beans, October 15, 1981.

SOR/82-768, s. 29.

B.11.050. **[S]. Olives** shall be the plain or stuffed fruit of the olive tree, and may contain

(*a*) vinegar;

(*b*) salt;

(*c*) a sweetening ingredient;

(*d*) spices;

(*e*) seasonings;

(*f*) lactic acid;

(*g*) sorbic acid or its potassium or sodium salt;

(*h*) calcium chloride;

(*i*) citric acid; and

(*j*) in the case of ripe olives, ferrous gluconate.

SOR/97-561, s. 2.

B.11.051. **[S].** Pickles and relishes shall be the product prepared from vegetables or fruits with salt and vinegar, and may contain

(*a*) spices;

(*b*) seasonings;

(*c*) sugar, invert sugar, dextrose or glucose, in dry or liquid form;

(*d*) food colour;

(*e*) a Class II preservative;

(*f*) a firming agent;

(*g*) polyoxyethylene (20) sorbitan monooleate in an amount not exceeding 0.05 per cent;

(*h*) lactic acid;

(*i*) vegetable oils; and

(*j*) in the case of relishes and mustard pickles, a thickening agent.

SOR/84-300, s. 32.

## Fruits

B.11.101. **[S].** Canned **(naming the fruit)**

(*a*) shall be the product prepared by heat processing the named fresh fruit after it has been properly prepared;

(*b*) shall be packed in hermetically sealed containers; and

(*c*) may contain

(i) a sweetening ingredient,

(ii) water,

(iii) fruit juice, fruit juice from concentrate, concentrated fruit juice or any combination thereof,

(iv) in the case of canned pears, citric acid, malic acid, L-tartaric or lactic acid at a level sufficient to maintain pH 4.2 to 4.5, lemon juice, spices, spice oils, mint and a flavouring preparation other than that which simulates the flavour of canned pears,

(v) in the case of canned apples, a firming agent,

(vi) in the case of canned applesauce, citric acid and malic acid at a level sufficient to maintain pH 4.2 to 4.5, ascorbic acid and isoascorbic acid provided the total does not exceed 150 parts per million, spices, salt and a flavouring preparation other than that which simulates the flavour of canned applesauce,

(vii) in the case of canned grapefruit, citric acid at a level sufficient to maintain pH 4.2 to 4.5, lemon juice, calcium chloride and calcium lactate provided the total calcium content, whether naturally present or added, does not exceed 0.035 per cent, spices and a flavouring preparation other than that which simulates the flavour of canned grapefruit,

(viii) in the case of canned mandarin oranges, citric acid at a level sufficient to maintain pH 4.2 to 4.5,

(ix) in the case of canned peaches, L-ascorbic acid at a level not to exceed 550 parts per million, spices, peach pits and peach kernels intended for flavour development and a flavouring preparation other than that which simulates the flavour of canned peaches,

(x) in the case of canned pineapple, citric acid at a level sufficient to maintain pH 4.2 to 4.5, spices, spice oils, mint, dimethylpolysiloxane not to exceed 10 parts per million when pineapple juice is used as a packing medium and a flavouring preparation other than that which simulates the flavour of canned pineapple,

(xi) in the case of canned plums, a flavouring preparation other than that which simulates the flavour of canned plums, and

(xii) in the case of canned strawberries, citric acid, lactic acid, malic acid or L-tartaric acid at a level sufficient to maintain pH 4.2 to 4.5.

SOR/84-300, s. 33.

B.11.102. **[S].** Frozen **(naming the fruit)** shall be the product obtained by freezing the named fresh fruit after it has been properly prepared and may contain

(*a*) a sweetening ingredient;

(*b*) water;

(*c*) fruit juice, fruit juice from concentrate, concentrated fruit juice or any combination thereof;

(*d*) ascorbic acid, citric acid, erythorbic acid or malic acid to prevent discolouration; and

(*e*) in the case of frozen sliced apples,

(i) a firming agent, and

(ii) sulphurous acid.

SOR/84-300, s. 34; SOR/95-436, s. 1.

B.11.103. and B.11.104. [Repealed, SOR/79-252, s. 1]

B.11.105. [Repealed, SOR/97-151, s. 20]

## Fruit Juices

B.11.120. **[S]. (Naming the fruit) Juice**

(*a*) shall be the juice obtained from the named fruit; and

(*b*) may contain a sweetening ingredient in dry form, a Class II preservative, amylase, cellulase and pectinase.

SOR/78-402, s. 2; SOR/84-300, s. 35; SOR/90-87, s. 1; SOR/92-591, s. 2.

B.11.121. Notwithstanding section B.11.120, the fruit juice prepared from any fruit named in any of sections B.11.123 to B.11.128A shall conform to the standard prescribed for that fruit juice in that section.

B.11.123. **[S]. Apple Juice**

(*a*) shall be the fruit juice obtained from apples;

(*b*) may contain a Class II preservative, vitamin C, amylase, cellulase and pectinase;

(*c*) shall have a specific gravity of not less than 1.041 and not more than 1.065 (20°C/20°C); and

(*d*) shall contain, in 100 millilitres measured at a temperature of 20°C, not less than 0.24 gram and not more than 0.60 gram of ash of which not less than 50 per cent shall be potassium carbonate.

SOR/90-87, s. 2.

B.11.124. **[S]. Grape Juice**

(*a*) shall be the fruit juice obtained from grapes;

(*b*) shall have a specific gravity of not less than 1.040 and not more than 1.124 (20°C/20°C);

(*c*) shall contain, before the addition of a sweetening ingredient, in 100 millilitres measured at a temperature of 20°C,

(i) not less than 0.20 gram and not more than 0.55 gram of ash, and

(ii) not less than 0.015 gram and not more than 0.070 gram of phosphoric acid calculated as phosphorous pentoxide; and

(*d*) may contain a pH-adjusting agent, a sweetening ingredient in dry form, a Class II preservative, vitamin C, amylase, cellulase and pectinase.

SOR/84-300, s. 36(E); SOR/86-1112, s. 2; SOR/90-87, s. 3.

B.11.125. **[S]. Grapefruit Juice**

(*a*) shall be fruit juice obtained from clean, sound, mature grapefruit;

(*b*) shall

(i) contain not less than 1.15 milliequivalents of free amino acid per 100 millilitres, as determined by official method FO-21, Determination of Amino Acids in Grapefruit Juice and Orange Juice, October 15, 1981,

(ii) contain not less than 70 milligrams of potassium per 100 millilitres, as determined by official method FO-22, Determination of Potassium in Grapefruit Juice and Orange Juice, October 15, 1981, and

(iii) have an absorbance value for total polyphenolics of not less than 0.310, as determined by official method FO-23, Determination of Absorbance Value for Total Polyphenolics in Grapefruit Juice and Orange Juice, October 15, 1981;

(*c*) shall, before the addition of sugar, invert sugar, dextrose or glucose solids,

(i) have a Brix reading of not less than 9.3°, as determined by official method FO-24, Determination of Brix Reading for Grapefruit Juice and Orange Juice, October 15, 1981, and

(ii) contain not less than 0.7 per cent and not more than 2.1 per cent of acid by weight calculated as anhydrous citric acid, as determined by official method FO-25, Determination of Acid in Grapefruit Juice or Orange Juice, October 15, 1981; and

(*d*) may contain sugar, invert sugar, dextrose in dry form, glucose solids, a Class II preservative, amylase, cellulase and pectinase.

SOR/82-768, s. 30; SOR/90-87, s. 4.

B.11.126. **[S]. Lemon Juice**

(*a*) shall be the fruit juice obtained from lemons;

(*b*) shall contain, before the addition of a sweetening ingredient, in 100 millilitres measured at a temperature of 20°C, not less than

(i) 8.0 grams of soluble solids, as determined by official method FO-26, Determination of Soluble Solids in Lemon Juice, Lime Juice or Lime Fruit Juice, October 15, 1981, and

(ii) 5.0 grams of acid calculated as anhydrous citric acid, as determined by official method FO-27, Determination of Acid in Lemon Juice, Lime Juice, or Lime Fruit Juice, October 15, 1981;

(*c*) may contain stannous chloride; and

(*d*) may contain a sweetening ingredient in a dry form, a Class II preservative, amylase, cellulase and pectinase.

SOR/82-768, s. 31; SOR/90-87, s. 5.

B.11.127. **[S]. Lime Juice** or **Lime Fruit Juice**

(*a*) shall be the fruit juice obtained from limes;

(*b*) shall have

(i) a specific gravity of not less than 1.030 and not more than 1.040 (20°C/20°C),

(ii) its optical rotation between +0.5 and -1.5 degrees Ventzke, determined at a temperature of 20°C, using a tube 200 millimetres in length;

(*c*) shall contain, before the addition of a sweetening ingredient, in 100 millilitres measured at a temperature of 20°C, not less than

(i) 8.0 grams of soluble solids, as determined by official method FO-26, Determination of Soluble Solids in Lemon Juice, Lime Juice or Lime Fruit Juice, October 15, 1981, and

(ii) 5.5 grams of acid calculated as anhydrous citric acid, as determined by official method FO-27, Determination of Acid in Lemon Juice, Lime Juice or Lime Fruit Juice, October 15, 1981;

(*d*) may contain stannous chloride; and

(*e*) may contain a sweetening ingredient in a dry form, a Class II preservative, amylase, cellulase and pectinase.

SOR/82-768, s. 32; SOR/90-87, s. 6.

B.11.128. **[S]. Orange Juice**

(*a*) shall be fruit juice obtained from clean, sound, mature oranges;

(*b*) shall

(i) contain not less than 1.20 milliequivalents of free amino acids per 100 millilitres, as determined by official method FO-21, Determination of Amino Acids in Grapefruit Juice and Orange Juice, October 15, 1981,

(ii) contain not less than 115 milligrams of potassium per 100 millilitres, as determined by official method FO-22, Determination of Potassium in Grapefruit Juice and Orange Juice, October 15, 1981, and

(iii) have an absorbance value for total polyphenolics of not less than 0.380, as determined by official method FO-23, Determination of Absorbance Value for Total Polyphenolics in Grapefruit Juice and Orange Juice, October 15, 1981;

(*c*) shall, before the addition of sugar, invert sugar, dextrose or glucose solids,

(i) have a Brix reading of not less than 9.7°, as determined by official method FO-24, Determination of Brix Reading for Grapefruit Juice and Orange Juice, October 15, 1981, and

(ii) contain not less than 0.5 per cent and not more than 1.8 per cent of acid by weight calculated as anhydrous citric acid, as determined by official method FO-25, Determination of Acid in Grapefruit Juice or Orange Juice, October 15, 1981;

(*d*) may contain orange essences, orange oils and orange pulp adjusted in accordance with good manufacturing practice; and

(*e*) may contain sugar, invert sugar, dextrose in dry form, glucose solids, a Class II preservative, amylase, cellulase and pectinase.

SOR/82-768, s. 33; SOR/90-87, s. 7.

B.11.128A. **[S]. Pineapple Juice**

(*a*) shall be the fruit juice obtained from pineapple; and

(*b*) may contain a sweetening ingredient in dry form, a Class II preservative, vitamin C, amylase, cellulase, pectinase and an antifoaming agent.

SOR/90-87, s. 8; SOR/91-90, s. 1.

B.11.129. **[S]. Carbonated (naming the fruit) Juice** or **Sparkling (naming the fruit) Juice** shall be the named fruit juice impregnated with carbon dioxide under pressure.

B.11.130. **[S].** (1) **Concentrated (naming the fruit) juice**

(*a*) shall be fruit juice that is concentrated to at least one half of its original volume by the removal of water;

(*b*) may contain

(i) vitamin C,

(ii) food colour,

(iii) stannous chloride,

(iv) a sweetening ingredient, and

(v) a class II preservative; and

(*c*) may have added to it, for the purpose of adjustment in accordance with good manufacturing practice, all or any of the following, namely,

(i) essence, oil and pulp from the named fruit, and

(ii) water.

(2) Subparagraphs (1)(*b*)(i), (ii), (iii) and (v) do not apply in respect of frozen concentrated orange juice.

SOR/89-198, s. 2; SOR/91-124, s. 3.

B.11.131. **[S]. (Naming the fruits) Juice** shall be a mixture of fruit juices each of which meets the standard prescribed for that fruit juice in this Division.

B.11.132. **[S]. Apple and (naming the fruit) Juice**

(*a*) shall be a mixture of apple juice and another fruit juice, each of which meets the standard, if any, prescribed for that fruit juice in this Division; and

(*b*) may contain added vitamin C.

B.11.133. **[S]. Reconstituted (naming the fruit) Juice** or **(naming the fruit) Juice from Concentrate**

(*a*) shall be fruit juice that has been prepared by the addition of water to fruit juice of the same name from which water has been removed;

(*b*) may contain juice of the same name, a sweetening ingredient, and natural pulp, oils and esters of the named fruit;

(*c*) shall conform to the standards for the named fruit juices as prescribed in this Division; and

(*d*) may contain, in the case of reconstituted lemon or lime juice, not more than 10 parts per million dimethylpolysiloxane.

SOR/78-637, s. 2.

B.11.134. **[S]. Apricot Nectar, Peach Nectar or Pear Nectar**

(*a*) shall be the unfermented but fermentable pulpy product, intended for direct consumption, obtained by blending the total edible part of sound and ripe apricots, peaches and pears, as the case may be, concentrated or unconcentrated with water and, subject to subparagraph (*e*)(i), a sweetening ingredient;

(*b*) shall contain

(i) in the case of peach nectar and pear nectar, not less than 40 per cent by weight of the fruit or the equivalent derived from the concentrated fruit, and

(ii) in the case of apricot nectar, not less than 35 per cent by weight of the fruit or the equivalent derived from the concentrated fruit;

(*c*) shall contain not less than 13 per cent soluble solids by weight expressed as °Brix on the International Sucrose Scales and calculated by refractometer at 20°C and uncorrected for acidity;

(*d*) shall not contain more than 3 g/kg (3000 p.p.m.) of ethanol and 10 mg/kg (10 p.p.m.) of hydroxy methyl furfural; and

(*e*) may contain

(i) honey if no other sweetening ingredient is employed,

(ii) citric acid and malic acid at levels consistent with good manufacturing practice,

(iii) lemon juice, and

(iv) vitamin C.

SOR/79-660, s. 2; SOR/2010-94, s. 9(E).

Previous Version

## Fruit Flavoured Drinks

B.11.150. No person shall label, package, sell or advertise a fruit flavoured drink in a manner that is likely to create an impression that the fruit flavoured drink contains vitamins or has any other nutritional value commonly associated with any fruit juice unless the following requirements are met:

(*a*) it is sold as a substitute for fruit juice or as a breakfast drink;

(*b*) it is not carbonated;

(*c*) it is not represented to be or is not commonly known as

(i) a soft drink, or

(ii) a thirst-quenching or refreshment drink; and

(*d*) notwithstanding sections D.01.009, D.01.011 and D.02.009,

(i) it contains vitamin C in an amount not less than 24 milligrams and not more than 48 milligrams, and

(ii) it contains

(A) where folic acid has been added, an amount of folic acid of not less than 40 micrograms and not more than 80 micrograms,

(B) where thiamine has been added, an amount of thiamine of not less than 0.08 milligram and not more than 0.11 milligram,

(C) where iron has been added, an amount of iron of not less than 0.56 milligram and not more than 0.80 milligram, or

(D) where potassium has been added, an amount of potassium of not less than 100 milligrams and not more than 200 milligrams,

per 100 millilitres when the drink is ready to serve.

SOR/78-478, s. 2.

B.11.151. No person shall label, package, sell or advertise a base, concentrate or mix that is used for making a fruit flavoured drink in a manner that is likely to create an impression that the drink made therefrom will contain vitamins or have any other nutritional value commonly associated with fruit juice unless the following requirements are met:

(*a*) the base, concentrate or mix

(i) is sold for the purpose of making a breakfast drink or a substitute for fruit juice,

(ii) is not represented to be or is not commonly known as a product that is used for making a soft drink or a thirst-quenching or refreshment drink; and

(*b*) where a drink is made therefrom as directed, the drink meets the requirements described in paragraph B.11.150(*d*).

SOR/78-478, s. 2.

## Jams

B.11.201. **[S]. (Naming the fruit) Jam**

(*a*) shall be the product obtained by processing fruit, fruit pulp, or canned fruit, by boiling to a suitable consistency with water and a sweetening ingredient;

(*b*) shall contain not less than

(i) 45 per cent of the named fruit, and

(ii) 66 per cent water soluble solids as estimated by the refractometer;

(*c*) may contain

(i) such amount of added pectin, pectinous preparation, or acid ingredient as reasonably compensates for any deficiency in the natural pectin content or acidity of the named fruit,

(ii) a Class II preservative,

(iii) a pH adjusting agent, and

(iv) an antifoaming agent; and

(*d*) shall not contain apple or rhubarb.

SOR/92-400, s. 16.

B.11.202. **[S]. (Naming the fruit) Jam with Pectin**

(*a*) shall be the product obtained by processing fruit, fruit pulp, or canned fruit by boiling to a suitable consistency with water and a sweetening ingredient;

(*b*) shall contain

(i) not less than 27 per cent of the named fruit,

(ii) not less than 66 per cent water soluble solids as estimated by the refractometer, and

(iii) pectin or pectinous preparations;

(*c*) may contain

(i) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the named fruit,

(ii) food colour,

(iii) a Class II preservative,

(iv) a pH adjusting agent, and

(v) an antifoaming agent; and

(*d*) shall not contain apple or rhubarb.

SOR/92-400, s. 17.

B.11.203. **[S]. Apple (or Rhubarb)** and **(naming the fruit) Jam**

(*a*) shall be the product obtained by processing fruit, fruit pulp or canned fruit by boiling to a suitable consistency with water and a sweetening ingredient;

(*b*) shall contain not less than

(i) 12.5 per cent of the named fruit, except that where the named fruit is strawberry it shall contain not less than 15 per cent strawberries,

(ii) 20 per cent apple or rhubarb pulp, and

(iii) 66 per cent water soluble solids as estimated by the refractometer; and

(*c*) may contain

(i) pectin or pectinous preparation,

(ii) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the fruit used in its preparation,

(iii) food colour,

(iv) a Class II preservative,

(v) a pH adjusting agent, and

(vi) an antifoaming agent.

B.11.204. Where a jam for which a standard is prescribed in section B.11.203 contains added pectin or pectinous preparation, a statement to the effect that pectin or pectinous preparation has been added shall be shown on the principal display panel.

## Marmalade

B.11.220. **[S]. (Naming the citrus fruit) Marmalade** shall be the food of jelly-like consistency made from any combination of peel, pulp or juice of the named citrus fruit by boiling with water and a sweetening ingredient and shall contain not less than 65 per cent water soluble solids as estimated by the refractometer and may contain

(*a*) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the named citrus fruit;

(*b*) a pH adjusting agent; and

(*c*) an antifoaming agent.

B.11.221. **[S]. (Naming the citrus fruit) Marmalade with Pectin**

(*a*) shall be the food of jelly-like consistency made from any combination of peel, pulp or juice of the named citrus fruit by boiling with water and a sweetening ingredient;

(*b*) shall contain

(i) not less than 27 per cent of any combination of peel, pulp or juice of the named citrus fruit,

(ii) not less than 65 per cent water soluble solids as estimated by the refractometer, and

(iii) pectin or pectinous preparation; and

(*c*) may contain

(i) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the citrus fruit used in its preparation,

(ii) a Class II preservative,

(iii) a pH adjusting agent, and

(iv) an antifoaming agent.

B.11.222. **[S]. Pineapple Marmalade** or **Fig Marmalade**

(*a*) shall be the food of jelly-like consistency made from the pulp of juice of the named fruit by boiling with water and a sweetening ingredient;

(*b*) shall contain not less than

(i) 45 per cent of the named fruit, and

(ii) 65 per cent water soluble solids, as estimated by the refractometer;

(*c*) may contain such amounts of added pectin, pectinous preparation or acid ingredient as reasonably compensates for any deficiency in the natural pectin content or acidity of the named fruit;

(*d*) a pH adjusting agent; and

(*e*) an antifoaming agent.

B.11.223. **[S]. Pineapple Marmalade with Pectin** or **Fig Marmalade with Pectin**

(*a*) shall be the food of jelly-like consistency made from the pulp and juice of the named fruit by boiling with water and a sweetening ingredient;

(*b*) shall contain

(i) not less than 27 per cent of the named fruit,

(ii) not less than 65 per cent water soluble solids as estimated by the refractometer, and

(iii) pectin or pectinous preparation; and

(*c*) may contain

(i) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the named fruit,

(ii) food colour,

(iii) a Class II preservative,

(iv) a pH adjusting agent, and

(v) an antifoaming agent.

SOR/84-300, s. 37(E).

B.11.224. **[S]. (Naming the fruit) Preserve (Conserve)** shall be the food made by processing fruit other than apple or rhubarb with a sweetening ingredient and shall contain not less than

(*a*) 45 parts by weight of the named fruit for each 55 parts by weight, on the dry basis, of a sweetening ingredient; and

(*b*) 60 per cent water-soluble solids, as estimated by the refractometer.

## Jelly

B.11.240. **[S]. (Naming the fruit) Jelly** shall be the gelatinous food, free of seeds and pulp, made from the named fruit, the juice of the named fruit or a concentrate of the juice of the named fruit, which has been boiled with water and a sweetening ingredient, shall contain not less than 62 per cent water soluble solids as estimated by the refractometer and may contain

(*a*) such amount of added pectin, pectinous preparation or acid ingredient as reasonably compensates for any deficiency of the natural pectin content or acidity of the named fruit;

(*b*) a pH adjusting agent; and

(*c*) an antifoaming agent.

B.11.241. **[S]. (Naming the fruit) Jelly with Pectin**

(*a*) shall be the gelatinous food, free of seeds and pulp, made from the named fruit, the juice of the named fruit or a concentrate of the juice of the named fruit, which has been boiled with water and a sweetening ingredient;

(*b*) shall contain

(i) not less than the equivalent of 32 per cent juice of the named fruit,

(ii) not less than 62 per cent water soluble solids, as estimated by the refractometer, and

(iii) pectin or pectinous preparation; and

(*c*) may contain

(i) such amount of acid ingredient as reasonably compensates for any deficiency in the natural acidity of the named fruit,

(ii) juice of another fruit,

(iii) a gelling agent,

(iv) food colour,

(v) a Class II preservative,

(vi) a pH adjusting agent, and

(vii) an antifoaming agent.

B.11.242. The standards prescribed in these Regulations for jam and jelly do not apply to cranberry sauce, jellied cranberry, cranberry jelly, mint jelly and jellied mint.

### Mince Meat

B.11.250. **[S]. Mince, Mince Meat** or **Fruit Mince**

(*a*) shall be the food prepared from

(i) fruit or dried fruit,

(ii) suet,

(iii) salt,

(iv) spices, and

(v) a sweetening agent; and

(*b*) may contain

(i) vinegar,

(ii) fresh, concentrated or fermented fruit juice,

(iii) spiritous liquor,

(iv) nuts,

(v) cooked meat,

(vi) a Class II preservative,

(vii) a thickening agent,

(viii) citric acid, and

(ix) caramel.

SOR/84-300, s. 38(F).

### Boiled Cider

B.11.260. **[S]. Boiled Cider** shall be the liquid expressed from whole apples, apple cores, apple trimmings or apple culls and concentrated by boiling.

# Division 12

# Prepackaged Water And Ice

[SOR/80-633, s. 1]

B.12.001. **[S].** Water represented as mineral water or spring water,

(*a*) shall be potable water obtained from an underground source but not obtained from a public community water supply;

(*b*) shall not contain any coliform bacteria, as determined by official method MFO-9, Microbiological Examination of Mineral Water, November 30, 1981;

(*c*) shall not have its composition modified through the use of any chemicals; and

(*d*) notwithstanding paragraph (*c*), may contain

(i) added carbon dioxide,

(ii) added fluoride, if the total fluoride ion content thereof does not exceed one part per million, and

(iii) added ozone.

SOR/80-633, s. 2; SOR/82-768, s. 34.

B.12.002. The principal display panel of the label on a container of water represented as mineral water or spring water shall carry a statement

(*a*) of the geographical location of the underground source from which it is obtained;

(*b*) of the total dissolved mineral salt content expressed in parts per million;

(*c*) of the total fluoride ion content expressed in parts per million; and

(*d*) of any addition of fluoride or ozone thereto.

SOR/84-300, s. 39(F); SOR/88-336, s. 3; SOR/92-626, s. 14(F).

B.12.003. Where carbon dioxide has been added to water represented as mineral water or spring water, the word “carbonated” (“gazéifiée”) shall appear on the principal display panel of the label on the container thereof, as the first designation in the common name of the water when the added carbon dioxide

(*a*) did not originate from decarbonation of the water upon emergence from the underground source; or

(*b*) is present in a quantity greater than was present originally in the water.

SOR/84-300, s. 40(F); SOR/88-336, s. 3.

B.12.004. No person shall sell water in sealed containers, other than water represented as mineral water or spring water, if it contains

(*a*) any coliform bacteria, as determined by official method MFO-15, Microbiological Examination of Water in Sealed Containers (Excluding Mineral and Spring Water) and of Prepackaged Ice, November 30, 1981;

(*b*) more than 100 total aerobic bacteria per millilitre, as determined by official method MFO-15, Microbiological Examination of Water in Sealed Containers (Excluding Mineral and Spring Water) and of Prepackaged Ice, November 30, 1981;

(*c*) naturally occurring fluoride ion in an amount that exceeds its naturally occurring amount; or

(*d*) added fluoride in such an amount that the total amount therein of added and naturally occurring fluoride ion exceeds one part per million.

SOR/80-633, s. 3; SOR/82-768, s. 35.

B.12.005. (1) No person shall sell prepackaged ice if it contains

(*a*) any coliform bacteria, as determined by official method MFO-15, Microbiological Examination of Water in Sealed Containers (Excluding Mineral and Spring Water) and of Prepackaged Ice, November 30, 1981;

(*b*) naturally occurring fluoride ion in an amount that exceeds its naturally occurring amount; or

(*c*) added fluoride in such an amount that the total amount therein of added and naturally occurring fluoride ion exceeds one part per million.

(2) No person shall manufacture prepackaged ice for sale if the water from which it is made contains

(*a*) any coliform bacteria, as determined by official method MFO-15, Microbiological Examination of Water in Sealed Containers (Excluding Mineral and Spring Water) and of Prepackaged Ice, November 30, 1981;

(*b*) naturally occurring fluoride ion in an amount that exceeds its naturally occurring amount; or

(*c*) added fluoride in such an amount that the total amount therein of added and naturally occurring fluoride ion exceeds one part per million.

SOR/80-633, s. 3; SOR/82-768, s. 36.

B.12.006. The common name of water in sealed containers, other than water represented as mineral water or spring water, shall be “Water”, modified by the word

(*a*) “Distilled” when the treatment of the water includes its vaporization and condensation;

(*b*) “Demineralized” when the treatment of the water is such that the mineral content of the water is reduced, by means other than distillation, to less than 10 parts per million; and

(*c*) “Carbonated” when the water contains added carbon dioxide.

SOR/80-633, s. 3.

B.12.007. Notwithstanding section B.01.008, when chlorine or any compounds of chlorine have been

(*a*) used in the treatment of water in sealed containers, other than water represented as mineral water or spring water, and

(*b*) subsequently removed from the water together with any chlorine and compounds of chlorine produced in the water,

chlorine or any compounds of chlorine need not be shown as ingredients on any part of the label on a sealed container of that water.

SOR/80-633, s. 3.

B.12.008. A statement of the total fluoride ion content expressed in parts per million shall appear on the principal display panel of the label on a sealed container of water, other than water represented as mineral water or spring water and on the label on a container of prepackaged ice.

SOR/80-633, s. 3; SOR/2000-353, s. 5(E).

B.12.009. The label on a sealed container of water, other than water represented as mineral water or spring water, shall bear a description on its principal display panel of any treatment the water has undergone, with the exception of the following:

(*a*) the addition of an ingredient declared in the list of ingredients;

(*b*) chlorination followed by the removal of the agent used for the chlorination together with any chlorine and compounds of chlorine produced in the water;

(*c*) decantation; and

(*d*) filtration.

SOR/80-633, s. 3; SOR/2000-353, s. 5(E).

# Division 13

# Grain And Bakery Products

B.13.001. **[S]. Flour, White Flour, Enriched Flour** or **Enriched White Flour**

(*a*) shall be the food prepared by the grinding and bolting through cloth having openings not larger than those of woven wire cloth designated “149 microns (No. 100)”, of cleaned milling grades of wheat;

(*b*) shall be free from bran coat and germ to such an extent that the percentage of ash therein, before the addition of any other material permitted by this section, calculated on a moisture-free basis, does not exceed 1.20 per cent;

(*c*) shall have a moisture content of not more than 15 per cent;

(*d*) shall contain in 100 grams of flour

(i) 0.64 milligram of thiamine,

(ii) 0.40 milligram of riboflavin,

(iii) 5.30 milligrams of niacin or niacinamide,

(iv) 0.15 milligram of folic acid, and

(v) 4.4 milligrams of iron;

(*e*) may contain

(i) malted wheat flour,

(ii) malted barley flour in an amount not exceeding 0.50 per cent of the weight of the flour,

(iii) amylase, amylase (maltogenic), bromelain, glucoamylase, glucose oxidase, lactase, lipase, lipoxidase, pentosanase, protease, pullulanase or xylanase,

(iv) chlorine,

(v) chlorine dioxide,

(vi) benzoyl peroxide in an amount not exceeding 150 parts by weight for each one million parts of flour, with or without not more than 900 parts by weight for each one million parts of flour of one or a mixture of two or more of calcium carbonate, calcium sulphate, dicalcium phosphate, magnesium carbonate, potassium aluminum sulphate, sodium aluminum sulphate, starch and tricalcium phosphate as carriers of the benzoyl peroxide,

(vii) [Repealed, SOR/94-227, s. 1]

(viii) ammonium persulphate in an amount not exceeding 250 parts by weight for each one million parts of flour,

(ix) ammonium chloride in an amount not exceeding 2,000 parts by weight for each one million parts of flour,

(x) acetone peroxide,

(xi) azodicarbonamide in an amount not exceeding 45 parts by weight for each one million parts of flour,

(xii) ascorbic acid in an amount not exceeding 200 parts by weight for each one million parts of flour,

(xiii) *l*-cysteine (hydrochloride) in an amount not exceeding 90 parts by weight for each one million parts of flour,

(xiv) monocalcium phosphate in an amount not exceeding 7,500 parts by weight for each one million parts of flour, and

(xv) in 100 grams of flour

(A) 0.31 milligram of vitamin $B_6$,

(B) 1.3 milligrams of *d*-pantothenic acid, and

(C) 190 milligrams of magnesium; and

(*f*) may contain calcium carbonate, edible bone meal, chalk (B.P.), ground limestone or calcium sulphate in an amount that will provide in 100 grams of flour 140 milligrams of calcium.

(*g*) [Repealed, SOR/97-151, s. 21]

SOR/78-402, s. 3; SOR/78-698, s. 2; SOR/80-632, s. 3; SOR/82-383, s. 5; SOR/84-300, s. 41(E); SOR/89-145, s. 1; SOR/92-63, s. 1; SOR/92-94, s. 1; SOR/94-227, s. 1; SOR/94-689, s. 2; SOR/96-527, s. 1; SOR/97-122, s. 1; SOR/97-151, s. 21; SOR/97-558, s. 1; SOR/98-550, s. 1; SOR/2003-130, s. 1.

B.13.002. Notwithstanding section B.13.001, flour, white flour, enriched flour or enriched white flour, used in or sold for the manufacture of gluten or starch is not required to contain added thiamine, riboflavin, niacin, folic acid or iron.

SOR/98-550, s. 2.

B.13.003. **[S]. Vitamin B White Flour (Canada Approved)**

(*a*) shall be flour that has been milled in such a way as to retain a high proportion of the vitamins naturally occurring in the original wheat berry;

(*b*) shall constitute not less than 70 per cent of the wheat from which it is milled;

(*c*) shall be bolted through at least one cloth having openings not larger than those of woven wire cloth designated “149 microns (No. 100)”; and

(*d*) shall contain, on a moisture-free basis,

(i) in one pound an amount of the vitamin B complex that will contribute not less than 1.2 milligrams of thiamine, and

(ii) not more than 0.70 per cent and not less than 0.61 per cent ash.

B.13.004. [Repealed, SOR/79-252, s. 2]

B.13.005. **[S]. Whole Wheat Flour** or **Entire Wheat Flour**

(*a*) shall be the food prepared by the grinding and bolting of cleaned, milling grades of wheat from which a part of the outer bran or epidermis layer may have been separated;

(*b*) shall contain the natural constituents of the wheat berry to the extent of not less than 95 per cent of the total weight of the wheat from which it is milled;

(*c*) shall have

(i) an ash content, calculated on a moisture-free basis, of not less than 1.25 per cent and not more than 2.25 per cent,

(ii) a moisture content of not more than 15 per cent, and

(iii) such a degree of fineness that not less than 90 per cent bolts freely through a No. 8 (2 380 micron) sieve, and not less than 50 per cent through a No. 20 (840 micron) sieve; and

(*d*) may contain

(i) malted wheat flour,

(ii) malted barley flour in an amount not exceeding 0.50 per cent of the weight of the flour,

(iii) amylase, amylase (maltogenic), bromelain, glucoamylase, glucose oxidase, lactase, lipase, lipoxidase, pentosanase, protease, pullulanase, or xylanase,

(iv) chlorine,

(v) chlorine dioxide,

(vi) benzoyl peroxide in an amount not exceeding 150 parts by weight for each one million parts of flour, with or without not more than 900 parts by weight for each one million parts of flour of one or a mixture of two or more of calcium carbonate, calcium sulphate, dicalcium phosphate, magnesium carbonate, potassium aluminum sulphate, sodium aluminum sulphate, starch and tricalcium phosphate as carriers of the benzoyl peroxide,

(vii) [Repealed, SOR/94-227, s. 2]

(viii) ammonium persulphate in an amount not exceeding 250 parts by weight for each one million parts of flour,

(ix) ammonium chloride in an amount not exceeding 2,000 parts by weight for each one million parts of flour,

(x) azodicarbonamide in an amount not exceeding 45 parts by weight for each one million parts of flour,

(xi) acetone peroxide,

(xii) ascorbic acid in an amount not exceeding 200 parts by weight for each one million parts of flour, and

(xiii) *l*-cysteine (hydrochloride) in an amount not exceeding 90 parts by weight for each one million parts of flour.

(*e*) [Repealed, SOR/97-151, s. 22]

SOR/78-402, s. 4; SOR/80-632, s. 4; SOR/82-383, s. 6; SOR/92-63, s. 2; SOR/92-94, s. 2; SOR/94-227, s. 2; SOR/94-689, s. 2; SOR/97-122, s. 2; SOR/97-151, s. 22; SOR/97-558, s. 2; SOR/2000-184, s. 63(F); SOR/2003-130, s. 2.

B.13.006. **[S]. Graham Flour** shall be flour to which has been added part of the bran and other constituents of the wheat berry, and shall have an ash content, calculated on a moisture-free basis, of not less than 1.20 per cent and not more than 2.25 per cent.

B.13.007. **[S]. Gluten Flour** shall be the food obtained by removing from flour a part of the starch and shall not contain more than

(*a*) 10 per cent moisture, and

(*b*) 44 per cent Starch, calculated on a moisture-free basis, as determined by official method FO-28, Determination of Starch in Gluten Flour, October 15, 1981.

SOR/82-768, s. 37.

B.13.008. **[S]. Crushed Wheat** or **Coarse Ground Wheat** shall be the food prepared by so crushing cleaned wheat that 40 per cent or more passes through a No. 8 (2 380 micron) sieve and less than 50 per cent through a No. 20 (840 micron) sieve, the proportions of the natural constituents of such wheat, other than moisture, remaining unaltered and shall have

(*a*) an ash content, calculated on a moisture-free basis, of not less than 1.50 per cent and not more than 2.25 per cent; and

(*b*) a moisture content of not more than 15.5 per cent.

B.13.009. **[S]. Cracked Wheat** shall be the food prepared by so cracking or cutting cleaned wheat into angular fragments that not less than 90 per cent passes through a No. 8 (2 380 micron) sieve and not more than 20 per cent through a No. 20 (840 micron) sieve, the proportions of the natural constituents of such wheat, other than moisture, remaining unaltered and shall have

(*a*) an ash content, calculated on a moisture-free basis, of not less than 1.50 per cent and not more than 2.25 per cent; and

(*b*) a moisture content of not more than 15.5 per cent.

B.13.010. **[S]. Rice** shall be the hulled or hulled and polished seed of the rice plant and, in the case of hulled and polished seeds, may be coated with magnesium silicate, talc and glucose.

SOR/78-403, s. 3.

B.13.010.1. (1) For the purposes of this Division, precooked rice means polished rice that has been cooked in water or steam and dried in such a manner as to retain the rice grains in a porous and open-structured condition.

(2) Notwithstanding sections D.01.009, D.01.011 and D.02.009, no person shall sell pre-cooked rice to which a vitamin or mineral nutrient set out in Column I of an item of the table to this section has been added, either singly or in any combination, unless each 100 g of the pre-cooked rice as sold contains the added vitamin or mineral nutrient in the amount set out in Column II of that item.

TABLE

| | Column I | Column II |
|---|---|---|
| Item | Vitamin or Mineral Nutrient | Amount per 100 g of Pre-cooked Rice |
| 1. | Thiamine | 0.45 mg |
| 2. | Niacin | 4.2 mg |
| 3. | Vitamin $B_6$ | 0.6 mg |
| 4. | Folic acid | 0.016 mg |
| 5. | Pantothenic acid | 1.2 mg |
| 6. | Iron | 1.6 mg |

(3) No person shall represent pre-cooked rice as “enriched” unless the food contains added thiamine, niacin and iron.

SOR/86-320, s. 1; SOR/98-458, s. 7(F).

B.13.011. **[S].** Corn Starch shall be starch made from maize and shall contain not less than 84 per cent starch.

SOR/84-300, s. 42.

B.13.014. For the purpose of this Division, moisture, ash and fineness shall be determined by the following applicable official methods:

(*a*) FO-29, Determination of Moisture in Grain, October 15, 1981;

(*b*) FO-30, Determination of Ash in Grain, October 15, 1981; and

(*c*) FO-31, Determination of Degree of Fineness of Grain, October 15, 1981.

SOR/82-768, s. 38.

B.13.015. **[S]. Cottonseed Flour** or similar products from cottonseed shall be derived from decorticated, defatted or partially defatted, cooked, ground cottonseed kernels and contain not more than 450 parts per million of free gossypol.

B.13.020. In this Division, “milk solids” means the entire solids content from milk, partly skimmed milk or skim milk or their concentrated, dried or reconstituted form, singly or in any combination.

SOR/89-170, s. 1.

## Bread

B.13.021. **[S]. Bread** or **White Bread** shall be the food made by baking a yeast-leavened dough prepared with flour and water and may contain

(*a*) salt;

(*b*) shortening, lard, butter or margarine;

(*c*) milk or milk product;

(*d*) whole egg, egg-white; egg-yolk, (fresh, dried, or frozen);

(*e*) a sweetening agent;

(*f*) malt syrup, malt extract or malt flour;

(*g*) inactive dried yeast of the genus *Saccharomyces cerevisiae* in an amount not greater than two parts by weight for each 100 parts of flour used;

(*h*) amylase, amylase (maltogenic), bromelain, glucoamylase, glucose oxidase, lactase, lipase, lipoxidase, pentosanase, protease, pullulanase, or xylanase;

(*i*) subject to section B.13.029, one or more of the following in a total amount not exceeding five parts by weight per 100 parts of flour used, namely, whole wheat flour, entire wheat flour, graham flour, gluten flour, wheat meal, wheat starch, non-wheat flour, non-wheat meal or non-wheat starch, any of which may be wholly or partially dextrinized;

(*j*) other parts of the wheat berry;

(*k*) lecithin or ammonium salt of phosphorylated glyceride;

(*l*) monoglycerides and diglycerides of fat-forming fatty acids,

(*m*) ammonium chloride, ammonium sulphate, calcium carbonate, calcium lactate, diammonium phosphate, dicalcium phosphate, monoammonium phosphate or any combination thereof in an amount not greater than 0.25 parts by weight of all such additives for each 100 parts of flour used;

(*n*) monocalcium phosphate in an amount not greater than 0.75 parts by weight for each 100 parts of flour used;

(*o*) calcium peroxide, ammonium persulphate, potassium persulphate or any combination thereof in an amount not greater than 0.01 part by weight of all such additives for each 100 parts of flour used;

(*p*) acetone peroxide;

(*q*) vinegar;

(*r*) Class III preservative;

(*s*) food colour;

(*t*) calcium stearoyl-2-lactylate or sodium stearoyl-2-lactylate in an amount not greater than 0.375 parts by weight for each 100 parts of flour used;

(*u*) *l*-cysteine (hydrochloride) in an amount not greater than 0.009 parts by weight for each 100 parts of flour used;

(*v*) calcium sulphate in an amount not greater than 0.5 parts by weight for each 100 parts of flour used;

(*w*) sodium stearyl fumarate in an amount not greater than 0.5 parts by weight for each 100 parts of flour used;

(*x*) ascorbic acid in an amount not greater than 0.02 parts by weight for each 100 parts of flour used;

(*y*) lactic acid;

(*z*) azodicarbonamide in an amount not exceeding 45 parts by weight for each one million parts of flour;

(*aa*) calcium iodate, potassium iodate or any combination thereof in an amount not greater than 45 parts by weight of all such additives for each one million parts of flour; and

(*bb*) acetylated tartaric acid esters of mono- and diglycerides in an amount not greater than 0.6 parts by weight for each 100 parts of flour used.

SOR/78-402, s. 5; SOR/79-251, s. 2; SOR/82-383, ss. 7, 8; SOR/84-300, s. 43(E); SOR/92-63, s. 3; SOR/92-94, s. 3; SOR/94-227, s. 3; SOR/97-122, s. 3; SOR/97-558, s. 3; SOR/2003-130, s. 3; SOR/2007-302, s. 4(F).

Previous Version

B.13.022. **[S]. Enriched Bread** or **Enriched White Bread**

(*a*) shall be bread that is baked from a dough in which enriched flour is the only wheat flour used;

(*b*) shall contain

(i) for each 100 parts of flour used, not less than

(A) two parts by weight of skim milk solids,

(B) four parts by weight of dried whey powder, or

(C) such amount of the protein product made from peas (*Pisum sativum*) or soybeans (*Glycine max*) as will provide 0.5 parts by weight of protein, and

(ii) in 100 grams of bread,

(A) 0.40 milligram of thiamine,

(B) 0.24 milligram of riboflavin,

(C) 3.3 milligrams of niacin or niacinamide,

(D) 0.10 milligram of folic acid, and

(E) 2.76 milligrams of iron;

(*c*) may contain, in 100 grams of bread,

(i) 0.14 milligram of vitamin $B_6$,

(ii) 0.6 milligram of *d*-pantothenic acid,

(iii) 90 milligrams of magnesium, and

(iv) 66 milligrams of calcium; and

(*d*) where it contains not less than six parts by weight of milk solids per 100 parts of enriched flour used, may be described by the common name “milk bread”.

SOR/78-698, s. 3; SOR/87-704, s. 1; SOR/89-170, s. 2; SOR/89-198, s. 3; SOR/98-550, s. 3.

B.13.023. and B.13.024. [Repealed, SOR/79-252, s. 3]

B.13.025. **[S]. Raisin Bread** shall be bread that contains for each 100 parts by weight of flour used not less than 50 parts by weight of seeded or seedless raisins, or raisins and currants of which not less than 35 parts shall be raisins and may contain spices or peel.

B.13.026. **[S]. (naming the percentage) Whole Wheat Bread**

(*a*) shall

(i) be bread in the making of which the named percentage of the flour used shall be whole wheat flour, and

(ii) contain not less than 60 per cent whole wheat flour in relation to the total flour used; and

(*b*) may

(i) contain caramel, and

(ii) where it contains not less than six parts by weight of milk solids per 100 parts of the total enriched flour and whole wheat flour used, be described by the common name “(naming the percentage) whole wheat milk bread”.

SOR/89-170, s. 3.

B.13.027. **[S]. Brown Bread** shall be bread coloured by the use of whole wheat flour, graham flour, bran, molasses or caramel.

B.13.028. [Repealed, SOR/97-151, s. 23]

B.13.029. A specialty bread may contain

(*a*) one or more of the ingredients specified in paragraph B.13.021(*i*) in a total amount greater than the total amount specified in that paragraph; and

(*b*) fruit, nuts, seeds and flavouring.

SOR/79-251, s. 3.

## Alimentary Paste

B.13.051. No person shall sell macaroni, spaghetti, noodles or similar alimentary pastes, as egg macaroni, egg spaghetti, egg noodles or egg alimentary pastes, respectively, unless they contain, on the dry basis, not less than four per cent, egg-yolk solids derived from whole egg, dried egg, frozen egg or frozen egg-yolk.

B.13.052. (1) Notwithstanding sections D.01.009, D.01.011 and D.02.009, no person shall sell an alimentary paste to which a vitamin or a mineral nutrient set out in column I of any item of the table to this section has been added unless each 100 g of the alimentary paste contains the added vitamin or mineral nutrient in an amount not less than the minimum amount set out in column II of that item and not more than the maximum amount set out in column III of that item.

(2) No person shall represent an alimentary paste as “enriched” unless the alimentary paste contains added thiamine, riboflavin, niacin, folic acid and iron, in accordance with the table to this section.

TABLE

| Item | Column I<br>Added Vitamin or Mineral Nutrient | Column II<br>Minimum Amount per 100 g of Alimentary Paste | Column III<br>Maximum Amount per 100 g of Alimentary Paste |
|---|---|---|---|
| 1. | Thiamine | 0.63 mg | 1.50 mg |
| 2. | Riboflavin | 0.11 mg | 0.60 mg |
| 3. | Niacin | 5.90 mg | 7.50 mg |
| 4. | Folic Acid | 0.20 mg | 0.27 mg |
| 5. | Pantothenic Acid | 1.00 mg | 2.00 mg |
| 6. | Vitamin $B_6$ | 0.40 mg | 0.80 mg |
| 7. | Iron | 2.90 mg | 4.30 mg |
| 8. | Magnesium | 150.00 mg | 300.00 mg |

SOR/94-37, s. 1; SOR/94-689, s. 2; SOR/96-527, s. 2; SOR/98-550, ss. 4, 5.

## Breakfast Cereal

B.13.060. Notwithstanding sections D.01.009, D.01.011 and D.02.009, no person shall sell a breakfast cereal to which a vitamin or mineral nutrient set out in Column I of an item of the table to this section has been added, either singly or in any combination, unless each 100 g of the breakfast cereal contains the added vitamin or mineral nutrient in the amount set out in Column II of that item.

TABLE

| Item | Column I<br>Vitamin or Mineral Nutrient | Column II<br>Amount per 100 g of Breakfast Cereal |
|---|---|---|
| 1. | Thiamine | 2.0 mg |
| 2. | Niacin | 4.8 mg |
| 3. | Vitamin $B_6$ | 0.6 mg |
| 4. | Folic Acid | 0.06 mg |
| 5. | Pantothenic Acid | 1.6 mg |
| 6. | Magnesium | 160.0 mg |
| 7. | Iron | 13.3 mg |
| 8. | Zinc | 3.5 mg |

SOR/83-858, s. 1; SOR/89-145, s. 2; SOR/98-458, s. 7(F).

# Division 14

# Meat, Its Preparations And Products

B.14.001. In this Division,

“animal” means any animal used as food, but does not include marine and fresh water animals; (animal)

“filler” means any vegetable material (except tomato or beetroot), milk, egg, yeast or any derivative or combination thereof that is acceptable as food. (agent de remplissage)

SOR/82-768, s. 39; SOR/86-875, s. 1.

B.14.002. **[S].** Meat shall be the edible part of the skeletal muscle of an animal that was healthy at the time of slaughter, or muscle that is found in the tongue, diaphragm, heart or oesophagus, and may contain accompanying and overlying fat together with the portions of bone, skin, sinew, nerve and blood vessels that normally accompany the muscle tissue and are not separated from it in the process of dressing, but does not include muscle found in the lips, snout, scalp or ears.

B.14.003. **[S].** Meat by-product shall be any edible part of an animal, other than meat, that has been derived from one or more animals that were healthy at the time of slaughter.

B.14.004. **[S].** Meat, meat by-products or preparations thereof are adulterated if any of the following substances or class of substances are present therein or have been added thereto:

(*a*) mucous membranes, any organ or portions of the genital system, black gut, spleens, udders, lungs or any other organ or portion of animal that is not commonly sold as an article of food;

(*b*) preservatives other than those provided for in this Division; or

(*c*) colour other than annatto, allura red and sunset yellow FCF, where provided for in this Division, and caramel.

SOR/92-725, s. 2; SOR/97-516, s. 2.

B.14.005. **[S]. Prepared meat** or a **prepared meat by-product** shall be any meat or any meat by-product, respectively, whether comminuted or not, to which has been added any ingredient permitted by these Regulations, or which has been preserved, placed in a hermetically-sealed container or cooked, and may contain

(*a*) in the case of prepared hams, shoulders, butts, picnics and backs, gelatin;

(*b*) in the case of partially defatted pork fatty tissue and partially defatted beef fatty tissue, a Class IV preservative;

(*c*) where a minimum total protein content or a minimum meat protein content is prescribed in this Division, phosphate salts that do not when calculated as sodium phosphate, dibasic, exceed the maximum level provided therefor in Table XII to section B.16.100 and that are one or more of the following phosphate salts, namely,

(i) sodium acid pyrophosphate,

(ii) sodium hexametaphosphate,

(iii) sodium phosphate, dibasic,

(iv) sodium phosphate, monobasic,

(v) sodium pyrophosphate, tetrabasic,

(vi) sodium tripolyphosphate,

(vii) potassium phosphate, monobasic,

(viii) potassium phosphate, dibasic, and

(ix) potassium pyrophosphate, tetrabasic; and

(*d*) in the case of vacuum-packed sliced roast beef and vacuum-packed sliced cooked ham, *Carnobacterium maltaromaticum* CB1.

SOR/94-262, s. 2; SOR/2010-264, s. 1.

Previous Version

B.14.006. Powdered hydrogenated cottonseed oil in an amount not greater than 0.25 per cent of the product may be applied as a release agent to the surface of meat, meat by-product, prepared meat, prepared meat by-product, extended meat product and simulated meat product.

SOR/2010-142, s. 59(F).

Previous Version

B.14.007. **[S]. Meat Binder** or **(naming the meat product) Binder** shall be a filler with any combination of salt, sweetening agents, spices or other seasonings (except tomato), egg, egg albumen, and

(*a*) where sold for use in preserved meat or preserved meat by-product, may contain any of ascorbic acid, calcium ascorbate, erythorbic acid, iso-ascorbic acid, potassium nitrate, potassium nitrite, sodium ascorbate, sodium carbonate, sodium erythorbate, sodium iso-ascorbate, sodium nitrate and sodium nitrite, provided that these nitrates and nitrites, if any, are packaged separately from any spice or seasoning.

(*b*) where sold for use in prepared meat or meat by-product in which a gelling agent is a permitted ingredient, may contain a gelling agent;

(*c*) where sold for use in fresh, uncooked sausage, may contain artificial maple flavour; and

(*d*) may contain an anticaking agent.

SOR/80-13, s. 1; SOR/82-913, s. 1; SOR/86-875, s. 2(F); SOR/2010-143, s. 9.

Previous Version

B.14.008. No person shall sell a meat binder, filler or preparations for pumping pickle, cover pickle or dry cure represented for use in meat products unless the label thereof carries directions for use that when followed will produce a food that will comply with the requirements of section B.14.030 insofar as the filler is concerned and the food will not contain food additives in excess of the maximum levels of use prescribed by these Regulations.

SOR/84-300, s. 44(E).

B.14.009. **[S].** Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product may contain

(*a*) Class I preservatives if the nitrate or nitrite salts or both are packaged separately from any spice or seasoning;

(*b*) citric acid, sodium citrate or vinegar;

(*c*) sweetening agents, including maple sugar and maple syrup;

(*d*) liquid smoke flavour, liquid smoke flavour concentrate, salt, seasonings, spices, spice extracts, spice oils or spice oleoresins;

(*e*) sodium bicarbonate, sodium hydroxide or potassium hydroxide;

(*f*) in the case of pumping pickle for cured pork, beef and lamb cuts, disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate in such amount calculated as disodium phosphate, as will result in the finished product containing not more than 0.5 per cent added phosphate;

(*g*) in the case of pumping pickle for cured beef cuts, enzymes, if the principal display panel of the label of the cured beef carries, immediately preceding or following the common name, the statement “Tenderized with (naming the proteolytic enzyme or enzymes)”;

(*h*) in the case of dry cure, an anticaking agent or a humectant; and

(*i*) in the case of pumping pickle

(i) for cured pork hams, shoulders and backs, artificial maple flavour, and

(ii) for cured pork bellies, artificial maple flavour and an orange flavour that meets the standard prescribed in section B.10.005.

SOR/79-251, s. 4; SOR/80-13, s. 2; SOR/82-596, s. 1; SOR/88-336, s. 3; SOR/94-567, s. 1; SOR/2010-143, s. 10(F).

Previous Version

B.14.010. No person shall sell as food a dead animal or any part thereof.

B.14.011. No person shall sell as food, meat, meat by-products, preparations containing meat or meat derivatives obtained, prepared or manufactured from a dead animal.

B.14.012. For the purpose of Sections B.14.010 and B.14.011, “dead animal” means a dead animal that

(*a*) was not killed for the purpose of food in accordance with commonly accepted practice of killing animals for the purpose of food, which shall include exsanguination; or

(*b*) was affected with disease at the time it was killed.

B.14.013. and B.14.014. [Repealed, SOR/97-148, s. 3]

## Meat, Meat By-products

B.14.015. **[S]. Regular Ground Beef** shall be beef meat processed by grinding and shall contain not more than 30 per cent beef fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981.

SOR/82-768, s. 40.

B.14.015A. **[S]. Medium Ground Beef** shall be beef meat processed by grinding and shall contain not more than 23 per cent beef fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981.

SOR/82-768, s. 40.

B.14.015B. **[S]. Lean Ground Beef** shall be beef meat processed by grinding and shall contain not more than 17 per cent beef fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981.

SOR/82-768, s. 40.

B.14.015C. No person shall sell ground beef that contains more than 30 per cent beef fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981.

SOR/82-768, s. 40.

B.14.016. No person shall sell horse-meat or horse-meat by-product, or any food containing horse-meat or horse-meat by-product unless

(*a*) it is labelled as such when offered or exposed for sale; and

(*b*) when in package form, the principal display panel of the label carries a declaration of the presence of horse-meat or of horse-meat by-product in type at least as legible and conspicuous as any other type upon such principal display panel.

SOR/88-336, s. 3.

B.14.017. [Repealed, SOR/2003-292, s. 2]

B.14.018 (1) Subject to subsection (2), if a carcass of beef or veal, or a portion of a carcass of beef or veal that weighs 7 kg or more, is advertised for sale, the advertisement shall indicate

(*a*) in the case of a carcass other than an imported carcass, the grade that was assigned to the carcass by a grading authority established under the Canada Agricultural Products Act or a provincial law;

(*b*) in the case of an imported beef carcass, the grade that was assigned to the carcass by a grading authority established under the Canada Agricultural Products Act or a provincial law or the grade that was assigned to the carcass by a grading authority established under the laws of the country from which the carcass was imported;

(*c*) in the case of an imported veal carcass, the grade that was assigned to the carcass by a grading authority established under the laws of the country from which the carcass was imported; and

(*d*) in the case of a beef carcass, the yield class, if any, that was assigned to the carcass by a grading authority established under the Canada Agricultural Products Act.

(2) Where, in the case of a carcass referred to in subsection (1), no grade has been assigned thereto as described in that subsection and the carcass or portion thereof that weighs 7 kg or more is advertised for sale, the advertisement shall clearly indicate that the carcass has not been graded.

SOR/92-626, s. 15; SOR/2003-6, s. 79.

B.14.019. (1) Where a carcass of beef, veal, pork or lamb or a portion thereof that weighs 7 kg or more is advertised for sale and a selling price is stated in the advertisement, the advertisement shall

(*a*) contain the words “price per kilogram is based on carcass weight before cutting, boning and trimming” or the words “price per kilogram is based on the weight of the meat after cutting, boning and trimming”, whichever words are applicable; and

(*b*) where in addition to the selling price a charge is payable for cutting, boning, trimming, wrapping or freezing the carcass or portion thereof, indicate

(i) the amount of the additional charge, and

(ii) where the additional charge is payable on a price per unit weight basis, whether the additional charge is based on the weight of the carcass or portion thereof before or after the carcass has been cut, boned and trimmed.

(2) Any information required by subsection (1) to appear in an advertisement shall be located therein immediately adjacent to the selling price stated therein, without any intervening written, printed or graphic matter.

SOR/92-626, s. 15; SOR/95-548, s. 5(F).

B.14.020. **[S]. Solid cut meat** shall be

(*a*) a whole cut of meat; or

(*b*) a product consisting of pieces of meat of which at least 80 per cent weigh at least 25 g each.

SOR/94-262, s. 3.

B.14.021. (1) No person shall sell solid cut meat to which phosphate salts or water has been added unless

(*a*) in the case of meat, other than side bacon, Wiltshire bacon, pork jowls, salt pork and salt beef, the meat

(i) where cooked, contains a meat protein content of not less than 12 per cent, and

(ii) where uncooked, contains a meat protein content of not less than 10 per cent; and

(*b*) that meat contains, phosphate salts that do not when calculated as sodium phosphate, dibasic, exceed the maximum level provided therefor in Table XII to section B.16.100 and that are one or more of the following phosphate salts, namely,

(i) sodium acid pyrophosphate,

(ii) sodium hexametaphosphate,

(iii) sodium phosphate, dibasic,

(iv) sodium phosphate, monobasic,

(v) sodium pyrophosphate, tetrabasic,

(vi) sodium tripolyphosphate,

(vii) potassium phosphate, monobasic,

(viii) potassium phosphate, dibasic, and

(ix) potassium pyrophosphate, tetrabasic.

(2) A bone or a visible fat layer shall not be included in any calculation used to determine meat protein content for the purposes of paragraph (1)(*a*).

SOR/94-262, s. 3.

## Prepared Meats, Prepared Meat By-products

B.14.030. (1) Subject to subsections (2) and (3) and section B.14.030A, no person shall sell a prepared meat or prepared meat by-product with a meat protein content of less than 1.5 percentage points below the total protein requirement for that food.

(2) Subsection (1) does not apply to an extended meat product.

(3) Where gelatin is an ingredient of a prepared meat or prepared meat by-product, that gelatin shall not be included when calculating the total protein content of the prepared meat or prepared meat by-product.

SOR/78-637, s. 3; SOR/79-251, s. 5(F); SOR/80-13, s. 3; SOR/82-768, s. 41; SOR/86-875, s. 3.

B.14.030A. For the purposes of sections B.14.030, B.14.032, B.14.033, B.14.035, B.14.074, B.14.075, B.14.076 and B.14.077, where any of the non-meat ingredients listed in paragraphs

B.14.032A(*a*) to (*g*) are present in a prepared meat or prepared meat by-product in separate identifiable pieces or chunks in any amount sufficient to differentiate those ingredients from the prepared meat or prepared meat by-product, those ingredients shall not be included when calculating the fat or protein content of the prepared meat or prepared meat by-product.

SOR/86-875, s. 3.

B.14.031. **[S]. Preserved Meat** or **Preserved Meat By-product** shall be cooked or uncooked meat or meat by-product that is salted, dried, pickled, corned, cured or smoked, may be glazed and may contain

(*a*) Class I preservative;

(*b*) sweetening agents;

(*c*) spices and seasonings, except tomato;

(*d*) vinegar;

(*e*) alcohol;

(*f*) smoke flavouring or artificial smoke flavouring;

(*g*) in the case of cured pork hams, shoulders, backs and bellies, artificial maple flavour;

(*gg*) in the case of cured pork bellies, an added orange flavour that meets the standard prescribed in section B.10.005;

(*h*) in the case of cured pork, beef and lamb cuts prepared with the aid of pumping pickle, disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate in such amount calculated as disodium phosphate, as will result in the finished product containing not more than 0.5 per cent added phosphate;

(*i*) in the case of tocino, annatto in such amount as will result in the finished product containing not more that 0.1 per cent annatto, if annatto is shown, by the word “annatto”, in the list of ingredients on the label; and

(*j*) in the case of vacuum-packed sliced cooked ham, *Carnobacterium maltaromaticum* CB1.

SOR/79-251, s. 6; SOR/80-13, s. 4; SOR/82-596, s. 2; SOR/84-300, s. 45(E); SOR/88-336, ss. 2, 3; SOR/92-725, s. 3; SOR/97-151, s. 24; SOR/2010-264, s. 2.

Previous Version

B.14.032. **[S]. Sausage** or **Sausage Meat**

(*a*) shall be fresh or preserved comminuted meat;

(*b*) may be enclosed in a casing;

(*c*) may be dipped in vinegar, smoked, cooked or dried;

(*d*) may contain

(i) animal fat,

(ii) filler,

(iii) beef tripe,

(iv) liver,

(v) fresh or frozen beef and pork blood,

(vi) sweetening agents,

(vii) salt and spices,

(viii) seasoning, other than tomato,

(ix) lactic acid producing starter culture,

(x) meat binder,

(xi) beef and pork blood plasma,

(xii) in the case of preserved comminuted meat, smoke flavouring or artificial smoke flavouring,

(xiii) if cooked

(A) glucono delta lactone,

(B) partially defatted beef fatty tissue or partially defatted pork fatty tissue, and

(C) a dried skim milk product, obtained from skim milk by the reduction of its calcium content and a corresponding increase in its sodium content, in an amount not exceeding three per cent of the finished food,

(xiv) in the case of fresh uncooked sausage, artificial maple flavour or apple powder as a flavouring ingredient,

(xv) in the case of dry sausage or dry sausage meat, glucono delta lactone,

(xvi) in the case of longaniza,

(A) annatto in such amount as will result in the finished product containing not more than 1000 parts per million annatto, if annatto is shown, by the word “annatto”, in the list of ingredients on the label,

(B) allura red in such amount as will result in the finished product containing not more than 80 parts per million allura red, if allura red is shown, by the words “allura red”, in the list of ingredients on the label, and

(C) sunset yellow FCF in such amount as will result in the finished product containing not more than 20 parts per million sunset yellow FCF, if sunset yellow FCF is shown, by the words “sunset yellow FCF”, in the list of ingredients on the label, and

(xvii) in the case of vacuum-packed wieners, *Carnobacterium maltaromaticum* CB1;

(*e*) shall contain, in the case of a product sold as fresh sausage, not more than 40 per cent fat, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

(*f*) shall have, if cooked, a total protein content of not less than 11 per cent;

(*g*) shall have, in the case of fresh uncooked sausage and fresh uncooked sausage meat, a total protein content of not less than nine per cent.

SOR/80-13, s. 5; SOR/82-768, s. 42; SOR/88-336, s. 3; SOR/92-725, s. 4; SOR/97-151, s. 25; SOR/97-516, s. 3; SOR/2010-264, s. 3.

Previous Version

B.14.032A. **[S]. (naming the prepared meat** or **prepared meat by-product)** with **(naming the non-meat ingredients)** shall be prepared meat to which has been added other non-meat ingredients including

(*a*) fruit;

(*b*) vegetables;

(*c*) nuts;

(*d*) cheese or processed cheese;

(*e*) macaroni;

(*f*) pickles; or

(*g*) olives.

SOR/84-300, s. 46.

B.14.032AA. Where the non-meat ingredients referred to in section B.14.032A are added to prepared meat in such a manner that they are not present in the final product in separate identifiable pieces or chunks, the final product shall meet the total protein content requirement established for (naming the prepared meat or prepared meat by-product) referred to in section B.14.032A.

SOR/86-875, s. 4.

B.14.033. **[S]. Potted Meat, Meat Paste,** or **Meat Spread** shall be comminuted and cooked, fresh or preserved meat and may contain meat binder, salt, sweetening agents, spices, other seasonings and a gelling agent and shall have a total protein content of not less than nine per cent.

SOR/80-13, s. 6.

B.14.034. **[S]. Potted Meat By-product, Meat By-product Paste or Meat By-product Spread** shall be a food that

(*a*) consists, wholly or in part, of meat by-products and conforms to the standard prescribed for potted meat; and

(*b*) in the case of liverpaste or liverwurst spread, may contain wheat germ and yeast.

SOR/78-637, s. 4; SOR/80-13, s. 7; SOR/86-875, s. 5.

B.14.035. **[S]. Meat Loaf, Meat Roll, Meat Lunch** or **Luncheon Meat** shall be comminuted and cooked, fresh or preserved meat, pressed into shape and may contain a dried skim milk product obtained from skim milk by the reduction of its calcium content and a corresponding increase in its sodium content, in an amount not exceeding three per cent of the finished food, filler, meat binder, salt, sweetening agents, glucono delta lactone, spices, other seasonings, milk, eggs, a gelling agent and partially defatted beef fatty tissue or partially defatted pork fatty tissue and shall have a total protein content of not less than 11 per cent.

SOR/80-13, s. 8.

B.14.036. **[S]. Meat By-product Loaf** or **Meat and Meat By-product Loaf** shall be the food consisting, wholly or in part, of meat by-products and shall otherwise conform to the standard prescribed for meat loaf.

B.14.037. **[S]. Headcheese**

(*a*) shall be comminuted cooked meat or comminuted cooked preserved meat,

(*b*) shall not contain

(i) less than 50 per cent head meat, or

(ii) skin, other than that naturally adherent to any pork meat used,

(*c*) may contain scalps, snouts, beef tripe, salt, spices, seasoning or an added gelling agent, and

(*d*) may contain

(i) ascorbic acid or its sodium salt, or

(ii) erythorbic acid or its sodium salt,

and for the purpose of this section scalp and snouts are deemed head meat.

SOR/80-500, s. 5.

B.14.038. **[S]. Brawn** shall be headcheese, except that it need not contain 50 per cent head meat.

B.14.039. Where a gelling agent has been added to prepared meat or prepared meat by-product, a statement to the effect that a gelling agent has been added shall be shown on the principal display panel or the word “jellied” shall be shown as an integral part of the common name of the food.

B.14.040. Subject to section B.14.032 and sections B.14.033 to B.14.036, no person shall sell a food that consists of a mixture of ground meat and filler, ground meat by-product and filler or ground meat, ground meat by-product and filler, unless that food

(*a*) has a total protein content of not less than 13 per cent;

(*b*) has a fat content of not more than 40 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case of a mixture containing pork meat or pork meat by-product or both; and

(*c*) has a fat content of not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case of any other meat mixture.

SOR/79-251, s. 7(F); SOR/82-768, s. 43.

B.14.041. Subject to section B.14.032 and sections B.14.033 to B.14.036, no person shall sell a food that consists of a mixture of ground meat and spices and seasonings, ground meat by-product and spices and seasonings, ground meat, ground meat by-product and spices and seasonings or ground meat and ground meat by-product, unless that food

(*a*) has a total protein content of not less than 16 per cent;

(*b*) has a fat content of not more than 40 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case of a mixture containing pork meat or pork meat by-product or both; and

(*c*) has a fat content of not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case of any other meat mixture.

SOR/79-251, s. 7(F); SOR/82-768, s. 44.

## Meat Derivatives

B.14.061. **[S]. Edible Bone Meal** or **Edible Bone Flour** shall be the food prepared by grinding dry, defatted bones, obtained from animals healthy at the time of slaughter and shall contain

(*a*) not less than 85 per cent ash, as determined by official method FO-34, Determination of Ash in Edible Bone Meal or Edible Bone Flour, October 15, 1981.

(*b*) and (*c*) [Repealed, SOR/97-148, s. 4]

SOR/82-768, s. 45; SOR/97-148, s. 4.

B.14.062. **[S].** (1) **Gelatin** or **Edible Gelatin**

(*a*) shall be the purified food obtained by the processing of skin, ligaments or bones of animals;

(*b*) shall contain not less than 82 per cent ash-free solids, when tested by official method FO-35, Determination of Ash-Free Solids in Gelatin, October 15, 1981;

(*c*) shall be free from objectionable taste and offensive odour when 2.5 grams thereof are dissolved in 100 millilitres of warm water;

(*d*) [Repealed, SOR/97-148, s. 5]

(*e*) shall not contain any residues of hydrogen peroxide where it has been used in the course of manufacture; and

(*f*) may contain

(i) not more than 2.6 per cent ash on a dry basis,

(ii) not more than 500 parts per million of sulphurous acid, including the salts thereof, calculated as sulphur dioxide, and

(iii) where intended for use in the manufacture of marshmallow, sodium hexametaphosphate or sodium lauryl sulphate.

(2) No person shall use, in the course of manufacturing gelatin or edible gelatin,

(*a*) acidic or basic compounds other than acetic acid, ammonium hydroxide, citric acid, fumaric acid, hydrochloric acid, lime, magnesium hydroxide, phosphoric acid, sodium carbonate, sodium hydroxide, sodium sulphide, sulphuric acid, sulphurous acid or tartaric acid; or

(*b*) filtering and clarifying agents other than activated carbon, alumina, aluminum sulphate, calcium phosphate, dibasic, cellulose, diatomaceous earth, perlite, strongly acidic cation exchange resin in the hydrogen ion form or basic anion exchange resins in the chloride ion or free base ion forms.

SOR/78-401, s. 2(E); SOR/78-874, s. 1; SOR/80-501, s. 3; SOR/82-768, s. 46; SOR/97-148, s. 5.

## Meat Stews

B.14.063. For the purposes of sections B.14.064 to B.14.068, “stew meat” means meat that contains when raw not more than

(*a*) 25 per cent fat, in the case of meat in meat ball stews; and

(*b*) 20 per cent fat, in the case of meat in other stews.

SOR/78-874, s. 2.

B.14.064. **[S]. Vegetable Stew with (naming the meat)**

(*a*) shall contain vegetables and the named meat in the following amounts, calculated as raw ingredients:

(i) 12 per cent or more stew meat, and

(ii) 38 per cent or more vegetables; and

(*b*) may contain gravy, salt, seasoning and spices.

SOR/78-874, s. 2.

B.14.065. **[S]. (naming the meat) Stew**

(*a*) shall contain vegetables and the named meat in the following amounts, calculated as raw ingredients:

(i) 20 per cent or more stew meat, and

(ii) 30 per cent or more vegetables; and

(*b*) may contain gravy, salt, seasoning and spices.

SOR/78-874, s. 2.

B.14.066. **[S]. Irish Stew**

(*a*) shall contain mutton, lamb or beef, singly or in any combination, and vegetables, in the following amounts, calculated as raw ingredients:

(i) 20 per cent or more stew meat,

(ii) 30 per cent or more vegetables; and

(*b*) may contain gravy, salt, seasoning and spices.

SOR/78-874, s. 2.

B.14.067. **[S]. Meat Ball Stew**

(*a*) shall contain vegetables and meat balls in the following amounts, calculated as raw ingredients:

(i) 22 per cent or more meat balls,

(ii) 30 per cent or more vegetables; and

(*b*) may contain gravy, salt, seasoning and spices.

SOR/78-874, s. 2.

B.14.068. **[S].** Specialty Meat Stews

(*a*) shall contain meat and vegetables in the following amounts, calculated as raw ingredients:

(i) 25 per cent or more stew meat,

(ii) 30 per cent or more vegetables; and

(*b*) may contain gravy, salt, seasoning and spices.

SOR/78-874, s. 2.

## Meat Specialties

B.14.070. **[S]. Wieners and Beans** or **Wieners with Beans** shall be the food prepared from dried beans and wieners, may contain sauce, seasoning, spices and a sweetening agent and shall contain not less than 25 per cent wieners, as determined by official method FO-36, Determination of Wiener Content of Meat Specialties, October 15, 1981.

SOR/82-768, s. 47.

B.14.071. **[S]. Beans and Wieners** or **Beans with Wieners** shall be the food prepared from dried beans and wieners, may contain sauce, seasoning, spices and a sweetening agent and shall contain not less than 10 per cent wieners, as determined by official method FO-36, Determination of Wiener Content of Meat Specialties, October 15, 1981.

SOR/82-768, s. 47.

## Sale of Barbecued, Roasted or Broiled Meat or Meat By-Products

B.14.072. No person shall sell meat or a meat by-product that has been barbecued, roasted or broiled and is ready for consumption unless the cooked meat or meat by-product

(*a*) at all times

(i) has a temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher, or

(ii) has been stored at an ambient temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher; and

(*b*) carries on the principal display panel of the label a statement to the effect that the food must be stored at a temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher.

SOR/78-403, s. 4(F); SOR/88-336, s. 3.

## Meat Product Extender

B.14.073. No person shall sell a meat product extender intended to be used in a food consisting of a mixture described in section B.14.074, B.14.075, B.14.076, B.14.077 or B.14.078, unless that extender

(*a*) has, in the rehydrated state,

(i) a total protein content of not less than 16 per cent, and

(ii) a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*b*) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively; and

(*c*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 48.

## Extended Meat Products

B.14.074. Subject to sections B.14.075 to B.14.079, no person shall sell a food that consists of a mixture of meat product and meat product extender, unless that food

(*a*) has a total protein content of not less than 16 per cent;

(*b*) has a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

(*c*) in respect of the meat product extender, meets the requirements of paragraphs B.14.073(*a*) to (*c*).

SOR/82-768, s. 49.

B.14.075. No person shall sell a food that consists of a mixture of meat product and meat product extender and that resembles fresh sausage, unless that food

(*a*) has a total protein content of not less than nine per cent;

(*b*) has a fat content of not more than 40 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

(*c*) in respect of the meat product extender, meets the requirements of paragraphs B.14.073(*a*) to (*c*).

SOR/82-768, s. 50; SOR/84-300, s. 47(F).

B.14.076. No person shall sell a food that consists of a mixture of meat product and meat product extender and that resembles cooked sausage, meat loaf, meat by-product loaf, meat roll, meat lunch, or luncheon meat, unless that food

(*a*) has a total protein content of not less than 11 per cent;

(*b*) has a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

(*c*) in respect of the meat product extender, meets the requirements of paragraphs B.14.073(*a*) to (*c*).

SOR/82-768, s. 51.

B.14.077. No person shall sell a food that consists of a mixture of meat product and meat product extender and that resembles potted meat, potted meat by-product, meat paste, meat by-product paste, meat spread, or meat by-product spread, unless that food

(*a*) has a total protein content of not less than nine per cent;

(*b*) has a fat content of not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

(*c*) in respect of the meat product extender, meets the requirements of paragraphs B.14.073(*a*) to (*c*).

SOR/82-768, s. 52; SOR/84-300, s. 48(E).

B.14.078. No person shall sell a food that consists of a mixture of meat product and meat product extender and that resembles regular ground beef, medium ground beef or lean ground beef, unless that food

(*a*) has a total protein content of not less than 16 per cent;

(*b*) has a fat content of

(i) not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being regular,

(ii) not more than 23 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being medium, or

(iii) not more than 17 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being lean; and

(*c*) in respect of the meat product extender, meets the requirements of paragraphs B.14.073(*a*) to (*c*).

SOR/82-768, s. 53.

B.14.079. No person shall sell a food that consists of a mixture of meat product, filler and meat product extender, unless that food

(*a*) has a total protein content of not less than 13 per cent;

(*b*) has a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981; and

(*c*) in respect of the meat product extender, meets the requirements of paragraphs B.14.073(*a*) to (*c*).

SOR/82-768, s. 54.

## Simulated Meat Products

B.14.085. Subject to sections B.14.086 to B.14.090 no person shall sell a simulated meat product unless that product

(*a*) has, in the rehydrated state,

(i) a total protein content of not less than 16 per cent,

(ii) a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981, and

(iii) a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

(*b*) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively; and

(*c*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 55.

B.14.086. No person shall sell a simulated meat product that resembles fresh sausage, unless that product

(*a*) has a total protein content of not less than nine per cent;

(*b*) has a protein rating of not less than 23, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*c*) has a fat content of not more than 40 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

(*d*) has, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively; and

(*e*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 56.

B.14.087. No person shall sell a simulated meat product that resembles cooked sausage, meat loaf, meat by-product loaf, meat roll, meat lunch, or luncheon meat, unless that product

(*a*) has a total protein content of not less than 11 per cent;

(*b*) has a protein rating of not less than 28, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*c*) has a fat content of not more than 25 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

(*d*) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively; and

(*e*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 57.

B.14.088. No person shall sell a simulated meat product that resembles potted meat, potted meat by-product, meat paste, meat by-product paste, meat spread, or meat by-product spread, unless that product

(*a*) has a total protein content of not less than nine per cent;

(*b*) has a protein rating of not less than 23, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*c*) has a fat content of not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981;

(*d*) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each vitamin and mineral nutrient respectively; and

(*e*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 58.

B.14.089. No person shall sell a simulated meat product that resembles regular ground beef, medium ground beef or lean ground beef, unless that product

(*a*) has a total protein content of not less than 16 per cent;

(*b*) has a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*c*) has a fat content of

(i) not more than 30 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being regular,

(ii) not more than 23 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being medium, or

(iii) not more than 17 per cent, as determined by official method FO-33, Determination of Fat in Meat and Simulated Meat Products, October 15, 1981, in the case where the product is represented as being lean;

(*d*) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient, respectively; and

(*e*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 59.

B.14.090. No person shall sell a simulated meat product that resembles side bacon, unless that product

(*a*) has a total protein content of not less than 25 per cent;

(*b*) has a protein rating of not less than 20, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*c*) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to this Division in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively; and

(*d*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 60.

TABLE

| Column I | Column II |
|---|---|

| Item No. | Vitamin or Mineral Nutrient | Amount per gram of protein |
|---|---|---|
| C.1 ..... | Copper ..... | 4.4 micrograms |
| F.1 ..... | Folic Acid ..... | 0.45 microgram |
| I.1 ..... | Iron ..... | 0.25 milligram |
| M.1 ..... | Magnesium ..... | 1.1 milligrams |
| N.1 ..... | Niacin ..... | 0.34 milligram |
| P.1 ..... | Pantothenic Acid ..... | 0.04 milligram |
| P.2 ..... | Potassium ..... | 20 milligrams |
| P.3 ..... | Pyridoxine ..... | 0.02 milligram |
| R.1 ..... | Riboflavin ..... | 0.01 milligram |
| T.1 ..... | Thiamine ..... | 0.02 milligram |
| V.1 ..... | Vitamin $B_{12}$..... | 0.08 microgram |
| Z.1 ..... | Zinc ..... | 0.20 milligram |

SOR/98-458, s. 7(F).

# Division 15

# Adulteration Of Food

B.15.001. A food named in Column III of an item of Table I to this Division is adulterated if the substance named in Column I of that item is present therein or has been added thereto in an amount exceeding the amount, expressed in parts per million, shown in Column II of that item for that food.

SOR/78-404, s. 1; SOR/79-249, s. 1.

B.15.002. (1) Subject to subsection (2), a food is adulterated if

(*a*) a pest control product as defined in subsection 2(1) of the Pest Control Products Act or its components or derivatives, for which no maximum residue limit has been specified under sections 9 or 10 of that Act for that food, are present in or on the food, singly or in any combination, in an amount exceeding 0.1 part per million; or

(*b*) an agricultural chemical or its components or derivatives, other than a pest control product as defined in subsection 2(1) of the Pest Control Products Act or its components or derivatives, are present in or on the food, singly or in any combination, in an amount exceeding 0.1 part per million.

(2) A food is exempt from paragraph 4(1)(*d*) of the Act if the following agricultural chemicals, or their components or derivatives, are the only agricultural chemicals, or components or derivatives of agricultural chemicals, that are present in or on the food, singly or in any combination:

(*a*) a fertilizer;

(*b*) an adjuvant or a carrier of an agricultural chemical;

(*c*) an inorganic bromide salt;

(*d*) silicon dioxide;

(*e*) sulphur;

(*f*) viable spores of *Bacillus thuringiensis Berliner*; or

(*g*) Kaolin.

(3) Subsection (2) does not apply to a food if there is present in or on the food an agricultural chemical, or a component or derivative of that agricultural chemical, referred to in that subsection that is a pest control product as defined in subsection 2(1) of the Pest Control Products Act, or a component or derivative of that product, in respect of which a maximum residue limit has been specified under sections 9 or 10 of that Act for that food.

(4) [Repealed, SOR/2008-181, s. 3]

SOR/78-404, s. 1; SOR/79-249, s. 1; SOR/81-83, s. 2; SOR/97-313, s. 2; SOR/98-98, s. 1; SOR/2005-67, s. 1; SOR/2008-181, s. 3; SOR/2008-182, s. 2.

Previous Version

B.15.003. A food named in Column IV of an item of Table III to this Division is exempt from paragraph 4(*d*) of the Act if the drug named in Column I, and analysed as being the substance named in Column II, of that item is present in the food in an amount not exceeding the limit, expressed in parts per million, set out in Column III of that item for that food.

SOR/78-404, s. 1; SOR/79-249, s. 1; SOR/91-255, s. 1.

TABLE I

| | I | II | III |
|---|---|---|---|
| Item No. | Substance | Tolerance p.p.m. | Foods |
| 1. | Arsenic | (1) 3.5 | (1) Fish protein |
| | | (2) 1 | (2) Edible bone meal |
| | | (3) 0.1 | (3) Fruit juice, fruit nectar, beverages when ready-to-serve and water in sealed containers other than mineral water or spring water |
| 2. | Fluoride | (1) 650 | (1) Edible bone meal |
| | | (2) 150 | (2) Fish Protein |
| 3. | Lead | (1) 10 | (1) Edible bone meal |
| | | (2) 1.5 | (2) Tomato paste and tomato sauce |
| | | (3) 0.5 | (3) Fish protein and whole tomatoes |
| | | (4) 0.2 | (4) Fruit juice, fruit nectar, beverages when ready-to-serve and water in sealed containers other than mineral water or spring water |
| | | (5) 0.15 | (5) Evaporated milk, condensed milk and concentrated infant formula |
| | | (6) 0.08 | (6) Infant formula when ready-to-serve |
| 4. | Tin | (1) 250 | (1) Canned foods |

SOR/78-404, s. 2; SOR/79-249, s. 2; SOR/86-258, s. 1; SOR/89-243, ss. 1, 2; SOR/91-149, s. 2(E); SOR/94-689, s. 2(F).

# TABLE II

# [Repealed, SOR/2008-182, s. 3]

TABLE III

VETERINARY DRUGS

| | Column I | Column II | Column III | Column IV |
|---|---|---|---|---|
| Item No. | Common Name (or Brand Name) of Drug | Name of Substance for Drug Analysis Purposes | Maximum Residue Limit p.p.m. | Foods |
| A.01 | albendazole | albendazole-2-aminosulfone | 0.2 | Liver of cattle |
| A.1 | ampicillin | ampicillin | 0.01 | Edible tissue of swine and cattle; milk |
| A.2 | amprolium | amprolium | 0.5 | Muscle of chickens and turkeys |
| | | | 1.0 | Liver and kidney of chickens and turkeys |
| | | | 7.0 | Eggs |
| A.3 | apramycin | apramycin | 0.1 | Kidney of swine |
| A.4 | arsanilic acid | arsenic | 0.5 | Muscle of swine, chickens and turkeys; eggs |
| | | | 2.0 | Liver of swine, chickens and turkeys |
| B.1 | buquinolate | buquinolate | 0.1 | Muscle of chickens |
| | | | 0.4 | Liver, kidney, skin and fat of chickens |
| C.01 | ceftiofur | desfuroyl-ceftiofur (DFC) | 0.1 | Milk |
| | | | 1.0 | Muscle of cattle, sheep and swine |
| | | | 2.0 | Liver and fat of cattle, sheep and swine |
| | | | 5.0 | Kidney of swine |
| | | | 6.0 | Kidney of cattle and sheep |
| C.1 | cephapirin | cephapirin | 0.02 | Milk |
| | | | 0.1 | Edible tissue of |

| Item No. | Column I<br>Common Name (or Brand Name) of Drug | Column II<br>Name of Substance for Drug Analysis Purposes | Column III<br>Maximum Residue Limit p.p.m. | Column IV<br>Foods |
|---|---|---|---|---|
| | | | | cattle |
| C.2 | chlortetracycline | chlortetracycline | 0.1 | Kidney, liver and muscle of cattle; muscle of sheep |
| | | | 0.2 | Fat of swine |
| | | | 0.5 | Liver of sheep |
| | | | 1.0 | Muscle, liver, skin and fat of chickens and turkeys; muscle of swine; muscle and fat of calves; kidney of sheep |
| | | | 2.0 | Liver of swine |
| | | | 4.0 | Kidney of swine, chickens and turkeys; liver and kidney of calves |
| C.3 | clopidol | clopidol | 5.0 | Muscle of chickens and turkeys |
| | | | 15.0 | Liver and kidney of chickens and turkeys |
| D.1 | decoquinate | decoquinate | 1.0 | Muscle of cattle, goats and chickens |
| | | | 2.0 | Kidney, liver and fat of cattle and goats; kidney, liver, skin and fat of chickens |
| D.1.1 | diclazuril | diclazuril | 0.5 | Muscle of chickens and turkeys |
| | | | 1.0 | Skin and fat of chickens and turkeys |
| | | | 3.0 | Liver of chickens and turkeys |
| D.2 | dihydrostreptomycin | dihydrostreptomycin | 0.125 | Milk |
| D.3 | dinitolmide (zoalene) | dinitolmide, including the metabolite 3-amino-5-nitro-o-toluamide | 2.0 | Fat of chickens |
| | | | 3.0 | Muscle of chickens and turkeys; liver and fat of turkeys |

| | Column I | Column II | Column III | Column IV |
|---|---|---|---|---|
| Item No. | Common Name (or Brand Name) of Drug | Name of Substance for Drug Analysis Purposes | Maximum Residue Limit p.p.m. | Foods |
| | | | 6.0 | Liver and kidney of chickens |
| D.4 | doramectin | doramectin | 0.01 | Muscle of swine |
| | | | 0.03 | Muscle of cattle |
| | | | 0.035 | Liver of swine |
| | | | 0.07 | Liver of cattle |
| E.01 | enrofloxacin | desethylene ciprofloxacin | 0.02 | Muscle of cattle |
| | | | 0.07 | Liver of cattle |
| E.02 | eprinomectin | eprinomectin $B_{1a}$ | 0.02 | Milk |
| | | | 0.1 | Muscle of cattle |
| | | | 1.0 | Liver of cattle |
| E.1 | erythromycin | erythromycin | 0.05 | Milk |
| | | | 0.1 | Edible tissue of swine |
| | | | 0.125 | Edible tissue of chickens and turkeys |
| F.1 | fenbendazole | fenbendazole | 0.45 | Liver of cattle |
| | | | 4.5 | Liver of swine |
| F.2 | florfenicol | florfenicol amine | 0.8 | Muscle of salmonids |
| | | | 2 | Liver of cattle |
| F.3 | flunixin | flunixin free acid | 0.02 | Muscle of cattle |
| | | | 0.08 | Liver of cattle |
| G.1 | gentamicin | gentamicin | 0.1 | Edible tissue of turkeys |
| | | | 0.4 | Kidney of swine |
| H.01 | halofuginone | halofuginone | 0.1 | Liver of chicken |
| H.1 | hydrocortisone | hydrocortisone | 0.01 | Milk |
| I.1 | ivermectin | 22,23-dihydro-avermectin $B_{1a}$ | 0.015 | Liver of swine |
| | | | 0.03 | Liver of sheep |
| | | | 0.07 | Liver of cattle |
| K.1 | ketoprofen | ketoprofen | 0.05 | Milk |
| | | | 0.1 | Muscle of swine |
| | | | 0.25 | Muscle of cattle |
| | | | 0.5 | Kidney of swine |
| | | | 0.8 | Kidney of cattle |
| L.01 | lasalocid | lasalocid | 0.35 | Fat and skin of chicken |

| | Column I | Column II | Column III | Column IV |
|---|---|---|---|---|
| Item No. | Common Name (or Brand Name) of Drug | Name of Substance for Drug Analysis Purposes | Maximum Residue Limit p.p.m. | Foods |
| | | | 0.65 | Liver of cattle |
| L.1 | levamisole hydrochloride | levamisole | 0.1 (calculated as levamisol hydro-chloride) | Edible tissue of cattle, sheep and swine |
| L.2 | lincomycin | lincomycin | 0.1 | Muscle of chickens and swine |
| | | | 0.5 | Liver of chickens and swine |
| M.01 | maduramicin | maduramicin | 0.4 | Fat and skin of chicken |
| M.1 | monensin | monensin | 0.01 | Milk |
| | | | 0.05 | Edible tissue of cattle, chickens and turkeys |
| M.2 | morantel tartrate | N-methyl-1,3-propane diamine | 0.1 | Milk |
| | | | 0.5 | Liver of cattle |
| M.3 | moxidectin | moxidectin | 0.55 | Fat of cattle |
| N.01 | narasin | narasin | 0.05 | Muscle of chickens and swine; liver of swine |
| | | | 0.5 | Fat of chickens |
| N.1 | neomycin | neomycin | 0.25 | Edible tissue of calves |
| N.2 | nicarbazin | $N,N^1$-bis(4-nitrophenyl)urea | 4.0 | Muscle, liver, kidney and skin of chickens |
| N.3 | nitarsone | arsenic | 0.5 | Muscle of turkeys |
| | | | 2.0 | Liver of turkeys |
| N.4 | novobiocin | novobiocin | 1.0 | Edible tissue of cattle, chickens and turkeys |
| O.1 | oxytetracycline | oxytetracycline | 0.2 | Muscle of cattle, chickens, lobster, salmonids, sheep, swine and turkeys |
| | | | 0.3 | Honey |
| | | | 0.4 | Eggs |
| | | | 0.6 | Liver of cattle, chickens, sheep, |

| | Column I | Column II | Column III | Column IV |
|---|---|---|---|---|
| Item No. | Common Name (or Brand Name) of Drug | Name of Substance for Drug Analysis Purposes | Maximum Residue Limit p.p.m. | Foods |
| | | | | swine and turkeys |
| | | | 1.2 | Kidneys of cattle, chickens, sheep, swine and turkeys; fat of cattle and sheep; skin and fat of chicken, swine, and turkeys |
| P.1 | penicillin G | penicillin G | 0.01 I.U./ml | Milk |
| | | | 0.01 | Edible tissue of turkeys |
| | | | 0.05 | Edible tissue of cattle and swine |
| P.1.1 | pirlimycin | pirlimycin | 0.3 | Muscle of cattle |
| | | | 0.4 | Milk |
| | | | 0.5 | Liver of cattle |
| P.2 | polymyxin B | polymyxin B | 4.0 u/ml | Milk |
| P.3 | pyrantel tartrate | N-methyl-1,3-propane-diamine | 1.0 (calculated as pyrantel tartrate) | Muscle of swine |
| | | | 10.0 (calculated as pyrantel tartrate) | Liver and kidney of swine |
| R.1 | robenidine hydro-chloride | robenidine | 0.1 (calculated as robenidine hydro-chloride) | Muscle, liver and kidney of chickens |
| | | | 0.2 (calculated as robenidine hydro-chloride) | Skin and fat of chickens |
| R.2 | roxarsone | arsenic | 0.5 | Muscle of swine, chickens and turkeys; eggs |
| | | | 2.0 | Liver of swine, chickens and turkeys |

| | Column I | Column II | Column III | Column IV |
|---|---|---|---|---|
| Item No. | Common Name (or Brand Name) of Drug | Name of Substance for Drug Analysis Purposes | Maximum Residue Limit p.p.m. | Foods |
| S.01 | salinomycin | salinomycin | 0.35 | Fat and skin of chicken; Liver of cattle and swine |
| S.1 | spectinomycin | spectinomycin | 0.1 | Edible tissue of chickens |
| S.2 | streptomycin | streptomycin | 0.125 | Milk |
| S.3 | sulfachlorpyridazine | sulfachlorpyridazine | 0.1 | Edible tissue of cattle and swine |
| S.3.1 | sulfadiazine | sulfadiazine | 0.1 | Muscle of salmonids |
| S.4 | sulfadimethoxine | sulfadimethoxine | 0.01 | Milk |
| | | | 0.1 | Edible tissue of cattle |
| S.5 | sulfaethoxypyridazine | sulfaethoxypyridazine | 0.1 | Edible tissue of cattle |
| S.6 | sulfamethazine | sulfamethazine | 0.01 | Milk |
| | | | 0.1 | Edible tissue of calves, cattle, chickens, swine and turkeys |
| S.7 | sulfathiazole | sulfathiazole | 0.1 | Edible tissue of swine |
| T.01 | teflubenzuron | teflubenzuron | 0.3 | Muscle of salmonids |
| | | | 3.2 | Skin of salmonids |
| T.1 | tetracycline | tetracycline | 0.25 | Edible tissue of calves, swine, sheep, chickens and turkeys |
| T.2 | thiabendazole | thiabendazole and total 5-hydroxythiabendazole metabolites (free form, glucuronide and sulfate conjugates) | 0.05 | Milk |
| | | | 0.1 | Edible tissue of cattle, goats and sheep |
| T.3 | tiamulin | 8-alpha-hydroxy-mutilin | 0.4 | Liver of swine |
| T.3.1 | tilmicosin | tilmicosin | 1.6 | Liver of cattle |
| T.3.2 | trimethoprim | trimethoprim | 0.1 | Muscle of salmonids |
| T.4 | tylosin | tylosin | 0.2 | Muscle, liver, kidney and fat of cattle, swine, chickens and |

| | Column I | Column II | Column III | Column IV |
|---|---|---|---|---|
| Item No. | Common Name (or Brand Name) of Drug | Name of Substance for Drug Analysis Purposes | Maximum Residue Limit p.p.m. | Foods |
| | | | | turkeys |

SOR/84-300, s. 49(E); SOR/91-255, s. 2; SOR/92-591, s. 2; SOR/2002-52, ss. 1 to 12; SOR/2005-396, ss. 1 to 4; SOR/2008-274, ss. 1 to 8; SOR/2010-39, ss. 1(F), 2(F).

Previous Version

# Division 16

# Food Additives

B.16.001. A quantitative statement of the amount of each additive present or directions for use that, if followed, will produce a food that will not contain such additives in excess of the maximum levels of use prescribed by these Regulations shall be shown, grouped together with the list of ingredients, of any substance or mixture of substances for use as a food additive.

B.16.002. A request that a food additive be added to or a change made in the Tables following section B.16.100 shall be accompanied by a submission to the Minister in a form, manner and content satisfactory to him and shall include

(*a*) a description of the food additive, including its chemical name and the name under which it is proposed to be sold, its method of manufacture, its chemical and physical properties, its composition and its specifications and, where that information is not available, a detailed explanation;

(*b*) a statement of the amount of the food additive proposed for use, and the purpose for which it is proposed, together with all directions, recommendations and suggestions for use;

(*c*) where necessary, in the opinion of the Director, an acceptable method of analysis suitable for regulatory purposes that will determine the amount of the food additive and of any substance resulting from the use of the food additive in the finished food;

(*d*) data establishing that the food additive will have the intended physical or other technical effect;

(*e*) detailed reports of tests made to establish the safety of the food additive under the conditions of use recommended;

(*f*) data to indicate the residues that may remain in or upon the finished food when the food additive is used in accordance with good manufacturing practice;

(*g*) a proposed maximum limit for residues of the food additive in or upon the finished food;

(*h*) specimens of the labelling proposed for the food additive; and

(*i*) a sample of the food additive in the form in which it is proposed to be used in foods, a sample of the active ingredient, and, on request a sample of food containing the food additive.

B.16.003. The Minister shall, within 90 days after the filing of a submission in accordance with section B.16.002, notify the person filing the submission whether or not it is his intention to recommend to the Governor-in-Council that the said food additive be so listed and the detail of any listing to be recommended.

B.16.004. [Repealed, SOR/97-148, s. 6]

B.16.006. Paragraph B.01.042(*c*) and paragraph B.01.043(*a*) do not apply to spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives.

B.16.007. No person shall sell a food containing a food additive other than a food additive provided for in sections B.01.042, B.01.043 and B.25.062.

SOR/87-640, s. 5.

B.16.008. [Repealed, SOR/88-418, s. 5]

B.16.100. No person shall sell any substance as a food additive unless the food additive is listed in one or more of the following Tables:

TABLE I

FOOD ADDITIVES THAT MAY BE USED AS ANTICAKING AGENTS

| | Column I | Column II | Column III |
|---|---|---|---|
| Item No. | Additive | Permitted in or Upon | Maximum Level of Use |
| C.1 | Calcium Aluminum | (1) Salt | (1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(*a*) |
| | Silicate | (2) Garlic salt; Onion salt | (2) 2.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |
| | | (3) Unstandardized dry mixes | (3) Good Manufacturing Practice |
| C.2 | Calcium Phosphate | (1) Salt | (1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(*a*) |
| | tribasic | (2) Garlic salt; Onion salt | (2) 2.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |
| | | (3) Dry cure | (3) Good Manufacturing Practice |
| | | (4) Unstandardized dry mixes | (4) Good Manufacturing Practice |
| | | (5) Oil soluble annatto | (5) Good Manufacturing Practice |
| | | (6) Icing sugar | (6) If used either singly or in combination with Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Magnesium |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | | Stearate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5% |
| C.3 | Calcium Silicate | (1) Salt | (1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(*a*) |
| | | (2) Garlic salt; Onion salt | (2) 2.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |
| | | (3) Baking Powder | (3) 5.0% |
| | | (4) Dry cure | (4) Good Manufacturing Practice |
| | | (5) Unstandardized dry mixes | (5) Good Manufacturing Practice |
| | | (6) Icing sugar | (6) If used either singly or in combination with Calcium Phosphate tribasic, Magnesium Carbonate, Magnesium Silicate, Magnesium Stearate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5% |
| | | (7) Meat Binder or (naming the meat product) Binder | (7) 1.0% |
| | | (8) Grated or shredded (naming the variety) cheese; Grated or shredded cheddar cheese; Unstandardized grated or shredded cheese preparations | (8) If used singly or in combination with microcrystalline cellulose or cellulose, the total amount not to exceed 2.0% |
| | | (9) Dried egg-white (dried albumen); Dried whole egg; Dried whole egg mix; Dried yolk; Dried yolk mix | (9) 2.0% |
| C.4 | Calcium Stearate | (1) Salt | (1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(*a*) |
| | | (2) Garlic salt; Onion salt | (2) 2.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | (3) Unstandardized dry mixes | (3) Good Manufacturing Practice |
| C.5 | Cellulose | Grated or shredded (naming the variety) cheese; Grated or shredded cheddar cheese; Unstandardized grated or shredded cheese preparations | If used singly or in combination with calcium silicate or microcrystalline cellulose, the total amount not to exceed 2.0% |
| M.1 | Magnesium Carbonate | (1) Salt (except when used in preparations of Meat and Meat By-products of Division 14) | (1) 1.0%, except in the case, of fine grained salt 2.0%, in accordance with the requirements of paragraph B.17.001(1)(*a*) |
| | | (2) Garlic salt, Onion salt (except when used in preparations of Meat and Meat By-products of Division 14) | (2) 2.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |
| | | (3) Unstandardized Dry Mixes (Except when used in preparations of Meat and Meat by-products of Division 14) | (3) Good Manufacturing Practice |
| | | (4) Icing sugar | (4) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Silicate, Magnesium Stearate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5% |
| M.2 | Magnesium Oxide | Unstandardized dry mixes (Except when used in preparations of Meat and Meat by-products of Division 14) | Good Manufacturing Practice |
| M.3 | Magnesium Silicate | (1) Salt | (1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(*a*) |
| | | (2) Garlic salt; Onion salt | (2) 2.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |
| | | (3) Unstandardized dry mixes | (3) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | (4) Icing sugar | (4) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5% |
| M.4 | Magnesium Stearate | (1) Salt | (1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(*a*) |
| | | (2) Garlic salt; Onion salt | (2) 2.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |
| | | (3) Unstandardized dry mixes | (3) Good Manufacturing Practice |
| | | (4) Icing sugar | (4) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Silicon Dioxide or Sodium Aluminum Silicate the total must not exceed 1.5% |
| M.5 | Microcrystalline Cellulose | Grated or shredded (naming the variety) cheese; Grated or shredded cheddar cheese; Unstandardized grated or shredded cheese preparations | If used singly or in combination with calcium silicate or cellulose, the total amount not to exceed 2.0% |
| P.1 | Propylene Glycol | Salt | 0.035% |
| S.1 | Silicon Dioxide | (1) Garlic salt; Onion salt | (1) 1.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |
| | | (2) Celery Salt; Celery Pepper | (2) 0.5% |
| | | (3) Unstandardized dry mixes | (3) Good Manufacturing Practice |
| | | (4) Icing sugar | (4) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Magnesium |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | | Stearate or Sodium Aluminum Silicate the total must not exceed 1.5% |
| | | (5) Foods sold in tablet form | (5) Good Manufacturing Practice |
| | | (6) Cayenne Pepper; Chili pepper; Chili Powder; Paprika; Red Pepper | (6) 2.0% |
| | | (7) Salt | (7) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(*a*) |
| S.2 | Sodium Aluminum Silicate | (1) Salt | (1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(*a*) |
| | | (2) Icing sugar | (2) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Magnesium Stearate or Silicon Dioxide the total must not exceed 1.5% |
| | | (3) Dried egg-white (dried albumen); Dried whole egg; Dried whole egg mix; Dried yolk; Dried yolk mix | (3) 2.0% |
| | | (4) Garlic salt; Onion salt | (4) 2.0% in accordance with the requirement of paragraphs B.07.020(*b*) and B.07.027(*b*) respectively |
| | | (5) Unstandardized dry mixes | (5) Good Manufacturing Practice |
| S.3 | Sodium Ferro-cyanide, decahydrate | Salt | 13 p.p.m. calculated as anhydrous sodium ferrocyanide |

SOR/79-662, ss. 3 to 13; SOR/82-913, s. 4; SOR/83-410, s. 2; SOR/84-17, s. 5; SOR/84-801, s. 2; SOR/86-1125, s. 1; SOR/88-534, s. 4; SOR/91-88, ss. 3, 4; SOR/93-477, ss. 3 to 5; SOR/94-689, s. 2(F); SOR/97-191, s. 3; SOR/2010-94, s. 8(E); SOR/2010-143, ss. 11, 12.

TABLE II

FOOD ADDITIVES THAT MAY BE USED AS BLEACHING, MATURING AND DOUGH CONDITIONING AGENTS

| Column I | Column II | Column III |
|---|---|---|

| Item No. | Additive | Permitted in or Upon | Maximum Level of Use |
|---|---|---|---|
| A.1 | Acetone Peroxide | (1) Bread; Flour; Whole wheat flour | (1) Good Manufacturing Practice |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| A.1A | [Repealed, SOR/79-660, s. 3] | | |
| A.2 | Ammonium | (1) Flour; Whole wheat flour | (1) 250 p.p.m. |
| | Persulphate | (2) Bread | (2) 100 p.p.m. of flour |
| | | (3) Unstandardized bakery products | (3) Good Manufacturing Practice |
| A.2A | Ascorbic Acid | (1) Bread; Flour; Whole wheat flour | (1) 200 p.p.m. of flour |
| | | (2) Unstandardized bakery products | (2) 200 p.p.m. of flour |
| A.3 | [Repealed, SOR/79-660, s. 4] | | |
| A.3A | [Repealed, SOR/79-660, s. 4] | | |
| A.4 | Azodicarbonamide | Bread; Flour; Whole wheat flour | 45 p.p.m. of flour |
| B.1 | Benzoyl Peroxide | Flour; Whole wheat flour | 150 p.p.m. |
| C.1 | Calcium Iodate | (1) Bread | (1) 45 p.p.m. of flour |
| | | (2) Unstandardized bakery products | (2) 45 p.p.m. of flour |
| C.2 | Calcium Peroxide | (1) Bread | (1) 100 p.p.m. of flour |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| C.3 | Calcium Stearoyl-2- | (1) Bread | (1) 3,750 p.p.m. of flour |
| | Lactylate | (2) Unstandardized bakery products | (2) 3,750 p.p.m. of flour |
| | | (3) Cake mixes | (3) 0.5% of dry weight of mix |
| C.4 | Chlorine | Flour; Whole wheat flour | Good Manufacturing Practice |
| C.5 | Chlorine Dioxide | Flour; Whole wheat flour | Good Manufacturing Practice |
| C.6 | L-Cysteine Hydrochloride | (1) Bread; Flour; Whole wheat flour | (1) 90 p.p.m. |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| P.1 | [Repealed, SOR/94-227, s. 4] | | |
| P.2 | Potassium Iodate | (1) Bread | (1) 45 p.p.m. of flour |
| | | (2) Unstandardized bakery products | (2) 45 p.p.m. of flour |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| P.3 | Potassium Persulphate | (1) Bread | (1) 100 p.p.m. of flour |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| S.1 | Sodium Stearoyl-2-Lactylate | (1) Bread | (1) 3,750 p.p.m. of flour |
| | | (2) Unstandardized bakery products | (2) 3,750 p.p.m. of flour |
| | | (3) Pancakes and pancake mixes | (3) 0.3% of dry ingredient weight |
| | | (4) Waffles and waffle mixes | (4) 0.3% of dry ingredient weight |
| | | (5) Cake mixes | (5) 0.5% of dry weight of mix |
| S.2 | Sodium Stearyl Fumarate | (1) Bread | (1) 5,000 p.p.m. of flour |
| | | (2) Unstandardized bakery products | (2) 5,000 p.p.m. of flour |
| S.3 | Sodium Sulphite | Biscuit dough | 500 p.p.m. calculated as Sulphur Dioxide |

SOR/79-660, ss. 3, 4; SOR/87-640, s. 6; SOR/92-591, s. 2; SOR/94-227, s. 4; SOR/94-689, s. 2(F); SOR/2005-98, ss. 3, 8(F); SOR/2010-41, s. 9(E).

TABLE III

FOOD ADDITIVES THAT MAY BE USED AS COLOURING AGENTS

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| 1. | Aluminum Metal<br>Alkanet<br>Annatto<br>Anthocyanins<br>Beet Red<br>Canthaxanthin<br>Carbon Black<br>Carotene<br>Charcoal<br>Chlorophyll<br>Cochineal<br>Iron Oxide<br>Orchil<br>Paprika<br>Riboflavin | (1) Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin: Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Liqueurs and alcoholic cordials; (naming the flavour) milk; Pickles and relishes; Pineapple marmalade with pectin; Sherbet; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim milk with added milk | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Tomato catsup; Marinated or similar cold-processed packaged fish and meat (Division 21) | | |
| | Saffron<br>Saunderswood<br>Silver Metal<br>Titanium Dioxide<br>Turmeric<br>Xanthophyll | (2) | Dried whole egg; Dried yolk; Frozen whole egg; Frozen yolk; Liquid whole egg; Liquid yolk | (2) | Good Manufacturing Practice in accordance with paragraphs B.22.034(*b*) and B.22.035(*b*) |
| | | (3) | Unstandardized foods | (3) | Good Manufacturing Practice |
| | | (4) | Vegetable fats and oils | (4) | Good Manufacturing Practice in accordance with section B.09.001 |
| | | (5) | Margarine | (5) | Good Manufacturing Practice |
| | | (6) | (naming the variety) Cheese; Cheddar cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (6) | Good Manufacturing Practice in accordance with the requirements of sections B.08.033, B.08.034, B.08.037, B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3, B.08.041.4, B.08.041.5, B.08.041.6, B.08.041.7 and B.08.041.8. |
| | | (7) | A blend of prepared fish and prepared meat referred to in | (7) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | paragraph B.21.006(*n*) | | | |
| | | (8) | Longaniza; Tocino | (8) | 0.1% in accordance with the requirements of paragraph B.14.031(*i*) or subparagraph B.14.032(*d*)(xvi) |
| | | (9) | Edible collagen film (iron oxide only) | (9) | Good Manufacturing Practice |
| | | (10) | Sausage casings (annatto only) | (10) | 1.0% (Residues of annatto in sausage prepared with such casings not to exceed 100 p.p.m.) |
| | | (11) | Sausage casings (cochineal only) | (11) | 0.75% (Residues of cochineal in sausage prepared with such casings not to exceed 75 p.p.m.) |
| 1A. | ß-apo- 8′-carotenal Ethyl ß-apo- 8′-carotenoate | (1) | Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Liqueurs and alcoholic cordials; Margarine; (naming the flavour) milk; Pickles and relishes; Pineapple marmalade with pectin; Sherbet; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Tomato catsup | (1) | 35 p.p.m. |
| | | (2) | Unstandardized foods | (2) | 35 p.p.m. |
| | | (3) | (naming the variety) Cheese; Cheddar cheese; Cream cheese with (naming the added ingredients); Cream | (3) | 35 p.p.m., in accordance with the requirements of sections B.08.033, B.08.034, B.08.037, B.08.038, B.08.039, B.08.040, |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | | B.08.041, B.08.041.1, B.08.041.2, B.08.041.3, B.08.041.4, B.08.041.5, B.08.041.6, B.08.041.7 and B.08.041.8 |
| | | (4) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (4) | 35 p.p.m. |
| 2. | Caramel | (1) | Ale; Apple (or rhubarb) and (naming the fruit) jam; Beer; Brandy; Bread; Brown bread; Butter; Cider; Cider vinegar; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Holland’s gin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Light beer; Liqueurs and alcoholic cordials; Malt liquor; Malt vinegar; (naming the flavour) milk; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Porter; Rum; Sherbet; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Stout; Tomato catsup; Whisky; Wine; Wine vinegar; Honey wine | | |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| | | (3) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (3) | Good Manufacturing Practice |
| | | (4) | Sausage casings | (4) | 15% (Residues of caramel in sausage prepared with such casings not to exceed 0.15%) |
| 3. | Allura Red<br>Amaranth<br>Erythrosine<br>Indigotine<br>Sunset Yellow FCF<br><br>Tartrazine | (1) | Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Liqueurs and alcoholic cordials; (naming the flavour) milk; Pickles and relishes; Pineapple marmalade with pectin; Sherbet; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Tomato catsup | (1) | 300 p.p.m. singly or in combination in accordance with section B.06.002 |
| | | (2) | Unstandardized foods | (2) | 300 p.p.m. singly or in combination in accordance with section B.06.002 |
| | | (3) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (3) | 300 p.p.m. singly or in combination in accordance with section B.26.002 |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | (4) | Salted anchovy, salted scad and salted shrimp | (4) | 125 p.p.m. in accordance with the requirements of paragraph B.21.021(*d*) |
| | | (5) | Longaniza | (5) | 80 p.p.m. allura red in accordance with the requirements of clause B.14.032(*d*)(xvi)(B) and 20 p.p.m. sunset yellow FCF in accordance with the requirements of clause B.14.032(*d*)(xvi)(C) |
| | | (6) | Sausage casings (sunset yellow FCF only) | (6) | 0.15% (Residues of sunset yellow FCF in sausage prepared with such casings not to exceed 15 p.p.m.) |
| | | (7) | Cheese-flavoured corn snacks (sunset yellow FCF only) | (7) | 600 p.p.m. singly. If used in combination with other colours listed in column I of this item and of item 4 of this table, the maximum level of use is 300 p.p.m. in accordance with paragraph B.06.002(*c*) |
| 4. | Brilliant Blue FCF<br><br>Fast Green FCF | (1) | Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated fruit juice except frozen concentrated orange juice; Fig marmalade with pectin; Ice cream mix; Ice milk mix; Icing sugar; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Liqueurs and alcoholic cordials; (naming the flavour) milk; Pickles and relishes; Pineapple marmalade with pectin; Sherbet; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) skim milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids; Smoked fish; Lobster paste and fish roe (caviar); Tomato catsup | (1) | 100 p.p.m. singly or in combination in accordance with section B.06.002 |

| Item No. | Column I Additive | Column II Permitted in or Upon | | Column III Maximum Level of Use | |
|---|---|---|---|---|---|
| | | (2) | Unstandardized foods | (2) | 100 p.p.m. singly or in combination in accordance with section B.06.002 |
| | | (3) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (3) | 100 p.p.m. singly or in combination in accordance with section B.06.002 |
| | | (4) | Feta cheese (brilliant blue FCF only) | (4) | 0.10 p.p.m. |
| 5. | Citrus Red No. 2 | | Skins of whole oranges | | 2 p.p.m. |
| 6. | Ponceau SX | | Fruit Peel; Glacé fruits; Maraschino Cherries | | 150 p.p.m. |
| 7. | Gold | | Alcoholic beverages | | Good Manufacturing Practice |

SOR/79-752, s. 5; SOR/80-500, s. 6; SOR/82-596, s. 3; SOR/84-440, s. 4; SOR/84-602, s. 1; SOR/89-198, ss. 6 to 10; SOR/92-725, s. 5; SOR/93-466, s. 2; SOR/94-689, s. 2(F); SOR/95-434, s. 1; SOR/95-493, s. 1; SOR/97-516, s. 4; SOR/98-580, s. 1(F); SOR/99-96, s. 1; SOR/2000-50, s. 1; SOR/2000-146, ss. 1 to 3; SOR/2007-75, s. 3; SOR/2010-94, s. 8(E); SOR/2010-143, s. 13.

TABLE IV

FOOD ADDITIVES THAT MAY BE USED AS EMULSIFYING, GELLING, STABILIZING AND THICKENING AGENTS

| Item No. | Column I Additive | Column II Permitted in or Upon | | Column III Maximum Level of Use | |
|---|---|---|---|---|---|
| A.1 | Acacia Gum | (1) | Cream; French dressing; (naming the flavour) Milk; Mustard pickles; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk solids; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Skim milk with added milk solids; | (1) | Good Manufacturing Practice |
| | | (2) | Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sherbet | (3) | 0.75% |
| | | (4) | Unstandardized foods | (4) | Good Manufacturing Practice |
| | | (5) | Calorie-reduced | (5) | 0.5% in accordance with the |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | margarine | | requirements of section B.09.017 |
| | | (6) | Canned asparagus; Canned green beans; Canned wax beans; Canned peas | (6) | 1.0% in accordance with the requirements of clause B.11.002(*d*)(viii)(C) |
| A.2 | Acetylated Mono-glycerides | | Unstandardized foods | | Good Manufacturing Practice |
| A.3 | Acetylated Tartaric Acid Esters of Mono- and Di-glycerides | (1) | Bread | (1) | 6,000 p.p.m. of flour |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| | | (3) | Infant formulas based on crystalline amino acids | (3) | 240 p.p.m. as consumed |
| A.4 | Agar | (1) | Brawn; Canned (naming the poultry); Cream; Headcheese; (naming the fruit) Jelly with pectin; Meat binder (when sold for use in prepared meat or meat by-products in which a gelling agent is a permitted ingredient); Meat by-product loaf; Meat loaf; (naming the flavour) Milk; Mustard pickles; Potted meat; Potted meat by-product; Prepared fish or prepared meat (Division 21); Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids | (1) | Good Manufacturing Practice |
| | | (2) | Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sherbet | (3) | 0.75% |
| | | (4) | Unstandardized foods | (4) | Good Manufacturing Practice |
| | | (5) | Calorie-reduced margarine | (5) | 0.5% in accordance with the requirements of section |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | | | B.09.017 |
| A.5 | Algin | (1) | Ale; Beer; Cream; French dressing; Light beer; Malt liquor; (naming the flavour) Milk; Mustard pickles; Porter; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids; Stout | (1) | Good Manufacturing Practice |
| | | (2) | Infant formula | (2) | 0.03% as consumed. If used in combination with carrageenan or guar gum or both, the total not to exceed 0.03% |
| | | (3) | Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix | (3) | 0.5% |
| | | (4) | Sherbet | (4) | 0.75% |
| | | (5) | Unstandardized foods | (5) | Good Manufacturing Practice |
| | | (6) | Calorie-reduced margarine | (6) | 0.5% in accordance with the requirements of section B.09.017 |
| | | (7) | Sour cream | (7) | 0.5% in accordance with the requirements of clause B.08.077(*b*)(vii)(A) |
| | | (8) | Canned asparagus; Canned green beans; Canned wax beans; Canned peas | (8) | 1.0% in accordance with the requirements of clause B.11.002(*d*)(viii)(C) |
| | | (9) | Infant formula based on isolated amino acids or protein hydrolysates, or both | (9) | 0.1% as consumed. If used in combination with carrageenan or guar gum or both, the total not to exceed 0.1% |
| | | (10) | Lactose-free infant formula based on milk protein | (10) | 0.05% as consumed. If used in combination with carrageenan or guar gum or |

| Item No. | Column I<br>Additive | | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|---|
| | | | | | both, the total not to exceed 0.05% |
| A.6 | Alginic Acid | | Same foods as listed for Algin | | Same levels as prescribed for Algin |
| A.7 | Ammonium Alginate | | Same foods as listed for Algin | | Same levels as prescribed for Algin |
| A.8 | Ammonium Carrageenan | | Same foods as listed for Carrageenan | | Same levels as prescribed for Carrageenan |
| A.9 | Ammonium Furcelleran | | Same foods as listed for Furcelleran | | Same levels as prescribed for Furcelleran |
| A.9A | Ammonium Salt of Phosphorylated Glyceride | (1) | Bread; Cream; (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids | (1) | Good Manufacturing Practice |
| | | (2) | Ice Cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sherbet | (3) | 0.75% |
| | | (4) | Unstandardized foods | (4) | Good Manufacturing Practice |
| | | (5) | Chocolate products; Cocoa products | (5) | 0.7% |
| A.10 | Arabino-galactan | (1) | Essential oils; unstandardized dressings, pudding mixes; beverage bases and mixes; pie filling mixes | (1) | Good Manufacturing Practice |
| B.1 | Baker’s yeast Glycan | | Unstandardized foods | | Good Manufacturing Practice |
| C.1 | Calcium Alginate | | Same foods as listed for Algin | | Same levels as prescribed for Algin |
| C.2 | Calcium Carbonate | (1) | Unstandardized Foods | (1) | Good Manufacturing Practice |
| | | (2) | A blend of prepared fish and prepared meat referred to in paragraph | (2) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | B.21.006(*n*) | |
| C.3 | Calcium Carrageenan | Same foods as listed for Carrageenan | Same levels as prescribed for Carrageenan |
| C.4 | Calcium Citrate | (1) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| C.5 | Calcium Furcelleran | Same foods as listed for Furcelleran | Same levels as prescribed for Furcelleran |
| C.6 | Calcium Gluconate | Unstandardized foods | Good Manufacturing Practice |
| C.7 | Calcium Glycerophosphate | Unstandardized dessert mixes | Good Manufacturing Practice |
| C.8 | Calcium Hypophosphite | Unstandardized dessert mixes | Good Manufacturing Practice |
| C.9 | Calcium Phosphate, dibasic | (1) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| C.10 | Calcium Phosphate, tribasic | | Unstandardized foods | | Good Manufacturing Practice |
| C.11 | Calcium Sulphate | (1) | Ice cream; Ice cream mix; Ice milk; Ice milk mix | (1) | 0.5% |
| | | (2) | Sherbet | (2) | 0.75% |
| | | (3) | Unstandardized foods | (3) | Good Manufacturing Practice |
| | | (4) | Creamed cottage cheese | (4) | 0.05% |
| | | (5) | Cream for whipping, heat-treated above 100°C | (5) | 0.005% |
| | | (6) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (6) | 0.06% |
| C.12 | Calcium Tartrate | | Unstandardized foods | | Good Manufacturing Practice |
| C.13 | Carboxymethyl Cellulose | | Same foods as listed for Sodium Carboxymethyl Cellulose | | Same levels as prescribed for Sodium Carboxymethyl Cellulose |
| C.14 | Carob Bean Gum | (1) | Cream; French dressing; (naming the flavour) Milk; Mustard pickles; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids | (1) | Good Manufacturing Practice |
| | | (2) | Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Calorie-reduced margarine | (3) | 0.5% in accordance with the requirements of paragraph B.09.017(*b*) |
| | | (4) | Sherbet | (4) | 0.75% |
| | | (5) | Sour cream | (5) | 0.5% in accordance with the requirements of clause B.08.077(*b*)(vii)(A) |
| | | (6) | Unstandardized Foods | (6) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | (7) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (7) | 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8 |
| C.15 | Carrageenan | (1) | Ale; Beer; Brawn; Canned (naming the poultry); Cream; French dressing; Headcheese; (naming the fruit) Jelly with pectin; Light beer; Malt liquor; Meat binder (when sold for use in prepared meat or prepared meat by-products in which a gelling agent is a permitted ingredient); Meat by-product loaf; Meat loaf; (naming the flavour) Milk; Mustard pickles; Porter; Potted meat; Potted meat by-product; Prepared fish or prepared meat (Division 21); Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | milk with added milk solids; Stout | | |
| | | (2) | Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Evaporated milk | (3) | 0.015% |
| | | (4) | Sherbet | (4) | 0.75% |
| | | (5) | Evaporated partly skimmed milk; Concentrated partly skimmed milk | (5) | 0.01% |
| | | (6) | Infant formula based on isolated amino acids or protein hydrolysates, or both | (6) | 0.1% as consumed. If used in combination with algin or guar gum or both, the total not to exceed 0.1% |
| | | (7) | Infant formula | (7) | 0.03% as consumed. If used in combination with algin or guar gum or both, the total not to exceed 0.03% |
| | | (8) | Unstandardized foods | (8) | Good Manufacturing Practice |
| | | (9) | Calorie-reduced margarine | (9) | 0.5% in accordance with the requirements of section B.09.017 |
| | | (10) | Sour cream | (10) | 0.5%, in accordance with the requirements of clause B.08.077(*b*)(vii)(A) |
| | | (11) | Canned asparagus; Canned green beans; Canned wax beans; Canned peas | (11) | 1.0% in accordance with the requirements of clause B.11.002(*d*)(viii)(C) |
| | | (12) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the | (12) | 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8 |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | | |
| | | (13) | Lactose-free infant formula based on milk protein | (13) | 0.05% as consumed. If used in combination with algin or guar gum or both, the total not to exceed 0.05% |
| C.17 | Cellulose Gum | | Same foods as listed for Sodium Carboxymethyl Cellulose | | Same levels as prescribed for Sodium Carboxymethyl Cellulose |
| F.1 | Furcelleran | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| | | (3) | Calorie-reduced margarine | (3) | 0.5% in accordance with the requirements of section B.09.017 |
| | | (4) | Canned asparagus; Canned green beans; Canned waxed beans; Canned peas | (4) | 1.0% in accordance with the requirements of clause B.11.002(*d*)(viii)(C) |
| G.1 | Gelatin | (1) | Brawn; Canned (naming the poultry); Cream; Headcheese; (naming the fruit) Jelly with pectin; Meat binder (when sold for use in prepared meat by-products in which a gelling agent is a permitted ingredient); Meat by-product loaf; Meat loaf; (naming the flavour) Milk; Mustard pickles; Potted meat; Potted meat by-product; Prepared fish or prepared meat (Division 21); Prepared hams, shoulders, butts and picnics; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids | | |
| | | (2) | Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sherbet | (3) | 0.75% |
| | | (4) | Sour cream | (4) | 0.5% in accordance with the requirements of clause B.08.077(*b*)(vii)(A) |
| | | (5) | Unstandardized Foods | (5) | Good Manufacturing Practice |
| | | (6) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (6) | 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8 |
| G.2 | Gellan Gum | (1) | Frostings; Unstandardized confectionery | (1) | 0.5% |
| | | (2) | Fruit spreads; Aspic; Processed fruit products; (except for any of these products for which standards are set out in these Regulations) | (2) | 0.3% |
| | | (3) | Calorie-reduced margarine; Reduced fat spreads | (3) | 0.25% |
| | | (4) | Dairy products (except for any of these products | (4) | 0.15% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | for which standards are set out in these Regulations) | | |
| | | (5) | French Dressing; Salad Dressing; Dressings (except for any of these products for which standards are set out in these Regulations); Gelatins; Puddings; Fillings | (5) | 0.1% |
| | | (6) | Baking mixes; Bakery products; (except for any of these products for which standards are set out in these Regulations) | (6) | 0.1% of the dry mix |
| | | (7) | Sauces; Toppings; Table syrups; (except for any of these products for which standards are set out in these Regulations) | (7) | 0.05% |
| | | (8) | Beverages (except for any of these products for which standards are set out in these Regulations) | (8) | 0.08% |
| | | (9) | Snack foods (except for any of these products for which standards are set out in these Regulations) | (9) | 0.1% |
| G.3 | Guar Gum | (1) | Cream; French dressing; (naming the flavour) Milk; Mince meat; Mustard pickles; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids; | (1) | Good Manufacturing Practice |
| | | (2) | Cottage cheese; Creamed cottage cheese; Ice cream; | (2) | 0.5% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | Ice cream mix; Ice milk; Ice milk mix | | |
| | | (3) | Infant formula | (3) | 0.03% as consumed. If used in combination with algin or carrageenan or both, the total not to exceed 0.03% |
| | | (4) | Sherbet | (4) | 0.75% |
| | | (5) | Unstandardized foods | (5) | Good Manufacturing Practice |
| | | (6) | Calorie-reduced margarine | (6) | 0.5% in accordance with the requirements of section B.09.017 |
| | | (7) | Sour cream | (7) | 0.5% in accordance with the requirements of clause B.08.077(*b*)(vii)(A) |
| | | (8) | Canned asparagus; Canned green beans; Canned waxed beans; Canned peas | (8) | 1.0% in accordance with the requirements of clause B.11.002(*d*)(viii)(C) |
| | | (9) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (9) | 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8 |
| | | (10) | Infant formula based on isolated amino acids or protein hydrolysates, or both | (10) | 0.1% as consumed. If used in combination with algin or carrageenan or both, the total not to exceed 0.1% |
| | | (11) | Lactose-free infant formula based on milk protein | (11) | 0.05% as consumed. If used in combination with algin or carrageenan or both, the total not to exceed 0.05% |

| Item No. | Column I<br>Additive | | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|---|
| G.4 | Gum Arabic | | Same foods as listed for Acacia Gum | | Same level as prescribed for Acacia Gum |
| H.1 | Hydroxylated Lecithin | (1) | Chocolate products; Cocoa products | (1) | 1.0% |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| H.1A | Hydroxypropyl Cellulose | | Unstandardized foods | | Good Manufacturing Practice |
| H.2 | Hydroxypropyl Methylcellulose | (1) | French dressing; (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids; Salad dressing | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| I.1 | Irish Moss Gelose | | Same foods as listed for Carrageenan | | Same levels as prescribed for Carrageenan |
| K.1 | Karaya Gum | (1) | French dressing; (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids; Salad dressing | (1) | Good Manufacturing Practice |
| | | (2) | Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sherbet | (3) | 0.75% |
| | | (4) | Unstandardized foods | (4) | Good Manufacturing Practice |
| | | (5) | Calorie-reduced margarine | (5) | 0.5% in accordance with the requirements of section |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | | | B.09.017 |
| L.1 | Lactylated Mono- and Di-glycerides | (1) | Shortening | (1) | 8.0% (except that the total combined mono- and di-glycerides and lactylated mono- and di-glycerides must not exceed 20.0% of the shortening) |
| | | (2) | Unstandardized foods | (2) | 8.0% of the fat content |
| L.1A | Lactylic Esters of Fatty Acids | | Unstandardized foods | | Good Manufacturing Practice |
| L.2 | Lecithin | (1) | Bread; Cream; (naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids | (1) | Good Manufacturing Practice |
| | | (2) | Ice Cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5%, singly or in combination with other emulsifiers |
| | | (3) | Infant formula | (3) | 0.03% as consumed |
| | | (4) | Sherbet | (4) | 0.75% |
| | | (5) | Unstandardized foods | (5) | Good Manufacturing Practice |
| | | (6) | Margarine | (6) | 0.2% |
| | | (7) | Calorie-reduced margarine | (7) | 0.5% |
| | | (8) | Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added | (8) | 0.2% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | ingredients) | | |
| | | (9) | Milk powder | (9) | 0.5% |
| | | (10) | Chocolate products; Cocoa products | (10) | 1.0% |
| L.3 | Locust Bean Gum | | Same foods as listed for Carob Bean Gum | | Same levels as prescribed for Carob Bean Gum |
| M.1 | Magnesium Chloride | | Tofu | | 0.3%, calculated as the anhydrous salt |
| M.2 | Methylcellulose | (1) | Ale; Beer; French dressing; Light beer; Malt liquor; Porter; Salad dressing; Stout | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| M.3 | Methyl Ethyl Cellulose | | Unstandardized foods | | Good Manufacturing Practice |
| M.4 | Mono-glycerides | (1) | Bread; Cream; Fish paste | (1) | Good Manufacturing Practice |
| | | (2) | Chocolate products; Cocoa products | (2) | 1.5% |
| | | (3) | Ice cream mix; Ice milk mix | (3) | A total of 0.5% of stabilizing agents in accordance with subparagraphs B.08.061(*b*)(vi) and B.08.071(*b*)(vi) |
| | | (4) | Creamed cottage cheese | (4) | Good Manufacturing Practice |
| | | (5) | Infant formula | (5) | 0.25% as consumed |
| | | (6) | Sausage casings | (6) | 0.35% of the casing |
| | | (7) | Margarine | (7) | 0.5% |
| | | (8) | Sherbet | (8) | 0.75% |
| | | (9) | Shortening | (9) | 10.0% (except that the total combined mono and diglycerides and lactylated mono and diglycerides must not exceed 20.0% of the shortening) |
| | | (10) | Sour Cream | (10) | 0.3% |
| | | (11) | Unstandardized Foods | (11) | Good Manufacturing Practice |
| | | (12) | Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; | (12) | 0.5% in accordance with the requirements of sections B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | |
| M.5 | Mono- and Di-glycerides | (1) Bread; Cream; Fish paste | (1) Good Manufacturing Practice |
| | | (2) Chocolate products; Cocoa products | (2) 1.5% |
| | | (3) Ice cream mix; Ice milk mix | (3) A total of 0.5% of stabilizing agents in accordance with subparagraphs B.08.061(*b*)(vi) and B.08.071(*b*)(vi) |
| | | (4) Cottage Cheese; Creamed Cottage Cheese | (4) Good Manufacturing Practice |
| | | (5) Infant formula | (5) 0.25% as consumed |
| | | (6) Sausage casings | (6) 0.35% of the casing |
| | | (7) Margarine | (7) 0.5% |
| | | (8) Sherbet | (8) 0.75% |
| | | (9) Shortening | (9) 10.0% (except that the total combined mono and diglycerides and lactylated mono and diglycerides must not exceed 20.0% of the shortening) |
| | | (10) Sour Cream | (10) 0.3% |
| | | (11) Unstandardized Foods | (11) Good Manufacturing Practice |
| | | (12) Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (12) 0.5% in accordance with the requirements of sections B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| M.6 | Monosodium Salts of Phosphorylated | (1) Edible vegetable oil-based cookware coating | (1) 4.0% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | Mono- and Diglycerides | | emulsions | | |
| O.1 | Oat Gum | (1) | Unstandardized Foods | (1) | Good Manufacturing Practice |
| P.1 | Pectin | (1) | Apple (or rhubarb) and (naming the fruit) Jam; Cream; Fig marmalade; Fig marmalade with pectin; French dressing; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade with pectin; (naming the flavour) Milk; Mince meat; Mustard pickles; Pineapple marmalade; Pineapple marmalade with pectin; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids | (1) | Good Manufacturing Practice |
| | | (2) | Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sour cream | (3) | 0.5% in accordance with the requirement of clause B.08.077(*b*)(vii)(A) |
| | | (4) | Sherbet | (4) | 0.75% |
| | | (5) | Unstandardized foods | (5) | Good Manufacturing Practice |
| P.1A | Polyglycerol Esters of Fatty Acids | (1) | Unstandardized foods | (1) | Good Manufacturing Practice |
| | | (2) | Vegetable oils | (2) | 0.025% |
| | | (3) | Calorie-reduced margarine | (3) | 0.2% in accordance with the requirements of paragraph B.09.017(*c*) |
| P.1B | Polyglycerol Esters | (1) | Chocolate products | (1) | 0.5% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | of Interesterified | | | | |
| | Castor Oil Fatty Acids | (2) | Unstandardized chocolate flavoured confectionery coatings | (2) | 0.25% |
| | | (3) | Edible vegetable oil-based pan coating emulsions for use on baking pans | (3) | 2.0% |
| P.2 | Polyoxyethylene (20) Sorbitan Monooleate; | (1) | Ice cream; Ice cream mix; Ice milk; Ice milk mix; Sherbet | (1) | 0.1%. If Polyoxyethylene (20) sorbitan tristearate is also used, the total must not exceed 0.1% |
| | Polysorbate 80 | (2) | Unstandardized frozen desserts | (2) | 0.1% |
| | | (3) | Pickles and relishes | (3) | 0.05% |
| | | (4) | Beverage base or mix | (4) | 0.05% of the beverage. If sorbitan monostearate is also used the total must not exceed 0.05% of the beverage |
| | | (5) | Imitation dry cream mix | (5) | 0.1%. If Polyoxyethylene (20) sorbitan monostearate, Polyoxyethylene (20) sorbitan tristearate or Sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.4% |
| | | (6) | Whipped vegetable oil topping | (6) | 0.05%. If Polyoxyethylene (20) sorbitan monostearate, Polyoxyethylene (20) sorbitan tristearate or Sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.4% |
| | | (7) | Cake icing; cake icing mix | (7) | 0.5% of the finished cake icing. If Polyoxyethylene (20) sorbitan monostearate, or Sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.5% of the finished cake icing |
| | | (8) | Salt | (8) | 10 p.p.m. |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | (9) Whipped cream | (9) 0.1% |
| | | (10) Breath freshener products | (10) 100 p.p.m. |
| | | (11) Creamed cottage cheese | (11) 80 p.p.m. |
| | | (12) Spice oils and spice oleoresins for use in pumping pickle employed in the curing of preserved meat or preserved meat by-product (Division 14) | (12) 0.2% of the pumping pickle |
| | | (13) Sausage casings | (13) 0.15% of the casing |
| | | (14) Liquid Smoke Flavours | (14) Good Manufacturing Practice. Residues of Polysorbate 80 must not exceed 275 p.p.m. in the finished food |
| | | (15) Vegetable oils | (15) 0.125% |
| | | (16) Annatto formulations | (16) 25% of the total colour formulation |
| | | (17) Turmeric formulations | (17) 50% of the total colour formulation |
| | | (18) Liquid smoke flavour concentrate | (18) Good Manufacturing Practice. Residues of Polysorbate 80 must not exceed 0.3% in the finished food. |
| | | (19) Unstandardized salad dressing | (19) 0.25% |
| P.3 | Polyoxyethylene (20) Sorbitan Monostearate;<br><br>Polysorbate 60 | (1) Imitation dry cream mix; Vegetable oil creaming agent; Whipped vegetable oil topping; Vegetable oil topping mix | (1) 0.4%. If Polyoxyethylene (20) sorbitan tristearate, Sorbitan monostearate or Polyoxyethylene (20) sorbitan mono-oleate, either singly or in combination is also used, the total must not exceed 0.4%, except that in the case of whipped vegetable oil topping a combination of Polysorbate 60 and Sorbitan monostearate may be used in excess of 0.4%, if the amount of the Polysorbate 60 does not exceed 0.77% and the amount of Sorbitan monostearate does not exceed 0.27% of the whipped vegetable oil topping |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|
| | | (2) | Cakes | (2) 0.5% on a dry weight basis. If Polyoxyethylene (20) sorbitan tristearate is also used, the total must not exceed 0.5% on a dry weight basis |
| | | (3) | Cakes; Cake mixes | (3) 0.5% on a dry weight basis. If Sorbitan monostearate is also used, the total must not exceed 0.7% on a dry weight basis |
| | | (4) | Unstandardized confectionery coatings and unstandardized moulded confectionery products for use as confectionery or in baking | (4) 0.5%. If any combination of Polyoxyethylene (20) Sorbitan tristearate, Sorbitan monostearate or Sorbitan tristearate are all used the total must not exceed 1.0% |
| | | (5) | Cake icing; Cake icing mix | (5) 0.5% of the finished cake icing. If Sorbitan monostearate or Polyoxyethylene (20) sorbitan mono-oleate either singly or in combination is also used, the total must not exceed 0.5% of the finished cake icing |
| | | (6) | Pudding; Pie filling | (6) 0.5% on a dry weight basis |
| | | (7) | Beverage base or mix | (7) 0.05% of the beverage. If Sorbitan monostearate is also used the total must not exceed 0.05% of the beverage |
| | | (8) | Sour Cream Substitute | (8) 0.1% |
| | | (9) | Unstandardized dressings; Unstandardized prepared canned cooking sauces | (9) 0.3% |
| | | (10) | Fat base formulation for self-basting of poultry by injection | (10) 0.25% |
| | | (11) | Unstandardized sandwich spreads; Unstandardized dips | (11) 0.2% |
| | | (12) | Dry soup base or mix | (12) 250 p.p.m. in soup as prepared for consumption |
| | | (13) | Dry batter coating mixes | (13) 0.5% of the dry mix |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | (14) | Prepared alcoholic cocktails | (14) | 120 p.p.m. in beverage as prepared for consumption |
| P.4 | Polyoxyethylene (20) Sorbitan Tristearate;<br><br>Polysorbate 65 | (1) | (Naming the flavour) Milk; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids | (1) | 0.5% |
| | | (2) | Ice cream; Ice cream mix; Ice milk; Ice milk mix; Sherbet | (2) | 0.1%. If Polyoxyethylene (20) sorbitan mono-oleate is also used, the total must not exceed 0.1% |
| | | (3) | Unstandardized frozen desserts | (3) | 0.1% |
| | | (4) | Cakes | (4) | 0.3% on a dry weight basis. If Polyoxyethylene (20) sorbitan monostearate is also used, the total must not exceed 0.5% on a dry weight basis |
| | | (5) | Unstandardized confectionery coatings | (5) | 0.5%. If any combination of Polyoxyethylene (20) sorbitan monostearate, Sorbitan monostearate, or Sorbitan tristearate are also used, the total must not exceed 1.0% |
| | | (6) | Beverage base or mix | (6) | 0.05% of the beverage. If Sorbitan monostearate is also used, the total must not exceed 0.05% of the beverage |
| | | (7) | Imitation dry cream mix; Vegetable oil creaming agent; Whipped vegetable oil topping; Vegetable oil topping mix | (7) | 0.4%. If Polyoxyethylene (20) sorbitan monostearate, Sorbitan monostearate or Polyoxyethylene (20) sorbitan mono-oleate, either singly or in combination is also used, the total must not exceed 0.4% |
| | | (8) | Breath freshener products | (8) | 200 p.p.m. |
| P.5 | Polyoxyethylene (8) Stearate | | Unstandardized bakery products | | 0.4% |

| Item No. | Column I<br>Additive | | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|---|
| P.6 | Potassium Alginate | | Same foods as listed for Algin | | Same levels as prescribed for Algin |
| P.7 | Potassium Carrageenan | | Same foods as listed for Carrageenan | | Same levels as prescribed for Carrageenan |
| P.8 | Potassium Chloride | | Unstandardized foods | | Good Manufacturing Practice |
| P.9 | Potassium Citrate | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) | 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| P.10 | Potassium Furcelleran | | Same foods as listed for Furcelleran | | Same levels as prescribed for Furcelleran |
| P.11 | Potassium Phosphate, dibasic | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) | 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| P.12 | Propylene Glycol Alginate | (1) | Ale; Beer; French dressing; Light beer; Malt liquor; Mustard pickles; Porter; Relishes; Salad | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | dressing; Stout | | |
| | | (2) | Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sherbet | (3) | 0.75% |
| | | (4) | Unstandardized foods | (4) | Good Manufacturing Practice |
| | | (5) | Calorie-reduced margarine | (5) | 0.5% in accordance with the requirements of section B.09.017 |
| | | (6) | Sour cream | (6) | 0.5% in accordance with the requirements of clause B.08.077(*b*)(vii)(A) |
| | | (7) | Canned asparagus; Canned green beans; Canned wax beans; Canned peas | (7) | 1.0% in accordance with the requirements of clause B.11.002(*d*)(viii)(C) |
| | | (8) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (8) | 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8 |
| P.13 | Propylene Glycol Ether of Methylcellulose | | Same foods as listed for Hydroxypropyl Methylcellulose | | Same levels as prescribed for Hydroxypropyl Methylcellulose |
| P.14 | Propylene Glycol Mono Fatty Acid Esters | (1) | Ice cream mix | (1) | 0.35% of the ice cream made from the mix |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| S.1 | Sodium Acid Pyrophosphate | (1) | Cream cheese spread; Cream cheese spread with (naming the added | (1) | 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | | B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| S.2 | Sodium Alginate | (1) | Same foods as listed for Algin | (1) | Same levels as prescribed for Algin |
| | | (2) | Coarse crystal salt | (2) | 15 p.p.m. |
| | | (3) | Glaze of frozen fish | (3) | Good Manufacturing Practice |
| S.2A | Sodium Alumi-num Phosphate | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) | 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| S.3 | Sodium Carboxymethyl Cellulose | (1) | Cream; French dressing; (naming the flavour) Milk; Mustard pickles; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk with added milk solids; | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | (naming the flavour) Partly skimmed milk with added milk solids | | |
| | | (2) | Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sherbet | (3) | 0.75% |
| | | (4) | Unstandardized foods | (4) | Good Manufacturing Practice |
| | | (5) | Glaze of frozen fish | (5) | Good Manufacturing Practice |
| | | (6) | Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients) | (6) | 0.5% |
| | | (7) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (7) | 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8 |
| S.4 | Sodium Carrageenan | | Same foods as listed for Carrageenan | | Same levels as prescribed for Carrageenan |
| S.5 | Sodium Cellulose Glycolate | | Same foods as listed for Sodium Carboxymethyl Cellulose | | Same levels as prescribed for Sodium Carboxymethyl Cellulose |
| S.6 | Sodium Citrate | (1) | Cream cheese spread; Cream cheese spread with (naming the added | (1) | 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, |

| Item No. | Column I<br>Additive | | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|---|
| | | | ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | | B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| | | (2) | Evaporated milk; evaporated skim milk or concentrated skim milk; evaporated partly skimmed milk or concentrated partly skimmed milk | (2) | 0.1% singly or in combination with sodium phosphate, dibasic |
| | | (3) | Ice cream; Ice cream mix; Ice milk; Ice milk mix | (3) | 0.5% |
| | | (4) | Sherbet | (4) | 0.75% |
| S.7 | Sodium Furcelleran | | Same foods as listed for Furcelleran | | Same levels as prescribed for Furcelleran |
| S.8 | Sodium Gluconate | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) | 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| S.9 | Sodium Hexameta-phosphate | (1) | Mustard pickles; Relishes | (1) | Good Manufacturing Practice |
| | | (2) | Ice cream; Ice cream mix; | (2) | 0.5% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | Ice milk; Ice milk mix | | |
| | | (3) | Infant formula | (3) | 0.05% as consumed |
| | | (4) | Sherbet | (4) | 0.75% |
| | | (5) | Unstandardized foods | (5) | Good Manufacturing Practice |
| | | (6) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (6) | 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| | | (7) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (7) | 0.1% |
| S.11 | Sodium Phosphate, dibasic | (1) | (Naming the flavour) Milk; Mustard pickles; Relishes; (naming the flavour) Skim milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim Milk with added milk solids; (naming the flavour) Partly skimmed milk with added milk solids | (1) | Good Manufacturing Practice |
| | | (2) | Cottage cheese; Creamed cottage cheese | (2) | 0.5% |
| | | (3) | Evaporated milk; evaporated skim milk or concentrated skim milk; evaporated partly skimmed milk or concentrated partly | (3) | 0.1% singly or in combination with sodium citrate |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | skimmed milk | | |
| | | (4) | Sour cream | (4) | 0.05% in accordance with the requirements of clause B.08.077(*b*)(vii)(C) |
| | | (5) | Unstandardized Foods | (5) | Good Manufacturing Practice |
| | | (6) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (6) | 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| S.12 | Sodium Phosphate, monobasic | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) | 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| S.13 | Sodium Phosphate, tribasic | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) | (1) | 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | | B.08.041.3 and B.08.041.4 |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| S.14 | Sodium Potassium Tartrate | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) | 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| S.15 | Sodium Pyrophosphate, tetrabasic | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with | (1) | 3.5%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | (naming the added ingredients) | | |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| | | (3) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (3) | 0.1% |
| S.15A | Sodium Stearoyl-2-Lac-tylate | (1) | Icing and icing mixes | (1) | 0.4% of dry ingredient weight |
| | | (2) | Fillings and filling mixes | (2) | 0.5% of dry ingredient weight |
| | | (3) | Puddings and pudding mixes | (3) | 0.2% of the finished product |
| | | (4) | Sour cream substitutes | (4) | 1.0% of dry ingredient weight |
| | | (5) | Vegetable oil creaming agents | (5) | 2.0% of dry ingredient weight |
| | | (6) | Batter mix | (6) | 0.75% of dry ingredient weight |
| | | (7) | Unstandardized cream-based liquors | (7) | 0.35% of the finished product |
| | | (8) | Salad dressing; French dressing | (8) | 0.4% of the finished product |
| | | (9) | Soups | (9) | 0.2% of the finished product |
| S.16 | Sodium Tartrate | (1) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (1) | 4.0%, in accordance with the requirements of sections B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3 and B.08.041.4 |
| S.16A | Sodium Tripolyphosphate | | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | | 0.1% |
| S.18 | Sorbitan | (1) | Imitation dry cream mix; | (1) | 0.4%. If Polyoxyethylene (20) |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | Monostearate | Vegetable oil creaming agent; Whipped vegetable oil topping; Vegetable oil topping mix | sorbitan tristearate, Polysorbate 60 or Polyoxyethylene (20) sorbitan mono-oleate, either singly or in combination is also used, the total must not exceed 0.4%, except that in the case of whipped vegetable oil topping a combination of Sorbitan monostearate and Polysorbate 60 may be used in excess of 0.4% if the amount of Sorbitan monostearate does not exceed 0.27% and the amount of Polysorbate 60 does not exceed 0.77% of the weight of the whipped vegetable oil topping |
| | | (2) Cake; Cake mix | (2) 0.6% on a dry weight basis. If Polyoxyethylene (20) sorbitan monostearate is also used, the total must not exceed 0.7% on a dry weight basis |
| | | (3) Unstandardized confectionery coatings and unstandardized moulded confectionery products for use as confectionery or in baking | (3) 1.0%. If any combination of Polyoxyethylene (20) sorbitan monostearate, Polyoxyethylene (20) sorbitan tristearate or Sorbitan tristearate are also used, the total must not exceed 1.0% |
| | | (4) Cake icing; Cake icing mix | (4) 0.5% of the finished cake icing. If Polyoxyethylene (20) sorbitan mono-oleate or Polyoxyethylene (20) sorbitan monostearate, either singly or in combination is also used, the total must not exceed 0.5% of the finished cake icing |
| | | (5) Beverage base or mix | (5) 0.05% of the beverage. If Polyoxyethylene (20) sorbitan mono-oleate is also used, the total must not exceed 0.05% of the beverage. If Polyoxyethylene (20) sorbitan |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | | | monostearate is also used, the total must not exceed 0.05% of the beverage. If Polyoxyethylene (20) sorbitan tristearate is also used, the total must not exceed 0.05% of the beverage |
| | | (6) | Dry soup base or mix | (6) | 250 p.p.m. in soup as prepared for consumption |
| | | (7) | Dried yeast | (7) | 1.5% (Residues of sorbitan monostearate in bread and other yeast leavened bakery products not to exceed 0.05%). |
| | | (8) | Chocolate products | (8) | 1.0% |
| | | (9) | Puddings | (9) | 0.5% |
| S.18A | Sorbitan trioleate | | Sausage casings | | 0.35% of the casing |
| S.18B | Sorbitan Tristearate | (1) | Margarine; Shortening | (1) | 1.0% |
| | | (2) | Unstandardized confectionery coatings and unstandardized moulded confectionery products for use as a confectionery or in baking | (2) | 1.0% If any combination of Polyoxyethylene (20) sorbitan monostearate, Polyoxyethylene (20) sorbitan tristearate or Sorbitan monostearate are also used, the total must not exceed 1.0% |
| | | (3) | Ice cream mix | (3) | 0.035% of the ice cream made from the mix |
| | | (4) | Unstandardized frozen desserts | (4) | 0.035% |
| S.19 | Stearyl Monoglyceridyl Citrate | | Shortening | | Good Manufacturing Practice |
| S.20 | Sucrose esters of fatty acids | (1) | Carotenoid colour preparations | (1) | 1.5% |
| | | (2) | Unstandardized confectionery; Unstandardized confectionery coatings | (2) | 0.5% |
| T.2 | [Repealed, SOR/2006-91, s. 5] | | | | |
| T.3 | Tragacanth Gum | (1) | French dressing; Mustard pickles; Salad dressing; | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | Relishes | | |
| | | (2) | Cottage cheese; Creamed cottage cheese; Ice cream; Ice cream mix; Ice milk; Ice milk mix | (2) | 0.5% |
| | | (3) | Sherbet | (3) | 0.75% |
| | | (4) | Lumpfish Caviar | (4) | 1.0% |
| | | (5) | Unstandardized foods | (5) | Good Manufacturing Practice |
| | | (6) | Calorie-reduced margarine | (6) | 0.5% in accordance with the requirements of section B.09.017 |
| | | (7) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients) | (7) | 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8 |
| | | (8) | Comminuted prepared fish or prepared meat, other than lumpfish caviar; Comminuted preserved fish or preserved meat (Division 21) | (8) | 0.75% |
| X.1 | Xanthan Gum | (1) | French Dressing; Salad Dressing; Unstandardized Foods | (1) | Good Manufacturing Practice |
| | | (2) | Cottage Cheese; Creamed Cottage Cheese | (2) | 0.5% or, if used in combination with other stabilizing agents, the total amount of the combined stabilizers shall not exceed 0.5% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|
| | | (3) | Calorie-reduced margarine | (3) 0.5% in accordance with the requirements of section B.09.017 |
| | | (4) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (4) 0.5%, in accordance with the requirements of sections B.08.035, B.08.037, B.08.038, B.08.039, B.08.041.3, B.08.041.4, B.08.041.6, B.08.041.7 and B.08.041.8 |
| | | (5) | Mustard pickles; relishes | (5) 0.1% |
| | | (6) | Ice Cream Mix | (6) 0.1% or, if used in combination with microcrystalline cellulose and other stabilizers, the total amount of combined stabilizers and microcrystalline cellulose shall not exceed 0.5% |
| | | (7) | Ice Milk Mix | (7) 0.1% or, if used in combination with other stabilizers, the total amount of combined stabilizers shall not exceed 0.5% |
| | | (8) | Sherbet | (8) 0.1% or, if used in combination with other stabilizers, the total amount of combined stabilizers shall not exceed 0.75% |
| | | (9) | Cream for whipping, heat-treated above 100°C | (9) 0.02% |

SOR/78-403, ss. 5(F) to 13(F), 14 to 16, 17(F) to 21(F), 22; SOR/78-656, ss. 14, 15; SOR/78-876, s. 2; SOR/79-660, ss. 5 to 10; SOR/79-752, s. 6; SOR/80-501, s. 4; SOR/81-60, ss. 7 to 10; SOR/81-565, ss. 4, 5; SOR/81-934, ss. 2 to 6; SOR/82-383, s. 9; SOR/82-1071, ss. 9 to

16; SOR/83-932, ss. 3, 4; SOR/84-300, s. 50(E); SOR/84-602, s. 2; SOR/84-801, s. 3; SOR/85-179, ss. 2 to 4; SOR/85-623, s. 3(E); SOR/88-99, s. 3; SOR/88-419, ss. 2, 3; SOR/90-87, s. 9; SOR/91-710, s. 1; SOR/92-64, s. 1; SOR/92-93, s. 2; SOR/92-344, s. 1; SOR/93-466, ss. 3, 4; SOR/94-38, s. 2; SOR/94-567, s. 2; SOR/94-689, s. 2(F); SOR/96-160, s. 2; SOR/96-376, s. 1; SOR/96-497, s. 1; SOR/96-499, s. 1; SOR/97-29, s. 1; SOR/97-263, ss. 4 to 10; SOR/98-580, s. 1(F); SOR/2000-353, s. 7(F); SOR/2005-316, s. 1; SOR/2005-395, ss. 1 to 4, 5(F); SOR/2006-91, ss. 4, 5; SOR/2007-75, ss. 4 to 6; SOR/2007-76, ss. 1, 2; SOR/2010-41, s. 9(E); SOR/2010-94, ss. 8(E), 9(E); SOR/2010-142, ss. 9, 10(F), 11 to 13, 14(F), 15(F), 16.

TABLE V

FOOD ADDITIVES THAT MAY BE USED AS FOOD ENZYMES

| | Column I | Column II | Column III | Column IV |
|---|---|---|---|---|
| Item No. | Additive | Permitted Source | Permitted in or Upon | Maximum Level of Use |
| A.01 | $\alpha$-Acetolactate decarboxylase | *Bacillus subtilis* ToC46 (pUW235) | (1) Brewers' Mash | (1) Good Manufacturing Practice |
| | | | (2) Distillers' Mash | (2) Good Manufacturing Practice |
| A.02 | Aminopeptidase | *Lactococcus lactis* | (1) Cheddar cheese; (naming the variety) Cheese | (1) Good Manufacturing Practice |
| | | | (2) Dairy based flavouring preparations | (2) Good Manufacturing Practice |
| | | | (3) Hydrolyzed animal, milk and vegetable protein | (3) Good Manufacturing Practice |
| A.1 | Amylase | *Aspergillus niger* var.; *Aspergillus oryzae* var.; *Bacillus subtilis* var.; *Rhizopus oryzae* var.; Barley Malt | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | | (2) Bread; Flour; Whole wheat flour | (2) Good Manufacturing Practice |
| | | | (3) Cider; Wine | (3) Good Manufacturing Practice |
| | | | (4) Chocolate syrups | (4) Good Manufacturing Practice |
| | | | (5) Distillers' Mash | (5) Good Manufacturing Practice |
| | | | (6) Malt-flavoured dry breakfast cereals | (6) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | (7) | Single-strength fruit juices | (7) | Good Manufacturing Practice |
| | | | (8) | Precooked (instant) cereals | (8) | Good Manufacturing Practice |
| | | | (9) | Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup) | (9) | Good Manufacturing Practice |
| | | | (10) | Unstandardized bakery products | (10) | Good Manufacturing Practice |
| | | | (11) | Plant-based beverages | (11) | Good Manufacturing Practice |
| | | | (12) | Infant cereal products | (12) | Good Manufacturing Practice |
| | | *Aspergillus niger* STz18-9 (pHUda7) | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | | (2) | Distillers' Mash | (2) | Good Manufacturing Practice |
| | | | (3) | Starch used in the production of dextrins, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup), maltose | (3) | Good Manufacturing Practice |
| | | *Bacillus amyloliquefaciens* EBA 20 (pUBH2); *Bacillus licheniformis*; *Bacillus licheniformis* BML 592 (pAmyAmp); *Bacillus licheniformis* BML 730 (pAmyAmp); *Bacillus licheniformis* LA 57 (pDN1981); *Bacillus* | (1) | Distillers' Mash | (1) | Good Manufacturing Practice |
| | | | (2) | Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried | (2) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | *licheniformis* LAT8(pLAT3); *Bacillus licheniformis* LiH 1159 (pLiH1108); *Bacillus licheniformis* LiH 1464 (pLiH1346); *Bacillus licheniformis* PL 1303 (pPL1117); *Bacillus licheniformis* MOL2083 (pCA164-LE399) | glucose syrup)<br>(3) Brewers' mash | (3) Good Manufacturing Practice |
| | | *Bacillus licheniformis* 3253 (plCatH-3253); *Bacillus licheniformis* 3266 (plCatH-3266ori1); *Bacillus stearothermophilus*; *Bacillus subtilis* B1.109 (pCPC800) | (1) Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup) | (1) Good Manufacturing Practice |
| | | | (2) Distillers' Mash | (2) Good Manufacturing Practice |
| | | | (3) Brewers' Mash | (3) Good Manufacturing Practice |
| | | | (4) Bread; Flour; Whole wheat flour | (4) Good Manufacturing Practice |
| | | | (5) Unstandardized bakery products | (5) Good Manufacturing Practice |
| | | *Bacillus subtilis* B1.109 (pCPC720) (ATCC 39, 705) | (1) Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup) | (1) Good Manufacturing Practice |
| | | | (2) Distillers' Mash | (2) Good Manufacturing Practice |
| | | | (3) Brewers' Mash | (3) Good Manufacturing Practice |
| | | | (4) Bakery Products | (4) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| A.2 | Amylase (maltogenic) | *Bacillus subtilis* BRG-1 (pBRG1); *Bacillus subtilis* DN1413 (pDN1413); *Bacillus subtilis* LFA 63 (pLFA63); *Bacillus subtilis* RB-147 (pRB147) | (1) | Starch used in the production of dextrins, maltose, dextrose, glucose, (glucose syrup) or glucose solids (dried glucose syrup) | (1) | Good manufacturing practice |
| | | | (2) | Bread; Flour; Whole wheat flour | (2) | Good manufacturing practice |
| | | | (3) | Unstandardized bakery products | (3) | Good manufacturing practice |
| B.1 | Bovine Rennet | Aqueous extracts from the fourth stomach of adult bovine animals, sheep and goats | | Cheddar cheese; Cottage cheese; Cream cheese; Cream cheese spread; Cream cheese spread with (naming the added ingredients); Cream cheese with (naming the added ingredients); (naming the variety) Cheese | | Good Manufacturing Practice |
| B.2 | Bromelain | The pineapples *Ananas comosus* and *Ananas bracteatus* | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | | (2) | Bread; Flour; Whole wheat flour | (2) | Good Manufacturing Practice |
| | | | (3) | Sausage casings | (3) | Good Manufacturing Practice |
| | | | (4) | Hydrolyzed animal, milk and vegetable protein | (4) | Good Manufacturing Practice |
| | | | (5) | Meat cuts | (5) | Good Manufacturing Practice |
| | | | (6) | Meat tenderizing preparations | (6) | Good Manufacturing Practice |
| | | | (7) | Pumping pickle for | (7) | Good |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | | the curing of beef cuts | | Manufacturing Practice in accordance with paragraph B.14.009(*g*) |
| | | | (8) | Sugar wafers, waffles, pancakes | (8) | Good Manufacturing Practice |
| C.1 | Catalase | | (1) | Soft drinks | (1) | Good Manufacturing Practice |
| | | *Aspergillus niger* var.; *Micrococcus lysodeikticus*; Bovine (*Bos taurus*) liver | (2) | Liquid egg-white (liquid albumen), liquid whole egg or liquid yolk, destined for drying | (2) | Good Manufacturing Practice |
| | | | (3) | Liquid whey treated with hydrogen peroxide in accordance with item H.1, Table VIII | (3) | Good Manufacturing Practice |
| C.2 | Cellulase | *Aspergillus niger* var. | (1) | Distillers' Mash | (1) | Good Manufacturing Practice |
| | | | (2) | Liquid coffee concentrate | (2) | Good Manufacturing Practice |
| | | | (3) | Spice extracts; Natural flavour and colour extractives | (3) | Good Manufacturing Practice |
| | | *Trichoderma reesei* QM 9414 | (1) | Single-strength fruit juices | (1) | Good Manufacturing Practice |
| | | | (2) | Tea leaves for the production of tea solids | (2) | Good Manufacturing Practice |
| C.3 | Chymosin<br>(i) Chymosin A | *Escherichia coli* K-12, GE81 (pPFZ87A) | (1) | Cheddar cheese; (naming the variety) cheese; Cottage cheese; Cream cheese; Cream cheese with (naming the added ingredients); Cream | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | | cheese spread; Cream cheese spread with (naming the added ingredients); Sour cream | | |
| | | | (2) | Unstandardized milk-based dessert preparations | (2) | Good Manufacturing Practice |
| | (ii) Chymosin B | *Aspergillus niger* var. *awamori*, GCC0349 (pGAMpR); *Kluyveromyces marxianus* var. *lactis*, DS1182 (pKS105) | (1) | Cheddar cheese; (naming the variety) cheese; Cottage cheese; Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Sour cream | (1) | Good Manufacturing Practice |
| | | | (2) | Unstandardized milk-based dessert preparations | (2) | Good Manufacturing Practice |
| F.1 | Ficin | Latex of fig tree (*Ficus* sp.) | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | | (2) | Sausage casings | (2) | Good Manufacturing Practice |
| | | | (3) | Hydrolyzed animal, milk and vegetable protein | (3) | Good Manufacturing Practice |
| | | | (4) | Meat cuts | (4) | Good Manufacturing Practice |
| | | | (5) | Meat tenderizing preparations | (5) | Good Manufacturing Practice |
| | | | (6) | Pumping pickle for the curing of beef cuts | (6) | Good Manufacturing Practice in accordance with paragraph B.14.009(*g*) |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| G.1 | Glucoamylase (Amyloglucosidase; Maltase) | *Aspergillus niger* var.; *Aspergillus oryzae* var.; *Rhizopus oryzae* var. | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | | (2) | Bread; Flour; Whole wheat flour | (2) | Good Manufacturing Practice |
| | | | (3) | Chocolate syrups | (3) | Good Manufacturing Practice |
| | | | (4) | Distillers' Mash | (4) | Good Manufacturing Practice |
| | | | (5) | Precooked (instant) cereals | (5) | Good Manufacturing Practice |
| | | | (6) | Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup), or glucose solids (dried glucose syrup) | (6) | Good Manufacturing Practice |
| | | | (7) | Unstandardized bakery products | (7) | Good Manufacturing Practice |
| | | *Aspergillus niger* STz18-9 (pHUda7) | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | | (2) | Distillers' Mash | (2) | Good Manufacturing Practice |
| | | | (3) | Starch used in the production of dextrins, dextrose, glucose (glucose syrup) or glucose solids (dried glucose syrup), maltose | (3) | Good Manufacturing Practice |
| | | *Rhizopus niveus* var. | (1) | Distillers' Mash | (1) | Good Manufacturing Practice |
| | | | (2) | Mash destined for vinegar manufacture | (2) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | *Rhizopus delemar* var.; *Multiplici sporus* | (1) Brewers' Mash | (1) Good Manufacturing Practice |
| | | | (2) Distillers' Mash | (2) Good Manufacturing Practice |
| | | | (3) Mash destined for vinegar manufacture | (3) Good Manufacturing Practice |
| | | | (4) Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup), or glucose solids (dried glucose syrup) | (4) Good Manufacturing Practice |
| G.2 | Glucanase | *Aspergillus niger* var.; *Bacillus subtilis* var. | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | | (2) Corn for degermination | (2) Good Manufacturing Practice |
| | | | (3) Distillers' Mash | (3) Good Manufacturing Practice |
| | | | (4) Mash destined for vinegar manufacture | (4) Good Manufacturing Practice |
| | | | (5) Unstandardized bakery products | (5) Good Manufacturing Practice |
| | | *Humicola insolens* var. | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | | (2) Distillers' Mash | (2) Good Manufacturing Practice |
| G.3 | Glucose oxidase | *Aspergillus niger* var.; *Aspergillus oryzae* Mtl-72 (pHUda107) | (1) Soft drinks | (1) Good Manufacturing Practice |
| | | | (2) Liquid egg-white (liquid albumen), liquid whole egg or liquid yolk, destined | (2) Good Manufacturing Practice in accordance |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | | for drying | | with paragraphs B.22.034(*b*), B.22.035(*b*) and B.22.036(*b*) |
| | | | (3) | Bread; flour; Whole wheat flour | (3) | Good manufacturing practice |
| | | | (4) | Unstandardized bakery products | (4) | Good manufacturing practice |
| G.4 | Glucose Isomerase | *Bacillus coagulans* var.; *Streptomyces olivochromogenes* var.; *Actinoplanes missouriensis* var.; *Streptomyces olivaceus* var.; *Microbacterium arborescens* NRRL B-11022; *Streptomyces murinus* DSM 3252; *Streptomyces rubiginosus* ATCC No. 21,175; *Streptomyces rubiginosus* SYC 5406 (pSYC5239) | (1) | Glucose (glucose syrup) to be partially or completely isomerized to fructose | (1) | Good Manufacturing Practice |
| H.1 | Hemicellulase | *Bacillus subtilis* var. | (1) | Distillers' Mash | (1) | Good Manufacturing Practice |
| | | | (2) | Liquid coffee concentrate | (2) | Good Manufacturing Practice |
| | | | (3) | Mash destined for vinegar manufacture | (3) | Good Manufacturing Practice |
| I.01 | Inulinase | *Aspergillus niger var. Tieghem* | | Inulin | | Good Manufacturing Practice |
| I.1 | Invertase | *Aspergillus japonicus* | | Sucrose used in the production of fructooligosaccharides | | Good Manufacturing Practice |
| | | *Saccharomyces* sp. | (1) | Unstandardized soft-centred and liquid-centred confectionery | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | (2) | Unstandardized bakery products | (2) | Good Manufacturing Practice |
| L.1 | Lactase | | (1) | Lactose-reducing enzyme preparations | (1) | Good Manufacturing Practice |
| | | | (2) | Milk destined for use in ice cream mix | (2) | Good Manufacturing Practice |
| | | *Aspergillus niger* var.; *Aspergillus oryzae* var.; *Kluyveromyces fragilis* (*Kluyveromyces marxianus* var. *marxianus*); *Kluyveromyces lactis* (*Kluyveromyces marxianus* var. *lactis*); *Saccharomyces* sp. | (3) | Bread; Flour; whole wheat flour | (3) | Good Manufacturing Practice |
| | | | (4) | (naming the flavour) milk; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) malted milk; (naming the flavour) skimmed milk with added milk solids; (naming the flavour) partly skimmed milk with added milk solids | (4) | Good Manufacturing Practice |
| | | Cell-free extracts from *Candida pseudotropicalis* | (1) | Milk destined for use in ice cream mix | (1) | Good Manufacturing Practice |
| | | | (2) | Yogurt | (2) | Good Manufacturing Practice |
| | | | (3) | Whey | (3) | Good Manufacturing Practice |
| | | | (4) | (naming the flavour) milk; (naming the flavour) skim milk; (naming the flavour) partly skimmed milk; (naming the flavour) malted milk; (naming the flavour) skim milk with added milk solids; (naming the flavour) partly | (4) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | | skimmed milk with added milk solids | | |
| L.2 | Lipase | | (1) | Dairy based flavouring preparations | (1) | Good Manufacturing Practice |
| | | Animal pancreatic tissue; *Aspergillus niger* var.; *Aspergillus oryzae* var.; Edible forestomach tissue of calves, kids or lambs; *Rhizopus oryzae* var. | (2) | Dried egg-white (dried albumen); Liquid egg-white ( liquid albumen) | (2) | Good Manufacturing Practice |
| | | | (3) | Cheddar cheese; (naming the variety) Cheese; Processed cheddar cheese | (3) | Good Manufacturing Practice |
| | | | (4) | Bread; Flour; Whole wheat flour | (4) | Good Manufacturing Practice |
| | | | (5) | Unstandardized bakery products | (5) | Good Manufacturing Practice |
| | | | (6) | Hydrolyzed animal, milk and vegetable protein | (6) | Good Manufacturing Practice |
| | | *Aspergillus oryzae* (MLT-2) (pRML 787) (p3SR2); *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (*Cooney and Emerson*)); *Rhizopus niveus* | (1) | Modified fats and oils | (1) | Good Manufacturing Practice |
| | | | (2) | Cheddar cheese; (naming the variety) Cheese | (2) | Good Manufacturing Practice |
| | | | (3) | Dairy based flavouring preparations | (3) | Good Manufacturing Practice |
| | | | (4) | Hydrolyzed animal, milk and vegetable protein | (4) | Good Manufacturing Practice |
| | | *Aspergillus oryzae* AI-11 (pBoel 960) | (1) | Bread; Flour; Whole wheat flour | (1) | Good Manufacturing Practice |
| | | | (2) | Unstandardized bakery products | (2) | Good Manufacturing Practice |
| | | | (3) | Modified fats and oils | (3) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | *Aspergillus oryzae* BECh2#3 (pCaHj559); *Aspergillus oryzae* (MStr115) (pMStr20) | (1) | Bread; Flour; Whole wheat flour | (1) | Good Manufacturing Practice |
| | | | (2) | Unstandardized bakery products | (2) | Good Manufacturing Practice |
| | | | (3) | Modified lecithin | (3) | Good Manufacturing Practice |
| | | | (4) | Unstandardized egg products | (4) | Good Manufacturing Practice |
| | | *Aspergillus niger* (pCaHj600/MBin118#11) | | Modified fats and oils | | Good Manufacturing Practice |
| | | *Penicillium camembertii* | (1) | Edible fats and oils | (1) | Good Manufacturing Practice |
| L.3 | Lipoxidase | Soyabean whey or meal | (1) | Bread; Flour; Whole wheat flour | (1) | Good Manufacturing Practice |
| L.4 | Lysozyme | Egg-white | | Cheddar cheese; (naming the variety) Cheese | | Good Manufacturing Practice |
| M.1 | Milk coagulating enzyme | *Rhizomucor miehei* (Cooney and Emerson) (previous name: *Mucor miehei* (Cooney and Emerson)) or *Mucor pusillus Lindt* by pure culture fermentation process or *Aspergillus oryzae* RET-1 (pBoel777) | (1) | Cheddar cheese; Cottage cheese; (naming the variety) Cheese; Sour cream | (1) | Good Manufacturing Practice |
| | | | (2) | Dairy based flavouring preparations | (2) | Good Manufacturing Practice |
| | | | (3) | Hydrolyzed animal, milk and vegetable protein | (3) | Good Manufacturing Practice |
| | | *Endothia parasitica* by pure culture fermentation processes | (1) | Emmentaler (Emmental, Swiss) Cheese | (1) | Good Manufacturing Practice |
| | | | (2) | Parmesan Cheese | (2) | Good Manufacturing Practice |
| | | | (3) | Romano Cheese | (3) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | (4) | Mozzarella (Scamorza) Cheese | (4) | Good Manufacturing Practice |
| | | | (5) | Part Skim Mozzarella (Part Skim Scamorza) Cheese | (5) | Good Manufacturing Practice |
| P.1 | Pancreatin | | (1) | Dried egg-white (dried albumen); Liquid egg-white (liquid albumen) | (1) | Good Manufacturing Practice |
| | | | (2) | Precooked (instant) cereals | (2) | Good Manufacturing Practice |
| | | Pancreas of the hog (*Sus scrofa*) or ox (*Bos taurus*) | (3) | Starch used in the production of dextrins, maltose, dextrose, glucose (glucose syrup), or glucose solids (dried glucose syrup) | (3) | Good Manufacturing Practice |
| | | | (4) | Hydrolyzed animal, milk and vegetable proteins | (4) | Good Manufacturing Practice |
| P.2 | Papain | | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | Fruit of the papaya *Carica papaya* L. (Fam. *Caricaceae*) | (2) | Beef before slaughter | (2) | Good Manufacturing Practice |
| | | | (3) | Sausage casings; Water-soluble edible collagen films | (3) | Good Manufacturing Practice |
| | | | (4) | Hydrolyzed animal, milk and vegetable protein | (4) | Good Manufacturing Practice |
| | | | (5) | Meat cuts | (5) | Good Manufacturing Practice |
| | | | (6) | Meat tenderizing preparations | (6) | Good Manufacturing Practice |
| | | | (7) | Precooked (instant) cereals | (7) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | (8) | Pumping pickle for the curing of beef cuts | (8) | Good Manufacturing Practice |
| | | | (9) | Unstandardized bakery products | (9) | Good Manufacturing Practice |
| P.3 | Pectinase | *Aspergillus niger* var.; *Rhizopus oryzae* var. | (1) | Cider; Wine | (1) | Good Manufacturing Practice |
| | | | (2) | Distillers' Mash | (2) | Good Manufacturing Practice |
| | | | (3) | Single-strength fruit juices | (3) | Good Manufacturing Practice |
| | | | (4) | Natural flavour and colour extractives | (4) | Good Manufacturing Practice |
| | | | (5) | Skins of citrus fruits destined for jam, marmalade and candied fruit production | (5) | Good Manufacturing Practice |
| | | | (6) | Vegetable stock for use in soups | (6) | Good Manufacturing Practice |
| | | | (7) | Tea leaves for the production of tea solids | (7) | Good Manufacturing Practice |
| | | *Aspergillus oryzae* Km-1-1 (pA2PEI) | (1) | Cider; Wine | (1) | Good Manufacturing Practice |
| | | | (2) | Single-strength fruit juices | (2) | Good Manufacturing Practice |
| | | | (3) | Unstandardized fruit and vegetable products | (3) | Good Manufacturing Practice |
| P.4 | Pentosanase | *Aspergillus niger* var.; *Bacillus subtilis* var. | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | | (2) | Corn for degermination | (2) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | | (3) Distillers' Mash | (3) Good Manufacturing Practice |
| | | | (4) Mash destined for vinegar manufacture | (4) Good Manufacturing Practice |
| | | | (5) Unstandardized bakery products | (5) Good Manufacturing Practice |
| | | | (6) Bread; Flour; Whole wheat flour | (6) Good Manufacturing Practice |
| | | *Trichoderma reesei* (QM9414) | (1) Bread; Flour; Whole wheat flour | (1) Good Manufacturing Practice |
| | | | (2) Distiller's Mash | (2) Good Manufacturing Practice |
| | | | (3) Unstandardized bakery products | (3) Good Manufacturing Practice |
| P.5 | Pepsin | Glandular layer of porcine stomach | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | | (2) Cheddar cheese; Cottage cheese; Cream cheese; Cream cheese spread; Cream cheese spread with (naming the added ingredients); Cream cheese with (naming the added ingredients); (naming the variety) Cheese | (2) Good Manufacturing Practice |
| | | | (3) Defatted soya flour | (3) Good Manufacturing Practice |
| | | | (4) Precooked (instant) cereals | (4) Good Manufacturing Practice |
| | | | (5) Hydrolyzed animal, milk and vegetable proteins | (5) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| P.5A | Phospholipase | *Streptomyces violaceoruber* | (1) Modified lecithin | (1) Good Manufacturing Practice |
| | | | (2) Unstandardized egg products | (2) Good Manufacturing Practice |
| | | *Aspergillus oryzae* (pPFJo142) | Cheddar cheese; (naming the variety) Cheese | Good Manufacturing Practice |
| P.6 | Protease | | (1) Ale; Beer; Light beer; Malt liquor;Porter; Stout | (1) Good Manufacturing Practice |
| | | *Aspergillus oryzae* var.; *Aspergillus niger* var.; *Bacillus subtilis* var. | (2) Bread; Flour; Whole wheat flour | (2) Good Manufacturing Practice |
| | | | (3) Dairy based flavouring preparations | (3) Good Manufacturing Practice |
| | | | (4) Distillers’ Mash | (4) Good Manufacturing Practice |
| | | | (5) Sausage casings | (5) Good Manufacturing Practice |
| | | | (6) Hydrolyzed animal, milk and vegetable protein | (6) Good Manufacturing Practice |
| | | | (7) Industrial spray-dried cheese powder | (7) Good Manufacturing Practice |
| | | | (8) Meat cuts | (8) Good Manufacturing Practice |
| | | | (9) Meat tenderizing preparations | (9) Good Manufacturing Practice |
| | | | (10) Precooked (instant) cereals | (10) Good Manufacturing Practice |
| | | | (11) Unstandardized bakery products | (11) Good Manufacturing Practice |
| | | | (12) Cheddar cheese; | (12) Good |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | | Cheddar cheese for processing (granular curd cheese; Stirred curd cheese; Washed curd cheese); Colby cheese | | Manufacturing Practice |
| | | | (13) | Plant-based beverages | (13) | Good Manufacturing Practice |
| | | *Micrococcus caseolyticus* var. | (1) | (naming the variety) Cheese | (1) | Good Manufacturing Practice |
| | | *Bacillus licheniformis* (Cx) | (1) | Hydrolyzed animal, milk and vegetable protein | (1) | Good Manufacturing Practice |
| P.7 | Pullulanase | | (1) | Bread; Flour; Whole wheat flour | (1) | Good Manufacturing Practice |
| | | *Bacillus acidopullulyticus* NCIB 11647; Bacillus licheniformis SE2-Pul-int211 (pUBCDEBR A11DNSI) | (2) | Starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or fructose syrups and solids, maltose | (2) | Good Manufacturing Practice |
| | | | (3) | Unstandardized bakery products | (3) | Good Manufacturing Practice |
| | | *Bacillus licheniformis* BMP 139 (pR11Amp) | (1) | Bread; Flour; Whole wheat flour | (1) | Good Manufacturing Practice |
| | | | (2) | Brewers’ Mash | (2) | Good Manufacturing Practice |
| | | | (3) | Starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or fructose syrups and solids, maltose | (3) | Good Manufacturing Practice |
| | | | (4) | Unstandardized | (4) | Good |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | | bakery products | | Manufacturing Practice |
| | | *Bacillus subtilis* B1-163 (pEB301) | (1) | Bread; Flour; Whole wheat flour | (1) | Good Manufacturing Practice |
| | | | (2) | Brewers' Mash | (2) | Good Manufacturing Practice |
| | | | (3) | Distillers' Mash | (3) | Good Manufacturing Practice |
| | | | (4) | Starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or fructose syrups and solids, maltose | (4) | Good Manufacturing Practice |
| | | | (5) | Unstandardized bakery products | (5) | Good Manufacturing Practice |
| | | *Bacillus subtilis* RB121 (pDG268) | (1) | Brewers' Mash | (1) | Good Manufacturing Practice |
| | | | (2) | Distillers' Mash | (2) | Good Manufacturing Practice |
| | | | (3) | Starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or maltose | (3) | Good Manufacturing Practice |
| R.1 | Rennet | Aqueous extracts from the fourth stomach of calves, kids or lambs | (1) | Cheddar cheese; Cottage cheese; Cream cheese; Cream cheese spread; Cream cheese spread with (naming the added ingredients); Cream cheese with (naming the added ingredients); (naming | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted Source | Column III<br>Permitted in or Upon | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|
| | | | | the variety) Cheese; Sour cream | | |
| | | | (2) | Unstandardized milk based dessert preparations | (2) | Good Manufacturing Practice |
| T.01 | Transglutaminase | *Streptoverticillium mobaraense* strain S-8112 | (1) | Unstandardized prepared fish products | (1) | Good Manufacturing Practice |
| | | | (2) | Simulated meat products | (2) | Good Manufacturing Practice |
| | | | (3) | Unstandardized cheese products | (3) | Good Manufacturing Practice |
| | | | (4) | Unstandardized processed cheese products | (4) | Good Manufacturing Practice |
| | | | (5) | Unstandardized cream cheese products | (5) | Good Manufacturing Practice |
| | | | (6) | Yogurt | (6) | Good Manufacturing Practice |
| | | | (7) | Unstandardized frozen dairy desserts | (7) | Good Manufacturing Practice |
| T.1 | Trypsin | Pancreas of the hog (*Sus scrofa*) | (1) | Hydrolyzed animal, milk and vegetable proteins | (1) | Good Manufacturing Practice |
| X.1 | Xylanase | *Aspergillus oryzae* Fa 1–1 (pA2X1TI) | (1) | Bread; Flour; Whole wheat flour | (1) | Good Manufacturing Practice |
| | | | (2) | Unstandardized bakery products | (2) | Good Manufacturing Practice |
| | | *Aspergillus oryzae* JaL 339 (pJaL537); *Bacillus subtilis* DIDK 0115 (pUB110 OIS2) | (1) | Bread; Flour; Whole wheat flour | (1) | Good Manufacturing Practice |
| | | | (2) | Unstandardized bakery products | (2) | Good Manufacturing Practice |

SOR/78-402, s. 6; SOR/78-876, s. 3; SOR/79-662, ss. 14 to 17; SOR/80-501, s. 4; SOR/80-632, s. 5; SOR/81-60, s. 11; SOR/81-934, ss. 7 to 10; SOR/82-383, s. 10; SOR/82-566, s. 2; SOR/82-1071, s. 17; SOR/84-302, s. 4; SOR/84-762, ss. 8, 9; SOR/84-801, s. 4; SOR/86-89, ss. 4 to 6; SOR/86-1112, s. 4; SOR/87-254, s. 2; SOR/87-640, s. 7; SOR/88-281, s. 1; SOR/90-24, ss. 1 to 3; SOR/90-87, ss. 10 to 12; SOR/90-469, s. 3; SOR/91-124, s. 5(F); SOR/91-487, s. 1; SOR/91-691, s. 1; SOR/92-63, s. 4; SOR/92-94, s. 4; SOR/92-195, s. 1; SOR/92-197, s. 9; SOR/92-231, s. 1; SOR/92-518, s. 1; SOR/92-591, s. 2(F); SOR/94-29, s. 1; SOR/94-182, s. 1; SOR/94-212, s. 9; SOR/94-417, s. 2; SOR/94-552, s. 1; SOR/94-689, s. 2; SOR/94-712, s. 1; SOR/95-65, s. 1; SOR/95-183, s. 9; SOR/95-525, ss. 1, 2; SOR/96-375, s. 1; SOR/97-81, s. 1; SOR/97-82, s. 1; SOR/97-122, ss. 4(F), 5;SOR/97-508, ss. 1, 2; SOR/97-513, s. 1; SOR/97-558, s. 4; SOR/98-454, s. 1; SOR/98-458, ss. 6, 7(F); SOR/2000-336, ss. 3 to 5; SOR/2000-417, s. 4; SOR/2003-130, s. 4; SOR/2004-84, s. 1; SOR/2005-98, ss. 4 to 7, 8(F); SOR/2005-394, ss. 1 to 6; SOR/2007-225, s. 1; SOR/2010-41, ss. 1 to 6, 9(E); SOR/2010-42, ss. 1 to 4; SOR/2010-94, s. 8(E); SOR/2010-142, s. 17; SOR/2010-143, ss. 14 to 26.

TABLE VI

FOOD ADDITIVES THAT MAY BE USED AS FIRMING AGENTS

| | Column I | Column II | Column III |
|---|---|---|---|
| Item No. | Additive | Permitted in or Upon | Maximum Level of Use |
| A.1 | Aluminum Sulphate | (1) Canned crabmeat, lobster, salmon, shrimp and tuna; Pickles and relishes | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| A.2 | Ammonium Aluminum Sulphate | (1) Pickles and relishes | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| C.1 | Calcium Chloride | (1) Canned apples | (1) 0.026% calculated as calcium |
| | | (2) Canned grapefruit | (2) 0.035% calculated as calcium in accordance with subparagraph B.11.101(*c*)(vii) |
| | | (3) (naming the variety) cheese; Cheddar cheese | (3) 0.02% of the milk and milk products used |
| | | (4) Cottage cheese | (4) Good Manufacturing Practice |
| | | (5) Glaze of frozen fish | (5) Good Manufacturing Practice |
| | | (6) Olives | (6) 1.5% of the brine |
| | | (7) Pickles and relishes | (7) 0.4% |
| | | (8) Tomatoes; Canned vegetables (naming the vegetable); Frozen apples | (8) 0.026% calculated as calcium, and in the case of canned peas 0.035% calculated as calcium |
| | | (9) Unstandardized foods | (9) Good Manufacturing Practice |
| C.2 | Calcium Citrate | (1) Tomatoes; Canned vegetables; Frozen apples; Frozen sliced apples | (1) 0.026% calculated as calcium |
| | | (2) Canned apples | (2) 0.026% calculated as calcium |

| Item No. | Column I Additive | Column II Permitted in or Upon | Column III Maximum Level of Use |
|---|---|---|---|
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |
| C.3 | Calcium Gluconate | Unstandardized foods | Good Manufacturing Practice |
| C.3A | Calcium Lactate | (1) Canned grapefruit | (1) 0.035% calculated as calcium in accordance with subparagraph B.11.101(*c*)(vii) |
| | | (2) Canned peas | (2) 0.035% calculated as calcium |
| C.4 | Calcium Phosphate, dibasic | Unstandardized foods | Good Manufacturing Practice |
| C.5 | Calcium Phosphate, monobasic | (1) Tomatoes; Canned vegetables; Frozen apples | (1) 0.026% calculated as calcium |
| | | (2) Canned apples | (2) 0.026% calculated as calcium |
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |
| C.6 | Calcium Sulphate | (1) Tomatoes; Canned vegetables; Frozen apples | (1) 0.026% calculated as calcium |
| | | (2) Canned apples | (2) 0.026% calculated as calcium |
| P.1 | Potassium Aluminum | (1) Pickles and relishes | (1) Good Manufacturing Practice |
| | Sulphate | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| S.1 | Sodium Aluminum | (1) Pickles and relishes | (1) Good Manufacturing Practice |
| | Sulphate | (2) Unstandardized foods | (2) Good Manufacturing Practice |

SOR/78-402, s. 7; SOR/79-660, ss. 11, 12; SOR/79-752, s. 7; SOR/93-445, s. 1; SOR/94-689, s. 2(F); SOR/2007-302, s. 4(F); SOR/2010-94, s. 8(E).

TABLE VII

FOOD ADDITIVES THAT MAY BE USED AS GLAZING AND POLISHING AGENTS

| Item No. | Column I Additive | Column II Permitted in or Upon | Column III Maximum Level of Use |
|---|---|---|---|
| A.1 | Acetylated Monoglycerides | (1) Unstandardized confectionery | (1) 0.4% |
| | | (2) Frozen fish | (2) Good Manufacturing Practice |
| B.1 | Beeswax | Unstandardized confectionery | 0.4% |
| C.1 | Carnauba Wax | Unstandardized confectionery | 0.4% |
| C.2 | Candelilla Wax | Unstandardized confectionery | 0.4% |
| G.1 | Gum Arabic | Unstandardized confectionery | 0.4% |
| G.2 | Gum Benzoin | Unstandardized confectionery | 0.4% |
| M.1 | Magnesium Silicate | Unstandardized confectionery | 0.4% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| M.2 | Mineral Oil | Unstandardized confectionery | 0.15% |
| P.1 | Petrolatum | Unstandardized confectionery | 0.15% |
| S.1 | Shellac | Cake decorations; Unstandardized confectionery | 0.4% |
| S.2 | Spermaceti Wax | Unstandardized confectionery | 0.4% |
| Z.1 | Zein | Unstandardized confectionery | 1.0% |

SOR/94-689, s. 2(F); SOR/2010-142, ss. 18 to 29.

TABLE VIII

MISCELLANEOUS FOOD ADDITIVES

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| A.01 | Acacia Gum | Ale; Beer; Light beer; Malt liquor; Porter; Stout; Wine | Fining agent | Good Manufacturing Practice |
| A.1 | Acetylated Monoglycerides | Unstandardized foods | Coating; Release agent | Good Manufacturing Practice |
| A.1.01 | Agar | Wine | Fining agent | Good Manufacturing Practice |
| A.1.1 | Aluminum Sulphate | Dried egg-white (dried albumen); Dried whole egg; Dried yolk; Frozen egg-white (frozen albumen); Frozen whole egg; Frozen yolk; Liquid egg-white (liquid albumen); Liquid whole egg; Liquid yolk | To stabilize albumen during pasteurization | 0.036% |
| A.2 | Ammonium Persulphate | Brewer’s yeast | Antimicrobial agent | 0.1% |
| A.3 | [Repealed, SOR/93-276, s. 4] | | | |
| A.4 | [Repealed, SOR/93-276, s. 5] | | | |
| B.2 | Beeswax | Unstandardized foods | Antisticking agent | 0.4% |
| B.2.1 | Benzoyl Peroxide | Liquid whey destined for the manufacture of dried whey | To decolourize | 100 p.p.m. |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Purpose of Use | | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|---|---|
| | | | products other than those for use in infant formula | | | |
| B.3 | Brominated vegetable oil | | (Naming the flavour) Flavour for use in beverages containing citrus or spruce oils | | Density adjusting agent | 15 p.p.m. in beverages containing citrus or spruce oils as consumed |
| B.4 | n-Butane | | Edible vegetable oil-based or lecithin-based pan coatings or a mixture of both | | Propellant | Good Manufacturing Practice |
| C.1 | Caffeine | | Cola type beverages | | To characterize the product | 200 p.p.m. in the finished product |
| C.2 | Caffeine Citrate | | Cola type beverages | | To characterize the product | 200 p.p.m. calculated as caffeine, in the finished product |
| C.3 | Calcium Carbonate | (1) | Flour; Whole wheat flour | (1) | Carrier of benzoyl peroxide | (1) 900 p.p.m., in accordance with subparagraphs B.13.001(*e*)(vi) and B.13.005(*d*)(vi) |
| | | (2) | [Repealed, SOR/94-227, s. 5] | | | |
| | | (3) | Unstandardized confectionery | (3) | Creaming and fixing agent | (3) Good Manufacturing Practice |
| | | (4) | Chewing gum | (4) | Filler | (4) Good Manufacturing Practice |
| | | (5) | Unstandardized foods | (5) | Carrier and dusting agent | (5) Good Manufacturing Practice |
| C.3A | Calcium Lactate | (1) | Egg albumen (delysozymized) | (1) | Restoration of functional properties | (1) Good Manufacturing Practice (Quantity of calcium added not to exceed that lost during processing) |
| | | (2) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (2) | To modify texture | (2) Good Manufacturing Practice |
| C.4 | Calcium Oxide | (1) | Frozen crustaceans | (1) | To facilitate | (1) When used in |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Purpose of Use | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|---|
| | | | and molluscs | | the removal of extraneous matter and to reduce moisture loss during cooking | | combination with sodium chloride (salt) and sodium hydroxide in solution, calcium oxide not to exceed 30 p.p.m. |
| | | (2) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (2) | To modify texture | (2) | Good Manufacturing Practice |
| C.5 | Calcium Phosphate dibasic | (1) | Flour; Whole wheat flour | (1) | Carrier of benzoyl peroxide | (1) | 900 p.p.m. in accordance with subparagraphs B.13.001(*e*)(vi) and B.13.005(*d*)(vi) |
| | | (2) | [Repealed, SOR/94-227, s. 6] | | | | |
| C.6 | Calcium Phosphate, tribasic | (1) | Flour; Whole wheat flour | (1) | Carrier of benzoyl peroxide | (1) | 900 p.p.m. in accordance with subparagraphs B.13.001(*e*)(vi) and B.13.005(*d*)(vi) |
| | | (2) | [Repealed, SOR/94-227, s. 7] | | | | |
| | | (3) | Liquid whey destined for the manufacture of dried whey products other than those for use in infant formula | (3) | Carrier of benzoyl peroxide | (3) | 0.04% of dried whey product |
| | | (4) | Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredient); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed | (4) | To improve colour, texture, consistency and spreadability | (4) | 1.0% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | cheese spread with (naming the added ingredients) | | |
| C.7 | Calcium Silicate | Oil-soluble annatto | Carrier | Good Manufacturing Practice |
| C.8 | Calcium Stearate | Unstandardized confectionery | Release agent | Good Manufacturing Practice |
| C.9 | Calcium Stearoyl- 2-Lactylate | (1) Frozen egg-white (frozen albumen); Liquid egg-white (liquid albumen) | (1) Whipping agent | (1) 0.05% |
| | | (2) Dried egg-white (dried albumen) | (2) Whipping agent | (2) 0.5% |
| | | (3) Vegetable fat toppings | (3) Whipping agent | (3) 0.3% |
| | | (4) Dehydrated potatoes | (4) Conditioning agent | (4) 0.2% of dry weight |
| C.10 | Calcium Sulphate | (1) Flour, Whole wheat flour | (1) Carrier of benzoyl peroxide | (1) 900 p.p.m. in accordance with subparagraphs B.13.001(*e*)(vi) and B.13.005(*d*)(vi) |
| | | (2) [Repealed, SOR/94-227, s. 8] | | |
| | | (3) Baking powder | (3) Neutral filler | (3) Good Manufacturing Practice |
| C.11 | Carbon Dioxide | (1) Ale; Beer; Carbonated (naming the fruit) juice; Cider; Light beer; Malt liquor; Porter; Stout; Wines; Water represented as mineral water or spring water | (1) Carbonation | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Carbonation and pressure dispensing agent | (2) Good Manufacturing Practice |
| | | (3) Cottage Cheese; Creamed Cottage Cheese | (3) To extend durable life | (3) Good Manufacturing Practice |
| C.12 | Castor Oil | Unstandardized confectionery | Release agent | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| C.13 | [Repealed, SOR/2010-142, s. 35] | | | |
| C.13.1 | Cellulose, Powdered | (1) Batter and breading | (1) Bulking agent | (1) 1% |
| | | (2) Canapé toast | (2) Bulking agent | (2) 2% |
| | | (3) Unstandardized confectionery that meet the conditions set out in column 2 of item 3 of the table following section B.01.513 for the subject “Reduced in energy” set out in column 1 | (3) Bulking agent | (3) 25% |
| | | (4) Unstandardized edible ices | (4) Bulking agent | (4) 3% |
| | | (5) Fillings | (5) Bulking agent | (5) 0.5% |
| | | (6) Foods sold in tablet form | (6) Bulking agent | (6) 50% |
| | | (7) Icings | (7) Bulking agent | (7) 1% |
| | | (8) Seasonings | (8) Bulking agent | (8) 3% |
| | | (9) Sweet baked goods | (9) Bulking agent | (9) 8% |
| C.14A | Chloropentafluo-roethane | Unstandardized foods | Pressure dispensing and aerating agent | Good Manufacturing Practice |
| C.15 | Citric Acid | (1) Beef blood | (1) Anticoagulant | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Culture nutrient | (2) Good Manufacturing Practice |
| C.16 | Copper gluconate | Breath freshener products | To characterize the product | 50 p.p.m. |
| C.17 | Copper Sulphate | Wine | Fining agent | 0.0001%, calculated as copper, in the finished product |
| D.1 | Dimethylpolysiloxane Formulations | (1) Apple (or rhubarb) and (naming the fruit) Jam; Fats and oils; Fig marmalade; Fig marmalade with pectin; (naming the fruit) Jam; (naming | (1) Antifoaming agent | (1) 10 p.p.m. of dimethylpolysiloxane |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Purpose of Use | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|---|
| | | | the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Pineapple marmalade; Pineapple marmalade with pectin; Reconstituted lemon juice; Reconstituted lime juice; Shortening; Skim milk powder; Wine | | | | |
| | | (2) | Pineapple juice; Blends of pineapple juice with other fruit juices; canned pineapple (when pineapple juice is used as the packing medium) | (2) | Anti-foaming agent | (2) | 10 p.p.m. of dimethylpolysiloxane |
| | | (3) | Surfaces that come in contact with food | (3) | Release agent | (3) | Good Manufacturing Practice (Residue of dimethylpolysiloxane in food not to exceed 10 p.p.m.) |
| | | (4) | Unstandardized foods | (4) | Antifoaming agent | (4) | 10 p.p.m. of dimethylpolysiloxane |
| | | (5) | Wort used in the manufacture of Ale, Beer, Light beer, Malt liquor, Porter and Stout | (5) | Antifoaming agent | (5) | 10 p.p.m. of dimethylpolysiloxane |
| D.3 | Dioctyl sodium sulfosuccinate | (1) | Fumaric acid-acidulated dry beverage bases | (1) | Wetting agent | (1) | 10 p.p.m. in the finished drink |

| Item No. | Column I Additive | Column II Permitted in or Upon | | Column III Purpose of Use | | Column IV Maximum Level of Use | |
|---|---|---|---|---|---|---|---|
| | | (2) | Sausage casings | (2) | Reduce casing breakage | (2) | 200 p.p.m. of the casing |
| E.1 | Ethoxyquin | | Paprika; Ground chili pepper | | To promote colour retention | | 100 p.p.m. |
| E.2 | Ethylene Oxide | | Whole or ground spice (except mixtures containing salt) | | Fumigation | | G.M.P. (Residues of ethylene chlorohydrin not to exceed 1,500 p.p.m.) |
| F.1 | Ferrous Gluconate | | Ripe olives | | Colour retention | | Good Manufacturing Practice |
| G.1 | Gelatin | | Beer; Cider; Wine | | Fining agent | | Good Manufacturing Practice |
| G.2 | [Repealed, SOR/89-175, s. 2] | | | | | | |
| G.2A | Glucono delta lactone | (1) | Cooked sausage, Meat Loaf | (1) | To accelerate colour fixing | (1) | 0.5% |
| | | (2) | Dry Sausage | (2) | To assist in curing | (2) | Good Manufacturing Practice |
| G.3 | Glycerol | (1) | Meat curing compounds; Sausage casings | (1) | Humectant | (1) | Good Manufacturing Practice |
| | | (2) | Preserved meats (Division 14) | (2) | Glaze for preserved meats | (2) | Good Manufacturing Practice |
| | | (3) | Unstandardized foods | (3) | Humectant; Plasticizer | (3) | Good Manufacturing Practice |
| G.4 | Glycerol ester of wood rosin | | Beverages containing citrus or spruce oils | | Density adjusting agent | | 100 p.p.m. |
| H.1 | Hydrogen Peroxide | (1) | Brewers’ mash | (1) | Clarification aid | (1) | 135 p.p.m. in the mash |
| | | (2) | Liquid whey destined for the manufacture of dried whey products | (2) | To decolourize and maintain pH | (2) | 100 p.p.m. (see also subitem C.1(3) of Table V) |
| | | (3) | Oat hulls used in the manufacture of oat hull fibre | (3) | Bleaching agent | (3) | Good Manufacturing Practice |
| I. | Isobutane | | Edible vegetable oil-based or lecithin-based pan coatings or a | | Propellant | | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | mixture of both | | |
| L.1 | Lactylic Esters of Fatty Acids | Unstandardized foods | Plasticizing agent | Good Manufacturing Practice |
| L.2 | Lanolin | Chewing gum | Plasticizing agent | Good Manufacturing Practice |
| L.3 | Lecithin | Surfaces that come in contact with food | Release agent | Good Manufacturing Practice |
| L.4 | L-Leucine | Table-top sweetener tablets containing aspartame | Lubricant in tablet manufacture | 3% of tablet weight |
| M.1 | Magnesium Aluminum Silicate | Chewing gum | Dusting agent | Good Manufacturing Practice |
| M.2 | Magnesium Carbonate | (1) Flour, Whole wheat flour | (1) Carrier of benzoyl peroxide | (1) 900 p.p.m. in accordance with subparagraphs B.13.001(*e*)(vi) and B.13.005(*d*)(vi) |
| | | (2) [Repealed, SOR/94-227, s. 9] | | |
| | | (3) Unstandardized confectionery | (3) Release agent | (3) Good Manufacturing Practice |
| M.2A | Magnesium Chloride | Egg albumen (delysozymized) | Restoration of functional properties | Good Manufacturing Practice (Quantity of magnesium added not to exceed that lost during processing) |
| M.3 | Magnesium Silicate | (1) Unstandardized confectionery | (1) Release agent | (1) Good Manufacturing Practice |
| | | (2) Chewing gum | (2) Dusting agent | (2) Good Manufacturing Practice |
| | | (3) Rice | (3) Coating | (3) Good Manufacturing Practice |
| M.4 | Magnesium Stearate | (1) Unstandardized confectionery | (1) Release agent | (1) Good Manufacturing Practice |
| | | (2) Foods sold in tablet form | (2) Binding agent | (2) Good Manufacturing Practice |
| M.4A | Magnesium Sulphate | Egg albumen (delysozymized) | Restoration of functional properties | Good Manufacturing Practice (Quantity of magnesium added not to exceed that lost during |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | | | processing) |
| M.5A | [Repealed, SOR/93-276, s. 6] | | | |
| M.5C | Methyl Ethyl Cellulose | Unstandardized foods | Aerating agent | Good Manufacturing Practice |
| M.6 | Microcrystalline Cellulose | (1) Ice milk mix | (1) Bodying and texturizing agent | (1) 1.5% |
| | | (2) Sherbet | (2) Bodying and texturizing agent | (2) 0.5% |
| | | (3) Unstandardized foods that meet the conditions set out in column 2 of item 3 of the table following section B.01.513 for the subject “Reduced in energy” set out in column 1 | (3) Filler | (3) Good Manufacturing Practice |
| | | (4) Whipped vegetable oil topping | (4) Bodying and texturizing agent | (4) 1.5% |
| | | (5) Unstandardized frozen desserts | (5) Bodying and texturizing agent | (5) 0.5% |
| | | (6) Unstandardized sandwich spreads; Unstandardized dips | (6) Bodying and texturizing agent | (6) 3.0% |
| | | (7) Unstandardized foods other than those unstandardized foods referred to in this item | (7) Bodying and texturizing agent | (7) 2.0% |
| | | (8) Ice cream mix | (8) Bodying and texturizing agent | (8) 0.5% or, if used in combination with stabilizing agents, the combined amount shall not exceed 0.5% of the ice cream made from the mix |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Purpose of Use | | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|---|---|
| | | (9) | Table-top sweetener tablets containing aspartame | (9) | Tablet disintegration | (9) 2.2% |
| | | (10) | Cream for whipping | (10) | Stabilizing and thickening agent | (10) 0.2% |
| | | (11) | Breath freshener products | (11) | Bodying and texturizing agent | (11) 9.0% |
| M.7 | Mineral Oil | (1) | Bakery products; Seeded raisins; Unstandardized confectionery | (1) | Release agent | (1) 0.3% in accordance with section B.01.047. If petrolatum is also used as a release agent in bakery products the total of any combination of petrolatum and mineral oil must not exceed 0.15% |
| | | (2) | Fresh fruits and vegetables | (2) | Coating | (2) 0.3% in accordance with section B.01.047 |
| | | (3) | Sausage casings | (3) | Lubricant | (3) 5% in accordance with paragraph B.01.047(*e*) (Residues of mineral oil in a raw sausage prepared with such casings not to exceed 200 p.p.m.; in cooked sausage, 30 p.p.m.) |
| | | (4) | Salt Substitute | (4) | Binding agent and protective coating | (4) 0.6% in accordance with paragraph B.01.047(*h*) |
| M.8 | Monoacetin | | Unstandardized bakery products | | Plasticizer | Good Manufacturing Practice |
| M.9 | Mono- and di-glycerides | (1) | Apple (or rhubarb) and (naming the fruit) Jam; Fats and oils; Fig marmalade; Fig marmalade with | (1) | Antifoaming agent | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Purpose of Use | | Column IV<br>Maximum Level of Use | |
|---|---|---|---|---|---|---|---|
| | | | pectin; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Pineapple marmalade; Pineapple marmalade with pectin | | | | |
| | | (2) | Unstandardized foods | (2) | Antifoaming agent; Humectant; Release agent | (2) | Good Manufacturing Practice |
| M.10 | Mono-glycerides | | Unstandardized foods | | Antifoaming agent; Humectant; Release agent | | Good Manufacturing Practice |
| N.1 | Nitrogen | (1) | Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients) | (1) | To improve spreadability | (1) | Good Manufacturing Practice |
| | | (2) | Margarine | (2) | To improve spreadability | (2) | Good Manufacturing Practice |
| | | (3) | Unstandardized foods | (3) | Pressure dispensing agent | (3) | Good Manufacturing Practice |
| N.2 | Nitrous Oxide | | Unstandardized foods | | Pressure dispensing agent | | Good Manufacturing Practice |
| O.1 | Octafluorocyclobu-tane | | Unstandardized foods | | Pressure dispensing and aerating agent | | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| O.2 | Oxystearin | Cotton seed oil; Peanut oil; Soy bean oil | To inhibit crystal formation | 0.125% |
| O.3 | Ozone | (1) Cider | (1) Maturing agent | (1) Good Manufacturing Practice |
| | | (2) Water represented as mineral water or spring water | (2) Chemosterilant | (2) Good Manufacturing Practice |
| | | (3) Wine | (3) Maturing agent | (3) Good Manufacturing Practice |
| P.1 | Pancreas Extract | Acid producing bacterial cultures | To control bacteriophages | Good Manufacturing Practice |
| P.1A | Paraffin Wax | (1) Fresh fruits and vegetables | (1) Coating | (1) 0.3% in accordance with section B.01.047 |
| | | (2) Cheese and turnips | (2) Coating | (2) Good Manufacturing Practice in accordance with section B.01.047 |
| P.2 | Petrolatum | (1) Bakery products | (1) Release agent | (1) 0.15% in accordance with section B.01.047. If mineral oil is also used as a release agent the total of any combination of petrolatum and mineral oil must not exceed 0.15% |
| | | (2) Fresh fruits and vegetables | (2) Coating | (2) 0.3% in accordance with section B.01.047 |
| P.2A | Polyethylene glycol (molecular weight 3000-9000) | (1) Soft drinks | (1) Antifoaming agent | (1) 10 p.p.m. |
| | | (2) Table-top sweetener tablets containing aspartame | (2) Lubricant | (2) 1.0% |
| | | (3) L-Lysine tablets | (3) Tablet binder | (3) 7.0% |
| P.2B | Polydextrose | Unstandardized foods | Bodying and texturizing agent | Good Manufacturing Practice |
| P.3 | Polyvinylpyrroli-done | (1) Ale; Beer; Cider; Light beer; Malt | (1) Fining agent | (1) 2 p.p.m. in the finished product |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | liquor; Porter; Stout; Wine | | |
| | | (2) Table-top sweetener tablets containing aspartame | (2) Tablet binder | (2) 0.3% |
| | | (3) Colour lake dispersions for use in unstandardized confectionery in tablet form | (3) Viscosity reduction agent and stabilizer in colour lake dispersions | (3) Good Manufacturing Practice (Residues of polyvinyl pyroliodone not to exceed 100 p.p.m. in the finished foods) |
| P.4 | Potassium Aluminum Sulphate | Flour; Whole wheat flour | Carrier of benzoyl peroxide | 900 p.p.m., in accordance with subparagraphs B.13.001(*e*)(vi) and B.13.005(*d*)(vi) |
| P.4.1 | Potassium Ferrocyanide | Wine | Fining agent | Good Manufacturing Practice |
| P.5 | | (1) Chewing gum | (1) Plasticizing agent | (1) Good Manufacturing Practice |
| | Potassium Stearate | (2) Emulsifying preparations containing propylene glycol monoesters | (2) Stabilizing agent | (2) 2% |
| P.6 | Propane | Unstandardized foods | Pressure dispensing and aerating agent | Good Manufacturing Practice |
| P.7 | Propylene Glycol | (1) Oil-soluble annatto | (1) Solvent | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Humectant | (2) Good Manufacturing Practice |
| Q.1 | Quillaia Extract | Beverage bases; Beverage mixes; Soft drinks | Foaming Agent | Good Manufacturing Practice |
| S.1 | Saponin | Beverage bases; Beverage mixes; Soft drinks | Foaming agent | Good Manufacturing Practice |
| S.1.01 | Silicon Dioxide | Edible vegetable oil-based cookware coating emulsions | Suspending agent | 2.0% of preparation |
| S.1.1 | Sodium Acid Pyrophosphate | Frozen fish fillets; frozen minced fish; | To reduce processing | Used in combination with sodium |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | frozen lobster; frozen crab; frozen clams; frozen shrimp | losses and to reduce thaw drip | tripolyphosphate and sodium pyrophosphate tetrabasic, total added pyrophosphate not to exceed 0.5% calculated as sodium phosphate, dibasic |
| S.2 | Sodium Aluminum Sulphate | Flour; Whole wheat flour | Carrier of benzoyl peroxide | 900 p.p.m. in accordance with subparagraphs B.13.001(*e*)(vi) and B.13.005(*d*)(vi) |
| S.3 | Sodium | (1) Unstandardized confectionery | (1) Aerating agent | (1) Good Manufacturing Practice |
| | Bicarbonate | (2) Salt | (2) To stabilize potassium iodide in salt | (2) Good Manufacturing Practice |
| S.3A | Sodium Carbonate | In combination with sodium hexametophosphate for use on frozen fish fillets, frozen lobster, frozen crabs, frozen clams and frozen shrimp | To reduce thaw drip | 15% of the combination of sodium carbonate and sodium hexametaphosphate |
| S.3B | Sodium Carboxymethyl Cellulose | Sausage casings | Coating to enable peeling | 0.25% of the casing |
| S.4 | Sodium Citrate | (1) Beef blood | (1) Anticoagulant | (1) 0.5% |
| | | (2) Sour cream | (2) Flavour precursor | (2) 0.1% |
| | | (3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (3) To modify texture | (3) Good Manufacturing Practice |
| S.5 | Sodium Ferrocyanide Decahydrate | Dendritic salt | As an adjuvant in the production of dendritic salt crystals | 13 p.p.m. calculated as anhydrous sodium ferrocyanide |
| S.6 | Sodium Hexameta- | (1) Beef blood | (1) Anti-coagulant | (1) 0.2% |

| Item No. | Column I<br>Additive | | Column II<br>Permitted in or Upon | | Column III<br>Purpose of Use | | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|---|---|---|
| | phosphate | (2) | Frozen fish fillets; frozen lobsters; frozen crab; frozen clams and frozen shrimp | (2) | To reduce thaw drip | (2) | 0.5% total added phosphate calculated as sodium phosphate, dibasic |
| | | (3) | Gelatin intended for marshmallow compositions | (3) | Whipping agent | (3) | 2% |
| S.6A | Sodium Hydroxide | | Frozen crustaceans and molluscs | | To facilitate the removal of extraneous matter and to reduce moisture loss during cooking | | When used in combination with sodium chloride (salt) and calcium oxide in solution, sodium hydroxide not to exceed 70 p.p.m. |
| S.6.1 | Sodium Lauryl Sulphate | (1) | Dried egg-white (dried albumen) | (1) | Whipping agent | (1) | 0.1% |
| | | (2) | Frozen egg-white (frozen albumen); Liquid egg-white (liquid albumen) | (2) | Whipping agent | (2) | 0.0125% |
| | | (3) | Gelatin intended for marshmallow compositions | (3) | Whipping agent | (3) | 0.5% |
| S.6.2 | Sodium Potassium Copper Chlorophyllin | | Breath freshener products | | To characterize the product | | 700 p.p.m. |
| S.7 | Sodium Phosphate, dibasic | (1) | Frozen fish | (1) | To prevent cracking of glaze | (1) | Good Manufacturing Practice |
| | | (2) | Frozen mushrooms | (2) | To prevent discolouration | (2) | Good Manufacturing Practice |
| S.7.1 | Sodium Pyrophosphate, tetrabasic | | Frozen fish fillets; frozen minced fish; frozen lobster; frozen crab; frozen clams; frozen shrimp | | To reduce processing losses and to reduce thaw drip | | Used in combination with sodium tripolyphosphate and sodium acid pyrophosphate, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic |
| S.8 | Sodium Silicate | | Canned drinking water | | Corrosion inhibitor | | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| S.9 | Sodium Stearate | Chewing gum | Plasticizing agent | Good Manufacturing Practice |
| S.9A | Sodium Stearoyl- 2-Lactylate | (1) Frozen egg-white (frozen albumen); Liquid egg-white (liquid albumen) | (1) Whipping agent | (1) 0.05% |
| | | (2) Dried egg-white (dried albumen) | (2) Whipping agent | (2) 0.5% |
| | | (3) Oil toppings or topping mixes | (3) Whipping agent | (3) 0.3% |
| | | (4) Dehydrated potatoes | (4) Conditioning agent | (4) 0.2% of dry weight |
| S.9B | Sodium Sulphate | Frozen mushrooms | To prevent discolouration | Good Manufacturing Practice |
| S.9C | Sodium Sulphite | Canned flaked tuna | To prevent discolouration | 300 p.p.m. |
| S.10 | Sodium Thiosulphate | Salt | To stabilize potassium iodine in salt | Good Manufacturing Practice |
| S.11 | Sodium Tripolyphosphate | Frozen fish fillets; frozen minced fish; frozen comminuted fish; frozen lobster; frozen crab; frozen clams and frozen shrimp | To reduce processing losses and to reduce thaw drip | Used singly or in combination with sodium acid pyrophosphate and sodium pyrophosphate tetrabasic, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic |
| S.12 | [Repealed, SOR/93-276, s. 8] | | | |
| S.13 | Stannous Chloride | (1) Asparagus packed in glass containers or fully lined (lacquered) cans | (1) Flavour and colour stabilizer | (1) 25 p.p.m. calculated as tin |
| | | (2) Canned carbonated soft drinks; concentrated fruit juices except frozen concentrated orange juice; lemon juice; lime juice | (2) Flavour and colour stabilizer | (2) Good Manufacturing Practice |
| S.14 | Stearic Acid | (1) Unstandardized confectionery | (1) Release agent | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | (2) Chewing gum | (2) Plasticizing agent | (2) Good Manufacturing Practice |
| | | (3) Foods sold in tablet form | (3) Release agent and lubricant | (3) Good Manufacturing Practice |
| S.15 | Sodium Methyl Sulphate | Pectin | A processing aid, the result of methylation of pectin by sulfuric acid and methyl alcohol and neutralized by sodium bicarbonate | 0.1% of pectin |
| S.15A | [Repealed, SOR/93-276, s. 9] | | | |
| S.16 | Sucrose Acetate Isobutyrate | (Naming the flavour) Flavour for use in beverages containing citrus or spruce oils | Density adjusting agent | 300 p.p.m. in beverages containing citrus or spruce oils as consumed |
| S.17 | Sulphuric Acid | Coffee beans | To improve the extraction yield of coffee solids | Good Manufacturing Practice |
| T.1 | Talc | (1) Rice | (1) Coating agent | (1) Good Manufacturing Practice |
| | | (2) Chewing gum base | (2) Filler | (2) Good Manufacturing Practice |
| | | (3) Chewing gum | (3) Dusting agent | (3) Good Manufacturing Practice |
| T.2 | Tannic Acid | (1) Chewing gum | (1) To reduce adhesion | (1) Good Manufacturing Practice |
| | | (2) Cider; Honey wine; Wine | (2) Fining agent | (2) 200 p.p.m |
| T.2A | [Repealed, SOR/93-276, s. 10] | | | |
| T.3 | Triacetin | Cake mixes | Wetting agent | Good Manufacturing Practice |
| T.4 | Triethyl Citrate | Dried egg-white (dried albumen); Frozen egg-white (frozen albumen); Liquid egg-white (liquid albumen) | Whipping agent | 0.25% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Purpose of Use | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| X.1 | [Repealed, SOR/93-276, s. 11] | | | |

SOR/78-401, s. 3; SOR/78-403, ss. 23 to 25; SOR/78-876, s. 4; SOR/79-660, s. 13; SOR/79-752, s. 8; SOR/80-632, ss. 6 to 13; SOR/81-83, s. 4; SOR/81-617, s. 3; SOR/81-934, ss. 11, 12; SOR/82-566, ss. 3, 4; SOR/82-1071, ss. 18 to 20; SOR/83-410, s. 3; SOR/83-584, s. 1; SOR/83-932, ss. 5, 6; SOR/84-17, s. 6; SOR/84-441, s. 1; SOR/84-602, s. 3; SOR/84-762, s. 10; SOR/84-801, ss. 5, 6; SOR/86-1112, s. 5; SOR/86-1125, s. 2; SOR/87-469, s. 1; SOR/87-640, s. 8; SOR/88-419, s. 4; SOR/88-534, ss. 5, 6; SOR/89-175, s. 2; SOR/89-197, s. 1; SOR/89-198, s. 11; SOR/89-555, ss. 2, 3; SOR/91-90, s. 2; SOR/91-124, ss. 6 to 9; SOR/91-149, s. 3; SOR/91-186, s. 1; SOR/91-409, s. 7; SOR/91-527, s. 4; SOR/92-229, s. 1; SOR/92-344, ss. 2 to 4; SOR/93-276, ss. 4 to 11; SOR/94-416, s. 1; SOR/94-227, ss. 5 to 10; SOR/94-689, s. 2(F); SOR/94-723, s. 1; SOR/96-260, s. 1; SOR/96-378, s. 1;SOR/97-509, s. 1; SOR/98-580, s. 1(F); SOR/99-97, s. 1; SOR/99-420, s. 11(F); SOR/2000-353, s. 8(F); SOR/2001-94, s. 3; SOR/2005-316, ss. 2(F), 3; SOR/2006-91, ss. 6 to 12; SOR/2007-75, s. 7; SOR/2010-41, s. 9(E); SOR/2010-94, s. 8(E); SOR/2010-142, ss. 30(F), 31 to 39, 40(F), 41 to 45, 46(F), 47 to 51, 59(F); SOR/2010-143, ss. 27 to 31.

TABLE IX

FOOD ADDITIVES THAT MAY BE USED AS SWEETENERS

| Item No. | Column I<br>Additive | Column II<br>Permitted in or on | Column III<br>Maximum Level of Use |
|---|---|---|---|
| A.01 | Acesulfame-potassium | (1) Table-top sweeteners | (1) Good Manufacturing Practice |
| | | (2) Carbonated beverages | (2) 0.025% in beverages as consumed |
| | | (3) Beverages; Beverage concentrates; Beverage mixes; Dairy beverages; (except for any of these products for which standards are set out in these Regulations) | (3) 0.05% in beverages as consumed |
| | | (4) Desserts; Dessert mixes; Toppings; Topping mixes; Fillings; Filling mixes; (except for any of these products for which standards are set out in these Regulations) | (4) 0.1% in products as consumed |
| | | (5) Chewing gum; Breath freshener products | (5) 0.35% |
| | | (6) Fruit spreads (except for any of these products for which standards are set out in these Regulations) | (6) 0.1% |
| | | (7) Salad dressings (except for any of | (7) 0.05% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or on | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | these products for which standards are set out in these Regulations) | | |
| | | (8) | Unstandardized confectionery | (8) | 0.25% |
| | | (9) | Bakery mixes; Bakery products; (except for any of these products for which standards are set out in these Regulations) | (9) | 0.1% in products as consumed |
| A.1 | Aspartame | (1) | Table-top sweeteners | (1) | Good Manufacturing Practice |
| | | (2) | Breakfast cereals | (2) | 0.5% |
| | | (3) | Beverages; Beverage concentrates; Beverage mixes; (except for any of these products for which standards are set out in these Regulations) | (3) | 0.1% in beverages as consumed |
| | | (4) | Desserts; Dessert mixes; Toppings; Topping mixes; Fillings; Filling mixes; (except for any of these products for which standards are set out in these Regulations) | (4) | 0.3% in products as consumed |
| | | (5) | Chewing gum; Breath freshener products | (5) | 1.0% |
| | | (6) | Fruit spreads; Purées and sauces; Table syrups; (except for any of these products for which standards are set out in these Regulations) | (6) | 0.2% |
| | | (7) | Salad dressings; Peanut and other nut spreads; (except for any of these products for which standards are set out in these Regulations) | (7) | 0.05% |
| | | (8) | Condiments (except for any of these products for which standards are set out in these Regulations) | (8) | 0.2% |
| | | (9) | Confectionery glazes for snack foods; Sweetened seasonings or coating mixes for snack foods | (9) | 0.1% |
| | | (10) | Unstandardized confectionery; Unstandardized confectionery coatings | (10) | 0.3% |
| A.2 | Aspartame, encapsulated to prevent degradation during baking | | Bakery products and baking mixes (except for any of these products for which standards are set out in these Regulations) | | 0.4% in product as consumed |
| E.1 | Erythritol | (1) | Table-top sweeteners | (1) | Good |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or on | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|
| | | | | Manufacturing Practice |
| | | (2) | Dietetic beverages | (2) 3.5% |
| | | (3) | Fat-based cream fillings and toppings | (3) 60% |
| | | (4) | Dietetic cookies and wafers | (4) 7% |
| | | (5) | Soft candies | (5) 40% |
| | | (6) | Hard candies | (6) 50% |
| | | (7) | Chewing gum | (7) 60% |
| H.1 | Hydrogenated starch hydrolysates | | Unstandardized foods | Good Manufacturing Practice |
| I.1 | Isomalt | | Unstandardized foods | Good Manufacturing Practice |
| L.1 | Lactitol | | Unstandardized foods | Good Manufacturing Practice |
| M.1 | Maltitol | | Unstandardized foods | Good Manufacturing Practice |
| M.2 | Maltitol syrup | | Unstandardized foods | Good Manufacturing Practice |
| M.3 | Mannitol | | Unstandardized foods | Good Manufacturing Practice |
| N.1 | Neotame | (1) | Table-top sweeteners | (1) Good Manufacturing Practice |
| | | (2) | Breakfast cereals | (2) 0.016% |
| | | (3) | Beverage mixes; Unstandardized beverages; Unstandardized beverage concentrates | (3) 0.003% in beverages as consumed |
| | | (4) | Dessert mixes; Fillings; Filling mixes; Toppings; Topping mixes; Unstandardized desserts; Yogurt | (4) 0.01% in products as consumed |
| | | (5) | Breath freshener products; Chewing gum | (5) 0.032% |
| | | (6) | Unstandardized fruit spreads; Unstandardized purées and sauces; Unstandardized table syrups | (6) 0.007% |
| | | (7) | Peanut and other nut spreads; | (7) 0.002% |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or on | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | Unstandardized salad dressings | | |
| | | (8) | Unstandardized condiments | (8) | 0.007% |
| | | (9) | Confectionary glazes for snack foods; Sweetened seasonings or coating mixes for snack foods | (9) | 0.0032% |
| | | (10) | Unstandardized confectionery; Unstandardized confectionery coatings | (10) | 0.01% |
| | | (11) | Unstandardized bakery products and baking mixes | (11) | 0.013% in products as consumed |
| S.1 | Sorbitol | (1) | A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (1) | 6.0% |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| S.1.1 | Sorbitol syrup | | Unstandardized foods | | Good Manufacturing Practice |
| S.2 | Sucralose | (1) | Table-top sweeteners | (1) | Good Manufacturing Practice |
| | | (2) | Breakfast cereals | (2) | 0.1% |
| | | (3) | Beverages; Beverage concentrates; Beverage mixes; Dairy beverages; (except for any of these products for which standards are set out in these Regulations) | (3) | 0.025% in beverages as consumed |
| | | (4) | Desserts; Dessert mixes; Toppings; Topping mixes; Dairy Desserts; Frozen Desserts; Fillings; Filling mixes; (except for any of these products for which standards are set out in these Regulations) | (4) | 0.025% in products as consumed |
| | | (5) | Chewing gum; Breath freshener products | (5) | 0.15% |
| | | (6) | Fruit spreads (except for any of these products for which standards are set out in these Regulations) | (6) | 0.045% |
| | | (7) | Salad dressings; Condiments; (except for any of these products for which standards are set out in these Regulations) | (7) | 0.04% |

| Item No. | Column I Additive | Column II Permitted in or on | | Column III Maximum Level of Use | |
|---|---|---|---|---|---|
| | | (8) | Confectionery glazes for snack foods; Sweetened seasonings or coating mixes for snack foods; Unstandardized confectionery; Unstandardized confectionery coatings | (8) | 0.07% |
| | | (9) | Baking mixes; Bakery products; (except for any of these products for which standards are set out in these Regulations) | (9) | 0.065% in products as consumed |
| | | (10) | Processed fruit and vegetable products (except for any of these products for which standards are set out in these Regulations) | (10) | 0.015% |
| | | (11) | Alcoholic beverages (except for any of these products for which standards are set out in these Regulations) | (11) | 0.07% |
| | | (12) | Puddings; Pudding mixes | (12) | 0.04% in products as consumed |
| | | (13) | Table syrups (except for any of these products for which standards are set out in these Regulations) | (13) | 0.15% |
| T.1 | Thaumatin | (1) | Chewing gum; Breath freshener products | (1) | 500 p.p.m. |
| | | (2) | Salt substitutes | (2) | 400 p.p.m. |
| | | (3) | (naming the flavour) Flavour referred to in section B.10.005; Unstandardized flavouring preparations | (3) | 100 p.p.m. |
| X.1 | Xylitol | | Unstandardized foods | | Good Manufacturing Practice |

SOR/93-276, s. 12; SOR/94-625, s. 5; SOR/94-689, s. 2(F); SOR/94-779, s. 3; SOR/97-512, ss. 3, 4; SOR/2004-261, s. 2; SOR/2007-76, s. 3; SOR/2007-176, s. 7; SOR/2010-142, ss. 52 to 55.

TABLE X

FOOD ADDITIVES THAT MAY BE USED AS PH ADJUSTING AGENTS, ACID-REACTING MATERIALS AND WATER CORRECTING AGENTS

| Item No. | Column I Additive | Column II Permitted in or Upon | | Column III Maximum Level of Use | |
|---|---|---|---|---|---|
| A.1 | Acetic Acid | (1) | Cream cheese spread; Cream cheese spread with (naming the | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | |
| | | (2) Canned Asparagus | (2) Good Manufacturing Practice |
| | | (3) Gelatin | (3) Good Manufacturing Practice |
| | | (4) Unstandardized foods | (4) Good Manufacturing Practice |
| A.2 | Adipic Acid | Unstandardized foods | Good Manufacturing Practice |
| A.3 | Ammonium Aluminum | (1) Baking powder | (1) Good Manufacturing Practice |
| | Sulphate | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| A.4 | Ammonium | (1) Cocoa products | (1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | Bicarbonate | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| A.5 | Ammonium Carbonate | (1) Cocoa products | (1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| A.6 | Ammonium Citrate, | Unstandardized foods | Good Manufacturing |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | dibasic | | Practice |
| A.7 | Ammonium Citrate, monobasic | Unstandardized foods | Good Manufacturing Practice |
| A.8 | Ammonium Hydroxide | (1) Cocoa products | (1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (2) Gelatin | (2) Good Manufacturing Practice |
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |
| A.9 | Ammonium Phosphate, dibasic | (1) Ale; Bacterial cultures; Baking powder; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| A.10 | Ammonium Phosphate, monobasic | (1) Ale; Bacterial cultures; Baking powder; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| | | (3) Uncultured buttermilk | (3) 0.1% |
| C.1 | Calcium Acetate | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| C.2 | Calcium Carbonate | (1) Ice cream mix; Ice milk mix; Wine | (1) Good Manufacturing Practice |
| | | (2) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added | (2) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | |
| | | (3) Grape juice | (3) Good Manufacturing Practice |
| | | (4) Unstandardized foods | (4) Good Manufacturing Practice |
| | | (5) Cocoa products | (5) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| C.3 | Calcium Chloride | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| C.4 | Calcium Citrate | (1) Infant formula | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| C.5 | Calcium Fumarate | Unstandardized foods | Good Manufacturing Practice |
| C.6 | Calcium Gluconate | Unstandardized foods | Good Manufacturing Practice |
| C.7 | Calcium Hydroxide | (1) Ale; Beer; Ice cream mix; Ice milk mix; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Canned peas | (2) 0.01% |
| | | (3) Infant formula | (3) Good Manufacturing Practice |
| | | (4) Grape Juice | (4) Good Manufacturing Practice |
| | | (5) Unstandardized foods | (5) Good Manufacturing Practice |
| C.8 | Calcium Lactate | (1) Baking powder | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| C.9 | Calcium Oxide | (1) Ale; Beer; Ice cream mix; Ice milk mix; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | | Practice |
| C.10 | Calcium Phosphate, dibasic | Unstandardized foods | Good Manufacturing Practice |
| C.11 | Calcium Phosphate, monobasic | (1) Ale; Baking powder; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| C.12 | Calcium Phosphate, tribasic | Unstandardized foods | Good Manufacturing Practice |
| C.13 | Calcium Sulphate | Ale; Beer; Light beer; Malt liquor; Porter; Stout; Wine | Good Manufacturing Practice |
| C.13A | Carbon Dioxide | (Naming the variety) Cheese | Good Manufacturing Practice |
| C.14 | Citric Acid | (1) Ale; Apple (or rhubarb) and (naming the fruit) jam; Beer; Canned artichokes; Canned asparagus; Canned bean sprouts; Canned chili peppers; Canned mushrooms; Canned onions; Canned pears; Canned shellfish; Canned spring mackerel; Cider; Cottage cheese; Creamed cottage cheese; Egg white (albumen) and yolk; Liquid, dried or frozen whole egg; Fig marmalade; Fig marmalade with pectin; French dressing; Frozen cooked shrimp; Frozen (naming the fruit); Gelatin; Grape juice; Honey wine; Ice cream mix; Ice milk mix; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; Light beer; Malt liquor; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Mayonnaise; Mincemeat; Olives; Peach nectar; Pear nectar;Pineapple marmalade; Pineapple marmalade with pectin; Porter; Salad dressing; Sherbet; Stout; Tomatoes; Wine | (1) Good Manufacturing Practice |
| | | (2) Canned applesauce; Canned grapefruit; Canned mandarin oranges; Canned pears; Canned | (2) Sufficient to maintain pH 4.2 to 4.5 |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | pineapple; Canned strawberries | |
| | | (3) Infant formula | (3) Good Manufacturing Practice |
| | | (4) Margarine | (4) Good Manufacturing Practice |
| | | (5) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | (5) Good Manufacturing Practice |
| | | (6) Unstandardized foods | (6) Good Manufacturing Practice |
| | | (7) Cocoa products | (7) 1%, singly or in combination with tartaric acid, calculated on a fat-free basis |
| C.15 | Cream of Tartar | Same foods as listed for Potassium Acid Tartrate | Same levels as prescribed for Potassium Acid Tartrate |
| F.1 | Fumaric Acid | (1) Gelatin | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| | | (3) Wine | (3) Good Manufacturing Practice |
| G.1 | Gluconic Acid | Unstandardized foods | Good Manufacturing Practice |
| G.2 | Glucono-delta- | Unstandardized foods | Good Manufacturing |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | lactone | | Practice |
| H.1 | Hydrochloric Acid | (1) Ale; Beer; Gelatin; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Infant formula | (2) Good Manufacturing Practice |
| L.1 | Lactic Acid | (1) Ale; Baking powder; Beer; Bread; Cider; Cottage cheese; Creamed cottage cheese; Dried egg-white (dried albumen); Dried whole egg; Dried yolk; French dressing; Frozen egg-white (frozen albumen); Frozen whole egg; Frozen yolk; Ice cream mix; Ice milk mix; Liquid egg-white (liquid albumen); Liquid whole egg; Liquid yolk; Malt liquor; Mayonnaise; Olives; Pickles; Porter; Relishes; Salad dressing; Sherbet; Stout | (1) Good Manufacturing Practice |
| | | (2) Canned pears; Canned strawberries | (2) Sufficient to maintain pH 4.2 to 4.5 |
| | | (3) Margarine | (3) Good Manufacturing Practice |
| | | (4) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | (4) Good Manufacturing Practice |
| | | (5) Unstandardized foods | (5) Good Manufacturing Practice |
| | | (6) Wine | (6) Good Manufacturing |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | | Practice |
| M.2 | Magnesium Carbonate | (1) Cocoa products | (1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (2) Ice cream mix; Ice milk mix | (2) Good Manufacturing Practice |
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |
| M.3 | Magnesium Citrate | Soft drinks | Good Manufacturing Practice |
| M.4 | Magnesium Fumarate | Unstandardized foods | Good Manufacturing Practice |
| M.5 | Magnesium Hydroxide | (1) Canned peas | (1) 0.05% |
| | | (2) Cocoa products | (2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (3) Gelatin; Ice cream mix; Ice milk mix | (3) Good Manufacturing Practice |
| | | (4) Bacterial cultures | (4) Good Manufacturing Practice |
| M.6 | Magnesium Oxide | Ice cream mix; Ice milk mix | Good Manufacturing Practice |
| M.6A | Magnesium Phosphate | Bacterial cultures | Good Manufacturing Practice |
| M.7 | Magnesium Sulphate | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Bacterial cultures | (2) Good Manufacturing Practice |
| M.8 | Malic Acid | (1) Apple (or rhubarb) and (naming the fruit) jam; Apricot nectar; Canned asparagus; Fig marmalade; Fig marmalade with pectin; Frozen (naming the fruit); (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | Peach nectar; Pear nectar; Pineapple marmalade; Pineapple marmalade with pectin | |
| | | (2) Canned applesauce; Canned pears; Canned strawberries | (2) Sufficient to maintain pH 4.2 to 4.5 |
| | | (3) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | (3) Good Manufacturing Practice |
| | | (4) Unstandardized foods | (4) Good Manufacturing Practice |
| | | (5) Wine | (5) Good Manufacturing Practice |
| M.8A | Manganese Sulphate | Bacterial cultures | Good Manufacturing Practice |
| M.9 | Metatartaric Acid | Wine | 0.01% |
| P.1 | Phosphoric Acid | (1) Ale; Beer; Cottage Cheese; Creamed cottage cheese; Gelatin; Light beer; Malt liquor; Mono-glycerides and mono- and diglycerides; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); | (2) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | |
| | | (3) Fish protein | (3) Good Manufacturing Practice |
| | | (4) Unstandardized foods | (4) Good Manufacturing Practice |
| | | (5) Cocoa products | (5) 0.5%, expressed as $P_2O_5$, calculated on a fat-free basis |
| P.2 | Potassium Acid Tartrate | (1) Baking powder; Honey wine | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| | | (3) Wine | (3) 0.42% |
| P.3 | Potassium Aluminum Sulphate | (1) Ale; Baking powder; Beer; Light beer; Malt liquor; Oil-soluble annatto; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| P.4 | Potassium Bicarbonate | (1) Baking powder; Malted milk; Malted milk powder | (1) Good Manufacturing Practice |
| | | (2) Cocoa products | (2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (3) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed | (3) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | |
| | | (4) Infant formula | (4) Good Manufacturing Practice |
| | | (5) Margarine | (5) Good Manufacturing Practice |
| | | (6) Unstandardized foods | (6) Good Manufacturing Practice |
| | | (7) Wine | (7) Good Manufacturing Practice |
| P.5 | Potassium Carbonate | (1) Cocoa products | (1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (2) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | (2) Good Manufacturing Practice |
| | | (3) Margarine | (3) Good Manufacturing Practice |
| | | (4) Unstandardized foods | (4) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | (5) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(*n*) | (5) Good Manufacturing Practice |
| | | (6) Wine | (6) Good Manufacturing Practice |
| P.6 | Potassium Chloride | Ale; Beer; Light beer; Malt liquor; Porter; Stout | Good Manufacturing Practice |
| P.7 | Potassium Citrate | (1) Infant formula | (1) Good Manufacturing Practice |
| | | (2) Margarine | (2) Good Manufacturing Practice |
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |
| | | (4) Wine | (4) Good Manufacturing Practice |
| P.8 | Potassium Fumarate | Unstandardized foods | Good Manufacturing Practice |
| P.9 | Potassium Hydroxide | (1) Oil-soluble annatto | (1) 1.0% |
| | | (2) Cocoa products | (2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (3) Ice cream mix; Ice milk mix; Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product | (3) Good Manufacturing Practice |
| | | (4) Infant formula | (4) Good Manufacturing Practice |
| | | (5) Margarine | (5) Good Manufacturing Practice |
| | | (6) Grape juice | (6) Good Manufacturing Practice |
| | | (7) Unstandardized foods | (7) Good Manufacturing Practice |
| P.9A | Potassium Lactate | Margarine | Good Manufacturing Practice |
| P.10 | Potassium Phosphate, dibasic | Unstandardized foods | Good Manufacturing Practice |
| P.11 | Potassium Sulphate | Ale; Beer; Light beer; Malt liquor; Porter; Stout | Good Manufacturing Practice |
| P.12 | Potassium Tartrate | Cider | Good Manufacturing |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | | Practice |
| S.1 | Sodium Acetate | Unstandardized foods | Good Manufacturing Practice |
| S.2 | Sodium Acid Pyrophosphate | (1) Baking powder | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| S.3 | Sodium Acid Tartrate | Baking Powder | Good Manufacturing Practice |
| S.4 | Sodium Aluminum Phosphate | Unstandardized foods | Good Manufacturing Practice |
| S.5 | Sodium Aluminum | (1) Baking powder | (1) Good Manufacturing Practice |
| | Sulphate | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| S.6 | Sodium Bicarbonate | (1) Apple (or rhubarb) and (naming the fruit) jam; Baking powder; Dried egg-white (dried albumen); Dried whole egg; Dried yolk; Fig marmalade; Fig marmalade with pectin; Frozen egg-white (frozen albumen); Frozen whole egg; Frozen yolk; Ice cream mix; Ice milk mix; Liquid egg-white (liquid albumen); Liquid whole egg; Liquid yolk; Malted milk powder; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; Oil-soluble annatto; Pineapple marmalade; Pineapple marmalade with pectin; Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product | (1) Good Manufacturing Practice |
| | | (2) Cocoa products | (2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | (3) | Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | (3) | Good Manufacturing Practice |
| | | (4) | Infant formula | (4) | Good Manufacturing Practice |
| | | (5) | Margarine | (5) | Good Manufacturing Practice |
| | | (6) | Unstandardized foods | (6) | Good Manufacturing Practice |
| S.7 | Sodium Bisulphate | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized bakery products | (2) | Good Manufacturing Practice |
| S.8 | Sodium Carbonate | (1) | Apple (or rhubarb) and (naming the fruit) jam; Dried egg-white (dried albumen); Dried whole egg; Dried yolk; Fig marmalade; Fig marmalade with pectin; Frozen egg-white (frozen albumen); Frozen whole egg; Frozen yolk; Gelatin; Ice cream mix; Ice milk mix; Liquid egg-white (liquid albumen); Liquid whole egg; Liquid yolk; Meat binder or (naming the meat product) binder where sold for use in preserved meat or preserved meat by-product; (naming the citrus fruit) Marmalade; (naming the citrus | (1) | Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | fruit) Marmalade with pectin; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; Pineapple marmalade; Pineapple marmalade with pectin | |
| | | (2) Cocoa products | (2) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (3) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | (3) Good Manufacturing Practice |
| | | (4) Margarine | (4) Good Manufacturing Practice |
| | | (5) Unstandardized foods | (5) Good Manufacturing Practice |
| S.9 | Sodium Citrate | (1) Apple (or rhubarb) and (naming the fruit) jam; Cottage cheese; Cream; Creamed cottage cheese; Ice cream mix; Ice milk mix; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Pineapple marmalade or Fig | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | marmalade; Pineapple marmalade with pectin or Fig marmalade with pectin; Sherbet | |
| | | (2) Infant formula | (2) Good Manufacturing Practice |
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |
| | | (4) Margarine | (4) Good Manufacturing Practice |
| S.12 | Sodium Fumarate | Unstandardized foods | Good Manufacturing Practice |
| S.13 | Sodium Gluconate | Unstandardized foods | Good Manufacturing Practice |
| S.14 | Sodium Hexametaphosphate | Unstandardized foods | Good Manufacturing Practice |
| S.15 | Sodium Hydroxide | (1) Cocoa products | (1) Sufficient to process the cocoa products in accordance with the requirements of section B.04.005 |
| | | (2) Gelatin; Ice cream mix; Ice milk mix; (naming the flavour) Partly skimmed milk; (naming the flavour) Skim milk; Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product | (2) Good Manufacturing Practice |
| | | (3) Infant formula | (3) Good Manufacturing Practice |
| | | (4) Margarine | (4) Good Manufacturing Practice |
| | | (5) Unstandardized foods | (5) Good Manufacturing Practice |
| | | (6) (Naming the variety) Whey cheese; Whey cheese | (6) Good Manufacturing Practice |
| S.16 | Sodium Lactate | (1) Margarine | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| S.17 | Sodium Phosphate, dibasic | (1) Ale; Bacterial culture; Beer; Cream; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| S.18 | Sodium Phosphate, | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | monobasic | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| S.19 | Sodium Phosphate, tribasic | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| S.20 | Sodium Potassium Tartrate | (1) Apple (or rhubarb) and (naming the fruit) jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Pineapple marmalade or Fig marmalade; Pineapple marmalade with pectin or Fig marmalade with pectin | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| | | (3) Margarine | (3) Good Manufacturing Practice |
| S.21 | Sodium Pyrophosphate, tetrabasic | Unstandardized foods | Good Manufacturing Practice |
| S.22 | Sodium Tripolyphos- phate | Unstandardized foods | Good Manufacturing Practice |
| S.23 | Sulphuric Acid | Ale; Beer; Light beer; Malt liquor; Porter; Stout | Good Manufacturing Practice |
| S.24 | Sulphurous Acid | Gelatin | Good Manufacturing Practice provided the finished product does not contain more than 500 p.p.m. calculated as sulphur dioxide |
| T.1 | Tartaric Acid | (1) Ale; Apple (or rhubarb) and (naming the fruit) jam; Baking powder; Beer; Cider; Canned asparagus; Fig marmalade; Fig marmalade with pectin; French | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | dressing; Honey wine; Ice cream mix; Ice milk mix; (naming the fruit) Jam; (naming the fruit) Jam with pectin; (naming the fruit) Jelly; (naming the fruit) Jelly with pectin; Light beer; Malt liquor; (naming the citrus fruit) Marmalade; (naming the citrus fruit) Marmalade with pectin; Mayonnaise; Pineapple marmalade; Pineapple marmalade with pectin; Porter; Salad dressing; Sherbet; Stout; Wine | |
| | | (2) Canned pears; Canned strawberries | (2) Sufficient to maintain pH 4.2 to 4.5 |
| | | (3) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); (naming the variety) Whey cheese | (3) Good Manufacturing Practice |
| | | (4) Margarine | (4) Good Manufacturing Practice |
| | | (5) Unstandardized foods | (5) Good Manufacturing Practice |
| | | (6) Cocoa products | (6) 1%, singly or in combination with citric acid, calculated on a fat-free basis |

SOR/78-874, s. 4; SOR/79-660, ss. 14 to 17; SOR/79-664, ss. 3 to 13; SOR/79-752, s. 9; SOR/80-501, s. 4; SOR/86-1112, ss. 6 to 8; SOR/92-106, s. 1; SOR/92-344, s. 5; SOR/94-689, s. 2(F); SOR/95-281, ss. 2 to 5; SOR/95-436, ss. 2, 3; SOR/97-263, ss. 11 to 25;

SOR/97-561, s. 3; SOR/98-580, s. 1(F); SOR/2001-94, s. 3; SOR/2006-91, ss. 13 to 20; SOR/2007-75, s. 8; SOR/2010-41, s. 9(E); SOR/2010-94, s. 8(E); SOR/2010-142, s. 56; SOR/2010-143, ss. 32 to 36.

# TABLE XI

PART I

FOOD ADDITIVES THAT MAY BE USED AS CLASS I PRESERVATIVES

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| A.1 | Acetic Acid | (1) Preserved fish; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods | (2) Good Manufacturing Practice |
| A.2 | Ascorbic Acid | (1) Ale; Beer; Canned mushrooms; Canned tuna; Canned white asparagus; Cider; Frozen fruit; Glaze of Frozen fish; Headcheese; Light beer; Malt liquor; Meat binder for preserved meat and preserved meat by-product (Division 14 only); Porter; Preserved fish; Frozen minced fish; Frozen comminuted fish; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle; Cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product; Stout; Wine | (1) Good Manufacturing Practice |
| | | (2) Canned applesauce | (2) If used either singly or in combination with Iso-Ascorbic Acid, the total not to exceed 150 p.p.m. |
| | | (3) Canned peaches | (3) 550 p.p.m. |
| | | (4) Unstandardized foods | (4) Good Manufacturing practice |
| C.1 | Calcium Ascorbate | Same foods as listed for Ascorbic Acid | Same levels as prescribed for Ascorbic Acid |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| E.1 | Erythorbic Acid | (1) Ale; Beer; Cider; Frozen fruit; Headcheese; Light beer; Malt liquor; Meat binder for preserved meat and preserved meat by-product (Division 14 only); Porter; Preserved fish; Frozen minced fish; Frozen comminuted fish; Glaze of frozen fish; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle; Cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product; Stout; Wine | (1) Good Manufacturing Practice |
| | | (2) Canned applesauce | (2) If used either singly or in combination with Ascorbic Acid, the total not to exceed 150 p.p.m. |
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |
| I.1 | Iso-Ascorbic Acid | Same foods as listed for Erythorbic Acid | Same levels as prescribed for Erythorbic Acid |
| P.1 | Potassium Nitrate | (1) Meat binder for dry sausage, semi-dry sausage, preserved meat and preserved meat by-products prepared by slow cure processes (Division 14) | (1) When the meat binder is used in accordance with label instructions, whether potassium nitrate is added alone or in combination with sodium nitrate, the total amount of such nitrates thereby added to each batch of dry sausage, semi-dry sausage, preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| | | (2) Cover pickle and dry cure employed in the curing of preserved meat and preserved meat by-products prepared by slow cure processes (Division 14) | (2) When the cover pickle or dry cure is used in accordance with label instructions, whether potassium nitrate is added alone or in combination with sodium nitrate, the total amount of such nitrates thereby added to each batch of preserved meat or |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | | preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| | | (3) Dry sausage, semi-dry sausage, preserved meat and preserved meat by-products prepared by slow cure processes (Division 14) | (3) Where potassium nitrate is added alone or in combination with sodium nitrate, the total amount of such nitrates added to each batch of dry sausage, semi-dry sausage, preserved meat or preserved meat by-products shall not exceed 0.32 ounces per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| | | (4) Ripened cheese, containing not more than 68% moisture on a fat free basis during manufacture of which the lactic acid fermentation and salting is completed later than 12 hours after coagulation of the curd by food enzymes and where the added salt is applied externally to the cheese as dry salt or in the form of brine | (4) If used singly or in combination with sodium nitrate, the total not to exceed 200 p.p.m. (based in milk). Residue in the finished cheese not to exceed 50 p.p.m. |
| | | (5) Mold ripened cheese packed in hermetically sealed containers | (5) If used singly or in combination with sodium nitrate, the total not to exceed 200 p.p.m. (based in milk). Residue in the finished cheese not to exceed 50 p.p.m. |
| P.2 | Potassium Nitrite | (1) Meat binder, pumping pickle, cover pickle and dry cure employed in the curing of preserved meat and preserved meat by-products (Division 14) | (1) When the meat binder, pumping pickle, cover pickle or dry cure is used in accordance with label instructions, whether potassium nitrite is added alone or in combination with sodium nitrite, the total amount of such nitrites thereby added to each batch of preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million calculated prior to any smoking, cooking or fermentation |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | (2) Preserved meat except side bacon and preserved meat by-products (Division 14) | (2) Where potassium nitrite is added alone or in combination with sodium nitrite, the total amount of such nitrites added to each batch of preserved meat, except side bacon or preserved meat by-products, shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| | | (3) Side bacon | (3) Where potassium nitrite is added alone or in combination with sodium nitrite, the total amount of such nitrites added to each batch of side bacon shall not exceed 0.19 ounce per 100 pounds or 120 parts per million, calculated prior to any smoking, cooking or fermentation |
| | | (4) Preserved poultry meat and preserved poultry meat by-products (Division 22) | (4) Where potassium nitrite is added alone or in combination with sodium nitrite, the total amount of such nitrites added to each batch of preserved poultry meat or preserved poultry meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| S.1 | Sodium Ascorbate | Same foods as listed for Ascorbic Acid | Same levels as prescribed for Ascorbic Acid |
| S.2 | Sodium Erythorbate | (1) Same foods as listed for Erythorbic Acid | (1) Same levels as prescribed for Erythorbic Acid |
| | | (2) Canned clams | (2) 350 p.p.m. |
| S.3 | Sodium Iso-Ascorbate | Same foods as listed for Erythorbic Acid | Same levels as prescribed for Erythorbic Acid |
| S.4 | Sodium Nitrate | (1) Meat binder for dry sausage, semi-dry sausage, preserved meat and preserved meat by-products prepared by slow cure processes (Division 14) | (1) When the meat binder is used in accordance with label instructions, whether sodium nitrate is added alone or in combination with potassium nitrate, the total amount of such nitrates thereby added to each |

| Item No. | Column I Additive | Column II Permitted in or Upon | Column III Maximum Level of Use |
|---|---|---|---|
| | | | batch of dry sausage, semi-dry sausage, preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| (2) | | Cover pickle and dry cure employed in the curing of preserved meat and preserved meat by-products prepared by slow cure processes (Division 14) | When the cover pickle or dry cure is used in accordance with label instructions, whether sodium nitrate is added alone or in combination with potassium nitrate, the total amount of such nitrates thereby added to each batch of preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| (3) | | Dry sausage, semi-dry sausage, preserved meat and preserved meat by-products prepared by the slow cure processes (Division 14) | Where sodium nitrate is added alone or in combination with potassium nitrate, the total amount of such nitrates added to each batch of dry sausage, semi-dry sausage, preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| (4) | | Ripened cheese, containing not more than 68% moisture on a fat free basis during manufacture of which the lactic acid fermentation and salting is completed later than 12 hours after coagulation of the curd by food enzymes and where the added salt is applied externally to the cheese as dry salt or in the form of brine | If used singly or in combination with potassium nitrate, the total not to exceed 200 p.p.m. (based in milk). Residue in the finished cheese not to exceed 50 p.p.m. |
| (5) | | Mold ripened cheese packed in hermetically sealed containers | If used singly or in combination with potassium nitrate, the total not to exceed 200 p.p.m. (based in milk). Residue in the finished cheese not to exceed 50 p.p.m. |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| S.5 | Sodium Nitrite | (1) Meat binder, pumping pickle, cover pickle and dry cure employed in the curing of preserved meat and preserved meat by-products (Division 14) | (1) When the meat binder, pumping pickle, cover pickle or dry cure is used in accordance with label instructions, whether sodium nitrite is added alone or in combination with potassium nitrite, the total amount of such nitrites thereby added to each batch of preserved meat or preserved meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| | | (2) Preserved meat, except side bacon, and preserved meat by-products (Division 14) | (2) Where sodium nitrite is added alone or in combination with potassium nitrite, the total amount of such nitrites added to each batch of preserved meat, except side bacon or preserved meat by-products, shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| | | (3) Side bacon | (3) Where sodium nitrite is added alone or in combination with potassium nitrite, the total amount of such nitrites added to each batch of side bacon shall not exceed 0.19 ounce per 100 pounds or 120 parts per million, calculated prior to any smoking, cooking or fermentation |
| | | (4) Preserved poultry meat and preserved poultry meat by-products (Division 22) | (4) Where sodium nitrite is added alone or in combination with potassium nitrite, the total amount of such nitrites added to each batch of preserved poultry meat or preserved poultry meat by-products shall not exceed 0.32 ounce per 100 pounds or 200 parts per million, calculated prior to any smoking, cooking or fermentation |
| W.1 | Wood | (1) (naming the variety) Cheese; | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | Smoke | Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | |
| | | (2) Preserved fish; Preserved meat (Divisions 14 and 21); Preserved meat by-product (Divisions 14 and 21); Preserved poultry meat; Preserved poultry meat by-product; Sausage | (2) Good Manufacturing Practice |
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |

PART II

FOOD ADDITIVES THAT MAY BE USED AS CLASS II PRESERVATIVES

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| B.1 | Benzoic Acid | (1) Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; Fruit juices except frozen concentrated orange juice; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Marinated or similar cold-processed packaged fish and meat (Division 21); (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree | (1) 1,000 p.p.m. |
| | | (2) Unstandardized foods [except | (2) 1,000 p.p.m. |

| Item No. | Column I<br>Additive | | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|---|
| | | | unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | | |
| | | (3) | Margarine | (3) | If used singly or in combination with Sorbic Acid, the total shall not exceed 1,000 p.p.m. |
| C.1 | Calcium Sorbate | | Same foods as listed for sorbic acid | | Same levels as prescribed for Sorbic Acid |
| C.2 | *Carnobacterium maltaromaticum* CB1 | (1) | Vacuum-packed wieners | (1) | Good Manufacturing Practice |
| | | (2) | Vacuum-packed sliced roast beef in accordance with section B.14.005 | (2) | Good Manufacturing Practice |
| | | (3) | Vacuum-packed sliced cooked ham in accordance with section B.14.005 or B.14.031 | (3) | Good Manufacturing Practice |
| | | (4) | Vacuum-packed sliced cooked turkey in accordance with section B.22.006 or B.22.021 | (4) | Good Manufacturing Practice |
| H.1 | 4-Hexylresorcinol | | Crustaceans | | Good Manufacturing Practice. Residues in the edible portion of the uncooked product not to exceed 1.0 p.p.m. |
| M.1 | Methyl-*ρ*-hydroxy Benzoate | (1) | Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; Fruit juices except frozen concentrated orange juice; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; Marinated or similar cold-processed packaged fish and meat (Division 21); (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade | (1) | 1,000 p.p.m. |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | with pectin; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree | | |
| | | (2) | Unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | (2) | 1,000 p.p.m. |
| M.2 | Methyl Paraben | | Same foods as listed for Methyl-p-hydroxy Benzoate | | Same levels as prescribed for Methyl-p-hydroxy Benzoate |
| P.1 | Potassium Benzoate | | Same foods as listed for Benzoic Acid | | 1,000 p.p.m. calculated as Benzoic Acid |
| P.2 | Potassium Bisulphite | | Same foods as listed for Sulphurous Acid | | Same levels as prescribed for Sulphurous Acid |
| P.3 | Potassium Metabi- sulphite | | Same foods as listed for Sulphurous Acid | | Same levels as prescribed for Sulphurous Acid |
| P.4 | Potassium Sorbate | | Same foods as listed for Sorbic Acid | | Same levels as prescribed for Sorbic Acid |
| P.5 | Propyl-*ρ*-hydroxy Benzoate | (1) | Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; Fruit juices except frozen concentrated orange juice; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; marinated or similar cold-processed packaged fish and meat (Division 21); (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree | (1) | 1,000 p.p.m. |
| | | (2) | Unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and | (2) | 1,000 p.p.m. |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | (*c*) poultry meat and poultry meat by-product] | |
| P.6 | Propyl Paraben | Same foods as listed for Propyl-p-hydroxy Benzoate | Same levels as prescribed for Propyl-p-hydroxy Benzoate |
| S.1 | Sodium Benzoate | Same foods as listed for Benzoic Acid | 1,000 p.p.m. calculated as Benzoic Acid |
| S.2 | Sodium Bisulphite | Same foods as listed for Sulphurous Acid | Same levels as prescribed for Sulphurous Acid |
| S.3 | Sodium Metabisulphite | Same foods as listed for Sulphurous Acid | Same levels as prescribed for Sulphurous Acid |
| S.4 | Sodium Salt of Methyl-*ρ*-hydroxy Benzoic Acid | Same foods as listed for Methyl-p-hydroxy Benzoate | 1,000 p.p.m. calculated as Methyl-p-hydroxy Benzoate |
| S.5 | Sodium Salt of Propyl-*ρ*-hydroxy Benzoic Acid | Same foods as listed for Propyl-p-hydroxy Benzoate | 1,000 p.p.m. calculated as Propyl-p-hydroxy Benzoate |
| S.6 | Sodium Sorbate | Same foods as listed for Sorbic Acid | Same levels as prescribed for Sorbic Acid |
| S.7 | Sodium Sulphite | Same foods as listed for Sulphurous Acid | Same levels as prescribed for Sulphurous Acid |
| S.8 | Sodium Dithionite | Same foods as listed for Sulphurous Acid | Same levels as prescribed for Sulphurous Acid |
| S.9 | Sorbic Acid | (1) Apple (or rhubarb) and (naming the fruit) jam; Fig marmalade with pectin; Fruit juices except frozen concentrated orange juice; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; Smoked or salted dried fish; Smoked or salted fish paste; (naming the source of the glucose) syrup; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree | (1) 1,000 p.p.m. |
| | | (2) Unstandardized foods [except | (2) 1,000 p.p.m. |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | unstandardized preparations of (*a*) meat and meat by-product (Divisions 14 and 21); (*b*) fish; and (*c*) poultry meat and poultry meat by-product] | | |
| | | (3) | Olive brine | (3) | 300 p.p.m. |
| | | (4) | Margarine | (4) | If used singly or in combination with Benzoic Acid, the total shall not exceed 1,000 p.p.m. |
| | | (5) | Unstandardized salad dressings | (5) | 3,350 p.p.m. |
| S.10 | Sulphurous Acid | (1) | Cider; Honey wine; Wine | (1) | 70 p.p.m. in the free state or 350 p.p.m. in the combined state calculated as sulphur dioxide |
| | | (2) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (2) | 15 p.p.m. calculated as sulphur dioxide |
| | | (3) | Apple (or rhubarb) and (naming the fruit) jam; Fancy molasses; Fig marmalade with pectin; Frozen sliced apples; Fruit juices except frozen concentrated orange juice; Gelatin; (naming the fruit) jam; (naming the fruit) jam with pectin; (naming the fruit) jelly with pectin; (naming the citrus fruit) marmalade with pectin; Mincemeat; Pickles and relishes; Pineapple marmalade with pectin; (naming the source of the glucose) syrup; Refiners' molasses; Table molasses; Tomato catsup; Tomato paste; Tomato pulp; Tomato puree | (3) | 500 p.p.m. calculated as sulphur dioxide |
| | | (4) | Beverages | (4) | 100 p.p.m. calculated as sulphur dioxide |
| | | (5) | Dried fruits and vegetables | (5) | 2,500 p.p.m. calculated as sulphur dioxide |
| | | (6) | Unstandardized foods [except in food recognized as a source of thiamine and except unstandardized preparations of | (6) | 500 p.p.m. calculated as sulphur dioxide |

| Item No. | Column I Additive | Column II Permitted in or Upon | Column III Maximum Level of Use |
|---|---|---|---|
| | | (*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | |
| | | (7) Frozen mushrooms | (7) 90 p.p.m. calculated as sulphur dioxide |
| | | (8) Dextrose Anhydrous; Dextrose Monohydrate | (8) 20 p.p.m. calculated as sulphur dioxide |
| | | (9) Glucose or glucose syrup | (9) 40 p.p.m. except glucose or glucose syrup for the manufacture of sugar confectionery not more than 400 p.p.m. calculated as sulphur dioxide |
| | | (10) Glucose solids or dried glucose syrup | (10) 40 p.p.m. except glucose solids or dried glucose syrup for the manufacture of sugar confectionary not more than 150 p.p.m. calculated as sulphur dioxide |
| | | (11) Crustaceans | (11) Good Manufacturing Practice. Residues in the edible portion of the uncooked product not to exceed 100 p.p.m., calculated as sulphur dioxide. |

PART III

FOOD ADDITIVES THAT MAY BE USED AS CLASS III PRESERVATIVES

| Item No. | Column I Additive | Column II Permitted in or Upon | Column III Maximum Level of Use |
|---|---|---|---|
| C.1 | Calcium Propionate | (1) Same foods as listed for Propionic Acid | (1) 2,000 p.p.m. calculated as Propionic Acid |
| | | (2) Soft flour tortillas | (2) 4,000 p.p.m. |
| C.2 | Calcium Sorbate | Same foods as listed for Sorbic Acid | Same maximum levels of use as listed for Sorbic Acid |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| N.1 | Natamycin | (1) The surface of (naming the variety) cheese and cheddar cheese | (1) 20 p.p.m. in accordance with the requirements of sections B.08.033 and B.08.034 |
| | | (2) The surface of grated or shredded (naming the variety) cheese and grated or shredded cheddar cheese | (2) 10 p.p.m. in accordance with the requirements of sections B.08.033 and B.08.034 |
| P.1 | Potassium Sorbate | (1) Same foods as listed for Sorbic Acid | (1) Same maximum levels of use as listed for Sorbic Acid |
| | | (2) Soft flour tortillas | (2) 5,000 p.p.m. |
| P.2 | Propionic Acid | (1) Bread | (1) 2,000 p.p.m. |
| | | (2) (naming the variety) Cheese; Cheddar cheese; Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (2) 2,000 p.p.m. or 3,000 p.p.m., as the case may be, in accordance with the requirements of sections B.08.033, B.08.034, B.08.035, B.08.037, B.08.038, B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3, B.08.041.4, B.08.041.5, B.08.041.6, B.08.041.7 and B.08.041.8 |
| | | (3) Unstandardized foods except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product | (3) 2,000 p.p.m. |
| S.1 | Sodium Diacetate | (1) Bread | (1) 3,000 p.p.m. |
| | | (2) Unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product | (2) 3,000 p.p.m. |

| Item No. | Column I Additive | Column II Permitted in or Upon | Column III Maximum Level of Use |
|---|---|---|---|
| | | (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | |
| S.2 | Sodium Propionate | Same foods as listed for Propionic Acid | 2,000 p.p.m. calculated as Propionic Acid |
| S.3 | Sodium Sorbate | Same foods as listed for Sorbic Acid | Same maximum levels of use as listed for Sorbic Acid |
| S.4 | Sorbic Acid | (1) Bread | (1) 1,000 p.p.m. |
| | | (naming the variety) Cheese; Cheddar cheese; Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Processed cheese | 3,000 p.p.m. in accordance with the requirements of sections B.08.033, B.08.034, B.08.035, B.08.037, B.08.038, |
| | | (2) food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients) | (2) B.08.039, B.08.040, B.08.041, B.08.041.1, B.08.041.2, B.08.041.3, B.08.041.4, B.08.041.5, B.08.041.6, B.08.041.7 and B.08.041.8 |
| | | (3) Cider; Wine; Honey Wine | (3) 500 p.p.m. |
| | | (4) Unstandardized foods except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-products | (4) 1,000 p.p.m. |

PART IV

FOOD ADDITIVES THAT MAY BE USED AS CLASS IV PRESERVATIVES

| Column I | Column II | Column III |
|---|---|---|

| Item No. | Additive | Permitted in or Upon | | Maximum Level of Use | |
|---|---|---|---|---|---|
| A.1 | Ascorbic Acid | (1) | Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| A.2 | Ascorbyl Palmitate | (1) | Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods [except unstandardized preparations of (*a*) meat and meat by-product (Divisions 14 and 21); (*b*) fish; and (*c*) poultry meat and poultry meat by-product] | (2) | Good Manufacturing Practice |
| | | (3) | Margarine | (3) | 0.02% of the fat content. If ascorbyl stearate is also used the total must not exceed 0.02% of the fat content |
| | | (4) | Infant formula | (4) | 0.001% as consumed |
| A.3 | Ascorbyl Stearate | (1) | Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) | Good Manufacturing Practice |
| | | (2) | Margarine | (2) | 0.02% of the fat content. If ascorbyl palmitate is also used the total must not exceed 0.02% of the fat content |
| B.1 | Butylated Hydro-xyanisole (a mixture of 2-tertiarybutyl-4-hydroxyanisole and 3-tertiarybutyl-4-hydroxyanisole) | (1) | Fats and oils, lard, shortening | (1) | 0.02%. If butylated hydroxytoluene, propyl gallate or tertiary butyl hydroquinone is also used, the total must not exceed 0.02% |
| | | (2) | Dried breakfast cereals; Dehydrated potato products | (2) | 0.005%. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.005% |
| | | (3) | Chewing gum | (3) | 0.02%. If butylated |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | | | hydroxytoluene or propyl gallate is also used the total must not exceed 0.02% |
| | | (4) | Essential oils; Citrus oil flavours; Dry flavours | (4) | 0.125%. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.125% |
| | | (5) | Citrus oils | (5) | 0.5%. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.5% |
| | | (6) | Partially defatted pork fatty tissue; Partially defatted beef fatty tissue | (6) | 0.0065%. If butylated hydroxytoluene is also used the total must not exceed 0.0065% |
| | | (7) | Vitamin A liquids for addition to food | (7) | 5 mg/1,000,000 International Units |
| | | (8) | Dry beverage mixes; Dry dessert and confection mixes | (8) | 0.009% |
| | | (9) | Active dry yeast | (9) | 0.1% |
| | | (10) | Other unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | (10) | 0.02% of the fat or the oil content of the food. If butylated hydroxytoluene or propyl gallate is also used the total must not exceed 0.02% of the fat or the oil content of the food |
| | | (11) | Dry Vitamin D preparations for addition to food | (11) | 10 mg/1,000,000 International Units |
| | | (12) | Margarine | (12) | 0.01% of the fat content. If butylated hydroxytoluene or propyl gallate or both are also used the total must not exceed 0.01% of the fat content |
| | | (13) | Dried cooked poultry meat | (13) | 0.015% of the fat content. If propyl gallate or citric acid or |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | | | both are also used, the total must not exceed 0.015% of the fat content. |
| B.2 | Butylated Hydroxytol-uene (3,5-ditertiary-butyl-4-hydroxytoluene | (1) | Fats and oils, lard, shortening | (1) | 0.02%. If butylated hydroxyanisole, propyl gallate or tertiary butyl hydroquinone is also used, the total must not exceed 0.02% |
| | | (2) | Dried breakfast cereals; Dehydrated potato products | (2) | 0.005%. If butylated hydroxyanisole or propyl gallate is also used the total must not exceed 0.005% |
| | | (3) | Chewing gum | (3) | 0.02%. If butylated hydroxyanisole or propyl gallate is also used the total must not exceed 0.02% |
| | | (4) | Essential oils; Citrus oil flavours; Dry flavours | (4) | 0.125%. If butylated hydroxyanisole or propyl gallate is also used the total must not exceed 0.125% |
| | | (5) | Citrus oils | (5) | 0.5%. If butylated hydroxyanisole or propyl gallate is also used the total must not exceed 0.5% |
| | | (6) | Partially defatted pork fatty tissue; Partially defatted beef fatty tissue | (6) | 0.0065%. If butylated hydroxyanisole is also used the total must not exceed 0.0065% |
| | | (7) | Vitamin A liquids for addition to food | (7) | 5 mg/1,000,000 International Units |
| | | (8) | Parboiled rice | (8) | 0.0035% |
| | | (9) | Other unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-products (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | (9) | 0.02% of the fat or the oil content of the food. If butylated hydroxyanisole or propyl gallate is also used the total must not exceed 0.02% of the fat or the oil content of the food |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | (10) Dry Vitamin D preparations for addition to food | (10) 10 mg/1,000,000 Internatinal Units |
| | | (11) Margarine | (11) 0.01% of the fat content. If butylated hydroxyanisole or propyl gallate or both are also used the total must not exceed 0.01% of the fat content |
| C.1 | Citric Acid | (1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods [except unstandardized preparations of (*a*) meat and meat by-product (Divisions 14 and 21); (*b*) fish; and (*c*) poultry meat and poultry meat by-product] | (2) Good Manufacturing Practice |
| | | (3) Dried cooked poultry meat | (3) 0.015% of the fat content. If butylated hydroxyanisole or propyl gallate or both are also used, the total must not exceed 0.015% of the fat content. |
| C.1.1 | L-Cysteine | Nutritional supplements set out in section B.24.201 | Good Manufacturing Practice |
| C.2 | L-Cysteine Hydrochloride | Sulphite replacement formulations for prepared fruits and vegetables | Good Manufacturing Practice |
| G.1 | Gum Guaiacum | (1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods [except unstandardized | (2) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | |
| L.1 | Lecithin | (1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | (2) Good Manufacturing Practice |
| L.2 | Lecithin Citrate | (1) Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) Good Manufacturing Practice |
| | | (2) Unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | (2) Good Manufacturing Practice |
| M.1 | Monoglyceride Citrate | (1) Fats and oils; Lard; Monoglycerides and | (1) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | diglycerides; Shortening | | |
| | | (2) | Unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | (2) | Good Manufacturing Practice |
| | | (3) | Margarine | (3) | 0.01% of the fat content. If monoisopropyl citrate or stearyl citrate or both are also used the total must not exceed 0.01% of the fat content |
| M.2 | Monoisopropyl Citrate | (1) | Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | (2) | Good Manufacturing Practice |
| | | (3) | Margarine | (3) | 0.01% of the fat content. If monoglyceride citrate or stearyl citrate or both are also used, the total must not exceed 0.01% of the fat content |
| P.1 | Propy1 Gallate | (1) | Fats and oils, lard, shortening | (1) | 0.02%. If butylated hydroxyanisole, butylated hydroxytoluene or tertiary butyl hydroquinone is also |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|
| | | | | used, the total must not exceed 0.02% |
| | | (2) | Dried breakfast cereals; Dehydrated potato products | (2) 0.005%. If butylated hydroxyanisole or butylated hydroxytoluene is also used the total must not exceed 0.005% |
| | | (3) | Chewing gum | (3) 0.02%. If butylated hydroxyanisole or butylated hydroxytoluene is also used the total must not exceed 0.02% |
| | | (4) | Essential oils; Dry flavours | (4) 0.125%. If butylated hydroxyanisole or butylated hydroxytoluene is also used the total must not exceed 0.125% |
| | | (5) | Citrus oils | (5) 0.5%. If butylated hydroxyanisole or butylated hydroxytoluene is also used the total must not exceed 0.5% |
| | | (6) | Other unstandardized foods [except unstandardized preparations of<br>(*a*) meat and meat by-product (Divisions 14 and 21);<br>(*b*) fish; and<br>(*c*) poultry meat and poultry meat by-product] | (6) 0.02% of the fat or the oil content of the food. If butylated hydroxyanisole or butylated hydroxytoluene is also used the total must not exceed 0.02% of the fat or the oil content of the food |
| | | (7) | Margarine | (7) 0.01% of the fat content. If butylated hydroxyanisole or butylated hydroxytoluene or both are also used the total must not exceed 0.01% of the fat content |
| | | (8) | Dried cooked poultry meat | (8) 0.015% of the fat content. If butylated hydroxyanisole or citric acid or both are also used the total must not exceed |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | | | 0.015% of the fat content. |
| T.1 | Tartaric Acid | (1) | Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods [except unstandardized preparations of (*a*) meat and meat by-product (Divisions 14 and 21); (*b*) fish; and (*c*) poultry meat and poultry meat by-product] | (2) | Good Manufacturing Practice |
| T.1A | Tertiary Butyl Hydroquinone | | Fats and oils, lard, shortening | | 0.02%. If butylated hydroxyanisole, butylated hydroxytoluene or propylgallate is also used, the total must not exceed 0.02% |
| T.2 | Tocopherols (alpha-tocopherol; tocopherols concentrate, mixed) | (1) | Fats and oils; Lard; Monoglycerides and diglycerides; Shortening | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods [except unstandardized preparations of (*a*) meat and meat by-product (Divisions 14 and 21); (*b*) fish; and (*c*) poultry meat and poultry meat by-product] | (2) | Good Manufacturing Practice |
| | | (3) | Infant formula | (3) | 0.001% as consumed |

SOR/79-285, ss. 1 to 4; SOR/79-660, s. 18; SOR/79-752, s. 10; SOR/80-500, s. 7; SOR/81-565, s. 6; SOR/81-934, ss. 13 to 15; SOR/82-383, s. 11; SOR/86-89, s. 7; SOR/86-1020, s. 1; SOR/87-138, ss. 1, 2; SOR/87-469, s. 2; SOR/89-198, ss. 12 to 16; SOR/91-124, ss. 10 to 12; SOR/92-226, s. 1; SOR/92-591, s. 2(F); SOR/94-689, s. 2(F); SOR/95-592, s. 1; SOR/96-241, s. 2; SOR/97-148, s. 7; SOR/97-191, s. 4; SOR/98-459, s. 1; SOR/99-289, ss. 1 to 4;

SOR/2003-156, s. 1; SOR/2005-316, ss. 4 to 6; SOR/2010-94, s. 8(E); SOR/2010-141, ss. 1, 2; SOR/2010-264, s. 4.

TABLE XII

FOOD ADDITIVES THAT MAY BE USED AS SEQUESTERING AGENTS

| | Column I | Column II | | Column III | |
|---|---|---|---|---|---|
| Item No. | Additive | Permitted in or Upon | | Maximum Level of Use | |
| A.1 | Ammonium Citrate, dibasic | | Unstandardized foods | | Good Manufacturing Practice |
| A.2 | Ammonium Citrate, monobasic | | Unstandardized foods | | Good Manufacturing Practice |
| C.1 | Calcium Citrate | | Unstandardized foods | | Good Manufacturing Practice |
| C.2 | Calcium Disodium Ethylenediamine-tetraacetate | (1) | Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) | 25 p.p.m. calculated as the anhydrous form |
| | | (2) | French dressing; Mayonnaise; Salad dressing; Unstandardized dressings and sauces | (2) | 75 p.p.m. calculated as the anhydrous form |
| | | (3) | Potato salad; Unstandardized sandwich spreads | (3) | 100 p.p.m. calculated as the anhydrous form |
| | | (4) | Canned shrimp; Canned tuna | (4) | 250 p.p.m. calculated as the anhydrous form |
| | | (5) | Canned crabmeat; Canned lobster; Canned salmon | (5) | 275 p.p.m. calculated as the anhydrous form |
| | | (6) | Margarine | (6) | 75 p.p.m. calculated as the anhydrous form |
| | | (7) | Canned clams | (7) | 340 p.p.m. calculated as the anhydrous form |
| | | (8) | Canned ripe lima beans (butter beans); Canned pinto beans | (8) | 130 p.p.m calculated as the anhydrous form and in accordance with the requirements of subparagraph B.11.002(*d*)(vi) |
| | | (9) | Canned snails; Canned sea snails | (9) | 300 p.p.m. calculated as the anhydrous form |
| | | (10) | Canned fava beans | (10) | 365 p.p.m. calculated as the anhydrous form and in accordance with the requirements of subparagraph B.11.002(*d*)(vi.1) |
| | | (11) | Soft drinks; Ready-to-drink | (11) | 33 p.p.m. calculated as the |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | teas | | anhydrous form |
| | | (12) | Pasteurized sous-vide potatoes | (12) | 100 p.p.m., singly or in combination with disodium EDTA, calculated as anhydrous disodium EDTA |
| C.3 | Calcium Disodium EDTA | | Same foods as listed for Calcium Disodium Ethylenediaminetetraacetate | | Same levels as prescribed for Calcium Disodium Ethylenediaminetetraacetate |
| C.4 | Calcium Phosphate, monobasic | (1) | Ice cream mix; Ice milk mix; Sherbet | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized dairy products | (2) | Good Manufacturing Practice |
| C.5 | Calcium Phosphate, tribasic | | Ice cream mix; Ice milk mix | | Good Manufacturing Practice |
| C.6 | Calcium Phytate | | Glazed fruit | | Good Manufacturing Practice |
| C.7 | Citric Acid | (1) | Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| D.1 | Disodium Ethylenediaminetetra-acetate | (3) | Frozen fish fillets; frozen minced fish; frozen comminuted fish | (3) | 0.1% |
| | | (1) | Dressing and sauces | (1) | 70 p.p.m. |
| | | (2) | Unstandardized sandwich spreads | (2) | 90 p.p.m |
| | | (3) | Canned red kidney beans; Canned chick peas (garbanzo beans); Canned black-eye peas | (3) | 150 p.p.m in accordance with the requirements of subparagraph B.11.002(*d*)(vii) |
| | | (4) | Dried banana products | (4) | 265 p.p.m |
| | | (5) | Aqueous suspensions of colour lake preparations for use in coating confectionery tablets | (5) | 1% of the colour preparation |
| | | (6) | Pasteurized *sous-vide* potatoes | (6) | 100 p.p.m., singly or in combination with calcium disodium EDTA, calculated as anhydrous disodium EDTA |

| Item No. | Column I<br>Additive | | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|---|
| D.2 | Disodium EDTA | | Same foods as listed for Disodium Ethylenediaminete-traacetate | | Same levels as prescribed for Disodium Ethylenediaminetetraacetate |
| G.1 | Glycine | | Mono- and diglycerides | | 0.02% |
| P.1 | Phosphoric Acid | | Mono- and diglycerides | | 0.02% |
| P.2 | Potassium Phosphate, monobasic | (1) | Ice cream mix; Ice milk mix; Sherbet | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| | | (3) | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | (3) | 0.5% total added phosphate, calculated as sodium phosphate, dibasic |
| P.3 | Potassium Pyrophosphate, tetrabasic | (1) | Meat tenderizers | (1) | Good Manufacturing Practice |
| | | (2) | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | (2) | 0.5% total added phosphate, calculated as sodium phosphate, dibasic |
| P.4 | Potassium Phosphate, dibasic | | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | | 0.5% total added phosphate, calculated as sodium phosphate, dibasic |
| S.1 | Sodium Acid Pyrophosphate | (1) | Canned seafoods | (1) | Used singly or in combination with sodium hexametaphosphate or sodium tripolyphosphate, or both, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic |
| | | (2) | Ice cream mix; Ice milk mix | (2) | Good Manufacturing Practice |
| | | (3) | Injection or cover solution for the curing of poultry or poultry meat | (3) | Good Manufacturing Practice, and in accordance with B.22.021(*e*) |
| | | (4) | Pumping pickle for the | (4) | Good Manufacturing |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use | |
|---|---|---|---|---|---|
| | | | curing of pork, beef and lamb cuts | | Practice, and in accordance with B.14.009(*f*) and B.14.031(*h*) |
| | | (5) | Unstandardized foods | (5) | Good Manufacturing Practice |
| | | (6) | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | (6) | 0.5% total added phosphate, calculated as sodium phosphate, dibasic |
| S.2 | Sodium Citrate | (1) | Ice cream mix; Ice milk mix; Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product; Sherbet | (1) | Good Manufacturing Practice |
| | | (2) | Unstandardized foods | (2) | Good Manufacturing Practice |
| S.3 | Sodium Hexametaphos- phate | (1) | Canned seafoods | (1) | Used singly or in combination with sodium acid pyrophosphate or sodium tripolyphosphate, or both, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic |
| | | (2) | Ice cream mix; Ice milk mix | (2) | Good Manufacturing Practice |
| | | (3) | Injection or cover solution for the curing of poultry or poultry meat | (3) | Good Manufacturing Practice, and in accordance with B.22.021(*e*) |
| | | (4) | Pumping pickle for the curing of pork, beef and lamb cuts | (4) | Good Manufacturing Practice, and in accordance with B.14.009(*f*) and B.14.031(*h*) |
| | | (5) | Unstandardized foods | (5) | Good Manufacturing Practice |
| | | (6) | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | (6) | 0.5% total added phosphate, calculated as sodium phosphate, dibasic |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|
| | | (7) | Liquid whey destined for the manufacture of concentrated or dried whey products | (7) 800 p.p.m. in the concentrated or dried whey products |
| S.4 | Sodium Phosphate, dibasic | (1) | Ice cream mix; Ice milk mix; Sherbet | (1) Good Manufacturing Practice |
| | | (2) | Injection or cover solution for the curing of poultry or poultry meat | (2) Good Manufacturing Practice, and in accordance with B.22.021(*e*) |
| | | (3) | Pumping pickle for the curing of pork, beef and lamb cuts | (3) Good Manufacturing Practice, and in accordance with B.14.009(*f*) and B.14.031(*h*) |
| | | (4) | Unstandardized foods | (4) Good Manufacturing Practice |
| | | (5) | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | (5) 0.5% total added phosphate, calculated as sodium phosphate, dibasic |
| S.5 | Sodium Phosphate, monobasic | (1) | Ice cream mix; Ice milk mix; Sherbet | (1) Good Manufacturing Practice |
| | | (2) | Injection or cover solution for the curing of poultry or poultry meat | (2) Good Manufacturing Practice, and in accordance with B.22.021(*e*) |
| | | (3) | Pumping pickle for the curing of pork, beef and lamb cuts | (3) Good Manufacturing Practice, and in accordance with B.14.009(*f*) and B.14.031(*h*) |
| | | (4) | Unstandardized foods | (4) Good Manufacturing Practice |
| | | (5) | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | (5) 0.5% total added phosphate, calculated as sodium phosphate, dibasic |
| S.6 | Sodium Pyrophosphate, tetrabasic | (1) | Ice cream mix; Ice milk mix; Sherbet | (1) Good Manufacturing Practice |
| | | (2) | Meat tenderizers | (2) Good Manufacturing Practice |
| | | (3) | Injection or cover solution for the curing of poultry or | (3) Good Manufacturing Practice, and in accordance |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | | Column III<br>Maximum Level of Use |
|---|---|---|---|---|
| | | | poultry meat | with B.22.021(*e*) |
| | | (4) | Pumping pickle for the curing of pork, beef and lamb cuts | (4) Good Manufacturing Practice, and in accordance with B.14.009(*f*) and B.14.031(*h*) |
| | | (5) | Unstandardized foods | (5) Good Manufacturing Practice |
| | | (6) | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | (6) 0.5% total added phosphate, calculated as sodium phosphate, dibasic |
| S.7 | Sodium Tripolyphos-phate | (1) | Injection or cover solution for the curing of poultry or poultry meat | (1) Good Manufacturing Practice, and in accordance with B.22.021(*e*) |
| | | (2) | Meat tenderizers | (2) Good Manufacturing Practice |
| | | (3) | Pumping pickle for the curing of pork, beef and lamb cuts | (3) Good Manufacturing Practice, and in accordance with B.14.009(*f*) and B.14.031(*h*) |
| | | (4) | Unstandardized foods | (4) Good Manufacturing Practice |
| | | (5) | Solid cut meat; prepared meat; prepared meat by-product; solid cut poultry meat; prepared poultry meat; prepared poultry meat by-product | (5) 0.5% total added phosphate, calculated as sodium phosphate, dibasic |
| | | (6) | Canned seafoods | (6) Used singly or in combination with sodium acid pyrophosphate or sodium hexametaphosphate, or both, total added phosphate not to exceed 0.5% calculated as sodium phosphate, dibasic |
| S.8 | Stearyl Citrate | | Margarine | 0.01% of the fat content. If monoglyceride citrate or monoisopropyl citrate or both are also used, the total must not exceed 0.01% of |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | | the fat content |

SOR/79-660, ss. 19, 20; SOR/80-501, s. 4; SOR/82-596, ss. 4 to 9; SOR/94-141, s. 1; SOR/94-262, ss. 4 to 12; SOR/94-689, s. 2; SOR/95-435, s. 2; SOR/97-30, s. 1; SOR/97-562, s. 1; SOR/580, s. 1(F); SOR/2005-316, ss. 7 to 11; SOR/2010-40, s. 2; SOR/2010-142, ss. 57, 58; SOR/2010-143, ss. 37(F), 38.

TABLE XIII

FOOD ADDITIVES THAT MAY BE USED AS STARCH MODIFYING AGENTS

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| A.1 | Acetic Anhydride | Starch | Good Manufacturing Practice |
| A.2 | Adipic Acid | Starch | Good Manufacturing Practice |
| A.3 | Aluminum Sulphate | Starch | Good Manufacturing Practice |
| E.1 | Epichlorhydrin | Starch | Good Manufacturing Practice |
| H.1 | Hydrochloric Acid | Starch | Good Manufacturing Practice |
| H.2 | Hydrogen Peroxide | Starch | Good Manufacturing Practice |
| M.1 | Magnesium Sulphate | Starch | 0.4% |
| N.1 | Nitric Acid | Starch | Good Manufacturing Practice |
| O.1 | Octenyl Succinic Anhydride | Starch | Good Manufacturing Practice |
| P.1 | Peracetic Acid | Starch | Good Manufacturing Practice |
| P.2 | Phosphorus Oxychloride | Starch | Good Manufacturing Practice |
| P.3 | Potassium Permanganate | Starch | 50 p.p.m. of Manganese Sulphate calculated as Manganese |
| P.4 | Propylene Oxide | Starch | 25% |
| S.1 | Sodium Acetate | Starch | Good Manufacturing Practice |
| S.2 | Sodium Bicarbonate | Starch | Good Manufacturing Practice |
| S.3 | Sodium Carbonate | Starch | Good Manufacturing Practice |
| S.4 | Sodium Chlorite | Starch | Good Manufacturing Practice |
| S.5 | Sodium Hydroxide | Starch | Good Manufacturing Practice |
| S.6 | Sodium Hypochlorite | Starch | Good Manufacturing Practice |
| S.7 | Sodium Trimetaphosphate | Starch | 400 p.p.m. calculated as Phosphorus |
| S.7A | Sodium Tripolyphosphate | Starch | Total residual phosphate not to exceed 0.4% (calculated as Phosphorus) |
| S.8 | Succinic Anhydride | Starch | Good Manufacturing Practice |
| S.9 | Sulphuric Acid | Starch | Good Manufacturing Practice |

SOR/94-689, s. 2(F).

TABLE XIV

FOOD ADDITIVES THAT MAY BE USED AS YEAST FOODS

| | Column I | Column II | Column III |
|---|---|---|---|
| Item No. | Additive | Permitted in or Upon | Maximum Level of Use |
| A.1 | Ammonium Chloride | (1) Flour; Whole wheat flour | (1) 2,000 p.p.m. of the flour |
| | | (2) Bread | (2) 2,500 p.p.m. of the flour. For combinations see paragraph B.13.021(*m*) |
| | | (3) Unstandardized foods | (3) Good Manufacturing Practice |
| A.2 | Ammonium Phosphate, dibasic | (1) Bread | (1) 2,500 p.p.m. of the flour. For combinations see paragraph B.13.021(*m*) |
| | | (2) Cider; Honey wine; Wine | (2) Good Manufacturing Practice |
| | | (3) Unstandardized bakery products | (3) Good Manufacturing Practice |
| A.3 | Ammonium Phosphate, monobasic | (1) Bread | (1) 2,500 p.p.m. of the flour. For combinations see paragraph B.13.021(*m*) |
| | | (2) Ale; Beer; Cider; Honey wine; Light beer; Malt liquor; Porter; Stout; Wine | (2) Good Manufacturing Practice |
| | | (3) Unstandardized bakery products | (3) Good Manufacturing Practice |
| A.4 | Ammonium Sulphate | (1) Bread | (1) 2,500 p.p.m. of the flour. For combinations see paragraph B.13.021(*m*) |
| | | (2) Cider; Honey wine; Wine | (2) Good Manufacturing Practice |
| | | (3) Unstandardized bakery products | (3) Good Manufacturing Practice |
| C.1 | Calcium Carbonate | (1) Bread | (1) 2,500 p.p.m. of the flour. For combinations see paragraph B.13.021(*m*) |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| C.2 | Calcium Chloride | Unstandardized bakery products | Good Manufacturing Practice |
| C.3 | Calcium Citrate | Unstandardized bakery products | Good Manufacturing Practice |
| C.4 | Calcium Lactate | (1) Bread | (1) 2,500 p.p.m. of the flour. For combinations see paragraph B.13.021(*m*) |
| | | (2) Unstandardized bakery | (2) Good Manufacturing Practice |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Level of Use |
|---|---|---|---|
| | | products | |
| C.5 | Calcium Phosphate, dibasic | (1) Bread | (1) 2,500 p.p.m. of the flour. For combinations see paragraph B.13.021(*m*) |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| C.6 | Calcium Phosphate, monobasic | (1) Bread | (1) 7,500 p.p.m. of flour. For combinations see paragraph B.13.021(*m*) |
| | | (2) Flour | (2) 7,500 p.p.m. of flour |
| | | (3) Unstandardized bakery products | (3) Good Manufacturing Practice |
| C.7 | Calcium Phosphate, tribasic | Unstandardized bakery products | Good Manufacturing Practice |
| C.8 | Calcium Sulphate | (1) Bread | (1) 5,000 p.p.m. of the flour |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| F.1 | Ferrous Sulphate | Bacterial cultures | Good Manufacturing Practice |
| M.1 | Manganese Sulphate | Ale; Beer; Light beer; Malt liquor; Porter; Stout | Good Manufacturing Practice |
| P.1 | Phosphoric Acid | Ale; Beer; Light beer; Malt liquor; Porter; Stout | Good Manufacturing Practice |
| P.2 | Potassium Chloride | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| P.4 | Potassium Phosphate, dibasic | (1) Ale; Beer; Cider; Honey wine; Light beer; Malt liquor; Porter; Stout; Wine | (1) Good Manufacturing Practice |
| | | (2) Unstandardized bakery products | (2) Good Manufacturing Practice |
| P.5 | Potassium Phosphate, monobasic | Ale; Beer; Cider; Honey wine; Light beer; Malt liquor; Porter; Stout; Wine | Good Manufacturing Practice |
| S.1 | Sodium Sulphate | Unstandardized bakery products | Good Manufacturing Practice |
| U.1 | [Repealed, SOR/87-5, s. 1] | | |
| Z.1 | Zinc Sulphate | (1) Ale; Beer; Light beer; Malt liquor; Porter; Stout | (1) Good Manufacturing Practice |
| | | (2) Bacterial cultures | (2) Good Manufacturing Practice |

SOR/87-5, s. 1; SOR/94-689, s. 2(F); SOR/95-281, ss. 6, 7; SOR/2010-41, ss. 7(E), 9(E).

TABLE XV

FOOD ADDITIVES THAT MAY BE USED AS CARRIER OR EXTRACTION SOLVENTS

| Item No. | Column I Additive | Column II Permitted in or Upon | Column III Maximum Residue | Column IV Maximum Level of Use |
|---|---|---|---|---|
| 1. | Acetone | (1) Spice extracts; Natural extractives | (1) 30 p.p.m. | |
| | | (2) Meat and Egg Marking Inks | | (2) Good Manufacturing Practice |
| 2. | Benzyl Alcohol | (1) (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| 3. | 1,3-Butylene Glycol | (1) (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| 3.1 | Carbon Dioxide | (1) Green coffee beans and tea leaves for decaffeination purposes | | (1) Good Manufacturing Practice |
| | | (2) Spice extracts; Natural extractives; (naming the flavour) Flavour (Division 10); Hop extract in accordance with subparagraph B.02.130(*b*)(v) and paragraph B.02.133(*b*); Pre-isomerized hop extract in accordance with subparagraph B.02.134(1)(*a*)(ii) | | (2) Good Manufacturing Practice |
| | | (3) Egg Products | | (3) Good Manufacturing Practice |
| | | (4) Cocoa powder | | (4) Good Manufacturing Practice |
| 4. | Castor Oil | Oil-soluble annatto; Annatto butter colour; | | Good Manufacturing |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Residue | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | Annatto margarine colour | | Practice |
| 5. | Ethyl Acetate | (1) Spice extracts; Natural extractives; (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| | | (3) Green coffee beans for decaffeination purposes | | (3) 10 p.p.m. in both roasted and decaffeinated soluble (instant) coffee |
| | | (4) Tea leaves for decaffeination purposes | | (4) 50 p.p.m. |
| 6. | Ethyl Alcohol (Ethanol) | (1) Spice extracts; Natural extractives; (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| | | (3) Colour mixtures and preparations (Division 6) | | (3) Good Manufacturing Practice |
| | | (4) Meat and Egg Marking Inks | | (4) Good Manufacturing Practice |
| | | (5) Food additive preparations | | (5) Good Manufacturing Practice |
| | | (6) Hop extract in accordance with subparagraph B.02.130(*b*)(v) and paragraph B.02.133(*b*); Pre-isomerized hop extract in accordance with subparagraph B.02.134(1)(*a*)(iii) | | (6) Good Manufacturing Practice |
| 6.A | Ethyl alcohol denatured with | Vegetable oil seed meals | 10 p.p.m. methanol | |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Residue | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | methanol | | | |
| 7. | [Repealed, SOR/82-406, s. 1] | | | |
| 8. | Glycerol (Glycerin) | (1) (naming the flavour) Extract; (naming the flavour) Essence; (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| | | (3) Colour mixtures and preparations (Division 6) | | (3) Good Manufacturing Practice |
| | | (4) Food additive preparations | | (4) Good Manufacturing Practice |
| 9. | Glyceryl diacetate | (1) (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| 10. | Glyceryl triacetate (Triacetin) | (1) (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| 11. | Glyceryl tributyrate (Tributyrin) | (1) (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| 12. | Hexane | (1) Spice extracts; Natural extractives | (1) 25 p.p.m. | |
| | | (2) Hop extract in accordance with subparagraph B.02.130(*b*)(v) and paragraph B.02.133(*a*) | (2) 2.2% | |
| | | (3) Vegetable fats and oils | (3) 10 p.p.m. | |
| | | (4) Vegetable oil seed meals | (4) 10 p.p.m. | |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Residue | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | (5) Pre-isomerized hop extract in accordance with subparagraph B.02.134(1)(*a*)(i) and subsection B.02.134(2) | (5) 1.5 p.p.m. per percent iso-alpha acid content of the pre-isomerized hop extract | |
| 13. | Isopropyl alcohol (Isopropanol) | (1) Spice extracts; Natural extractives | (1) 50 p.p.m. | |
| | | (2) Fish protein | (2) 0.15% | |
| | | (3) (naming the flavour) Flavour (Division 10) | | (3) Good Manufacturing Practice |
| | | (4) Unstandardized flavouring preparations | | (4) Good Manufacturing Practice |
| | | (5) Meat and Egg Marking Inks | | (5) Good Manufacturing Practice |
| 14. | Methyl Alcohol (methanol) | (1) Spice extracts; Natural extractives | (1) 50 p.p.m. | |
| | | (2) Hop extract in accordance with subparagraph B.02.130(*b*)(v) and paragraph B.02.133(*a*) | (2) 2.2% | |
| | | (3) Meat and Egg Marking Inks | | (3) Good Manufacturing Practice |
| 14.1 | Methyl ethyl ketone (2-Butanone) | Spice extracts; Natural extractives | 50 p.p.m. | |
| 15. | Methylene Chloride (Dichloro-methane) | (1) Spice extracts; Natural extractives | (1) 30 p.p.m. | |
| | | (2) Hop extract in accordance with subparagraph B.02.130(*b*)(v) and paragraph B.02.133(*a*) | (2) 2.2% in hop extract | |
| | | (3) Green coffee beans and Tea leaves for decaffeination purposes | (3) 10 p.p.m. in decaffeinated roasted coffee, decaffeinated soluble (instant) coffee, | |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Residue | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | | | decaffeinated tea leaves and decaffeinated instant tea | |
| 16. | Monoglycerides and diglycerides | (1) (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Oil-soluble annatto; Annatto butter colour; Annatto margarine colour | | (2) Good Manufacturing Practice |
| | | (3) Unstandardized flavouring preparations | | (3) Good Manufacturing Practice |
| | | (4) Food additive preparations | | (4) Good Manufacturing Practice |
| 17. | Monoglyceride citrate | (1) Spice extracts; Natural extractives | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |
| 18. | 2-Nitropropane | Vegetable oils | 0.5 p.p.m. | |
| 19. | 1,2-Propylene glycol (1,2-propanediol) | (1) (naming the flavour) Extract; (naming the flavour) Essence; (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Oil-soluble annatto; Annatto butter colour; Annatto margarine colour | | (2) Good Manufacturing Practice |
| | | (3) Unstandardized flavouring preparations | | (3) Good Manufacturing Practice |
| | | (4) Colour mixtures and preparations (Division 6) | | (4) Good Manufacturing Practice |
| | | (5) Food additive preparations | | (5) Good Manufacturing Practice |
| 20. | Propylene glycol mono-esters and | Oil-soluble annatto; Annatto butter colour; | | Good Manufacturing |

| Item No. | Column I<br>Additive | Column II<br>Permitted in or Upon | Column III<br>Maximum Residue | Column IV<br>Maximum Level of Use |
|---|---|---|---|---|
| | diesters of fat-forming fatty acids | Annatto margarine colour | | Practice |
| 21. | Triethyl-citrate | (1) (naming the flavour) Flavour (Division 10) | | (1) Good Manufacturing Practice |
| | | (2) Unstandardized flavouring preparations | | (2) Good Manufacturing Practice |

SOR/78-403, ss. 26, 27; SOR/82-383, s. 12; SOR/82-406, s. 1; SOR/82-913, s. 5; SOR/82-1071, ss. 21, 22; SOR/84-541, s. 1; SOR/86-89, ss. 8, 9; SOR/86-178, ss. 4 to 7; SOR/86-1112, s. 9; SOR/90-667, s. 1; SOR/94-689, s. 2; SOR/96-259, s. 1; SOR/96-377, s. 1.

Previous Version

# Division 17

# Salt

B.17.001. (1) **[S]. Salt**, other than crude rock salt, shall be crystalline sodium chloride and may contain

(*a*) one or more of the following anti-caking agents,

(i) calcium aluminum silicate, calcium phosphate tribasic, calcium silicate, calcium stearate, magnesium carbonate, magnesium silicate, magnesium stearate, silicon dioxide and sodium aluminum silicate, the total amount not to exceed one per cent and, in the case of fine grained salt, the total amount not to exceed two per cent,

(ii) propylene glycol in an amount not exceeding 0.035 per cent, and

(iii) sodium ferrocyanide decahydrate in an amount not exceeding 13 parts per million calculated as anhydrous sodium ferrocyanide;

(*b*) not more than

(i) 1.4 per cent, singly or in combination, of calcium sulphate or potassium chloride,

(ii) 13 parts per million anhydrous sodium ferrocyanide when added as sodium ferrocyanide decahydrate in the production of dendritic crystals of salt,

(iii) 10 parts per million of polyoxyethylene (20) sorbitan monooleate when used in the production of coarse crystal salt,

(iv) 15 parts per million of sodium alginate when used in the production of coarse crystal salt, and

(v) 0.1 per cent other ingredients; and

(*c*) notwithstanding paragraphs (*a*) and (*b*), the total level of sodium ferrocyanide decahydrate, whether added as an anti-caking agent or as an adjuvant in the production of dendritic salt, shall not exceed 13 parts per million, calculated as anhydrous sodium ferrocyanide.

(2) [Repealed, SOR/97-151, s. 26]

SOR/79-662, s. 18; SOR/86-1125, s. 3; SOR/97-151, s. 26.

B.17.002. [Repealed, SOR/79-662, s. 18]

B.17.003. Notwithstanding section B.17.001, salt for table or general household use shall contain 0.01 per cent potassium iodide, with or without dextrose, sodium thiosulphate or sodium bicarbonate as a stabilizer of the iodide and the presence of iodide shall be shown on the principal display panel.

# Division 18

## Sweetening Agents

B.18.001. **[S]. Sugar**

(*a*) shall be the food chemically known as sucrose; and

(*b*) shall contain not less than 99.8 per cent sucrose.

B.18.002. **[S]. Liquid Sugar** shall be the food obtained by dissolving sugar in water.

B.18.003. **[S]. Invert Sugar** shall be the food obtained by the partial or complete hydrolysis of sugar.

B.18.004. **[S]. Liquid Invert Sugar** shall be the food consisting of a solution of invert sugar in water.

B.18.005. **[S].** No person shall sell liquid sugar or liquid invert sugar unless the label carries a statement of the percentage of sugar or invert sugar contained therein.

B.18.006. **[S]. Icing Sugar**

(*a*) shall be powdered sugar; and

(*b*) may contain

(i) food colour, and

(ii) either not more than five per cent starch or an anticaking agent.

B.18.007. **[S]. Brown Sugar, Yellow Sugar** or **Golden Sugar**

(*a*) shall be the food obtained from the syrups originating in the sugar refining process;

(*b*) may contain not more than

(i) 4.5 per cent moisture, and

(ii) 3.5 per cent sulphate ash; and

(*c*) shall not contain less than 90 per cent sugar and invert sugar.

B.18.008. **[S]. Refined Sugar Syrup, Refiners' Syrup** or **Golden Syrup**

(*a*) shall be the food made from syrup originating in the sugar refining process;

(*b*) may be hydrolyzed; and

(*c*) shall not contain more than

(i) 35 per cent moisture, and

(ii) 2.5 per cent sulphated ash.

B.18.009. **[S]. Fancy Molasses**

(*a*) shall be the syrupy food obtained by the evaporation and partial inversion of the clarified or unclarified sugar cane juice from which sugar has not been previously extracted;

(*b*) may contain sulphurous acid or its salts; and

(*c*) shall not contain more than

(i) 25 per cent moisture, and

(ii) 3 per cent sulphated ash.

B.18.010. **[S]. Table Molasses**

(*a*) shall be the liquid food obtained in the process of manufacturing raw or refined sugar;

(*b*) may contain sulphurous acid or its salts;

(*c*) shall not contain more than

(i) 25 per cent moisture, and

(ii) 3 per cent sulphated ash.

B.18.011. **[S]. Refiners' Molasses, Blackstrap Molasses** or **Cooking Molasses**

(*a*) shall be the residual liquid food obtained in the process of manufacturing raw or refined sugar;

(*b*) may contain sulphurous acid or its salts;

(*c*) shall not contain more than

(i) 25 per cent moisture, and

(ii) 12 per cent sulphated ash.

B.18.015. **[S].** (1) Dextrose Anhydrous, for the purpose of Part B of these Regulations

(*a*) shall be the food chemically known as dextrose;

(*b*) shall contain not less than 99.5 per cent D-glucose on a dry basis;

(*c*) shall contain not more than 0.25 per cent sulphated ash on a dry basis;

(*d*) shall contain not less than 98 per cent total solids; and

(*e*) may contain sulphurous acid or its salts.

(2) Dextrose Monohydrate, for the purpose of Part B of these Regulations

(*a*) shall be the food chemically known as dextrose;

(*b*) shall contain not less than 99.5 per cent D-glucose on a dry basis;

(*c*) shall contain not more than 0.25 per cent sulphated ash on a dry basis;

(*d*) shall contain not less than 90 per cent total solids; and

(*e*) may contain sulphurous acid or its salts.

SOR/84-300, s. 51.

B.18.016. **[S]. Glucose** or **Glucose Syrup**

(*a*) shall be the purified concentrated solution of nutritive saccharides obtained from the incomplete hydrolysis, by means of acid or enzymes, of starch or of a starch-containing substance;

(*b*) shall have a total solids content of not less than 70 per cent;

(*c*) shall have a sulphated ash content of not more than 1.0 per cent on a dry basis;

(*d*) shall have a reducing sugar content (dextrose equivalent) of not less than 20 per cent expressed as D-glucose on a dry basis; and

(*e*) may contain sulphurous acid or its salts.

SOR/78-402, s. 8.

B.18.017. **[S]. Glucose Solids** or **Dried Glucose Syrup**

(*a*) shall be glucose or glucose syrup from which the water has been partially removed;

(*b*) shall have a total solids content of not less than 93 per cent;

(*c*) shall have a sulphated ash content of not more than 1.0 per cent on a dry basis;

(*d*) shall have a reducing sugar content (dextrose equivalent) of not less than 20 per cent expressed as D-glucose, on a dry basis; and

(*e*) may contain sulphurous acid or its salts.

B.18.018. **[S]. (Naming the source of the glucose) Syrup**

(*a*) shall be glucose;

(*b*) may contain

(i) a sweetening agent,

(ii) a flavouring preparation,

(iii) sorbic acid,

(iv) sulphurous acid or its salts,

(v) salt, and

(vi) water; and

(*c*) shall not contain more than

(i) 35 per cent moisture; and

(ii) 3 per cent ash.

SOR/94-83, s. 1.

B.18.019. **[S]. Lactose**

(*a*) shall be the carbohydrate normally obtained from whey and may

(i) be anhydrous,

(ii) contain one molecule of water of crystalization, or

(iii) be a mixture of both subparagraphs (i) and (ii);

(*b*) shall not contain less than 99.0 per cent anhydrous lactose on a moisture free basis;

(*c*) shall not contain more than 0.3 per cent sulphated ash on a moisture free basis;

(*d*) shall have a weight loss of not more than 6.0 per cent on drying; and

(*e*) shall have, in a 10 per cent solution, a pH of not less than 4.5 and not more than 7.0.

## Honey

B.18.025. **[S]. Honey** shall be the food produced by honey bees and derived from

(*a*) the nectar of blossoms,

(*b*) secretions of living plants, or

(*c*) secretions on living plants,

and shall have

(*d*) a fluid, viscous or partly or wholly crystallized consistency;

(*e*) a diastase activity, determined after processing and blending, as represented by a diastase figure on the Gothe scale of not less than eight where the hydroxy-methyl-furfural content is not more than 0.004 per cent; or

(*f*) a diastase activity, determined after processing and blending, as represented by a diastase figure on the Gothe scale of not less than three where the hydroxy-methyl-furfural content is not more than 0.0015 per cent.

B.18.026. (1) Subject to subsection (2), honey derived mainly from nectar of blossoms shall not contain

(*a*) less than 65 per cent apparent reducing sugar, calculated as invert sugar;

(*b*) more than 20 per cent moisture;

(*c*) more than 5 per cent apparent sucrose;

(*d*) more than 0.1 per cent water insoluble solids, except that pressed honey shall contain not more than 0.5 per cent water insoluble solids;

(*e*) more than 0.6 per cent ash; and

(*f*) more than 40 milliequivalents acid per 1 000 grams.

(2) Honey derived mainly from the nectar of lavender, rubinia, alfalfa, or banksia menziesii shall meet the requirements of paragraphs (1)(*a*), (*b*) and (*d*) to (*f*) and shall contain not more than 10 per cent apparent sucrose.

B.18.027. Honey derived from secretions of living plants or from secretions on living plants shall not contain

(*a*) less than 60 per cent apparent reducing sugar, calculated as invert sugar;

(*b*) more than 20 per cent moisture;

(*c*) more than 10 per cent apparent sucrose;

(*d*) more than 0.1 per cent water insoluble solids, except that pressed honey shall contain not more than 0.5 per cent water insoluble solids;

(*e*) more than 1.0 per cent ash; and

(*f*) more than 40 milliequivalents acid per 1 000 grams.

SOR/84-300, s. 52.

# Division 19

# Vinegar

B.19.001. Vinegar shall be the liquid obtained by the acetous fermentation of an alcoholic liquid and shall contain not less than 4.1 per cent and not more than 12.3 per cent acetic acid.

SOR/92-626, s. 16; SOR/93-243, s. 2.

B.19.002. The percentage of acetic acid by volume contained in any vinegar described in Division 19 shall be shown on the principal display panel followed by the words “acetic acid”.

B.19.003. **[S]. Wine Vinegar** shall be vinegar made from wine and may contain caramel.

B.19.004. **[S]. Spirit Vinegar, Alcohol Vinegar, White Vinegar** or **Grain Vinegar** shall be vinegar made from diluted distilled alcohol.

B.19.005. **[S]. Malt Vinegar** shall be vinegar made from an infusion of malt undistilled prior to acetous fermentation, may contain other cereals or caramel, shall be dextro-rotatory, and shall contain, in 100 millilitres measured at a temperature of 20°C, not less than

(*a*) 1.8 grams of solids, and

(*b*) 0.2 gram of ash.

B.19.006. **[S]. Cider Vinegar** or **Apple Vinegar** shall be vinegar made from the liquid expressed from whole apples, apple parts or apple culls and may contain caramel.

B.19.007. **[S]. Blended Vinegar** shall be a combination of two or more varieties of vinegar of which spirit vinegar shall contribute not more than 55 per cent of the total acetic acid.

B.19.008. No person shall name any of the varieties of vinegar forming a blended vinegar unless the label of such blended vinegar carries a complete list of all the varieties of vinegar present, in descending order of proportionate content, based on acetic acid.

B.19.009. The maximum limits for the acetic acid content of a vinegar described in section B.19.001 do not apply to vinegar sold only for manufacturing use if the words “For Manufacturing Use Only” are shown on the principal display panel and upon all documents pertaining to such vinegar.

# Division 20

# Tea

B.20.001. **[S]. Tea** shall be the dried leaves and buds of *Thea sinensis* (L.) Sims prepared by the usual trade processes.

B.20.002. **[S]. Black Tea** shall be black tea or a blend of two or more black teas and shall contain, on the dry basis, not less than 30 per cent water-soluble extractive, as determined by official method FO-37, Determination of Water-Soluble Extractive in Tea, October 15, 1981, and not less than four per cent and not more than seven per cent total ash.

SOR/82-768, s. 61.

B.20.003. The provisions of B.20.002 do not apply to original unblended black tea that contains, on the dry basis, not less than 25 per cent water-soluble extractive, as determined by official method FO-37, Determination of Water-Soluble Extractive in Tea, October 15, 1981, and not less than four per cent and not more than seven per cent total ash, and is packaged according to good commercial practice in the country of origin.

SOR/82-768, s. 61.

B.20.004. **[S]. Green Tea** shall contain, on the dry basis, not less than 33 per cent water-soluble extractive, as determined by official method FO-37, Determination of Water-Soluble Extractive in Tea, October 15, 1981, and not less than four per cent and not more than seven per cent total ash.

SOR/82-768, s. 61.

B.20.005. **[S]. Decaffeinated (indicating the type of tea)**

(*a*) shall be tea of the type indicated, from which caffeine has been removed and that, as a result of the removal, contains not more than 0.4 per cent caffeine; and

(*b*) may have been decaffeinated by means of extraction solvents set out in Table XV to Division 16.

SOR/90-429, s. 2.

# Division 21

# Marine And Fresh Water Animal Products

B.21.001. The foods referred to in this Division are included in the term *marine and fresh water animal products*.

B.21.002. In this Division,

“filler” means

(*a*) flour or meal prepared from grain or potato, but not from a legume,

(*b*) processed wheat flour containing not less than the equivalent of 80 per cent dextrose, as determined by official method FO-32, Determination of Fillers, Binders and Dextrose Equivalent, October 15, 1981,

(*c*) bread, biscuit or bakery products, but not those containing or made with a legume,

(*d*) milk powder, skim milk powder, buttermilk powder or whey powder, and

(*e*) starch; (remplissage)

“Marine and fresh water animal” includes

(*a*) fish,

(*b*) crustaceans, molluscs, other marine invertebrates,

(*c*) marine mammals, and

(*d*) frogs. (animaux marine et animaux d’eau douce)

SOR/82-768, s. 62.

B.21.003. **[S].** Fish shall be the clean, dressed edible portion of fish, with or without salt or seasoning, and may

(*a*) in the case of frozen fillets, contain ascorbic acid or its sodium salt, citric acid, or erythorbic acid or its sodium salt, and

(i) sodium tripolyphosphate, sodium hexametaphosphate or a combination of sodium tripolyphosphate, sodium acid pyrophosphate and sodium pyrophosphate tetrabasic, or

(ii) a mixture of sodium hexametaphosphate and sodium carbonate;

(*b*) if frozen, have a glaze consisting of water, acetylated monoglycerides, calcium chloride, sodium alginate, sodium carboxymethyl cellulose, sodium phosphate (dibasic), corn syrup,

dextrose, glucose, glucose solids, ascorbic acid or its sodium salt or erythorbic acid or its sodium salt; and

(*c*) if frozen minced, contain sodium tripolyphosphate, sodium hexametaphosphate, ascorbic acid or its sodium salt, citric acid, erythorbic acid or its sodium salt, or a combination of sodium tripolyphosphate, sodium acid pyrophosphate and sodium pyrophosphate tetrabasic.

SOR/84-300, s. 53; SOR/88-534, s. 7; SOR/91-149, s. 4; SOR/97-562, s. 2; SOR/2000-353, s. 9(F).

B.21.004. **[S].** In this Division, meat shall be the clean, dressed flesh of crustaceans, molluscs, other marine invertebrates and marine mammals, whether minced or not, with or without salt or seasoning, and in the case of frozen lobster, frozen crab, frozen shrimp and frozen clams, may contain sodium tripolyphosphate or sodium hexametaphosphate or a combination of sodium 0hexametaphosphate and sodium carbonate or a combination of sodium tripolyphosphate, sodium acid pyrophosphate and sodium pyrophosphate tetrabasic.

SOR/88-534, s. 8; SOR/91-149, s. 5.

B.21.005. Fish, except fish protein, and meat products or preparations thereof are adulterated if any of the following substances or any substance in one of the following classes is present therein or has been added thereto:

(*a*) mucous membranes, any organ or portion of the genital system, or any organ or portion of a marine or fresh water animal that is not commonly sold as an article of food;

(*b*) preservatives, other than those provided for in this Division, except

(i) sorbic acid or its salts in dried fish that has been smoked or salted, and in cold processed smoked and salted fish paste, and

(ii) benzoic acid or its salts, methyl-*p*-hydroxy benzoate and propyl-*p*-hydroxy benzoate in marinated or similar cold-processed, packaged fish and meat products; and

(*c*) food colour except as provided for in this Division.

B.21.006. **[S].** Prepared fish or prepared meat shall be the whole or comminuted food prepared from fresh or preserved fish or meat respectively, may be canned or cooked, and may,

(*a*) in the case of lobster paste and fish roe (caviar), contain food colour;

(*b*) in the case of canned shellfish, canned spring mackerel and frozen cooked shrimp, contain citric acid or lemon juice;

(*c*) in the case of fish paste, contain filler, fish binder, monoglycerides or mono and diglycerides;

(*d*) in the case of canned salmon, tuna, lobster, crabmeat and shrimp, contain calcium disodium ethylenediaminetetraacetate (calcium disodium EDTA) and aluminum sulphate;

(*e*) in the case of canned tuna, contain ascorbic acid;

(*f*) in the case of canned seafoods, contain sodium acid pyrophosphate, sodium hexametaphosphate or sodium tripolyphosphate, singly, or in combination, at a maximum level of total added phosphate not to exceed 0.5%, calculated as sodium phosphate, dibasic;

(*g*) contain liquid smoke flavour or liquid smoke flavour concentrate;

(*h*) contain edible oil, vegetable broth and tomato sauce or puree;

(*i*) contain a gelling agent if the principal display panel carries the word “jellied” as an integral part of the common name;

(*j*) contain salt;

(*k*) in the case of canned snails, canned sea snails and canned clams, contain calcium disodium ethylenediamine tetra-acetate;

(*l*) in the case of canned flaked tuna, contain sodium sulphite;

(*m*) in the case of lumpfish caviar, contain tragacanth gum;

(*n*) in the case of a blend of prepared fish and prepared meat that has the appearance and taste of the flesh of a marine or freshwater animal, contain filler, fish binder, whole egg, egg-white, egg-yolk, food colour, gelling or stabilizing agents, texture-modifying agents, natural and artificial flavouring preparations, pH-adjusting agents, sweetener and, in a proportion not exceeding two per cent of the blend, a legume;

(*o*) in the case of crustaceans, contain potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium dithionite, sodium metabisulphite, sodium sulphite or sulphurous acid;

(*p*) in the case of frozen crustaceans and molluscs, contain calcium oxide and sodium hydroxide;

(*q*) in the case of frozen pre-cooked battered or breaded fish products, contain citric acid at a level of use not exceeding 0.1 per cent;

(*r*) in the case of canned clams, contain sodium erythorbate at a level of use not exceeding 350 parts per million; and

(*s*) in the case of comminuted products, other than lumpfish caviar, contain tragacanth gum at a level of use not exceeding 0.75 per cent.

SOR/80-13, s. 9; SOR/81-60, s. 12; SOR/84-602, s. 4; SOR/86-1020, s. 2; SOR/89-197, s. 2; SOR/92-344, s. 6; SOR/93-276, s. 13; SOR/94-141, s. 2; SOR/94-567, s. 3; SOR/94-689, s. 2(E); SOR/97-151, s. 27; SOR/97-562, s. 3; SOR/2005-316, s. 12; SOR/2007-76, s. 4.

Previous Version

B.21.007. **[S]. Fish binder** for use in or upon prepared fish or prepared meat shall be filler with any combination of salt, sugar, dextrose, glucose, spices and other seasonings.

B.21.008. No person shall sell filler or a fish binder represented for use in fish products either by label or in any advertisement unless the label carries adequate directions for use in accordance with the limits provided in section B.21.020.

B.21.009. Powdered hydrogenated cottonseed oil in an amount not greater than 0.25 per cent of the product may be applied as a release agent to the surface of marine and fresh water animal products.

SOR/2010-142, s. 59(F).

Previous Version

## Prepared Fish

B.21.020. No person shall sell prepared fish or prepared meat that contains more than

(*a*) that amount of filler, fish binder or other ingredients that is represented by four per cent reducing sugars, calculated as dextrose, as determined by official method FO-32, Determination of Fillers, Binders and Dextrose Equivalent, October 15, 1981; and

(*b*) 70 per cent moisture where such prepared fish contains filler.

SOR/82-768, s. 63.

B.21.021. **[S].** Preserved fish or preserved meat shall be cooked or uncooked fish or meat that is dried, salted, pickled, cured or smoked and may contain Class I Preservatives, dextrose, glucose, spices, sugar and vinegar, and

(*a*) dried fish that has been smoked or salted, and cold-processed smoked and salted fish paste may contain sorbic acid or its salts;

(*b*) smoked fish may contain food colour;

(*c*) packaged fish and meat products that are marinated or otherwise cold-processed may contain saunderswood (sandalwood), benzoic acid or its salts, methyl-*p*-hydroxy benzoate and propyl-*p*-hydroxy benzoate;

(*d*) salted anchovy, salted scad and salted shrimp may contain erythrosine in such amount as will result in the finished product containing not more than 125 parts per million of erythrosine; and

(*e*) comminuted products may contain tragacanth gum at a level of use not exceeding 0.75 per cent.

SOR/95-493, s. 2; SOR/97-562, s. 4(F); SOR/2007-76, s. 5.

Previous Version

B.21.022. and B.21.023. [Repealed, SOR/79-252, s. 4]

B.21.024. Notwithstanding section B.21.020 lobster paste shall not contain more than two per cent filler or fish binder.

B.21.025. No person shall sell marine and fresh water animals, or marine and fresh water animal products, that are packed in a container that has been sealed to exclude air and that are smoked or to which liquid smoke flavour or liquid smoke flavour concentrate has been added, unless

(*a*) the container has been heat-processed after sealing at a temperature and for a time sufficient to destroy all spores of the species *Clostridium botulinum*;

(*b*) the contents of the container contain not less than nine per cent salt, as determined by official method FO-38, Determination of Salt in Smoked Fish, dated March 15, 1985;

(*c*) the contents of the container are customarily cooked before eating; or

(*d*) the contents of the container are frozen and the principal display panel of the label of the container carries the statement “Keep Frozen Prior to Use” in the same size type used for the common name of the contents of the container.

SOR/80-13, s. 10; SOR/82-566, s. 5; SOR/82-768, s. 64; SOR/89-198, s. 17; SOR/94-567, s. 4.

B.21.027. **[S]. Fish Protein**

(*a*) shall be the food prepared by

(i) extracting water, fat and other soluble components through the use of isopropyl alcohol from fresh whole edible fish of the order Clupeiformes, families Clupeidae and Osmeridae and the order Gadiformes, family Gadidae, or from trimmings resulting from the filleting of such fish when eviscerated, and

(ii) drying and grinding the protein concentrate resulting from the operation described in subparagraph (i);

(*b*) may contain a pH adjusting agent; and

(*c*) shall not contain

(i) less than 75 per cent protein, which protein shall be at least equivalent to casein in protein quality, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981.

(ii) and (iii) [Repealed, SOR/97-148, s. 8]

SOR/82-768, s. 65; SOR/97-148, s. 8.

### Froglegs

B.21.031. No person shall sell fresh or frozen froglegs unless they are free from bacteria of the genus *Salmonella*, as determined by official method MFO-10, Microbiological Examination of Froglegs, November 30, 1981.

SOR/82-768, s. 66.

# Division 22

# Poultry, Poultry Meat, Their Preparations And Products

B.22.001. **[S].** Poultry shall be any bird that is commonly used as food.

B.22.002. **[S].** Poultry meat shall be the clean, dressed flesh including the heart and gizzard of eviscerated poultry that is healthy at the time of slaughter.

SOR/80-13, s. 11.

B.22.003. **[S].** Poultry meat by-product shall be the clean parts of poultry other than poultry meat commonly used as food and includes liver and skin but excludes the oesophagus, feet and head.

SOR/80-13, s. 12.

B.22.004. **[S].** Giblets shall be the heart, liver and gizzard of poultry.

B.22.005. Poultry meat, poultry meat by-products or preparations thereof are adultered if any of the following substances or any substance in the following classes is present therein or has been added thereto:

(*a*) any organ or portion of poultry that is not commonly sold as food;

(*b*) preservatives, other than those provided for in this Division; and

(*c*) colour, other than caramel.

B.22.006. **[S]. Prepared poultry meat** or a **prepared poultry meat by-product** shall be any poultry meat or any poultry meat by-product, respectively, whether comminuted or not, to which has been added any ingredient permitted by these Regulations or that has been preserved, placed in a hermetically-sealed container or cooked, and may contain

(*a*) where a minimum total protein content or minimum meat protein requirement is prescribed in this Division, phosphate salts that do not when calculated as sodium phosphate, dibasic, exceed the maximum level provided therefor in Table XII to section B.16.100 and that are one or more of the following phosphate salts, namely,

(i) sodium acid pyrophosphate,

(ii) sodium hexametaphosphate,

(iii) sodium phosphate, dibasic,

(iv) sodium phosphate, monobasic,

(v) sodium pyrophosphate, tetrabasic,

(vi) sodium tripolyphosphate,

(vii) potassium phosphate, monobasic,

(viii) potassium phosphate, dibasic, and

(ix) potassium pyrophosphate, tetrabasic;

(*b*) in the case of dried, cooked poultry meat, a Class IV preservative; and

(*c*) in the case of vacuum-packed sliced cooked turkey, *Carnobacterium maltaromaticum* CB1.

SOR/81-934, s. 16; SOR/94-262, s. 13; SOR/2010-264, s. 5.

Previous Version

B.22.008. In this Division, “filler” means any vegetable material (except tomato or beetroot), milk, egg, yeast, or any derivative or combination thereof that is acceptable as food.

SOR/82-768, s. 67; SOR/84-300, s. 54(E); SOR/86-875, s. 6.

B.22.009. No person shall sell

(*a*) any poultry intended for consumption as food if any preparation having oestrogenic activity has been administered to the poultry; or

(*b*) poultry meat or poultry meat by-product that contains any residues of exogenous oestrogenic substances.

SOR/87-626, s. 2.

B.22.010. Powdered hydrogenated cottonseed oil in an amount not greater than 0.25 per cent of the product may be applied as a release agent to the surface of poultry meat, poultry meat by-product, prepared poultry meat, prepared poultry meat by-product, extended poultry product and simulated poultry product.

SOR/2010-142, s. 59(F).

Previous Version

B.22.011. **[S]. Solid cut poultry meat** shall be

(*a*) a whole cut of poultry meat; or

(*b*) a product consisting of pieces of poultry meat of which at least 80 per cent weigh at least 25 g each.

SOR/94-262, s. 14.

B.22.012. (1) No person shall sell solid cut poultry meat to which phosphate salts or water has been added unless

(*a*) that meat

(i) where cooked, contains a meat protein content of not less than 12 per cent, and

(ii) where uncooked, contains a meat protein content of not less than 10 per cent; and

(*b*) that meat contains, phosphate salts that do not when calculated as sodium phosphate, dibasic, exceed the maximum level provided therefor in Table XII to section B.16.100 and that are one or more of the following phosphate salts, namely,

(i) sodium acid pyrophosphate,

(ii) sodium hexametaphosphate,

(iii) sodium phosphate, dibasic,

(iv) sodium phosphate, monobasic,

(v) sodium pyrophosphate, tetrabasic,

(vi) sodium tripolyphosphate,

(vii) potassium phosphate, monobasic,

(viii) potassium phosphate, dibasic, and

(ix) potassium pyrophosphate, tetrabasic.

(2) A bone or a visible fat layer shall not be included in any calculation used to determine meat protein content for the purposes of paragraph (1)(*a*).

SOR/94-262, s. 14.

B.22.013. No person shall sell the whole or any part of a dressed poultry carcass that has been placed in a chilling tank containing fluids to which phosphate salts have been added.

SOR/94-262, s. 14.

## Poultry Meat Stews

B.22.016. For the purposes of sections B.22.017 to B.22.019, “stew poultry meat” means cooked or uncooked poultry meat containing not more than 15 per cent fat, calculated on the weight of uncooked stew poultry meat.

SOR/78-874, s. 3.

B.22.017. **[S]. Vegetable Stew with (naming the poultry meat)**

(*a*) shall contain vegetables and the named poultry meat in the following amounts:

(i) if uncooked, 12 per cent or more of the named stew poultry meat,

(ii) if cooked, 6 per cent or more of the named stew poultry meat,

(iii) 38 per cent or more vegetables; and

(*b*) may contain gravy, salt, seasoning and spices.

SOR/78-874, s. 3.

B.22.018. **[S]. (naming the poultry meat) Stew**

(*a*) shall contain vegetables and the named poultry meat in the following amounts:

(i) if uncooked, 20 per cent or more of the named stew poultry meat,

(ii) if cooked, 10 per cent or more of the named stew poultry meat,

(iii) 30 per cent or more vegetables; and

(*b*) may contain gravy, salt, seasoning and spices.

SOR/78-874, s. 3.

B.22.019. **[S].** Specialty Poultry Meat Stew

(*a*) shall contain poultry meat and vegetables in the following amounts:

(i) if uncooked, 25 per cent or more of stew poultry meat,

(ii) if cooked, 15 per cent or more of stew poultry meat,

(iii) 30 per cent or more vegetables; and

(*b*) may contain gravy, salt, seasoning and spices.

SOR/78-874, s. 3.

## Prepared Poultry Meats, Prepared Poultry Meat By-Products

B.22.020. [Repealed, SOR/86-875, s. 7]

B.22.021. **[S].** Preserved poultry meat or poultry meat by-product shall be cooked or uncooked poultry meat or poultry meat by-product that is cured or smoked and may contain

(*a*) Class 1 preservatives;

(*b*) liquid smoke flavour, liquid smoke flavour concentrate or spices;

(*c*) sweetening agents;

(*d*) vinegar;

(*e*) in the case of cured poultry or poultry meat prepared by means of injection or cover solution, disodium phosphate, monosodium phosphate, sodium hexametaphosphate, sodium tripolyphosphate, tetrasodium pyrophosphate and sodium acid pyrophosphate, in such amount calculated as disodium phosphate, as will result in the finished product containing not more than 0.5 per cent added phosphate; and

(*f*) in the case of vacuum-packed sliced cooked turkey, *Carnobacterium maltaromaticum* CB1.

SOR/80-13, s. 13; SOR/82-596, s. 10; SOR/94-567, s. 5; SOR/2010-264, s. 6.

Previous Version

B.22.022. **[S].** Canned (naming the poultry) shall be prepared from poultry meat and may contain

(*a*) those bones or pieces of bones attached to the portion of the poultry meat that is being canned;

(*b*) broth;

(*c*) salt;

(*d*) seasoning;

(*e*) gelling agents; and

(*f*) small amounts of fat.

SOR/84-300, s. 55.

B.22.023. **[S].** Broth that is used in canned (naming the poultry) shall be the liquid in which the poultry meat has been cooked.

B.22.024. Where a gelling agent has been added to canned poultry, a statement to the effect that a gelling agent has been added shall be shown on the principal display panel or the word “jellied” shall be shown as an integral part of the common name of the food.

B.22.025. **[S].** Boneless (naming the poultry) shall be canned poultry meat from which the bones and skin have been removed, shall contain not less than 50 per cent of the named poultry meat, as determined by official method FO-39, Determination of Meat in Boneless Poultry, October 15, 1981, and may contain broth having a specific gravity of not less than 1.000 at a temperature of 50°C.

SOR/82-768, s. 69.

B.22.026. No person shall sell poultry, poultry meat or poultry meat by-product that has been barbecued, roasted or broiled and is ready for consumption unless the cooked poultry, poultry meat or poultry meat by-product

(*a*) at all times

(i) has a temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher, or

(ii) has been stored at an ambient temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher; and

(*b*) carries on the principal display panel of the label a statement to the effect that the food must be stored at a temperature of 40°F (4.4°C) or lower, or 140°F (60°C) or higher.

SOR/78-403, s. 28(F); SOR/88-336, s. 3.

## Poultry Product Extender

B.22.027. No person shall sell a poultry product extender unless that extender

(*a*) has, in the rehydrated state,

(i) a total protein content of not less than 16 per cent; and

(ii) a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*b*) has, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to Division 14 in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively; and

(*c*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 70.

## Extended Poultry Products

B.22.028. No person shall sell a food that consists of a mixture of poultry product and poultry product extender, unless that food

(*a*) has a total protein content of not less than 16 per cent, and

(*b*) has a protein rating of not less than 40, as determined by official method, and unless

the poultry product extender meets the requirements of paragraphs B.22.027(*a*) to (*c*).

## Simulated Poultry Products

B.22.029. No person shall sell a simulated poultry product unless that product

(*a*) has a total protein content of not less than 16 per cent;

(*b*) has a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*c*) has a fat content of not more than 15 per cent;

(*d*) contains, notwithstanding sections D.01.009 and D.02.009, each vitamin and mineral nutrient listed in Column I of the Table to Division 14 in an amount not less than the amount shown in Column II of that Table opposite each such vitamin and mineral nutrient respectively; and

(*e*) where isolated essential amino acids have been added, contains those acids in an amount not exceeding an amount that improves the nutritional quality of the protein.

SOR/82-768, s. 71.

## Egg Products

B.22.032. No person shall sell any product simulating whole egg unless that product

(*a*) is made from liquid, dried or frozen egg albumen or mixtures thereof;

(*b*) has a protein rating of not less than 40, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981;

(*c*) notwithstanding sections D.01.009 and D.02.009, contains, per 100 grams on a ready-to-use basis,

(i) not less than

(A) 50 milligrams calcium,

(B) 2.3 milligrams iron,

(C) 1.5 milligrams zinc,

(D) 130 milligrams potassium,

(E) 1000 International Units Vitamin A,

(F) 0.10 milligram thiamine,

(G) 0.30 milligram riboflavin,

(H) 3.60 milligrams niacin,

(I) 1.60 milligrams pantothenic acid,

(J) 0.20 milligram Vitamin $B_{6'}$,

(K) 0.50 microgram Vitamin $B_{12'}$,

(L) 0.02 milligram folic acid, and

(M) 2.0 International Units alpha tocopherol, and

(ii) not more than 3 milligrams cholesterol;

(*d*) has a calcium to phosphorous ratio of not less than one part calcium to four parts phosphorous; and

(*e*) contains in the total fat of any fat or oil used not less than 40 per cent cis-cis methylene interrupted polyunsaturated fatty acids and not more than 20 per cent saturated fatty acids.

SOR/82-768, s. 72; SOR/84-300, s. 56.

B.22.033. No person shall sell any egg product referred to in sections B.22.032, B.22.034, B.22.035, B.22.036 and B.22.037 for use as food unless it is free from bacteria of the genus *Salmonella*, as determined by official method MFO-6, Microbiological Examination of Egg Products and Liquid Eggs, November 30, 1981.

SOR/82-768, s. 73.

B.22.034. **[S]. Liquid Whole Egg, Dried Whole Egg** or **Frozen Whole Egg**

(*a*) shall be the product obtained by removing the shell from wholesome fresh eggs or wholesome stored eggs, and

(i) in the case of dried whole egg, drying the product, or

(ii) in the case of frozen whole egg, freezing the product; and

(*b*) may

(i) contain aluminum sulphate, pH adjusting agents and the colour beta carotene,

(ii) in the case of liquid whole egg destined for drying, contain yeast autolysate and may be treated with hydrogen peroxide and catalase, glucose oxidase and catalase or yeast and suitable glucose fermenting bacterial culture, or

(iii) in the case of dried whole egg, contain anti-caking agents.

B.22.035. **[S]. Liquid Yolk, Dried Yolk** or **Frozen Yolk**

(*a*) shall be the product obtained by removing the shell and egg-white from wholesome fresh eggs or wholesome stored eggs, and

(i) in the case of dried yolk, drying the product, or

(ii) in the case of frozen yolk, freezing the product, and

(*b*) may

(i) contain aluminum sulphate, pH adjusting agents and the colour beta carotene,

(ii) in the case of liquid yolk destined for drying, contain yeast autolysate and may be treated with hydrogen peroxide and catalase, glucose oxidase and catalase or yeast and suitable glucose fermenting bacterial culture, or

(iii) in the case of dried yolk, contain anti-caking agents.

B.22.036. **[S]. Liquid Egg-White, (Liquid Albumen), Dried Egg-White, (Dried Albumen)** or **Frozen Egg-White (Frozen Albumen)**

(*a*) shall be the product obtained by removing the shell and yolk from wholesome fresh eggs or wholesome stored eggs, and

(i) in the case of dried egg-white, drying the product, or

(ii) in the case of frozen egg-white, freezing the product; and

(*b*) may

(i) contain whipping agents, aluminum sulphate and pH adjusting agents,

(ii) in the case of liquid egg-white destined for drying, contain yeast autolysate and may be treated with hydrogen peroxide and catalase, glucose oxidase and catalase or yeast and suitable glucose fermenting bacterial culture,

(iii) in the case of liquid egg-white and dried egg-white, contain lipase or pancreatin, or

(iv) in the case of dried egg-white, contain anti-caking agents.

B.22.037. **[S]. Liquid Whole Egg Mix, Dried Whole Egg Mix, Frozen Whole Egg Mix, Liquid Yolk Mix, Dried Yolk Mix** or **Frozen Yolk Mix**

(*a*) shall be the product obtained by adding salt, sweetening agent or both to Liquid Whole Egg, Dried Whole Egg, Frozen Whole Egg, Liquid Yolk, Dried Yolk or Frozen Yolk; and

(*b*) may, in the case of dried whole egg mix or dried yolk mix, contain anti-caking agents.

B.22.038. (1) No person shall use a common name referred to in sections B.22.034 to B.22.037 for an egg product that has been subjected to a process, other than a process referred to in those sections, if that process results in a decrease in the amount of a vitamin or mineral nutrient that before processing was present in 100 g of the egg product in an amount equal to at least 10 per cent of the weighted recommended nutrient intake, unless the amount of the vitamin or mineral nutrient is restored to the amount that was present before processing.

(2) Notwithstanding sections D.01.009, D.01.011 and D.02.009, a person may add any vitamin or mineral nutrient referred to in column II of item 27 of the table to section D.03.002 to any egg product referred to in sections B.22.034 to B.22.037 to restore the vitamin or mineral nutrient to the amount that was present in the egg product before processing.

(3) In this section, “weighted recommended nutrient intake” has the same meaning as in subsection D.01.001(1).

SOR/96-259, s. 2.

# Division 23

# Food Packaging Materials

B.23.001. No person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food.

B.23.002. Subject to section B.23.003 no person shall sell any food in a package that has been manufactured from a polyvinyl chloride formulation containing an octyltin chemical.

B.23.003. A person may sell food, other than milk, skim milk, partly skimmed milk, sterilized milk, malt beverages and carbonated non-alcoholic beverage products, in a package that has been manufactured from a polyvinyl chloride formulation containing any or all of the octyltin chemicals, namely, di(*n*-octyl)tin S,S′-bis(isooctylmercaptoacetate), di(*n*-octyl)tin maleate polymer and (*n*-octyl)tin S,S′,S″-tris(isooctylmercaptoacetate) if the proportion of such chemicals, either singly or in combination, does not exceed a total of three per cent of the resin, and the food in contact with the package contains not more than one part per million total octyltin.

SOR/81-60, s. 13; SOR/86-1125, s. 4.

B.23.004. (1) Di (*n*-octyl)tin S,S′-bis (isooctylmercaptoacetate) shall be the octyltin chemical made from di (*n*-octyl)tin dichloride and shall contain 15.1 to 16.4 per cent of tin and 8.1 to 8.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, di (*n*-octyl)tin dichloride shall be the chemical having an organotin composition of not less than 95 per cent di (*n*-octyl)tin dichloride and shall contain no more than

(*a*) five per cent total of *n*-octyltin trichloride or tri(*n*-octyl)tin chloride or both;

(*b*) 0.2 per cent total of other eight (8) carbon isomeric alkyltin derivatives; and

(*c*) 0.1 per cent total of the higher and lower homologous alkyltin derivatives.

SOR/86-1125, s. 5.

B.23.005. Di(*n*-octyl)tin maleate polymer shall be the octyltin chemical made from di(*n*-octyl)tin dichloride and shall have the formula $((C_8H_{17})_2\ SnC_4H_2O_4)n$ (where *n* is between 2 and 4 inclusive), and a saponification number of 225 to 255, and shall contain 25.2 to 26.6 per cent of tin.

SOR/86-1125, s. 6(F).

B.23.006. (1) (*n*-octyl)tin S,S′,S″-tris (isooctylmercaptoacetate), being an octyltin chemical having the formula $n\text{-}C_8H_{17}Sn(SCH_2CO_2C_8H_{17})_3$, shall be made from (*n*-octyl)tin trichloride and shall contain 13.4 to 14.8 per cent of tin and 10.9 to 11.9 per cent of mercapto sulfur.

(2) For the purposes of this Division, (*n*-octyl)tin trichloride shall be the chemical having an organotin composition of not less than 95 per cent (*n*-octyl)tin trichloride and shall contain not more than

(*a*) five per cent total of di(*n*-octyl)tin dichloride, tri(*n*-octyl)tin chloride or the higher (more than eight (8) carbons) alkyltin chlorides or any combination of the foregoing;

(*b*) 0.2 per cent total of alkyltin derivatives; and

(*c*) 0.1 per cent of the lower (less than eight carbons) homologous alkyltin derivatives.

SOR/86-1125, s. 7.

B.23.007. No person shall sell a food in a package than may yield to its contents any amount of vinyl chloride, as determined by official method, FO-40, Determination of Vinyl Chloride in Food, October 15, 1981, in respect of that food.

SOR/82-768, s. 74.

B.23.008. No person shall sell a food in a package that may yield to its contents any amount of acrylonitrile as determined by official method FO-41, Determination of Acrylonitrile in Food, February 16, 1982, in respect of that food.

SOR/82-541, s. 1.

# Division 24

## Foods for Special Dietary Use

B.24.001. In this Division,

“expiration date” means, in respect of a formulated liquid diet, a food represented for use in a very low-energy diet, a meal replacement or a nutritional supplement, the date

(*a*) after which the manufacturer does not recommend that it be consumed, and

(*b*) up to which it maintains its microbiological and physical stability and the nutrient content declared on the label; (date limite d’utilisation)

“food for special dietary use” means food that has been specially processed or formulated to meet the particular requirements of a person

(*a*) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or

(*b*) for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods; (aliment à usage diététique spécial)

“formulated liquid diet” means a food that

(*a*) is sold for consumption in liquid form, and

(*b*) is sold or represented as a nutritionally complete diet for oral or tube feeding of a person described in paragraph (*a*) of the definition “food for special dietary use”; (préparation pour régime liquide)

“hospital” means a facility

(*a*) that is licensed, approved or designated as a hospital by a province, in accordance with the laws of the province, to provide care or treatment to persons suffering from any form of disease or illness, or

(*b*) that is owned or operated by the government of Canada or of a province and that provides health services; (hôpital)

“major change” means, in respect of a food that is represented for use in a very low energy diet, any change in any of the following, where the manufacturer’s experience or generally

accepted theory would predict an adverse effect on the levels or availability of nutrients in, the microbiological or chemical safety of or the safe use of the food:

(*a*) an ingredient or the amount of an ingredient in the food,

(*b*) the manufacturing process or the packaging of the food, or

(*c*) the directions for the preparation and use of the food; (changement majeur)

“meal replacement”[Repealed, SOR/95-474, s. 3]

“pharmacist” means a person who is registered and entitled under the laws of a province to practise pharmacy and who is practising pharmacy under those laws in that province; (pharmacien)

“physician” means a person who is registered and entitled under the laws of a province to practise medicine and who is practicing medicine under those laws in that province; (médecin)

“prepackaged meal”[Repealed, SOR/95-474, s. 3]

“target body weight” means the anticipated body weight at the end of the weight reduction diet, as determined by the physician before the weight reduction diet begins; (poids corporel cible)

“very low energy diet” means a diet for weight reduction that provides less than 900 kilocalories per day when followed as directed. (régime à très faible teneur en énergie)

SOR/78-64, s. 1; SOR/78-698, s. 4; SOR/94-35, s. 1; SOR/95-474, s. 3.

B.24.003. (1) No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a food for special dietary use unless the food is

(*a*) to (*e*) [Repealed, SOR/2003-11, s. 21]

(*f*) a formulated liquid diet that meets the requirements contained in sections B.24.101 and B.24.102;

(*f.1*) a meal replacement for special dietary use that meets the requirements contained in section B.24.200;

(*f.2*) a nutritional supplement that meets the requirements contained in section B.24.201;

(*g*) a gluten-free food that meets the requirements contained in section B.24.018;

(*h*) represented for protein-restricted diets;

(*i*) represented for low (naming the amino acid) diets; or

(*j*) a food represented for use in a very low energy diet, where the food meets the requirements contained in section B.24.303.

(1.1) Despite subsection (1), a person may label, package, sell or advertise a food in a manner likely to create an impression that it is a food for special dietary use if its label carries a statement or claim set out in column 4 of the table following section B.01.513, in accordance with section B.01.503, in respect of any of the following subjects set out in column 1:

(*a*) “free of energy”, set out in item 1;

(*b*) “low in energy”, set out in item 2;

(*c*) “free of sodium or salt”, set out in item 31;

(*d*) “low in sodium or salt”, set out in item 32; or

(*e*) “free of sugars”, set out in item 37.

(2) Subsection (1) does not apply to infant formulas.

(3) No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is for use in a weight reduction diet unless that food is

(*a*) a meal replacement that meets the compositional requirements contained in section B.24.200;

(*b*) a prepackaged meal;

(*c*) a food sold by a weight reduction clinic to clients of the clinic for use in a weight reduction program supervised by the staff of the clinic; or

(*d*) a food represented for use in a very low-energy diet that meets the compositional requirements contained in section B.24.303.

(4) Except as otherwise permitted by these Regulations, no person shall label, package, sell or advertise a food as “dietetic” or “diet”, or use those words as part of the brand name of the food, unless its label carries a statement or claim set out in column 4 of the table following section B.01.513, in accordance with section B.01.503, in respect of any of the following subjects set out in column 1:

(*a*) “free of energy”, set out in item 1;

(*b*) “low in energy”, set out in item 2;

(*c*) “reduced in energy”, set out in item 3;

(*d*) “lower in energy”, set out in item 4; or

(*e*) “free of sugars”, set out in item 37.

SOR/78-64, s. 2; SOR/78-698, s. 5; SOR/84-334, s. 1; SOR/86-178, s. 8(E); SOR/94-35, s. 2; SOR/95-444, s. 1; SOR/95-474, s. 4; SOR/2003-11, s. 21.

B.24.004. to B.24.014. [Repealed, SOR/2003-11, s. 22]

B.24.015. and B.24.016. [Repealed, SOR/88-559, s. 6]

B.24.017. (1) Where the manufacturer of a formulated liquid diet, a meal replacement or a food represented for use in a very low energy diet is requested in writing by the Director to submit, on or before a specified day, evidence with respect to that product, the manufacturer shall make no further sales of that product after that day unless the manufacturer has submitted the evidence requested.

(2) Where the Director is of the opinion that the evidence submitted by a manufacturer pursuant to subsection (1) is not sufficient, he shall so notify the manufacturer in writing.

(3) Where, pursuant to subsection (2), a manufacturer is notified that the evidence with respect to a formulated liquid diet, a meal replacement or a food represented for use in a very low energy diet is not sufficient, the manufacturer shall make no further sales of that product unless the manufacturer submits further evidence and is notified in writing by the Director that the further evidence is sufficient.

(4) A reference in this section to evidence with respect to a formulated liquid diet, a meal replacement or a food represented for use in a very low energy diet means evidence to establish that the food is nutritionally adequate to be used as the sole source of nutrition in meeting the nutritional needs of a person for whom it is intended, when the food is consumed in accordance with the directions for use.

SOR/78-698, s. 6; SOR/94-35, s. 3.

B.24.018. No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye or triticale or any part thereof.

SOR/95-444, s. 2.

B.24.019. [Repealed, SOR/2003-11, s. 23]

## Formulated Liquid Diets

B.24.100. No person shall advertise a formulated liquid diet to the general public.

SOR/78-64, s. 7; SOR/78-698, s. 7.

B.24.101. No person shall sell a formulated liquid diet unless the food

(*a*) if sold ready to serve, or

(*b*) if not sold ready to serve, when diluted with water, milk, or water and milk,

is a complete substitute for the total diet in meeting the nutritional requirements of a person.

SOR/78-64, s. 7.

B.24.102. (1) Subject to subsection (4), a formulated liquid diet shall contain, when ready to serve,

(*a*) either

(i) not less than 20 grams of protein of nutritional quality equivalent to casein, as determined by official method FO-1, Determination of Protein Rating, October 15, 1981, or

(ii) such an amount and quality of protein, including those proteins to which amino acids are added, that, when the quality of the protein is expressed as a fraction of the quality of casein,

(A) the fraction will not be less than 85/100, and

(B) the result obtained by multiplying the fraction by the gram weight of the protein will not be less than 20; and

(*b*) not less than one gram linoleic acid in the form of a glyceride.

(2) Notwithstanding sections D.01.009, D.01.011 and D.02.009, a formulated liquid diet shall contain, when ready to serve, the vitamins and minerals named in Column I of the table to this section in amounts,

(*a*) where the recommended intake of the food is 2,500 kilocalories per day or less, not less than the amounts set out in Column II and not more than the amounts, if any, set out in Column III of that table opposite those vitamins and minerals; and

(*b*) where the recommended intake of the food is greater than 2,500 kilocalories per day, not less than the amounts set out in Column IV and not more than the amounts, if any, set out in Column V of the table opposite those vitamins and minerals.

(3) The amounts of the nutrients specified in paragraphs (1)(*a*) and (*b*) and subsection (2) shall be calculated

(*a*) per 1,000 available kilocalories, where the recommended intake of the food is 2,500 kilocalories per day or less; and

(*b*) per 1,500 available kilocalories, where recommended intake of the food is greater than 2,500 kilocalories per day.

(4) Paragraph (1)(*a*) does not apply to a formulated liquid diet represented as being for a protein restricted diet or a low (named amino acid) diet.

TABLE

| | Per 1,000 available kilocalories | | Per 1,500 available kilocalories | |
|---|---|---|---|---|
| Column I | Column II | Column III | Column IV | Column V |
| *Vitamins* | *Minimum* | *Maximum* | *Minimum* | *Maximum* |
| Vitamin A | 2,000 International Units | 5,000 International Units | 2,000 International Units | 3,000 International Units |
| Vitamin D | 100 International Units | 400 International Units | 100 International Units | 200 International Units |
| Vitamin E (*a*-tocopherol) | 5.0 International Units | | 5.0 International Units | |
| Ascorbic Acid | 20 milligrams | | 20 milligrams | |
| Thiamine | 0.5 milligram | | 0.6 milligram | |
| Riboflavin | 0.7 milligram | | 0.84 milligram | |
| Niacin | 6.6 milligrams | | 7.9 milligrams | |
| Vitamin $B_6$ | 0.9 milligram | | 0.9 milligram | |
| Vitamin $B_{12}$ | 1.5 micrograms | | 1.5 micrograms | |
| Folic Acid | 100 micrograms | | 100 micrograms | |
| d-pantothenic Acid | 2.5 milligrams | | 2.5 milligrams | |
| *Mineral Nutrients* | | | | |
| Calcium | 400 milligrams | | 400 milligrams | |

| | Per 1,000 available kilocalories | | Per 1,500 available kilocalories | |
|---|---|---|---|---|
| Column I | Column II | Column III | Column IV | Column V |
| *Vitamins* | *Minimum* | *Maximum* | *Minimum* | *Maximum* |
| Phosphorus | 400 milligrams | | 400 milligrams | |
| Iron | 8 milligrams | | 8 milligrams | |
| Iodine | 50 micrograms | | 50 micrograms | |
| Magnesium | 150 milligrams | | 150 milligrams | |
| Copper | 1 milligram | | 1 milligram | |
| Zinc | 7 milligrams | | 7 milligrams | |

SOR/78-64, s. 7; SOR/78-698, s. 8; SOR/82-768, s. 75; SOR/87-640, s. 9(F); SOR/90-830, s. 6(F).

B.24.103. The label of a formulated liquid diet shall carry the following information:

(*a*) a statement that the food is intended to be consumed orally or by tube feeding;

(*b*) a statement of the energy value of the food, expressed in Calories

(i) per 100 grams or per 100 millilitres of the food as offered for sale, and

(ii) per unit of ready-to-serve food;

(*c*) a statement of the content in the food of protein or protein equivalent, fat, linoleic acid, available carbohydrate and, where present, crude fibre, expressed in grams

(i) per 100 grams or per 100 millilitres of the food as offered for sale, and

(ii) per unit of ready-to-serve food;

(*d*) a statement of the content of vitamins and mineral nutrients that are listed in the table to section B.24.102, expressed in International Units or milligrams

(i) per 100 grams or per 100 millilitres of the food as offered for sale, and

(ii) per unit of ready-to-serve food;

(*e*) a statement of the content of any vitamin or mineral nutrient that is not listed in the table to section B.24.102, expressed in milligrams

(i) per 100 grams or per 100 millilitres of the food as offered for sale, and

(ii) per unit of ready-to-serve food;

(*f*) complete directions for the preparation and use of the food and for its storage after the container has been opened; and

(*g*) the expiration date of the formulated liquid diet.

SOR/78-64, s. 7; SOR/88-559, s. 27.

## Meal Replacements, Nutritional Supplements, Prepackaged Meals and Foods Sold by Weight Reduction Clinics

B.24.200. (1) No person shall sell or advertise a meal replacement unless, when in a ready-to-serve form or when prepared according to directions for use, with water, milk, partially skim milk or skim milk, or a combination thereof, it meets the following requirements:

(*a*) the meal replacement provides a minimum of 225 kcal or 945 kJ per serving;

(*b*) not less than 15 per cent and not more than 40 per cent of the energy available from the meal replacement is derived from its protein content, except that a meal replacement for use in a weight reduction diet shall derive not less than 20 per cent of its available energy from its protein content;

(*c*) subject to subsection (2), not more than 35 per cent of the energy available from the meal replacement is derived from its fat content;

(*d*) not less than 3.0 per cent of the energy available from the meal replacement is derived from linoleic acid in the form of a glyceride and not less than 0.5 per cent of the energy available from the meal replacement is derived from n-3 linolenic acid in the form of a glyceride, and the ratio of linoleic acid to n-3 linolenic acid is not less than 4 to 1 and not more than 10 to 1;

(*e*) the proteins present in the meal replacement are

(i) of a nutritional quality equivalent to that of casein, or

(ii) of a nutritional quality and in an amount sufficient to yield a result of not less than 15 per cent, or not less than 20 per cent in the case of a meal replacement for use in a weight reduction diet, when the nutritional quality of those proteins is divided by the nutritional quality of casein and multiplied by the percentage of energy available from the proteins present in the meal replacement; and

(*f*) each serving of the meal replacement contains each vitamin and mineral nutrient listed in column I of the table to this section

(i) subject to subsection (3), in an amount not less than the minimum amount shown for that vitamin or mineral nutrient in column II of the table, and

(ii) subject to subsections (4) and (5), in an amount that, including overage, is not more than the maximum amount shown for that vitamin or mineral nutrient in column III of the table.

(2) No person shall sell or advertise a meal replacement that is represented as a replacement for all daily meals unless, when in a ready-to-serve form or when prepared according to directions for use, with water, milk, partially skim milk or skim milk, or a combination thereof, it meets the following requirements:

(*a*) not more than 30 per cent of the energy available from the meal replacement is derived from its fat content; and

(*b*) not more than 10 per cent of the energy available from the meal replacement is derived from its saturated fatty acid content.

(3) The minimum amount required under subparagraph (1)(*f*)(i) for selenium, chromium or molybdenum does not apply in respect of a meal replacement that is not represented as a replacement for all daily meals and that does not contain added selenium, chromium or molybdenum, as the case may be.

(4) A vitamin or mineral nutrient that is not an added ingredient in the meal replacement shall not be taken into account for the purposes of subparagraph (1)(*f*)(ii).

(5) The maximum amount shown for vitamin C in column III of the table to this section does not include overage.

TABLE

| **COLUMN I** | **COLUMN II** | | **COLUMN III** | |
|---|---|---|---|---|
| Nutrients | Minimum Amount per Serving | | Maximum Amount per Serving | |
| **VITAMINS** | | | | |
| Vitamin A | 250 | RE | 630 | RE |
| Vitamin D | 1.25 | µg | 2.50 | µg |
| Vitamin E | 2.5 | mg | 5.0 | mg |
| Vitamin C | 10 | mg | 20 | mg |
| Thiamine | 300 | µg | 750 | µg |
| Riboflavin | 400 | µg | 800 | µg |
| Niacin | 6 | NE | 12 | NE |
| Vitamin $B_6$ | 400 | µg | 750 | µg |
| Vitamin $B_{12}$ | 0.25 | µg | 0.75 | µg |
| Folacin | 60 | µg | 120 | µg |
| Pantothenic acid | 1.25 | mg | 2.50 | mg |
| Biotin | 25 | µg | 75 | µg |
| **MINERAL NUTRIENTS** | | | | |
| Calcium | 200 | mg | 400 | mg |
| Phosphorus | 250 | mg | 500 | mg |
| Iron | 2.5 | mg | 5.0 | mg |
| Iodide | 40 | µg | 120 | µg |
| Magnesium | 60 | mg | 120 | mg |
| Copper | 0.5 | mg | 1.0 | mg |
| Zinc | 3 | mg | 6 | mg |
| Potassium | 375 | mg | | |
| Sodium | 250 | mg | | |
| Manganese | 1 | mg | 2 | mg |
| Selenium | 10 | µg | 20 | µg |
| Chromium | 10 | µg | 20 | µg |
| Molybdenum | 20 | µg | 40 | µg |

SOR/78-698, s. 9; SOR/80-13, s. 14; SOR/95-474, s. 5.

B.24.201. (1) No person shall sell or advertise a nutritional supplement that contains less than 225 kcal or 945 kJ per serving, unless it meets the following requirements:

(*a*) the nutritional supplement contains at least 150 kcal or 630 kJ per serving;

(*b*) not less than 15 per cent and no more than 40 per cent of the energy available from the nutritional supplement is derived from its protein content;

(*c*) the proteins present in the nutritional supplement are

(i) of a nutritional quality equivalent to that of casein, or

(ii) of a nutritional quality and in an amount sufficient to yield a result of not less than 15 per cent when the nutritional quality of those proteins is divided by the nutritional quality of casein and multiplied by the percentage of energy available from the proteins present in the nutritional supplement; and

(*d*) the nutritional supplement contains, per 100 kcal or 420 kJ, each vitamin and mineral nutrient listed in column I of the table to this section

(i) subject to subsection (3), in an amount not less than the minimum amount shown for that vitamin or mineral nutrient in column II of the table, and

(ii) subject to subsections (4) and (5), in an amount that, including overage, is not more than the maximum amount shown for that vitamin or mineral nutrient in column III of the table.

(2) No person shall sell or advertise a nutritional supplement that provides 225 kcal or 945 kJ, or more, per serving unless, when in a ready-to-serve form or when prepared according to directions for use, with water, milk, partially skim milk, skim milk, or a combination thereof, it meets the following requirements:

(*a*) the nutritional supplement provides at least 225 kcal or 945 kJ per serving;

(*b*) not more than 35 per cent of the energy available from the nutritional supplement is derived from its fat content;

(*c*) not less than 3.0 per cent of the energy available from the nutritional supplement is derived from linoleic acid in the form of a glyceride and not less than 0.5 per cent of the energy available from the nutritional supplement is derived from n-3 linolenic acid in the form of a glyceride, and the ratio of linoleic acid to n-3 linolenic acid is not less than 4 to 1 and not more than 10 to 1;

(*d*) not less than 15 per cent and not more than 40 per cent of the energy available from the nutritional supplement is derived from its protein content;

(*e*) the proteins present in the nutritional supplement are

(i) of a nutritional quality equivalent to that of casein, or

(ii) of a nutritional quality and in an amount sufficient to yield a result of not less than 15 per cent when the nutritional quality of those proteins is divided by the nutritional quality of casein and multiplied by the percentage of energy available from the proteins present in the nutritional supplement; and

(*f*) the nutritional supplement contains, per 100 kcal or 420 kJ, each vitamin and mineral nutrient listed in column I of the table to this section

(i) subject to subsection (3), in an amount not less than the minimum amount shown for that vitamin or mineral nutrient in column II of the table, and

(ii) subject to subsections (4) and (5), in an amount that, including overage, is not more than the maximum amount shown for that vitamin or mineral nutrient in column III of the table.

(3) The minimum amount required under subparagraph (1)(*d*)(i) or (2)(*f*)(i) for selenium, chromium or molybdenum does not apply in respect of a nutritional supplement that does not contain added selenium, chromium or molybdenum, as the case may be.

(4) A vitamin or mineral nutrient that is not an added ingredient in the nutritional supplement shall not be taken into account for the purposes of subparagraphs (1)(*d*)(ii) and (2)(*f*)(ii).

(5) The maximum amount shown for vitamin C in column III of the table to this section does not include overage.

TABLE

| **COLUMN I** | **COLUMN II** | | **COLUMN III** | |
|---|---|---|---|---|
| Nutrients | Minimum Amount per Available 100 Kcal or 420 KJ | | Maximum Amount per Available 100 Kcal or 420 KJ | |
| **VITAMINS** | | | | |
| Vitamin A | 100 | RE | 250 | RE |
| Vitamin D | 0.25 | µg | 1 | µg |
| Vitamin E | 1.0 | mg | 2.0 | mg |
| Vitamin C | 5 | mg | 10 | mg |
| Thiamine | 140 | µg | 350 | µg |
| Riboflavin | 180 | µg | 360 | µg |
| Niacin | 3 | NE | 6 | NE |
| Vitamin $B_6$ | 180 | µg | 350 | µg |
| Vitamin $B_{12}$ | 0.1 | µg | 0.3 | µg |
| Folacin | 30 | µg | 60 | µg |
| Pantothenic acid | 0.6 | mg | 1.2 | mg |
| Biotin | 12 | µg | 35 | µg |
| **MINERAL NUTRIENTS** | | | | |
| Calcium | 100 | mg | 175 | mg |
| Phosphorus | 100 | mg | 175 | mg |
| Iron | 1.0 | mg | 2.0 | mg |
| Iodide | 15 | µg | 45 | µg |
| Magnesium | 20 | mg | 40 | mg |
| Copper | 0.15 | mg | 0.30 | mg |
| Zinc | 1.4 | mg | 2.0 | mg |
| Potassium | 175 | mg | | |
| Manganese | 0.45 | mg | 0.90 | mg |
| Selenium | 4 | µg | 8 | µg |
| Chromium | 4 | µg | 8 | µg |
| Molybdenum | 8 | µg | 15 | µg |

SOR/78-698, s. 9; SOR/95-474, s. 5.

B.24.202. The label of a meal replacement or nutritional supplement shall

(*a*) show the following information per serving of stated size and per stated quantity of food, when prepared according to the directions for use:

(i) the energy value of the food, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat, linoleic acid, n-3 linolenic acid, saturated fatty acid and carbohydrate contents of the food, expressed in grams,

(iii) the vitamin A, vitamin D, vitamin E, vitamin C, thiamin or vitamin $B_1$, riboflavin or vitamin $B_2$, niacin, vitamin $B_6$, vitamin $B_{12}$, folacin and pantothenic acid or pantothenate contents of the food, expressed, in the case of a meal replacement, as a percentage of the recommended daily intake specified in column II of the table to Division 1 of Part D for that vitamin and, in the case of a nutritional supplement, in retinol equivalents (RE) for vitamin A, in niacin equivalents (NE) for niacin and in milligrams for vitamin D, vitamin E, vitamin C, thiamin or vitamin $B_1$, riboflavin or vitamin $B_2$, vitamin $B_6$, vitamin $B_{12}$, folacin and pantothenic acid or pantothenate,

(iv) the calcium, phosphorus, iron, iodide, magnesium and zinc contents of the food, expressed, in the case of a meal replacement, as a percentage of the recommended daily intake specified for that mineral nutrient in column II of the table to Division 2 of Part D and, in the case of a nutritional supplement, expressed in milligrams, and

(v) the biotin, copper, potassium, sodium, manganese, selenium, chromium and molybdenum contents of the food, expressed in milligrams;

(*b*) in the case of a meal replacement or a nutritional supplement to which milk, partially skim milk or skim milk is to be added, carry a statement that the nutrient content of the food has been determined taking into consideration the milk, partially skim milk or skim milk that will be added according to the directions for use;

(*c*) in the case of a meal replacement that is sold or advertised as a replacement for all daily meals in a weight reduction diet, include directions for use that would result in a daily energy intake of at least 900 kcal or 3 780 kJ;

(*d*) include the expiration date of the meal replacement or nutritional supplement;

(*e*) in the case of a meal replacement for use in a weight reduction diet, carry the statement "USEFUL IN WEIGHT REDUCTION ONLY AS PART OF AN ENERGY-REDUCED DIET/UTILE POUR PERDRE DU POIDS SEULEMENT DANS LE CADRE D'UN RÉGIME À TENEUR RÉDUITE EN ÉNERGIE" prominently displayed on the principal display panel; and

(*f*) in the case of a meal replacement for use in a weight reduction diet that is not represented as a replacement for all daily meals in a diet, include the information required under section B.24.204.

SOR/78-698, s. 9; SOR/88-559, s. 28; SOR/95-474, s. 5.

B.24.203. The label of a prepackaged meal for use in a weight reduction diet or of a food to be sold in a weight reduction clinic shall

(*a*) [Repealed, SOR/2003-11, s. 24]

(*b*) carry the statement “USEFUL IN WEIGHT REDUCTION ONLY AS PART OF AN ENERGY-REDUCED DIET/UTILE POUR PERDRE DU POIDS SEULEMENT DANS LE CADRE D’UN RÉGIME À TENEUR RÉDUITE EN ÉNERGIE” prominently displayed on the principal display panel; and

(*c*) include the information required under section B.24.204.

SOR/78-698, s. 9; SOR/88-559, s. 29; SOR/95-474, s. 5; SOR/2003-11, s. 24.

B.24.204. The label of a prepackaged meal, or of a meal replacement other than a meal replacement represented as a replacement for all daily meals in a diet, that is packaged, sold or advertised for use in a weight reduction diet, or of a food to be sold in a weight reduction clinic, shall include, in the directions for use, a sample seven-day menu in which the prepackaged meal, meal replacement or food is used and which meets the following requirements:

(*a*) each daily meal includes a minimum of one serving, as described in Canada’s Food Guide to Healthy Eating, published in 1992 by the Department of Supply and Services by authority of the Minister of National Health and Welfare, of one food from each of the following groups:

(i) milk, milk products or their alternatives,

(ii) meat and meat alternatives,

(iii) bread and grain products, and

(iv) vegetables and fruit;

(*b*) the daily energy intake provided for is not less than 1 200 kcal or 5 040 kJ;

(*c*) not more than 30 per cent of the total daily energy intake of the seven-day menu is derived from its fat content and not more than 10 per cent of the total daily energy intake of the menu is derived from its saturated fatty acid content;

(*d*) the mean daily intake of each nutrient listed in column I of the table to this section is not less than the amount shown in column II, in the case of a menu recommended for men, or in column III, in the case of a menu recommended for women; and

(*e*) the menu does not include any reference to vitamin or mineral supplements.

TABLE

| **COLUMN I** | **COLUMN II** | | **COLUMN III** | |
|---|---|---|---|---|
| | **MEAN DAILY INTAKE** | | | |
| **NUTRIENTS** | **MEN** | | **WOMEN** | |
| Protein | 65 | g | 55 | g |
| **VITAMINS** | | | | |
| Vitamin A | 1000 | RE | 800 | RE |

| COLUMN I | COLUMN II | | COLUMN III | |
|---|---|---|---|---|
| | MEAN DAILY INTAKE | | | |
| **NUTRIENTS** | **MEN** | | **WOMEN** | |
| Vitamin D | 5 | µg | 5 | µg |
| Vitamin E | 10 | mg | 7 | mg |
| Vitamin C | 40 | mg | 30 | mg |
| Thiamin | 1 | mg | 1 | mg |
| Riboflavin | 1 | mg | 1 | mg |
| Niacin | 14 | NE | 14 | NE |
| Vitamin $B_6$ | 1.5 | mg | 1.5 | mg |
| Vitamin $B_{12}$ | 1 | µg | 1 | µg |
| Folacin | 230 | µg | 200 | µg |
| Pantothenic Acid | 5 | mg | 5 | mg |
| **MINERAL NUTRIENTS** | | | | |
| Calcium | 800 | mg | 800 | mg |
| Phosphorus | 1000 | mg | 850 | mg |
| Iron | 9 | mg | 13 | mg |
| Iodide | 160 | µg | 160 | µg |
| Magnesium | 250 | mg | 210 | mg |
| Copper | 2 | mg | 2 | mg |
| Zinc | 12 | mg | 9 | mg |

SOR/78-698, s. 9; SOR/95-474, s. 5.

B.24.205. (1) No person shall label, package, sell or advertise a prepackaged meal or meal replacement for use in a weight reduction diet, or a food to be sold in a weight reduction clinic, in a manner likely to create an impression that consumption of a vitamin or mineral supplement must be part of a weight reduction diet.

(2) No person shall, on a label of or in an advertisement for a prepackaged meal or meal replacement for use in a weight reduction diet, or a food to be sold in a weight reduction clinic, make any direct or indirect reference to a vitamin or mineral supplement.

(3) Every person who advertises a prepackaged meal or meal replacement for use in a weight reduction diet, or a food to be sold in a weight reduction clinic, shall include in the advertisement the statement “USEFUL IN WEIGHT REDUCTION ONLY AS PART OF AN ENERGY-REDUCED DIET/UTILE POUR PERDRE DU POIDS SEULEMENT DANS LE CADRE D’UN RÉGIME À TENEUR RÉDUITE EN ÉNERGIE”.

SOR/78-698, s. 9; SOR/95-474, s. 5.

## Foods Represented for Use in Very Low Energy Diets

B.24.300. No person shall advertise to the general public a food represented for use in a very low energy diet.

SOR/94-35, s. 4.

B.24.301. (1) No person shall sell, without a written order from a physician, a food represented for use in a very low energy diet.

(2) Notwithstanding subsection (1), a person may sell, without a written order from a physician, a food represented for use in a very low energy diet to

(*a*) a physician;

(*b*) a wholesale druggist;

(*c*) a pharmacist; or

(*d*) a hospital.

(3) No person other than a pharmacist shall sell to the general public a food represented for use in a very low energy diet.

SOR/94-35, s. 4.

B.24.302. A pharmacist shall retain the written order of a physician for a food represented for use in a very low energy diet for at least two years after the date on which the order is filled.

SOR/94-35, s. 4.

B.24.303. (1) A food represented for use in a very low energy diet, whether ready to serve or diluted with water according to the manufacturer's directions, shall provide, per daily allowance recommended by the manufacturer

(*a*) either

(i) not less than 60 g of protein of a nutritional quality equivalent to that of casein, or

(ii) such an amount and quality of protein that, when the quality of the protein is expressed as a fraction of the quality of casein,

(A) the fraction is not less than 85/100, and

(B) the product obtained by multiplying the fraction by the gram weight of the protein is not less than 60;

(*b*) each vitamin or mineral nutrient named in column I of an item of the table to this subsection, in an amount not less than the minimum amount per day set out in column II of that item; and

(*c*) any nutritive substance added to the food other than those referred to in paragraph (*a*) or (*b*), in an amount that is appropriate for the purpose of the substance in the food as determined from clinical trials.

TABLE

| | Column I | Column II |
|---|---|---|
| Item | Vitamin or Mineral Nutrient | Minimum amount per day |
| 1. | Thiamine | 1.3 mg |
| 2. | Riboflavin | 1.6 mg |
| 3. | Niacin | 23 mg |

| | Column I | Column II |
|---|---|---|
| Item | Vitamin or Mineral Nutrient | Minimum amount per day |
| 4. | Folacin | 0.22 mg |
| 5. | Biotin | 0.15 mg |
| 6. | Pantothenic acid | 7.0 mg |
| 7. | Vitamin $B_6$ | 1.5 mg |
| 8. | Vitamin $B_{12}$ | 0.001 mg |
| 9. | Vitamin A | 1000 RE |
| 10. | Vitamin D | 0.005 mg |
| 11. | Vitamin E | 10 mg |
| 12. | Vitamin C | 40 mg |
| 13. | Calcium | 800 mg |
| 14. | Phosphorus | 1000 mg |
| 15. | Magnesium | 250 mg |
| 16. | Iron | 13 mg |
| 17. | Iodine | 0.16 mg |
| 18. | Zinc | 12 mg |
| 19. | Copper | 2 mg |
| 20. | Manganese | 3.5 mg |
| 21. | Selenium | 0.07 mg |
| 22. | Chromium | 0.05 mg |
| 23. | Molybdenum | 0.1 mg |
| 24. | Sodium | 2000 mg |
| 25. | Potassium | 3000 mg |
| 26. | Chloride | 1500 mg |

(2) Notwithstanding paragraph (1)(*a*), a food represented for use in a very low energy diet shall be accompanied by directions for use that when followed would result in the daily intake by a person of at least 1.2 g of protein per kilogram target body weight.

SOR/94-35, s. 4.

B.24.304. The label of a food represented for use in a very low energy diet shall carry the following information:

(*a*) a statement of the energy value of the food, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ) per 100 g or 100 mL of the food as offered for sale and per unit of ready-to-serve food;

(*b*) a statement of the content in the food of protein, fat, carbohydrate and, where present, fibre expressed in grams per 100 g or 100 mL of the food as offered for sale and per unit of ready-to-serve food;

(*c*) a statement of the content in the food of all those vitamins and mineral nutrients that are listed in the table to subsection B.24.303(1) expressed in milligrams, in the case of vitamin A expressed in retinol equivalents (RE), per 100 g or 100 mL of the food as offered for sale and per unit of ready-to-serve food;

(*d*) a statement of the content in the food of any other nutritive substance added to the food in an amount described in paragraph B.24.303(1)(*c*), expressed in milligrams or in grams per 100 g or 100 mL of the food as offered for sale and per unit of ready-to-serve food;

(*e*) the statement “USE ONLY UNDER MEDICAL SUPERVISION” prominently displayed on the principal display panel;

(*f*) directions for use of the food, including

(i) a statement of the rationale for the use of the food,

(ii) criteria to be used for the selection of the persons to whom the food may be prescribed,

(iii) instructions for consultation with and evaluation of the patient and patient follow-up, and

(iv) a statement concerning adequate precautions and contra-indications;

(*g*) directions for the preparation of the food, and storage instructions for the food before and after the container has been opened; and

(*h*) the expiration date of the food.

SOR/94-35, s. 4.

B.24.305. (1) No person shall sell or advertise for sale a food represented for use in a very low energy diet unless the manufacturer, at least 90 days before the sale or advertisement, notifies the Director in writing of the intention to sell the food or advertise the food for sale.

(2) The notification referred to in subsection (1) shall be signed by the manufacturer and shall include, in respect of the food represented for use in a low energy diet, the following information:

(*a*) the name under which the food is to be sold or advertised for sale;

(*b*) the name and address of the principal place of business of the manufacturer;

(*c*) the name and address of each establishment in which the food is manufactured;

(*d*) a list of the ingredients of the food, stated quantitatively;

(*e*) the specifications for nutrient, microbiological and physical quality for each ingredient and for the food;

(*f*) details of quality control procedures respecting the testing of the ingredients and of the food;

(*g*) details of the manufacturing process and quality control procedures used throughout the process;

(*h*) the results of tests carried out to determine the expiration date of the food;

(*i*) the evidence relied on to establish that the food meets the nutritional requirements, other than energy requirements, of a person for whom it is intended, when the food is consumed in accordance with the directions for use;

(*j*) a description of the type of packaging to be used;

(*k*) directions for use;

(*l*) the written text of all labels, including package inserts, to be used in connection with the food; and

(*m*) the name and title of the person who signed the notification and the date of signature.

(3) Notwithstanding subsection (1), a person may sell or advertise for sale a food represented for use in a very low energy diet, if the Director, after having been notified by the manufacturer pursuant to that subsection, has informed the manufacturer in writing that the notification meets the requirements of subsection (2).

SOR/94-35, s. 4.

B.24.306. (1) No person shall sell or advertise for sale a food represented for use in a very low energy diet that has undergone a major change, unless the manufacturer, at least 90 days before the sale or advertisement, notifies the Director in writing of the intention to sell or advertise for sale the food that has undergone the major change.

(2) The notification referred to in subsection (1) shall be signed by the manufacturer and shall include, in respect of the food represented for use in a very low energy diet that has undergone a major change, the following information:

(*a*) the name under which the food is to be sold or advertised for sale;

(*b*) the name and address of the principal place of business of the manufacturer;

(*c*) a description of the major change;

(*d*) the evidence relied on to establish that the food meets the nutritional requirements, other than energy requirements, of a person for whom it is intended, when the food is consumed in accordance with the directions for use;

(*e*) the evidence relied on to establish that the major change has no adverse effect on the food or its use;

(*f*) the written text of all labels, including package inserts, to be used in connection with the food; and

(*g*) the name and title of the person who signed the notification and the date of signature.

(3) Notwithstanding subsection (1), a person may sell or advertise for sale a food represented for use in a very low energy diet that has undergone a major change, if the Director, after having been notified by the manufacturer pursuant to that subsection, has informed the manufacturer in writing that the notification meets the requirements of subsection (2).

SOR/94-35, s. 4.

# Division 25

## Interpretation

B.25.001. In this Division,

“expiration date” means, in respect of a human milk substitute, the date

(*a*) after which the manufacturer does not recommend that it be consumed, and

(*b*) up to which it maintains its microbiological and physical stability and the nutrient content declared on the label; (date limite d'utilisation)

"human milk substitute" means any food that is represented

(*a*) for use as a partial or total replacement for human milk and intended for consumption by infants, or

(*b*) for use as an ingredient in a food referred to in paragraph (*a*); (succédané de lait humain)

"infant" means a person who is under the age of one year; (bébé)

"infant food" means a food that is represented for consumption by infants; (aliment pour bébés)

"junior (naming a food)" means the named food where it contains particles of a size to encourage chewing by infants, but may be readily swallowed by infants without chewing; ((nom d'un aliment) pour enfants en bas âge)

"major change" means, in respect of a human milk substitute, any change of an ingredient, the amount of an ingredient or the processing or packaging of the human milk substitute where the manufacturer's experience or generally accepted theory would predict an adverse effect on the levels or availability of nutrients in, or the microbiological or chemical safety of, the human milk substitute; (changement majeur)

"new human milk substitute" means a human milk substitute that is

(*a*) manufactured for the first time,

(*b*) sold in Canada for the first time, or

(*c*) manufactured by a person who manufactures it for the first time; (succédané de lait humain nouveau)

"strained (naming a food)" means the named food where it is of a generally uniform particle size that does not require and does not encourage chewing by infants before being swallowed. ((nom d'un aliment) en purée ou tamisé)

SOR/78-637, s. 5; SOR/83-933, s. 1; SOR/90-174, s. 1.

## Infant Foods

B.25.002. No person shall sell or advertise for sale an infant food that is set out in Column I of an item of Table I to this Division and contains more than the amount of sodium set out in Column II of that item.

SOR/83-933, s. 1.

B.25.003. (1) Subject to subsection (2), no person shall sell infant food that contains

(*a*) strained fruit,

(*b*) fruit juice,

(*c*) fruit drink, or

(*d*) cereal,

if sodium chloride has been added to that food.

(2) Subsection (1) does not apply to strained desserts containing any of the foods mentioned in paragraphs (1)(*a*) to (*d*).

SOR/83-933, s. 1.

## Human Milk Substitutes and Food Containing Human Milk Substitutes

B.25.045. The common name of a human milk substitute or a new human milk substitute shall be “infant formula”. (*préparation pour nourrissons*)

SOR/90-174, s. 2.

B.25.046. (1) No person shall sell or advertise for sale a new human milk substitute unless the manufacturer, at least 90 days before the sale or advertisement, notifies the Director in writing of the intention to sell or advertise for sale the new human milk substitute.

(2) The notification referred to in subsection (1) shall be signed and shall include, in respect of the new human milk substitute, the following information:

(*a*) the name under which it will be sold or advertised for sale;

(*b*) the name and the address of the principal place of business of the manufacturer;

(*c*) the names and addresses of each establishment in which it is manufactured;

(*d*) a list of all of its ingredients, stated quantitatively;

(*e*) the specifications for nutrient, microbiological and physical quality for the ingredients and for the new human milk substitute;

(*f*) details of quality control procedures respecting the testing of the ingredients and of the new human milk substitute;

(*g*) details of the manufacturing process and quality control procedures used throughout the process;

(*h*) the results of tests carried out to determine the expiration date of the new human milk substitute;

(*i*) the evidence relied on to establish that the new human milk substitute is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions for use;

(*j*) a description of the type of packaging to be used;

(*k*) directions for use;

(*l*) the written text of all labels, including package inserts, to be used in connection with the new human milk substitute; and

(*m*) the name and title of the person who signed the notification and the date of signature.

(3) Notwithstanding subsection (1), a person may sell or advertise for sale a new human milk substitute if the manufacturer has notified the Director pursuant to subsection (1) and is informed in writing by the Director that the notification is satisfactory.

SOR/90-174, s. 2.

B.25.047. Sections B.25.051 to B.25.059 apply in respect of new human milk substitutes.

SOR/90-174, s. 2; SOR/2003-11, s. 25.

B.25.048. (1) No person shall sell or advertise for sale a human milk substitute that has undergone a major change unless the manufacturer of the human milk substitute, at least 90 days before the sale or advertisement, notifies the Director in writing of the intention to sell or advertise for sale the human milk substitute.

(2) The notification referred to in subsection (1) shall be signed and shall include, in respect of the human milk substitute, the following information:

(*a*) the name under which it will be sold or advertised for sale;

(*b*) the name and the address of the principal place of business of the manufacturer;

(*c*) a description of the major change;

(*d*) the evidence relied on to establish that the human milk substitute is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions for use;

(*e*) the evidence relied on to establish that the major change has had no adverse effect on the human milk substitute;

(*f*) the written text of all labels, including package inserts, to be used in connection with the human milk substitute; and

(*g*) the name and title of the person who signed the notification and the date of signature.

(3) Notwithstanding subsection (1), a person may sell or advertise for sale a human milk substitute that has undergone a major change if the manufacturer has notified the Director pursuant to subsection (1) and is informed in writing by the Director that the notification is satisfactory.

SOR/90-174, s. 2.

B.25.050. [Repealed, SOR/90-174, s. 2]

B.25.051. (1) No person shall sell or advertise for sale a human milk substitute unless, when prepared according to directions for use, it complies with the provisions of this Division respecting human milk substitutes.

(2) No person shall sell or advertise for sale a food that is represented as containing a human milk substitute unless the human milk substitute portion of the food complies with the nutritional requirements set out in this Division for human milk substitutes.

SOR/83-933, s. 1.

B.25.052. (1) No person shall sell or advertise for sale a human milk substitute unless it meets the nutritional requirements of infants with normal or special dietary needs and it is of such a consistency that, when ready-to-serve, it passes freely through a nursing bottle nipple.

(2) No person shall sell or advertise for sale a food that is represented as containing a human milk substitute unless the human milk substitute portion of the food meets the nutritional requirements of infants with normal or special dietary needs.

SOR/78-637, s. 6; SOR/82-768, s. 76; SOR/83-933, s. 1.

B.25.053. (1) No person shall sell or advertise for sale a human milk substitute that requires, when prepared according to directions for use, the addition of a nutritive substance, other than water or a source of carbohydrate or both.

(2) No person shall sell or advertise for sale a food represented as containing a human milk substitute that requires, when prepared according to directions for use, the addition of a nutritive substance other than water.

SOR/78-637, s. 7; SOR/83-933, s. 1.

B.25.054. (1) Except as otherwise provided in this Division, no person shall sell or advertise for sale a human milk substitute unless it contains, when prepared according to directions for use,

(*a*) per 100 available kilocalories

(i) not less than 3.3 and not more than 6.0 grams of fat,

(ii) not less than 500 milligrams of linoleic acid in the form of a glyceride,

(iii) not more than 1 kilocalorie from $C_{22}$ Monoenoic Fatty Acids,

(iv) not less than 1.8 and not more than 4.0 grams of protein,

(v) not less than 1.8 grams of protein of nutritional quality equivalent to casein, or such an amount and quality of protein, including those proteins to which amino acids are added, that, when the quality of the protein is expressed as a fraction of the quality of casein,

(A) the fraction will not be less than 85/100, and

(B) the product obtained by multiplying the fraction by the gram weight of the protein will not be less than 1.8,

(vi) notwithstanding sections D.01.010, D.01.011 and D.02.009, the vitamin and mineral nutrient set out in Column I of an item of Table II to this Division in an amount not less than the amount set out in Column II of that item and not more than the amount set out in Column III of that item, and

(vii) not less than 12 milligrams of choline; and

(*b*) a ratio of

(i) alpha-tocopherol to linoleic acid of not less than 0.6 International Units to one gram,

(ii) calcium to phosphorus of not less than 1.2 grams to one gram and not more than 2.0 grams to one gram, and

(iii) vitamin $B_6$ to protein of not less than 15 micrograms to one gram.

(2) No person shall sell or advertise for sale a food that is represented as containing a human milk substitute unless the human milk substitute portion of the food complies with subsection (1).

SOR/78-637, s. 7; SOR/83-933, s. 1.

B.25.055. (1) Subparagraph B.25.054(1)(*a*)(i) does not apply to a human milk substitute represented as being for a fat-modified diet.

(2) Subparagraph B.25.054(1)(*a*)(iv), except that portion thereof that prescribes the maximum amount of protein, and subparagraph B.25.054(1)(*a*)(v) do not apply to a human milk substitute represented as being for a low (naming the amino acid) diet.

(3) All that portion of subparagraph B.25.054(1)(*a*)(vi) that prescribes the minimum amounts of vitamin D, calcium and phosphorus and subparagraph B.25.054(1)(*b*)(ii) do not apply to a human milk substitute represented as being for a low (naming the mineral) diet or a low vitamin D diet or both.

SOR/83-933, s. 1.

B.25.056. No person shall sell a human milk substitute or a food that is represented as containing a human milk substitute

(*a*) that contains an added nutritive substance that is

(i) normally contained in human milk, and

(ii) not referred to in paragraph B.25.054(1)(*a*)

unless the amount of that substance present per 100 available kilocalories of the human milk substitute or human milk substitute portion of the food, when prepared according to directions for use, is equal to the amount thereof present per 100 available kilocalories of human milk; or

(*b*) that contains added amino acids unless

(i) the amino acids are required to improve the quality of the protein in the human milk substitute or human milk substitute portion of the food and are present in an amount not exceeding the minimum required for that purpose, or

(ii) the protein content of the human milk substitute or human milk substitute portion of the food is supplied by isolated amino acids or by protein hydrolysate, or both

and only the L forms of the amino acids have been added.

SOR/78-637, s. 8; SOR/83-933, s. 1.

B.25.057. (1) The label of a human milk substitute shall carry the following information:

(*a*) a statement of the content of protein, fat, available carbohydrate, ash and, where present, crude fibre in the food

(i) in grams per 100 grams or in grams per 100 millilitres of the human milk substitute as offered for sale, and

(ii) in grams in a stated quantity of the human milk substitute when ready-to-serve;

(*b*) a statement of the energy value expressed in

(i) calories per 100 grams or calories per 100 millilitres of the human milk substitute as offered for sale, and

(ii) calories in a stated quantity of the human milk substitute when ready-to-serve;

(*c*) a statement of the quantity of all vitamins and mineral nutrients listed in Table II to this Division

(i) in International Units or milligrams per 100 grams or in International Units or milligrams per 100 millilitres of the human milk substitute as offered for sale, and

(ii) in International Units or milligrams in a stated quantity of the human milk substitute when ready-to-serve;

(*d*) a statement of the quantity of choline and of any added nutritive substance normally contained in human milk and not referred to in paragraph B.25.054(1)(*a*)

(i) in milligrams or grams per 100 grams, or in milligrams or grams per 100 millilitres, of the human milk substitute as offered for sale, and

(ii) in milligrams or grams in a stated quantity of the human milk substitute when ready-to-serve;

(*e*) adequate directions for the preparation, use and storage of the human milk substitute after the container has been opened; and

(*f*) the expiration date of the human milk substitute.

(2) The label of a food that is represented as containing human milk substitute shall carry the following information:

(*a*) a statement on the principal display panel of the proportion of the human milk substitute contained in the food as offered for sale in close proximity to any claim regarding the presence of the human milk substitute and given equal prominence to such a claim;

(*b*) the common name of the human milk substitute in the list of ingredients to be followed by a statement of all the components contained in the human milk substitute;

(*c*) a statement of

(i) the content of protein, fat, available carbohydrate, ash and, where present, crude fibre contained in the human milk substitute portion of the food, expressed in grams per 100 grams or per 100 millilitres of the human milk substitute portion of the food as offered for sale,

(ii) the energy value of the human milk substitute portion of the food expressed in calories per 100 grams or in calories per 100 millilitres of the human milk substitute portion of the food as offered for sale,

(iii) the quantity of all the vitamins and mineral nutrients set out in Table II to this Division that are contained in the human milk substitute portion of the food in International Units or milligrams per 100 grams or in International Units or milligrams per 100 millilitres of the human milk substitute portion of the food as offered for sale, and

(iv) the quantity of choline and of any added nutritive substance normally contained in human milk and not referred to in paragraph B.25.054(1)(*a*) contained in the human milk substitute portion of the food in milligrams or grams per 100 grams or in milligrams or grams per 100 millilitres of the human milk substitute portion of the food as offered for sale;

(*d*) a statement of

(i) the content of protein, fat, available carbohydrate, ash and, where present, crude fibre in grams per 100 grams or per 100 millilitres of the food as offered for sale and in grams per stated quantity of ready-to-serve food,

(ii) the energy value expressed in calories per 100 grams or in calories per 100 millilitres of the food as offered for sale and in grams per a stated quantity of the food when ready-to-serve,

(iii) the quantity of all vitamins and mineral nutrients set out in Table II to this Division in International Units or milligrams per 100 grams or in International Units or milligrams per 100 millilitres of the food as offered for sale and in International Units or milligrams in a stated quantity of the food when ready-to-serve, and

(iv) the quantity of choline and of any added nutritive substance normally contained in human milk and not referred to in paragraph B.25.054(1)(*a*) in milligrams or grams per 100 grams or in milligrams or grams per 100 millilitres of the food as offered for sale and in milligrams or grams in a stated quantity of the food when ready-to-serve;

(*e*) adequate directions for the preparation, use and storage of the food after the container has been opened; and

(*f*) the expiration date of the food.

SOR/83-933, s. 1; SOR/88-559, s. 30.

B.25.058. Notwithstanding section D.02.005, no person shall make any claim with respect to the iron content of a human milk substitute except as required by paragraph B.25.057(1)(*c*), unless the human milk substitute contains at least one milligram of iron per 100 available kilocalories.

SOR/78-637, s. 9(F); SOR/83-933, s. 1.

B.25.059. No person shall, on the label of or in any advertisement for a human milk substitute or a food represented as containing a human milk substitute, make any statement or claim relating to the content in the food of

(*a*) the percentage of the daily value of

(i) fat,

(ii) saturated fatty acids and *trans* fatty acids,

(iii) sodium,

(iv) potassium,

(v) carbohydrate,

(vi) fibre, or

(vii) cholesterol; or

(*b*) the number of Calories from

(i) fat, or

(ii) saturated fatty acids and *trans* fatty acids.

SOR/2003-11, s. 26.

B.25.060. (1) Where the manufacturer of a human milk substitute or of a food that is represented as containing a human milk substitute is requested in writing by the Director to submit on or before a specified day evidence with respect to the human milk substitute, the manufacturer shall make no further sales of that human milk substitute or food that is represented as containing human milk substitute after that day unless he has submitted the evidence requested.

(2) Where the Director is of the opinion that the evidence submitted by a manufacturer pursuant to subsection (1) is not sufficient, he shall notify the manufacturer in writing that the evidence is not sufficient.

(3) Where, pursuant to subsection (2), a manufacturer is notified that the evidence with respect to the human milk substitute is not sufficient, he shall make no further sales of that human milk substitute or of that food that is represented as containing the human milk substitute unless he submits further evidence and is notified in writing by the Director that the further evidence is sufficient.

(4) In this section, “evidence with respect to the human milk substitute” means

(*a*) evidence that establishes that the human milk substitute is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions for use; and

(*b*) the results of tests carried out to determine the expiration date of the human milk substitute.

SOR/83-933, s. 1; SOR/88-424, s. 2; SOR/90-174, s. 3.

B.25.061. (1) Subject to subsection (2), no person shall include on the label of a food any representation respecting the consumption of the food by an infant who is less than six months of age.

(2) Subsection (1) does not apply in respect of a human milk substitute or a new human milk substitute.

SOR/83-933, s. 1; SOR/90-174, s. 4.

B.25.062. (1) Subject to subsection (2), no person shall sell a food that is labelled or advertised for consumption by infants if the food contains a food additive.

(2) Subsection (1) does not apply to

(*a*) bakery products that are labelled or advertised for consumption by infants;

(*b*) ascorbic acid used in the following foods that are labelled or advertised for consumption by infants:

(i) fruit purées, and

(ii) cereals containing banana;

(*c*) soyabean lecithin used in rice cereal labelled or advertised for consumption by infants;

(*d*) citric acid used in foods that are labelled or advertised for consumption by infants;

(*e*) infant formula that contains the food additives set out in Tables IV and X to section B.16.100 for use in infant formula;

(*f*) infant formula that contains ingredients manufactured with food additives set out in Table V to section B.16.100;

(*g*) infant formula that contains concentrated or dried whey products manufactured with liquid whey to which sodium hexametaphosphate has been added;

(*h*) infant cereal products that contain amylase in accordance with Table V to section B.16.100;

(*i*) infant formula that contains ascorbyl palmitate or tocopherols; or

(*j*) infant formula that contains oils to which ascorbyl palmitate or tocopherols have been added.

SOR/83-933, s. 1; SOR/90-24, s. 4; SOR/91-149, s. 6; SOR/97-559, s. 1; SOR/2010-40, s. 3; SOR/2010-41, s. 8; SOR/2010-94, s. 6; SOR/2010-141, s. 3.

TABLE I

SODIUM CONTENT IN INFANT FOODS

| | Column I<br>Food | Column II<br>Total Sodium in Grams per 100 Grams of Food |
|---|---|---|
| 1. | Junior Desserts ..... | 0.10 |
| 2. | Junior Meat, Junior Meat Dinners, Junior Dinners, Junior Breakfasts ..... | 0.25 |
| 3. | Junior Vegetables, Junior Soups ..... | 0.20 |

| | Column I | Column II |
|---|---|---|
| | Food | Total Sodium in Grams per 100 Grams of Food |
| 4. | Strained Desserts ..... | 0.05 |
| 5. | Strained Meats, Strained Meat Dinners, Strained Dinners, Strained Breakfasts ..... | 0.15 |
| 6. | Strained Vegetables, Strained Soups ..... | 0.10 |

SOR/78-637, s. 10; SOR/83-933, s. 1.

TABLE II

| | Column I | Column II | Column III |
|---|---|---|---|
| Item No. | Vitamin or Mineral nutrient | Minimum amount per 100 available kilocalories | Maximum amount per 100 available kilocalories |
| B.1 | Biotin | 2 mcg | — |
| F.1 | Folic acid | 4 mcg | — |
| N.1 | Niacin | 250 mcg | — |
| P.1 | d-pantothenic acid | 300 mcg | — |
| R.1 | Riboflavin | 60 mcg | — |
| T.1 | Thiamine | 40 mcg | — |
| T.2 | Alpha-tocopherol | 0.6 I.U. | — |
| V.1 | Vitamin A | 250 I.U. | 500 I.U. |
| V.2 | Vitamin $B_6$ | 35 mcg | — |
| V.3 | Vitamin $B_{12}$ | 0.15 mcg | — |
| V.4 | Vitamin C | 8 mg | — |
| V.5 | Vitamin D | 40 I.U. | 80 I.U. |
| V.6 | Vitamin $K_1$ | 8 mcg | — |
| C.1 | Calcium | 50 mg | — |
| C.2 | Chloride | 55 mg | 150 mg |
| C.3 | Copper | 60 mcg | — |
| L.1 | Iodine | 5 mcg | — |
| L.2 | Iron | 0.15 mg | — |
| M.1 | Magnesium | 6 mg | — |
| M.2 | Manganese | 5 mcg | — |
| P.2 | Phosphorous | 25 mg | — |
| P.3 | Potassium | 80 mg | 200 mg |
| S.1 | Sodium | 20 mg | 60 mg |
| Z.1 | Zinc | 0.5 mg | — |

SOR/83-933, s. 1; SOR/98-458, s. 7(F).

Previous Version

# Division 26

# Food Irradiation

## Interpretation

B.26.001. In this Division,

“ionizing radiation” means

(*a*) gamma-radiation from a Cobalt-60 or Cesium-137 source,

(*b*) X-rays generated from a machine source operated at or below an energy level of 5 MeV, and

(*c*) electrons generated from a machine source operated at or below an energy level of 10 MeV; (rayonnement ionisant)

“irradiation” means treatment with ionizing radiation. (irradiation)

SOR/89-175, s. 3.

## Application

B.26.002. This Division does not apply to foods exposed to ionizing radiation from a measuring instrument used to determine weight, estimate bulk solids, measure the total solids in liquids or perform other inspection procedures.

SOR/89-175, s. 3.

## General

B.26.003. (1) Subject to subsection (2), no person shall sell a food that has been irradiated.

(2) A food set out in Column I of an item of the table to this Division that has been irradiated may be sold if

(*a*) the food was irradiated from a source set out in Column II of that item for the purpose set out in Column III of that item; and

(*b*) the dose of ionizing radiation absorbed by the food is within the permitted absorbed dose set out in Column IV of that item.

SOR/89-175, s. 3.

## Records

B.26.004. (1) A manufacturer who sells a food that has been irradiated shall keep on his premises, for at least two years after the date of the irradiation, a record containing the following information:

(*a*) the food irradiated and the quantity and lot numbers of the food;

(*b*) the purpose of the irradiation;

(*c*) the date of the irradiation;

(*d*) the dose of ionizing radiation absorbed by the food;

(*e*) the source of the ionizing radiation; and

(*f*) a statement indicating whether the food was irradiated prior to the irradiation by the manufacturer and, if so, the information referred to in paragraphs (*a*) to (*e*) in respect of that prior irradiation.

(2) Every person who imports a food that is intended for sale in Canada that has been irradiated shall keep on his premises a record of the information referred to in subsection (1) for at least two years after the date of importation.

SOR/89-175, s. 3.

## Changes to the Table

B.26.005. A request that a food be added or a change made to the table to this Division shall be accompanied by a submission to the Director containing the following information:

(*a*) the purpose and details of the proposed irradiation, including the source of ionizing radiation and the proposed frequency of and minimum and maximum dose of ionizing radiation;

(*b*) data indicating that the minimum dose of ionizing radiation proposed to be used accomplishes the intended purpose of the irradiation and the maximum dose of ionizing radiation proposed does not exceed the amount required to accomplish the purpose of the irradiation;

(*c*) information on the nature of the dosimeter used, the frequency of the dosimetry on the food and data pertaining to the dosimetry and phantoms used to assure that the dosimetry readings reflect the dose absorbed by the food during irradiation;

(*d*) data indicating the effects, if any, on the nutritional quality of the food, raw and ready-to-serve, under the proposed conditions of irradiation and any other processes that are combined with the irradiation;

(*e*) data establishing that the irradiated food has not been significantly altered in chemical, physical or microbiological characteristics to render the food unfit for human consumption;

(*f*) where the Director so requests, data establishing that the proposed irradiation is safe under the conditions proposed for the irradiation;

(*g*) the recommended conditions of storage and shipment of the irradiated food including the time, temperature and packaging and a comparison of the recommended conditions for the same food that has not been irradiated;

(*h*) details of any other processes to be applied to the food prior to or after the proposed irradiation; and

(*i*) such other data as the Director may require to establish that consumers and purchasers of the irradiated food will not be deceived or misled as to the character, value, composition, merit or safety of the irradiated food.

TABLE

| Column I | Column II | Column III | Column IV |
|---|---|---|---|

| Item | Food | Permitted Sources of Ionizing Radiation | Purpose of Treatment | Permitted Absorbed Dose |
|---|---|---|---|---|
| 1. | Potatoes (*Solanum tuberosum L.*) | Cobalt-60 | To inhibit sprouting during storage | 0.15 kGy max. |
| 2. | Onions (*Allium cepa*) | Cobalt-60 | To inhibit sprouting during storage | 0.15 kGy max. |
| 3. | Wheat, Flour, Whole Wheat Flour (*Triticum sp.*) | Cobalt-60 | To control insect infestation in stored food | 0.75 kGy max. |
| 4. | Whole or ground spices and dehydrated seasoning preparations | Cobalt-60, Cesium-137, or electrons from machine sources (3 MeV max.) | To reduce microbial load | 10.00 kGy max. total overall average dose |

SOR/89-175, s. 3; SOR/98-458, s. 7(F).

# Division 27

# Low-Acid Foods Packaged In Hermetically Sealed Containers

B.27.001. In this Division,

“commercially sterile” means the condition obtained in a food that has been processed by the application of heat, alone or in combination with other treatments, to render the food free from viable forms of microorganisms, including spores, capable of growing in the food at temperatures at which the food is designed normally to be held during distribution and storage; (stérilité commerciale)

“hermetically sealed container” means a container designed and intended to be secure against the entry of microorganisms, including spores; (récipient hermétiquement fermé)

“low-acid food” means a food, other than an alcoholic beverage, where any component of the food has a pH greater than 4.6 and a water activity greater than 0.85; (aliment peu acide)

“refrigeration” means exposure to a temperature of 4°C or less but does not mean frozen; (réfrigéré)

“shipping container” means a receptacle, package or wrapper in which containers of food are placed for transportation; (contenant d’expédition)

“water activity” means the ratio of the water vapour pressure of a food to the vapour pressure of pure water, at the same temperature and pressure. (activité de l’eau)

SOR/89-309, s. 1.

B.27.002. (1) No person shall sell a low-acid food packaged in a hermetically sealed container unless the food is commercially sterile.

(2) Subsection (1) does not apply in respect of a low-acid food packaged in a hermetically sealed container where

(*a*) the low-acid food is kept under refrigeration and the statement “Keep Refrigerated” and “Garder au froid” is carried on the principal display panel of the label of its container, as well as on the label of its shipping container; or

(*b*) the low-acid food is kept frozen and the statement “Keep Frozen” and “Garder congelé” is carried on the principal display panel of the label of its container, as well as on the label of its shipping container.

(3) Subsection (1) does not apply in respect of tomatoes or tomato products packaged in hermetically sealed containers where the tomatoes or tomato products have a pH of 4.7 or less after heat processing.

SOR/89-309, s. 1; SOR/91-149, s. 7.

B.27.003. No person shall sell a low-acid food packaged in a hermetically sealed container where the container

(*a*) is swollen;

(*b*) is not properly sealed; or

(*c*) has any defect that may adversely affect its hermetic seal.

SOR/89-309, s. 1.

B.27.004. (1) Where, in the opinion of the Director, the sale of a low-acid food packaged in a hermetically sealed container may contravene section B.27.002 or B.27.003, the Director may, by notice in writing, request that the manufacturer or importer of the food submit, on or before the date specified in the notice, evidence that establishes that the processes used to manufacture, process and package the food rendered and maintained the food commercially sterile.

(2) Where a manufacturer or an importer receives a notice issued pursuant to subsection (1), the manufacturer or importer shall make no further sales of the food on or after the day specified in the notice until he has submitted the evidence requested in that notice.

(3) Where the Director is of the opinion that the evidence submitted by a manufacturer or importer pursuant to subsection (1) is not sufficient, the Director shall notify the manufacturer or importer in writing that the evidence is not sufficient.

(4) Where, pursuant to subsection (3), a manufacturer or importer is notified that the evidence he has submitted is not sufficient, the manufacturer or importer shall make no further sales of the food until he submits further evidence and is notified in writing by the Director that the further evidence is sufficient.

SOR/89-309, s. 1.

B.27.005. No person shall sell a commercially sterile low-acid food packaged in a hermetically sealed container unless

(*a*) the label or container of the food bears a code or lot number that identifies, in a legible and permanent manner,

(i) the establishment in which the product was rendered commercially sterile, and

(ii) the day, month and year on which the food was rendered commercially sterile; and

(*b*) the exact meaning of each item in any code or lot number referred to in paragraph (*a*) is available to an inspector at the establishment or, where the food is imported, from the importer.

SOR/89-309, s. 1.

# Division 28

# Novel Foods

## Interpretation

B.28.001. The definitions in this section apply in this Division.

“genetically modify” means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation. (modifier génétiquement)

“major change” means, in respect of a food, a change in the food that, based on the manufacturer’s experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to

(*a*) the composition, structure or nutritional quality of the food or its generally recognized physiological effects;

(*b*) the manner in which the food is metabolized in the body; or

(*c*) the microbiological safety, the chemical safety or the safe use of the food. (changement majeur)

“novel food” means

(*a*) a substance, including a microorganism, that does not have a history of safe use as a food;

(*b*) a food that has been manufactured, prepared, preserved or packaged by a process that

(i) has not been previously applied to that food, and

(ii) causes the food to undergo a major change; and

(*c*) a food that is derived from a plant, animal or microorganism that has been genetically modified such that

(i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,

(ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or

(iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. (aliment nouveau)

SOR/99-392, s. 1.

## Pre-market notification

B.28.002. (1) No person shall sell or advertise for sale a novel food unless the manufacturer or importer of the novel food

(*a*) has notified the Director in writing of their intention to sell or advertise for sale the novel food; and

(*b*) has received a written notice from the Director under paragraph B.28.003(1)(*a*) or subsection B.28.003(2).

(2) A notification referred to in paragraph (1)(*a*) shall be signed by the manufacturer or importer, or a person authorized to sign on behalf of the manufacturer or importer, and shall include the following information:

(*a*) the common name under which the novel food will be sold;

(*b*) the name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;

(*c*) a description of the novel food, together with

(i) information respecting its development,

(ii) details of the method by which it is manufactured, prepared, preserved, packaged and stored,

(iii) details of the major change, if any,

(iv) information respecting its intended use and directions for its preparation,

(v) information respecting its history of use as a food in a country other than Canada, if applicable, and

(vi) information relied on to establish that the novel food is safe for consumption;

(*d*) information respecting the estimated levels of consumption by consumers of the novel food;

(*e*) the text of all labels to be used in connection with the novel food; and

(*f*) the name and title of the person who signed the notification and the date of signing.

SOR/99-392, s. 1.

B.28.003. (1) Within 45 days after receiving a notification referred to in paragraph B.28.002(1)(*a*), the Director shall review the information included in the notification and

(*a*) if the information establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient; or

(*b*) if additional information of a scientific nature is necessary in order to assess the safety of the novel food, request in writing that the manufacturer or importer submit that information.

(2) Within 90 days after receiving the additional information requested under paragraph (1)(*b*) the Director shall assess it and, if it establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient.

SOR/99-392, s. 1.

# PART C

# DRUGS

## Division 1

### General

C.01.001. (1) In this Part

“acetaminophen product” has the same meaning as in Division 9; (produit d’acétaminophène)

“adult standard dosage unit” has, with reference to a drug, the same meaning as in Division 9; (dose normale pour adultes)

“adverse drug reaction” means a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function; (réaction indésirable à une drogue)

“antibiotic” means any drug or combination of drugs such as those named in C.01.410 to C.01.592 which is prepared from certain micro-organisms, or which formerly was prepared from micro-organisms but is now made synthetically and which possesses inhibitory action on the growth of other micro-organisms; (antibiotique)

“brand name” means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French,

(*a*) that is assigned to the drug by its manufacturer,

(*b*) under which the drug is sold or advertised, and

(*c*) that is used to distinguish the drug; (marque nominative)

“case report” means a detailed record of all relevant data associated with the use of a drug in a subject; (fiche d’observation)

“children’s standard dosage unit” has, with reference to a drug, the same meaning as in Division 9; (dose normale pour enfants)

“child resistant package” means a package that meets the requirements of subsection (2); (emballage protège-enfants)

“common name” means, with reference to a drug, the name in English or French by which the drug is

(*a*) commonly known, and

(*b*) designated in scientific or technical journals, other than the publications referred to in Schedule B to the Act; (nom usuel)

“expiration date” means the earlier of

(*a*) the date, expressed at minimum as a year and month, up to and including which a drug maintains its labelled potency, purity and physical characteristics, and

(*b*) the date, expressed at minimum as a year and month, after which the manufacturer recommends that the drug not be used; (date limite d’utilisation)

“immediate container” means the receptacle that is in direct contact with a drug; (récipient immédiat)

“internal use” means ingestion by mouth or application for systemic effect to any part of the body in which the drug comes into contact with mucous membrane; (usage interne)

“official drug” means any drug

(*a*) for which a standard is provided in these Regulations, or

(*b*) for which no standard is provided in these Regulations but for which a standard is provided in any of the publications mentioned in Schedule B to the Act; (drogue officielle)

“parenteral use” means administration of a drug by means of a hypodermic syringe, needle or other instrument through or into the skin or mucous membrane; (usage parentéral)

“per cent” means per cent by weight unless otherwise stated; (pour cent)

“practitioner” means a person authorized by the law of a province of Canada to treat patients with any drug listed or described in Schedule F to the Regulations; (praticien)

“prescription” means an order given by a practitioner directing that a stated amount of any drug or mixture of drugs specified therein be dispensed for the person named in the order; (ordonnance)

“proper name” means, with reference to a drug, the name in English or French

(*a*) assigned to the drug in section C.01.002,

(*b*) that appears in bold-face type for the drug in these Regulations and, where the drug is dispensed in a form other than that described in this Part, the name of the dispensing form,

(*c*) specified in the Canadian licence in the case of drugs included in Schedule C or Schedule D to the Act, or

(*d*) assigned in any of the publications mentioned in Schedule B to the Act in the case of drugs not included in paragraph (*a*), (*b*) or (*c*); (nom propre)

“salicylate product” has the same meaning as in Division 9; (produit de salicylate)

“serious adverse drug reaction” means a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death; (réaction indésirable grave à une drogue)

“serious unexpected adverse drug reaction” means a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug; (réaction indésirable grave et imprévue à une drogue)

“teaspoon” means, for the purpose of calculation of dosage, a volume of 5 cubic centimetres; (cuillerée à thé)

“test group” means a group that meets the requirements of subsection (3); (groupe d’essai)

“withdrawal period” means the length of time between the last administration of a drug to an animal and the time when tissues or products collected from the treated animal for consumption as food contain a level of residue of the drug that would not likely cause injury to human health. (délai d’attente)

(2) A child resistant package is a package that

(*a*) when tested in accordance with an acceptable method,

(i) in the case of a test group comprising children, cannot be opened

(A) by at least 85 per cent of those children prior to a demonstration to them of the proper means of opening the package, and

(B) by at least 80 per cent of those children after the demonstration, and

(ii) in the case of a test group comprising adults

(A) can be opened by at least 90 per cent of those adults, and

(B) where the package is designed so that, once opened and reclosed, it continues to meet the requirements of subparagraph (i), can be so reclosed by at least 90 per cent of those adults; or

(*b*) complies with the requirements of one of the following standards, namely,

(i) Canadian Standards Association Standard CAN/CSA-Z76.1-M90, entitled Recloseable Child-Resistant Packages, published January 1990, as amended from time to time,

(ii) European Standard EN 28317:1992, entitled Child-resistant packaging—Requirements and testing procedures for reclosable packages, as adopted by the European Committee for Standardization on October 30, 1992, recognized by the British Standards Institution, and effective February 15, 1993 and by the Association française de normalisation, and effective December 20, 1992, and which reiterates fully the international standard ISO 8317:1989, as amended from time to time, and

(iii) Code of Federal Regulations (United States), Title 16, Section 1700.15, entitled Poison prevention packaging standards, as amended from time to time.

(3) For the purposes of this section, “test group” means

(*a*) in relation to children, a group of at least 200 children who

(i) are healthy and have no obvious physical or mental disability,

(ii) are between 42 and 51 months of age, and

(iii) represent evenly, within plus or minus 10 per cent, each monthly age between 42 and 51 months calculated to the nearest month; and

(*b*) in relation to adults, a group of at least 100 adults who

(i) are healthy and have no obvious physical or mental disability,

(ii) are between 18 and 45 years of age, and

(iii) represent evenly, within plus or minus 10 per cent, each yearly age between 18 and 45 years calculated to the nearest year.

(4) For the purpose of this section, an amendment from time to time to a standard referred to in paragraph (2)(*b*) becomes effective 18 months after the date designated by the competent authority as the effective date for the amendment.

SOR/80-543, s. 1; SOR/85-966, s. 1; SOR/86-93, s. 1; SOR/87-484, s. 1; SOR/92-654, s. 1; SOR/93-202, s. 1; SOR/95-411, s. 1; SOR/95-521, s. 1; SOR/96-399, s. 1; SOR/96-240, s. 1; SOR/97-543, s. 5.

C.01.001A. [Repealed, SOR/98-423, s. 1]

C.01.002. The Proper Name of a drug shown opposite an item number in the following Table in the column headed “Chemical Names and Synonyms” shall be the name shown opposite that item number in the column headed “Proper Names”.

TABLE

| Item No. | Proper Names | Chemical Names and Synonyms |
|---|---|---|
| A.1 | Acepromazine ..... | 2-acetyl-10-(3-dimethylaminopropyl) iephenothiazine |
| A.2 | Acetaminophen ..... | *p*-Acetaminophenol, Paracetamol, *p*-Hydroxyacetanilide: N-acetyl-*p*-aminophenol |
| A.3 | Acetanilide: Acetanilid ..... | Acetylaminobenzene: Antifebrin: Phenylacetamide |
| A.4 | Acetylsalicylic Acid ..... | Acetylsalicylic acid |
| A.5 | Allopurinol ..... | 1-H-Pyrazolo [3,4-*d*] pyrimidin-4-ol: 4-Hydroxypyrazolo (3,4-*d*) pyrimidine |
| A.6 | Amantadine ..... | 1-Adamantanamine |
| A.7 | Aminocaproic acid ..... | 6-Aminohexanoic acid |
| A.8 | Aminopterin ..... | N-[4-(2,4-diamino-6-pteridyl methyl) amino-benzoyl]-L-glumatic acid |
| A.9 | Aminopyrine: Amidopyrine ..... | 1,5-dimethyl-2-phenyl-4-dimethylamino-3-pyrazolone: Dimethylaminophenazone |
| A.10 | Amitriptyline ..... | 3-(3-Dimethylaminopropylidene)-1,2: 4,5-dibenzocyclohepta-1,4-diene |
| A.11 | Azacyclonol ..... | *α*,*α*-diphenyl-4-piperidinecarbinol |
| B.1 | Bemegride ..... | 3-Ethyl-3-methylglutarimide |

| Item No. | Proper Names | Chemical Names and Synonyms |
|---|---|---|
| B.2 | Benactyzine ..... | Dimethylaminoethyl-1,1-diphenylglycolate |
| B.3 | Bendroflumethiazide ..... | 3-benzyl-3,4-dihydro-6-(trifluoro- methyl)-2H-1,2,4-benzothiadiazine-7-sulfonamide-1,1-dioxide: Bendrofluazide (B.A.N.) |
| B.4 | Betahistine ..... | 2-[2-(Methylamino)ethyl] pyridine |
| B.5 | Bethanidine ..... | N-Benzyl-N′N″-dimethylguanidine: 1-Benzyl-2,3-dimethylguanidine |
| B.6 | Bretylium tosylate ..... | N-2-Bromobenzyl-N-ethyl-N, N-dimethylammonium tosylate (Tosylic acid is trivial name for *p*-toluenesulphonic acid) |
| B.7 | Bromisoval ..... | 2-monobromoisovalerylurea: Bromisovalum: Bromvalitone |
| C.1 | Calcium Carbimide ..... | Calcium cyanamide |
| C.2 | Captodiamine ..... | 4-butylthio-*α*-phenylbenzyl-2- dimethylaminoethylsulfide |
| C.3 | Carisoprodol ..... | N-Isopropyl-2-methyl-2-propyl-1, 3-propanediol dicarbamate |
| C.4 | Carphenazine ..... | 1-[10-(3[4-(2-Hydroxyethyl)-1-piperazinyl]propyl) phenothiazin-2yl]-1-propapone |
| C.5 | Cephaloridine ..... | 7-[(2-Thienyl) acetamido]-3-(1-pyridylmethyl)-3-cephem-4-carboxylic acid betaine |
| C.6 | Chlormezanone ..... | 2-(4-chlorophenyl)-3-methyl-4-methathiazanone-1,1-dioxide: Chlormethazone: Chlormethazanone |
| C.7 | Chloromethapyrilene ..... | N,N-dimethyl-N′-(2-pyridyl)-N′-(5-chloro-2-thenyl)-ethylenediamine: Chlorothen |
| C.8 | Chlorphentermine ..... | 4-Chloro-*α*,*α*-dimethylphenethylamine |
| C.9 | Cinchocaine ..... | 2-butoxy-N-(2-diethylaminoethyl) cinchoninamide: Dibucaine |
| C.10 | Cinchophen ..... | 2-phenylquinoline-4-carboxylic acid: Quinophan |
| C.11 | Clofibrate ..... | Ethyl 2-(*p*-chlorophenoxy)-2-methylpropionate |
| C.12 | Clomiphene ..... | 1-Chloro-2-[4-(2-diethylamino-ethoxy)phenyl]-1,2-diphenylethylene: 2-[*p*-(2-Chloro-1,2-diphenylvinyl)phenoxy] triethylamine |
| D.1 | Desipramine ..... | 5-(3-Methylaminopropyl)-10,11-dihydro-5H-dibenz[b,f]azepine |
| D.2 | Diazepam ..... | 7-Chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one |
| D.3 | Diethylpropion ..... | 1-phenyl-2-diethylaminopropanone-1 |
| D.4 | Diphenidol ..... | 1,1-Diphenyl-4-piperidinobutan-1-ol |
| D.5 | Disulfiram ..... | Tetraethylthiuram disulphide |
| E.1 | Ectylurea ..... | 2-ethyl-*cis*-crotonylurea |
| E.2 | Emylcamate ..... | 1-Ethyl-1-methylpropyl carbamate |
| E.3 | Ethacrynic Acid ..... | [2,3-Dichloro-4-(2-methylenebutyryl) phenoxy] acetic acid: 2,3-Dichloro-4-(2-ethylacryloyl) phenoxyacetic acid |
| E.4 | Ethchlorvynol ..... | 3-(2-chlorovinyl)-1-pentyn-3-ol |
| E.5 | Ethinamate ..... | 1-ethynylcyclohexyl carbamate |

| Item No. | Proper Names | Chemical Names and Synonyms |
|---|---|---|
| E.6 | Ethionamide ..... | 2-Ethylisonicotinthioamide |
| E.7 | Ethomoxane ..... | 2-*n*-Butylaminomethyl-8-ethoxy-benzo-1,4-dioxan |
| E.8 | Ethyl Trichloramate ..... | Ethyl *n*-[1-(2,2,2,-trichloro-1-hydroxyethyl)] carbamate |
| E.9 | Etryptamine ..... | 3-(2-Aminobutyl) indole |
| E.10 | Etymemazine ..... | 10-(3-Dimethylamino-2-methylpro-pyl)-2-ethylphenothiazine |
| F.1 | Fluphenazine ..... | 10-{3-[4-(2-Hydroxyethyl) piperazin-1-yl] propyl}-2-tri-fluoromethylphenothiazine |
| F.2 | Furosemide ..... | 4-Chloro-N-furfuryl-5-sulphamoylanthranilic acid: Frusemide (B.A.N.) |
| G.1 | Glyburide ..... | 5-chloro-N-[2-[4-[[[(cyclohexylamino carbonyl]amino]sulfonyl]phenyl]ethyl]-2-methoxy benzamide: 1-4[4-[2-(5-chloro-2-methoxybenzamido)ethyl]phenyl-sulfonyl]-3-cyclohexylurea: Glibenclamide |
| H.1 | Haloperidol ..... | 4-(4-Chlorophenyl)-1-[3-(4-fluorobenzoyl) propyl]-piperidin-4-ol: 4-[4-(*p*-Chlorophenyl)-4-hydro-xypiperidino]-4'-fluorobutyro-phenone |
| H.2 | Hydroxychloroquine ..... | 7-Chloro-4[4-(N-ethyl-N-2-hydro-xyethylamino)-1-methylbutyl-amino] quinoline |
| H.3 | Hydroxyzine ..... | 1-(*p*-chloro-*α*-phenylbenzyl)-4-(2-hydroxy ethoxyethyl) piperazine |
| I.1 | Idoxuridine ..... | 5-Iodo-2′-deoxyuridine |
| I.2 | Imipramine ..... | 5-(3-dimethylaminopropyl)-10,11-dihydro-5H-dibenz[b,f]azepine |
| I.3 | Indomethacin ..... | 1-(*p*-Chlorobenzoyl)-5-methoxy-2-methyl-indole-3-acetic acid |
| I.4 | Iproniazid ..... | 1-isonicotinoyl-2-isopropylhydrazine |
| I.5 | Isocarboxazid ..... | 3-N-Benzylhydrazinocarbonyl-5-methylisoxazole |
| I.6 | Isoproterenol ..... | 3,4-Dihydroxy-*α*-[isopropylamino) methyl] benzyl alcohol: Isoprenaline |
| L.1 | Liothyronine ..... | L-*α*-Amino-3-[(4-hydroxy-3-iodophenoxy)-3,5-di-iodo-phenyl] propionic acid |
| M.1 | Mefenamic acid ..... | N-(2,3-Xylyl)-anthranilic acid |
| M.2 | Melphalan ..... | 4-Di-(2-chlorethyl)amino-L-phenylalanine |
| M.3 | Mepazine ..... | 10-[(1-methyl-3-piperidyl) methyl] phenothiazine |
| M.4 | Mephenesin ..... | 3-o-toloxy-1,2-propanediol |
| M.5 | Mephenoxalone ..... | 5-(o-Methoxyphenoxymethyl)-2-oxazolidinone |
| M.6 | Meprobamate ..... | 2,2-di(carbamoylmethyl) pentane |
| M.7 | Methaqualone ..... | 2-Methyl-3-o-tolyquinazolin-4-one: 2-Methyl-3-o-tolyl-4-quinazolone |
| M.8 | Methisazone ..... | 1-Methylindoline-2,3-dione-3-thiosemicarbazone: N-Methylisatin-*ß*-thiosemicarbazone |
| M.9 | Methotrimeprazine | 10-[3-(2-Methyl)dimethylamino propyl]-2- |

| Item No. | Proper Names | Chemical Names and Synonyms |
|---|---|---|
| | ..... | methoxyphenothiazine: Levomepromazine |
| M.10 | Methyldopa ..... | 1-3(3,4-Dihydroxyphenyl)-2-methylalanine |
| M.11 | Methylparafynol ..... | 3-methyl-1-pentyn-3-ol: Methylpentynol |
| M.12 | Methylphenidate ..... | Methyl-1-phenyl-1-(2-piperidyl) acetate |
| M.13 | Methyprylon ..... | 3,3-diethyl-5-methyl-2,4-piperidinedione |
| M.14 | Methysergide ..... | 1-(Hydroxymethyl)propylamide of 1-methyl-*d*-lysergic acid |
| M.15 | Metyrapone ..... | 2-Methyl-1,2-di(3-pyridyl)propan-1-one |
| N.1 | Nalidixic Acid ..... | 1-Ethyl-7-methyl-4-oxo-1,8-naphthyridine-3-carboxylic acid |
| N.2 | Nialamide ..... | 1-[2-(benzycarbamyl)ethyl]-2-isonicotinoyl-hydrazine |
| N.3 | Nortriptyline ..... | 3-(3-Methylaminopropylidene)-1,2, 4,5-dibenzocyclohepta-1,4-diene |
| O.1 | Oxanimide ..... | 2-ethyl-3-propyl-glycidamide |
| O.2 | Oxazepam ..... | 7-Chloro-1,3-dihydro-3-hydroxy-5-phenyl-1,4-benzodiazepin-2-one |
| O.3 | Oxyphenbutazone ..... | 4-*n*-Butyl-2-(4-hydroxyphenyl)-1-phenyl-pyrazolidine-3,5-dione |
| P.1 | Paramethadione ..... | 3,5-dimethyl-5-ethyl-2,4-oxazolidinedione |
| P.2 | Pargyline ..... | N-Benzyl-N-methylprop-2-ynylamine |
| P.3 | Pemoline ..... | 2-Imino-5-phenyloxazolidin-4-one |
| P.4 | Pentazocine ..... | 1,2,3,4,5,6-Hexahydro-8-hydroxy-6,11-dimethyl-3-(3-methylbut-2-enyl)-2,6-methano-3-benzazocine: 1,2,3,4,5,6-Hexahydro-6,11-dimethyl-3-(3-methyl-2-butenyl)-2,6-methano-3-benzazocin-8-ol |
| P.5 | Pentolinium Tartrate ..... | NN′-Pentamethylenedi-(methylpryrrolidinium hydrogen, tartrate) |
| P.6 | Perphenazine ..... | 2-chloro-10-{3-[1-(2-hydroxyethyl)-4-piperazinyl]propyl} phenothiazine |
| P.7 | Phacetoperane ..... | *l*-1-Phenyl-1(2′-piperidyl)-1-acetoxymethane |
| P.8 | Phenacemide ..... | (Phenylacetyl)urea |
| P.9 | Phenacetin ..... | *p*-acetphenetidin: Acetphenetidin: Acetophenetidin: *p*-ethoxyacetanilid |
| P.10 | Phenaglycodol ..... | 2-*p*-chlorophenyl-3-methyl-2,3-butanediol |
| P.11 | Phendimetrazine ..... | 3,4-Dimethyl-2 Phenylmorpholine |
| P.12 | Phenelzine ..... | 2-phenylethylhydrazine |
| P.13 | Phenformin ..... | N′-*ß*-phenethylformamidinyliminourea |
| P.14 | Pheniprazine ..... | *α*-Methylphenethylhydrazine |
| P.15 | Phenmetrazine ..... | Tetrahydro-3-methyl-2-phenyl-1,4-oxazine: 3-methyl-2-phenylmorpholine |
| P.16 | Phentermine ..... | *α*, *α*-Dimethylphenethylamine: phenyl-*tert*-butylamine |
| P.17 | Phenylindanedione ..... | 2-phenylindane-1,3-dione |

| Item No. | Proper Names | Chemical Names and Synonyms |
|---|---|---|
| P.18 | Phenyltoloxamine ..... | N,N-dimethyl-2-(*α*-phenyl-o-tolyloxy) ethylamine |
| P.19 | Pholedrine ..... | *p*-(4-hydroxyphenyl)-isopropylmethylamine |
| P.20 | Piperliate ..... | 1-piperidine-ethanol benzilate |
| P.21 | Pipradol ..... | Diphenyl-2-piperidylmethanol |
| P.22 | Prochlorperazine ..... | 2-Chloro-10-[3-(1-methyl-4-piperazinyl) propyl]phenothiazine |
| P.23 | Prodilidine ..... | 1,2-Dimethyl-3-phenyl-3-pyrrolidinyl propionate |
| P.24 | Propranolol ..... | 1-(Isopropylamino)-3-(1-naphthyloxy)-2-propanol |
| P.25 | Prothipendyl ..... | 9-(3-Dimethylaminopropyl)-10-thia-1,9-diaza-anthracene |
| P.26 | Protriptyline ..... | 7-(3-Methylaminopropyl)-1,2:5,6-dibenzocycloheptatrien: N-Methyl-5H-dibenzo [*a, d*] cycloheptene-5-propylamine |
| P.27 | Pyrazinamide ..... | Pyrazinoic acid amide |
| R.1 | Rifampin ..... | 3-{[(4-methyl-1-piperazinyl)imino]methyl} rifamycin SV : Rifampicin (I.N.N.) (Rifamycin SV is an antibiotic produced by *Streptomyces mediterranei*) |
| S.01 | Sodium Cromoglycate ..... | 4H-1-Benzopyran-2-carboxylic acid, 5,5′-[(2-hydroxy-1,3-propanediyl) bis(oxy)]bis[4-oxo-,disodium salt]: Disodium 5,5′-(2-hydroxytrimethylenedioxy) bis[4-oxo-4H-1-benzopyran-2- carboxylate]: Disodium 4,4′-dioxo-5,5′-(2-hydroxytrimethylenedioxy)di (chromene-2-carboxylate): Cromolyn Sodium (USP): Disodium Cromoglycate |
| S.1 | Sulfameter ..... | 2-(4-Aminobenzenesulphonamido)-5-methoxypyrimidine: N′-(5-methoxy-2-pyrimidinyl) sulfanilamide: Sulfamethoxydiazine (B.A.N.) |
| S.2 | Sulfamethazine ..... | N′-(4,6-dimethyl-2- pyrimidyl)sulfanilamide: 2-(*p*-aminobenzenesulphonamide)-4,6-dimethylpyrimidine: sulphadimedine |
| S.3 | Sulfinpyrazone ..... | 1,2-diphenyl-4-(2-phenylsulfinilethyl)-3,5-pyrazolidinedione |
| S.4 | Sulfisoxazole ..... | 3,4-dimethyl-5-sulfanilamidoisoxazole: Sulphafurazole |
| T.1 | Tetracaine ..... | 2-dimethylaminoethyl-*p*-*n*- butylaminobenzoate: Amethocaine |
| T.2 | Thiethylperazine ..... | 2-Ethylthio-10-[3-(4- methylpiperazin-1-yl) propyl]phenothiazine |
| T.3 | Thiopropazate ..... | 2-chloro-10-[3-[1-(2-acetoxyethyl)-4-piperazinyl] propyl]phenothiazine |
| T.4 | Thioproperazine ..... | 2-Dimethylsulphamoyl-10-[3-(4-methylpiperazin-1-yl)-propyl]phenothiazine |
| T.5 | Thioridazine ..... | 10-{2-[2-(1-methylpiperidyl)] ethyl *α*}-2-methylthiopheno-thiazine |
| T.6 | Tranylcypromine ..... | *Trans d*, 1-2-phenylcyclopropyl- amine |
| T.7 | Triamterene ..... | 2,4,7-Triamino-6-phenylpteridine |
| T.8 | Triflupromazine ..... | 10-(3-dimethylaminopropyl)-2-trifluoromethylphenothiazine: Fluopremazine |

| Item No. | Proper Names | Chemical Names and Synonyms |
|---|---|---|
| T.9 | Trimeprazine ..... | 10-(3-dimethylamino-2-methylpropyl) phenothiazine |
| T.10 | Trimethadione ..... | 3,5,5-trimethyl-2,4-oxazolidine- dione: Troxidone |
| T.11 | Trimipramine ..... | 5-(3-Dimethylamino-2-methylpropyl)-10,11-dihydro-5H-dibenz[b,f]azepine: 5-(3′-Dimethylamino-2′-methylpropyl)iminodibenzyl |
| T.12 | Tybamate ..... | 2-Methyl-2-propyltrimethylene butylcarbamate carbamate: 2-(Hydroxymethyl)-2-methyl-pentyl butylcarbamate carbamate |
| V.1 | Vinblastine ..... | An alkaloid derived from *Vinca rosea* |
| V.2 | Vincristine ..... | An alkaloid derived from *Vinca rosea* |

SOR/87-565, s. 1; SOR/88-182, s. 1; SOR/88-482, s. 1(F); SOR/90-173, s. 1(F).

C.01.003. No person shall sell a drug that is not labelled as required by these Regulations.

SOR/80-544, s. 1.

C.01.004. (1) The inner and outer labels of a drug shall show

(*a*) on the principal display panel

(i) the proper name, if any, of the drug which, if there is a brand name for the drug, shall immediately precede or follow the brand name in type not less than one-half the size of that of the brand name,

(ii) if there is no proper name, the common name of the drug,

(iii) where a standard for the drug is prescribed in Division 6 of this Part, a statement that the drug is a Canadian Standard Drug, for which the abbreviation C.S.D. may be used,

(iv) where a standard for the drug is not prescribed in Division 6 of this Part but is contained in a publication mentioned in Schedule B to the Act, the name of the publication containing the standard used or its abbreviation as provided in Schedule B or, if a manufacturer's standard is used, a statement setting forth the fact that such a standard is used, and

(v) in both official languages, the notation "sterile"stérile if the drug is required to be sterile by these Regulations;

(*b*) on the upper left quarter of the principal display panel

(i) the symbol **Pr** in the case of a drug required by this Part or Part D to be sold on prescription, but in no other case shall the symbol **Pr** appear on the label of a drug,

(ii) the symbol [*]"C" in a clear manner and a conspicuous colour and size, in the case of a controlled drug, other than a controlled drug contained in an agricultural implant and set out in Part III of the schedule to Part G,

[*]Small graphic is not displayed.

(iii) the symbol "N" in a colour contrasting with the rest of the label or in type not less than half the size of any letters used thereon, in the case of a narcotic as defined in the Narcotic Control Regulations, and

(iv) in the case of a targeted substance as defined in subsection 1(1) of the Benzodiazepines and Other Targeted Substances Regulations, the following symbol in a colour contrasting with the rest of the label and in type not less than half the size of any other letter used on the main panel, namely,

GRAPHIC IS NOT DISPLAYED, SEE SOR/2000-219, S. 1

(*c*) on any panel

(i) the name and address of the manufacturer of the drug,

(ii) the lot number of the drug,

(iii) adequate directions for use of the drug,

(iv) a quantitative list of the medicinal ingredients of the drug by their proper names or, if they have no proper names, by their common names,

(v) the expiration date of the drug, and

(vi) in the case of a new drug for extraordinary use in respect of which a notice of compliance has been issued under section C.08.004.01, the following statement, displayed in capital letters and in a legible manner:

“HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS EXTRAORDINARY USE NEW DRUG FOR [naming purpose] BASED ON LIMITED CLINICAL TESTING IN HUMANS.

SANTÉ CANADA A AUTORISÉ LA VENTE DE CETTE DROGUE NOUVELLE POUR USAGE EXCEPTIONNEL AUX FINS DE [indication de la fin] EN SE FONDANT SUR DES ESSAIS CLINIQUES RESTREINTS CHEZ L’ÊTRE HUMAIN.”.

(2) In addition to the requirements of subsection (1), the outer label of a drug shall show

(*a*) the net amount of the drug in the container in terms of weight, measure or number;

(*b*) in the case of a drug intended for parenteral use, a quantitative list of any preservatives present therein by their proper names or, if they have no proper names, by their common names; and

(*c*) in the case of a drug for human use that contains mercury or a salt or derivative thereof as a preservative, a quantitative list of all mercurial preservatives present therein by their proper names or, if they have no proper names, by their common names.

(3) Where the container of a drug is too small to accommodate an inner label that conforms to the requirements of these Regulations, the inner label requirements of these Regulations do not apply to the drug in that container if

(*a*) there is an outer label that complies with the labelling requirements of these Regulations; and

(*b*) the inner label shows

(i) the proper name of the drug, the common name of the drug if there is no proper name or, in the case of a drug with more than one medicinal ingredient, the brand name of the drug,

(ii) the potency of the drug except where, in the case of a drug with more than one medicinal ingredient, the name used pursuant to subparagraph (i) for that drug is unique for a particular potency of the drug,

(iii) the net contents of the drug if it is not in a discrete dosage form,

(iv) the route of administration of the drug if other than oral,

(v) the lot number of the drug,

(vi) the name of the manufacturer of the drug,

(vii) the expiration date of the drug, and

(viii) the identification of special characteristics of the dosage form if they are not evident from the name of the drug under subparagraphs (i) or (ii).

(4) [Repealed, SOR/92-654, s. 2]

(5) This section does not apply to

(*a*) a drug sold to a drug manufacturer; or

(*b*) a drug dispensed pursuant to a prescription, if its label carries suitable directions for use and complies with the requirements of section C.01.005.

SOR/80-543, s. 2; SOR/81-334, s. 1(E); SOR/85-715, s. 2; SOR/89-229, s. 1; SOR/90-216, s. 1; SOR/90-586, s. 1; SOR/92-654, s. 2; SOR/93-202, s. 2; SOR/97-228, s. 1; SOR/97-515, s. 1; SOR/2000-219, s. 1; SOR/2001-181, s. 4; SOR/2011-88, s. 1.

Previous Version

C.01.004.1 (1) No person shall import a drug in dosage form into Canada for the purpose of sale unless they have in Canada a person who is responsible for the sale of the drug.

(2) No person who imports a drug in dosage form into Canada shall sell any lot or batch of the drug unless the name of the person who imports it, and the address of the principal place of business in Canada of the person responsible for its sale, appears on the inner and outer labels of the drug.

SOR/82-524, s. 1; SOR/93-475, s. 1; SOR/97-12, s. 2.

C.01.005. (1) The principal display panel of both the inner and outer label of a drug sold in dosage form shall show in a clear and legible manner the drug identification number assigned by the Director for that drug pursuant to subsection C.01.014.2(1), preceded by the words “Drug Identification Number” or Drogue : identification numérique or both, or the letters “DIN”.

(2) Subsection (1) does not apply to a drug

(*a*) compounded by a pharmacist pursuant to a prescription or by a practitioner; or

(*b*) sold pursuant to a prescription, where the label of that drug indicates:

(i) the proper name, the common name or the brand name of the drug,

(ii) the potency of the drug, and

(iii) the name of the manufacturer of the drug.

(3) For the purposes of this section and section C.01.014, “a drug in dosage form” means a drug in a form in which it is ready for use by the consumer without requiring any further manufacturing.

(4) and (5) [Repealed, SOR/81-248, s. 1]

SOR/81-248, s. 1; SOR/93-202, s. 3; SOR/98-423, s. 2; SOR/2001-181, s. 4.

C.01.006. Where a package of a drug has only one label, that label shall contain all the information required by these Regulations to be shown on both the inner and the outer labels.

C.01.007. No reference, direct or indirect, to the Act or to these Regulations shall be made upon any label of or in any advertisement for a drug unless such reference is a specific requirement of the Act or these Regulations.

C.01.008. [Repealed, SOR/80-544, s. 2]

C.01.009. Where by any statute of the Parliament of Canada or any regulation made thereunder a standard or grade is prescribed for a drug and that standard is given a name or designation by such statute or regulation, no person shall on a label of or in any advertisement for that drug use that name or designation unless the drug conforms with the standard or grade.

C.01.010. Where it is necessary to provide adequate directions for the safe use of a parenteral drug or Schedule F drug that is used in the treatment or prevention of any disease, disorder or abnormal physical state mentioned in Schedule A to the Act, such diseases, disorders or abnormal physical state may be mentioned on the labels and inserts accompanying that drug and to such extent, that drug is hereby exempted from the provisions of section 3 of the Act.

C.01.011. (1) A drug referred to in subsection 10(2) of the Act shall be exempt from the standard for any drug contained in any publication mentioned in Schedule B to the Act to the extent that such drug differs from that standard with respect to colour, flavour, shape and size, if such difference does not interfere with any method of assay prescribed in any such publication.

(2) [Repealed, SOR/93-243, s. 2]

(3) Where a manufacturer’s standard is used for a drug, the manufacturer shall make available to the Director, on request, details of that standard and of a method of analysis for the drug acceptable to the Director.

(4) No person shall use a manufacturer’s standard for a drug that provides

(*a*) a lesser degree of purity than the highest degree of purity, or

(*b*) a greater variation in potency than the least variation in potency,

provided for that drug in any publication mentioned in Schedule B to the Act.

SOR/93-243, s. 2.

C.01.012. A manufacturer who makes representations on a label of a drug in oral dosage form, or in any advertisement, with respect to the site, rate or extent of release to the body of a

medicinal ingredient of the drug, or the availability to the body of a medicinal ingredient of the drug, shall

(*a*) before making the representations, conduct such investigations, using an acceptable method, as may be necessary to demonstrate that the site, rate or extent of release to the body of the medicinal ingredient of the drug and the availability to the body of the medicinal ingredient of the drug, correspond to the representations; and

(*b*) on request submit the record of such investigations to the Director.

SOR/89-455, s. 2; SOR/94-36, s. 1.

C.01.013. (1) Where the manufacturer of a drug is requested in writing by the Director to submit on or before a specified day evidence with respect to a drug, the manufacturer shall make no further sales of that drug after that day unless he has submitted the evidence requested.

(2) Where the Director is of the opinion that the evidence submitted by a manufacturer, pursuant to subsection (1), is not sufficient, he shall notify the manufacturer in writing that the evidence is not sufficient.

(3) Where, pursuant to subsection (2), a manufacturer is notified that the evidence with respect to a drug is not sufficient, he shall make no further sales of that drug unless he submits further evidence and is notified in writing by the Director that that further evidence is sufficient.

(4) A reference in this section to evidence with respect to a drug means evidence to establish the safety of the drug under the conditions of use recommended and the effectiveness of the drug for the purposes recommended.

## Assignment and Cancellation of Drug Identification Numbers

C.01.014. (1) No manufacturer shall sell a drug in dosage form unless a drug identification number has been assigned for that drug and the assignment of the number has not been cancelled pursuant to section C.01.014.6.

(2) Subsection (1) does not apply in respect of a drug listed in Schedule C to the Act, whole blood and its components, or a medicated feed as defined in section 2 of the Feeds Regulations, 1983.

SOR/81-248, s. 2; SOR/97-12, s. 3.

C.01.014.1. (1) A manufacturer of a drug, a person authorized by a manufacturer or, in the case of a drug to be imported into Canada, the importer of the drug may make an application for a drug identification number for that drug.

(2) An application under subsection (1) shall be made to the Director in writing and shall set out the following information:

(*a*) the name of the manufacturer of the drug as it will appear on the label;

(*b*) the pharmaceutical form in which the drug is to be sold;

(*c*) in the case of any drug other than a drug described in paragraph (*d*), the recommended route of administration;

(*d*) in the case of a drug for disinfection in premises, the types of premises for which its use is recommended;

(*e*) a quantitative list of the medicinal ingredients contained in the drug by their proper names or, if they have no proper names, by their common names;

(*f*) the brand name under which the drug is to be sold;

(*g*) whether the drug is for human use, veterinary use or disinfection in premises;

(*h*) the name and quantity of each colouring ingredient that is not a medicinal ingredient;

(*i*) the use or purpose for which the drug is recommended;

(*j*) the recommended dosage of the drug;

(*k*) the address of the manufacturer referred to in paragraph (*a*) and, where the address is outside the country, the name and address of the importer of the drug;

(*l*) the name and address of any individual, firm, partnership or corporation, other than the names and addresses referred to in paragraphs (*a*) and (*k*), that will appear on the label of the drug;

(*m*) the written text of all labels and package inserts to be used in connection with the drug and of any further prescribing information stated to be available on request; and

(*n*) the name and position of the person who signed the application and the date of signature.

(3) In the case of a new drug, a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission filed under section C.08.002, C.08.002.01 or C.08.002.1 shall be regarded as an application for a drug identification number.

SOR/81-248, s. 2; SOR/93-202, s. 4; SOR/98-423, s. 3; SOR/2011-88, s. 2.

Previous Version

C.01.014.2. (1) Subject to subsection (2), if a manufacturer or importer has provided all the information described in subsection C.01.014.1(2) or section C.08.002, C.08.002.01 or C.08.002.1, as the case may be, in respect of a drug, the Director shall issue to the manufacturer or importer a document that

(*a*) sets out

(i) the drug identification number assigned for the drug, preceded by the letters “DIN”, or

(ii) if there are two or more brand names for the drug, the drug identification numbers assigned by the Director for the drug, each of which pertains to one of the brand names and is preceded by the letters “DIN”; and

(*b*) contains the information referred to in paragraphs C.01.014.1(2)(*a*) to (*f*).

(2) Where the Director believes on reasonable grounds that a product in respect of which an application referred to in section C.01.014.1 has been made

(*a*) is not a drug, or

(*b*) is a drug but that its sale would cause injury to the health of the consumer or purchaser or would be a violation of the Act or these Regulations,

he may refuse to issue the document referred to in subsection (1).

(3) Where the Director, pursuant to subsection (2), refuses to issue the document, the applicant may submit additional information and request the Director to reconsider his decision.

(4) On the basis of the additional information submitted pursuant to subsection (3), the Director shall reconsider the grounds on which the refusal to issue the document was made.

SOR/81-248, s. 2; SOR/92-230, s. 1; SOR/98-423, s. 4; SOR/2011-88, s. 3.

Previous Version

C.01.014.3. The manufacturer or importer or person authorized by the manufacturer or importer shall, within 30 days after commencing sale of a drug, date and sign the document issued pursuant to subsection C.01.014.2(1) in respect of the drug and return the document

(*a*) with a confirmation that the information recorded therein is correct;

(*b*) indicating the date on which the drug was first sold in Canada; and

(*c*) accompanied by samples or facsimiles of all labels and package inserts and any further prescribing information stated to be available on request.

SOR/81-248, s. 2; SOR/98-423, s. 5.

C.01.014.4. If the information referred to in subsection C.01.014.1(2) in respect of a drug is no longer correct owing to a change in the subject matter of the information,

(*a*) in the case of a change in the subject matter of any of the information referred to in paragraphs C.01.014.1(2)(*a*) to (*f*)

(i) that occurs prior to the sale of the drug, a new application shall be made, or

(ii) that occurs after the sale of the drug, no further sale of the drug shall be made until a new application for a drug identification number in respect of that drug is made and a number is assigned; and

(*b*) in the case of a change in the subject matter of any of the information referred to in paragraphs C.01.014.1(2)(*g*) to (*k*)

(i) that occurs prior to the sale of the drug, the particulars of the change shall be submitted with the return of the document referred to in section C.01.014.3, or

(ii) that occurs after the sale of the drug, the person to whom the drug identification number in respect of that drug was issued shall, within 30 days of the change, inform the Director of the change.

SOR/81-248, s. 2; SOR/92-230, s. 2; SOR/98-423, s. 6.

C.01.014.5. Every manufacturer of a drug shall, annually before the first day of October and in a form authorized by the Director, furnish the Director with a notification signed by the

manufacturer or by a person authorized to sign on his behalf, confirming that all the information previously supplied by the manufacturer with respect to that drug is correct.

SOR/81-248, s. 2.

C.01.014.6. (1) The Director shall cancel the assignment of a drug identification number for a drug where

(*a*) the person to whom the number was assigned advises that the sale or import of the drug has been discontinued;

(*b*) the drug is a new drug in respect of which the notice of compliance has been suspended pursuant to section C.08.006; or

(*c*) it has been determined that the product in respect of which the number was assigned is not a drug.

(2) The Director may cancel the assignment of a drug identification number for a drug where

(*a*) the manufacturer of the drug has failed to comply with section C.01.014.5; or

(*b*) the manufacturer to whom the number was assigned has been notified pursuant to section C.01.013 that the evidence he submitted in respect of the drug is insufficient.

SOR/81-248, s. 2.

C.01.014.7. Where a person who has been assigned a drug identification number for a drug discontinues sale of the drug in Canada, he shall, within 30 days of such discontinuation, inform the Director that he is no longer selling the drug.

SOR/81-248, s. 2.

## Tablet Disintegration Times

C.01.015. (1) Subject to subsection (2), no person shall sell for human use a drug in the form of a tablet that is intended to be swallowed whole unless, when tested by the official method DO-25, Determination of the Disintegration Time of Tablets, dated July 5, 1989,

(*a*) in the case of an uncoated tablet, the tablet disintegrates in not more than 45 minutes;

(*b*) in the case of a plain coated tablet, the tablet disintegrates in not more than 60 minutes; and

(*c*) in the case where the label of the drug indicates that the tablet carries an enteric coating or a coating designed to serve a purpose similar to that of an enteric coating, the tablet does not disintegrate when exposed for 60 minutes to simulated gastric fluid, but when it is subsequently exposed for a continuous period to simulated intestinal fluid, the tablet disintegrates in not more than 60 minutes.

(2) Subsection (1) does not apply in respect of a drug in the form of a tablet where

(*a*) a notice of compliance in respect of the drug in the form of a tablet has been issued under section C.08.004 or C.08.004.01;

(*b*) [Repealed, SOR/98-423, s. 7]

(*c*) a dissolution or disintegration test for the drug in the form of a tablet is prescribed in Division 6 of this Part;

(*d*) the drug is labelled as complying with a standard contained in a publication referred to in Schedule B to the Act;

(*e*) the drug has been demonstrated by an acceptable method to be available to the body; or

(*f*) representations regarding the drug are made on its label, or in any advertisement, with respect to the site, rate or extent of release to the body of a medicinal ingredient of that drug, or the availability to the body of a medicinal ingredient of that drug.

SOR/89-429, s. 2; SOR/89-455, s. 3; SOR/94-36, s. 2; SOR/98-423, s. 7; SOR/2011-88, s. 4.

Previous Version

## Prohibition

C.01.016. No manufacturer shall sell a drug unless the manufacturer complies with the conditions set out in sections C.01.017 to C.01.019.

SOR/95-521, s. 2; SOR/2011-31, s. 1.

Previous Version

## Serious Adverse Drug Reaction Reporting

C.01.017. The manufacturer shall submit to the Minister a report of all information relating to the following serious adverse drug reactions within 15 days after receiving or becoming aware of the information, whichever occurs first:

(*a*) any serious adverse drug reaction that has occurred in Canada with respect to the drug; and

(*b*) any serious unexpected adverse drug reaction that has occurred outside Canada with respect to the drug.

SOR/95-521, s. 2; SOR/2011-31, s. 1.

Previous Version

## Annual Summary Report and Case Reports

C.01.018. (1) The manufacturer shall prepare an annual summary report of all information relating to adverse drug reactions and serious adverse drug reactions to the drug that it received or became aware of during the previous 12 months.

(2) The annual summary report shall contain a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions to the drug.

(3) In preparing the annual summary report, the manufacturer shall determine, on the basis of the analysis referred to in subsection (2), whether there has been a significant change in what is known about the risks and benefits of the drug during the period covered by the report and shall include its conclusions in this regard in the summary report.

(4) If, in preparing the annual summary report, the manufacturer concludes that there has been a significant change, it shall notify the Minister without delay, in writing, unless this has already been done.

(5) The Minister may, for the purposes of assessing the safety and effectiveness of the drug, request in writing that the manufacturer submit to the Minister one or both of the following:

(*a*) the annual summary reports;

(*b*) the case reports relating to the adverse drug reactions and serious adverse drug reactions to the drug that are known to the manufacturer.

(6) The Minister shall, after giving the manufacturer an opportunity to be heard, specify a period for the submission of the annual summary reports or case reports, or both, that is reasonable in the circumstances, and the manufacturer shall submit the reports within that period.

SOR/2011-31, s. 1.

Previous Version

## Issue-related Summary Report

C.01.019. (1) The Minister may, for the purposes of assessing the safety and effectiveness of the drug, request in writing that the manufacturer submit to the Minister an issue-related summary report.

(2) The report shall contain a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions to the drug, as well as case reports of all or specified adverse drug reactions and serious adverse drug reactions to the drug that are known to the manufacturer in respect of the issue that the Minister directs the manufacturer to analyze in the report.

(3) The Minister shall, after giving the manufacturer an opportunity to be heard, specify a period for the submission of the report that is reasonable in the circumstances. The Minister may specify a period that is shorter than 30 days if the Minister needs the information in the report to determine whether the drug poses a serious and imminent risk to human health.

(4) The manufacturer shall submit the report within the specified period.

SOR/2011-31, s. 1.

## Maintenance of Records

C.01.020. (1) The manufacturer shall maintain records of the reports and case reports referred to in sections C.01.017 to C.01.019.

(2) The manufacturer shall retain the records for 25 years after the day on which they were created.

SOR/2011-31, s. 1.

## Limits of Drug Dosage

C.01.021. Except as provided in these Regulations, no person shall sell a drug for human use listed in the following table unless both the inner and the outer labels other than the inner label of a single dose container carry a statement of

(*a*) the quantitative content of the drug,

(*b*) the recommended single and daily adult dose designated as such, except for

(i) preparations solely for external use, or

(ii) preparations solely for children's use; and

(*c*) adequate directions for use when the drug is recommended for children which shall be either

(i) the statement "CHILDREN: As directed by the physician", or

(ii) a suitable reduced maximum single and daily dose which shall not exceed the following:

*Age in years* *Proportion of adult dose*

| | |
|---|---|
| 10 - 14 | one-half |
| 5 - 9 | one-fourth |
| 2 - 4 | one-sixth |

under 2 years as directed by physician

TABLE

TABLE OF LIMITS OF DRUG DOSAGE FOR ADULTS

| Item | External Use | Internal Use | |
|---|---|---|---|
| | — | — | |
| | Maximum Limit | Maximum Dosage Unless otherwise stated, doses are in milligrams | |
| | Per cent | Single | Daily |
| Acetaminophen ..... | — | 650 | 4.0 g |
| Acetanilide and derivatives (except N-Acetyl-*ρ*-amino phenol) ..... | — | 65 | 195 |
| Acetylsalicylic Acid ..... | — | 650 | 4.0 g |
| Aconitine, its preparations and derivatives ..... | 0.2 | 0.1 | 0.1 |
| Adonis vernalis ..... | — | 65 | 195 |
| Amylocaine, its salts and derivatives when sold or recommended for opthalmic use ..... | 0.0 | 0.0 | 0.0 |
| Amylocaine Hydrochloride, except when sold or recommended for ophthalmic use ..... | 1.0 | 0.0 | 0.0 |
| Antimony, compounds of ..... | — | 3.3 | 13 |
| Atropine, Methylatropine, and their salts ..... | 1.0 | 0.13 | 0.44 |
| Belladonna and its preparations, on the basis of belladonna alkaloids ..... | 0.375 | 0.13 | 0.44 |
| Benzene (Benzol) ..... | — | — | — |
| Benzocaine ..... | 8.0 | 195 | 585 |
| Beta-Naphthol ..... | — | 195 | 585 |

| Item | External Use | Internal Use | |
|---|---|---|---|
| | — | — | |
| | Maximum Limit | Maximum Dosage Unless otherwise stated, doses are in milligrams | |
| | Per cent | Single | Daily |
| Butacaine, its salts and derivatives when sold or recommended for ophthalmic use ..... | 0.0 | 0.0 | 0.0 |
| Butacaine Sulphate, except when sold or recommended for opthalmic use ..... | 1.0 | 0.0 | 0.0 |
| Cadexomer Iodine ..... | 0.0 | 0.0 | 0.0 |
| Cantharides, cantharidin, and their preparations, on the basis of cantharidin, except blisters ..... | 0.03 | 0.0 | 0.0 |
| Cantharides, blisters only ..... | 0.2 | 0.0 | 0.0 |
| Cedar Oil ..... | 25.0 | 0.0 | 0.0 |
| Chlorbutol (not more often than every 4 hours) ..... | — | 325 | 975 |
| Choline Salicylate ..... | — | 870 | 5.22 g |
| Cinchocaine Hydrochloride, except suppositories ..... | 1.0 | 0.0 | 0.0 |
| Cinchocaine Hydrochloride, suppositories only ..... | — | 11 | 11 |
| Colchicine and its salts ..... | — | 0.55 | 1.65 |
| Colchicum and its preparations, on the basis of colchicine ..... | — | 0.27 | 0.81 |
| Croton Oil ..... | 10.0 | 0.0 | 0.0 |
| Cyproheptadine and its salts—when sold or recommended for the promotion of weight gain | — | 0.0 | 0.0 |
| Ephedrine and its salts ..... | — | 11 | 32.5 |
| Ephedrine and its salts, sprays ..... | 1.0 | — | — |
| Epinephrine and its salts, sprays ..... | 1.0 | — | — |
| Gelseminine (Gelsemine) and its salts (not to be repeated within 4 hours) ..... | — | 0.55 | 1.65 |
| Gelsemium and its preparations, on the basis of the crude drug ..... | — | 16.2 | 48.6 |
| Hydrocyanic (Prussic) Acid as 2 per cent solution ..... | — | 0.062 ml | 0.31 ml |
| Hydroquinone ..... | 2.0 | — | — |
| Hyoscine (Scopolamine) and its salts ..... | 0.5 | 0.325 | 0.975 |
| Hyoscine aminoxide hydrobromide ..... | 0.5 | 0.325 | 0.975 |
| Hyoscyamine and its salts ..... | — | 0.325 | 0.975 |
| Hyoscyamus and its preparations, on the basis | — | 0.073 | 0.22 |

| Item | External Use | Internal Use | |
|---|---|---|---|
| | — | — | |
| | Maximum Limit | Maximum Dosage Unless otherwise stated, doses are in milligrams | |
| | Per cent | Single | Daily |
| of hyoscyamus alkaloids ..... | | | |
| Lobelia and its preparations, on the basis of the crude drug ..... | — | 130 | 390 |
| Lobeline and its salts ..... | — | 2.0 | 6.0 |
| Magnesium Salicylate ..... | — | 650 | 4.0 g |
| Methyl Salicylate ..... | 30 | — | — |
| Methylene Blue ..... | — | 130 | 390 |
| Phenacetin ..... | — | 650 | 1.95 g |
| Phenazone and compounds thereof ..... | — | 325 | 975 |
| Phenol ..... | 2.0 | 32.5 | 260 |
| Phenylpropanolamine when sold or recommended as an appetite depressent ..... | — | 0.0 | 0.0 |
| Phosphorus ..... | — | 0.0 | 0.0 |
| Podophyllin ..... | 0.0 | 0.0 | 0.0 |
| Potassium Chlorate ..... | — | 325 | 975 |
| Potassium Chlorate, gargle ..... | 2.5 | — | — |
| Procaine and its salts ..... | — | — | — |
| Proxymetacaine, its salts and derivatives when sold or recommended for ophthalmic use ..... | 0.0 | 0.0 | 0.0 |
| Salicylamide ..... | — | 975 | 2.925 g |
| Santonin ..... | — | 65 | 130 |
| Selenium and its compounds ..... | 2.5 | 0.0 | 0.0 |
| Sodium Chlorate ..... | — | 325 | 975 |
| Sodium Fluoride ..... | — | 0.1 | 0.1 |
| Sodium Salicylate ..... | — | 650 | 4.0 g |
| Squill and its preparations, on the basis of crude drug ..... | — | 32.5 | 97.5 |
| Stramonium and its preparations, on the basis of stramonium alkaloids ..... | — | 0.16 | 0.65 |
| Strychnine and its salts ..... | — | 0.0 | 0.0 |
| Tannic Acid ..... | — | 150 | 1 000 |
| Tetracaine, its salts and derivatives when sold or recommended for ophthalmic use ..... | 0.0 | 0.0 | 0.0 |
| Thiocyanates ..... | 0.0 | 0.0 | 0.0 |
| Urethane ..... | 0.0 | 0.0 | 0.0 |

Where drugs having similar physiological actions occur in combination, the dosage of each shall be proportionately reduced.

Accurate dosagesmay be expressed in either metric units or imperial units. If the dosage is expressed in both systems, then an approximation may be used for one expression, but such approximation must precede or follow the accurate statement by which the product will be judged and must be in brackets.

SOR/78-422, s. 1; SOR/80-544, s. 3; SOR/84-145, s. 1; SOR/85-715, s. 3; SOR/85-966, s. 2; SOR/88-94, s. 1; SOR/89-229, s. 2; SOR/89-548, s. 1.

C.01.022. Notwithstanding paragraph C.01.021(*b*), the recommended single and daily dosage of a drug

(*a*) intended to be burned and the smoke inhaled may be increased to 10 times the oral dose, and

(*b*) intended for use as suppositories may be increased to 33 1/3 per cent in excess of the oral dose.

C.01.024. (1) Sections C.01.021 and C.01.022 do not apply to

(*a*) a drug sold to a drug manufacturer; or

(*b*) a drug sold on prescription.

(2) Paragraph C.01.021(*c*) does not apply to

(*a*) acetaminophen;

(*b*) acetylsalicylic acid;

(*c*) magnesium salicylate;

(*d*) sodium salicylate; or

(*e*) choline salicylate.

(3) Where a drug mentioned in any of paragraphs (2)(*a*) to (*d*) is recommended for children, no person shall sell the drug for human use unless both the inner and the outer labels carry a statement that it is recommended

(*a*) that the drug be used as directed by a physician; or

(*b*) that the maximum doses of the drug not exceed the amounts set out in the following table and that single doses not be administered more frequently than every four hours.

TABLE

MAXIMUM DOSE

| Column I | Column II | Column III | Column IV | Column V | Column VI | Column VII |
|---|---|---|---|---|---|---|

| Item | Age | Maximum Children's Dose (80 mg units) Acetaminophen Drops | Maximum Children's Dose (80 mg units) | Maximum Children's Dose (160 mg units) Acetaminophen | Maximum Adult's Dose (325 mg units) | Maximum Single Dose (mg) | Maximum Daily Dose (mg) |
|---|---|---|---|---|---|---|---|
| 1. | 11 to under 12 years | — | 6 | 3 | 1.5 | 480 | 2 400 |
| 2. | 9 to under 11 years | — | 5 | 2.5 | 1.25 | 400 | 2 000 |
| 3. | 6 to under 9 years | — | 4 | 2 | 1 | 320 | 1 600 |
| 4. | 4 to under 6 years | — | 3 | 1.5 | — | 240 | 1 200 |
| 5. | 2 to under 4 years | — | 2 | 1 | — | 160 | 800 |
| 6. | 1 to under 2 years | 1.5 or as directed by a physician | — | — | — | 120 | 600 |
| 7. | 4 months to under 1 year | 1 or as directed by a physician | — | — | — | 80 | 400 |
| 8. | 0 to under 4 months | 0.5 or as directed by a physician | — | — | — | 40 | 200 |

(4) Where choline salicylate is recommended for children, no person shall sell the drug for human use unless both the inner and the outer labels carry a statement that it is recommended

(*a*) that the drug be used as directed by physician; or

(*b*) that the maximum doses of the drug not exceed the amounts set out in the following table and that single doses not be administered more frequently than every four hours.

TABLE

MAXIMUM DOSE

| Age (Years) | Adult Dosage Units (435 mg) | Single Dose (mg) | Maximum Daily Dose (mg) |
|---|---|---|---|
| 11 to under 12 | 1 1/2 | 660 | 3 300 |
| 9 to under 11 | 1 1/4 | 550 | 2 750 |
| 6 to under 9 | 1 | 440 | 2 200 |
| 4 to under 6 | 3/4 | 330 | 1 650 |
| 2 to under 4 | 1/2 | 220 | 1 100 |
| Under 2 | As directed by physician | | |

SOR/84-145, s. 2; SOR/90-587, s. 1.

C.01.025. Both the inner and the outer labels of a drug that carry a recommended single or daily dosage or a statement of concentration in excess of the limits provided by section C.01.021 shall carry a caution that the product is to be used only on the advice of a physician.

C.01.026. The provisions of section C.01.025 do not apply to

(*a*) a drug sold on prescription, or

(*b*) the inner label of a single-dose container.

C.01.027. (1) Where a person advertises to the general public a drug for human use, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug if it

(*a*) contains a drug set out in the table to section C.01.021; and

(*b*) carries on its label

(i) a statement of the recommended single or daily adult dosage that results in a single or daily adult dosage of the drug referred to in paragraph (*a*) in excess of the maximum dosage set out in the table to section C.01.021 for that drug, or

(ii) a statement that shows a concentration of the drug referred to in paragraph (*a*) in excess of the maximum limit set out in the table to section C.01.021 for that drug.

(2) Subsection (1) does not apply to products containing

(*a*) acetaminophen;

(*b*) acetylsalicylic acid;

(*c*) choline salicylate;

(*d*) magnesium salicylate; or

(*e*) sodium salicylate.

(3) [Repealed, SOR/94-409, s. 1]

(4) Where a person advertises to the general public a drug for human use that contains acetylsalicylic acid, the person shall not make any representation with respect to its administration to or use by children or teenagers.

SOR/81-358, s. 1; SOR/84-145, s. 3; SOR/85-715, s. 4(F); SOR/85-966, s. 3; SOR/93-202, s. 5; SOR/93-411, s. 1; SOR/94-409, s. 1.

## Cautionary Statements and Child Resistant Packages

C.01.028. (1) Subject to subsection (2), the inner and outer labels of a drug that contains

(*a*) acetylsalicylic acid or any of its salts or derivatives, salicylic acid or a salt thereof, or salicylamide, where the drug is recommended for children, shall carry a cautionary statement to the effect that the drug should not be administered to a child under two years of age except on the advice of a physician;

(*b*) boric acid or sodium borate as a medicinal ingredient shall carry a cautionary statement to the effect that the drug should not be administered to a child under three years of age;

(*c*) hyoscine (scopolamine) or a salt thereof shall carry a cautionary statement to the effect that the drug should not be used by persons suffering from glaucoma or where it causes blurring of the vision or pressure pain within the eye;

(*d*) phenacetin, either singly or in combination with other drugs, shall carry the following cautionary statement:

"CAUTION: May be injurious if taken in large doses or for a long time. Do not exceed the recommended dose without consulting a physician."; or

(*e*) acetylsalicylic acid for internal use shall carry a cautionary statement to the effect that the drug should not be administered to or used by children or teenagers who have chicken pox or manifest flu symptoms before a physician or pharmacist is consulted about Reye's syndrome, which statement shall also refer to the fact that Reye's syndrome is a rare and serious illness.

(2) Subsection (1) does not apply to a drug that is

(*a*) intended for parenteral use only;

(*b*) dispensed pursuant to a prescription; or

(*c*) required to be sold on prescription pursuant to these Regulations or pursuant to the Narcotic Control Regulations.

SOR/86-93, s. 2; SOR/88-323, s. 2(F); SOR/93-411, s. 2.

C.01.029. (1) Subject to subsections C.01.031.2(1) and (2), the inner and outer labels of a drug

(*a*) that contains

(i) salicylic acid, a salt thereof or salicylamide,

(ii) acetylsalicylic acid, or any of its salts or derivatives,

(iii) acetaminophen, or

(iv) more than five per cent alkyl salicylates, or

(*b*) that is in a package that contains

(i) more than the equivalent of 250 mg of elemental iron, or

(ii) more than the equivalent of 120 mg of fluoride ion, unless the drug is intended solely for use in dentists' offices,

shall carry a cautionary statement to the effect that the drug should be kept out of the reach of children.

(2) Subject to subsections C.01.031.2(1) and (2), the inner and outer labels of a drug that is in a package that contains

(*a*) more than 1.5 g of salicylic acid or the equivalent quantity of any of its salts or salicylamide,

(*b*) more than 2 g of acetylsalicylic acid or the equivalent quantity of any of its salts or derivatives,

(*c*) more than 3.2 g of acetaminophen,

(*d*) more than the equivalent of 250 mg of elemental iron, or

(*e*) more than the equivalent of 120 mg of fluoride ion, unless the drug is intended solely for use in dentists' offices,

shall carry a cautionary statement to the effect that there is enough drug in the package to seriously harm a child.

(3) The cautionary statements required under subsections (1) and (2) shall be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour.

SOR/86-93, s. 2; SOR/87-484, s. 2; SOR/88-323, s. 3(F); SOR/90-587, s. 2; SOR/93-468, s. 1.

C.01.030. [Repealed, SOR/2003-196, s. 104]

C.01.031. (1) Subject to section C.01.031.2,

(*a*) no person shall sell a drug described in subsection C.01.029(1) unless

(i) where the drug is recommended solely for children, it is packaged in a child resistant package, or

(ii) where the drug is not recommended solely for children, at least one of the sizes of packages available for sale is packaged in a child resistant package; and

(*b*) where a drug described in subsection C.01.029(1) is packaged in a package that is not a child resistant package, the outer label shall carry a statement that the drug is available in a child resistant package.

(2) [Repealed, SOR/93-468, s. 2]

SOR/86-93, s. 2; SOR/87-16, s. 1; SOR/93-468, s. 2.

C.01.031.1. [Repealed, SOR/87-484, s. 3]

C.01.031.2. (1) Sections C.01.029 to C.01.031 do not apply to a drug that is

(*a*) required by these Regulations or the Narcotic Control Regulations to be sold on prescription;

(*b*) intended for parenteral use only;

(*c*) in effervescent or powder form;

(*d*) in suppository form;

(*e*) intended for topical use, unless it is a liquid preparation containing more than five per cent alkyl salicylates;

(*f*) packaged in a non-reclosable package containing not more than two adult standard dosage units per package; or

(*g*) in toothpaste form.

(2) Sections C.01.029 to C.01.031 do not apply to a drug that is repackaged by a pharmacist or practitioner at the time of sale.

(3) Section C.01.031 does not apply to a drug that is

(*a*) sold only in containers that have roll-on or spray applicators or permanently installed wick applicators;

(*b*) sold for exclusive use in animals other than household pets; or

(*c*) intended solely for use in dentists' offices, or packaged for hospital use only.

SOR/86-93, s. 2; SOR/87-484, s. 4; SOR/88-323, s. 5(F); SOR/93-468, s. 3.

C.01.032. No person shall sell a corticosteroid drug for ophthalmic use unless

(*a*) the outer label or the package insert carries, as part of the directions for use, the following statements:

*"Contraindications*

Viral diseases of the cornea and conjunctiva;

Tuberculosis of the eye;

Fungal diseases of the eye;

Acute purulent untreated infections of the eye, which, like other diseases caused by micro-organisms, may be masked or enhanced by the presence of the steroid.

*Side Effects*

Extended ophthalmic use of corticosteroid drugs may cause increased intraocular pressure in certain individuals and in those diseases causing thinning of the cornea, perforation has been known to occur.";

and

(*b*) the inner label carries the statements required by paragraph (*a*) or instructions to see the outer label or package insert for information about contraindications and side effects.

C.01.033. Section C.01.032 does not apply to a corticosteroid drug that is dispensed by a registered pharmacist pursuant to a prescription.

C.01.034. No person shall disseminate to a practitioner promotional literature about corticosteroid drugs for ophthalmic use unless the statements required by paragraph C.01.032(*a*) are included in that literature.

C.01.035. Sections C.01.032 and C.01.034 do not apply to a drug sold solely for veterinary use.

## Miscellaneous

C.01.036. (1) No manufacturer or importer shall sell

(*a*) a drug that contains phenacetin in combination with any salt or derivative of salicylic acid;

(*b*) a drug for human use that contains

(i) oxyphenisatin,

(ii) oxyphenisatin acetate, or

(iii) phenisatin; or

(*c*) a drug for human use that contains mercury or a salt or derivative thereof, unless the drug is

(i) a drug described in Schedule C or D to the Act, or

(ii) one of the following drugs, namely,

(A) an ophthalmic drug or other drug to be used in the area of the eye,

(B) a drug for nasal administration,

(C) a drug for otic administration, or

(D) a drug for parenteral administration that is packaged in a multi-dose container,

in which the mercury or the salt or derivative thereof is present as a preservative and the manufacturer or importer has submitted evidence to the Director demonstrating that the only satisfactory way to maintain the sterility or stability of the drug is to use that preservative.

(2) For the purpose of clause (1)(*c*)(ii)(A), “area of the eye” means the area bounded by the supraorbital and infraorbital ridges and includes the eyebrows, the skin underlying the eyebrows, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball and the soft tissue that lies below the eye and within the infraorbital ridge.

SOR/78-423, s. 2; SOR/86-93, s. 3; SOR/89-229, s. 3.

C.01.036.1 No person shall sell, or advertise for sale, nitrous oxide to the general public.

SOR/78-875, s. 1.

C.01.037. (1) No person shall sell to the general public a drug that is recommended solely for children if the package in which the drug is sold contains

(*a*) more than 1.92 g of salicylamide or salicylic acid or the equivalent quantity of a salt of salicylic acid;

(*b*) more than 1.92 g of acetylsalicylic acid or the equivalent quantity of a salt or derivative thereof;

(*c*) more than 3.2 g of acetaminophen in 160 mg dosage units; or

(*d*) more than 1.92 g of acetaminophen in 80 mg dosage units.

(2) Subsection (1) does not apply to a drug dispensed pursuant to a prescription.

SOR/86-93, s. 4; SOR/87-484, s. 5; SOR/88-323, s. 6; SOR/90-587, s. 3.

C.01.038. A drug for human use is adulterated if it contains

(*a*) Strychnine or any of its salts;

(*b*) extracts or tinctures of

(i) *Strychnos nux vomica*,

(ii) *Strychnos Ignatii*, or

(iii) a *Strychnos* species containing strychnine, other than those species mentioned in subparagraphs (i) and (ii);

(*c*) Methapyrilene or any of its salts;

(*d*) Echimidine or any of its salts; or

(*e*) any of the following plant species or extracts or tinctures thereof:

(i) *Symphytum asperum*,

(ii) *Symphytum x uplandicum*, or

(iii) any other plant species containing echimidine.

SOR/79-512, s. 1; SOR/88-173, s. 1.

C.01.039. *In vitro* diagnostic products that are or contain drugs other than drugs listed in Schedule E to the Act, and drugs listed in Schedule D to the Act that are labelled for veterinary use only, are exempt from the application of this Part.

SOR/97-12, s. 4.

C.01.040. No manufacturer or importer shall sell a drug for human use that contains as an ingredient

(*a*) chloroform; or

(*b*) arsenic or any of its salts or derivatives.

SOR/89-229, s. 4.

C.01.040.1. No manufacturer shall use methyl salicylate as a medicinal ingredient in a drug for internal use in humans.

SOR/78-422, s. 2; SOR/78-801, s. 1; SOR/81-334, s. 2(F); SOR/89-176, s. 1; SOR/92-662, s. 1.

## Colouring Agents

C.01.040.2 (1) No manufacturer shall use a colouring agent in a drug other than a colouring agent listed in subsections (3) and (4).

(2) No person shall import for sale a drug that contains a colouring agent other than a colouring agent listed in subsections (3) and (4).

(2.1) In subsections (3) and (4),

"C.I. (indication of the number)" means the designation used to identify a colouring agent in the Colour Index published by The Society of Dyers and Colourists, as amended from time to time; (C.I. (indication du numéro))

"D & C (indication of the colour and the number)" means the designation used to identify, in accordance with the Code of Federal Regulations of the United States, a colouring agent that can be used in the United States in drugs and cosmetics; (D&C (indication de la couleur et du numéro))

"FD & C (indication of the colour and the number)" means the designation used to identify, in accordance with the Code of Federal Regulations of the United States, a colouring agent that can be used in the United States in food, drugs and cosmetics. (FD&C (indication de la couleur et du numéro))

(3) The following colouring agents are permitted in drugs for internal and external use, namely,

(*a*) ACID FUCHSIN D (D & C Red No. 33; C.I. No. 17200),

ALIZARIN CYANINE GREEN F (D & C Green No. 5; C.I. No. 61570),

ALLURA RED AC (FD & C Red No. 40; C.I. No. 16035),

AMARANTH (Delisted FD & C Red No. 2; C.I. No. 16185),

ANTHOCYANIN DERIVED FROM JUICE EXPRESSED FROM FRESH EDIBLE FRUITS OR VEGETABLES,

ß-APO-$8^1$-CAROTENAL (C.I. No. 40820),

BRILLIANT BLUE FCF SODIUM SALT (FD & C Blue No. 1; C.I. No. 42090),

BRILLIANT BLUE FCF AMMONIUM SALT (D & C Blue No. 4; C.I. No. 42090),

CANTHAXANTHIN (C.I. No. 40850),

CARAMEL,

CARBON BLACK (C.I. No. 77266),

CARMINE (C.I. No. 75470),

CARMOISINE (Delisted Ext. D & C Red No. 10; C.I. No. 14720),

ß-CAROTENE (C.I. No. 40800),

CHLOROPHYLL (C.I. No. 75810),

EOSIN YS ACID FORM (D & C Red No. 21; C.I. No. 45380:2),

EOSIN YS SODIUM SALT (D & C Red No. 22; C.I. No. 45380),

ERYTHROSINE (FD & C Red No. 3; C.I. No. 45430),

FAST GREEN FCF (FD & C Green No. 3; C.I. No. 42053),

FLAMING RED (D & C Red No. 36; C.I. No. 12085),

HELINDONE PINK CN (D & C Red No. 30; C.I. No. 73360),

INDIGO (D & C Blue No. 6; C.I. No. 73000),

INDIGOTINE (FD & C Blue No. 2; C.I. No. 73015),

IRON OXIDES (C.I. Nos . 77489, 77491, 77492, 77499),

LITHOL RUBIN B SODIUM SALT (D & C Red No. 6; C.I. No. 15850),

LITHOL RUBIN B CALCIUM SALT (D & C Red No. 7; C.I. No. 15850:1),

PHLOXINE B ACID FORM (D & C Red No. 27; C.I. No. 45410:1),

PHLOXINE B SODIUM SALT (D & C Red No. 28; C.I. No. 45410),

PONCEAU 4R (C.I. No. 16255),

PONCEAU SX (FD & C Red No. 4; C.I. No. 14700),

QUINOLINE YELLOW WS (D & C Yellow No. 10; C.I. No. 47005),

RIBOFLAVIN,

SUNSET YELLOW FCF (FD & C Yellow No. 6; C.I. No. 15985),

TARTRAZINE (FD & C Yellow No. 5; C.I. No. 19140),

TITANIUM DIOXIDE (C.I. No. 77891);

(*b*) preparations made by extending any of the colouring agents listed in paragraph (*a*) on a substratum of

(i) alumina,

(ii) blanc fixe,

(iii) gloss white,

(iv) clay,

(v) zinc oxide,

(vi) talc,

(vii) rosin,

(viii) aluminum benzoate,

(ix) calcium carbonate, or

(x) any combination of the substances listed in subparagraphs (i) to (ix); and

(*c*) preparations made by extending any sodium, potassium, aluminum, barium, calcium, strontium or zirconium salt of any of the colouring agents listed in paragraph (*a*) on a substratum of

(i) alumina,

(ii) blanc fixe,

(iii) gloss white,

(iv) clay,

(v) zinc oxide,

(vi) talc,

(vii) rosin,

(viii) aluminum benzoate,

(ix) calcium carbonate, or

(x) any combination of the substances listed in subparagraphs (i) to (ix).

(4) The following colouring agents are permitted in drugs for external use, namely,

(*a*) ACID VIOLET 43 (Ext. D & C Violet No. 2; C.I. No. 60730),

ALIZUROL PURPLE SS (D&C Violet No. 2; C.I. No. 60725),

ANNATTO (C.I. No. 75120),

BISMUTH OXYCHLORIDE (C.I. No. 77163),

CHROMIUM HYDROXIDE GREEN (PIGMENT GREEN 18 (C.I. No. 77289)),

DEEP MAROON (D&C Red No. 34; C.I. No. 15880:1),

DIBROMOFLUORESCEIN (SOLVENT RED 72 (C.I. No. 45370:1); ORANGE No. 5 (D & C Orange No. 5)),

FERRIC FERROCYANIDE (C.I. No. 77510),

GUANINE (C.I. No. 75170),

MANGANESE VIOLET (C.I. No. 77742),

MICA (C.I. No. 77019),

ORANGE II (D&C Orange No. 4; C.I. No. 15510),

PYRANINE CONCENTRATED (D&C Green No. 8; C.I. No. 59040),

QUINIZARIN GREEN SS (D&C Green No. 6; C.I. No. 61565),

TONEY RED (D&C Red No. 17; C.I. No. 26100),

URANINE ACID FORM (D&C Yellow No. 7; C.I. No. 45350:1),

URANINE SODIUM SALT (D&C Yellow No. 8; C.I. No. 45350);

ZINC OXIDE (C.I. No. 77947);

(*b*) preparations made by extending any of the colouring agents listed in paragraph (*a*) on a substratum of

(i) alumina,

(ii) blanc fixe,

(iii) gloss white,

(iv) clay,

(v) zinc oxide,

(vi) talc,

(vii) rosin,

(viii) aluminum benzoate,

(ix) calcium carbonate, or

(x) any combination of the substances listed in subparagraphs (i) to (ix); and

(*c*) preparations made by extending any sodium, potassium, aluminum, barium, calcium, strontium or zirconium salt of any of the colouring agents listed in paragraph (*a*) on a substratum of

(i) alumina,

(ii) blanc fixe,

(iii) gloss white,

(iv) clay,

(v) zinc oxide,

(vi) talc,

(vii) rosin,

(viii) aluminum benzoate,

(ix) calcium carbonate, or

(x) any combination of the substances listed in subparagraphs (i) to (ix).

(5) Subsections (1) and (2) do not apply in respect of a drug that is represented as being solely for use in the disinfection, for disease prevention, of

(*a*) medical devices;

(*b*) health care facilities; or

(*c*) premises in which food is manufactured, prepared or kept.

SOR/84-949, s. 1; SOR/86-590, s. 1(E); SOR/94-460, s. 1; SOR/95-431, s. 1; SOR/2002-369, s. 1; SOR/2005-95, s. 1.

## Schedule F Drugs

C.01.041. (1) In this section and sections C.01.041.1 to C.01.046, “Schedule F Drug” means a drug listed or described in Schedule F to these Regulations.

(1.1) Subject to sections C.01.043 and C.01.046, no person shall sell a substance containing a Schedule F Drug unless

(*a*) the sale is made pursuant to a verbal or written prescription received by the seller; and

(*b*) where the prescription has been transferred to the seller under section C.01.041.1, the requirements of section C.01.041.2 have been complied with.

(2) Where the prescription for a Schedule F Drug is written, the person selling the drug shall retain the prescription for at least two years from the date of filling.

(3) Where the prescription for a Schedule F Drug is verbal, the person to whom the prescription is communicated by the practitioner shall forthwith reduce the prescription to writing and the person selling the drug shall retain that written prescription for a period of at least two years from the date of filling.

(4) The person reducing a verbal prescription to writing shall indicate on the written prescription

(*a*) the date and number of the prescription;

(*b*) the name and address of the person for whose benefit the prescription is given;

(*c*) the proper name, common name or brand name of the specified drug and the quantity thereof;

(*d*) his name and the name of the practitioner who issued the prescription; and

(*e*) the directions for use given with the prescription, including whether or not the practitioner authorized the refilling of the prescription and, if the prescription is to be refilled, the number of times it may be refilled.

(5) Subsections (1.1) to (4) do not apply to a substance containing

(*a*) chloral hydrate in preparations for external use, where it constitutes not more than one per cent of the substance, or

(*b*) hexachlorophene and its salts, where it constitutes not more than 0.75 per cent of the substance, calculated as hexachlorophene.

SOR/78-424, s. 2; SOR/80-543, s. 3; SOR/93-202, s. 6; SOR/93-407, s. 2.

C.01.041.1. A pharmacist may transfer to another pharmacist a prescription for a Schedule F Drug.

SOR/78-424, s. 3.

C.01.041.2. A pharmacist to whom a prescription has been transferred under section C.01.041.1 shall not sell a drug pursuant thereto until

(*a*) he has obtained from the pharmacist transferring the prescription his name and address, the number of authorized refills remaining and the date of the last refill; and

(*b*) he has

(i) received a copy of the prescription as written by the practitioner or as reduced to writing as required by subsections C.01.041(3) and (4), as the case may be, or

(ii) where the prescription has been transferred to him verbally, reduced the prescription to writing indicating therein the information specified in subsection C.01.041(4).

SOR/78-424, s. 3.

C.01.041.3. The pharmacist to whom a prescription for a Schedule F Drug is transferred under section C.01.041.1 shall retain in his files for a period of two years the information and documents referred to in section C.01.041.2.

SOR/78-424, s. 3.

C.01.041.4. A pharmacist who transfers a prescription under section C.01.041.1

(*a*) shall enter on the original of the prescription or in a suitable record of prescription kept under the name of each patient, the date of transfer; and

(*b*) shall not make any further sales under the prescription nor transfer it to another pharmacist.

SOR/78-424, s. 3.

C.01.042. (1) No person shall refill a prescription for a Schedule F Drug unless the practitioner so directs and no person shall refill such a prescription more times than the number of times prescribed by the practitioner.

(2) The person filling or refilling a prescription for a Schedule F Drug shall enter on the original of the prescription or in a suitable record of prescriptions kept under the name of each patient

(*a*) the date of filling;

(*b*) the date of each refill, if applicable;

(*c*) the quantity of drug dispensed at the original filling and each refill; and

(*d*) his name.

SOR/78-424, s. 4.

C.01.043. (1) A person may sell a Schedule F Drug, without having received a prescription therefor, to

(*a*) a drug manufacturer;

(*b*) a practitioner;

(*c*) a wholesale druggist;

(*d*) a registered pharmacist;

(*e*) a hospital certified by the Department of National Health and Welfare;

(*f*) a Department of the Government of Canada or of a province, upon receipt of a written order signed by the Minister thereof or his duly authorized representative; or

(*g*) any person, upon receipt of a written order signed by the Director.

(2) Where a person makes a sale authorized by paragraph (1)(*f*) or (1)(*g*), he shall retain the written order for the drug for a period of at least two years from the date of filling the order.

C.01.044. (1) Where a person advertises to the general public a Schedule F Drug, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug.

(2) Subsection (1) does not apply where

(*a*) the drug is listed in Part II of Schedule F; and

(*b*) the drug is

(i) in a form not suitable for human use, or

(ii) labelled in the manner prescribed by paragraph C.01.046(*b*).

SOR/78-424, s. 5; SOR/93-202, s. 7; SOR/93-407, s. 3.

C.01.045. (1) Subject to subsection (2), no person other than

(*a*) a practitioner,

(*b*) a drug manufacturer,

(*c*) a wholesale druggist,

(*d*) a registered pharmacist, or

(*e*) a resident of a foreign country while a visitor in Canada,

shall import a Schedule F Drug.

(2) Any person may import a Schedule F Drug listed in Part II of Schedule F if the drug is imported in such form or so labelled that it could be sold by that person pursuant to section C.01.046.

SOR/93-407, s. 4.

C.01.046. A person may sell a drug listed or described in Part II of Schedule F to the Regulations, without having received a prescription therefor, if

(*a*) the drug is in a form not suitable for human use; or

(*b*) the principal display panel of both the inner label and the outer label carries, in both official languages, the statement “For Veterinary Use Only/Pour usage vétérinaire seulement” or “Veterinary Use Only/Usage vétérinaire seulement”, immediately following or preceding the brand name, proper name or common name, in type size not less than one-half as large as the largest type on the label.

SOR/93-202, s. 8; SOR/93-407, s. 5; SOR/2001-181, s. 1(E).

C.01.047. [Repealed, SOR/80-543, s. 4]

C.01.048. (1) Where a person who is a physician, dentist, veterinary surgeon or pharmacist registered and entitled to practise that person’s profession in a province has signed an order specifying the brand name, proper name or common name and the quantity of a drug, other than

(*a*) a narcotic as defined in the Narcotic Control Regulations,

(*b*) a controlled drug as defined in subsection G.01.001(1), or

(*c*) a new drug in respect of which a notice of compliance has not been issued under section C.08.004,

the person who receives the order may distribute the drug to the physician, dentist, veterinary surgeon or pharmacist as a sample if the drug is labelled in accordance with these Regulations.

(2) An order referred to in subsection (1) may provide that the order be repeated at specified intervals during any period not exceeding six months.

SOR/93-202, s. 9; SOR/97-228, s. 2.

C.01.049. A person who, under section C.01.048, distributes a drug as a sample shall

(*a*) maintain records showing

(i) the name, address and description of each person to whom the drug is distributed,

(ii) the brand name, quantity and form of the drug distributed, and

(iii) the date upon which each such distribution was made; and

(*b*) keep those records and all orders received for drugs in accordance with section C.01.048 for a period of not less than two years from the date upon which the distribution referred to in the records was made.

SOR/93-202, s. 10.

## Recalls

C.01.051. Where a manufacturer who sells a drug in dosage form or a person who imports into and sells in Canada a drug in dosage form commences a recall of the drug, the manufacturer or importer shall forthwith submit to the Director the following information:

(*a*) the proper name of the drug, the common name of the drug if there is no proper name, the brand name of the drug and the lot number;

(*b*) in the case of an imported drug, the names of the manufacturer and importer;

(*c*) the quantity of the drug manufactured or imported;

(*d*) the quantity of the drug distributed;

(*e*) the quantity of the drug remaining on the premises of the manufacturer or importer;

(*f*) the reasons for initiating the recall; and

(*g*) a description of any other action taken by the manufacturer or importer with respect to the recall.

SOR/82-524, s. 2; SOR/93-202, s. 11.

C.01.052. [Repealed, SOR/82-524, s. 2]

C.01.055. and C.01.056. [Repealed, SOR/82-524, s. 2]

## Limits of Variability

C.01.061. (1) Where the net amount of a drug in a package is not expressed on the label in terms of number of dosage units, any 10 packages of the drug selected as provided by official method DO-31, Determination of Net Contents, dated December 7, 1988, shall contain an amount of the drug such that, when determined by that official method, the average of the net amounts of the drug in the 10 packages is not less than the net amount of the drug shown on the label.

(2) Where the net amount of a drug in a package is expressed on the label in terms of the number of dosage units, any 10 packages of the drug selected as provided by official method DO-31, Determination of Net Contents, dated December 7, 1988, shall contain a number of units such that, when determined by that official method,

(*a*) the average number of dosage units in the 10 packages is not less than the number of dosage units shown on the label;

(*b*) no package contains less than the number of dosage units shown on the label except as provided in the table; and

(*c*) where the drug is a controlled drug as defined in subsection G.01.001(1) or a narcotic as defined in the Narcotic Control Regulations, no package contains more than the number of dosage units shown on the label except as provided in the table to this section.

TABLE

| | Column I | Column II |
|---|---|---|
| Item | Labelled Number of Dosage Units Per Package | Permitted Variation from the Labelled Number |

| Item | Column I<br>Labelled Number of Dosage Units Per Package | Column II<br>Permitted Variation from the Labelled Number |
|---|---|---|
| 1. | 50 or less | 0 |
| 2. | More than 50, but less than 101 | 1 |
| 3. | 101 or more | the greater of one unit or 0.75% of the labelled number, rounded up to the next whole number |

SOR/82-429, s. 4; SOR/89-455, s. 4; SOR/97-228, s. 3.

C.01.062. (1) Subject to subsections (2) to (5), no manufacturer shall sell a drug in dosage form where the amount of any medicinal ingredient therein, determined using an acceptable method, is

(*a*) less than 90.0 per cent of the amount of the medicinal ingredient shown on the label; or

(*b*) more than 110.0 per cent of the amount of the medicinal ingredient shown on the label.

(2) Subject to subsection (5), where a drug in dosage form contains a medicinal ingredient that is a volatile substance of botanical origin or its synthetic equivalent, the amount of that ingredient, determined using an acceptable method, shall be

(*a*) not less than 85.0 per cent of the amount of the medicinal ingredient shown on the label; and

(*b*) not more than 120.0 per cent of the amount of the medicinal ingredient shown on the label.

(3) Subject to subsection (5), where a drug in capsule form contains a medicinal ingredient that is a vitamin in a fish-liver oil, no variation from the amount of the medicinal ingredient as shown on the label, determined using an acceptable method, is permitted other than that which is in accordance with the variation for that fish-liver oil as stated in any publication whose name is referred to in Schedule B to the Act.

(4) Subject to subsection (5), where a drug in dosage form contains a medicinal ingredient that is a vitamin, no variation from the amount of the medicinal ingredient shown on the label, determined using an acceptable method, is permitted other than the variation set out in column III or IV of an item of the table to this section opposite the vitamin set out in column I of that item for the amount of vitamin set out in column II of that item.

(5) Subsections (1) to (4) do not apply in respect of

(*a*) a drug for which a notice of compliance has been issued under section C.08.004 or C.08.004.01;

(*b*) [Repealed, SOR/98-423, s. 8]

(*c*) a drug for which a standard is contained in any publication whose name is referred to in Schedule B to the Act;

(*d*) a drug described in Schedule C or D to the Act or Division 6 of Part C of these Regulations; or

(*e*) a drug for which a drug identification number has been assigned under subsection C.01.014.2(1) and in respect of which

(i) the conditions of pharmaceutical production and quality control are suitable for controlling the identity, quality, purity, stability, safety, strength and potency of the drug,

(ii) all labels, package inserts, product brochures and file cards to be used in connection with the drug make proper claims in respect of the drug,

(iii) the drug can, without undue foreseeable risk to humans, be used for the purposes and under the conditions of use recommended by the manufacturer, and

(iv) the drug is effective for the purposes and under the conditions of use recommended by the manufacturer.

TABLE

| | Column I | Column II | Column III | Column IV |
|---|---|---|---|---|
| Item | Vitamin | Recommended daily dose | Limits of variation when the recommended daily dose shown on label is equal to or less then amount set out in column II | Limits of variation when the recommended daily dose shown on label is greater than amount set out in column II |
| 1. | vitamin A (or as B-carotene) | 10 000 I.U. | 90.0 - 165.0 % | 90.0 - 115.0 % |
| 2. | thiamine | 4.5 mg | 90.0 - 145.0 % | 90.0 - 125.0 % |
| 3. | riboflavin | 7.5 mg | 90.0 - 125.0 % | 90.0 - 125.0 % |
| 4. | niacin or niacinamide | 45 mg | 90.0 - 125.0 % | 90.0 - 125.0 % |
| 5. | pyridoxine | 3 mg | 90.0 - 125.0 % | 90.0 - 125.0 % |
| 6. | d-pantothenic acid | 15 mg | 90.0 - 135.0 % | 90.0 - 125.0 % |
| 7. | folic acid | 0.4 mg | 90.0 - 135.0 % | 90.0 - 115.0 % |
| 8. | vitamin $B_{12}$ | 14 µg | 90.0 - 135.0 % | 90.0 - 125.0 % |
| 9. | vitamin C | 150 I.U. | 90.0 - 145.0 % | 90.0 - 125.0 % |
| 10. | vitamin D | 400 I.U. | 90.0 - 145.0 % | 90.0 - 115.0 % |
| 11. | vitamin E | 25 I.U. | 90.0 - 125.0 % | 90.0 - 125.0 % |
| 12. | vitamin K | 0.0 mg | | 90.0 - 115.0 % |
| 13. | biotin | 0.0 mg | | 90.0 - 135.0 % |

SOR/92-131, s. 1; SOR/92-591, s. 2; SOR/94-689, s. 2(E); SOR/95-530, s. 2; SOR/98-423, s. 8; SOR/2011-88, s. 5.

Previous Version

C.01.063. [Repealed, SOR/96-399, s. 2]

C.01.064. Where a drug is prepared for ophthalmic or parenteral use and contains a preservative ingredient, that ingredient

(*a*) shall be present only in an amount necessary to obtain the intended action and that does not pose undue risk to humans or animals; and

(*b*) shall not interfere with the therapeutic properties of the drug.

SOR/90-586, s. 2.

C.01.065. No person shall sell a drug that is prepared for ophthalmic or parenteral use unless a representative sample of each lot of the drug in its immediate container

(*a*) is tested by an acceptable method for identity, and the drug is found to be true to its proper name, or to its common name if there is no proper name;

(*b*) is tested by an acceptable method for sterility, except

(i) for living vaccines, or

(ii) where the manufacturer has submitted evidence, satisfactory to the Director to prove that processing controls ensure the sterility of the drug in its immediate container,

and the drug is found to be sterile; and

(*c*) is subjected to such further tests satisfactory to the Director to ensure that the drug is safe to use according to directions.

SOR/86-552, s. 1; SOR/90-586, s. 3; SOR/93-202, s. 12; SOR/96-399, s. 3.

C.01.066. No person shall sell a drug in aqueous solution that is prepared for parenteral use unless it has been prepared with non-pyrogenic water produced by distillation or reverse osmosis.

C.01.067. (1) Subject to subsection (2), no person shall sell a drug that is prepared for parenteral use unless a representative sample of each lot of the drug in its immediate container

(*a*) is tested by an acceptable method for the presence of pyrogens; and

(*b*) when so tested, is found to be non-pyrogenic.

(2) Subsection (1) does not apply in respect of a drug that cannot be tested for the presence of pyrogens or that is inherently pyrogenic.

SOR/81-335, s. 1; SOR/96-399, s. 4.

C.01.068. Detailed records of the tests required by sections C.01.065 and C.01.067 shall be retained by the manufacturer for a period of at least one year after the expiration date on the label of the drug.

SOR/85-715, s. 5; SOR/92-654, s. 3.

C.01.069. The packaging of a drug that is prepared for parenteral use shall meet the following requirements:

(*a*) the immediate container shall be of such material and construction that

(i) no deleterious substance is yielded to the drug,

(ii) it is non-reactive with the drug,

(iii) visual or electronic inspection of the drug is possible,

(iv) protection against environmental factors that cause deterioration or contamination of the drug is provided or, where that protection cannot be provided by the immediate container, it is provided by the secondary packaging, and

(v) a sufficient quantity of the drug is contained to allow withdrawal of the labelled amount of the drug; and

(*b*) the immediate closures and any material coming into contact with the drug in its immediate container shall meet the requirements of subparagraphs (*a*)(i) and (ii).

SOR/96-399, s. 5.

C.01.070. No person shall sell a drug that is a hypodermic tablet that does not completely dissolve in and form a clear solution with water.

## Mercuric Chloride Tablets

C.01.071. No person shall sell mercuric chloride tablets for household use that are packaged in lots of 200 or less, unless

(*a*) such tablets are

(i) of an irregular or angular shape,

(ii) coloured blue, and

(iii) packed in an immediate container that is readily distinguishable by touch; and

(*b*) the principal display panel of both the inner and the outer labels carries in prominent type and in a colour contrasting to that of such labels

(i) the design of a skull and cross-bones, and

(ii) the word “Poison”.

SOR/2001-181, s. 2.

C.01.081. [Repealed, SOR/80-544, s. 4]

C.01.085. [Repealed, SOR/80-544, s. 5]

## Synthetic Sweeteners

C.01.101. (1) [Repealed, SOR/78-422, s. 3]

(2) [Repealed, SOR/78-800, s. 1]

(3) [Repealed, SOR/78-422, s. 3]

C.01.121. and C.01.122. [Repealed, SOR/80-544, s. 6]

## Aminopyrine and Dipyrone

C.01.131. No person shall sell Aminopyrine or Dipyrone (a derivative of Aminopyrine) for oral or parenteral use, unless

(*a*) the inner label carries the statement:

“WARNING: Fatal agranulocytosis may be associated with the use of Aminopyrine and Dipyrone. It is essential that adequate blood studies be made. (See enclosed warnings and precautions)”; and

(*b*) the outer label or the package insert carries the following statements:

“WARNING: Serious and even fatal agranulocytosis is known to occur after the administration of Aminopyrine or Dipyrone. Fatal agranulocytosis has occurred after short term, intermittent and prolonged therapy with the drugs. Therefore, the use of these drugs should be as brief as possible. Bearing in mind the possibility that such reactions may occur, Aminopyrine or Dipyrone should be used only when other less potentially dangerous agents are ineffective.

PRECAUTIONS: It is essential that frequent white blood cell counts and differential counts be made during treatment with these drugs. However, it is emphasized that agranulocytosis may occur suddenly without prior warning. The drug should be discontinued at the first evidence of any alteration of the blood count or sign of agranulocytosis, and the patient should be instructed to discontinue use of the drug at the first indication of sore throat or sign of other infection in the mouth or throat (pain, swelling, tenderness, ulceration).”

C.01.132. No person shall disseminate to a practitioner promotional literature about Aminopyrine or Dipyrone unless the statements set out in section C.01.131 are included in such literature.

C.01.133. The provisions of sections C.01.131 and C.01.132 do not apply to preparations containing Aminopyrine or Dipyrone that are

(*a*) dispensed by a pharmacist pursuant to a prescription; or

(*b*) sold for veterinary use only.

## Coated Potassium Salts

C.01.134. No person shall sell coated tablets containing potassium salts, with or without thiazide diuretics, unless the inner label thereof or the package insert carries the following statement:

“WARNING: A probable association exists between the use of coated tablets containing potassium salts, with or without thiazide diuretics, and the incidence of serious small bowel ulceration. Such preparations should be used only when adequate dietary supplementation is not practical, and should be discontinued if abdominal pain, distension, nausea, vomiting or gastro-intestinal bleeding occur.”

C.01.135. No person shall disseminate to a practitioner promotional literature about coated tablets containing potassium salts, with or without thiazide diuretics, unless the statement set out in section C.01.134 is included in such literature.

C.01.136. The provisions of sections C.01.134 and C.01.135 do not apply to coated tablets containing potassium salts with or without thiazide diuretics that

(*a*) are sold for veterinary use only;

(*b*) are dispensed by a pharmacist pursuant to a prescription; or

(*c*) contain 100 milligrams or less of elemental potassium per tablet.

## Antibiotics

C.01.401. Except as provided in these Regulations, an antibiotic for other than parenteral use shall, in addition to meeting the requirements of section C.01.004, carry on both the inner label and outer label the potency of the drug, expressed in terms of International Units where established or, if no International Unit has been established, in terms of units, milligrams, micrograms or fractions of a gram,

(*a*) per gram in the case of solids or viscous liquids;

(*b*) per millilitre in the case of other liquids; and

(*c*) per individual dosage or dispensing form in the case of antibiotic preparations put up in individual dosage or dispensing form.

SOR/80-544, s. 7; SOR/92-654, s. 4.

C.01.402. [Repealed, SOR/92-654, s. 4]

C.01.410. to C.01.412. [Repealed, SOR/80-544, s. 8]

C.01.420. to C.01.422. [Repealed, SOR/80-544, s. 8]

## Chloramphenicol

C.01.430. to C.01.432. [Repealed, SOR/80-544, s. 8]

C.01.433. No person shall sell chloramphenicol and its salts and derivatives, for oral or parenteral use, unless

(*a*) the inner label carries a warning statement to the effect that

(i) bone marrow depression has been associated with the use of chloramphenicol, and

(ii) the enclosed warnings and precautions should be read carefully; and

(*b*) the outer label or the package insert carries the following:

(i) a warning statement to the effect that chloramphenicol should not be used in the treatment or prophylaxis of minor infections or where it is not indicated, as in cold, influenza, or infections of the upper respiratory tract; that there are two types of bone marrow depression associated with the use of chloramphenicol; that some degree of depression of the bone marrow is commonly seen during therapy, is dose-related and is potentially reversible; that blood studies may detect early changes and; that the other type of bone marrow depression, a sudden, delayed and usually fatal bone marrow hypoplasia that may occur without warning, is very rare, and

(ii) a statement of precautions to be taken to the effect that it is essential that appropriate blood studies be made during treatment with chloramphenicol and that while blood studies

may detect early peripheral blood changes, such studies cannot be relied on to detect the rare and generally irreversible bone marrow depression prior to development of aplastic anemia.

C.01.434. The provisions of section C.01.433 do not apply to chloramphenicol and its salts or derivatives sold by a registered pharmacist.

C.01.435. No person shall disseminate to a practitioner promotional literature about chloramphenicol and its salts or derivatives for oral or parenteral use unless the statements set out in paragraph C.01.433(*b*) are included in such literature.

C.01.436. The provisions of sections C.01.433 and C.01.435 do not apply to a drug sold solely for veterinary use.

C.01.440. to C.01.442. [Repealed, SOR/80-544, s. 8]

C.01.450. to C.01.452. [Repealed, SOR/80-544, s. 8]

C.01.460. to C.01.462. [Repealed, SOR/80-544, s. 8]

C.01.470. to C.01.472. [Repealed, SOR/80-544, s. 8]

C.01.480. [Repealed, SOR/80-544, s. 8]

C.01.490. to C.01.497. [Repealed, SOR/80-544, s. 8]

C.01.510. to C.01.513. [Repealed, SOR/80-544, s. 8]

C.01.520. to C.01.522. [Repealed, SOR/80-544, s. 8]

C.01.530. to C.01.532. [Repealed, SOR/80-544, s. 8]

C.01.540. to C.01.542. [Repealed, SOR/80-544, s. 8]

C.01.550. to C.01.552. [Repealed, SOR/80-544, s. 8]

C.01.560. to C.01.563. [Repealed, SOR/80-544, s. 8]

C.01.570. to C.01.572. [Repealed, SOR/80-544, s. 8]

C.01.580. [Repealed, SOR/80-544, s. 8]

C.01.590. to C.01.592. [Repealed, SOR/80-544, s. 8]

## Veterinary Drugs

C.01.600. No person shall sell for veterinary use a drug listed in the Table of Limits of Drug Dosage for Adults, other than a drug in a form not suitable for human use, unless both the inner and outer labels carry the statement “For Veterinary Use Only” or “Veterinary Use Only”.

SOR/80-543, s. 5.

C.01.601. [Repealed, SOR/93-407, s. 6]

C.01.602. The provisions of sections C.01.401 and C.01.402 do not apply to an antibiotic in amounts less than 50 parts per million contained in an animal food.

C.01.603. The provisions of paragraphs C.01.401 (*b*) and (*c*) and section C.01.402 do not apply to an antibiotic in amounts greater than 50 parts per million contained in an animal food.

C.01.604. Both the inner and outer labels of a veterinary drug represented as containing a vitamin shall carry

(*a*) a statement of the amount of each vitamin present in the drug, expressed in terms of the proper name only of the vitamin in

(i) International Units per gram or per millilitre for vitamin A, provitamin A, vitamin D, and vitamin E,

(ii) milligrams per gram in the case of solids or viscous liquids, or per millilitre in the case of other liquids, for thiamine, riboflavin, niacin, niacinamide, pyridoxine, *d*-pantothenic acid, *d*-panthenol, folic acid, ascorbic acid, and vitamin K,

(iii) micrograms per gram in the case of solids or viscous liquids, or per millilitre in the case of other liquids, for biotin, and vitamin $B_{12}$,

(iv) Oral Units for vitamin $B_{12}$ with intrinsic factor concentrate, or

(v) for vitamin products put up in individual dosage or dispensing form, the specified units per individual dosage or dispensing form;

(*b*) except for drugs in a form not suitable for human use, the statement “For Veterinary Use Only” or “Veterinary Use Only”.

SOR/80-543, s. 6.

C.01.605. An antibiotic for parenteral use that is recommended for veterinary use only shall carry on both the inner and outer labels

(*a*) the potency of the drug expressed in terms of International Units where established, or, if no International Unit has been established, in terms of units, milligrams or fractions of a gram, per gram in the case of solids or viscous liquids, per millilitre in the case of other liquids, or per individual dosage or dispensing form for antibiotic preparations put up in individual dosage or dispensing form; and

(*b*) [Repealed, SOR/92-654, s. 5]

(*c*) the statement “For Veterinary Use Only” or “Veterinary Use Only”.

SOR/80-543, s. 7; SOR/92-654, s. 5.

C.01.606. No person shall sell an antibiotic preparation for the treatment of animals, other than an antibiotic preparation that is a new drug sold pursuant to section C.08.013, unless,

(*a*) where the preparation is not to be used for lactating animals providing milk to be consumed as food, the inner and outer labels of the preparation carry a statement to that effect; or

(*b*) where the preparation may be used for lactating animals providing milk to be consumed as food,

(i) there has been submitted, on request, to the Director, acceptable evidence to show the period of time, not exceeding 96 hours, that must elapse after the last treatment with the preparation in order that the milk from treated lactating animals will contain no residue of antibiotics that would cause injury to human health, and

(ii) the principal display panel of the outer label of the preparation, the inner label and the packaging insert, if any, describing the antibiotic preparation carry the warning **"WARNING: MILK TAKEN FROM TREATED ANIMALS DURING TREATMENT AND WITHIN ... HOURS AFTER THE LATEST TREATMENT MUST NOT BE USED AS FOOD"**, where the number of hours to be inserted is determined according to evidence submitted pursuant to subparagraph (i).

SOR/88-378, s. 1; SOR/92-664, s. 2; SOR/93-467, s. 1.

C.01.606.1. No person shall sell a product intended for the prevention or treatment of foot rot of cattle if that product contains Ethylenediamine Dihydroiodide (EDDI).

SOR/90-327, s. 1.

C.01.607. Notwithstanding subparagraph C.01.004(1)(*c*)(ii), the declaration of a lot number is not required on the label of an animal feeding-stuff containing a drug.

SOR/80-543, s. 8.

C.01.608. The provisions of section C.01.604 do not apply to medicated feeds registered under the Feeds Act.

C.01.609. Notwithstanding the provisions of section C.01.401(*a*), the potency of an antibiotic in in amounts greater than 50 parts per million contained in a medicated feed registered under the Feeds Act may be declared in grams per ton.

C.01.610. No person shall sell any substance having oestrogenic activity for administration to poultry that may be consumed as food.

C.01.610.1 No person shall sell a drug for administration to animals that produce food or that are intended for consumption as food if that drug contains

(*a*) chloramphenicol or its salts or derivatives;

(*b*) a 5-nitrofuran compound;

(*c*) clenbuterol or its salts or derivatives;

(*d*) a 5-nitroimidazole compound; or

(*e*) diethylstilbestrol or other stilbene compounds.

SOR/85-539, s. 1; SOR/85-685, s. 2; SOR/91-546, s. 1; SOR/94-568, s. 2; SOR/97-510, s. 2; SOR/2003-292, s. 3.

C.01.610.2 No person shall sell an antibiotic preparation containing chloramphenicol, its salts or derivatives, for administration to animals that do not produce food and that are not intended for consumption as food unless

(*a*) both the inner label and outer label of the preparation carry the words “WARNING: FEDERAL LAW PROHIBITS THE ADMINISTRATION OF THIS PREPARATION TO ANIMALS THAT PRODUCE FOOD OR ANIMALS THAT ARE INTENDED FOR CONSUMPTION AS FOOD/MISE EN GARDE : EN VERTU DES LOIS FÉDÉRALES, IL EST INTERDIT D’ADMINISTRER CETTE PRÉPARATION AUX ANIMAUX QUI PRODUISENT DES ALIMENTS OU AUX ANIMAUX DESTINÉS À ÊTRE CONSOMMÉS COMME ALIMENTS”;

(*b*) where the preparation is for parenteral use, the preparation contains, in the form of chloramphenicol sodium succinate, not more than one gram of chloramphenicol per vial;

(*c*) where the preparation is for ophthalmic use, the preparation contains not more than one per cent chloramphenicol; and

(*d*) where the preparation is for oral use, the preparation

(i) is in tablet or capsule form and contains not more than one gram of chloramphenicol per tablet or capsule, or

(ii) is in the form of a chloramphenicol palmitate suspension and contains not more than three grams of chloramphenicol per container.

SOR/91-546, s. 1.

C.01.611. (1) The Director may, in writing, from time to time require the manufacturer of a drug recommended for administration to animals that may be consumed as food

(*a*) to file with him in respect of that drug a submission, in form and content satisfactory to the Director, describing in detail tests carried out to determine that no residues of the drug, except residues within the limits prescribed by these Regulations, remain in meat, meat by-products, eggs or milk; and

(*b*) to print on the principal display panel of the outer label, the inner label and the packaging insert, if any, that describes the drug, a warning that meat, meat by-products, eggs or milk from animals to which the drug has been administered cannot be sold for consumption as food unless there has elapsed since the administration of the drug a period of time specified by the Director, based on a review of the available data with respect to drug residue.

(2) No manufacturer shall sell a drug in respect of which the Director has required a warning to be printed pursuant to paragraph (1)(*b*) unless the manufacturer has complied with that request.

SOR/93-467, s. 2.

C.01.612. [Repealed, SOR/94-568, s. 3]

### Contraceptive Drugs

C.01.625. Contraceptive drugs that are manufactured, sold or represented for use in the prevention of conception and that are not listed in Schedule F may be advertised to the general public.

# Division 1A

# Establishment Licences

## Interpretation

C.01A.001. (1) The definitions in this subsection apply in this Division and in Divisions 2 to 4.

“antimicrobial agent” means a drug that is capable of destroying pathogenic micro-organisms and that is labelled as being for use in the disinfection of environmental surfaces or medical devices, as defined in the Medical Devices Regulations, that

(*a*) are not invasive devices as defined in those Regulations; and

(*b*) are intended to come into contact with intact skin only. (agent antimicrobien)

“batch certificate” means a certificate issued by the fabricator of a lot or batch of a drug that is exported within the framework of a mutual recognition agreement and in which the fabricator

(*a*) identifies the master production document for the drug and certifies that the lot or batch has been fabricated, packaged/labelled and tested in accordance with the procedures described in that document;

(*b*) provides a detailed description of the drug, including

(i) a statement of all properties and qualities of the drug, including the identity, potency and purity of the drug, and

(ii) a statement of tolerances for the properties and qualities of the drug;

(*c*) identifies the analytical methods used in testing the lot or batch and provides details of the analytical results obtained;

(*d*) sets out the addresses of the buildings at which the lot or batch was fabricated, packaged/labelled and tested; and

(*e*) certifies that the lot or batch was fabricated, packaged/labelled and tested in accordance with the good manufacturing practices of the regulatory authority that has recognized those buildings as meeting its good manufacturing practices standards. (certificat de lot)

“class monograph” means a document prepared by the Department of Health that

(*a*) lists the types and strengths of medicinal ingredients that may be contained in drugs of a specified class; and

(*b*) sets out labelling and other requirements that apply to those drugs. (monographie de classe)

“dilute drug premix” means a drug for veterinary use that results from mixing a drug premix with a feed as defined in section 2 of the Feeds Act, to such a level that at least 10 kg of the resulting mixture is required to medicate one tonne of complete feed, as defined in section 2 of the Feeds Regulations, 1983, with the lowest approved dosage level of the drug. (prémélange médicamenteux dilué)

“dosage form class” means a parenteral, tablet, capsule, solution, suspension, aerosol, powder, suppository, medical gas or drug premix, or any other dosage form class designated by the Minister. (classe de forme posologique)

“drug premix” means a drug for veterinary use to which a drug identification number has been assigned, where the directions on its label specify that it is to be mixed with feed as defined in section 2 of the Feeds Act. (prémélange médicamenteux)

“fabricate” means to prepare and preserve a drug for the purposes of sale. (manufacturer)

“import” means to import into Canada a drug for the purpose of sale. (importer)

“MRA country” means a country that is a participant in a mutual recognition agreement with Canada. (pays participant)

“mutual recognition agreement” means an international agreement that provides for the mutual recognition of compliance certification for good manufacturing practices for drugs. (accord de reconnaisance mutuelle)

“package/label” means to put a drug in its immediate container or to affix the inner or outer label to the drug. (emballer-étiqueter)

“pharmaceutical” means a drug other than a drug listed in Schedule C or D to the Act. (produit pharmaceutique)

“recognized building” means, in respect of the fabrication, packaging/labelling or testing of a drug, a building that a regulatory authority that is designated under subsection C.01A.019(1) in respect of that activity for that drug has recognized as meeting its good manufacturing practices standards in respect of that activity for that drug. (bâtiment reconnu)

“regulatory authority” means a government agency or other entity in an MRA country that has a legal right to control the use or sale of drugs within that country and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with legal requirements. (autorité réglementaire)

“site”[Repealed, SOR/2002-368, s. 1]

“wholesale” means to sell any of the following drugs, other than at retail sale, where the seller’s name does not appear on the label of the drugs:

(*a*) a drug listed in Schedule C or D to the Act or in Schedule F to these Regulations or a controlled drug as defined in subsection G.01.001(1); or

(*b*) a narcotic as defined in the Narcotic Control Regulations. (vendre en gros)

(2) In this Division and in Division 2, “drug” means a drug in dosage form, or a drug that is a bulk process intermediate that can be used in the preparation of a drug listed in Schedule C to the Act or in Schedule D to the Act that is of biological origin. It does not include a dilute drug premix, a medicated feed as defined section 2 of the Feeds Regulations, 1983, a drug that is used only for the purposes of an experimental study in accordance with a certificate issued under section C.08.015 or a drug listed in Schedule H to the Act.

(3) Where the Minister designates additional dosage form classes, the Minister shall make a list of those classes available on request.

SOR/97-12, s. 5; SOR/98-7, s. 1; SOR/2000-120, s. 1; SOR/2002-368, s. 1; SOR/2004-282, s. 1.

## Application

C.01A.002. (1) This Division does not apply to

(*a*) wholesaling a drug premix;

(*b*) importing or compounding, pursuant to a prescription, a drug that is not commercially available in Canada by one of the following persons, namely,

(i) a pharmacist,

(ii) a practitioner, and

(iii) a person who compounds a drug under the supervision of a practitioner;

(*c*) any activity with respect to a drug that is used only for the purposes of clinical testing in accordance with subsection C.05.006(1) or section C.08.005,

(*d*) fabricating, packaging/labelling, testing as required under Division 2, distributing as a distributer referred to in section C.01A.003, wholesaling or importing any of the following drugs for which prescriptions are not required and that are for human use in dosage form and not represented as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states set out in Schedule A to the Act, namely,

(i) homeopathic drugs,

(ii) drugs that meet the requirements of a class monograph entitled “Vitamin Supplements”, “Mineral Supplements”, “Dietary Vitamin Supplements” or “Dietary Mineral Supplements”, as the case may be, and

(iii) drugs that

(A) contain a plant, mineral or animal substance in respect of which therapeutic activity or disease prevention activity is claimed, including traditional herbal medicines, traditional Chinese medicines, ayurvedic (East Indian) medicines and traditional aboriginal (North American) medicines, and

(B) the medical use of which is based solely on historical and ethnological evidence from references relating to a medical system other than one based on conventional scientific standards; and

(*e*) fabricating, packaging/labelling, testing, distributing, and importing of antimicrobial agents.

(2) This Division and Divisions 2 to 4 do not apply to the affixing of a label to a previously labelled container.

SOR/97-12, s. 5; SOR/98-7, s. 2; SOR/2001/-203, s. 1; SOR/2004-282, s. 2.

C.01A.003. This Division and Divisions 2 to 4 apply to the following distributors:

(*a*) a distributor of a drug listed in Schedule C or D to the Act or in Schedule F to these Regulations, a controlled drug as defined in subsection G.01.001(1) or a narcotic as defined in the Narcotic Control Regulations, who does not hold the drug identification number for the drug or narcotic; and

(*b*) a distributor of a drug for which that distributor holds the drug identification number.

SOR/97-12, s. 5; SOR/2002-368, s. 2.

## Prohibition

C.01A.004. (1) Subject to subsection (2), no person shall, except in accordance with an establishment licence,

(*a*) fabricate, package/label, distribute as set out in section C.01A.003, import or wholesale a drug; or

(*b*) perform the tests, including examinations, required under Division 2.

(2) A person does not require an establishment licence to perform tests under Division 2 if the person holds an establishment licence as a fabricator, a packager/labeller, a distributor referred to in paragraph C.01A.003(*b*) or an importer.

(3) No person shall carry on an activity referred to in subsection (1) in respect of a narcotic as defined in the Narcotic Control Regulations or a controlled drug as defined in subsection G.01.001(1) unless the person holds a licence for that narcotic or drug under the Narcotic Control Regulations or Part G of these Regulations, as the case may be.

SOR/97-12, s. 5; SOR/2002-368, s. 3.

## Application

[SOR/2011-81, s. 1(E)]

C.01A.005. A person who wishes to apply for an establishment licence shall submit an application to the Minister, in a form established by the Minister, that contains the following information and documents:

(*a*) the applicant’s name, address and telephone number, and their facsimile number and electronic mail address, if any;

(*b*) the name and telephone number, and the facsimile number and electronic mail address, if any, of a person to contact in case of an emergency;

(*c*) each activity set out in Table I to section C.01A.008 for which the licence is requested;

(*d*) each category of drugs set out in Table II to section C.01A.008 for which the licence is requested;

(*e*) each dosage form class in respect of which the applicant proposes to carry out a licensed activity, and whether it will be in a sterile dosage form;

(*f*) whether the applicant proposes to carry out a licensed activity in respect of a drug that is a bulk process intermediate;

(*g*) the address of each building in Canada in which the applicant proposes to fabricate, package/label, test as required under Division 2 or store drugs, specifying for each building which of those activities and for which category of drugs and, for each category,

(i) the dosage form classes, and whether any drugs will be in a sterile dosage form, and

(ii) whether any drugs will be bulk process intermediates;

(*h*) the address of each building in Canada at which records will be maintained;

(*i*) whether any building referred to in paragraphs (*g*) and (*h*) is a dwelling-house;

(*j*) the drug identification number, if any, or a name that clearly identifies the drug,

(i) for each narcotic as defined in the Narcotic Control Regulations or each controlled drug as defined in subsection G.01.001(1) for which the licence is requested, and

(ii) for each other drug within a category of drugs for which the licence is requested, unless the licence is to perform tests required under Division 2, distribute as set out in paragraph C.01A.003(*a*), or wholesale;

(*k*) if any of the buildings referred to in paragraph (*g*) have been inspected under the Act or these Regulations, the date of the last inspection;

(*l*) evidence that the applicant's buildings, equipment and proposed practices and procedures meet the applicable requirements of Divisions 2 to 4;

(*m*) in the case of an importer of a drug that is fabricated, packaged/labelled or tested in an MRA country at a recognized building,

(i) the name and address of each fabricator, packager/labeller and tester of the drug and the address of each building at which the drug is fabricated, packaged/labelled or tested, specifying for each building the activities and the category of drug and

(A) the dosage form class and whether the drug is in a sterile dosage form, and

(B) whether the drug is a bulk process intermediate,

(ii) in respect of each activity done in an MRA country at a recognized building, the name of the regulatory authority that is designated under subsection C.01A.019(1) in respect of that activity for that drug and that has recognized that building as meeting its good manufacturing practices standards in respect of that activity for that drug, and

(iii) in respect of any other activities,

(A) a certificate from a Canadian inspector indicating that the fabricator's, packager/labeller's or tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4, or

(B) other evidence establishing that the fabricator's, packager/labeller's or tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4;

(*n*) in the case of any other importer, the name and address of each fabricator, packager/labeller and tester of the drugs proposed to be imported and the address of each building at which the drugs will be fabricated, packaged/labelled and tested, specifying for

each building which of those activities and for which category of drugs and, for each category,

(i) the dosage form classes and whether any drugs will be in a sterile dosage form, and

(ii) whether any drugs will be bulk process intermediates; and

(*o*) in the case of an importer referred to in paragraph (*n*),

(i) a certificate from a Canadian inspector indicating that the fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4, or

(ii) other evidence establishing that the fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the applicable requirements of Divisions 2 to 4.

SOR/97-12, s. 5; SOR/2000-120, s. 2; SOR/2002-368, s. 4; SOR/2011-81, s. 2.

Previous Version

C.01A.006. (1) A person who wishes to amend an establishment licence shall submit an application to the Minister, in a form established by the Minister, that contains the information and documents referred to in section C.01A.005 that relate to the amendment.

(2) An establishment licence must be amended where the licensee proposes

(*a*) to add an activity or category of drugs, as set out in the tables to section C.01A.008;

(*b*) in respect of a category of drugs and activity indicated in the licence, to authorize sterile dosage forms of the category;

(*c*) to add any building in Canada at which drugs are authorized to be fabricated, packaged/labelled, tested as required under Division 2 or stored, or to add, for an existing building, an authorization to fabricate, package/label, test or store a category of drugs, or sterile dosage forms of the category; and

(d) in addition to the matters set out in paragraphs (*a*) to (*c*), in the case of an importer,

(i) to add a fabricator, packager/labeller or tester of a drug,

(ii) to amend the name or address of a fabricator, packager/labeller or tester indicated in the licence, and

(iii) if the address of the buildings at which drugs are authorized to be fabricated, packaged/labelled or tested is indicated in the licence, to add additional buildings or, for an existing building, to add an authorization to fabricate, package/label or test a category of drugs, or sterile dosage forms of the category.

SOR/97-12, s. 5; SOR/2011-81, s. 3.

Previous Version

C.01A.007. (1) The Minister may, on receipt of an application for an establishment licence, an amendment to an establishment licence or the review of an establishment licence, require the applicant to submit further details pertaining to the information contained in the application that are necessary to enable the Minister to make a decision.

(2) When considering an application, the Minister may require that

(*a*) an inspection be made during normal business hours of any building referred to in paragraph C.01A.005(1)(*g*) or (*h*); and

(*b*) the applicant, if a fabricator, a packager/labeller, a person who performs tests required under Division 2, a distributor referred to in paragraph C.01A.003(*b*) or an importer, supply samples of any material to be used in the fabrication, packaging/labelling or testing of a drug.

SOR/97-12, s. 5; SOR/2011-81, s. 4.

Previous Version

## Issuance

C.01A.008. (1) Subject to section C.01A.010, the Minister shall, on receipt of the information and material required by sections C.01A.005 to C.01A.007, issue or amend an establishment licence.

(2) The establishment licence shall indicate

(*a*) each activity that is authorized and the category of drugs for which each activity is authorized, as set out in the tables to this section, specifying for each activity and category whether sterile dosage forms are authorized;

(*b*) the address of each building in Canada at which a category of drugs is authorized to be fabricated, packaged/labelled, tested as required under Division 2 or stored, specifying for each building which of those activities and for which category of drugs, and whether sterile dosage forms of the category are authorized; and

(*c*) in addition to the matters referred to in paragraphs (*a*) and (*b*), in the case of an importer,

(i) the name and address of each fabricator, packager/labeller and tester from whom the importer is authorized to obtain the drug for import, and

(ii) the address of each building at which the drug is authorized to be fabricated, packaged/labelled or tested, specifying for each building the activities and the category of drugs that are authorized, and whether sterile dosage forms are authorized.

(*d*) [Repealed, SOR/2002-368, s. 5]

(3) The Minister may indicate in an establishment licence a period for which records shall be retained under Division 2 that, based on the safety profile of the drug or materials, is sufficient to ensure the health of the consumer.

(4) The Minister may, in addition to the requirements of subsection (2), set out in an establishment licence terms and conditions respecting

(*a*) the tests to be performed in respect of a drug, and the equipment to be used, to ensure that the drug is not unsafe for use; and

(*b*) any other matters necessary to prevent injury to the health of consumers, including conditions under which drugs are fabricated, packaged/labelled or tested.

TABLE I

Item Activities

1. Fabricate
2. Package/label
3. Perform the tests, including any examinations, required under Division 2
4. Distribute as set out in paragraph C.01A.003(*a*)
5. Distribute as set out in paragraph C.01A.003(*b*)
6. Import
7. Wholesale

TABLE II

Item Categories of drugs

1. Pharmaceuticals
2. Vaccines
3. Whole blood and its components
4. Drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components
5. Drugs listed in Schedule C to the Act
6. Drugs listed in Schedule F to these Regulations, controlled drugs as defined in subsection G.01.001(1) and narcotics as defined in the Narcotic Control Regulations

SOR/97-12, s. 5; SOR/2000-120, s. 3; SOR/2002-368, s. 5.

## Annual Licence Review

C.01A.009. (1) The holder of an establishment licence that is not suspended shall submit an application for the review of their licence to the Minister before April 1 of each year and include with it the information and documents referrred to in section C.01A.005.

(2) The Minister shall conduct an annual review of the licence on the basis of the information and documents submitted by the holder and any other relevant information in the Minister's possession.

SOR/97-12, s. 5; SOR/97-298, s. 1; SOR/2011-81, s. 5.

Previous Version

## Refusal to Issue

C.01A.010. (1) The Minister may refuse to issue or amend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if

(*a*) the applicant has made a false or misleading statement in relation to the application for the licence; or

(*b*) the applicant has had an establishment licence suspended in respect of the matter.

(2) The Minister shall refuse to issue or amend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that issuing or amending an establishment licence in respect of the matter would constitute a risk to the health of the consumer.

(3) Where the Minister refuses to issue or amend an establishment licence, the Minister shall

(*a*) notify the applicant in writing of the reasons for the refusal; and

(*b*) give the applicant an opportunity to be heard.

SOR/97-12, s. 5.

## Terms and Conditions

C.01A.011. (1) Every person who holds an establishment licence shall comply with

(*a*) the requirements and the terms and conditions of the establishment licence; and

(*b*) the applicable requirements of Divisions 2 to 4.

(2) [Repealed, SOR/2000-120, s. 4]

SOR/97-12, s. 5; SOR/2000-120, s. 4.

C.01A.012. (1) The Minister may amend the terms and conditions of an establishment licence if the Minister believes on reasonable grounds that an amendment is necessary to prevent injury to the health of the consumer.

(2) The Minister shall give at least 15 days notice in writing to the holder of the establishment licence of the proposed amendment, the reasons for the amendment and its effective date.

SOR/97-12, s. 5.

## Notification

C.01A.013. Every person who holds an establishment licence shall notify the Minister in writing within 15 days after

(*a*) there is any change to the information referred to in any of paragraphs C.01A.005(*a*),(*b*),(*e*),(*f*),(*h*) and (*i*), and subparagraphs C.01A.005(*g*)(i) and (ii); or

(*b*) an event occurs that results in their being in contravention of any of the applicable requirements of Divisions 2 to 4, where it may affect the quality, safety or efficacy of a drug fabricated, packaged/labelled, tested as required under Division 2 or stored by them.

SOR/97-12, s. 5.

C.01A.014. (1) No licensee shall carry on a licensed activity in respect of any category of drugs if a change referred to in subsection (2) has occurred in respect of that category, unless

(*a*) they have filed with the Minister a notice that contains sufficient information to enable the Minister to assess the safety of the drug, taking into account the change; and

(*b*) the Minister has issued to them a letter indicating that the information will be reviewed and has not, within 90 days after issuing the letter, sent them a notice indicating that the change is not acceptable.

(2) Notification is required in respect of the following changes where they may affect whether a drug can be fabricated, packaged/labelled, tested or stored in accordance with the applicable requirements of Divisions 2 to 4:

(*a*) changes to the plans and specifications of a building where a drug is fabricated, packaged/labelled, tested or stored;

(*b*) changes to the equipment that is used in the fabrication, packaging/labelling or testing of a drug;

(*c*) changes to the practices or procedures; and

(*d*) in the case of an importer, other than an importer of a drug that is fabricated, packaged/labelled or tested in an MRA country at a recognized building, any change referred to in paragraphs (*a*) to (*c*) that relates to the fabricator, packager/labeller or tester of the drug being imported.

SOR/97-12, s. 5; SOR/2000-120, s. 5; SOR/2002-368, s. 6.

C.01A.015. (1) An importer of a drug that is fabricated, packaged/labelled or tested in an MRA country at a recognized building shall immediately notify the Minister if the fabricator, packager/labeller or tester indicated in the importer's establishment licence no longer holds a valid permit, licence or other authorization issued by the regulatory authority that recognized that building.

(2) The Minister shall, on receiving a notification under subsection (1), amend the importer's establishment licence by removing the name and address of that fabricator, packager/labeller or tester.

SOR/97-12, s. 5; SOR/2000-120, s. 6; SOR/2002-368, s. 7.

## Suspension

C.01A.016. (1) Subject to subsection (3), the Minister may suspend an establishment licence in respect of any or all matters indicated in subsection C.01A.008(2) if the Minister has reasonable grounds to believe that

(*a*) the licensee has contravened any provision of the Act or these Regulations; or

(*b*) the licensee has made a false or misleading statement in the application for the establishment licence.

(2) Before suspending an establishment licence, the Minister shall consider

(*a*) the licensee's history of compliance with the Act and these Regulations; and

(*b*) the risk that allowing the licence to continue in force would constitute for the health of the consumer.

(3) Subject to subsection C.01A.017(1), the Minister shall not suspend an establishment licence until

(*a*) an inspector has sent the licensee a written notice that sets out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;

(*b*) if corrective action is required, the time set out in the notice has passed without the action having been taken; and

(*c*) the licensee has been given an opportunity to be heard in respect of the suspension.

SOR/97-12, s. 5.

C.01A.017. (1) The Minister may suspend an establishment licence without giving the licensee an opportunity to be heard if it is necessary to do so to prevent injury to the health of the consumer, by giving the licensee a notice in writing that states the reason for the suspension.

(2) A licensee may request of the Minister, in writing, that the suspension be reconsidered.

(3) The Minister shall, within 45 days after the date of receiving the request, provide the licensee with the opportunity to be heard.

SOR/97-12, s. 5.

C.01A.018. The Minister may reinstate an establishment licence after it has been suspended.

SOR/97-12, s. 5.

## Cancellation

C.01A.018.1 The Minister shall cancel an establishment licence in either of the following circumstances:

(*a*) the licence has been suspended for a period of more than 12 months, or

(*b*) the licence holder has failed to submit an application for the review of their licence in accordance with subsection C.01A.009(1).

SOR/2011-81, s. 6.

## Designation

C.01A.019 (1) For the purposes of this Division and Divisions 2 to 4, a regulatory authority that is set out in column 1 of the table to this section is hereby designated in respect of the activities set out in column 3 for the drug or category of drugs set out in column 2.

(2) Whole blood and its components are excluded from the drugs and categories of drugs set out in column 2 of the table to this section.

(3) The lot release of drugs listed in Schedule D to the Act is excluded from the activity of testing set out in column 3 of the table to this section.

TABLE

DESIGNATED REGULATORY AUTHORITIES

| | Column 1 | Column 2 | Column 3 |
|---|---|---|---|
| Item | Regulatory authority | Drug or category of drugs | Activities |
| 1. | Swissmedic, Swiss Agency for Therapeutic Products, Bern, Switzerland | Pharmaceuticals for human or veterinary use<br>Drugs listed in | Fabricating, packaging/labelling, testing |

| Item | Column 1<br>Regulatory authority | Column 2<br>Drug or category of drugs | Column 3<br>Activities |
|---|---|---|---|
| | | Schedules C and D to the Act | |
| 2. | Regional Medicines Inspectorate of Northwestern Switzerland (RFS-NW), Basel, Switzerland | Pharmaceuticals for human or veterinary use<br>Drugs listed in Schedules C and D to the Act | Fabricating, packaging/labelling, testing |
| 3. | Regional Medicines Inspectorate of Eastern and Central Switzerland (RFS-OZ), Zurich, Switzerland | Pharmaceuticals for human or veterinary use<br>Drugs listed in Schedules C and D to the Act | Fabricating, packaging/labelling, testing |
| 4. | Regional Medicines Inspectorate of Southern Switzerland (RFS-S), Ticino, Switzerland | Pharmaceuticals for human or veterinary use<br>Drugs listed in Schedules C and D to the Act | Fabricating, packaging/labelling, testing |
| 5. | Regional Medicines Inspectorate of Western Switzerland (RFS-W), Lausanne, Switzerland | Pharmaceuticals for human or veterinary use<br>Drugs listed in Schedules C and D to the Act | Fabricating, packaging/labelling, testing |

SOR/97-12, s. 5; SOR/2000-120, s. 7; SOR/2002-368, s. 8.

# Division 2

# Good Manufacturing Practices

C.02.001. [Repealed, SOR/97-12, s. 5.1]

C.02.002. In this Division,

“drug”[Repealed, SOR/97-12, s. 6]

“importer”[Repealed, SOR/97-12, s. 6]

“medical gas” means any gas or mixture of gases manufactured, sold or represented for use as a drug; (gaz médical)

“packaging material” includes a label; (matériel d’emballage)

“produce”[Repealed, SOR/97-12, s. 6]

“quality control department”[Repealed, SOR/2010-95, s. 1]

“specifications” means a detailed description of a drug, the raw material used in a drug or the packaging material for a drug and includes

(*a*) a statement of all properties and qualities of the drug, raw material or packaging material that are relevant to the manufacture, packaging and use of the drug, including the identity, potency and purity of the drug, raw material or packaging material,

(*b*) a detailed description of the methods used for testing and examining the drug, raw material or packaging material, and

(*c*) a statement of tolerances for the properties and qualities of the drug, raw material or packaging material. (spécifications)

SOR/82-524, s. 3; SOR/85-754, s. 1; SOR/89-174, s. 1; SOR/97-12, s. 6; SOR/2010-95, s. 1.

Previous Version

C.02.002.1. This Division does not apply to fabricating, packaging/labelling, testing, storing and importing of antimicrobial agents.

SOR/2004-282, s. 3.

## Sale

C.02.003. No distributor referred to in paragraph C.01A.003(*b*) and no importer shall sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with the requirements of this Division.

SOR/82-524, s. 3; SOR/97-12, s. 7; SOR/2000-120, s. 8; SOR/2010-95, s. 2(F).

Previous Version

## Premises

C.02.004. The premises in which a lot or batch of a drug is fabricated, packaged/labelled or stored shall be designed, constructed and maintained in a manner that

(*a*) permits the operations therein to be performed under clean, sanitary and orderly conditions;

(*b*) permits the effective cleaning of all surfaces therein; and

(*c*) prevents the contamination of the drug and the addition of extraneous material to the drug.

SOR/82-524, s. 3; SOR/97-12, s. 8; SOR/2010-95, s. 3.

Previous Version

## Equipment

C.02.005. The equipment with which a lot or batch of a drug is fabricated, packaged/labelled or tested shall be designed, constructed, maintained, operated and arranged in a manner that

(*a*) permits the effective cleaning of its surfaces;

(*b*) prevents the contamination of the drug and the addition of extraneous material to the drug; and

(*c*) permits it to function in accordance with its intended use.

SOR/82-524, s. 3; SOR/97-12, s. 9.

## Personnel

C.02.006. Every lot or batch of a drug shall be fabricated, packaged/labelled, tested and stored under the supervision of personnel who, having regard to the duties and responsibilities involved, have had such technical, academic and other training as the Director considers satisfactory in the interests of the health of the consumer or purchaser.

SOR/82-524, s. 3; SOR/85-754, s. 2; SOR/97-12, s. 52.

## Sanitation

C.02.007. (1) Every person who fabricates or packages/labels a drug shall have a written sanitation program that shall be implemented under the supervision of qualified personnel.

(2) The sanitation program referred to in subsection (1) shall include

(*a*) cleaning procedures for the premises where the drug is fabricated or packaged/labelled and for the equipment used in the fabrication or packaging/labelling; and

(*b*) instructions on the sanitary fabrication and packaging/labelling of drugs and the handling of materials used in the fabrication and packaging/labelling of drugs.

SOR/82-524, s. 3; SOR/97-12, ss. 10, 53.

C.02.008. (1) Every person who fabricates or packages/labels a drug shall have, in writing, minimum requirements for the health and the hygienic behaviour and clothing of personnel to ensure the clean and sanitary fabrication and packaging/labelling of the drug.

(2) No person shall have access to any area where a drug is exposed during its fabrication or packaging/labelling if the person

(*a*) is affected with or is a carrier of a disease in a communicable form; or

(*b*) has an open lesion on any exposed surface of the body.

SOR/82-524, s. 3; SOR/97-12, s. 11.

## Raw Material Testing

C.02.009. (1) Each lot or batch of raw material shall be tested against the specifications for that raw material prior to its use in the fabrication of a drug.

(2) No lot or batch of raw material shall be used in the fabrication of a drug unless that lot or batch of raw material complies with the specifications for that raw material.

(3) Notwithstanding subsection (1), water may, prior to the completion of its tests under that subsection, be used in the fabrication of a drug.

(4) Where any property of a raw material is subject to change on storage, no lot or batch of that raw material shall be used in the fabrication of a drug after its storage unless the raw material is retested after an appropriate interval and complies with its specifications for that property.

(5) Where the specifications referred to in subsections (1), (2) and (4) are not prescribed, they shall

(*a*) be in writing;

(*b*) be acceptable to the Director who shall take into account the specifications contained in any publication mentioned in Schedule B to the Act; and

(*c*) be approved by the person in charge of the quality control department.

SOR/82-524, s. 3; SOR/97-12, s. 59.

C.02.010. (1) The testing referred to in section C.02.009 shall be performed on a sample taken

(*a*) after receipt of each lot or batch of raw material on the premises of the fabricator; or

(*b*) subject to subsection (2), before receipt of each lot or batch of raw material on the premises of the fabricator, if

(i) the fabricator

(A) has evidence satisfactory to the Director to demonstrate that raw materials sold to him by the vendor of that lot or batch of raw material are consistently manufactured in accordance with and consistently comply with the specifications for those raw materials, and

(B) undertakes periodic complete confirmatory testing with a frequency satisfactory to the Director, and

(ii) the raw material has not been transported or stored under conditions that may affect its compliance with the specifications for that raw material.

(2) After a lot or batch of raw material is received on the premises of the fabricator, the lot or batch of raw material shall be tested for identity.

SOR/82-524, s. 3; SOR/97-12, ss. 12, 60.

## Manufacturing Control

C.02.011. (1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall have written procedures prepared by qualified personnel in respect of the drug to ensure that the drug meets the specifications for that drug.

(2) Every person required to have written procedures referred to in subsection (1) shall ensure that each lot or batch of the drug is fabricated, packaged/labelled and tested in compliance with those procedures.

SOR/82-524, s. 3; SOR/97-12, s. 13.

C.02.012. (1) Every fabricator, packager/labeller, distributor referred to in section C.01A.003, importer and wholesaler of a drug shall maintain

(*a*) a system of control that permits complete and rapid recall of any lot or batch of the drug that is on the market; and

(*b*) a program of self-inspection.

(2) Every fabricator and packager/labeller and, subject to subsections (3) and (4), every distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall maintain a system designed to ensure that any lot or batch of the drug fabricated and packaged/labelled on premises other than their own is fabricated and packaged/labelled in accordance with the requirements of this Division.

(3) The distributor referred to in paragraph C.01A.003(*b*) of a drug that is fabricated, packaged/labelled and tested in Canada by a person who holds an establishment licence that authorizes those activities is not required to comply with the requirements of subsection (2) in respect of that drug.

(4) If a drug is fabricated or packaged/labelled in an MRA country at a recognized building, the distributor referred to in paragraph C.01A.003(*b*) or importer of the drug is not required to comply with the requirements of subsection (2) in respect of that activity for that drug if

(*a*) the address of the building is set out in that person's establishment licence; and

(*b*) that person retains a copy of the batch certificate for each lot or batch of the drug received by that person.

SOR/82-524, s. 3; SOR/97-12, s. 13; SOR/2000-120, s. 9; SOR/2002-368, s. 9.

## Quality Control Department

C.02.013. (1) Every fabricator, packager/labeller, wholesaler, distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall have on their premises in Canada a quality control department that is supervised by personnel described in section C.02.006.

(2) Except in the case of a wholesaler, the quality control department shall be a distinct organizational unit that functions and reports to management independently of any other functional unit, including the manufacturing, processing, packaging or sales unit.

SOR/82-524, s. 3; SOR/89-174, s. 8(F); SOR/97-12, s. 55; SOR/2000-120, s. 10; SOR/2010-95, s. 4.

Previous Version

C.02.014. (1) Except in the case of a wholesaler, no lot or batch of a drug shall be made available for sale unless the sale of that lot or batch is approved by the person in charge of the quality control department.

(2) A drug that is returned to the fabricator, packager/labeller, wholesaler, distributor referred to in paragraph C.01A.003(*b*) or importer shall not be made available for further sale unless the sale of that drug is approved by the person in charge of the quality control department.

(3) No lot or batch of raw material or of packaging/labelling material shall be used in the fabrication or packaging/labelling of a drug unless the material is approved for that use by the person in charge of the quality control department.

(4) No lot or batch of a drug shall be reprocessed without the approval of the person in charge of the quality control department.

SOR/82-524, s. 3; SOR/89-174, s. 8(F); SOR/97-12, ss. 14, 55; SOR/2010-95, s. 5.

Previous Version

C.02.015. (1) All fabrication, packaging/labelling, testing, storage and transportation methods and procedures that may affect the quality of a drug shall be examined and approved by the person in charge of the quality control department before their implementation.

(2) The person in charge of the quality control department shall cause to be investigated any complaint or information that is received respecting the quality of a drug or its deficiencies or hazards and cause any necessary corrective action to be taken, in the case where the complaint or information relates to an activity over which the department exercises quality control.

(2.1) In the case where the complaint or information that is received does not relate to an activity over which the quality control department exercises quality control, the person in charge of the department shall forward the complaint or information to the person in charge of the quality control department that exercises quality control over that activity.

(3) The person in charge of the quality control department shall cause all tests or examinations required pursuant to this Division to be performed by a competent laboratory.

SOR/82-524, s. 3; SOR/97-12, s. 15; SOR/2010-95, s. 6.

Previous Version

## Packaging Material Testing

C.02.016. (1) Each lot or batch of packaging material shall, prior to its use in the packaging of a drug, be examined or tested against the specifications for that packaging material.

(2) No lot or batch of packaging material shall be used in the packaging of a drug unless the lot or batch of packaging material complies with the specifications for that packaging material.

(3) The specifications referred to in subsections (1) and (2) shall

(*a*) be in writing;

(*b*) be acceptable to the Director who shall take into account the specifications contained in any publication mentioned in Schedule B to the Act; and

(*c*) be approved by the person in charge of the quality control department.

SOR/82-524, s. 3; SOR/89-174, s. 8(F).

C.02.017. (1) The examination or testing referred to in section C.02.016 shall be performed on a sample taken

(*a*) after receipt of each lot or batch of packaging material on the premises of the person who packages a drug; or

(*b*) subject to subsection (2), before receipt of each lot or batch of packaging material on the premises of the person who packages a drug, if

(i) that person

(A) has evidence satisfactory to the Director to demonstrate that packaging materials sold to him by the vendor of that lot or batch of packaging material are consistently manufactured in accordance with and consistently comply with the specifications for those packaging materials, and

(B) undertakes periodic complete confirmatory examination or testing with a frequency satisfactory to the Director,

(ii) the packaging material has not been transported or stored under conditions that may affect its compliance with the specifications for that packaging material.

(2) After a lot or batch of packaging material is received on the premises of the person who packages a drug,

(*a*) the lot or batch of the packaging material shall be examined or tested for identity; and

(*b*) the labels shall be examined or tested in order to ensure that they comply with the specifications for those labels.

SOR/82-524, s. 3; SOR/89-174, ss. 2(F), 8(F); SOR/97-12, s. 56(F).

## Finished Product Testing

C.02.018. (1) Each lot or batch of a drug shall, prior to its availability for sale, be tested against the specifications for that drug.

(2) No lot or batch of a drug shall be available for sale unless it complies with the specifications for that drug.

(3) The specifications referred to in subsections (1) and (2) shall

(*a*) be in writing;

(*b*) be approved by the person in charge of the quality control department; and

(*c*) comply with the Act and these Regulations.

SOR/82-524, s. 3.

C.02.019. (1) Subject to subsections (3) and (4), in the case of a packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer, the testing referred to in section C.02.018 shall be performed on a sample taken

(*a*) after receipt of each lot or batch of the drug on the premises in Canada of the packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer of the drug; or

(*b*) subject to subsection (2), before receipt of each lot or batch of the drug on the premises described in paragraph (*a*), if

(i) the packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer

(A) has evidence satisfactory to the Director to demonstrate that drugs sold to him by the vendor of that lot or batch of the drug are consistently manufactured in accordance with and consistently comply with the specifications for those drugs, and

(B) undertakes periodic complete confirmatory testing with a frequency satisfactory to the Director, and

(ii) the drug has not been transported or stored under conditions that may affect its compliance with the specifications for that drug.

(2) Where the packager/labeller, distributor referred to in paragraph C.01A.003(*b*) or importer of a drug receives a lot or batch of the drug on their premises in Canada, and the useful life of the drug is more than 30 days, the lot or batch shall be tested for identity, and the packager/labeller shall confirm the identity after the lot or batch is packaged/labelled.

(3) The distributor referred to in paragraph C.01A.003(*b*) of a drug that is fabricated, packaged/labelled and tested in Canada by a person who holds an establishment licence that authorizes those activities is not required to comply with the requirements of subsections (1) and (2) in respect of that drug.

(4) If a drug is fabricated, packaged/labelled and tested in an MRA country at a recognized building, the distributor referred to in paragraph C.01A.003(*b*) or importer of that drug is not required to comply with the requirements of subsections (1) and (2) in respect of that drug if

(*a*) the address of the building is set out in that person's establishment licence; and

(*b*) that person retains a copy of the batch certificate for each lot or batch of the drug received by that person.

SOR/82-524, s. 3; SOR/89-174, s. 8(F); SOR/97-12, ss. 16, 57; SOR/2000-120, s. 11; SOR/2002-368, s. 10.

## Records

C.02.020. (1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(*b*) and importer shall maintain on their premises in Canada, for each drug sold,

(*a*) master production documents for the drug;

(*b*) evidence that each lot or batch of the drug has been fabricated, packaged/labelled, tested and stored in accordance with the procedures described in the master production documents;

(*c*) evidence that the conditions under which the drug was fabricated, packaged/labelled, tested and stored are in compliance with the requirements of this Division;

(*d*) evidence establishing the period of time during which the drug in the container in which it is sold will meet the specifications for that drug; and

(*e*) adequate evidence of the testing referred to in section C.02.018.

(2) Every distributor referred to in paragraph C.01A.003(*b*) and importer shall make available to the Director, on request, the results of testing performed on raw materials and packaging/labelling material for each lot or batch of a drug sold.

(3) Every fabricator shall maintain on his premises

(*a*) the written specifications for the raw material; and

(*b*) adequate evidence of the testing of the raw materials referred to in section C.02.009.

(4) Every person who packages a drug shall maintain on his premises

(*a*) the written specifications for the packaging material; and

(*b*) adequate evidence of the packaging material examination or testing referred to in section C.02.016.

(5) Every fabricator shall maintain on their premises in Canada

(*a*) detailed plans and specifications of each building in Canada at which they fabricate, package/label or test; and

(*b*) a description of the design and construction of those buildings.

(6) Every fabricator, packager/labeller and tester shall maintain on their premises in Canada details of the personnel employed to supervise the fabrication, packaging/labelling and testing, including each person's title, responsibilities, qualifications, experience and training.

SOR/82-524, s. 3; SOR/89-174, ss. 3(F), 8(F); SOR/97-12, ss. 17, 52, 60.

C.02.021. (1) Subject to subsection (2), all records and evidence on the fabrication, packaging/labelling, testing and storage of a drug that are required to be maintained under this Division shall be retained for a period of at least one year after the expiration date on the label of the drug, unless otherwise specified in the person's establishment licence.

(2) All records and evidence on the testing of raw materials and packaging/labelling materials that are required to be maintained under this Division shall be retained for a period of at least five years after the materials were last used in the fabrication or packaging/labelling of a drug, unless otherwise specified in the person's establishment licence.

SOR/82-524, s. 3; SOR/89-174, s. 8(F); SOR/92-654, s. 6; SOR/97-12, s. 18.

C.02.022. Every distributor referred to in section C.01A.003, wholesaler and importer of a drug shall retain records of the sale of each lot or batch of the drug, which enable them to recall the lot or batch from the market, for a period of at least one year after the expiration date of that lot or batch, unless otherwise specified in their establishment licence.

SOR/82-524, s. 3; SOR/92-654, s. 7; SOR/97-12, s. 18.

C.02.023. (1) On receipt of a complaint or any information respecting the quality of a drug or its deficiencies or hazards, every fabricator, packager/labeller, wholesaler, distributor referred to in paragraph C.01A.003(*b*) or importer of the drug, as the case may be, shall

(*a*) in the case of a complaint or information described in subsection C.02.015(2), make a record of the complaint or information, its investigation and, if applicable, any corrective action taken; and

(*b*) in the case of a complaint or information described in subsection C.02.015(2.1), make a record of the complaint or information, the name and business address of the person in charge of the quality control department to whom it was forwarded and the date on which it was forwarded.

(2) The fabricator, packager/labeller, wholesaler, distributor referred to in paragraph C.01A.003(*b*) or importer of the drug, as the case may be, shall retain the record for a period of at least one year after the expiration date of the lot or batch of that drug, unless their establishment licence specifies otherwise.

SOR/82-524, s. 3; SOR/92-654, s. 7; SOR/97-12, s. 18; SOR/2010-95, s. 7.

Previous Version

C.02.024. (1) Every fabricator, packager/labeller, distributor referred to in section C.01A.003, importer and wholesaler shall

(*a*) maintain records of the results of the self-inspection program required by section C.02.012 and of any action taken in connection with that program; and

(*b*) retain those records for a period of at least three years.

(2) Every person who fabricates or packages/labels a drug shall

(*a*) maintain records on the operation of the sanitation program required to be implemented under section C.02.007; and

(*b*) retain those records for a period of at least three years.

SOR/82-524, s. 3; SOR/97-12, ss. 19, 53.

## Samples

C.02.025. (1) Every distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall retain in Canada a sample of each lot or batch of the packaged/labelled drug for a period of at least one year after the expiration date on the label of the drug, unless otherwise specified in the distributor's or importer's establishment licence.

(2) The fabricator shall retain a sample of each lot or batch of raw materials used in the fabrication of a drug for a period of at least two years after the materials were last used in the fabrication of the drug, unless otherwise specified in the fabricator's establishment licence.

SOR/82-524, s. 3; SOR/89-174, s. 4(F); SOR/92-654, s. 8; SOR/97-12, s. 20.

C.02.026. The samples referred to in section C.02.025 shall be in an amount that is sufficient to determine whether the drug or raw material complies with the specifications for that drug or raw material.

SOR/82-524, s. 3.

## Stability

C.02.027. Every distributor referred to in paragraph C.01A.003(*b*) and importer shall establish the period of time during which each drug in the package in which it is sold will comply with the specifications.

SOR/82-524, s. 3; SOR/97-12, s. 58.

C.02.028. Every distributor referred to in paragraph C.01A.003(*b*) and importer shall monitor, by means of a continuing program, the stability of the drug in the package in which it is sold.

SOR/82-524, s. 3; SOR/97-12, s. 58.

### Sterile Products

C.02.029. In addition to the other requirements of this Division, a drug that is intended to be sterile shall be fabricated and packaged/labelled

(*a*) in separate and enclosed areas;

(*b*) under the supervision of personnel trained in microbiology; and

(*c*) by a method scientifically proven to ensure sterility.

SOR/82-524, s. 3; SOR/97-12, s. 21.

### Medical Gases

C.02.030. The provisions of sections C.02.025, C.02.027 and C.02.028 do not apply to medical gases.

SOR/85-754, s. 3.

## Division 3

### Schedule C Drugs

C.03.001. In this Division,

“drug” means a drug listed in Schedule C to the Act that is in dosage form, or a drug that is a bulk process intermediate that can be used in the preparation of a drug listed in Schedule C to the Act that is of biological origin; (drogue)

“licence” or “Canadian licence”[Repealed, SOR/97-12, s. 22]

“manufacturer”[Repealed, SOR/97-12, s. 22]

“master lot” means a quantity of a drug from which a lot is prepared for sale by subsequent dilution or mixture; (maître-lot)

“radionuclide generator” means a radioactive parent and daughter

(*a*) contained in an ion-exchange column, or

(*b*) dissolved in a suitable solvent in a liquid-liquid extraction system

where the radioactive daughter is separated from its parent by

(*c*) elution from the ion exchange column, or

(*d*) a solvent extraction procedure. (générateur de radionucléide)

SOR/97-12, s. 22.

C.03.001.1 No distributor referred to in paragraph C.01A.003(*b*) or importer shall sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with this Division.

SOR/97-12, s. 23.

C.03.002. to C.03.005. [Repealed, SOR/97-12, s. 24]

C.03.006. [Repealed, SOR/97-12, s. 67]

C.03.007. to C.03.011 [Repealed, SOR/97-12, s. 26]

C.03.012. On written request from the Director, every fabricator, packager/labeller, tester, distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall submit protocols of tests together with samples of any lot or master lot of the drug before it is sold, and no person shall sell a lot of which the protocol or sample fails to meet the requirements of these Regulations.

SOR/97-12, s. 27.

C.03.013. No person shall fabricate or import a drug that is derived from animal tissue unless the tissue is obtained from a healthy animal free from infectious disease.

SOR/97-12, s. 27.

C.03.014. (1) Section C.01.004 does not apply to a drug.

(2) and (3) [Repealed, SOR/97-12, s. 28]

SOR/79-236, s. 1; SOR/93-202, s. 15; SOR/97-12, s. 28.

C.03.015. Every package of a drug listed or described in Schedule F in the Regulations, other than

(*a*) a drug sold to a drug fabricator,

(*b*) a drug dispensed pursuant to a prescription,

(*c*) a radiopharmaceutical as defined in section C.03.201, or

(*d*) a component or kit as defined in section C.03.205,

shall carry the symbol **Pr** on the upper left quarter of the principal display panel of both its inner and outer labels or, in the case of a single dose container, on the upper left quarter of its outer label.

SOR/80-543, s. 9; SOR/97-12, s. 61; SOR/2001-181, s. 4.

C.03.030. to C.03.045. [Repealed, SOR/81-335, s. 2]

## Radiopharmaceuticals

C.03.201. In these Regulations, “radiopharmaceutical” means a drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons.

SOR/97-12, s. 29.

C.03.202. (1) Every package containing a radiopharmaceutical, other than a radionuclide generator, shall carry,

(*a*) on both the inner and the outer labels,

(i) the proper name of the drug, which proper name, where there is a brand name, shall immediately precede or follow the brand name,

(ii) the name of the distributor referred to in paragraph C.01A.003(*b*), and

(iii) the lot number; and

(*b*) on the outer label

(i) the address of the distributor referred to in paragraph C.01A.003(*b*),

(ii) the standard that the drug professes to meet, if that standard is referred to in any publication mentioned in Schedule B to the Act,

(iii) a statement of the pharmaceutical form or the route of administration of the drug,

(iv) a statement of the recommended use and the recommended radioactivity to be administered for that use, or a reference to an accompanying package insert that shows such information,

(v) the establishment licence number of the distributor preceded by the words “Establishment Licence Number”, “Numéro de licence d’établissement” or an abbreviation thereof,

(vi) the radiation warning symbol required by the Atomic Energy Control Regulations and the statement “Caution — Radioactive Material” “Attention — Produit radioactif”,

(vii) the names and a statement of the amounts of any preservatives or stabilizing agents contained in the drug,

(viii) the names and a statement of the amounts of all other non-radioactive contents of the drug,

(ix) a statement of the total radioactivity content of the drug including overfill,

(x) a statement of the total volume of the drug including overfill, except where its contents are entirely in gaseous, capsule or lyophilized form,

(xi) a statement of the concentration of radioactive material in the drug expressed as

(A) units of radioactivity per capsule or

(B) units of radioactivity per unit volume,

except where the contents of the drug are entirely in gaseous or lyophilized form,

(xii) a statement of the specific activity of the drug expressed as units of radioactivity per unit weight of carrier present or the statement “carrier-free” or “sans entraîneur”, whichever is applicable,

(xiii) a statement of the reference time in respect of the radioactivity values mentioned in subparagraphs (ix), (xi) and (xii), the name of the month being written or designated by letter abbreviation,

(xiv) a statement of the recommended useful life or the date after which the drug is not recommended for use, the name of the month being written or designated by letter abbreviation, and

(xv) a statement of the special storage requirements with reference to temperature and light.

(2) [Repealed, SOR/2001-203, s. 2]

(3) Subparagraph (1)(*b*)(viii) of this section does not apply where the information referred to in that subparagraph is shown on a package insert that accompanies the drug.

(4) Section C.01.005 does not apply to a radiopharmaceutical.

SOR/79-236, s. 2; SOR/93-202, s. 16; SOR/97-12, ss. 54, 58, 62; SOR/2001-203, s. 2.

C.03.203. (1) Every radionuclide generator shall carry on the inner label

(*a*) the proper name of the radionuclide generator, which proper name, where there is a brand name, shall immediately precede or follow the brand name;

(*b*) the name and address of the distributor referred to in paragraph C.01A.003(*b*);

(*c*) the lot number;

(*d*) the standard that the radionuclide generator professes to meet, if that standard is referred to in any publication mentioned in Schedule B to the Act;

(*e*) the establishment licence number of the distributor preceded by the words “Establishment Licence Number”, “Numéro de licence d’établissement” or an abbreviation thereof;

(*f*) the radiation warning symbol required by the Atomic Energy Control Regulations and the statement “Caution — Radioactive Material” “Attention — Produit radioactif”;

(*g*) a statement of the total parent radioactivity contained in the radionuclide generator;

(*h*) a statement of the hour and date at which the radioactivity value mentioned in paragraph (*g*) is valid, the name of the month being written or designated by letter abbreviation;

(*i*) a statement of the recommended useful life or the date after which the radionuclide generator is not recommended for use, the name of the month being written or designated by letter abbreviation;

(*j*) a statement of the recommended useful life of the drug after removal from the radionuclide generator;

(*k*) a statement of special storage requirements with reference to temperature or shielding;

(*l*) complete directions for use or a reference to an accompanying package insert that sets out such directions; and

(*m*) a statement cautioning against the dismantling of the radionuclide generator.

(2) Paragraphs (1)(*i*) and (*j*) of this section do not apply where the information referred to in those subparagraphs is shown on a package insert that accompanies the radionuclide generator.

SOR/79-236, s. 3; SOR/93-202, s. 17; SOR/97-12, ss. 54, 58, 62.

C.03.204. (1) No person shall sell a drug containing technetium-99m at any time during the useful life of the drug if the drug also contains a radionuclidic impurity mentioned in the monograph for Sodium Pertechnetate Tc-99m Injection referred to in the publication mentioned in item 7 of Schedule B to the Act, in an amount greater than that shown in the monograph.

(2) No person shall sell a radionuclide generator from which can be removed a drug that contains technetium-99m, at any time during the useful life of the drug, if the drug also contains a radionuclidic impurity mentioned in the monograph for Sodium Pertechnetate Tc-99m Injection referred to in the publication mentioned in item 7 of Schedule B to the Act, in an amount greater than that shown in the monograph.

SOR/97-12, s. 30.

## Drugs, other than Radionuclides, Sold or Represented for Use in the Preparation of Radiopharmaceuticals

C.03.205. For the purposes of sections C.03.206 to C.03.209,

“component” means

(*a*) a unit of a drug, other than a radionuclide, separately packaged in a kit for use in the preparation of a radiopharmaceutical, or

(*b*) an empty vial or other accessory item in a kit; (constituants)

“kit” means a package

(*a*) that contains one or more separately packaged units of a drug, other than a radionuclide, and

(*b*) that may contain empty vials or other accessory items, for use in the preparation of radiopharmaceuticals. (trousse)

SOR/79-236, s. 4.

C.03.206. Sections C.01.005 and C.04.019 do not apply to a component or kit.

SOR/79-236, s. 4.

C.03.207. Every component shall be labelled to show

(*a*) adequate identification of the component and an adequate description of its function;

(*b*) where applicable, a quantitative list of its ingredients or a reference to the label of the kit that shows such information;

(*c*) the name of the distributor referred to in paragraph C.01A.003(*b*);

(*d*) the lot number;

(*e*) a statement of any special storage requirements with respect to temperature and light;

(*f*) the date after which the component is not recommended for use, the name of the month being written in full or designated by letter abbreviation; and

(*g*) adequate directions for use or a reference to the accompanying package insert that shows such directions.

SOR/79-236, s. 4; SOR/97-12, s. 58.

C.03.208. Every kit shall be labelled to show

(*a*) its proper name;

(*b*) its brand name, if any;

(*c*) a list of its contents;

(*d*) the name and address of the distributor referred to in paragraph C.01A.003(*b*);

(*e*) the establishment licence number of the distributor preceded by the words “Establishment Licence Number”, “Numéro de licence d’établissement” or an abbreviation thereof;

(*f*) the lot number;

(*g*) a statement of any special storage requirements with respect to temperature and light;

(*h*) the date after which the kit is not recommended for use, the name of the month being written in full or designated by letter abbreviation;

(*i*) where the label of a component makes reference to the label of the kit that shows information as to the ingredients of the component, a quantitative list of the ingredients of that component;

(*j*) a statement of the sterility and apyrogenicity of the components;

(*k*) adequate directions for preparing the radiopharmaceutical or a reference to the accompanying package insert that shows such directions;

(*l*) a statement of the duration of the useful life of the prepared radiopharmaceutical;

(*m*) a statement of the storage requirements for the prepared radiopharmaceutical;

(*n*) a statement of the recommended use for the prepared radiopharmaceutical and the recommended radioactivity to be administered for that use, or a reference to the accompanying package insert that shows such information; and

(*o*) a statement of the route of administration of the prepared radiopharmaceutical.

(*p*) [Repealed, SOR/2001-203, s. 3]

SOR/79-236, s. 4; SOR/93-202, s. 18; SOR/97-12, ss. 58, 62; SOR/2001-203, s. 3.

C.03.209. A package insert shall be included in every kit and shall show

(*a*) the proper name and the brand name, if any, of the kit and a description of its use;

(*b*) a list of the contents of the kit;

(*c*) the name and address of the distributor referred to in paragraph C.01A.003(*b*) of the kit;

(*d*) identification of the radionuclides that can be used to prepare the radiopharmaceutical;

(*e*) directions for preparing the radiopharmaceutical and a statement of the storage requirements for the prepared radiopharmaceutical;

(*f*) a statement of the duration of the useful life of the prepared radiopharmaceutical;

(*g*) a description of the biological actions of the prepared radiopharmaceutical;

(*h*) indications and contraindications in respect of the prepared radiopharmaceutical;

(*i*) warnings and precautions in respect of the components and the prepared radiopharmaceutical;

(*j*) the adverse reactions, if any, associated with the prepared radiopharmaceutical;

(*k*) where applicable, the pharmacology and toxicology of the prepared radiopharmaceutical or a statement that such information is available on request;

(*l*) the radiation dosimetry in respect of the prepared radiopharmaceutical;

(*m*) a statement of the recommended use for the prepared radiopharmaceutical and the recommended radioactivity to be administered for that use;

(*n*) a statement of the route of administration of the prepared radiopharmaceutical; and

(*o*) a recommendation that the radiochemical purity and radioactivity content of the prepared radiopharmaceutical be checked prior to administration.

SOR/79-236, s. 4; SOR/93-202, s. 19; SOR/97-12, s. 58.

# Division 4

## Schedule D Drugs

C.04.001. In this Division,

“date of manufacture” means

(*a*) in the case of a product for which a standard of potency exists, the date it satisfactorily passes a potency test,

(*b*) in the case of an animal product for which no standard of potency exists, the date of its removal from the animal, and

(*c*) in the case of a product other than an animal product for which no standard of potency exists, the date of cessation of growth; (date de fabrication)

“drug” means a drug listed in Schedule D to the Act that is in dosage form, or a drug that is a bulk process intermediate that can be used in the preparation of a drug listed in Schedule D to the Act; (drogue)

“licence” or “Canadian licence”[Repealed, SOR/97-12, s. 31]

“manufacturer” [Repealed, SOR/97-12, s. 31]

SOR/97-12, s. 31.

C.04.001.1 No distributor referred to in paragraph C.01A.003(*b*) or importer shall sell a drug unless it has been fabricated, packaged/labelled, tested and stored in accordance with this Division.

SOR/97-12, s. 32.

C.04.002. This Division does not apply to a drug in oral dosage form that contains micro-organisms if the drug is recommended solely for restoring, normalizing or stabilizing the intestinal flora.

SOR/97-12, s. 33.

C.04.003. The date of issue of a drug shall be the date on which the finished product is removed from cold storage but in any case shall be, not later than

(*a*) six months after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 10°C;

(*b*) 12 months after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 5°C; or

(*c*) two years after the date of manufacture for a drug that has been kept constantly at a temperature not exceeding 0°C.

C.04.004. to C.04.006. [Repealed, SOR/97-12, s. 34]

C.04.007. [Repealed, SOR/97-12, s. 67]

C.04.008. to C.04.012 [Repealed, SOR/97-12, s. 36]

C.04.013. Every fabricator and packager/labeller shall safely segregate all work with spore-bearing, pathogenic micro-organisms and other infectious agents known to require special precautions in manipulation and shall take such care of equipment and arrangements for supervision that the possibility of contamination of other drugs is avoided.

SOR/97-12, s. 63.

C.04.014. No person shall conduct laboratory procedures of a diagnostic nature in their premises unless those procedures are entirely segregated from the fabrication, packaging/labelling and testing of drugs.

SOR/97-12, s. 37.

C.04.015. On written request from the Director, every fabricator, packager/labeller, tester, distributor referred to in paragraph C.01A.003(*b*) and importer of a drug shall submit protocols of tests together with samples of any lot of the drug before it is sold, and no person shall sell any lot of that drug if the protocol or sample fails to meet the requirements of these Regulations.

SOR/97-12, s. 37.

C.04.016. All animals from which drugs are prepared and preserved shall be

(*a*) under the direct supervision of competent medical or veterinary personnel;

(*b*) kept in quarantine by the fabricator for at least seven days before use; and

(*c*) healthy and free from infectious disease.

SOR/97-12, s. 38.

C.04.017. A fabricator shall keep necropsy records of all animals that die or are killed after having been used in the production of a drug.

SOR/97-12, s. 61.

C.04.018. A fabricator shall immediately segregate, and report the fact to the Minister, any animal with actual or suspected vesicular stomatitis, foot and mouth disease, encephalomyelitis, infectious anaemia, glanders, anthrax, tetanus or any other serious infectious disease.

SOR/97-12, s. 61.

C.04.019. The provisions of section C.01.004 do not apply to a drug as defined in this Division but every package of such drug shall carry

(*a*) on both the inner and the outer labels

(i) the proper name of the drug, which proper name, where there is a brand name, shall immediately precede or follow the brand name in type not less than one-half the size of that of the brand name,

(ii) the name of the distributor referred to in paragraph C.01A.003(*b*),

(iii) the potency of the drug, where applicable,

(iv) the recommended dose of the drug,

(v) the lot number,

(vi) the expiration date except upon the inner label of a single-dose container, and

(vii) adequate direction for use; and

(*b*) on the outer label

(i) the address of the distributor referred to in paragraph C.01A.003(*b*),

(ii) for whole blood and its components, the establishment licence number of the distributor referred to in paragraph C.01A.003(*b*), preceded by the words “Establishment Licence Number”, “Numéro de licence d’établissement” or an abbreviation thereof,

(iii) the proper name, or the common name if there is no proper name, and the amount, of any preservative in the drug,

(iv) a statement that the drug shall be stored at a temperature of not less than 2°C and not more than 10°C, unless the Minister has received evidence demonstrating that such a statement is not required,

(v) a statement of the net contents in terms of weight, measure, or number, and

(vi) in the case of a new drug for extraordinary use in respect of which a notice of compliance has been issued under section C.08.004.01, the following statement, displayed in capital letters and in a legible manner:

“HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS EXTRAORDINARY USE NEW DRUG FOR [naming purpose] BASED ON LIMITED CLINICAL TESTING IN HUMANS.

SANTÉ CANADA A AUTORISÉ LA VENTE DE CETTE DROGUE NOUVELLE POUR USAGE EXCEPTIONNEL AUX FINS DE [indication de la fin] EN SE FONDANT SUR DES ESSAIS CLINIQUES RESTREINTS CHEZ L’ÊTRE HUMAIN.”.

SOR/78-424, s. 7; SOR/93-202, s. 21; SOR/97-12, ss. 39, 54, 58; SOR/2011-88, s. 6.

Previous Version

C.04.020. Except in the case of the following drugs, every package of a drug listed in Schedule F of these Regulations shall carry the symbol Pr on the upper left quarter of the principal display panel of both its inner and outer labels or, in the case of a single dose container, on the upper left quarter of its outer label:

(*a*) a drug sold to a person who holds an establishment licence; and

(*b*) a drug dispensed pursuant to a prescription.

SOR/80-543, s. 10; SOR/97-12, s. 40; SOR/2001-181, s. 4.

## Bacterial Vaccines, Products Analogous to Bacterial Vaccines

C.04.050. Except as provided in this Division, a bacterial vaccine shall be a sterile suspension of killed cultures of bacteria, with or without the addition of other medication, and shall not include an autogenous vaccine.

C.04.051. No person shall sell a bacterial vaccine unless the culture that has been used in its preparation has been tested by an acceptable method for identity and purity and when so tested it shall be true to name and a pure strain, and a record of the culture shall be maintained which shall include a statement of its origin, properties and characteristics.

C.04.052. No fabricator shall use a substrate (culture medium), in the production of a bacterial vaccine, that contains any horse meat or horse serum.

SOR/97-12, s. 61.

C.04.053. A fabricator of a bacterial vaccine prepared from a bacterium that does not grow readily in ordinary culture media shall test its sterility in media which are specially favourable to the growth of such bacterium, and it shall be sterile.

SOR/97-12, s. 61.

C.04.054. Except as provided in sections C.04.083, C.04.084 and C.04.090, both the inner and outer labels of every multiple-dose container and the outer label of every single-dose container of a bacterial vaccine shall carry a statement of

(*a*) the number of bacteria per millilitre, or the weight of dried substance of bacteria per millilitre,

(*b*) the number of bacteria per millilitre, or the weight of dried substance of bacteria per millilitre, of each species or immunogenic type for a vaccine that contains a number of different species or immunogenic types of bacteria,

(*c*) the exact nature and amount of any substance, other than a simple diluent, combined with such vaccine, and

(*d*) the recommended dose,

and the inner label of a single-dose container shall carry a statement that it contains only one dose.

C.04.055. The expiration date of a bacterial vaccine shall be not later than 18 months after the date of manufacture or the date of issue.

## Typhoid Vaccine

C.04.060. Cultures of *Salmonella typhosa* used in the preparation of typhoid vaccine shall be smooth, motile, and in the Vi form, with the following antigenic structure IX,XII,Vi; d.-.

C.04.061. No person shall sell any lot of typhoid vaccine unless such lot has been shown to meet a test for potency made by an acceptable method.

## Pertussis Vaccine

C.04.065. A fabricator shall, in the preparation of pertussis (whooping cough) vaccine, use only strains of *Bordetella pertussis* that meet the requirements of an antigenic test made by an acceptable method.

SOR/90-217, s. 1; SOR/97-12, s. 61.

C.04.066. No person shall sell any lot of pertussis (whooping cough) vaccine unless such lot has been shown to meet a test for potency made by an acceptable method.

## B.C.G. (Bacille Calmette-Guerin) Vaccine

C.04.070. B.C.G. vaccine shall be prepared from living B.C.G. organisms that

(*a*) have been obtained directly from a source approved by the Director;

(*b*) are proved to be non-pathogenic by an acceptable method; and

(*c*) have a history of successful use in the production of B.C.G. vaccine.

C.04.071. No fabricator shall employ any person in the manufacture of B.C.G. vaccine unless such person

(*a*) has been and remains free from all forms of tuberculous infection,

(*b*) undergoes every six months a medical examination, that shall include an X-ray examination of the chest, for the presence of tuberculosis, such examination being made by a qualified, practising physician who shall sign a certificate of such person's freedom from tuberculosis, and such certificate shall be kept on file and be available at all times, and

(*c*) resides in a household that is at all times free from active tuberculosis,

nor shall a fabricator employ such person in any other laboratory position.

SOR/97-12, s. 61.

C.04.072. The preparation, preservation and packaging/labelling of B.C.G. vaccine shall be conducted under the direct supervision of an experienced bacteriologist who has

(*a*) not less than three years postgraduate training in bacteriology and immunology;

(*b*) specialized in the field of bacteriology; and

(*c*) at least one year of practical experience in the manufacture of B.C.G. vaccine.

SOR/97-12, s. 41.

C.04.073. No fabricator shall permit any culture that is not a B.C.G. culture to be at any time on any premises that are used for the manufacture of B.C.G. vaccine.

SOR/97-12, s. 61.

C.04.074. A packager/labeller shall test by an acceptable method, after filling of the final container, each lot of B.C.G. vaccine for the presence of contaminating micro-organisms and when so tested it shall be free therefrom.

SOR/97-12, s. 65.

C.04.075. Notwithstanding section C.04.074, a fluid B.C.G. vaccine may be released for sale if no growth has appeared upon the test culture medium after an incubation of 24 hours, but if there is evidence of the presence of contaminating micro-organisms in any lot during the test period of 10 days the packager/labeller shall at once recall such lot.

SOR/97-12, s. 65.

C.04.076. Every fabricator and packager/labeller shall determine the number of viable B.C.G. organisms in each lot of vaccine by an acceptable method and shall keep a record of the number.

SOR/97-12, s. 63.

C.04.077. A fabricator of B.C.G. vaccine shall keep, at a temperature not exceeding 5.0°C, and for not less than six months,

(*a*) the culture on glycerine-water potato medium from which the Sauton I and Sauton II subcultures were made, and

(*b*) not less than six vials of the final product

from each lot thereof.

SOR/97-12, s. 61.

C.04.078. Every fabricator and packager/labeller of B.C.G. vaccine shall keep, in form satisfactory to the Minister, continuous clinical records of the use of B.C.G. vaccine in humans.

SOR/97-12, s. 63.

C.04.079. A fabricator of B.C.G. vaccine shall examine pathologically all test animals used and shall immediately report to the Minister any evidence of active, progressive tuberculosis in any such animals.

SOR/97-12, s. 61.

C.04.080. The expiration date for B.C.G. vaccine shall be not more than

(*a*) 10 days after harvesting in the case of fluid vaccine;

(*b*) 12 months after harvesting in the case of freeze dried vaccine stored at a temperature of 4°C or above; or

(*c*) 20 months after harvesting in the case of freeze dried vaccine stored at a temperature below 4°C.

C.04.081. No person shall sell fluid B.C.G. vaccine that is not packaged in containers sealed by fusion.

C.04.082. No inner label shall be required for fluid B.C.G. vaccine in single-dose containers.

C.04.083. The label of fluid B.C.G. vaccine shall carry, in lieu of the statements provided in paragraphs C.04.054(*a*) and (*b*), a statement of

(*a*) the weight of bacteria per millilitre; and

(*b*) the route of administration of the vaccine.

C.04.084. The label of freeze-dried B.C.G. vaccine shall carry, in lieu of the statements provided in paragraphs C.04.054(*a*) and (*b*), a statement of

(*a*) the amount of bacteria per vial or per dose; and

(*b*) the route of administration of the vaccine.

C.04.085. The provisions of subparagraph C.04.019(*b*)(iv) do not apply to freeze-dried B.C.G. vaccine.

## Products Analogous to Bacterial Vaccines

C.04.090. A product analogous to a bacterial vaccine shall be

(*a*) a bacterial antigen, other than a bacterial vaccine, such as a lysate, or

(*b*) an extract prepared from a bacterial culture,

and shall conform to the requirements of these Regulations for bacterial vaccines except those of paragraphs (*a*) and (*b*) of C.04.054.

C.04.091. The expiration date of a product analogous to a bacterial vaccine shall be not later than 18 months after the date of manufacture or the date of issue, but for dried tuberculin and tuberculin containing at least 50 per cent glycerin the expiration date shall be not later than five years after the date of manufacture or the date of issue, and for all other tuberculins not more than 12 months after the date of manufacture or the date of issue.

## Virus and Rickettsial Vaccines

C.04.100. A virus vaccine, rickettsial vaccine, shall be a suspension of, or prepared from, living or killed viruses or rickettsiae.

C.04.101. No person shall sell a virus or a rickettsial vaccine unless the fabricator has submitted to the Minister details of the source of the strains of viruses or rickettsiae used, the method of their propagation, the method of fabrication of the vaccine, the methods employed for determining sterility, safety, identity and potency and any other tests required by these Regulations.

SOR/95-411, s. 2; SOR/97-12, s. 42.

C.04.102. Upon written request from the Director every fabricator and packager/labeller shall submit with respect to each lot of virus or rickettsial vaccine, when ready for sale, detailed protocols of sterility, safety, identity, potency, and of any other tests required by these Regulations.

SOR/97-12, s. 63.

## Smallpox Vaccine

C.04.110. Smallpox vaccine

(*a*) shall be a virus vaccine;

(*b*) shall be the living virus of vaccinia or its derivatives obtained from

(i) the vesicles produced in the skin of healthy calves by inoculation of vaccinia virus,

(ii) specifically infected membranes of chick embryos, or

(iii) suitable tissue culture infected with vaccinia virus or its derivatives; and

(*c*) shall be in fluid or dried form.

SOR/2006-2, s. 1.

C.04.111. Every fabricator and packager/labeller shall fabricate and package/label smallpox vaccine only in an independent unit that is isolated from all other laboratory activities, and in or about which no extraneous materials are permitted or stored.

SOR/97-12, s. 43.

C.04.112. A fabricator shall exclude the personnel who care for the vaccine animals from horse stables and paddocks and from contact with horses while smallpox vaccine is being propagated.

SOR/97-12, s. 61.

C.04.113. Every fabricator and packager/labeller shall dispense smallpox vaccine only in sterile glass containers that are sealed under aseptic conditions.

SOR/97-12, s. 63.

C.04.114. Every fabricator and packager/labeller shall test smallpox vaccine to establish that it is free from

(*a*) spore-forming anaerobic micro-organisms;

(*b*) coagulase positive staphylococci;

(*c*) haemolytic streptococci; and

(*d*) any other contaminating pathogenic micro-organisms.

SOR/97-12, s. 63.

C.04.115. Smallpox vaccine, when tested by acceptable methods,

(*a*) shall be free from extraneous micro-organisms, in the case of vaccine prepared for use by jet gun; and

(*b*) shall contain not more than 500 viable non-pathogenic bacteria per millilitre, in the case of vaccine prepared for use by the multiple pressure technique or by scarification.

C.04.116. Smallpox vaccine must demonstrate evidence of disease prevention that is at least equivalent to that of a vaccine that

(*a*) is known to prevent human to human transmission of smallpox; and

(*b*) meets the potency of equal to or greater than $10^8$ pockforming units per millilitre, as determined using chick embryo chorioallantoic membranes.

SOR/2006-2, s. 2.

C.04.117. No person shall sell smallpox vaccine unless

(*a*) in the case of fluid vaccine, it has been stored at a temperature below -10°C;

(*b*) in the case of dried vaccine, it has been stored at a temperature below 10°C; and

(*c*) the outer label carries a statement that it shall be stored at a temperature of not more than 5°C.

SOR/97-12, s. 44.

C.04.118. Notwithstanding the provisions of section C.04.003, the date of issue of smallpox vaccine shall be not later than

(*a*) in the case of fluid vaccine, nine months after the date of manufacture; and

(*b*) in the case of dried vaccine, 24 months after the date of manufacture.

C.04.119. The expiration date of smallpox vaccine shall not exceed the following, unless supported by evidence of stability satisfactory to the Minister:

(*a*) in the case of fluid vaccine, 3 months after the date of issue; or

(*b*) in the case of dried vaccine, 12 months after the date of issue.

SOR/2006-2, s. 3.

C.04.120. No inner label shall be required for smallpox vaccine in single-dose containers or when dispensed in capillary tubes.

C.04.121. No person shall sell smallpox vaccine to which an antibiotic has been added.

## Poliomyelitis Vaccine

C.04.122. Poliomyelitis vaccine shall be an aqueous suspension of killed poliomyelitis viruses, Types I, II, and III.

C.04.123. Poliomyelitis vaccine shall be prepared in acceptable tissue culture medium from strains of poliomyelitis virus proven capable of producing vaccine of acceptable potency.

C.04.124. Poliomyelitis vaccine in its final form shall contain not more than 0.35 milligram per millilitre of total nitrogen, nor more than one part per million of animal serum.

C.04.125. No person shall sell poliomyelitis vaccine unless it has been tested by an acceptable method for potency and safety and when so tested it shall be safe and of acceptable potency.

C.04.126. The outer label shall carry a statement of any antibiotic present in the vaccine.

C.04.127. The expiration date of the poliomyelitis vaccine shall be not later than 12 months after the date of the last satisfactory potency test unless evidence, satisfactory to the Director, is presented that a longer period is appropriate.

SOR/85-715, s. 6.

## Poliovirus Vaccine, Live, Oral

C.04.128. **Poliovirus Vaccine, Live, Oral** or **Poliovirus Vaccine, Live, Oral (Naming the strains)** shall be prepared from living poliomyelitis virus types I, II and III that

(*a*) have been obtained directly from a source acceptable to the Director;

(*b*) are shown to be genetically stable by an acceptable method;

(*c*) are shown to be non-pathogenic when given orally to humans;

(*d*) are proved to be capable of multiplying in the human alimentary tract and of producing type specific neutralizing antibodies when administered orally; and

(*e*) have a history of successful use in the production of polio-virus vaccine, live, oral.

C.04.129. Poliovirus vaccine, live, oral, shall be fabricated, packaged/labelled and tested in premises separated from buildings where other products are fabricated, packaged/labelled or tested, and from buildings where control tests involving the use of cell lines or virus strains not employed in the fabrication, packaging/labelling and testing of poliovirus vaccine, live, oral, are carried out.

SOR/97-12, s. 45.

C.04.130. No fabricator shall permit the introduction of any bacterial or viral cultures other than those used in the manufacture of poliovirus vaccine, live, oral on any premises that are used for the manufacture of poliovirus vaccine, live, oral.

SOR/97-12, s. 61.

C.04.131. Notwithstanding sections C.04.129 and C.04.130, a fabricator may manufacture other drugs in an area in which polio-virus vaccine, live, oral is manufactured at times when that vaccine is not being manufactured, if

(*a*) both prior to and following each manufacture the area is cleaned and disinfected by methods acceptable to the Director; and

(*b*) the fabricator has received written permission from the Director to carry out such manufacture.

SOR/97-12, s. 61.

C.04.132. Poliovirus vaccine, live, oral shall be prepared only

(*a*) in a tissue culture,

(*b*) in a medium, and

(*c*) by methods

acceptable to the Director.

C.04.133. No fabricator shall sell poliovirus vaccine, live, oral, unless he has tested each lot for extraneous micro-organisms and the vaccine is free therefrom.

SOR/97-12, s. 61.

C.04.134. A fabricator of poliovirus vaccine, live, oral shall test, by a method acceptable to the Director, each lot of vaccine for neurovirulence and for genetic markers and it shall meet the requirements established by the Director.

SOR/97-12, s. 61.

C.04.135. No fabricator shall employ any person in the manufacture of poliovirus vaccine, live, oral unless such person

(*a*) is free from infectious disease;

(*b*) has been vaccinated successfully against poliomyelitis by poliovirus vaccine, live, oral; and

(*c*) has been proved by periodic tests to be a non-carrier of poliomyelitis virus.

SOR/97-12, s. 61.

C.04.136. A fabricator of poliovirus vaccine, live, oral shall not permit the entry to a building in which the vaccine is manufactured of any person who

(*a*) is not directly concerned with the manufacturing processes; or

(*b*) has been working on the same day with experimental animals or with infectious agents.

SOR/97-12, s. 61.

## Bacteriophage

C.04.137. Bacteriophage shall be a virus preparation with specific lytic action against micro-organisms actually or potentially pathogenic.

C.04.138. The expiration date of bacteriophage shall be not later than 12 months after the date of manufacture or the date of issue.

## Toxins, Toxoids

### Schick Test Reagents

C.04.140. Schick test reagents for the diagnosis of susceptibility to diphtheria shall be

(*a*) diphtheria toxin for Schick test;

(*b*) Schick control; and

(*c*) diphtheria toxin for Schick test with control.

C.04.141. Diphtheria toxin for Schick test shall be sterile diluted diphtheria toxin stabilized by an acceptable method.

C.04.142. Schick control shall be suitably diluted

(*a*) diphtheria toxoid; or

(*b*) sterile diphtheria toxin heated at a temperature of 95°C for five minutes.

C.04.143. The human test dose of diphtheria toxin for Schick test, when aged toxin containing a preservative is used, shall be determined by

(*a*) intracutaneous injection into normal guinea pigs in mixtures with different proportions of diphtheria antitoxin, and one test dose mixed with 1/750 or more of a unit of antitoxin must cause no local reaction but mixed with 1/1,250 or less of a unit of antitoxin must cause a definite local reaction of the type known as the “positive Schick reaction”; and

(*b*) intracutaneous injection into normal guinea pigs without admixture with antitoxin, and 1/50 of one test dose must not cause, and 1/25 of one test dose must cause, a definite local reaction of the type known as the “positive Schick reaction”.

C.04.144. The human test dose of diphtheria toxin for Schick test, when fresh toxin containing no preservative is used, shall be determined by

(*a*) intracutaneous injection into normal guinea pigs in mixtures with different proportions of diphtheria antitoxin, and one test dose mixed with 1/750 or more of a unit of antitoxin must cause no local reaction, but mixed with 1/1,500 or less of a unit of antitoxin must cause a definite local reaction of the type known as the “positive Schick reaction”; and

(*b*) intracutaneous injection into normal guinea pigs without admixture with antitoxin, and 1/100 of one test dose must not cause, and 1/50 of one test dose must cause, a definite local reaction of the type known as the “positive Schick reaction”.

C.04.145. The human test dose for the Schick control shall give a negative Schick reaction when injected intracutaneously into normal guinea pigs.

C.04.146. No person shall sell diphtheria toxin for Schick test unless both the inner and the outer labels carry a statement of the number of human test doses it contains together with the name of any stabilizer.

C.04.147. The expiration date of Schick test reagents for the diagnosis of susceptibility to diphtheria shall be not later than 12 months after the date of manufacture or the date of issue.

**Diphtheria Toxoid**

C.04.160. Liquid diphtheria toxoid shall be sterile, formalized, detoxified diphtheria toxin and shall not contain more than 0.02 per cent free formaldehyde.

C.04.161. Diphtheria toxoid alum precipitated shall be prepared from diphtheria toxoid, and shall not contain more than 15 milligrams of alum per human dose.

C.04.162. The alum used in the preparation of diphtheria toxoid alum precipitated shall contain not less than 99.5 per cent pure potassium alum, $Al\ K(SO_4)_2,12H_2O$.

C.04.163. No fabricator shall use a culture medium for the production of diphtheria toxin that contains horse protein or Witte peptone or that has not been freed as far as possible from any other allergenic ingredient.

SOR/97-12, s. 61.

C.04.164. Diphtheria toxin from which diphtheria toxoid is prepared shall have a toxicity, as indicated by an L+dose, of not more than 0.20 millilitre or by an M.L.D. of not more than 0.0025 millilitre.

C.04.165. A fabricator shall test each bulk container of diphtheria toxoid, before being dispensed into the final containers, for toxicity by an acceptable method, and it shall be non-toxic.

SOR/97-12, s. 61.

C.04.166. No person shall sell any lot of diphtheria toxoid unless such lot has been shown to meet a test for antigenicity made by an acceptable method.

C.04.167. A fabricator shall fill diphtheria toxoid aseptically into clear glass containers and where preservative is not added shall seal the containers by fusion.

SOR/97-12, s. 61.

C.04.168. No person shall sell diphtheria toxoid that contains phenol.

C.04.169. No person shall sell diphtheria toxoid unless both the inner and the outer labels carry a statement of the appropriate dose for purposes of immunization.

C.04.170. The expiration date of diphtheria toxoid shall be not later than two years after the date of manufacture or the date of issue.

**Tetanus Toxoid**

C.04.180. Liquid tetanus toxoid shall be sterile, formalized, detoxified tetanus toxin, and shall not contain more than 0.02 per cent free formaldehyde.

C.04.181. Tetanus toxoid alum precipitated shall be prepared from tetanus toxoid, and shall not contain more than 15 milligrams of alum per human dose.

C.04.182. The alum used in the preparation of tetanus toxoid alum precipitated shall contain not less than 99.5 per cent pure potassium alum, Al $K(SO_4)_2$, $12H_2O$.

C.04.183. No fabricator shall use a culture medium for the production of tetanus toxin that contains horse protein or Witte peptone or that has not been freed as far as possible from any other allergenic ingredient.

SOR/97-12, s. 61.

C.04.184. Tetanus toxin from which tetanus toxoid is prepared shall have a toxicity as indicated by an M.L.D. for the guinea pig of not more than 0.0001 millilitre.

C.04.185. A packager/labeller shall test each bulk container of tetanus toxoid, before being dispensed into the final containers, for toxicity by an acceptable method, and it shall be non-toxic.

SOR/97-12, s. 65.

C.04.186. No person shall sell any lot of tetanus toxoid unless such lot has been shown to meet a test for antigenicity made by an acceptable method.

C.04.187. No person shall sell tetanus toxoid unless both the inner and the outer labels carry a statement of the appropriate dose for purposes of immunization.

C.04.188. A fabricator shall fill tetanus toxoid aseptically into clear glass containers and where a preservative is not added shall seal the container by fusion.

SOR/97-12, s. 61.

C.04.189. No person shall sell tetanus toxoid that contains phenol.

C.04.190. The expiration date of tetanus toxoid shall be not later than two years after the date of manufacture or the date of issue.

## Antitoxins, Antisera

C.04.210. An antitoxin or antiserum shall be the serum or fraction thereof separated from the blood of animals that have been artificially immunized against the by-products or antigenic fractions of specific cultures of micro-organisms, or against specific venoms.

C.04.211. The potency of an antitoxin or antiserum shall be determined by an acceptable method and where applicable the unit of potency shall be the International Unit.

C.04.212. Liquid diphtheria antitoxin shall have a potency of not less than 500 International Units per millilitre.

C.04.213. Liquid tetanus antitoxin shall have a potency of not less than 400 International Units per millilitre.

C.04.214. A liquid antitoxin or antiserum shall contain not more than 20 per cent solids.

C.04.215. A dried antitoxin shall be prepared from a liquid antitoxin and, when reconstituted to the original volume of the liquid antitoxin, shall have a potency not less than that prescribed for such liquid antitoxin.

C.04.216. A dried antitoxin or antiserum shall not contain more than one per cent moisture when determined by an acceptable method.

C.04.217. Each lot of antitoxin or antiserum shall be tested by an acceptable method for pyrogenicity and it shall be pyrogen-free, and, after filling into the final containers, for identity and it shall be true to name.

C.04.218. No person shall sell an antitoxin or antiserum unless both the inner and the outer labels carry a statement of the species of animal used, when other than the horse, and the net contents in millilitres or the number of units in the container.

C.04.219. In respect of antitoxins, the expiration date shall be

(*a*) for liquid antitoxins with standards of potency, not later than five years after the date of manufacture;

(*b*) for dried antitoxins with standards of potency, not later than five years after the date of manufacture;

(*c*) for liquid antioxins with no standards of potency, not later than 12 months after the date of manufacture; and

(*d*) for dried antitoxins with no standards of potency, not later than five years after the date of manufacture.

C.04.220. In respect of antisera, the expiration date shall be

(*a*) for liquid antisera with standards of potency, not later than three years after the date of manufacture;

(*b*) for dried antisera with standards of potency, not later than five years after the date of manufacture;

(*c*) for liquid antisera with no standards of potency, not later than 12 months after the date of manufacture; and

(*d*) for dried antisera with no standards of potency, not later than five years after the date of manufacture.

## Preparations from Human Sources

C.04.230. Preparations from human sources shall be pooled blood plasma, or pooled blood serum, or fractions of either separated by a method satisfactory to the Minister.

C.04.231. A fabricator shall obtain human serum, or human plasma, only from a person certified by a qualified medical practitioner to be healthy.

SOR/97-12, s. 61.

C.04.232. A fabricator shall not use a person to serve as a donor of blood, placenta, or cord who has a history of a disease transmissible by blood transfusion including syphilis, infectious hepatitis, or malaria.

SOR/97-12, s. 61.

C.04.233. The operation of drawing blood from a donor shall be under the supervision of a qualified medical practitioner, and shall be carried out in a suitable bleeding room under the control of the fabricator.

SOR/97-12, s. 61.

C.04.234. A fabricator shall obtain human placenta and cord used in the manufacture of preparations from human sources only from women confined in public hospitals, and the donor of such placenta and cord shall have been free from the toxaemias of pregnancy, and the placenta and cord shall not show gross evidence of any pathological condition.

SOR/97-12, s. 61.

C.04.235. (1) Subject to subsections (2) and (3), dried human serum, dried human plasma or dried fractions of either shall not contain more than one per cent moisture when determined by an acceptable method.

(2) Dried $Rh_o$(D) Immune Human globulin shall not contain more than three per cent moisture when determined by an acceptable method.

(3) Dried Antihemophilic Factor Human shall not contain more than two per cent moisture when determined by an acceptable method.

SOR/81-334, s. 3.

C.04.236. A fabricator shall provide directions or means for the removal of particles of such size as to be dangerous to the recipient from preparations from human sources that are issued in fluid form or that are reconstituted from the dried form.

SOR/97-12, s. 61.

C.04.237. A fabricator of preparations from human sources shall maintain complete records of all donors, which records shall include the medical certificate required by section C.04.231.

SOR/97-12, s. 61.

C.04.238. A fabricator, packager/labeller or distributor referred to in paragraph C.01A.003(*b*) may issue human serum or human plasma, or fractions of either of them, for prophylactic or therapeutic use in any of the following forms:

(*a*) immune human serum, which shall be serum separated from the blood of persons recovered from the disease or from persons specifically immunized against the disease for which the serum is intended as a prophylactic or therapeutic agent;

(*b*) immune human globulins, or other immune human serum fractions, which shall be prepared from immune human serum or plasma;

(*c*) normal human serum, or normal human plasma, or fractions of either of these prepared from the blood of normal individuals; and

(*d*) dried products prepared from any of these.

SOR/97-12, s. 46.

C.04.239. No person shall sell a preparation from human sources unless both the inner and the outer labels clearly indicate that the preparation is derived from human sources.

C.04.240. The expiration date for preparations from human sources issued in fluid or dried form shall be not later than five years after the date of filling the immediate container.

C.04.241. The date of manufacture of preparations from human sources shall be the date of bleeding the donor.

C.04.300. and C.04.301. [Repealed, SOR/81-335, s. 3]

## Human Plasma Collected by Plasmapheresis

### Interpretation

C.04.400. The following definitions apply in this section and in sections C.04.401 to C.04.423.

“accident” means an unexpected event that is not attributable to a deviation from a fabricator’s procedures or applicable laws and that could adversely affect the safety of a donor or the safety, efficacy or quality of plasma. (accident)

“donor” means a person aged 17 years or older who has given their name to a fabricator for the purpose of participating in plasmapheresis with that fabricator. (donneur)

“error” means a deviation from a fabricator’s procedures or applicable laws that could adversely affect the safety of a donor or the safety, efficacy or quality of plasma. (manquement)

“fabricator” means a person who is the holder of an establishment licence issued under these Regulations that authorizes the person to fabricate source plasma. (manufacturier)

“personal identifier” means a unique group of letters, numbers or symbols, or any combination of them, that is assigned to a donor by a fabricator. (identificateur personnel)

“physician” means a person who is entitled to practise the profession of medicine under the laws of the province in which the person provides medical service in connection with plasmapheresis or specific immunization. (médecin)

“physician substitute” means a person who

(*a*) acts under the general supervision and direction of a physician; and

(*b*) is authorized to provide the services that may be provided by a physician substitute under sections C.04.401 to C.04.423, according to the applicable laws of the province in which the person provides any of those services. (substitut)

“plasmapheresis” means a process during which:

(*a*) blood is taken from a donor from which plasma is separated; and

(*b*) red blood cells and formed elements from the blood are returned to the donor. (plasmaphérèse)

“plasmapheresis session” means a meeting between a fabricator and a donor held for the purpose of proceeding with plasmapheresis. (séance de plasmaphérèse)

“serious adverse reaction” means an unexpected and undesirable response in a donor, associated with plasmapheresis or specific immunization, that results in any of the following consequences for the donor:

(*a*) hospitalization;

(*b*) persistent or significant disability or incapacity;

(*c*) a medical or surgical intervention to preclude a persistent or significant disability or incapacity;

(*d*) a life-threatening condition; or

(*e*) death. (effet indésirable grave)

“source plasma” means human plasma collected by plasmapheresis that is intended for use in producing a drug for human use. (plasma destiné au fractionnement)

“specific immunization” means the administration of an immunogen to a donor with the intention of eliciting an immune response in their blood for the purpose of plasmapheresis. (immunisation spécifique)

“unique identifier” means a unique group of letters, numbers or symbols, or any combination of them, that is assigned by a fabricator to source plasma or red blood cells to be used in specific immunization. (identificateur unique)

SOR/78-545, s. 1; SOR/85-1022, s. 1; SOR/2006-353, s. 1.

Previous Version

**Prohibitions**

C.04.401. No person shall

(*a*) sell source plasma unless it has been fabricated, tested, packaged/labelled and stored in accordance with sections C.04.402 to C.04.423; or

(*b*) fabricate source plasma from blood collected from a person who is not suitable to participate in plasmapheresis according to sections C.04.402 to C.04.423.

SOR/78-545, s. 1; SOR/85-1022, s. 2; SOR/2006-353, s. 1.

Previous Version

**Fabricator's Responsibility**

C.04.402. (1) A fabricator shall ensure that a person who provides services to them in connection with plasmapheresis or specific immunization is qualified by education and by training or experience to provide the services.

(2) The fabricator shall ensure that the premises used for donor screening, plasmapheresis or specific immunization are designed, constructed and maintained in a manner that permits medical information to be communicated in confidence.

SOR/78-545, s. 1; SOR/85-1022, s. 2; SOR/97-12, s. 47; SOR/2006-353, s. 1.

Previous Version

**Consent and Preliminary Evaluation**

C.04.403. (1) A fabricator shall not begin plasmapheresis with a donor unless

(*a*) the fabricator has informed the donor of what is involved with plasmapheresis, including the risks to the donor's health associated with plasmapheresis and with participating in plasmapheresis more frequently than once every eight weeks; and

(*b*) after paragraph (*a*) has been satisfied, the fabricator obtains from the donor

(i) a written acknowledgement that the information specified in paragraph (*a*) has been provided to them, and

(ii) in accordance with the applicable laws governing consent, written informed consent to participate in plasmapheresis.

(2) A fabricator shall not begin the specific immunization of a donor unless

(*a*) a physician has selected the immunogen to be administered to the donor and informed the donor of

(i) the name and nature of the selected immunogen,

(ii) the proposed frequency and the maximum number of specific immunization injections the donor is expected to receive, and

(iii) what is involved with specific immunization, including the risks to the donor's health associated with specific immunization and with receiving the selected immunogen; and

(*b*) after paragraph (*a*) has been satisfied, the fabricator obtains from the donor

(i) a written acknowledgement that the information specified in paragraph (*a*) has been provided to them, and

(ii) in accordance with the applicable laws governing consent, written informed consent to receive the selected immunogen.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

Previous Version

C.04.404. (1) A fabricator shall not proceed with plasmapheresis or specific immunization unless a physician or physician substitute has determined the donor's suitability to participate

in plasmapheresis more frequently than once every eight weeks based on the donor's medical history and a medical examination of the donor.

(2) If the donor is determined to be suitable, the fabricator shall document the following information:

(*a*) the fact that the donor is suitable to participate in plasmapheresis more frequently than once every eight weeks;

(*b*) the donor's name and personal identifier;

(*c*) the name and signature of the physician who makes the determination, or supervises the physician substitute making the determination; and

(*d*) the date of the determination.

(3) The fabricator shall not proceed with plasmapheresis or specific immunization if the most recent determination under subsection (1) in respect of the donor was made more than

(*a*) 30 days before the date set for the donor's first participation in plasmapheresis or specific immunization; or

(*b*) one year before any other date set for the donor's participation in plasmapheresis or specific immunization.

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

Previous Version

**Specific Immunization**

C.04.405. (1) No one other than a physician or physician substitute shall administer an immunogen to a donor for the purpose of specific immunization.

(2) A physician shall monitor the donor's response to the immunogen to determine if the donor can continue to receive specific immunization.

(3) If the donor cannot continue to receive specific immunization, the fabricator shall cease to provide it to the donor until a physician determines that the donor can receive specific immunization using the same or another immunogen.

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

Previous Version

**Evaluation Before Collection**

C.04.406. (1) At the beginning of each plasmapheresis session, a physician or physician substitute shall determine if the donor is suitable to participate in plasmapheresis.

(2) If the donor is determined to be temporarily not suitable to participate in plasmapheresis based on the criteria set out in Table 1 or any other medical reason justifying a determination of temporary non-suitability, the fabricator shall cancel the session, inform the donor of the reason why they are temporarily not suitable and indicate the date when the donor may continue to participate in plasmapheresis.

(3) If the donor is determined to be not suitable to participate in plasmapheresis for an indefinite period based on the exclusion criteria set out in Table 2 or any other medical reason justifying a determination of indefinite non-suitability, the fabricator shall cancel the session and inform the donor of the reason why they are not suitable to participate in plasmapheresis for an indefinite period.

TABLE 1

| Item | Criteria |
|---|---|
| 1. | Weight of less than 50 kg |
| 2. | Temperature outside of normal limits |
| 3. | Blood pressure above 100 mmHg diastolic or 180 mmHg systolic |
| 4. | Haemoglobin level of less than 125 g/L of blood or haematocrit value of less than 0.38 L/L of blood |
| 5. | Total protein level of less than 60 g/L of blood |
| 6. | Substantial blood loss |
| 7. | Prior donation of plasma or other blood components |
| 8. | Pregnancy |
| 9. | History of medical or surgical procedures |
| 10. | History of convulsions requiring medical treatment |
| 11. | Ability to answer questions compromised by alcohol or drug use |
| 12. | Prior transfusion of blood, blood components or a blood product, or prior transplantation of a cell, tissue or organ other than dura mater |
| 13. | Skin infection at the site of the phlebotomy |
| 14. | Sign or symptom of infection |
| 15. | Risk of infection with HIV, hepatitis B virus or hepatitis C virus based on, but not limited to, a history of acupuncture, skin piercing, tattooing, accidental needle-stick injury or occasional sexual relations with a person at risk of having any of those infections |
| 16. | Current or past use of medication that poses a risk to a recipient of a product manufactured from source plasma |
| 17. | Receipt of a live attenuated vaccine |
| 18. | Animal bite requiring prophylaxis for rabies or for which the need for post-exposure prophylaxis has not been assessed |

TABLE 2

| Item | Exclusion Criteria |
|---|---|
| 1. | Abnormal cardiovascular function or serious or chronic cardiovascular disease |
| 2. | Abnormal respiratory function or serious or chronic respiratory disease |
| 3. | Bleeding disorder that poses a risk to the donor in relation to plasmapheresis |
| 4. | Serious disease or medical condition of the liver, kidneys, another organ, a system or blood |
| 5. | Persistent abnormal plasma proteins including monoclonal or polyclonal gammopathy |
| 6. | Current or past use of medication that poses an ongoing risk to a recipient of a product manufactured from source plasma |

| Item | Exclusion Criteria |
|---|---|
| 7. | History of recurrent fainting associated with the donation of blood or plasma |
| 8. | History, signs or symptoms of injectable drug abuse such as skin punctures, scars or sharing needles to inject drugs |
| 9. | History, signs or symptoms of AIDS or HIV infection |
| 10. | Risk of HIV infection based on sexual practices |
| 11. | History, signs or symptoms of a chronic or persistent infection or parasitic disease transmissible by blood |
| 12. | History, signs or symptoms of hepatitis, other than hepatitis A |
| 13. | Cancer, other than non-melanoma skin cancer or in-situ cervical cancer |
| 14. | Risk factor for Creutzfeldt-Jacob disease (CJD) or its variant (vCJD) based on, but not limited to, the receipt of dura mater transplant or a treatment using a human pituitary hormone |
| 15. | Positive test result for any transmissible disease agent |

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

Previous Version

**Plasma Protein Composition**

C.04.407. (1) Before beginning plasmapheresis with a donor, a fabricator shall take a blood sample from the donor to determine the plasma protein composition of the donor's blood by means of a serum protein electrophoresis test or an equivalent test.

(2) A blood sample shall be taken within seven days before the donor's first plasmapheresis session at which the fabricator proceeds with plasmapheresis.

(3) If 21 days have elapsed from the taking of the sample without a physician examining the test result, the fabricator may not proceed with plasmapheresis until a physician examines the test result.

(4) If a physician concludes that the plasma protein composition of the donor's blood is not within normal limits, the fabricator may not proceed with plasmapheresis until a physician determines that the plasma protein composition of the donor's blood is within normal limits.

(5) If the fabricator has not taken a blood sample from the donor as required under subsection (1) for more than four months, the fabricator may not proceed with plasmapheresis until the blood sample is taken from the donor.

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

Previous Version

**Ongoing Review of Collection Records**

C.04.408. (1) A physician shall determine if a donor is suitable to continue to participate in plasmapheresis more frequently than once every eight weeks, based on the test results and collection records for the donor that have been made or received by the fabricator within the preceding four months.

(2) The determination shall be made at least every four months after the date of the initial determination that the donor is suitable under section C.04.404.

(3) If the donor is determined to be temporarily not suitable to participate in plasmapheresis the fabricator shall inform the donor of the reason why they are temporarily not suitable and indicate the date when the donor may continue to participate in plasmapheresis.

(4) If the donor is determined to be not suitable for an indefinite period, the fabricator may not proceed with plasmapheresis and shall inform the donor of the reason why they are not suitable.

(5) If the requirement of subsection (2) is not met, the fabricator may not proceed with plasmapheresis until the determination is made.

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

Previous Version

**Plasmapheresis Procedures**

C.04.409. A fabricator who conducts a plasmapheresis session shall

(*a*) use aseptic methods and a sterile collection system licensed under the Medical Devices Regulations;

(*b*) ensure that all surfaces intended to come into contact with blood or plasma are pyrogen free;

(*c*) ensure that the donor's skin where the phlebotomy is to be made is

(i) determined to be free from lesion, rash or other source of infection, and

(ii) cleaned and disinfected; and

(*d*) ensure that emergency medical personnel are capable of attending to the medical needs of the donor within 10 minutes after being contacted by the fabricator.

SOR/78-545, s. 1; SOR/85-1022, s. 4; SOR/2006-353, s. 1.

Previous Version

**Maximum Volumes and Minimum Intervals**

C.04.410. (1) A fabricator shall not collect plasma from a donor in a total amount, excluding anticoagulant solution, that exceeds

(*a*) if the donor's weight is 50 kg or more but less than 68 kg,

(i) 625 mL or 640 g in respect of a single plasmapheresis session, and

(ii) 11.5 L in respect of all plasmapheresis sessions during the preceding six months;

(*b*) if the donor's weight is 68 kg or more but less than 80 kg,

(i) 750 mL or 770 g in respect of a single plasmapheresis session, and

(ii) 15.5 L in respect of all plasmapheresis sessions during the preceding six months; and

(*c*) if the donor's weight is 80 kg or more,

(i) 800 Ml or 820 g in respect of a single plasmapheresis session, and

(ii) 18.5 L in respect of all plasmapheresis sessions during the preceding six months.

(2) The fabricator shall have written procedures that describe

(*a*) the minimum waiting period for a donor between donations of plasma and between a donation of plasma and a donation of blood or other blood components; and

(*b*) the maximum number of plasma donations a donor may make in a given period.

SOR/78-545, s. 1; SOR/85-1022, s. 5; SOR/95-203, s. 1; SOR/2006-353, s. 1.

Previous Version

**Anticoagulant Solution**

C.04.411. (1) During plasmapheresis, the fabricator shall mix an anticoagulant solution with the blood collected from the donor.

(2) The anticoagulant solution shall have a valid drug identification number under these Regulations that indicates the solution is suitable for use in plasmapheresis.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

Previous Version

**Samples for Testing**

C.04.412. (1) During a plasmapheresis session, the fabricator shall take a sample of blood or plasma in a manner that does not contaminate the sample or the source plasma.

(2) When the sample is taken, the fabricator shall clearly and permanently label the sample container with the unique identifier assigned to the source plasma.

(3) The fabricator shall ensure that the person who labels the sample container is the same person who labels the container holding the source plasma under subsection C.04.416(2).

SOR/78-545, s. 1; SOR/2006-353, s. 1.

Previous Version

C.04.413. (1) The fabricator shall test a sample taken under section C.04.412 to detect evidence of the following disease agents:

(*a*) HIV types 1 and 2;

(*b*) hepatitis B virus;

(*c*) hepatitis C virus; and

(*d*) syphilis.

(2) The fabricator shall retain the source plasma collected at the plasmapheresis session until all the test results are determined to be negative or non-reactive.

(3) In the case of a positive or reactive test result for any disease agent referred to in subsection (1), the fabricator shall

(*a*) clearly and permanently label the container holding the source plasma collected at the session with

(i) the statement “Caution: Not for Manufacturing Use” or “Précaution : Non destiné à la fabrication”, and

(ii) the hazard symbol for Biohazardous Infectious Material set out in Schedule II to the Controlled Products Regulations; and

(*b*) segregate and dispose of the source plasma.

(4) In the case of a positive or reactive test result for syphilis, the fabricator may not proceed with plasmapheresis until a subsequent test shows that the donor is not infected with syphilis and a physician determines that the donor can continue to participate in plasmapheresis.

(5) In the case of a positive or reactive test result for a disease agent referred to in subsection (1), other than syphilis, the fabricator shall discontinue plasmapheresis and inform the donor of the reason why they are not suitable to participate in plasmapheresis for an indefinite period.

SOR/78-545, s. 1; SOR/97-12, s. 48; SOR/2006-353, s. 1.

Previous Version

**Preservatives and Additives**

C.04.414. No person shall add a preservative or additive to source plasma.

SOR/78-545, s. 1; SOR/85-1022, s. 6; SOR/2006-353, s. 1.

Previous Version

**Containers**

C.04.415. A fabricator shall place source plasma in a container

(*a*) in respect of which a medical device licence has been issued under the Medical Devices Regulations for the purpose of collecting and storing plasma;

(*b*) that permits visual, electronic or automated inspection of the plasma;

(*c*) that has been visually inspected at the plasmapheresis session and found to be intact; and

(*d*) that has not been previously used for any purpose, including holding source plasma from the same donor.

SOR/78-545, s. 1; SOR/85-1022, s. 6; SOR/2006-353, s. 1.

Previous Version

**Labelling**

C.04.416. (1) Sections C.01.004 and C.04.019 do not apply to source plasma.

(2) A fabricator shall clearly and permanently label the container used to hold source plasma with

(*a*) the unique identifier assigned to the source plasma in the container;

(*b*) the statement “Source Plasma” or “Plasma destiné au fractionnement”;

(*c*) the statement “Caution: For Manufacturing Use Only” or “Précaution : À utiliser uniquement pour la fabrication”;

(*d*) the quantity of the source plasma;

(*e*) the name and quantity of the anticoagulant solution used during the plasmapheresis;

(*f*) the expiry date of the source plasma, expressed in an unambiguous format;

(*g*) subject to subsection C.04.413(3), a statement indicating that the source plasma tests negative for the disease agents for HIV, hepatitis B and hepatitis C;

(*h*) if the source plasma was collected from a donor who has received specific immunization, a statement indicating the immunogen that was used;

(*i*) the name, address and establishment licence number of the fabricator; and

(*j*) a statement indicating that the source plasma must be stored at a temperature of -20°C or colder.

(3) The unique identifier shall be placed on the container at the time of collection.

SOR/78-545, s. 1; SOR/85-1022, s. 7; SOR/2006-353, s. 1.

Previous Version

**Storage**

C.04.417. (1) In respect of the storage of source plasma, including storage during transportation, a fabricator shall ensure that the storage environment

(*a*) is designed to maintain a temperature of -20°C or colder; and

(*b*) remains consistently at a temperature of -20°C or colder.

(2) If the temperature of the environment rises above -20°C, the fabricator shall record the following information:

(*a*) the reason for the elevated temperature;

(*b*) the source plasma affected; and

(*c*) the final disposition of the source plasma.

(3) If the temperature of the environment rises to between - 20°C and +10°C, the fabricator shall clearly and permanently label the container of the source plasma with the statement “Source Plasma — Salvaged” or “Plasma destiné au fractionnement — recyclé”.

(4) Subsection (3) does not apply if the temperature of the environment rises to between -20°C and -5°C for a single period lasting less than 72 hours.

(5) If the temperature of the environment rises above +10°C, the fabricator shall dispose of the source plasma.

(6) Paragraph (1)(*b*) and subsections (2) to (5) do not apply in respect of the storage of source plasma during transportation, if the transportation is not conducted by the fabricator.

SOR/78-545, s. 1; SOR/85-1022, s. 8; SOR/2006-353, s. 1.

Previous Version

C.04.418. (1) A fabricator shall inspect each container of source plasma to determine if the container and its label are intact and if there are any indications that the source plasma has been subject to thawing.

(2) The fabricator shall dispose of the source plasma if the inspection shows that

(*a*) the container is defective or damaged to the extent that it does not provide protection against external factors that could result in deterioration or contamination of the source plasma;

(*b*) the unique identifier assigned to the source plasma is missing or illegible;

(*c*) any information required under paragraphs C.04.416(2)(*b*) to (*i*) is missing or illegible, unless the missing or illegible information can be retrieved from the fabricator's records; or

(*d*) the source plasma has been subject to thawing.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

Previous Version

**Records**

C.04.419. (1) A fabricator shall use and maintain a recordkeeping system according to which the fabricator shall

(*a*) assign a personal identifier to each donor;

(*b*) keep on the donor's file a photograph of the donor or some other reliable means of identification; and

(*c*) assign a unique identifier to the source plasma collected by the fabricator at each plasmapheresis session.

(2) The system shall be structured so that a fabricator may, based on a personal identifier or a unique identifier, identify the donor and retrieve sufficient records to permit the traceability and recall of source plasma.

(3) The fabricator shall keep the records referred to in subsection (2) indefinitely.

SOR/78-545, s. 1; SOR/85-1022, s. 9; SOR/2006-353, s. 1.

Previous Version

C.04.420. (1) For each donor, the fabricator shall keep

(*a*) the original or a copy of the donor's acknowledgement and consent under paragraphs C.04.403(1)(*b*) and (2)(*b*), if any;

(*b*) the original or a copy of any determinations, examinations, test results, reports and written notices made under sections C.04.401 to C.04.423;

(*c*) for each specific immunization given by the fabricator to the donor, a record indicating

(i) the date and location of the immunization,

(ii) the physician or physician substitute who administered the immunogen, and

(iii) for the immunogen injected, its name and manufacturer's name, the quantity and expiry date and either the immunogen's lot number and drug identification number or, if the immunogen is red blood cells, its unique identifier;

(*d*) for each plasmapheresis session held by the fabricator for the donor, a record indicating

(i) the date and location of the session,

(ii) the volume of source plasma collected,

(iii) the unique identifier assigned to the source plasma,

(iv) the volume of red blood cells collected that was not returned to the donor, including the volume of red blood cells collected during sampling,

(v) for the anticoagulant solution used, its name, its manufacturer's name and its lot number and drug identification number, and

(vi) for the container used, the manufacturer's name and the container's lot number and expiry date.

(2) The fabricator shall maintain a summary of all accidents, errors, serious adverse reactions and recalls of source plasma involving the fabricator.

(3) The fabricator shall maintain temperature records made under subsection C.04.417(2).

SOR/78-545, s. 1; SOR/85-1022, s. 10; SOR/97-12, s. 61; SOR/2006-353, s. 1.

Previous Version

**Information to the Minister**

C.04.421. (1) A fabricator shall notify the Minister of any serious adverse reaction

(*a*) within 24 hours after the fabricator becomes aware of the occurrence, in the case of a fatality; and

(*b*) within 15 days after the fabricator becomes aware of the occurrence, in any other case.

(2) In the case of a verbal notice under subsection (1), the fabricator shall submit a written report of the serious adverse reaction to the Minister within 24 hours after submitting the notice.

(3) The notice, if in writing, or the written report shall include a description of the serious adverse reaction and any steps taken to address it.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

Previous Version

C.04.422. If a fabricator recalls source plasma for a reason involving product safety, the fabricator shall provide the Minister with a written report stating the reason for the recall, the number of units involved and the location from which the units were recalled.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

Previous Version

C.04.423. In order to prevent injury to the health and safety of donors and recipients of products manufactured from source plasma, a fabricator shall, on request, provide the Minister with a copy of any record pertaining to plasmapheresis, specific immunization or source plasma that is required by sections C.04.401 to C.04.422 to be kept by the fabricator.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

Previous Version

C.04.424. [Repealed, SOR/2006-353, s. 1]

Previous Version

C.04.425. [Repealed, SOR/2006-353, s. 1]

Previous Version

C.04.426. [Repealed, SOR/2006-353, s. 1]

Previous Version

C.04.427. [Repealed, SOR/97-12, s. 50]

C.04.428. [Repealed, SOR/2006-353, s. 1]

Previous Version

## Insulin Preparations

[SOR/82-769, s. 5]

C.04.550. (1) “Insulin” means the active principle of the pancreas that affects the metabolism of carbohydrates in the animal body and that is of value in the treatment of *diabetes mellitus*.

(2) The Canadian Reference Standard for insulin shall be the International Standard therefor.

(3) The insulin preparations described in these Regulations shall contain insulin to which may be added only such ingredients as are prescribed in these Regulations.

(4) The potency of an insulin preparation shall be expressed in units per cubic centimetre and each unit per cubic centimetre shall provide one International Unit of insulin per cubic centimetre.

SOR/82-769, s. 4.

C.04.551. No person shall sell or dispense an insulin preparation that has not been stored by him continuously at a temperature between 35° and 50°F (2° and 10°C).

SOR/82-769, s. 4.

C.04.552. The zinc-insulin crystals used in an insulin preparation shall contain, as determined by an acceptable method,

(*a*) not less than 21 International Units of insulin per milligram, and

(*b*) on the dry basis, not less than 0.30 per cent and not more than 0.90 per cent zinc.

SOR/82-769, s. 4.

## Insulin Injection or Insulin

C.04.553. The insulin preparation, “Insulin injection” or “Insulin” shall be a clear colourless or almost colourless sterile solution free from turbidity and insoluble matter, prepared from insulin or zinc insulin crystals, shall have a pH of not less than 2.5 or more than 3.5, or not less than 7.0 or more than 7.8 and shall contain

(*a*) weight by volume,

(i) not less than 0.1 per cent and not more than 0.25 per cent of either phenol or cresol, and

(ii) not less than 1.4 per cent and not more than 1.8 per cent glycerin; and

(*b*) as determined by an acceptable method, for each 1,000 International Units of insulin,

(i) not more than 7.0 milligrams of nitrogen for Insulin Injection prepared from zinc-insulin crystals, and not more than 8.5 milligrams of nitrogen for Insulin Injection other than that made from zinc-insulin crystals,

(ii) not less than 0.10 milligram and not more than 0.40 milligram of zinc for Insulin Injection prepared from zinc-insulin crystals, and not more than 0.40 milligram of zinc for Insulin Injection other than that made from zinc-insulin crystals, and

(iii) in the case of Insulin Injection other than that made from zinc-insulin crystals, not more than 1.0 milligram of ash.

SOR/82-769, s. 4; SOR/85-715, s. 7.

C.04.554. No person shall sell Insulin Injection unless,

(*a*) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres;

(*b*) the vial label indicates that each cubic centimetre has a potency equal to

(i) 40 International Units of insulin,

(ii) 80 International Units of insulin, or

(iii) 100 International Units of insulin; and

(*c*) each cubic centimetre thereof has an actual potency that is at least 95 per cent and does not exceed 105 per cent of the potency indicated on the label as determined by an acceptable method.

SOR/82-769, s. 4.

C.04.555. (1) A fabricator shall not sell Insulin Injection unless he

(*a*) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(*b*) has furnished the Director with such additional information as the Director may require; and

(*c*) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(*a*) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Insulin Injection

(i) protocols of assay of its potency expressed in International Units per cubic centimetre, in the case of insulin, and in International Units per milligram, in the case of zinc-insulin crystals,

(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals,

(iii) a report of the ash content in the case of insulin, and

(iv) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;

(*b*) for the first finished lot of Insulin Injection prepared from each master lot of insulin or zinc-insulin crystals, a report on the amount of each component thereof; and

(*c*) for the first filling of the first finished lot of Insulin Injection from each master lot of insulin or zinc-insulin crystals,

(i) a report of assay of its nitrogen content in milligrams per 1,000 International Units of insulin,

(ii) a report of assay of its zinc content in milligrams per 1,000 International Units of insulin, and

(iii) a report on the determination of its pH.

(iv) [Repealed, SOR/95-203, s. 2]

SOR/82-769, s. 4; SOR/95-203, s. 2; SOR/97-12, s. 61.

C.04.556. The expiration date printed on the inner and outer labels of every package of Insulin Injection shall be a date not later than two years after the date of removal for distribution from the fabricator’s place of storage.

SOR/82-769, s. 4; SOR/97-12, s. 61.

## Insulin Zinc Suspension — Rapid

C.04.557. The insulin preparation “Insulin Zinc Suspension — Rapid” shall be a sterile suspension in a buffered aqueous medium, of insulin modified by the addition of zinc in such a way that the suspended precipitate consists of amorphous material, shall have a pH of not less than 7.0 and not more than 7.8 and shall contain,

(*a*) weight by volume,

(i) not less than 0.15 per cent and not more than 0.17 per cent of sodium acetate ($NaC_2H_3O_2.3H_2O$),

(ii) not less than 0.65 per cent and not more than 0.75 per cent of sodium chloride, and

(iii) not less than 0.09 per cent and not more than 0.11 per cent of methyl-*p*-hydroxybenzoate; and

(*b*) as determined by an acceptable method, for each 1,000 International Units of insulin,

(i) not more than 7.0 milligrams of nitrogen; and

(ii) not less than 1.2 milligrams and not more than 2.5 milligrams of zinc, of which not less than 20 per cent and not more than 65 per cent shall be in the supernatant liquid.

SOR/80-545, s. 1; SOR/82-769, s. 4; SOR/85-715, s. 8.

C.04.558. The insulin used in the preparation of Insulin Zinc Suspension — Rapid shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of Insulin Zinc Suspension-Rapid when the precipitate is suspended uniformly.

SOR/82-769, s. 4.

C.04.559. The clear supernatant liquid obtained from Insulin Zinc Suspension — Rapid shall contain not more than 1.0 International Unit of Insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, and not more than 1.5 International Units of insulin per cubic centimetre when the potency of the insulin preparation is either 80 units or 100 units per cubic centimetre, as determined by an acceptable method.

SOR/82-769, s. 4.

C.04.560. No person shall sell Insulin Zinc Suspension — Rapid unless

(*a*) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(*b*) each cubic centimetre thereof provides, when the precipitate is suspended uniformly,

(i) 40 International Units of insulin,

(ii) 80 International Units of insulin, or

(iii) 100 International Units of insulin.

SOR/82-769, s. 4.

C.04.561. (1) A fabricator shall not sell Insulin Zinc Suspension — Rapid unless he

(*a*) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(*b*) has furnished the Director such additional information as the Director may require; and

(*c*) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(*a*) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Insulin Zinc Suspension — Rapid,

(i) protocols of assay of its potency expressed in International Units per cubic centimetre in the case of insulin, and in International Units per milligram in the case of zinc-insulin crystals,

(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and

(iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;

(*b*) for the first finished lot of Insulin Zinc Suspension — Rapid prepared from each master lot of insulin or zinc-insulin crystals

(i) a report on the amount of each component used in the preparation,

(ii) a report of assay of its nitrogen content per 1,000 International Units of insulin,

(iii) a report of assay of its zinc content per 1,000 International Units of insulin,

(iv) a report of the insulin content in International Units per cubic centimetre of the supernatant liquid after removal of the suspended precipitate,

(v) a report of assay of the zinc content of the supernatant liquid after removal of the suspended precipitate,

(vi) a report on the determination of its pH, and

(vii) a report on the microscopic appearance of the suspended precipitate; and

(*c*) for the first filling of the first finished lot of Insulin Zinc Suspension — Rapid from each master lot of insulin or zinc-insulin crystals,

(i) a report on the determination of its pH,

(ii) a report on the microscopic examination of the precipitate, and

(iii) a report on its identification, as determined by an acceptable method.

(iv) [Repealed, SOR/95-203, s. 3]

SOR/82-769, s. 4; SOR/95-203, s. 3; SOR/97-12, s. 61.

C.04.562. The expiration date printed on the inner and outer labels of every package of Insulin Zinc Suspension — Rapid shall be a date not later than two years after the date of filling of the immediate container.

SOR/82-769, s. 4.

## Insulin Zinc Suspension — Medium

C.04.563. The insulin preparation “Insulin Zinc Suspension — Medium” shall be a sterile suspension, in a buffered aqueous medium, of insulin modified by the addition of zinc in such a way that the suspended precipitate consists of a mixture of crystals and amorphous material

in an approximate ratio of seven parts of crystals to three parts of amorphous material, shall have a pH of not less than 7.0 and not more than 7.8 and shall contain,

(*a*) weight by volume,

(i) not less than 0.15 per cent and not more than 0.17 per cent of sodium acetate ($NaC_2H_3O_2.3H_2O$),

(ii) not less than 0.65 per cent and not more than 0.75 per cent of sodium chloride, and

(iii) not less than 0.09 per cent and not more than 0.11 per cent of methyl-*p*-hydroxybenzoate; and

(*b*) as determined by an acceptable method, for each 1,000 International Units of insulin,

(i) not more than 7.0 milligrams of nitrogen of which not less than 63 per cent and not more than 73 per cent shall be in the crystalline component, and

(ii) not less than 1.2 milligrams and not more than 2.5 milligrams of zinc, of which not less than 20 per cent and not more than 65 per cent shall be in the supernatant liquid.

SOR/80-545, s. 2; SOR/82-769, s. 4; SOR/85-715, s. 9; SOR/88-323, s. 7.

C.04.564. The insulin used in the preparation of Insulin Zinc Suspension — Medium shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of the preparation when the precipitate is suspended uniformly.

SOR/82-769, s. 4.

C.04.565. The clear supernatant liquid obtained from Insulin Zinc Suspension — Medium shall contain not more than 1.0 International Unit of insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, and not more than 1.5 International Units of insulin per cubic centimetre when the potency of the insulin preparation is either 80 units or 100 units per cubic centimetre, as determined by an acceptable method.

SOR/82-769, s. 4.

C.04.566. No person shall sell Insulin Zinc Suspension-Medium unless

(*a*) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(*b*) each cubic centimetre thereof provides, when the precipitate is suspended uniformly,

(i) 40 International Units of insulin,

(ii) 80 International Units of insulin, or

(iii) 100 International Units of insulin.

SOR/82-769, s. 4.

C.04.567. (1) A fabricator shall not sell Insulin Zinc Suspension-Medium unless he

(*a*) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(*b*) has furnished the Director with such additional information as the Director may require; and

(*c*) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(*a*) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Insulin Zinc Suspension-Medium,

(i) protocols of assay of its potency expressed in International Units per cubic centimetre in the case of insulin, and in International Units per milligram in the case of zinc-insulin crystals,

(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and

(iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;

(*b*) for the first finished lot of Insulin Zinc Suspension-Medium prepared from each master lot of insulin or zinc-insulin crystals,

(i) a report on the amount of each component used in the preparation,

(ii) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iv) a report of the insulin content, in International Units per cubic centimetre, of the supernatant liquid after removal of the suspended precipitate,

(v) a report on the determination of the proportion of the nitrogen in the crystalline component of the suspended precipitate,

(vi) a report of assay of the zinc content of the supernatant liquid after removal of the suspended precipitate,

(vii) a report on the determination of its pH, and

(viii) a report on the microscopic appearance of the suspended precipitate; and

(*c*) for the first filling of the first finished lot of Insulin Zinc Suspension — Medium from each master lot of insulin or zinc-insulin crystals,

(i) a report on the determination of its pH,

(ii) a report on the microscopic examination of the precipitate, and

(iii) a report on its identification as determined by an acceptable method.

(iv) [Repealed, SOR/95-203, s. 4]

SOR/82-769, s. 4; SOR/95-203, s. 4; SOR/97-12, s. 61.

C.04.568. The expiration date printed on the inner and outer labels of Insulin Zinc Suspension — Medium shall be a date not later than two years after the date of filling of the immediate container.

SOR/82-769, s. 4.

## Insulin Zinc Suspension — Prolonged

C.04.569. The insulin preparation “Insulin Zinc Suspension — Prolonged” shall be a sterile suspension in a buffered aqueous medium of insulin modified by the addition of zinc in such a way that the suspended precipitate consists of crystals with not more than a trace of amorphous material, shall have a pH of not less than 7.0 and not more than 7.8 and shall contain

(*a*) weight by volume,

(i) not less than 0.15 per cent and not more than 0.17 per cent of sodium acetate ($NaC_2H_3O_2.3H_2O$),

(ii) not less than 0.65 per cent and not more than 0.75 per cent of sodium chloride, and

(iii) not less than 0.09 per cent and not more than 0.11 per cent of methyl-*p*-hydroxybenzoate; and

(*b*) as determined by an acceptable method, for each 1,000 International Units of insulin,

(i) not more than 7.0 milligrams of nitrogen, of which not less than 90 per cent shall be in the crystalline component, and

(ii) not less than 1.2 milligrams and not more than 2.5 milligrams of zinc, of which not less than 20 per cent and not more than 65 per cent shall be in the supernatant liquid.

SOR/80-545, s. 3; SOR/82-769, s. 4; SOR/85-715, s. 10.

C.04.570. The insulin used in the preparation of Insulin Zinc Suspension — Prolonged shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of the preparation when the precipitate is suspended uniformly.

SOR/82-769, s. 4.

C.04.571. The clear supernatant liquid obtained from Insulin Zinc Suspension — Prolonged shall contain not more than 1.0 International Unit of insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, and not more than 1.5 International Units of insulin per cubic centimetre when the potency of the insulin preparation is either 80 units or 100 units per cubic centimetre, as determined by an acceptable method.

SOR/82-769, s. 4.

C.04.572. No person shall sell Insulin Zinc Suspension — Prolonged unless

(*a*) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(*b*) each cubic centimetre thereof provides, when the precipitate is suspended uniformly,

(i) 40 International Units of insulin,

(ii) 80 International Units of insulin, or

(iii) 100 International Units of insulin.

SOR/82-769, s. 4.

C.04.573. (1) A fabricator shall not sell Insulin Zinc Suspension — Prolonged unless he

(*a*) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(*b*) has furnished the Director with such additional information as the Director may require; and

(*c*) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(*a*) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Insulin Zinc Suspension — Prolonged,

(i) protocols of assay of its potency expressed in International Units per cubic centimetre in the case of insulin, and in International Units per milligram in the case of zinc-insulin crystals,

(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and

(iii) reports of assay of the nitrogen content in milligrams and of its zinc content in milligrams per 1,000 International Units of insulin;

(*b*) for the first finished lot of Insulin Zinc Suspension — Prolonged prepared from each master lot of insulin or zinc-insulin crystals,

(i) a report on the amount of each component used in the preparation,

(ii) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iv) a report of the insulin content, in International Units per cubic centimetre, of the supernatant liquid after removal of the suspended precipitate,

(v) a report of the determination of the proportion of the nitrogen in the crystalline component of the suspended precipitate,

(vi) a report of assay of the zinc content of the supernatant liquid after removal of the suspended precipitate,

(vii) a report on the determination of its pH, and

(viii) a report on the microscopic appearance of the suspended precipitate; and

(*c*) for the first filling of the first finished lot of Insulin Zinc Suspension — Prolonged from each master lot of insulin or zinc-insulin crystals,

(i) a report on the determination of its pH,

(ii) a report on the microscopic examination of the precipitate, and

(iii) a report on its identification as determined by an acceptable method.

(iv) [Repealed, SOR/95-203, s. 5]

SOR/82-769, s. 4; SOR/95-203, s. 5; SOR/97-12, s. 61.

C.04.574. The expiration date printed on the inner and outer labels of every package of Insulin Zinc Suspension — Prolonged shall be a date not later than two years after the date of filling of the immediate container.

SOR/82-769, s. 4.

## Globin Insulin with Zinc

C.04.575. The insulin preparation **"Globin Insulin with Zinc"** shall be a sterile solution of insulin modified by the addition of globin prepared from beef blood, in the form of globin hydrochloride, and zinc, shall be a clear, yellowish, or almost colourless liquid free from insoluble matter and acceptably free from turbidity, shall have a pH of not less than 3.4 and not more than 3.8 and shall contain,

(*a*) weight by volume, not less than 1.3 per cent and not more than 1.7 per cent glycerin, and either

(i) not less than 0.15 per cent and not more than 0.20 per cent cresol, or

(ii) not less than 0.20 per cent and not more than 0.26 per cent phenol, and

(*b*) as determined by an acceptable method, for each 1,000 International Units of insulin,

(i) not more than 15.0 milligrams of total nitrogen,

(ii) not less than 36.0 milligrams and not more than 40.0 milligrams of globin calculated as 6.0 times the nitrogen content of the globin, and

(iii) not less than 2.5 milligrams and not more than 3.5 milligrams of zinc.

SOR/82-769, s. 4.

C.04.576. The globin hydrochloride used in the preparation of Globin Insulin with Zinc shall contain not less than 16.0 per cent and not more than 17.5 per cent nitrogen calculated on a dry, ash-free and hydrochloric acid-free basis, and its ash content shall be not more than 0.3 per cent as determined by an acceptable method.

SOR/82-769, s. 4.

C.04.577. The insulin used in the preparation of Globin Insulin with Zinc shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40 or 80 International Units of insulin in each cubic centimetre of the Globin Insulin with Zinc.

SOR/82-769, s. 4.

C.04.578. (1) The Canadian Reference Standard for Globin Insulin with Zinc shall be the standard adopted therefor by the Director from time to time.

(2) Upon application of a person who holds an establishment licence, the Director shall furnish him with a portion of the Canadian Reference Standard with directions for comparative testing.

(3) The testing of the biological reaction of Globin Insulin with Zinc shall be made by an acceptable method and that biological reaction shall be comparable to the biological reaction of the portion of the Canadian Reference Standard furnished by the Director.

SOR/82-769, s. 4; SOR/97-12, s. 64.

C.04.579. No person shall sell Globin Insulin with Zinc unless

(*a*) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(*b*) each cubic centimetre thereof provides,

(i) 40 International Units of insulin, or

(ii) 80 International Units of insulin.

SOR/82-769, s. 4.

C.04.580. (1) A fabricator shall not sell Globin Insulin with Zinc unless he

(*a*) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(*b*) has furnished the Director with such additional information as the Director may require; and

(*c*) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(*a*) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Globin Insulin with Zinc,

(i) protocols of assay of its potency expressed in International Units per cubic centimetre in the case of insulin, and in International Units per milligram in the case of zinc-insulin crystals,

(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and

(iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;

(*b*) for the master lot of globin hydrochloride used in the preparation of Globin Insulin with Zinc, reports of assay of

(i) its nitrogen content in per cent calculated on a dry, ash-free and hydrochloric acid free basis,

(ii) its chloride content in per cent calculated as hydrochloride, and

(iii) its ash content in percentage;

(*c*) for the components used in the preparation of the trial mixture of Globin Insulin with Zinc, a report on the quantity of

(i) insulin in grams, or in International Units,

(ii) zinc in grams, or in milligrams, per 1,000 International Units of insulin,

(iii) globin hydrochloride in grams or in milligrams, per 1,000 International Units of insulin, and

(iv) the volume of the preparation in cubic centimetres or litres;

(*d*) for the trial mixture of Globin Insulin with Zinc,

(i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iii) protocols of the biological reaction showing the retardation of the insulin effect, and

(iv) a report on the determination of its pH;

(*e*) for the first finished lot of Globin Insulin with Zinc from each trial mixture of Globin Insulin with Zinc, a report on the amount of each component in the preparation; and

(*f*) for the first filling of the first finished lot of Globin Insulin with Zinc from each trial mixture of Globin Insulin with Zinc,

(i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin, and

(iii) a report on the determination of its pH.

(iv) [Repealed, SOR/95-203, s. 6]

SOR/82-769, s. 4; SOR/95-203, s. 6; SOR/97-12, s. 61.

C.04.581. The expiration date printed on the inner and outer labels of every package of Globin Insulin with Zinc shall be a date not later than two years after the date of filling of the immediate container.

SOR/82-769, s. 4.

## NPH Insulin or Isophane Insulin

C.04.582. The insulin preparation “NPH Insulin” or “Isophane Insulin” shall be a sterile preparation of rod-shaped crystals containing insulin, protamine and zinc, suspended in a buffered aqueous medium, shall have a pH of not less than 7.0 and not more than 7.8 and shall contain

(*a*) weight by volume, not less than 0.15 per cent and not more than 0.25 per cent anhydrous disodium phosphate, and either

(i) not less than 1.4 per cent and not more than 1.8 per cent glycerin and not less than 0.15 per cent and not more than 0.17 per cent metacresol and not less than 0.06 and not more than 0.07 per cent phenol, or

(ii) not less than 0.40 per cent and not more than 0.45 per cent sodium chloride and not less than 0.7 per cent and not more than 0.9 per cent glycerin and not less than 0.18 per cent and not more than 0.22 per cent metacresol; and

(*b*) as determined by an acceptable method, for each 1,000 International Units of insulin,

(i) not more than 8.5 milligrams of nitrogen,

(ii) not less than 3.0 milligrams and not more than 6.0 milligrams of protamine except that the ratio of the protamine to the insulin shall be not less than the isophane ratio and shall not exceed the isophane ratio by more than 10 per cent,

(iii) not less than 0.16 milligram and not more than 0.40 milligram of zinc, and

(iv) no protease activity significant for the stability of NPH insulin.

SOR/82-769, s. 4; SOR/85-715, s. 11.

C.04.583. The protamine used in preparing NPH Insulin shall be obtained from the sperm or from the mature testes of fish belonging to the family *Salmonidae*, genera *Oncorhynchus* Suckley, or *Salmo* Linne.

SOR/82-769, s. 4.

C.04.584. The “isophane ratio” means the minimum number of milligrams of protamine required to precipitate 100 International Units of insulin and shall be determined by an acceptable method.

SOR/82-769, s. 4.

C.04.585. The insulin used in the preparation of NPH Insulin shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of the preparation when the precipitate is suspended uniformly.

SOR/82-769, s. 4.

C.04.586. The clear supernatant liquid obtained from NPH insulin shall contain not more than 0.4 International Units of insulin per cubic centimetre when the potency of the insulin preparation is 40 units per cubic centimetre, not more than 0.6 International Units of insulin per cubic centimetre when the potency of the insulin preparation is 80 units per cubic centimetre and not more than 0.7 International Units of insulin per cubic centimetre when the potency of the insulin preparation is 100 units per cubic centimetre, as determined by an acceptable method.

SOR/82-769, s. 4.

C.04.587. No person shall sell NPH Insulin unless

(*a*) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(*b*) each cubic centimetre thereof provides,

(i) 40 International Units of insulin,

(ii) 80 International Units of insulin, or

(iii) 100 International Units of insulin.

SOR/82-769, s. 4.

C.04.588. (1) A fabricator shall not sell NPH Insulin unless he

(*a*) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(*b*) has furnished the Director with such additional information as the Director may require; and

(*c*) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(*a*) for each master lot of zinc-insulin crystals employed in the manufacture of NPH Insulin,

(i) protocols of assay of its potency in International Units per milligram,

(ii) a report of its moisture content in per cent determined by drying to constant weight at 100°C, and

(iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin;

(*b*) for the master lot of protamine, a report of the isophane ratio for the insulin used in the preparation of the NPH Insulin;

(*c*) for the trial mixture of NPH Insulin,

(i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iii) a report of the insulin content in International Units per cubic centimetre of the supernatant liquid after removal of the suspended precipitate,

(iv) a report on the determination of its pH, and

(v) a report on the microscopic examination of the precipitate;

(*d*) for the first finished lot of NPH Insulin from each trial mixture of NPH Insulin, a report on the amount of each component in the preparation; and

(*e*) for the first filling of the first finished lot of NPH Insulin from each trial mixture of NPH Insulin,

(i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(iii) a report on the determination of its pH,

(iv) a report on the microscopic examination of the precipitate, and

(v) a report of its identification as determined by an acceptable method.

(vi) [Repealed, SOR/95-203, s. 7]

SOR/82-769, s. 4; SOR/95-203, s. 7; SOR/97-12, s. 61.

C.04.589. The expiration date printed on the inner and outer labels of NPH Insulin shall be a date not later than two years after the date of filling of the immediate container.

SOR/82-769, s. 4.

## Protamine Zinc Insulin

C.04.590. The insulin preparation **"Protamine Zinc Insulin"** shall be a sterile white suspension in a buffered aqueous medium, containing insulin modified by the addition of protamine and zinc, shall have a pH of not less than 7.1 and not more than 7.4, and shall contain,

(*a*) weight by volume,

(i) not less than 0.15 per cent and not more than 0.25 per cent anhydrous disodium phosphate,

(ii) not less than 1.4 per cent and not more than 1.8 per cent glycerin, and

(iii) either not less than 0.18 per cent and not more than 0.22 per cent cresol, or not less than 0.22 per cent and not more than 0.28 per cent phenol; and

(*b*) as determined by an acceptable method, for each 1,000 International Units of insulin,

(i) not more than 12.5 milligrams of total nitrogen,

(ii) not less than 10.0 milligrams and not more than 15.0 milligrams of protamine,

(iii) not less than 1.7 milligrams and not more than 2.5 milligrams of zinc.

SOR/82-769, s. 4.

C.04.591. The protamine used in the preparation of Protamine Zinc Insulin shall be obtained from the sperm or from the mature testes of fish belonging to the family *Salmonidae*, genera *Oncorhunchus* Suckley or *Salmo* Linne.

SOR/82-769, s. 4.

C.04.592. The insulin used in the preparation of Protamine Zinc Insulin shall be obtained from one or more master lots and shall be present in an amount sufficient to provide either 40, 80 or 100 International Units of insulin in each cubic centimetre of the preparation when the precipitate is suspended uniformly.

SOR/82-769, s. 4.

C.04.593. (1) The Canadian Reference Standard for Protamine Zinc Insulin shall be the standard adopted therefor by the Director from time to time.

(2) Upon application of a person who holds an establishment licence, the Director shall furnish him with a portion of the Canadian Reference Standard with directions for comparative testing.

(3) The testing of the biological reaction of Protamine Zinc Insulin shall be made by an acceptable method and that biological reaction shall be comparable to the biological reaction of the portion of the Canadian Reference Standard furnished by the Director.

SOR/82-769, s. 4; SOR/97-12, s. 64.

C.04.594. No person shall sell Protamine Zinc Insulin unless

(*a*) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres; and

(*b*) each cubic centimetre thereof provides

(i) 40 International Units of insulin,

(ii) 80 International Units of insulin, or

(iii) 100 International Units of insulin.

SOR/82-769, s. 4.

C.04.595. (1) A fabricator shall not sell Protamine Zinc Insulin unless he

(*a*) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(*b*) has furnished the Director with such additional information as the Director may require; and

(*c*) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(*a*) for each master lot of insulin or zinc-insulin crystals employed in the manufacture of Protamine Zinc Insulin,

(i) protocols of assay of its potency in International Units per cubic centimetre in the case of insulin and in International Units per milligram in the case of zinc-insulin crystals,

(ii) a report on its moisture content in percentage determined by drying to constant weight at 100°C in the case of zinc-insulin crystals, and

(iii) reports of assay of its nitrogen content in milligrams, and its zinc content in milligrams per 1,000 International Units of insulin;

(*b*) for the components used in the preparation of the trial mixture of Protamine Zinc Insulin, a report on the quantity of

(i) insulin in grams or in International Units,

(ii) zinc in grams or in milligrams, per 1,000 International Units of insulin,

(iii) protamine in grams or in milligrams, per 1,000 International Units of insulin, and

(iv) the volume of the preparation in cubic centimetres or litres;

(*c*) for the trial mixture of Protamine Zinc Insulin,

(i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units of insulin,

(ii) a report of assay of its zinc content in milligrams per cubic centimetre per 1,000 International Units of insulin,

(iii) protocols of its biological reaction showing retardation of the insulin effect, and

(iv) a report on the determination of its pH;

(*d*) for the first finished lot of Protamine Zinc Insulin from each trial mixture of Protamine Zinc Insulin, a report on the amount of each component in the preparation; and

(*e*) for the first filling of the first finished lot of Protamine Zinc Insulin from each trial mixture of Protamine Zinc Insulin,

(i) a report of assay of its nitrogen content in milligrams per cubic centimetre or per 1,000 International Units,

(ii) a report of assay of its zinc content in milligrams per cubic centimetre or per 1,000 International Units, and

(iii) a report on the determination of its pH.

(iv) [Repealed, SOR/95-203, s. 8]

SOR/82-769, s. 4; SOR/95-203, s. 8; SOR/97-12, s. 61.

C.04.596. The expiration date printed on the inner and outer labels of every package of Protamine Zinc Insulin shall be a date not later than two years after the date of filling of the immediate container.

SOR/82-769, s. 4.

## Sulphated Insulin

C.04.597. The insulin preparation **"Sulphated Insulin"** shall be a clear or slightly turbid, colourless or almost colourless, sterile, isotonic preparation of zinc-insulin crystals chemically modified by treatment with sulphuric acid, shall have a pH of not less than 6.0 and not more than 7.0, and shall contain,

(*a*) weight by volume,

(i) not less than 0.6 per cent and not more than 1.0 per cent sodium chloride, and

(ii) not less than 0.2 per cent and not more than 0.3 per cent phenol; and

(*b*) as determined by an acceptable method,

(i) not more than 200 milligrams protein for each 1,000 International Units of insulin, and

(ii) not less than 5.5 and not more than 6.5 sulphate groups per insulin molecule.

SOR/82-769, s. 4.

C.04.598. The "neutralization ratio" means the amount of anti-beef-insulin serum required to neutralize one unit of Sulphated Insulin divided by the amount required to neutralize one unit of beef insulin, and shall be determined by an acceptable method.

SOR/82-769, s. 4.

C.04.599. The neutralization ratio of Sulphated Insulin shall be not less than 4 to 1.

SOR/82-769, s. 4.

C.04.600. No person shall sell Sulphated Insulin unless

(*a*) it is dispensed in a vial of approximately 10 cubic centimetre capacity that contains an excess volume sufficient to permit withdrawal of 10 cubic centimetres, and

(*b*) each cubic centimetre thereof provides 100 International Units of insulin as determined by an acceptable method.

SOR/82-769, s. 4.

C.04.601. (1) A fabricator shall not sell Sulphated Insulin unless he

(*a*) has filed with the Director, in accordance with subsection (2), a submission relating to that preparation, in a form and having a content satisfactory to the Director;

(*b*) has furnished the Director with such additional information as the Director may require; and

(*c*) has received from the Director a notice that the information contained in the submission is in accordance with the requirements of this section.

(2) A submission filed pursuant to subsection (1) shall include at least,

(*a*) for each master lot of zinc-insulin crystals employed in the manufacture of Sulphated Insulin,

(i) protocols of assay of its potency in International Units per milligram,

(ii) a report of its moisture content in percentage determined by drying to constant weight at 100°C, and

(iii) reports of assay of its nitrogen content in milligrams and its zinc content in milligrams per 1,000 International Units of insulin; and

(*b*) for each lot of Sulphated Insulin prepared from each master lot of zinc-insulin crystals,

(i) a report of the amount of each component,

(ii) a report of the protein content in milligrams per 1,000 International Units of insulin,

(iii) a report on the determination of the neutralization ratio,

(iv) a report on the determination of the number of sulphate groups per insulin molecule,

(v) protocols of assay of its potency expressed as International Units per cubic centimetre, and

(vi) a report on the determination of its pH.

(vii) [Repealed, SOR/95-203, s. 9]

SOR/82-769, s. 4; SOR/95-203, s. 9; SOR/97-12, s. 61.

C.04.602. The expiration date printed on the inner and outer labels of every package of Sulphated Insulin shall be a date not later than two years after the date of filling of the immediate container.

SOR/80-545, s. 4; SOR/82-769, s. 4.

## Labelling of Insulin Preparations

[SOR/82-769, s. 8]

C.04.650. The packager/labeller of Insulin Injection may label that insulin preparation "Insulin made from Zinc-Insulin crystals" only when it has been prepared from zinc-insulin crystals.

SOR/82-769, s. 7; SOR/97-12, s. 65.

C.04.651. The packager/labeller of an insulin preparation shall print the information required by these Regulations to appear on both the inner and outer labels of every package of that insulin preparation as set out in the Table to this section.

TABLE

| Item | Column I<br>Insulin Preparation | Column II<br>Potency of Preparation | Column III<br>Special Printing Requirements for Label |
|---|---|---|---|
| 1. | Insulin Injection, not labelled as set out in item 2. | (*a*) 40 units per cc. | (*a*) black ink on yellow stock. |
| | | (*b*) 80 units per cc. | (*b*) black ink on green stock. |
| | | (*c*) 100 units per cc. | (*c*) black ink on white stock. |
| 2. | Insulin Injection, labelled "Insulin made from Zinc-Insulin crystals." | (*a*) 40 units per cc. | (*a*) red ink on grey stock. |
| | | (*b*) 80 units per cc. | (*b*) green ink on grey stock. |
| | | (*c*) 100 units per cc. | (*c*) black ink on white stock. |
| 3. | Insulin Zinc Suspension — Rapid, Insulin Zinc Suspension — Medium and Insulin Zinc Suspension — Prolonged. | (*a*) 40 units per cc. | (*a*) red ink on lavender stock plus a distinguishing mark or design. |
| | | (*b*) 80 units per cc. | (*b*) green ink on lavender stock plus a distinguishing mark or design. |
| | | (*c*) 100 units per cc. | (*c*) black ink on white stock. |
| 4. | Globin Insulin with Zinc. | (*a*) 40 units per cc. | (*a*) red ink on brown stock except that the expression "40 units per cubic centimetre" may be printed in white letters on a red background. |
| | | (*b*) 80 units per cc. | (*b*) green ink on brown stock except that the expression "80 units per cubic centimetre" may be printed in white letters on a green background. |
| 5. | NPH Insulin. | (*a*) 40 units per cc. | (*a*) red ink on blue stocks. |
| | | (*b*) 80 units per cc. | (*b*) green ink on blue stock. |
| | | (*c*) 100 units per cc. | (*c*) black ink on white stock. |
| 6. | Protamine Zinc Insulin. | (*a*) 40 units per cc. | (*a*) red ink on white stock. |
| | | (*b*) 80 units per cc. | (*b*) green ink on white stock. |
| | | (*c*) 100 units per cc. | (*c*) black ink on white stock |
| 7. | Sulphated Insulin. | 100 units per cc. | black ink on white stock plus the statement "Warning... Not for Ordinary Use... See Package Leaflet". |

SOR/82-769, s. 7; SOR/97-12, s. 65.

C.04.652. The packager/labeller of an insulin preparation shall print on the outer label of every package thereof instructions to store the preparation in a refrigerator at 35° to 50°F (2° to 10°C) and to avoid exposing it to freezing.

SOR/82-769, s. 7; SOR/97-12, s. 65.

C.04.653. The packager/labeller of an insulin preparation that consists of a precipitate suspended in a buffered aqueous medium shall print on the inner label of every package thereof the statement “Shake Carefully”.

SOR/82-769, s. 7; SOR/97-12, s. 65.

C.04.654. The packager/labeller of an insulin preparation may, in lieu of printing adequate directions for its use on both the inner and outer labels thereof as required by subparagraph C.04.019(*a*)(vii), print the descriptions for use in a descriptive circular prepared in accordance with section C.04.655, but in such case he shall

(*a*) enclose a copy of the circular in the package containing the preparation; and

(*b*) state on the outer label of the package that such a circular is enclosed therein.

SOR/82-769, ss. 7, 9; SOR/97-12, s. 65.

C.04.655. The descriptive circular referred to in section C.04.654 shall include, at least, the following information:

(*a*) a statement that

(i) the treatment of *diabetes mellitus* requires medical supervision and review,

(ii) insulin preparations should be used only as determined by a physician for each patient in the light of blood-sugar and urinary-sugar findings, and

(iii) the physician’s instructions concerning diet, dosage, rest and exercise should be followed carefully;

(*b*) an outline of the procedure to be followed in withdrawing the insulin preparation from the vial, including techniques for sterilization of the syringe and needle, vial-stopper and site of injection;

(*c*) a statement explaining that injections should be subcutaneous, and not intravenous or intramuscular, and a caution against successive injections in any one site;

(*d*) a statement that doses are specified in terms of *Units* of potency per cubic centimetre and that the *volume* of each dose will depend upon the potency in terms of units per cubic centimetre stated on the label of the insulin preparation and that, for these reasons, it is important that the patient understand the markings on syringes;

(*e*) a brief explanation of *hypoglycemia* together with emergency measures suitable for use by patients and those caring for patients in the event of hypoglycemic reactions;

(*f*) a statement indicating the possibility of undesirable reactions associated with illness or infection, with the omission or loss of a meal, and with a shortage of the insulin preparation;

(*g*) a statement warning against using any other type of insulin preparation than that prescribed by the physician;

(*h*) a statement that the use of a package should not be commenced after the expiration date printed on the package;

(*i*) a statement that the contents should be used as continuously as practicable and that any vial from which a part of the contents has been withdrawn should be discarded in the event of its being in disuse for several weeks' time;

(*j*) a statement stressing the importance of visiting a physician regularly and of carefully following his instructions;

(*k*) in the case of insulin preparations consisting of a clear, colourless or almost colourless solution, free from turbidity and from insoluble matter, a statement that if the contents of the vial become cloudy or turbid, use of that vial should be discontinued;

(*l*) in the case of insulin preparations consisting of a precipitate suspended in a buffered aqueous medium, a statement explaining that it is necessary to shake the vial carefully before withdrawing a dose, noting that if the contents have become lumpy or granular in appearance or have formed a deposit of particles on the wall of the container, the use of that vial should be discontinued;

(*m*) instructions that the insulin preparation should be stored in a refrigerator at 35° to 50°F (2° to 10°C) and should not be exposed to freezing; and

(*n*) in the case of Sulphated Insulin, a statement explaining that this insulin preparation is not for ordinary use, but is a chemically modified insulin which may be more effective than the usual insulin preparations in certain insulin-resistant or insulin-allergic diabetic patients.

SOR/82-769, ss. 7, 10.

C.04.656. (1) Notwithstanding section C.04.554, a person who holds an establishment licence may sell Insulin Injection made from zinc-insulin crystals contained in vials of approximately 20 cubic centimetre capacity each of which vials

(*a*) contains an excess volume sufficient to permit withdrawal of 20 cubic centimetres, and

(*b*) provides 500 International Units of insulin per cubic centimetre,

if

(*c*) notwithstanding section C.04.651, both the inner and outer labels are printed in black ink on white stock and overprinted in narrow brown and white diagonal stripes, of which there shall be at least five but not more than 20 to each inch;

(*d*) both the inner and the outer labels carry the statement "Warning — High Potency — Not for Ordinary Use"; and

(*e*) each package contains a descriptive circular that conforms to the requirements of section C.04.655 and, in addition, includes,

(i) at the beginning of the circular the statement:

“Warning — This insulin preparation contains 500 International Units of insulin in each cubic centimetre. Extreme caution must be observed in the measurement of doses because inadvertent overdose may result in irreversible shock. Serious consequences may result if it is used other than under constant medical supervision. Unless specifically prescribed it should never be used by patients to replace use of any other insulin preparations.”,

(ii) a statement that Insulin made from Zinc-Insulin crystals 500 International Units per cubic centimetre should not be administered intravenously, and

(iii) a statement giving information for the safe and effective use by physicians of the drug in insulin shock therapy and in the treatment of diabetic patients with high insulin resistance (daily requirement more than 200 International Units of insulin).

(2) [Repealed, SOR/95-203, s. 10]

SOR/82-769, ss. 7, 11; SOR/95-203, s. 10; SOR/97-12, s. 64.

## Anterior Pituitary Extracts

[SOR/82-769, s. 14]

C.04.675. Anterior pituitary extract shall include all natural products, prepared from the anterior lobe of the pituitary gland of animals, having physiological properties associated with the hormones of the anterior pituitary gland and their proper names shall be

(*a*) **Adrenocorticotrophic Hormone, Corticotrophin,**

(*b*) **Thyrotrophic Hormone, Thyrotrophin,**

(*c*) **Growth Hormone Pituitary, Somatotrophin,**

(*d*) **Lactogenic Hormone, Prolactin,**

(*e*) **Gonadotrophic Hormone, Gonadotrophin,** followed by qualifying words to indicate the gonadotrophic activity associated with the extract,

and if unpurified anterior pituitary extract

(*f*) **Pituitary Extract Anterior Lobe** followed by qualifying words to indicate the physiological properties associated with it.

SOR/82-769, s. 13.

C.04.676. Reference standards for anterior pituitary extract shall be

(*a*) the International Standard,

(*b*) where no International Standard exists, the Canadian Reference Standard shall be that established and kept by the Director from whom portions for comparative testing may be had upon application, and

(*c*) where neither an International Standard nor a Canadian Reference Standard exists, a provisional reference standard that shall be a suitable quantity of the product submitted by the distributor referred to in paragraph C.01A.003(*b*) to the Director for checking the uniformity of the product.

SOR/82-769, s. 13; SOR/97-12, s. 58.

C.04.677. Both the inner and outer labels of an anterior pituitary extract shall carry a statement of the potency in terms of the reference standard for anterior pituitary extract provided in section C.04.676 as determined by an acceptable method, except that where no reference standard for an anterior pituitary extract exists, the distributor referred to in paragraph C.01A.003(*b*) shall include, with every package of the anterior pituitary extract, an acceptable statement of the unit of potency and the method of assay used.

SOR/82-769, s. 13; SOR/97-12, s. 58; SOR/97-543, s. 6.

C.04.678. No person who holds an establishment licence shall sell corticotrophic hormones for subcutaneous or intramuscular use unless the preparation has been assayed by an acceptable method involving subcutaneous injection and, where the preparation is recommended for intravenous use, the label carries specific dosage instructions for that use.

SOR/82-769, s. 13; SOR/97-12, s. 64.

C.04.679. No person shall sell as such adrenocorticotrophic hormone, thyrotrophic hormone, growth hormone pituitary, lactogenic hormone, or gonadotrophic hormone that is not acceptable free from any anterior pituitary extract other than the one for which it is named.

SOR/82-769, s. 13.

C.04.680. The outer label of a mixture of two or more of adrenocorticotrophic hormone, thyrotrophic hormone, growth hormone pituitary, lactogenic hormone and gonadotrophic hormone, or a mixture of any of those with pituitary extract anterior lobe, shall carry a declaration of the proper name and the amount of each component of the mixture.

SOR/82-769, s. 13; SOR/93-202, s. 22.

C.04.681. The outer label of an anterior pituitary extract or mixture of anterior pituitary extracts shall carry a statement

(*a*) showing the species of animal from which the glands used in the preparation of the anterior pituitary extract were obtained,

(*b*) that it shall be stored at refrigerator temperature, and

(*c*) that, except in the case of gonadotrophic hormones, it is to be used only on the advice or on the prescription of a physician.

SOR/82-769, s. 13.

C.04.682. Both the inner and outer labels of adrenocorticotrophic hormone shall carry a statement indicating the route of administration, in addition to meeting the requirements of paragraphs C.04.681(*a*) and (*b*).

SOR/82-769, ss. 13, 15.

C.04.683. The expiration date for an anterior pituitary extract or mixture of anterior pituitary extracts shall be not more than two years after the date of passing a potency test.

SOR/82-769, s. 13.

# Division 5

# Drugs For Clinical Trials Involving Human Subjects

## Interpretation

C.05.001. The definitions in this section apply in this Division.

“adverse drug reaction” means any noxious and unintended response to a drug that is caused by the administration of any dose of the drug. (réaction indésirable à une drogue)

“adverse event” means any adverse occurrence in the health of a clinical trial subject who is administered a drug, that may or may not be caused by the administration of the drug, and includes an adverse drug reaction. (incident thérapeutique)

“clinical trial” means an investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug. (essai clinique)

“drug” means a drug for human use that is to be tested in a clinical trial. (drogue)

“good clinical practices” means generally accepted clinical practices that are designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons, and the good clinical practices referred to in section C.05.010. (bonnes pratiques cliniques)

“import” means to import a drug into Canada for the purpose of sale in a clinical trial. (importer)

“investigator’s brochure” means, in respect of a drug, a document containing the preclinical and clinical data on the drug that are described in paragraph C.05.005(*e*). (brochure du chercheur)

“protocol” means a document that describes the objectives, design, methodology, statistical considerations and organization of a clinical trial. (protocole)

“qualified investigator” means the person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located, and who is

(*a*) in the case of a clinical trial respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and

(*b*) in any other case, a physician and a member in good standing of a professional medical association. (chercheur qualifié)

“research ethics board” means a body that is not affiliated with the sponsor, and

(*a*) the principal mandate of which is to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects in order to ensure the protection of their rights, safety and well-being; and

(*b*) that has at least five members, that has a majority of members who are Canadian citizens or permanent residents under the Immigration and Refugee Protection Act, that is composed of both men and women and that includes at least

(i) two members whose primary experience and expertise are in a scientific discipline, who have broad experience in the methods and areas of research to be approved and one of whom is from a medical discipline or, if the clinical trial is in respect of a drug to be used for dental purposes only, is from a medical or dental discipline,

(ii) one member knowledgeable in ethics,

(iii) one member knowledgeable in Canadian laws relevant to the biomedical research to be approved,

(iv) one member whose primary experience and expertise are in a non-scientific discipline, and

(v) one member who is from the community or is a representative of an organization interested in the areas of research to be approved and who is not affiliated with the sponsor or the site where the clinical trial is to be conducted. (comité d'éthique de la recherche)

"serious adverse drug reaction" means an adverse drug reaction that requires in-patient hospitalization or prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability or incapacity, that is life threatening or that results in death. (réaction indésirable grave à une drogue)

"serious unexpected adverse drug reaction" means a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out in the investigator's brochure or on the label of the drug. (réaction indésirable grave et imprévue à une drogue)

"sponsor" means an individual, corporate body, institution or organization that conducts a clinical trial. (promoteur)

SOR/2001-203, s. 4; 2001, c. 27, s. 273.

## Application

C.05.002. (1) Subject to subsection (2), this Division applies to the sale or importation of drugs to be used for the purposes of clinical trials involving human subjects.

(2) Except for paragraph C.05.003(*a*), subsections C.05.006(2) and (3), paragraphs C.05.010(*a*) to (*i*), section C.05.011, subsections C.05.012(1) and (2), paragraphs C.05.012(3)(*a*) to (*d*) and (*f*) to (*h*), subsection C.05.012(4) and sections C.05.013, C.05.016 and C.05.017, this Division does not apply to the sale or importation of a drug for the purposes of a clinical trial authorized under subsection C.05.006(2).

SOR/2001-203, s. 4.

## Prohibition

C.05.003. Despite sections C.01.014, C.08.002, C.08.002.02 and C.08.003, no person shall sell or import a drug for the purposes of a clinical trial unless

(*a*) the person is authorized under this Division;

(*b*) the person complies with this Division and sections C.01.015, C.01.036, C.01.037 to C.01.040, C.01.040.2, C.01.064 to C.01.067, C.01.070, C.01.131, C.01.133 to C.01.136, and C.01.435; and

(*c*) if the drug is to be imported, the person has a representative in Canada who is responsible for the sale of the drug.

SOR/2001-203, s. 4; SOR/2011-88, s. 7.

Previous Version

## General

C.05.004. Despite these Regulations, a sponsor may submit an application under this Division to sell or import a drug for the purposes of a clinical trial that contains a substance the sale of which is prohibited by these Regulations, if the sponsor establishes, on the basis of scientific information, that the inclusion of the substance in the drug may result in a therapeutic benefit for a human being.

SOR/2001-203, s. 4.

## Application for Authorization

C.05.005. An application by a sponsor for authorization to sell or import a drug for the purposes of a clinical trial under this Division shall be submitted to the Minister, signed and dated by the sponsor's senior medical or scientific officer in Canada and senior executive officer and shall contain the following information and documents:

(*a*) a copy of the protocol for the clinical trial;

(*b*) a copy of the statement, as it will be set out in each informed consent form, that states the risks and anticipated benefits arising to the health of clinical trial subjects as a result of their participation in the clinical trial;

(*c*) a clinical trial attestation, signed and dated by the sponsor's senior medical or scientific officer in Canada and senior executive officer, containing

(i) the title of the protocol and the clinical trial number,

(ii) the brand name, the chemical name or the code for the drug,

(iii) the therapeutic and pharmacological classifications of the drug,

(iv) the medicinal ingredients of the drug,

(v) the non-medicinal ingredients of the drug,

(vi) the dosage form of the drug,

(vii) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the sponsor,

(viii) if the drug is to be imported, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the sponsor's representative in Canada who is responsible for the sale of the drug,

(ix) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the qualified investigator, if known at the time of submitting the application,

(x) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved the protocol referred to in paragraph (*a*) and approved an informed consent form containing the statement referred to in paragraph (*b*), if known at the time of submitting the application, and

(xi) a statement

(A) that the clinical trial will be conducted in accordance with good clinical practices and these Regulations, and

(B) that all information contained in, or referenced by, the application is complete and accurate and is not false or misleading;

(*d*) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of any research ethics board that has previously refused to approve the protocol referred to in paragraph (*a*), its reasons for doing so and the date on which the refusal was given, if known at the time of submitting the application;

(*e*) an investigator's brochure that contains the following information, namely,

(i) the physical, chemical and pharmaceutical properties of the drug,

(ii) the pharmacological aspects of the drug, including its metabolites in all animal species tested,

(iii) the pharmacokinetics of the drug and the drug metabolism, including the biological transformation of the drug in all animal species tested,

(iv) any toxicological effects in any animal species tested under a single dose study, a repeated dose study or a special study in respect of the drug,

(v) any results of carcinogenicity studies in any animal species tested in respect of the drug,

(vi) any results of clinical pharmacokinetic studies of the drug,

(vii) any information regarding drug safety, pharmacodynamics, efficacy and dose responses of the drug that were obtained from previous clinical trials in humans, and

(viii) if the drug is a radiopharmaceutical as defined in section C.03.201, information regarding directions for preparing the radiopharmaceutical, the radiation dosimetry in respect of the prepared radiopharmaceutical and a statement of the storage requirements for the prepared radiopharmaceutical;

(*f*) if the drug contains a human-sourced excipient, including any used in the placebo,

(i) information that indicates the human-sourced excipient has been assigned a drug identification number under subsection C.01.014.2(1) or, in the case of a new drug, issued a notice of compliance under subsection C.08.004(1), as the case may be, or

(ii) in any other case, sufficient information to support the identity, purity, potency, stability and safety of the human-sourced excipient;

(*g*) if the drug has not been assigned a drug identification number under subsection C.01.014.2(1) or, in the case of a new drug, a notice of compliance has not been issued under section C.08.004 or C.08.004.01, the chemistry and manufacturing information in respect of the drug, including its site of manufacture; and

(*h*) the proposed date for the commencement of the clinical trial at each clinical trial site, if known at the time of submitting the application.

SOR/2001-203, s. 4; SOR/2011-88, s. 8.

Previous Version

## Authorization

C.05.006. (1) Subject to subsection (3), a sponsor may sell or import a drug, other than a drug described in subsection (2), for the purposes of a clinical trial if

(*a*) the sponsor has submitted to the Minister an application in accordance with section C.05.005;

(*b*) the Minister does not, within 30 days after the date of receipt of the application, send to the sponsor a notice in respect of the drug indicating that the sponsor may not sell or import the drug for any of the following reasons:

(i) that the information and documents in respect of the application

(A) were not provided in accordance with these Regulations, or

(B) are insufficient to enable the Minister to assess the safety and risks of the drug or the clinical trial, or

(ii) that based on an assessment of the application, an assessment of any information submitted under section C.05.009 or a review of any other information, the Minister has reasonable grounds to believe that

(A) the use of the drug for the purposes of the clinical trial endangers the health of a clinical trial subject or other person,

(B) the clinical trial is contrary to the best interests of a clinical trial subject, or

(C) the objectives of the clinical trial will not be achieved;

(*c*) for each clinical trial site, the sponsor has obtained the approval of the research ethics board in respect of the protocol referred to in paragraph C.05.005(*a*) and in respect of an informed consent form that contains the statement referred to in paragraph C.05.005(*b*); and

(*d*) before the sale or importation of the drug at a clinical trial site, the sponsor submits to the Minister the information referred to in subparagraphs C.05.005(*c*)(ix) and (x) and paragraphs C.05.005(*d*) and (*h*), if it was not submitted in respect of that clinical trial site at the time of submitting the application.

(2) Subject to subsection (3), a sponsor may sell or import a drug for the purposes of a clinical trial in respect of

(*a*) a new drug that has been issued a notice of compliance under subsection C.08.004(1), if the clinical trial is in respect of a purpose or condition of use for which the notice of compliance was issued; or

(*b*) a drug, other than a new drug, that has been assigned a drug identification number under subsection C.01.014.2(1), if the clinical trial is in respect of a use or purpose for which the drug identification number was assigned.

(3) A sponsor may not sell or import a drug for the purposes of a clinical trial

(*a*) during the period of any suspension made under section C.05.016 or C.05.017; or

(*b*) after a cancellation made under section C.05.016 or C.05.017.

SOR/2001-203, s. 4.

## Notification

C.05.007. If the sale or importation of a drug is authorized under this Division, the sponsor may make one or more of the following changes if the sponsor notifies the Minister in writing within 15 days after the date of the change:

(*a*) a change to the chemistry and manufacturing information that does not affect the quality or safety of the drug, other than a change for which an amendment is required by section C.05.008; and

(*b*) a change to the protocol that does not alter the risk to the health of a clinical trial subject, other than a change for which an amendment is required by section C.05.008.

SOR/2001-203, s. 4.

## Amendment

C.05.008. (1) Subject to subsections (4) and (5), when the sale or importation of a drug is authorized under this Division and the sponsor proposes to make an amendment referred to in subsection (2), the sponsor may sell or import the drug for the purposes of the clinical trial in accordance with the amended authorization, if the following conditions are met:

(*a*) the sponsor has submitted to the Minister an application for amendment in accordance with subsection (3);

(*b*) the Minister does not, within 30 days after the date of receipt of the application for amendment, send to the sponsor a notice in respect of the drug indicating that the sponsor may not sell or import the drug in accordance with the amendment for any of the following reasons, namely,

(i) that the information and documents in respect of the application for amendment

(A) were not provided in accordance with these Regulations, or

(B) are insufficient to enable the Minister to assess the safety and risks of the drug or the clinical trial, or

(ii) that based on an assessment of the application for amendment, an assessment of any information submitted under section C.05.009 or a review of any other information, the Minister has reasonable grounds to believe that

(A) the use of the drug for the purposes of the clinical trial endangers the health of a clinical trial subject or other person,

(B) the clinical trial is contrary to the best interests of a clinical trial subject, or

(C) the objectives of the clinical trial will not be achieved;

(*c*) before the sale or importation of the drug, the sponsor submits to the Minister

(i) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved any amended protocol submitted under paragraph (3)(*a*) or approved any amended statement submitted under paragraph (3)(*c*), and

(ii) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of any research ethics board that has previously refused to approve any amendment to the protocol, its reasons for doing so and the date on which the refusal was given;

(*d*) before the sale or importation of the drug, the sponsor maintains records concerning

(i) the information referred to in paragraph C.05.005(*h*), and

(ii) the information referred to in subparagraph C.05.005(*c*)(ix), if any of that information has changed since it was submitted;

(*e*) before the sale or importation of the drug in accordance with the amended authorization, the sponsor ceases to sell or import the drug in accordance with the existing authorization; and

(*f*) the sponsor conducts the clinical trial in accordance with the amended authorization.

(2) For the purposes of subsection (1), amendments are

(*a*) amendments to the protocol that affect the selection, monitoring or dismissal of a clinical trial subject;

(*b*) amendments to the protocol that affect the evaluation of the clinical efficacy of the drug;

(*c*) amendments to the protocol that alter the risk to the health of a clinical trial subject;

(*d*) amendments to the protocol that affect the safety evaluation of the drug;

(*e*) amendments to the protocol that extend the duration of the clinical trial; and

(*f*) amendments to the chemistry and manufacturing information that may affect the safety or quality of the drug.

(3) The application for amendment referred to in subsection (1) shall contain a reference to the application submitted under section C.05.005 and shall contain the following documents and information:

(*a*) if the application is in respect of an amendment referred to in any of paragraphs (2)(*a*) to (*e*), a copy of the amended protocol that indicates the amendment, a copy of the protocol submitted under paragraph C.05.005(*a*), and the rationale for the amendment;

(*b*) if the application is in respect of an amendment referred to in paragraph (2)(*e*), a copy of the amended investigator's brochure or an addendum to the investigator's brochure that indicates the new information, including supporting toxicological studies and clinical trial safety data;

(*c*) if the application is in respect of an amendment referred to in any of paragraphs (2)(*a*) to (*f*) and, as a result of that amendment, it is necessary to amend the statement referred to in paragraph C.05.005(*b*), a copy of the amended statement that indicates the new information; and

(*d*) if the application is in respect of an amendment referred to in paragraph (2)(*f*), a copy of the amended chemistry and manufacturing information that indicates the amendment, and the rationale for that amendment.

(4) If the sponsor is required to immediately make one or more of the amendments referred to in subsection (2) because the clinical trial or the use of the drug for the purposes of the clinical trial endangers the health of a clinical trial subject or other person, the sponsor may immediately make the amendment and shall provide the Minister with the information referred to in subsection (3) within 15 days after the date of the amendment.

(5) A sponsor may not sell or import a drug for the purposes of a clinical trial

(*a*) during the period of any suspension made under section C.05.016 or C.05.017; or

(*b*) after a cancellation made under section C.05.016 or C.05.017.

SOR/2001-203, s. 4.

## Additional Information and Samples

C.05.009. If the information and documents submitted in respect of an application under section C.05.005 or an application for amendment under section C.05.008 are insufficient to enable the Minister to determine whether any of the reasons referred to in paragraph C.05.006(1)(*b*) or C.05.008(1)(*b*) exist, the Minister may require the sponsor to submit, within two days after receipt of the request, samples of the drug or additional information relevant to the drug or the clinical trial that are necessary to make the determination.

SOR/2001-203, s. 4.

## Sponsor's Obligations

## Good Clinical Practices

C.05.010. Every sponsor shall ensure that a clinical trial is conducted in accordance with good clinical practices and, without limiting the generality of the foregoing, shall ensure that

(*a*) the clinical trial is scientifically sound and clearly described in a protocol;

(*b*) the clinical trial is conducted, and the drug is used, in accordance with the protocol and this Division;

(*c*) systems and procedures that assure the quality of every aspect of the clinical trial are implemented;

(*d*) for each clinical trial site, the approval of a research ethics board is obtained before the clinical trial begins at the site;

(*e*) at each clinical trial site, there is no more than one qualified investigator;

(*f*) at each clinical trial site, medical care and medical decisions, in respect of the clinical trial, are under the supervision of the qualified investigator;

(*g*) each individual involved in the conduct of the clinical trial is qualified by education, training and experience to perform his or her respective tasks;

(*h*) written informed consent, given in accordance with the applicable laws governing consent, is obtained from every person before that person participates in the clinical trial but only after that person has been informed of

(i) the risks and anticipated benefits to his or her health arising from participation in the clinical trial, and

(ii) all other aspects of the clinical trial that are necessary for that person to make the decision to participate in the clinical trial;

(*i*) the requirements respecting information and records set out in section C.05.012 are met; and

(*j*) the drug is manufactured, handled and stored in accordance with the applicable good manufacturing practices referred to in Divisions 2 to 4 except sections C.02.019, C.02.025 and C.02.026.

SOR/2001-203, s. 4.

## Labelling

C.05.011. Despite any other provision of these Regulations respecting labelling, the sponsor shall ensure that the drug bears a label that sets out the following information in both official languages:

(*a*) a statement indicating that the drug is an investigational drug to be used only by a qualified investigator;

(*b*) the name, number or identifying mark of the drug;

(*c*) the expiration date of the drug;

(*d*) the recommended storage conditions for the drug;

(*e*) the lot number of the drug;

(*f*) the name and address of the sponsor;

(*g*) the protocol code or identification; and

(*h*) if the drug is a radiopharmaceutical as defined in section C.03.201, the information required by subparagraph C.03.202(1)(*b*)(vi).

SOR/2001-203, s. 4.

## Records

C.05.012. (1) The sponsor shall record, handle and store all information in respect of a clinical trial in a way that allows its complete and accurate reporting as well as its interpretation and verification.

(2) The sponsor shall maintain complete and accurate records to establish that the clinical trial is conducted in accordance with good clinical practices and these Regulations.

(3) The sponsor shall maintain complete and accurate records in respect of the use of a drug in a clinical trial, including

(*a*) a copy of all versions of the investigator's brochure for the drug;

(*b*) records respecting each change made to the investigator's brochure, including the rationale for each change and documentation that supports each change;

(*c*) records respecting all adverse events in respect of the drug that have occurred inside or outside Canada, including information that specifies the indication for use and the dosage form of the drug at the time of the adverse event;

(*d*) records respecting the enrolment of clinical trial subjects, including information sufficient to enable all clinical trial subjects to be identified and contacted in the event that the sale of the drug may endanger the health of the clinical trial subjects or other persons;

(*e*) records respecting the shipment, receipt, disposition, return and destruction of the drug;

(*f*) for each clinical trial site, an undertaking from the qualified investigator that is signed and dated by the qualified investigator prior to the commencement of his or her responsibilities in respect of the clinical trial, that states that

(i) the qualified investigator will conduct the clinical trial in accordance with good clinical practices, and

(ii) the qualified investigator will immediately, on discontinuance of the clinical trial by the sponsor, in its entirety or at a clinical trial site, inform both the clinical trial subjects and the research ethics board of the discontinuance, provide them with the reasons for the discontinuance and advise them in writing of any potential risks to the health of clinical trial subjects or other persons;

(*g*) for each clinical trial site, a copy of the protocol, informed consent form and any amendment to the protocol or informed consent form that have been approved by the research ethics board for that clinical trial site; and

(*h*) for each clinical trial site, an attestation, signed and dated by the research ethics board for that clinical trial site, stating that it has reviewed and approved the protocol and informed consent form and that the board carries out its functions in a manner consistent with good clinical practices.

(4) The sponsor shall maintain all records referred to in this Division for a period of 25 years.

SOR/2001-203, s. 4.

## Submission of Information and Samples

C.05.013. (1) The Minister shall require a sponsor to submit, within two days after receipt of the request, information concerning the drug or the clinical trial, or samples of the drug, if the Minister has reasonable grounds to believe that

(*a*) the use of the drug for the purposes of the clinical trial endangers the health of a clinical trial subject or other person;

(*b*) the clinical trial is contrary to the best interests of a clinical trial subject;

(*c*) the objectives of the clinical trial will not be achieved;

(*d*) a qualified investigator is not respecting the undertaking referred to in paragraph C.05.012(3)(*f*); or

(*e*) information submitted in respect of the drug or the clinical trial is false or misleading.

(2) The Minister may require the sponsor to submit, within seven days after receipt of the request, any information or records kept under section C.05.012, or samples of the drug, in order to assess the safety of the drug or the health of clinical trial subjects or other persons.

SOR/2001-203, s. 4.

## Serious Unexpected Adverse Drug Reaction Reporting

C.05.014. (1) During the course of a clinical trial, the sponsor shall inform the Minister of any serious unexpected adverse drug reaction in respect of the drug that has occurred inside or outside Canada as follows:

(*a*) if it is neither fatal nor life threatening, within 15 days after becoming aware of the information; and

(*b*) if it is fatal or life threatening, within seven days after becoming aware of the information.

(2) The sponsor shall, within eight days after having informed the Minister under paragraph (1)(*b*), submit to the Minister a complete report in respect of that information that includes an assessment of the importance and implication of any findings made.

(3) Sections C.01.016 and C.01.017 do not apply to drugs used for the purposes of a clinical trial.

SOR/2001-203, s. 4.

## Discontinuance of a Clinical Trial

C.05.015. (1) If a clinical trial is discontinued by the sponsor in its entirety or at a clinical trial site, the sponsor shall

(*a*) inform the Minister no later than 15 days after the date of the discontinuance;

(*b*) provide the Minister with the reason for the discontinuance and its impact on the proposed or ongoing clinical trials in respect of the drug conducted in Canada by the sponsor;

(*c*) as soon as possible, inform all qualified investigators of the discontinuance and of the reasons for the discontinuance, and advise them in writing of any potential risks to the health of clinical trial subjects or other persons; and

(*d*) in respect of each discontinued clinical trial site, stop the sale or importation of the drug as of the date of the discontinuance and take all reasonable measures to ensure the recovery of all unused quantities of the drug that have been sold.

(2) If the sponsor has discontinued the clinical trial in its entirety or at a clinical trial site, the sponsor may resume selling or importing the drug for the purposes of a clinical trial in its entirety or at a clinical trial site if, in respect of each clinical trial site where the sale or importation is to be resumed, the sponsor submits to the Minister the information referred to in subparagraphs C.05.005(*c*)(ix) and (x) and paragraphs C.05.005(*d*) and (*h*).

SOR/2001-203, s. 4.

## Suspension and Cancellation

C.05.016. (1) Subject to subsection (2), the Minister shall suspend the authorization to sell or import a drug for the purposes of a clinical trial, in its entirety or at a clinical trial site, if the Minister has reasonable grounds to believe that

(*a*) the sponsor has contravened these Regulations or any provisions of the Act relating to the drug;

(*b*) any information submitted in respect of the drug or clinical trial is false or misleading;

(*c*) the sponsor has failed to comply with good clinical practices; or

(*d*) the sponsor has failed to provide

(i) information or samples of the drug as required under section C.05.009 or C.05.013, or

(ii) information or a report under section C.05.014.

(2) Subject to section C.05.017, the Minister shall not suspend an authorization referred to in subsection (1) unless

(*a*) the Minister has sent to the sponsor a written notice of the intention to suspend the authorization that indicates whether the authorization is to be suspended in its entirety or at a clinical trial site and the reason for the intended suspension;

(*b*) the sponsor has not, within 30 days after receipt of the notice referred to in paragraph (*a*), provided the Minister with information or documents that demonstrate that the authorization should not be suspended on the grounds that

(i) the situation giving rise to the intended suspension did not exist, or

(ii) the situation giving rise to the intended suspension has been corrected; and

(*c*) the Minister has provided the sponsor with the opportunity to be heard in paragraph (*b*).

(3) The Minister shall suspend the authorization by sending to the sponsor a written notice of suspension of the authorization that indicates the effective date of the suspension, whether the

authorization is suspended in its entirety or at a clinical trial site and the reason for the suspension.

(4) If the Minister has suspended an authorization, the Minister shall

(*a*) reinstate the authorization in its entirety or at a clinical trial site, as the case may be, if within 30 days after the effective date of the suspension the sponsor provides the Minister with information or documents that demonstrate that the situation giving rise to the suspension has been corrected; or

(*b*) cancel the authorization in its entirety or at a clinical trial site, as the case may be, if within 30 days after the effective date of the suspension the sponsor has not provided the Minister with the information or documents referred to in paragraph (*a*).

SOR/2001-203, s. 4.

C.05.017. (1) The Minister shall suspend an authorization to sell or import a drug for the purposes of a clinical trial, in its entirety or at a clinical trial site, before giving the sponsor an opportunity to be heard if the Minister has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a clinical trial subject or other person.

(2) The Minister shall suspend the authorization by sending to the sponsor a written notice of suspension of the authorization that indicates the effective date of the suspension, whether the authorization is suspended in its entirety or at a clinical trial site and the reason for the suspension.

(3) If the Minister has suspended an authorization, the Minister shall

(*a*) reinstate the authorization in its entirety or at a clinical trial site, as the case may be, if within 60 days after the effective date of the suspension the sponsor provides the Minister with information or documents that demonstrate that the situation giving rise to the suspension did not exist or that it has been corrected; or

(*b*) cancel the authorization in its entirety or at a clinical trial site, as the case may be, if within 60 days after the effective date of the suspension the sponsor has not provided the Minister with the information or documents referred to in paragraph (*a*).

SOR/2001-203, s. 4.

# Division 6

CANADIAN STANDARD DRUGS

1. Conjugated Estrogens
2. Conjugated Estrogens for Injection
3. Conjugated Estrogens Tablets
4. Digitoxin
5. Digitoxin Tablets
6. Digoxin

7. Digoxin Elixir
8. Digoxin Injection
9. Digoxin Tablets
10. Esterified Estrogens
11. Esterified Estrogens Tablets
12. Gelatin
13. Thyroid

SOR/80-544, s. 11.

## General

C.06.001. In this Division,

(*a*) solubility and specific gravity shall be determined at 25°C;

(*b*) tests for identity, quantitative tests for arsenic, lead, copper, zinc, fluorine, and sulphur dioxide, and limit tests shall be made by the official methods; and

(*c*) determination of physical and chemical constants shall be carried out by acceptable methods.

## Conjugated Estrogens

C.06.002. **[S]. Conjugated estrogens** shall be the drug conjugated estrogens described in The Pharmacopeia of the United States of America, XVIII (1970), except that

(*a*) the dilute assay preparation A, assay preparations A and B and equilin reagent described therein shall be prepared by official method DO-29, Conjugated Estrogens, October 15, 1981; and

(*b*) the identification test described therein shall be performed by official method DO-29, Conjugated Estrogens, October 15, 1981.

SOR/82-429, s. 5.

## Conjugated Estrogens for Injection

C.06.003. **[S]. Conjugated estrogens for injection** shall be the drug conjugated estrogens for injection described in The Pharmacopeia of the United States of America, XVIII (1970), except that

(*a*) the dilute assay preparation A, assay preparations A and B and equilin reagent described therein shall be prepared by official method DO-29, Conjugated Estrogens, October 15, 1981; and

(*b*) the identification test described therein shall be performed by official method DO-29, Conjugated Estrogens, October 15, 1981.

SOR/82-429, s. 6.

## Conjugated Estrogens Tablets

C.06.004. **[S]. Conjugated estrogens tablets** shall be the drug conjugated estrogens tablets described in The Pharmacopeia of the United States of America, XVIII (1970), except that

(*a*) the dilute assay preparation A, assay preparations A and B and equilin reagent described therein shall be prepared by official method DO-29, Conjugated Estrogens, October 15, 1981; and

(*b*) the identification test described therein shall be performed by official method DO-29, Conjugated Estrogens, October 15, 1981.

SOR/82-429, s. 7.

C.06.100. and C.06.101. [Repealed, SOR/80-544, s. 12]

## Digitoxin

C.06.120. **[S]. Digitoxin** shall be the drug digitoxin described in the Pharmacopeia of the United States of America.

## Digitoxin Tablets

C.06.121. **[S]. Digitoxin tablets** shall be the drug digitoxin tablets described in the Pharmacopeia of the United States of America.

## Digoxin

C.06.130. **[S]. Digoxin** shall be the drug digoxin described in the Pharmacopeia of the United States of America.

## Digoxin Elixir

C.06.131. **[S]. Digoxin Elixir** shall be the drug digoxin elixir described in the Pharmacopeia of the United States of America.

## Digoxin Injection

C.06.132. **[S]. Digoxin injection** shall be the drug digoxin injection described in the Pharmacopeia of the United States of America.

## Digoxin Tablets

C.06.133. **[S]. Digoxin tablets** shall be the drug digoxin tablets described in the Pharmacopeia of the United States of America.

C.06.140. to C.06.142. [Repealed, SOR/80-544, s. 12]

C.06.150. to C.06.153. [Repealed, SOR/80-544, s. 12]

C.06.154. to C.06.156. [Repealed, SOR/80-544, s. 12]

C.06.157. to C.06.160. [Repealed, SOR/80-544, s. 12]

## Esterified Estrogens

C.06.161. **[S]. Esterified estrogens** shall be the drug esterified estrogens described in the Pharmacopeia of the United States of America.

## Esterified Estrogens Tablets

C.06.162. **[S]. Esterified estrogens tablets** shall be the drug esterified estrogens tablets described in the Pharmacopeia of the United States of America.

## Gelatin

C.06.170. Gelatin shall be the drug gelatin described in the Pharmacopeia of the United States or the British Pharmacopeia.

C.06.180. to C.06.183. [Repealed, SOR/80-544, s. 12]

C.06.230. to C.06.233. [Repealed, SOR/80-544, s. 12]

C.06.240. to C.06.242. [Repealed, SOR/80-544, s. 12]

## Thyroid

C.06.250. **Thyroid** shall be the cleaned, dried, powdered thyroid glands of domestic animals used for food, and shall contain not less than 0.17 per cent, and not more than 0.23 per cent iodine and no added iodine in either inorganic or organic form, and

(*a*) its characters are

*Description*, —

(i) *General*, — thyroid occurs as a cream-coloured, amorphous powder; the odour and taste are faint and meat-like, and

(ii) *Microscopical*, — when suitably mounted and examined under the microscope, thyroid shows the following: numerous smooth to striated hyaline fragments of colloids, of angular to irregular shape, that are colourless to pale yellow in water mounts, brown in *Mallory's stain* and pink in *solution of eosin*, some of these fragments containing granules, minute vacuoles, crystalloidal bodies and cells; numerous irregular fragments of follicular epithelium staining brown with *Mallory's stain*, the individual cells more or less polygonal to rounded-angular or irregularly cuboidal, often with prominent nuclei staining dark blue, their cytoplasm purplish with *Delafield's solution of haematoxylin*; slender glistening segments of capillaries of closely undulate outline; numerous slender segments of neuraxons; numerous aggregates of particles of intercellular substance and slender, mostly straight connective tissue fibres staining blue to greenish blue with a mixture of *Mallory's stain* and *solution of phosphotungstic acid*, the bundles of fibres often appearing reddish in *Mallory's stain*; few glistening fragments of blood vessels with serrated or crenated ends as viewed in water mounts; and

(*b*) the tests for its purity are

(i) *Inorganic iodine*, — add to one gram of thyroid 10 millilitres of a saturated solution of *zinc sulphate* in *water*, shake, allow to stand five minutes, and filter through a fritted glass filter; add to five millilitres of the filtrate 0.5 millilitre of *mucilage of starch* and four drops each of a 10 per cent w/v solution of *sodium nitrite* in *water and dilute sulphuric acid*, shaking after each addition: no blue colour is produced, and

(ii) *Moisture*, — thyroid loses not more than six per cent moisture.

C.06.251. Thyroid shall be

(*a*) assayed by official method DO-26, Thyroid, October 15, 1981; and

(*b*) stored in a cool place and in a tightly-closed container.

SOR/82-429, s. 8.

C.06.252. [Repealed, SOR/80-544, s. 12]

C.06.260. to C.06.264. [Repealed, SOR/80-544, s. 12]

C.06.270. to C.06.280. [Repealed, SOR/80-544, s. 12]

# Division 7

# Sale of Drugs for the Purposes of Implementing the General Council Decision

## Interpretation

C.07.001. The definitions in this section apply in this Division.

“Commissioner of Patents” means the Commissioner of Patents appointed under subsection 4(1) of the Patent Act. (commissaire aux brevets)

“General Council Decision” has the meaning assigned by subsection 30(6) of the Act. (décision du Conseil général)

SOR/2005-141, s. 1.

## Application

C.07.002. This Division applies to the sale of drugs for the purposes of implementing the General Council Decision.

SOR/2005-141, s. 1.

## Application for Authorization

C.07.003. An application by a manufacturer for authorization to sell a drug under this Division shall be submitted to the Minister and shall contain the following information and documents:

(*a*) a statement that the manufacturer intends to file an application with the Commissioner of Patents under section 21.04 of the Patent Act;

(*b*) in respect of a new drug, the submission number and date of filing of the new drug submission or abbreviated new drug submission filed under section C.08.002 or C.08.002.1, respectively, and of any supplement filed under section C.08.003 in respect of the drug;

(*c*) in respect of a drug that is not a new drug,

(i) the application number and date of filing of the application that has been filed under section C.01.014.1 in respect of the drug, or

(ii) the drug identification number, if one has been assigned in respect of the drug pursuant to section C.01.014.2;

(*d*) for a drug in a solid dosage form, the manner in which the drug is marked in accordance with paragraph C.07.008(*a*) and evidence that such manner does not alter the safety and efficacy of the drug;

(*e*) for a drug in a dosage form that is not solid, the manner in which the immediate container is marked in accordance with paragraph C.07.008(*a*); and

(*f*) a sample of the label for the drug that includes the information required by paragraph C.07.008(*c*).

SOR/2005-141, s. 1.

## Authorization

C.07.004. The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.04(3)(*b*) of the Patent Act that the manufacturer's drug meets the requirements of the Act and these Regulations if

(*a*) the manufacturer has submitted to the Minister an application in accordance with section C.07.003 and a copy of the application filed by the manufacturer with the Commissioner of Patents under section 21.04 of the Patent Act;

(*b*) in respect of a new drug, an examination of the new drug submission or abbreviated new drug submission or supplement to either submission by the Minister demonstrates that the submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1;

(*c*) in respect of a drug that is not a new drug, a drug identification number has been assigned pursuant to section C.01.014.2; and

(*d*) the Minister is satisfied that the manufacturer and the drug comply with the Act and these Regulations.

SOR/2005-141, s. 1.

C.07.005. Despite sections C.01.014, C.08.002 and C.08.003, a manufacturer may sell a drug under this Division if

(*a*) the Minister has notified the Commissioner of Patents for the purposes of paragraph 21.04(3)(*b*) of the Patent Act that the drug meets the requirements of the Act and these Regulations; and

(*b*) the manufacturer has received authorization under section 21.04 of the Patent Act.

SOR/2005-141, s. 1.

C.07.006. Sections C.01.005 and C.01.014.1 to C.01.014.4 do not apply to new drugs sold under this Division.

SOR/2005-141, s. 1.

## Notice to Commissioner of Patents

C.07.007. The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.13(*b*) of the Patent Act in the event that the Minister is of the opinion that the manufacturer's drug authorized to be sold under this Division has ceased to meet the requirements of the Act and these Regulations.

SOR/2005-141, s. 1.

## Marking and Labelling

C.07.008. No person shall sell a drug under this Division unless

(*a*) the drug itself permanently bears the mark "XCL", in the case of a drug in a solid dosage form, or the immediate container permanently bears the mark "XCL", in the case of a drug in a dosage form that is not solid;

(*b*) the colour of the drug itself is significantly different from the colour of the version of the drug sold in Canada, in the case of a drug in a solid dosage form; and

(*c*) the label of the drug permanently bears the mark "XCL", followed by the export tracking number assigned by the Minister under section C.07.009 and the words "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA." or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA."

SOR/2005-141, s. 1.

C.07.009. The Minister shall assign an export tracking number to each drug in respect of which the Minister has notified the Commissioner of Patents under section C.07.004.

SOR/2005-141, s. 1.

## Records

C.07.010. The manufacturer shall, with respect to a drug authorized to be sold under this Division,

(*a*) establish and maintain records, in a manner that enables an audit to be made, respecting the information described in section C.08.007; and

(*b*) provide to the Minister the reports referred to in section C.08.008.

SOR/2005-141, s. 1.

## Notice to Minister

C.07.011. The manufacturer shall notify the Minister in writing not less than 15 days before commencing the manufacture of the first lot of a drug authorized to be sold under this Division and not less than 15 days before the exportation of each subsequent lot of the drug.

SOR/2005-141, s. 1.

# Division 8

## New Drugs

C.08.001. For the purposes of the Act and this Division, “new drug” means

(*a*) a drug that contains or consists of a substance, whether as an active or inactive ingredient, carrier, coating, excipient, menstruum or other component, that has not been sold as a drug in Canada for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that substance for use as a drug;

(*b*) a drug that is a combination of two or more drugs, with or without other ingredients, and that has not been sold in that combination or in the proportion in which those drugs are combined in that drug, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that combination and proportion for use as a drug; or

(*c*) a drug, with respect to which the manufacturer prescribes, recommends, proposes or claims a use as a drug, or a condition of use as a drug, including dosage, route of administration, or duration of action and that has not been sold for that use or condition of use in Canada, for sufficient time and in sufficient quantity to establish in Canada the safety and effectiveness of that use or condition of use of that drug.

SOR/95-172, s. 2.

C.08.001.1. For the purposes of this Division,

“Canadian reference product” means

(*a*) a drug in respect of which a notice of compliance is issued under section C.08.004 or C.08.004.01 and which is marketed in Canada by the innovator of the drug,

(*b*) a drug, acceptable to the Minister, that can be used for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics, where a drug in respect of which a notice of compliance has been issued under section C.08.004 or C.08.004.01 cannot be used for that purpose because it is no longer marketed in Canada, or

(*c*) a drug, acceptable to the Minister, that can be used for the purpose of demonstrating bioequivalence on the basis of pharmaceutical and, where applicable, bioavailability characteristics, in comparison to a drug referred to in paragraph (*a*); (produit de référence canadien)

“pharmaceutical equivalent” means a new drug that, in comparison with another drug, contains identical amounts of the identical medicinal ingredients, in comparable dosage forms, but that does not necessarily contain the same non-medicinal ingredients; (équivalent pharmaceutique)

“specifications” means a detailed description of a new drug and of its ingredients and includes

(*a*) a statement of all properties and qualities of the ingredients that are relevant to the manufacture and use of the new drug, including the identity, potency and purity of the ingredients,

(*b*) a detailed description of the methods used for testing and examining the ingredients, and

(*c*) a statement of the tolerances associated with the properties and qualities of the ingredients. (spécifications)

SOR/95-411, s. 3; SOR/2011-88, s. 9.

Previous Version

C.08.002. (1) No person shall sell or advertise a new drug unless

(*a*) the manufacturer of the new drug has filed with the Minister a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission or an abbreviated extraordinary use new drug submission relating to the new drug that is satisfactory to the Minister;

(*b*) the Minister has issued, under section C.08.004 or C.08.004.01, a notice of compliance to the manufacturer of the new drug in respect of the submission;

(*c*) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006; and

(*d*) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a statement setting out the proposed date on which those labels will first be used.

(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(*a*) a description of the new drug and a statement of its proper name or its common name if there is no proper name;

(*b*) a statement of the brand name of the new drug or the identifying name or code proposed for the new drug;

(*c*) a list of the ingredients of the new drug, stated quantitatively, and the specifications for each of those ingredients;

(*d*) a description of the plant and equipment to be used in the manufacture, preparation and packaging of the new drug;

(*e*) details of the method of manufacture and the controls to be used in the manufacture, preparation and packaging of the new drug;

(*f*) details of the tests to be applied to control the potency, purity, stability and safety of the new drug;

(*g*) detailed reports of the tests made to establish the safety of the new drug for the purpose and under the conditions of use recommended;

(*h*) substantial evidence of the clinical effectiveness of the new drug for the purpose and under the conditions of use recommended;

(*i*) a statement of the names and qualifications of all the investigators to whom the new drug has been sold;

(*j*) a draft of every label to be used in conjunction with the new drug;

(*k*) a statement of all the representations to be made for the promotion of the new drug respecting

(i) the recommended route of administration of the new drug,

(ii) the proposed dosage of the new drug,

(iii) the claims to be made for the new drug, and

(iv) the contra-indications and side effects of the new drug;

(*l*) a description of the dosage form in which it is proposed that the new drug be sold;

(*m*) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and

(*n*) for a drug intended for administration to food-producing animals, the withdrawal period of the new drug.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of a new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(*a*) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;

(*b*) samples of the ingredients of the new drug;

(*c*) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and

(*d*) any additional information or material respecting the safety and effectiveness of the new drug.

SOR/85-143, s. 1; SOR/93-202, s. 24; SOR/95-411, s. 4; SOR/2011-88, s. 10.

Previous Version

C.08.002.01 (1) A manufacturer of a new drug may file an extraordinary use new drug submission for the new drug if

(*a*) the new drug is intended for

(i) emergency use in situations where persons have been exposed to a chemical, biological, radiological or nuclear substance and action is required to treat, mitigate or prevent a life-threatening or other serious disease, disorder or abnormal physical state, or its symptoms, that results, or is likely to result, from that exposure, or

(ii) preventative use in persons who are at risk of exposure to a chemical, biological, radiological or nuclear substance that is potentially lethal or permanently disabling; and

(*b*) the requirements set out in paragraphs C.08.002(2)(*g*) and (*h*) cannot be met because

(i) exposing human volunteers to the substance referred to in paragraph (*a*) would be potentially lethal or permanently disabling, and

(ii) the circumstances in which exposure to the substance occurs are sporadic and infrequent.

(2) Subject to subsections (3) and (5), an extraordinary use new drug submission shall contain

(*a*) an attestation, signed and dated by the senior executive officer in Canada of the manufacturer filing the submission and by the manufacturer's senior medical or scientific officer, certifying that the conditions referred to in paragraphs (1)(*a*) and (*b*) are met, together with sufficient supporting information to enable the Minister to determine that those conditions are met; and

(*b*) sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(i) the information and material described in paragraphs C.08.002(2)(*a*) to (*f*) and (*i*) to (*m*),

(ii) information respecting the pathophysiological mechanism for the toxicity of the chemical, biological, radiological or nuclear substance and describing the new drug's ability to treat, mitigate or prevent that mechanism,

(iii) detailed reports of in vitro studies respecting the toxicity and activity of the new drug in relation to the recommended purpose,

(iv) detailed reports of studies, in an animal species that is expected to react with a response that is predictive for humans, establishing the safety of the new drug, and providing substantial evidence of its effect, when used for the purpose and under the conditions of use recommended,

(v) information confirming that the end point of animal studies is clearly related to the desired benefit in humans,

(vi) information demonstrating that there is a sufficient understanding of the pharmacokinetics and pharmacodynamics of the new drug in animals and in humans to enable inferences to be drawn in respect of humans so as to allow for the selection of an effective dose in humans,

(vii) information respecting the safety of the new drug in humans, including detailed reports of clinical trials, if any, establishing the safety of the new drug,

(viii) information, if any, respecting the effectiveness of the new drug in humans for the purpose or under the conditions of use recommended,

(ix) a plan for monitoring and establishing the safety and effectiveness of the new drug under the conditions of use recommended that includes procedures for gathering and analyzing data, and

(x) any available assessment reports regarding the new drug prepared by regulatory authorities in countries other than Canada.

(3) Reports referred to in subparagraph (2)(*b*)(iii) or information referred to in subparagraph (2)(*b*)(vi) may be omitted if the extraordinary use new drug submission includes a detailed scientific explanation as to why the reports are or the information is not available.

(4) Any information or material that is necessary to enable the Minister to assess the safety and effectiveness of the new drug shall, at the request of the Minister, be added to the extraordinary use new drug submission, including

(*a*) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed to be sold;

(*b*) samples of the ingredients of the new drug;

(*c*) samples of the new drug in the dosage form in which it is proposed to be sold; and

(*d*) any information omitted by virtue of subsection (3).

(5) If an extraordinary use new drug submission is in respect of a new purpose for a new drug for which a notice of compliance has been issued under section C.08.004, the information and material referred to in subparagraph (2)(*b*)(i) may be omitted unless any of it is different from that which was originally submitted.

SOR/2011-88, s. 11.

C.08.002.02 Despite sections C.08.002 and C.08.003, no manufacturer or importer shall sell a new drug for extraordinary use in respect of which a notice of compliance has been issued under section C.08.004.01 except to

(*a*) the Government of Canada or the government of a province for the use of a department or agency of that government, on receipt of a written order signed by the minister responsible for the department or by the person in charge of the agency, or by their duly authorized representative; or

(*b*) a municipal government, or an institution of such a government, on receipt of a written order signed by a senior official of the government or institution or by his or her duly authorized representative.

SOR/2011-88, s. 11.

C.08.002.1. (1) A manufacturer of a new drug may file an abbreviated new drug submission or an abbreviated extraordinary use new drug submission for the new drug where, in comparison with a Canadian reference product,

(*a*) the new drug is the pharmaceutical equivalent of the Canadian reference product;

(*b*) the new drug is bioequivalent with the Canadian reference product, based on the pharmaceutical and, where the Minister considers it necessary, bioavailability characteristics;

(*c*) the route of administration of the new drug is the same as that of the Canadian reference product; and

(*d*) the conditions of use for the new drug fall within the conditions of use for the Canadian reference product.

(2) An abbreviated new drug submission or an abbreviated extraordinary use new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

(*a*) the information and material described in

(i) paragraphs C.08.002(2)(*a*) to (*f*) and (*j*) to (*l*), in the case of an abbreviated new drug submission, and

(ii) paragraphs C.08.002(2)(*a*) to (*f*) and (*j*) to (*l*) and subparagraphs C.08.002.01(2)(*b*)(ix) and (x), in the case of an abbreviated extraordinary use new drug submission;

(*b*) information identifying the Canadian reference product used in any comparative studies conducted in connection with the submission;

(*c*) evidence from the comparative studies conducted in connection with the submission that the new drug is

(i) the pharmaceutical equivalent of the Canadian reference product, and

(ii) where the Minister considers it necessary on the basis of the pharmaceutical and, where applicable, bioavailability characteristics of the new drug, bioequivalent with the Canadian reference product as demonstrated using bioavailability studies, pharmacodynamic studies or clinical studies;

(*d*) evidence that all test batches of the new drug used in any studies conducted in connection with the submission were manufactured and controlled in a manner that is representative of market production; and

(*e*) for a drug intended for administration to food-producing animals, sufficient information to confirm that the withdrawal period is identical to that of the Canadian reference product.

(3) The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of an abbreviated new drug submission or an abbreviated extraordinary use new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material:

(*a*) the names and addresses of the manufacturers of each of the ingredients of the new drug and the names and addresses of the manufacturers of the new drug in the dosage form in which it is proposed that the new drug be sold;

(*b*) samples of the ingredients of the new drug;

(*c*) samples of the new drug in the dosage form in which it is proposed that the new drug be sold; and

(*d*) any additional information or material respecting the safety and effectiveness of the new drug.

(4) For the purposes of this section, in the case of an abbreviated new drug submission, a new drug for extraordinary use in respect of which a notice of compliance has been issued under section C.08.004.01 is not a Canadian reference product.

SOR/95-411, s. 5; SOR/2011-88, s. 12.

Previous Version

C.08.003. (1) Despite section C.08.002, no person shall sell a new drug in respect of which a notice of compliance has been issued to the manufacturer of that new drug and has not been suspended under section C.08.006, if any of the matters specified in subsection (2) are

significantly different from the information or material contained in the new drug submission, extraordinary use new drug submission, abbreviated new drug submission or abbreviated extraordinary use new drug submission, unless

(*a*) the manufacturer of the new drug has filed with the Minister a supplement to that submission;

(*b*) the Minister has issued a notice of compliance to the manufacturer of the new drug in respect of the supplement;

(*c*) the notice of compliance in respect of the supplement has not been suspended pursuant to section C.08.006; and

(*d*) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any label, including any package insert, product brochure and file card, intended for use in connection with the new drug, where a change with respect to any of the matters specified in subsection (2) is made that would require a change to the label.

(2) The matters specified for the purposes of subsection (1), in relation to the new drug, are the following:

(*a*) the description of the new drug;

(*b*) the brand name of the new drug or the identifying name or code proposed for the new drug;

(*c*) the specifications of the ingredients of the new drug;

(*d*) the plant and equipment used in manufacturing, preparation and packaging the new drug;

(*e*) the method of manufacture and the controls used in manufacturing, preparation and packaging the new drug;

(*f*) the tests applied to control the potency, purity, stability and safety of the new drug;

(*g*) the labels used in connection with the new drug;

(*h*) the representations made with regard to the new drug respecting

(i) the recommended route of administration of the new drug,

(ii) the dosage of the new drug,

(iii) the claims made for the new drug,

(iv) the contra-indications and side effects of the new drug, and

(v) the withdrawal period of the new drug; and

(*i*) the dosage form in which it is proposed that the new drug be sold.

(3) A supplement to a submission referred to in subsection (1), with respect to the matters that are significantly different from those contained in the submission, shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug in relation to those matters.

(4) If a supplement to an extraordinary use new drug submission or an abbreviated extraordinary use new drug submission concerns a matter specified in subparagraph (2)(*h*)(iii), the supplement shall contain the attestation and supporting information referred to in paragraph C.08.002.01(2)(*a*).

SOR/85-143, s. 2; SOR/93-202, s. 25; SOR/95-411, s. 6; SOR/2011-88, s. 13.

Previous Version

C.08.003.1 In examining a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission or a supplement to any of those submissions, the Minister may examine any information or material filed with the Minister by any person pursuant to Division 5 or section C.08.002, C.08.002.01, C.08.002.1, C.08.003, C.08.005 or C.08.005.1 to establish the safety and effectiveness of the new drug for which the submission or supplement has been filed.

SOR/95-411, s. 6; SOR/2001-203, s. 5; SOR/2011-88, s. 14.

Previous Version

C.08.004. (1) Subject to section C.08.004.1, the Minister shall, after completing an examination of a new drug submission or abbreviated new drug submission or a supplement to either submission,

(*a*) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or

(*b*) if that submission or supplement does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

(2) Where a new drug submission or abbreviated new drug submission or a supplement to either submission does not comply with section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, the manufacturer who filed the submission or supplement may amend the submission or supplement by filing additional information or material.

(3) Subject to section C.08.004.1, the Minister shall, after completing an examination of any additional information or material filed in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission,

(*a*) if that submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or

(*b*) if that submission or supplement does not comply with the requirements of section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

(4) A notice of compliance issued in respect of a new drug on the basis of information and material contained in a submission filed pursuant to section C.08.002.1 shall state the name of the Canadian reference product referred to in the submission and shall constitute a declaration of equivalence for that new drug.

SOR/84-267, ss. 1 to 3; SOR/85-143, s. 3; SOR/86-1009, s. 1; SOR/86-1101, s. 1; SOR/88-42, s. 1; SOR/88-257, s. 1; SOR/95-411, s. 6.

C.08.004.01 (1) Subject to section C.08.004.1, the Minister shall, after completing an examination of an extraordinary use new drug submission or an abbreviated extraordinary use new drug submission or a supplement to either submission,

(*a*) if that submission or supplement complies with section C.08.002.01, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or

(*b*) if that submission or supplement does not comply with section C.08.002.01, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

(2) Where an extraordinary use new drug submission or an abbreviated extraordinary use new drug submission or a supplement to either submission does not comply with section C.08.002.01, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, the manufacturer who filed the submission or supplement may amend the submission or supplement by filing additional information or material.

(3) Subject to section C.08.004.1, the Minister shall, after completing an examination of any additional information or material filed in respect of an extraordinary use new drug submission or an abbreviated extraordinary use new drug submission or a supplement to either submission,

(*a*) if that submission or supplement complies with section C.08.002.01, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1, issue a notice of compliance; or

(*b*) if that submission or supplement does not comply with section C.08.002.01, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1, notify the manufacturer that the submission or supplement does not so comply.

(4) A notice of compliance issued in respect of a new drug for extraordinary use on the basis of information and material contained in a submission filed pursuant to section C.08.002.1 shall state the name of the Canadian reference product referred to in the submission and shall constitute a declaration of equivalence for that new drug.

SOR/2011-88, s. 15.

C.08.004.1 (1) The following definitions apply in this section.

“abbreviated new drug submission” includes an abbreviated extraordinary use new drug submission. (présentation abrégée de drogue nouvelle)

“innovative drug” means a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. (drogue innovante)

“new drug submission” includes an extraordinary use new drug submission. (présentation de drogue nouvelle)

“pediatric populations” means the following groups: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age. (population pédiatrique)

(2) This section applies to the implementation of Article 1711 of the North American Free Trade Agreement, as defined in the definition "Agreement" in subsection 2(1) of the North American Free Trade Agreement Implementation Act, and of paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the World Trade Organization Agreement, as defined in the definition "Agreement" in subsection 2(1) of the World Trade Organization Agreement Implementation Act.

(3) If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug,

(*a*) the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and

(*b*) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.

(4) The period specified in paragraph (3)(*b*) is lengthened to eight years and six months if

(*a*) the innovator provides the Minister with the description and results of clinical trials relating to the use of the innovative drug in relevant pediatric populations in its first new drug submission for the innovative drug or in any supplement to that submission that is filed within five years after the issuance of the first notice of compliance for that innovative drug; and

(*b*) before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug, the Minister determines that the clinical trials were designed and conducted for the purpose of increasing knowledge of the use of the innovative drug in those pediatric populations and this knowledge would there-by provide a health benefit to members of those populations.

(5) Subsection (3) does not apply if the innovative drug is not being marketed in Canada.

(6) Paragraph (3)(*a*) does not apply to a subsequent manufacturer if the innovator consents to the filing of a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission by the subsequent manufacturer before the end of the period of six years specified in that paragraph.

(7) Paragraph (3)(*a*) does not apply to a subsequent manufacturer if the manufacturer files an application for authorization to sell its new drug under section C.07.003.

(8) Paragraph (3)(*b*) does not apply to a subsequent manufacturer if the innovator consents to the issuance of a notice of compliance to the subsequent manufacturer before the end of the period of eight years specified in that paragraph or of eight years and six months specified in subsection (4).

(9) The Minister shall maintain a register of innovative drugs that includes information relating to the matters specified in subsections (3) and (4).

SOR/95-411, s. 6; SOR/2006-241, s. 1; SOR/2011-88, s. 16.

Previous Version

C.08.005. (1) Subject to subsection (1.1) and notwithstanding sections C.08.002 and C.08.003, a manufacturer of a new drug may sell it to a qualified investigator to be used solely for the purpose of clinical testing to obtain evidence with respect to the safety, dosage and effectiveness of that new drug, when the following conditions are met:

(*a*) before the sale, the manufacturer has filed with the Minister, in compliance with section C.08.005.1, a preclinical submission containing information and material respecting

(i) the brand name of the new drug or the identifying name or code proposed for the new drug,

(ii) the chemical structure or other specific identification of the composition of the new drug,

(iii) the source of the new drug,

(iv) a detailed protocol of the clinical testing,

(v) the results of investigations made to support the clinical use of the new drug,

(vi) the contra-indications and precautions known in respect of the new drug and the suggested treatment of overdosage of the new drug,

(vii) all ingredients of the new drug, stated quantitatively,

(viii) the methods, equipment, plant and controls used in the manufacture, processing and packaging of the new drug,

(ix) the tests applied to control the potency, purity and safety of the new drug, and

(x) the names and qualifications of all investigators to whom the drug is to be sold and the names of all institutions in which the clinical testing is to be carried out;

(*b*) the Director has not, within 60 days after the date of receipt of the preclinical submission, sent by registered mail to the manufacturer a notice in respect of that new drug indicating that the preclinical submission is not satisfactory;

(*c*) all inner labels and outer labels used in conjunction with the sale of the new drug to qualified investigators carry the statements

(i) “Investigational Drug” or “Drogue de recherche”, and

(ii) “To Be Used By Qualified Investigators Only” or “Réservée uniquement à l’usage de chercheurs compétents”;

(*d*) before the sale, the manufacturer ascertains that every qualified investigator to whom the new drug is to be sold

(i) has the facilities for the clinical testing to be conducted by the investigator, and

(ii) has received the information and material referred to in subparagraphs (*a*)(i) to (vi); and

(*e*) every qualified investigator to whom the new drug is to be sold has agreed in writing with the manufacturer that the investigator will

(i) not use the new drug or permit it to be used other than for clinical testing,

(ii) not permit the new drug to be used by any person other than the investigator except under the investigator's direction,

(iii) report immediately to that manufacturer and, if so required by the Director, report to the Director all serious adverse reactions encountered during the clinical testing, and

(iv) account to the manufacturer for all quantities of the new drug received, where so requested by the manufacturer.

(1.1) This section applies only in respect of a new drug for veterinary use.

(2) Notwithstanding subsection (1), no manufacturer shall sell a new drug to a qualified investigator unless that manufacturer has, in respect of all previous sales of that new drug to any qualified investigator,

(*a*) kept accurate records of the distribution of that new drug and of the results of the clinical testing and has made those records available to the Director for inspection on the request of the Director; and

(*b*) immediately reported to the Director all information he has obtained with respect to serious adverse reactions.

(3) The Minister may notify the manufacturer of a new drug that sales of that new drug to qualified investigators are prohibited if, in the opinion of the Minister, it is in the interest of public health to do so.

(4) Notwithstanding subsection (1), no manufacturer shall sell a new drug to a qualified investigator if the Minister has notified the manufacturer of that drug that such sales are prohibited.

(5) Paragraph (1)(*c*) does not apply to a radiopharmaceutical as defined in section C.03.201 or to a component or kit as defined in section C.03.205.

SOR/79-236, s. 5; SOR/85-143, s. 4; SOR/87-511, s. 1; SOR/93-202, s. 26; SOR/95-411, s. 7; SOR/2001-203, s. 6.

C.08.005.1. (1) Every manufacturer who files a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission, a supplement to any of those submissions or a submission for the clinical testing of a new drug for veterinary use shall, in addition to any information and material that is required under section C.08.002, C.08.002.01, C.08.002.1, C.08.003 or C.08.005, include in the submission or supplement

(*a*) a copy of all clinical case reports respecting any subject of a study included in the submission or supplement if that subject has died, suffered a serious adverse reaction or an unexpected adverse reaction, or the study, insofar as it relates to this subject, has not been completed;

(*b*) a sectional report in respect of each human, animal and *in vitro* study included in the submission or supplement;

(*c*) a comprehensive summary of each human, animal and *in vitro* study referred to or included in the submission or supplement; and

(*d*) a submission certificate in respect of all information and material contained in the submission or supplement and any additional information or material filed to amend the submission or supplement.

(2) A sectional report referred to in paragraph (1)(*b*) shall include

(*a*) a summary of each study included in the submission or supplement;

(*b*) a summary of any additional information or material filed to amend the submission or supplement; and

(*c*) where raw data is available to the manufacturer in respect of a study,

(i) a summary of the data,

(ii) a cross-referencing of the data to the relevant portions of the sectional report,

(iii) a description of the conditions under which the experiments from which the data were obtained were conducted,

(iv) the details of the data treatment process, and

(v) the results and conclusions of the study.

(3) The comprehensive summary referred to in paragraph (1)(*c*) shall include a summary of the methods used, results obtained and conclusions arrived at in respect of all studies referred to or included in the submission or supplement and shall be cross-referenced to the relevant portions of the sectional reports.

(4) The submission certificate referred to in paragraph (1)(*d*) shall

(*a*) certify that all information and material included in the submission or supplement and any additional information or material filed to amend the submission or supplement are accurate and complete, and that the sectional reports and the comprehensive summary correctly represent the information and material referred to or included in the submission or supplement; and

(*b*) be signed and dated by

(i) the senior executive officer in Canada of the manufacturer filing the submission or supplement, and

(ii) the senior medical or scientific officer of the manufacturer.

(5) No person shall sign a submission certificate if a sectional report, comprehensive summary or any information or material included in the submission or supplement, or any additional information and material filed to amend the submission or supplement,

(*a*) is false or misleading; or

(*b*) contains omissions that may affect its accuracy and completeness.

(6) Every manufacturer who has filed a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission, a supplement to any of those submissions or a submission for the clinical testing

of a new drug for veterinary use and who has any relating clinical case reports or raw data that were not included in the submission or supplement shall keep those reports or data and shall, within 30 days after receiving a written request from the Minister, submit them to the Minister.

SOR/85-143, s. 5; SOR/92-543, s. 1; SOR/94-689, s. 2(F); SOR/95-411, s. 8; SOR/2001-203, s. 7; SOR/2011-88, s. 17.

Previous Version

C.08.006. (1) For the purposes of this section, evidence or new information obtained by the Minister includes any information or material filed by any person pursuant to Division 5 or section C.08.002, C.08.002.01, C.08.002.1, C.08.003, C.08.005 or C.08.005.1.

(2) The Minister may, by notice to a manufacturer, suspend, for a definite or indefinite period, a notice of compliance issued to that manufacturer in respect of a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission or a supplement to any of those submissions if the Minister considers

(*a*) that the drug is not safe for the use represented in the submission or supplement, as shown by evidence obtained from

(i) clinical or other experience not reported in the submission or supplement or not available to the Minister at the time the notice of compliance was issued, or

(ii) tests by new methods or tests by methods not reasonably applicable at the time the notice of compliance was issued;

(*b*) that, upon the basis of new information obtained after the issuance of the notice of compliance, there is lack of substantial evidence that the drug will have the effect it is represented to have under the conditions of use prescribed, recommended or proposed by the manufacturer;

(*c*) that the submission or supplement contained an untrue statement of material fact;

(*d*) that the manufacturer has failed to establish a system for maintaining required records or has repeatedly or deliberately failed to maintain such records;

(*e*) that, on the basis of new information obtained after the issuance of the notice of compliance, the methods, equipment, plant and controls used in the manufacturing, processing and packaging of the drug are inadequate to assure and preserve the identity, strength, quality or purity of the new drug;

(*f*) that, on the basis of new information obtained after the issuance of the notice of compliance, the labelling of the drug is false or misleading or incomplete in any particular and that this defect was not corrected by the manufacturer upon receipt of a written notice from the Director specifying the respect in which the labelling is false or misleading or incomplete; or

(*g*) that, in the case of a new drug for extraordinary use, the manufacturer has not adhered to the plan referred to in subparagraph C.08.002.01(2)(*b*)(ix).

SOR/95-411, s. 9; SOR/2001-203, s. 8; SOR/2011-88, s. 18.

Previous Version

C.08.007. (1) Where a manufacturer has received a notice of compliance issued in respect of a new drug submission, an extraordinary use new drug submission, an abbreviated new drug submission, an abbreviated extraordinary use new drug submission or a supplement to any of those submissions, the manufacturer shall establish and maintain records, in a manner that enables an audit to be made, respecting

(*a*) animal or clinical experience, studies, investigations and tests conducted by the manufacturer or reported to him by any person concerning that new drug;

(*b*) reports from the scientific literature or the bibliography therefrom that are available to him concerning that new drug;

(*c*) experience, investigations, studies and tests involving the chemical or physical properties or any other properties of that new drug;

(*d*) any substitution of another substance for that new drug or any mixing of another substance with that new drug;

(*e*) any error in the labelling of that new drug or in the use of the labels designed for that new drug;

(*f*) any bacteriological or any significant chemical or physical or other change or deterioration in any lot of that new drug;

(*g*) any failure of one or more distributed lots of the new drug to meet the specifications established for that new drug in the submission or supplement; and

(*h*) any unusual failure in efficacy of that new drug.

(*i*) [Repealed, SOR/95-521, s. 3]

(2) A manufacturer or importer who sells a new drug for extraordinary use in accordance with section C.08.002.02 shall retain the written order for at least 15 years from the day on which the order was filled.

SOR/95-411, s. 10; SOR/95-521, s. 3; SOR/2011-88, s. 19.

Previous Version

C.08.008. No manufacturer shall sell a new drug unless the manufacturer has, with respect to all the manufacturer’s previous sales of that new drug, furnished to the Minister

(*a*) on request, reports of all records respecting the information described in paragraphs C.08.007(*a*) to (*c*);

(*b*) immediately on receipt by the manufacturer, reports of all records respecting the information described in paragraphs C.08.007(*d*) to (*f*); and

(*c*) within 15 days after the receipt by the manufacturer of information referred to in paragraphs C.08.007(*g*) and (*h*), a report on the information received.

SOR/95-411, s. 11; SOR/95-521, s. 4.

C.08.008.1 Where a manufacturer has received a notice of compliance issued in respect of an extraordinary use new drug submission, an abbreviated extraordinary use new drug submission or a supplement to either of those submissions, the manufacturer

(*a*) shall adhere to the plan referred to in subparagraph C.08.002.01(2)(*b*)(ix); and

(*b*) shall, before the first day of October in each year and whenever requested to do so by the Minister for the purposes of assessing the safety and effectiveness of the drug to which the notice of compliance relates, provide a report on the use of the drug, including a critical analysis of any available updated information respecting the drug's safety and effectiveness.

SOR/2011-88, s. 20.

C.08.009. (1) Where the Minister has decided

(*a*) to notify the manufacturer of a new drug for veterinary use that the sale of that drug to qualified investigators is prohibited, or

(*b*) to suspend a notice of compliance issued under section C.08.004 or C.08.004.01,

the manufacturer, if dissatisfied with that decision, may require the Minister to provide him with the reasons for the decision.

(2) Where the manufacturer has received the reasons for a decision of the Minister pursuant to subsection (1), he may require the Minister to refer that decision to a New Drug Committee and thereupon shall provide the Minister with a statement of the reasons for his dissatisfaction and any information and material upon which he relies in support of those reasons.

(3) Where the Minister has been required to refer a decision to a New Drug Committee pursuant to subsection (2), he shall appoint a member of the New Drug Committee, the dissatisfied manufacturer shall appoint a member of the New Drug Committee and the two members so appointed shall appoint a third member of the New Drug Committee who shall be chairman, or, if they are unable to do so within a reasonable time, the Minister shall appoint a third member of the New Drug Committee who shall be chairman.

(4) Any person who is in the full-time employment of the Department or in the full-time employment of the dissatisfied manufacturer shall not be appointed a member of a New Drug Committee.

(4.1) A member of a New Drug Committee shall, on appointment, sign an undertaking not to disclose or use any information, material, data, evidence or representations considered pursuant to subsection (6).

(5) The Minister shall pay the reasonable fees and costs incurred by the member of the New Drug Committee appointed by the Minister, and the dissatisfied manufacturer shall pay the reasonable fees and costs incurred by the member appointed by the dissatisfied manufacturer, and the Minister and the dissatisfied manufacturer shall each pay half of the reasonable fees and costs incurred by the chairman.

(6) The New Drug Committee formed pursuant to subsection (3) shall consider the reasons for the decision of the Minister, the reasons for the dissatisfaction of the dissatisfied manufacturer and any information or material in support of the reasons of the Minister or the dissatisfied manufacturer and may consider other evidence, material, information or representations.

(7) The New Drug Committee formed pursuant to subsection (3) shall report its findings and recommendations to the Minister.

(7.1) No member of a New Drug Committee shall disclose or use any information, material, data, evidence or representations considered pursuant to subsection (6).

(8) Where the Minister has received the findings and recommendations of a New Drug Committee, he may reconsider the decision to which those findings and recommendations relate.

SOR/95-411, s. 12; SOR/2001-203, s. 9; SOR/2011-88, s. 21.

Previous Version

## Sale of New Drug for Emergency Treatment

C.08.010. (1) The Director may issue a letter of authorization authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the emergency treatment of a patient under the care of that practitioner, if

(*a*) the practitioner has supplied to the Director information concerning

(i) the medical emergency for which the drug is required,

(ii) the data in the possession of the practitioner with respect to the use, safety and efficacy of that drug,

(iii) the names of all institutions in which the drug is to be used, and

(iv) such other data as the Director may require; and

(*b*) the practitioner has agreed to

(i) report to the manufacturer of the new drug and to the Director on the results of the use of the drug in the medical emergency, including information respecting any adverse reactions encountered, and

(ii) account to the Director on request for all quantities of the drug received by him.

(2) The Director shall, in any letter of authorization issued pursuant to subsection (1), state

(*a*) the name of the practitioner to whom the new drug may be sold;

(*b*) the medical emergency in respect of which the new drug may be sold; and

(*c*) the quantity of the new drug that may be sold to that practitioner for that emergency.

C.08.011. (1) Notwithstanding section C.08.002, a manufacturer may sell to a practitioner named in a letter of authorization issued pursuant to section C.08.010, a quantity of the new drug named in that letter that does not exceed the quantity specified in the letter.

(2) A sale of a new drug made in accordance with subsection (1) is exempt from the provisions of the Act and these Regulations.

## Sale of Medicated Feeds

C.08.012. (1) Notwithstanding anything in this Division, a person may sell, pursuant to a written prescription of a veterinary practitioner, a medicated feed if

(*a*) as regards the drug or drugs used as the medicating ingredient of the medicated feed,

(i) the Director has assigned a drug identification number pursuant to section C.01.014.2, or

(ii) the sale is permitted by section C.08.005, C.08.011 or C.08.013;

(*b*) the medicated feed is for the treatment of animals under the direct care of the veterinary practitioner who signed the prescription;

(*c*) the medicated feed is for therapeutic purposes only; and

(*d*) the written prescription contains the following information:

(i) the name and address of the person named on the prescription as the person for whom the medicated feed is to be mixed,

(ii) the species, production type and age or weight of the animals to be treated with the medicated feed,

(iii) the type and amount of medicated feed to be mixed,

(iv) the proper name, or the common name if there is no proper name, of the drug or each of the drugs, as the case may be, to be used as medicating ingredients in the preparation of the medicated feed, and the dosage levels of those medicating ingredients,

(v) any special mixing instructions, and

(vi) labelling instructions including

(A) feeding instructions,

(B) a warning statement respecting the withdrawal period to be observed following the use of the medicated feed, and

(C) where applicable, cautions with respect to animal health or to the handling or storage of the medicated feed.

(2) For the purpose of this section, “medicated feed” has the same meaning as in the Feeds Regulations.

SOR/80-741, s. 1; SOR/92-130, s. 1; SOR/93-202, s. 27.

## Experimental Studies

### Conditions of Sale

C.08.013. (1) Notwithstanding anything in this Division, a person may sell a new drug proposed for use in animals to an experimental studies investigator in a quantity specified by the Director for the purpose of conducting an experimental study in animals if

(*a*) the experimental studies investigator has been issued an experimental studies certificate pursuant to subsection C.08.015(1) and the certificate has not been suspended or cancelled pursuant to section C.08.018; and

(*b*) the drug is labelled in accordance with subsection C.08.016(1).

(2) For the purposes of this section and sections C.08.014 to C.08.018,

“experimental studies certificate” means a certificate issued pursuant to subsection C.08.015(1); (certificat d’études expérimentales)

“experimental studies investigator” means a person named as the investigator in an experimental studies certificate; (expert en études expérimentales)

“experimental study” means a limited test of a new drug in animals carried out by an experimental studies investigator. (étude expérimentale)

SOR/81-333, s. 1.

**Experimental Studies Certificate**

C.08.014. (1) For the purpose of obtaining an experimental studies certificate, an applicant shall submit to the Director, in writing, the following information and material:

(*a*) the brand name of the new drug or the identifying name or code proposed for the new drug;

(*b*) the objectives and an outline of the proposed experimental study of the new drug;

(*c*) the species, number and production type of animals in respect of which the new drug is to be administered;

(*d*) the name and address of the manufacturer of the new drug;

(*e*) the address of the premises in which the experimental study is to be conducted;

(*f*) a description of the facilities to be used to conduct the experimental study;

(*g*) the name, address and qualifications of the proposed experimental studies investigator;

(*h*) the chemical structure, if known, and the relevant compositional characteristics of the new drug;

(*i*) the proposed quantity of the new drug to be used for the experimental study;

(*j*) the results of any toxicological or pharmacological studies that may have been conducted with the new drug;

(*k*) the written agreement referred to in subsection (2); and

(*l*) such other information and material as the Director may require.

(2) Where a food-producing animal is involved in an experimental study, the applicant referred to in subsection (1) shall, for the purposes of obtaining an experimental studies certificate, obtain from the owner of the animals, or from a person authorized by the owner, a written agreement not to sell the animal or any products from it without prior authorization from the experimental studies investigator.

(3) The Director may request the manufacturer of a new drug to submit to him samples of the new drug or of any ingredient of the drug and, in satisfactory form and manner, any other

information that the Director requests and where such samples or information are not submitted, the Director may refuse to issue an experimental studies certificate.

SOR/81-333, s. 1; SOR/93-202, s. 28.

C.08.015. (1) Where, on receipt of the information and material submitted pursuant to section C.08.014, the Director is satisfied that

(*a*) the applicant is qualified as an experimental studies investigator for the purposes of the proposed experimental study,

(*b*) the facilities for the conduct of the experimental study are adequate for the purposes of the proposed experimental study, and

(*c*) the proposed experimental study can be conducted without undue foreseeable risk to humans or animals,

the Director shall issue an experimental studies certificate for the purposes of the proposed experimental study and shall specify therein the quantity of the new drug that may be sold to the experimental studies investigator.

(2) Where, on receipt of the information and material submitted pursuant to section C.08.014, the Director is not satisfied that the requirements of paragraphs (1)(*a*), (*b*) and (*c*) have been met, he shall refuse to issue an experimental studies certificate.

SOR/81-333, s. 1.

**Labelling**

C.08.016. (1) The label of a new drug that is sold pursuant to section C.08.013 shall show

(*a*) the brand name of the new drug or the identifying name or code proposed for the new drug;

(*b*) a warning statement to the effect that the drug is for use only in an experimental study in animals;

(*c*) the lot number of the drug;

(*d*) the name and address of the manufacturer of the drug; and

(*e*) the name of the person to whom the drug has been supplied.

(2) Sections C.01.004, C.01.005 and C.01.014 do not apply to a drug that is sold pursuant to section C.08.013 and labelled in accordance with subsection (1).

SOR/81-333, s. 1; SOR/88-378, s. 2; SOR/93-202, s. 29.

**Conditions of Experimental Study**

C.08.017. An experimental studies investigator shall

(*a*) use the new drug only in accordance with the outline of the experimental study;

(*b*) report immediately to the Director all serious adverse drug reactions associated with the use of the new drug;

(*c*) report promptly to the Director, on request, the results of the experimental study;

(*d*) return to the manufacturer, on request, all quantities of the new drug not used in the experimental study;

(*e*) maintain all records of the experimental study for a period of at least two years after the conclusion of the study and, on request, make such records available to the Director;

(*f*) report promptly to the Director any known disposition of animals involved in the study or of any products from the animals that is contrary to the terms of the agreement referred to in subsection C.08.014(2); and

(*g*) account to the Director, on request, for all quantities of the new drug received by him.

SOR/81-333, s. 1; SOR/2001-203, s. 10.

**Suspension or Cancellation of Experimental Studies Certificate**

C.08.018. (1) Where the Director is of the opinion that it is necessary in order to safeguard animal health or public health or to promote public safety, he may suspend for a definite or indefinite period or cancel an experimental studies certificate.

(2) Without limiting the generality of subsection (1), the Director may suspend or cancel an experimental studies certificate if

(*a*) the information and material submitted pursuant to section C.08.014 contains an untrue statement or contains any omission concerning the properties of the drug that were known or ought reasonably to have been known to the manufacturer or the experimental studies investigator;

(*b*) the labelling of the new drug is, at any time, false, misleading, deceptive or incomplete;

(*c*) the qualifications of the experimental studies investigator prove to be inadequate;

(*d*) there is evidence that the experimental studies investigator has not complied with the conditions referred to in section C.08.017; or

(*e*) an action of the manufacturer in respect of the new drug has resulted in his conviction for a violation of section C.08.002.

SOR/81-333, s. 1.

# Division 9

## Non-prescription Drugs

C.09.001. This Division does not apply to

(*a*) a drug that is required by these Regulations or the Narcotic Control Regulations to be sold only on prescription; or

(*b*) a drug for use exclusively in animals.

SOR/84-145, s. 4.

## Analgesics

### General

C.09.010. No manufacturer or importer shall, after June 30, 1986, sell a drug for analgesia that contains a combination of

(*a*) a salt or derivative of salicylic acid with another salt or derivative of salicylic acid or with salicylamide; or

(*b*) acetaminophen with a salt or derivative of salicylic acid or with salicylamide.

SOR/84-145, s. 4.

C.09.011. Each label of a drug that is intended for internal use and contains acetaminophen, salicylic acid or a salt or derivative thereof shall, after June 30, 1986, carry a caution

(*a*) to consult a physician if the underlying condition requires continued use for more than five days; and

(*b*) that it is hazardous to exceed the maximum recommended dose unless advised by a physician.

SOR/84-145, s. 4; SOR/86-589, s. 1.

C.09.012. Each label of a drug that is intended for internal use and contains salicylic acid or a salt or derivative thereof shall after June 30, 1986, carry a warning statement to consult a physician before taking the drug during the last three months of pregnancy or when nursing.

SOR/84-145, s. 4.

## Acetaminophen

C.09.020. (1) The adult standard dosage unit of acetaminophen shall be 325 mg.

(2) The children’s standard dosage units of acetaminophen shall be 80 mg or 160 mg.

SOR/84-145, s. 4; SOR/90-587, s. 4.

C.09.021. (1) In this Division, “acetaminophen product” means a drug that contains

(*a*) acetaminophen as a single medicinal ingredient; or

(*b*) acetaminophen in combination with caffeine.

(2) No manufacturer or importer shall sell an acetaminophen product unless it meets the requirements of this Division.

(3) [Repealed, SOR/90-587, s. 5]

SOR/84-145, s. 4; SOR/90-587, s. 5.

C.09.022. (1) Subject to subsections (2) to (4), an acetaminophen product sold in the form of a tablet, capsule or other solid dosage form intended for oral administration shall contain one adult standard dosage unit of acetaminophen per individual dosage form.

(2) An acetaminophen product in the form of a tablet, capsule or other solid dosage form intended for oral administration may contain 500 mg of acetaminophen per individual dosage form if it has a label that states that it is not a standard dosage unit product.

(3) An acetaminophen product sold in the form of a tablet, capsule or other solid dosage form that is intended for oral administration may contain 325 mg of acetaminophen for immediate release and another 325 mg for subsequent release, if it has a label that states that it is not a standard dosage unit product.

(4) An acetaminophen product sold in the form of a tablet, capsule or other solid dosage form that is intended for oral administration and that is specially recommended for children shall contain one children's standard dosage unit of acetaminophen per individual dosage form.

(5) An acetaminophen product in the form of a liquid that is intended to be taken as drops and that is specially recommended for children shall contain one children's standard dosage unit of acetaminophen per millilitre of the product.

(6) A package of an acetaminophen product described in subsection (5) shall be accompanied by a measuring device capable of accurately delivering 0.5 mL of the product.

(7) An acetaminophen product in the form of a liquid that is not intended to be taken as drops and that is specially recommended for children shall contain one children's standard dosage unit per teaspoon of the product.

(8) An acetaminophen product in the form of a liquid shall contain one adult standard dosage unit of acetaminophen per teaspoon of the product.

SOR/84-145, s. 4; SOR/85-966, s. 4; SOR/86-954, s. 1; SOR/99-441, s. 1.

## Salicylates

C.09.030. (1) The adult standard dosage unit of a salicylate shall be

(*a*) in the case of acetylsalicylic acid, sodium salicylate and magnesium salicylate, 325 mg; and

(*b*) in the case of choline salicylate, 435 mg.

(2) The children's standard dosage unit of a salicylate shall be

(*a*) in the case of acetylsalicylic acid, sodium salicylate and magnesium salicylate, 80 mg; and

(*b*) in the case of choline salicylate, 110 mg.

SOR/84-145, s. 4.

C.09.031. (1) In this Division, "salicylate product" means a drug that contains

(*a*) a salt or derivative of salicylic acid as a single medicinal ingredient;

(*b*) a salt or derivative of salicylic acid in combination with caffeine;

(*c*) a salt or derivative of salicylic acid in combination with one or more buffering agents or antacids; or

(*d*) a salt or derivative of salicylic acid in combination with caffeine and one or more buffering agents or antacids.

(2) No manufacturer or importer shall sell a salicylate product after June 30, 1986 unless it meets the requirements of this Division.

(3) No manufacturer or importer shall, until June 30, 1986, sell a salicylate product in a dosage unit other than one mentioned in this Division, unless the salicylate product was legally available for sale in Canada on February 1, 1984.

SOR/84-145, s. 4; SOR/85-966, s. 5(E).

C.09.032. (1) Subject to subsections (2) and (3) and section C.09.035, a salicylate product in the form of a tablet, capsule or other solid dosage form intended for oral administration shall contain one adult standard dosage unit of a salicylate per individual dosage form.

(2) A salicylate product in the form of a tablet, capsule or other solid dosage form intended for oral administration may contain

(*a*) 500 mg of acetylsalicylic acid, sodium salicylate or magnesium salicylate, or

(*b*) 670 mg of choline salicylate

per individual dosage form if it has a label that states that it is not a standard dosage unit product.

(3) A salicylate product in the form of a tablet, capsule or other solid dosage form intended for oral administration may contain

(*a*) two adult standard dosage units of a salicylate per individual dosage form if the label of the salicylate product states that each individual dosage form contains two adult standard dosage units; and

(*b*) three adult standard dosage units of a salicylate per individual dosage form if the label of the salicylate product states that each individual dosage form contains three adult standard dosage units.

SOR/84-145, s. 4; SOR/85-966, s. 6.

C.09.033. (1) Subject to subsection (2), a salicylate product in the form of a liquid shall contain one adult standard dosage unit of a salicylate per teaspoon.

(2) A salicylate product in the form of a liquid may contain

(*a*) two adult standard dosage units of a salicylate per teaspoon if the label of the salicylate product states that each teaspoon of the product contains two adult standard dosage units; and

(*b*) three adult standard dosage units of a salicylate per teaspoon if the label of the salicylate product states that each teaspoon of the product contains three adult standard dosage units.

SOR/84-145, s. 4.

C.09.034. A salicylate product that is claimed to be buffered shall provide at least 1.9 milliequivalents of acid neutralizing capacity per adult standard dosage unit of a salicylate.

SOR/84-145, s. 4.

C.09.035. A salicylate product in the form of a tablet, capsule or other solid dosage form intended for oral administration and that is specially recommended for children shall contain one children’s standard dosage unit of a salicylate per individual dosage form.

SOR/84-145, s. 4.

## Division 10

## [Repealed, SOR/98-423, s. 9]

# PART D

# VITAMINS, MINERALS AND AMINO ACIDS

D.01.001. (1) In this Part,

“advertise” means to advertise to the general public; (faire de la publicité)

“brand name” means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French,

(*a*) that is assigned to the drug by its manufacturer,

(*b*) under which the drug is sold or advertised, and

(*c*) that is used to distinguish the drug; (marque nominative)

“common name” means, with reference to a salt or derivative of a vitamin, the name in English or French by which the salt or derivative is

(*a*) commonly known, and

(*b*) designated in scientific or technical journals; (nom usuel)

“prepackaged product” means any food that is contained in a package in the manner in which it is ordinarily sold to, or used or purchased by, a person; (produit préemballé)

“reasonable daily intake”, in respect of a food named in an item in Column I of Schedule K, means the amount of that food set out in Column II of that item; (ration quotidienne normale)

“recommended daily intake” means, in respect of a vitamin or mineral nutrient, the amount of the vitamin or mineral nutrient set out in

(*a*) column II of Table I to Division 1 and column II of Table I to Division 2, for foods intended for persons 2 years of age or older, and

(*b*) column III of Table I to Division l and column III of Table I to Division 2, for foods intended for infants and children less than 2 years of age; (apport quotidien recommandé)

“testimonial”, with respect to a food or drug that is represented as containing a vitamin, mineral nutrient or mineral, means any dramatized or undramatized pictorial, written or oral representation as to the result that is, has been or may be produced by the addition to a person’s diet of that vitamin, mineral nutrient or mineral, as the case may be; (témoignage)

“weighted recommended nutrient intake” means, in respect of a vitamin or mineral nutrient, the amount of the vitamin or mineral nutrient set out in Table II to Division 1 and Table II to Division 2. (apport nutritionnel recommandé pondéré)

(2) For the purposes of this Part, a serving of stated size of a food shall be

(*a*) based on the food as offered for sale; and

(*b*) expressed

(i) in grams, if

(A) the net quantity of the food is declared on the label by weight or by count, or

(B) the food is set out in column 1 of item 78, 149 or 150 of Schedule M, and

(ii) in millilitres, if the net quantity of the food is declared on the label by volume, except in the case of a food referred to in clause (i)(B).

(3) A serving of stated size shall be the net quantity of the food in the package if

(*a*) the quantity of food can reasonably be consumed by one person at a single eating occasion;

(*b*) the reference amount, as defined in section B.01.001, of the food is less than 100 g or 100 mL and the package contains less than 200% of that amount; or

(*c*) the reference amount, as defined in section B.01.001, of the food is 100 g or 100 mL or more and the package contains 150% or less of that amount.

SOR/88-559, s. 31; SOR/93-202, s. 31; SOR/96-259, s. 3; SOR/2003-11, s. 27.

# Division 1

# Vitamins In Foods

D.01.002. (1) In this Division, “vitamin” means any of the following vitamins:

(*a*) vitamin A;

(*b*) vitamin D;

(*c*) vitamin E;

(*d*) vitamin K;

(*e*) vitamin C;

(*f*) thiamin, thiamine or vitamin $B_1$;

(*g*) riboflavin or vitamin $B_2$;

(*h*) niacin;

(*i*) vitamin $B_6$;

(*j*) folacin or folate;

(*k*) vitamin $B_{12}$;

(*l*) pantothenic acid or pantothenate; and

(*m*) biotin. (*vitamin*)

(2) For the purposes of this Division, no expression, other than an expression set out in subsection (1), shall be used to declare the vitamin content of a food.

(3) This Division applies only in respect of foods represented as containing a vitamin for use in human nutrition.

SOR/88-559, s. 32; SOR/2003-11, s. 28.

D.01.003. (1) For the purposes of these Regulations, the vitamin content of a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, shall be determined

(*a*) in the case of vitamin A, in terms of the content of retinol and its derivatives and beta-carotene, expressed as retinol equivalents (RE) on the basis of the following relationships:

(i) 1 RE = 1 microgram retinol, and

(ii) 1 RE = 6 micrograms beta-carotene;

(*b*) in the case of vitamin D, in terms of the content of cholecalciferol and ergocalciferol, expressed in micrograms;

(*c*) in the case of vitamin E, in terms of the content of *d*-alpha-tocopherol and *dl*-alpha-tocopherol and their derivatives, expressed in milligrams on the basis of the following relationships:

(i) one milligram *d*-alpha-tocopherol = one milligram vitamin E, and

(ii) one milligram *dl*-alpha-tocopherol = 0.74 milligram vitamin E;

(*d*) in the case of vitamin K, in terms of the content of phylloquinone and menaquinones, expressed in micrograms;

(*e*) in the case of vitamin C, in terms of the content of L-ascorbic acid and L-dehydroascorbic acid and their derivatives, calculated in milligram equivalents of L-ascorbic acid and expressed in milligrams;

(*f*) in the case of thiamin, thiamine or vitamin $B_1$, and its derivatives, in terms of the content of thiamin, expressed in milligrams;

(*g*) in the case of riboflavin or vitamin $B_2$ and its derivatives, in terms of the content of riboflavin, expressed in milligrams;

(*h*) in the case of niacin, in terms of the content of niacin and its derivatives, calculated in milligrams of nicotinic acid, plus the content of tryptophan, calculated in milligrams and divided by 60, with the total expressed as niacin equivalents (NE);

(*i*) in the case of vitamin $B_6$, in terms of the content of pyridoxine, pyridoxal and pyridoxamine and their derivatives, calculated in milligram equivalents of pyridoxine and expressed in milligrams;

(*j*) in the case of folacin, in terms of the content of folic acid (pteroylmonoglutamic acid) and related compounds exhibiting the biological activity of folic acid, calculated in microgram equivalents of folic acid and expressed in micrograms;

(*k*) in the case of vitamin $B_{12}$, in terms of the content of cyanocobalamin and related compounds exhibiting the biological activity of cyanocobalamin, calculated in microgram equivalents of cyanocobalamin and expressed in micrograms;

(*l*) in the case of pantothenic acid or pantothenate, in terms of the content of *d*-pantothenic acid, expressed in milligrams; and

(*m*) in the case of biotin, in terms of the content of biotin, expressed in milligrams.

(2) For the purpose of paragraph (1)(*h*), the content of tryptophan may be calculated

(*a*) where the protein originates from a food that contains protein from more than one source or from a source other than milk, meat, poultry, fish or eggs, as constituting 1.1 per cent of the protein;

(*b*) where the protein originates from milk, meat, poultry or fish, as constituting 1.3 per cent of the protein; and

(*c*) where the protein originates from eggs, as constituting 1.5 per cent of the protein.

SOR/88-559, s. 32; SOR/90-830, s. 7.

D.01.004. (1) No person shall, on the label of or in any advertisement for a food, other than a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim concerning the vitamin content of the food unless

(*a*) the vitamin is set out in column I of Table I to this Division;

(*b*) the percentage of the recommended daily intake of the vitamin, per serving of stated size, is 5% or more; and

(*c*) the vitamin content is declared on the label or in the advertisement as a percentage of the daily value, per serving of stated size.

(2) If a statement or claim described in subsection (1) is made in an advertisement for a food that is not a prepackaged product or in an advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the percentage of the daily value, per serving of stated size, shall,

(*a*) in the case of an advertisement, other than a radio or television advertisement, be

(i) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and

(ii) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once;

(*b*) in the case of a radio advertisement or the audio portion of a television advertisement, immediately precede or follow the statement or claim; or

(*c*) in the case of a television advertisement, be communicated

(i) in the audio mode, if the statement or claim is made only in the audio portion of the advertisement or in both the audio and visual portions, or

(ii) in the audio or visual mode, if the statement or claim is made only in the visual portion of the advertisement.

(3) The percentage of the daily value, per serving of stated size, that is communicated in the visual mode of a television advertisement in accordance with subparagraph (2)(*c*)(ii) shall

(*a*) appear concurrently with and for at least the same amount of time as the statement or claim;

(*b*) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and

(*c*) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

(4) Paragraph (1)(*b*) does not apply in respect of a declaration of the vitamin content in a nutrition facts table.

(5) Paragraph (1)(*c*) does not apply in respect of a declaration of the biotin content as required by subparagraph B.24.202(*a*)(v).

SOR/84-300, s. 57(E); SOR/88-559, s. 32; SOR/90-830, s. 8; SOR/96-259, s. 9; SOR/2003-11, s. 29.

D.01.005. [Repealed, SOR/2003-11, s. 29]

D.01.006. No person shall, on the label of or in any advertisement for a food, make any claim concerning the action or effects of a vitamin contained in the food, except to the effect that the vitamin

(*a*) is a factor in the maintenance of good health; and

(*b*) is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

SOR/88-559, s. 32.

D.01.007. (1) If a component of an ingredient of a prepackaged product set out in the table to subsection B.01.009(1) is a vitamin, no person shall, on the label of or in any advertisement for the prepackaged product, make a statement or claim concerning the vitamin as a component of that ingredient unless

(*a*) despite subsection B.01.008(6), the vitamin is declared by its common name immediately following the declaration of the ingredient in such a manner as to indicate that it is a component of that ingredient; and

(*b*) all components of the ingredient are declared.

(2) Paragraph (1)(*b*) does not apply to flour used as an ingredient in the manufacture of a prepackaged product referred to in subsection (1).

SOR/84-300, s. 59(E); SOR/88-559, s. 32; SOR/2003-11, s. 30.

D.01.008. [Repealed, SOR/88-559, s. 32]

D.01.009. Subject to section D.01.010, no person shall sell a food to which any of the following vitamins have been added unless a reasonable daily intake of that food by a person would result in the daily intake by such person of not less than,

(*a*) in the case of vitamin A, 1,600 International Units;

(*b*) in the case of thiamine, 0.6 milligram;

(*c*) in the case of riboflavin, 1.0 milligram;

(*d*) in the case of niacin or niacinamide, six milligrams;

(*e*) in the case of ascorbic acid, 20 milligrams; and

(*f*) in the case of vitamin D, 300 International Units.

D.01.010. Where a food to which a vitamin has been added is represented as being solely for use in the feeding of children under two years of age, no person shall sell such food unless a reasonable daily intake of that food by a child under two years of age would result in the daily intake by the child of not less than,

(*a*) in the case of vitamin A, 1,000 International Units;

(*b*) in the case of thiamine, 0.4 milligram;

(*c*) in the case of riboflavin, 0.6 milligram;

(*d*) in the case of niacin or niacinamide, four milligrams;

(*e*) in the case of pyridoxine, 0.6 milligram;

(*f*) in the case of ascorbic acid, 20 milligrams;

(*g*) in the case of vitamin D, 300 International Units; and

(*h*) in the case of vitamin E, five International Units.

D.01.011. No person shall sell a food to which any of the following vitamins have been added if a reasonable daily intake of that food by a person would result in the daily intake by such person of more than,

(*a*) in the case of vitamin A, 2,500 International Units;

(*b*) in the case of thiamine, two milligrams;

(*c*) in the case of riboflavin, three milligrams;

(*d*) in the case of niacin or niacinamide, 20 milligrams;

(*e*) in the case of pyridoxine, 1.5 milligrams;

(*f*) in the case of ascorbic acid, 60 milligrams;

(*g*) in the case of vitamin D, 400 International Units; and

(*h*) in the case of vitamin E, 15 International Units.

D.01.012. No person shall, in advertising a food that is represented as containing a vitamin or on a label of such food,

(*a*) give any assurance or guarantee of any kind with respect to the result that may be, has been or will be obtained by the addition of the vitamin to a person’s diet; or

(*b*) refer to, reproduce or quote any testimonial.

D.01.013. [Repealed, SOR/2003-11, s. 31]

TABLE I

RECOMMENDED DAILY INTAKE

| | Column I | | Column II | Column III |
|---|---|---|---|---|
| Item | Vitamin | Units* | Intake of persons 2 years of age or older | Intake of infants or children less than 2 years of age |
| 1. | Vitamin A | (RE) | 1000 | 400 |
| 2. | Vitamin D | (µg) | 5 | 10 |
| 3. | Vitamin E | (mg) | 10 | 3 |
| 4. | Vitamin C | (mg) | 60 | 20 |
| 5. | Thiamin, thiamine or vitamin $B_1$ | (mg) | 1.3 | 0.45 |
| 6. | Riboflavin or vitamin $B_2$ | (mg) | 1.6 | 0.55 |
| 7. | Niacin | (NE) | 23 | 8 |
| 8. | Vitamin $B_6$ | (mg) | 1.8 | 0.7 |
| 9. | Folacin or folate | (µg) | 220 | 65 |
| 10. | Vitamin $B_{12}$ | (µg) | 2 | 0.3 |
| 11. | Pantothenic acid or pantothenate | (mg) | 7 | 2 |
| 12. | Vitamin K | (µg) | 80 | 30 |

| | Column I | | Column II | Column III |
|---|---|---|---|---|
| Item | Vitamin | Units* | Intake of persons 2 years of age or older | Intake of infants or children less than 2 years of age |
| 13. | Biotin | (µg) | 30 | 8 |

* RE = retinol equivalents
mg = milligrams
µg = micrograms
NE = niacin equivalents

SOR/88-559, s. 33; SOR/96-259, s. 4; SOR/2003-11, ss. 32, 33.

TABLE II

WEIGHTED RECOMMENDED NUTRIENT INTAKE

| | Column I | Column II | Column III |
|---|---|---|---|
| Item | Vitamin | Units | Amount |
| 1. | Biotin | micrograms | 90 |
| 2. | Folacin | micrograms | 195 |
| 3. | Niacin | niacin equivalents | 16 |
| 4. | Pantothenic Acid | milligrams | 5.0 |
| 5. | Riboflavin | milligrams | 1.2 |
| 6. | Thiamine | milligrams | 1.0 |
| 7. | Vitamin A | retinol equivalents | 870 |
| 8. | Vitamin $B_6$ | milligrams | 1.0 |
| 9. | Vitamin $B_{12}$ | micrograms | 1.0 |
| 10. | Vitamin C | milligrams | 34 |
| 11. | Vitamin D | micrograms | 3.0 |
| 12. | Vitamin E | milligrams | 7.0 |

SOR/96-259, s. 5.

# Division 2

# Mineral Nutrients In Foods

D.02.001. (1) In this Division, “mineral nutrient” means any of the following chemical elements, whether alone or in a compound with one or more other chemical elements:

(*a*) sodium;

(*b*) potassium;

(*c*) calcium;

(*d*) phosphorus;

(*e*) magnesium;

(*f*) iron;

(*g*) zinc;

(*h*) iodide;

(*i*) chloride;

(*j*) copper;

(*k*) fluoride;

(*l*) manganese;

(*m*) chromium;

(*n*) selenium;

(*o*) cobalt;

(*p*) molybdenum;

(*q*) tin;

(*r*) vanadium;

(*s*) silicon; and

(*t*) nickel. (*minéral nutritif*)

(2) This Division applies only in respect of foods that are represented as containing a mineral nutrient for use in human nutrition.

SOR/88-559, s. 34; SOR/90-830, s. 9(F).

D.02.002. (1) No person shall, on the label of or in any advertisement for a food, other than salt for table or general household use containing added iodide, prepackaged water and ice, a formulated liquid diet, a human milk substitute or a food represented as containing a human milk substitute, make a statement or claim concerning the mineral nutrient content of the food unless

(*a*) the mineral nutrient is set out in column I of Table I to this Division;

(*b*) the percentage of the recommended daily intake of the mineral nutrient, per serving of stated size, is 5% or more; and

(*c*) the mineral nutrient content is declared on the label or in the advertisement as a percentage of the daily value, per serving of stated size.

(2) If a statement or claim described in subsection (1) is made in an advertisement for a food that is not a prepackaged product or in an advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the percentage of the daily value, per serving of stated size, shall,

(*a*) in the case of an advertisement, other than a radio or television advertisement, be

(i) adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once, and

(ii) shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once;

(*b*) in the case of a radio advertisement or the audio portion of a television advertisement, immediately precede or follow the statement or claim; or

(*c*) in the case of a television advertisement, be communicated

(i) in the audio mode, if the statement or claim is made only in the audio portion of the advertisement or in both the audio and visual portions, or

(ii) in the audio or visual mode, if the statement or claim is made only in the visual portion of the advertisement.

(3) The percentage of the daily value, per serving of stated size, that is communicated in the visual mode of a television advertisement in accordance with subparagraph (2)(*c*)(ii) shall

(*a*) appear concurrently with and for at least the same amount of time as the statement or claim;

(*b*) be adjacent to, without any intervening printed, written or graphic material, the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once; and

(*c*) be shown in letters of at least the same size and prominence as those of the statement or claim, if the statement or claim is made only once, or the most prominent statement or claim, if the statement or claim is made more than once.

(4) Subsection (1) does not apply to a statement or claim made in respect of the sodium or potassium content.

(5) Paragraphs (1)(*a*) and (*c*) do not apply in respect of a declaration of the total fluoride ion content as required by sections B.12.002 and B.12.008.

(6) Paragraph (1)(*b*) does not apply in respect of a declaration of the mineral nutrient content in a nutrition facts table.

(7) Paragraph (1)(*c*) does not apply in respect of a declaration of the chromium, copper, manganese, molybdenum and selenium content as required by subparagraph B.24.202(*a*)(v).

SOR/84-300, s. 60(E); SOR/88-559, s. 34; SOR/90-830, s. 10; SOR/96-259, s. 9; SOR/2003-11, s. 34.

D.02.003. [Repealed, SOR/2003-11, s. 34]

D.02.004. No person shall, on the label of or in any advertisement for a food, make any claim concerning the action or effects of a mineral nutrient contained in the food, except to the effect that the mineral nutrient

(*a*) is a factor in the maintenance of good health; and

(*b*) is generally recognized as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development.

SOR/84-300, s. 61(E); SOR/88-559, s. 34.

D.02.005. (1) If a component of an ingredient of a prepackaged product set out in the table to subsection B.01.009(1) is a mineral nutrient, no person shall, on the label of or in any advertisement for the prepackaged product, make a statement or claim concerning the mineral nutrient as a component of that ingredient unless

(*a*) despite subsection B.01.008(6), the mineral nutrient is declared by its common name immediately following the declaration of the ingredient in such a manner as to indicate that it is a component of that ingredient; and

(*b*) all components of the ingredient are declared.

(2) Paragraph (1)(*b*) does not apply to flour used as an ingredient in the manufacture of a prepackaged product referred to in subsection (1).

SOR/88-559, s. 34; SOR/2003-11, s. 35.

D.02.006. [Repealed, SOR/2003-11, s. 35]

TABLE I

RECOMMENDED DAILY INTAKE

| | Column I | | Column II | Column III |
|---|---|---|---|---|
| Item | Mineral Nutrient | Units* | Intake of persons 2 years of age or older | Intake of infants and children less than 2 years of age |
| 1. | Calcium | (mg) | 1100 | 500 |
| 2. | Phosphorus | (mg) | 1100 | 500 |
| 3. | Magnesium | (mg) | 250 | 55 |
| 4. | Iron | (mg) | 14 | 7 |
| 5. | Zinc | (mg) | 9 | 4 |
| 6. | Iodide | (µg) | 160 | 55 |
| 7. | Selenium | (µg) | 50 | 15 |
| 8. | Copper | (mg) | 2 | 0.5 |
| 9. | Manganese | (mg) | 2 | 1.2 |
| 10. | Chromium | (µg) | 120 | 12 |
| 11. | Molybdenum | (µg) | 75 | 15 |
| 12. | Chloride | (mg) | 3400 | 1000 |

* mg = milligrams
µg = micrograms

SOR/88-559, s. 34; SOR/96-259, s. 6; SOR/2003-11, s. 36.

TABLE II

WEIGHTED RECOMMENDED NUTRIENT INTAKE

| Item | Column I<br>Mineral Nutrient | Column II<br>Units | Column III<br>Amount |
|---|---|---|---|
| 1. | Calcium | milligrams | 780 |
| 2. | Iodide | micrograms | 155 |
| 3. | Iron | milligrams | 10 |
| 4. | Phosphorus | milligrams | 885 |
| 5. | Magnesium | milligrams | 210 |
| 6. | Zinc | milligrams | 10 |

SOR/96-259, s. 7.

D.02.007. [Repealed, SOR/88-559, s. 34]

D.02.008. No person shall, in advertising a food that is represented as containing a mineral nutrient or on a label of such food,

(*a*) give any assurance or guarantee of any kind with respect to the result that may be, has been or will be obtained by the addition of the mineral nutrient to a person's diet; or

(*b*) refer to, reproduce or quote any testimonial.

D.02.009. No person shall sell a food to which any of the following mineral nutrients have been added unless a reasonable daily intake of that food by a person would result in the daily intake by such person of not less than,

(*a*) in the case of calcium, 300 milligrams;

(*b*) in the case of phosphorus, 300 milligrams;

(*c*) in the case of iron, four milligrams; and

(*d*) in the case of iodine, 0.10 milligram.

D.02.010. (1) No person shall sell elemental iron powder for use in foods as a source of iron as a mineral nutrient unless

(*a*) subject to paragraph (*b*), the powder meets the specifications for

(i) Iron, Carbonyl,

(ii) Iron, Electrolytic, or

(iii) Iron, Reduced,

as set out in the Food Chemicals Codex, Third Edition, 1981, published by the National Academy of Sciences of the United States of America; and

(*b*) in the case of Iron, Reduced, 100 per cent by weight of the particles pass through a 100 mesh sieve and at least 95 per cent by weight of the particles pass through a 325 mesh sieve.

(2) No person shall sell a food to which elemental iron powder has been added as a source of iron as a mineral nutrient unless the powder meets the requirements referred to in paragraphs (1)(*a*) and (*b*).

SOR/84-303, s. 1.

D.02.011. No person shall sell a food to which sodium iron pyrophosphate has been added as a source of iron as a mineral nutrient unless

(*a*) the bioavailability of the iron in the food is not less than 50 per cent of the bioavailability of ferrous sulphate as determined by official method FO-42, Determination of Bioavailability of Iron, December 15, 1982; and

(*b*) that person retains documentary evidence showing that the bioavailability of the iron in the food has been determined by the official method referred to in paragraph (*a*) and, on request by the Director, submits such evidence to the Director.

SOR/84-303, s. 1.

# Division 3

# Addition Of Vitamins, Mineral Nutrients Or Amino Acids To Foods

D.03.001. (1) In this Division, the expressions “vitamin” and “mineral nutrient” have the same meaning as in Divisions 1 and 2.

(2) This Division applies only in respect of foods that are represented as containing a vitamin, mineral nutrient or amino acid for use in human nutrition.

SOR/88-559, s. 35.

D.03.002. (1) Subject to section D.03.003, no person shall sell a food to which a vitamin, mineral nutrient or amino acid has been added unless the food is listed in Column I of the Table to this section and the vitamin, mineral nutrient or amino acid, as the case may be, is listed opposite that food in Column II of the Table.

(2) No milk or milk product or derivative listed in Column I of the Table to this section applies to the lacteal secretion obtained from the mammary gland of any animal other than a cow, genus *Bos*, or a product or derivative of such secretion unless that animal is identified therein.

TABLE

| | Column I<br>Food | Column II<br>Vitamin, Mineral Nutrient or Amino Acid |
|---|---|---|
| 1. | Breakfast cereals | Thiamine, niacin, vitamin $B_6$, folic acid, pantothenic acid, magnesium, iron and zinc. |
| 2. | Fruit nectars, vegetable drinks, bases and mixes for vegetable drinks and a mixture of vegetable juices | Vitamin C. |
| 2.1 | Fruit flavoured drinks that meet all the requirements of section B.11.150 | Vitamin C, folic acid, thiamine, iron, potassium. |
| 2.2 | Bases, concentrates and mixes that are used for making fruit flavoured drinks and that | Vitamin C, folic acid, thiamine, iron, potassium. |

| | Column I<br>Food<br>meet all the requirements of section B.11.151 | Column II<br>Vitamin, Mineral Nutrient or Amino Acid |
|---|---|---|
| 3. | Infant cereal products | Thiamine, riboflavin, niacin or niacinamide, calcium, phosphorus, iron, iodine. |
| 4. | Margarine and other similar substitutes for butter | Vitamin A, Vitamin D, alpha-tocopherol |
| 5. | Alimentary pastes | Thiamine, riboflavin, niacin or niacinamide, folic acid, pantothenic acid, vitamin $B_6$, iron, magnesium |
| 6. | Infant formulas and formulated liquid diets | Amino acids — alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine;<br>Minerals — calcium, chloride, chromium, copper, iodide, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc;<br>Vitamins — alpha-tocopherol, biotin, *d*-pantothenic acid, folic acid, niacin, riboflavin, thiamin, vitamin A, vitamin $B_6$, vitamin $B_{12}$, vitamin C, vitamin D, vitamin K. |
| 6.1 | Foods represented for use in a very low energy diet | Vitamins — alpha-tocopherol, biotin, *d*-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin $B_6$, vitamin $B_{12}$, vitamin C, vitamin D, vitamin K<br>Minerals — calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc |
| 7. | Flavoured beverage mixes and bases recommended for addition to milk | Vitamin A, thiamine, niacin or niacinamide, vitamin C, iron. |
| 8. | Simulated meat products, simulated poultry meat products, meat product extenders and poultry product extenders | Thiamine, riboflavin, niacin, pyridoxine, d-pantothenic acid, folic acid, vitamin $B_{12}$, iron, magnesium, potassium, zinc, copper, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine. |
| 9. | Meal replacements and nutritional supplements | Vitamins — alpha-tocopherol, biotin, *d*-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin $B_6$, vitamin $B_{12}$, vitamin C, vitamin D<br>Minerals — calcium, chloride, chromium, |

| | Column I<br>Food | Column II<br>Vitamin, Mineral Nutrient or Amino Acid |
|---|---|---|
| | | copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc |
| 9.1 | Ready breakfast, instant breakfast and other similar breakfast replacement foods however described | Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin C, iron |
| 10. | Condensed milk, milk, milk powder, sterilized milk, (naming the flavour) milk | Vitamin D. |
| 11. | Skim milk with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, skim milk, partly skimmed milk, skim milk powder | Vitamin A, vitamin D. |
| 12. | Evaporated milk | Vitamin C, vitamin D. |
| 13. | Evaporated skim milk, concentrated skim milk, evaporated partly skimmed milk, concentrated partly skimmed milk | Vitamin A, vitamin C, vitamin D. |
| 14. | Apple juice, reconstituted apple juice, grape juice, reconstituted grape juice, pineapple juice, reconstituted pineapple juice, apple and (naming the fruit) juice as described in section B.11.132, concentrated fruit juice except frozen concentrated orange juice | Vitamin C. |
| 15. | Flour, White Flour, Enriched Flour or Enriched White Flour | Thiamine, riboflavin, niacin, vitamin $B_6$, folic acid, d-pantothenic acid, calcium, iron, magnesium. |
| 16. | [Repealed, SOR/94-689, s. 2] | |
| 17. | Table salt, table salt substitutes | Iodine. |
| 18. | Dehydrated potatoes | Vitamin C. |
| 19. | Products simulating whole egg | Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin $B_6$, d-pantothenic acid, folic acid, vitamin $B_{12}$, alphatocopherol, calcium, iron, zinc, potassium. |
| 20. | [Repealed, SOR/90-830, s. 11] | |
| 21. | Goat’s milk, goat’s milk powder | Vitamin D |
| 22. | Partly skimmed goat’s milk, skimmed goat’s milk, partly skimmed goat’s milk powder, skimmed goat’s milk powder | Vitamins A and D |
| 23. | Evaporated goat’s milk | Vitamins C, D, folic acid |
| 24. | Evaporated partly skimmed goat’s milk, evaporated skimmed goat’s milk | Vitamins A, C, D, folic acid |

| | Column I<br>Food | Column II<br>Vitamin, Mineral Nutrient or Amino Acid |
|---|---|---|
| 25. | Pre-cooked rice as defined in subsection B.13.010.1(1) | Thiamine, niacin, vitamin $B_6$, folic acid, pantothenic acid, iron |
| 26. | Mineral water, spring water, water in sealed containers, prepackaged ice | Fluorine |
| 27. | Liquid whole egg, dried whole egg, frozen whole egg, liquid yolk, dried yolk, frozen yolk, liquid egg-white, (liquid albumen), dried egg-white (dried albumen), frozen egg-white (frozen albumen), liquid whole egg mix, dried whole egg mix, frozen whole egg mix, liquid yolk mix, dried yolk mix, frozen yolk mix | Vitamin A, Vitamin D, Vitamin E, thiamine, riboflavin, niacin, vitamin $B_6$, folacin, vitamin $B_{12}$, pantothenic acid, calcium, phosphorus, magnesium, potassium, iron, zinc |

SOR/78-64, s. 8; SOR/78-403, s. 29; SOR/78-478, s. 3; SOR/78-637, s. 11(E); SOR/78-698, s. 10; SOR/79-6, s. 1; SOR/81-60, s. 14; SOR/83-858, s. 2; SOR/84-300, s. 62; SOR/85-623, s. 4; SOR/86-320, s. 2; SOR/87-640, s. 10; SOR/88-559, s. 36; SOR/89-145, s. 3; SOR/89-198, s. 18; SOR/90-830, s. 11; SOR/94-35, s. 5; SOR/94-689, s. 2; SOR/95-474, s. 6; SOR/96-259, s. 8; SOR/2010-143, s. 39(E).

Previous Version

D.03.003. Section D.03.002 does not apply to a food when all of the following conditions are met:

(*a*) the food is

(i) a gluten-free food referred to in paragraph B.24.003(1)(*g*), or

(ii) represented for a special dietary use referred to in paragraph B.24.003(1)(*h*) or (*i*);

(*b*) no standard is prescribed in these Regulations for the food; and

(*c*) the food is not advertised.

SOR/78-64, s. 9; SOR/84-334, s. 2; SOR/90-830, s. 12; SOR/95-444, s. 3.

# Division 4

# [Repealed, SOR/2003-196, s. 105]

# Division 5

# Minerals In Drugs

D.05.001. to D.05.007 [Repealed, SOR/2003-196, s. 106]

D.05.008. (1) Subject to subsection (2), no person shall sell a drug containing fluorine if the largest recommended daily dosage of that drug as shown on the label thereof would, if consumed by a person, result in a daily intake by that person of more than one milligram of fluoride ion.

(2) Subsection (1) does not apply to a drug sold by prescription.

SOR/81-196, s. 2.

D.05.009. Where a drug contains fluorine, both the inner and outer labels of the drug shall carry a cautionary statement that, if the drug is used in an area where the drinking water has a natural fluorine content in excess of 0.7 parts of fluoride ion per million parts of water or is artificially fluoridated, mottling of the tooth enamel of a user of the drug may result.

D.05.010. [Repealed, SOR/2003-196, s. 107]

# PART E

# CYCLAMATE AND SACCHARIN SWEETENERS

E.01.001. (1) In this Part,

“cyclamate sweetener” means

(*a*) cyclohexyl sulfamic acid or a salt thereof, or

(*b*) any substance containing cyclohexyl sulfamic acid or a salt thereof

that is sold as a sweetener; (édulcorant au cyclamate)

“saccharin sweetener” means

(*a*) saccharin or a salt thereof, or

(*b*) any substance containing saccharin or a salt thereof

that is sold as a sweetener. (édulcorant à la saccharine)

(2) Part B of these Regulations does not apply to any cyclamate sweetener or saccharin sweetener.

SOR/78-422, s. 4.

## Sale

E.01.002. No person shall

(*a*) sell a cyclamate sweetener or saccharin sweetener that is not labelled as required by this Part; or

(*b*) commencing June 15, 1978, sell any saccharin sweetener to the general public except on the premises of a pharmacy.

SOR/78-422, s. 4.

## Advertising

E.01.003. No person shall, in advertising to the general public a cyclamate sweetener or saccharin sweetener, make any representation other than with respect to the name, price and quantity of the sweetener.

SOR/78-422, s. 4.

## Labelling

E.01.004. (1) Every cyclamate sweetener that is not also a saccharin sweetener shall be labelled to state that such sweetener should be used only on the advice of a physician.

(2) Commencing June 1, 1979, every saccharin sweetener shall be labelled to state that

(*a*) continued use of saccharin may be injurious to health; and

(*b*) it should not be used by pregnant women except on the advice of a physician.

SOR/78-422, s. 4.

E.01.005. Commencing June 1, 1979, every cyclamate sweetener or saccharin sweetener shall be labelled to show

(*a*) a list of all the ingredients and, in the case of

(i) cyclohexyl sulfamic acid,

(ii) a salt of cyclohexyl sulfamic acid,

(iii) saccharin,

(iv) a saccharin salt, or

(v) carbohydrates,

the quantity thereof contained in the sweetener; and

(*b*) the energy value of the sweetener expressed in calories

(i) per teaspoonful, drop, tablet or other measure used in the directions for use, and

(ii) per 100 grams or 100 millilitres

of the sweetener.

SOR/78-422, s. 4.

# PART G

# CONTROLLED DRUGS

## Division 1

### General

G.01.001. (1) In this Part,

“agricultural implant” means a product that is presented in a form suitable to allow sustained release of an active ingredient over a certain period of time and that is intended for insertion under the skin of a food-producing animal for the purpose of increasing weight gain and improving feed efficiency; (implant agricole)

“common name” with reference to a controlled drug means the name in English or French by which the controlled drug is commonly known; (nom usuel)

“competent authority” means a public authority of a foreign country that is authorized under the laws of the country to approve the importation or exportation of controlled drugs into or from the country; (autorité compétente)

“controlled drug” means a drug set out in the schedule to this Part and includes a preparation; (drogue contrôlée)

“hospital” means a facility

(*a*) that is licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness, or

(*b*) that is owned or operated by the Government of Canada or the government of a province and that provides health services; (hôpital)

“international obligation” means an obligation in respect of a controlled drug set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres; (obligation internationale)

“licence”[SOR/2004-238, s. 1]

“licensed dealer” means the holder of a licence issued under section G.02.003.2; (distributeur autorisé)

“parenteral use” with reference to a controlled drug means administration by means of a hypodermic syringe, needle or other instrument through or into the skin of mucous membrane; (usage parentéral)

“permit” means a permit issued under section G.02.008; (permis)

“pharmacist”

(*a*) means a person who is registered and entitled under the laws of a province

(i) to practise pharmacy, and

(ii) to operate a pharmacy or dispensary

and who is operating a pharmacy or dispensary and is practising pharmacy thereunder in that province, and

(*b*) includes, for the purposes of sections G.01.002, G.01.003, G.03.002 to G.03.008, G.03.014, G.03.015 and G.03.017 and subsections G.05.003(3) and (4), a person who is

registered and entitled under the laws of a province to practise pharmacy and who is practising pharmacy in that province; (pharmacien)

“practitioner”[Repealed, SOR/97-228, s. 7]

“preparation” means a drug that contains a controlled drug and one or more active medicinal ingredients, in a recognized therapeutic dose, other than a controlled drug; (préparation)

“prescription” means a direction given by a practitioner that a stated amount of a specified controlled drug be dispensed for the person named therein; (ordonnance)

“proper name” with reference to a controlled drug means the name in English or French

(*a*) assigned to the drug in section C.01.002,

(*b*) that appears in bold face type for the drug in the Regulations and where the drug is dispensed in a form other than that described in Part C, the name of the dispensing form, or

(*c*) assigned in any of the publications mentioned in Schedule B to the Food and Drugs Act in the case of a drug not included in paragraph (*a*) or (*b*) of this definition; (nom propre)

“qualified person in charge” means the individual with the qualifications specified in subsection G.02.001.2(2) who is responsible for supervising the activities carried out by a licensed dealer under their licence at the premises specified in the licence; (personne qualifiée responsable)

“test kit” means an apparatus

(*a*) that contains reagent systems or buffering agents or both,

(*b*) that is used in the course of a chemical or analytical procedure for medical, laboratory, industrial, educational or research purposes, and

(*c*) the contents of which are not intended for administration to humans; (nécessaire d’essai)

“verbal order” means an order given orally. (commande verbale)

“written order”[Repealed, SOR/85-550, s. 1]

(2) The definitions in this subsection apply in this Part and Part J.

“Act” means the Controlled Drugs and Substances Act (Loi)

“advertisement” has the same meaning as in section 2 of the Food and Drugs Act. (publicité ou annonce)

“Department” has the same meaning as in section 2 of the Food and Drugs Act. (ministère)

“designated criminal offence” means

(*a*) an offence involving the financing of terrorism against any of sections 83.02 to 83.04 of the Criminal Code;

(*b*) an offence involving fraud against any of sections 380 to 382 of the Criminal Code;

(*c*) the offence of laundering proceeds of crime against section 462.31 of the Criminal Code;

(*d*) an offence involving a criminal organization against any of sections 467.11 to 467.13 of the Criminal Code; or

(*e*) a conspiracy or an attempt to commit, being an accessory after the fact in relation to, or any counselling in relation to, an offence referred to in paragraphs (*a*) to (*d*). (infraction désignée en matière criminelle)

“designated drug offence” means

(*a*) an offence against section 39, 44.2, 44.3, 48, 50.2 or 50.3 of the Food and Drugs Act, as those provisions read immediately before May 14, 1997,

(*b*) an offence against section 4, 5, 6, 19.1 or 19.2 of the Narcotic Control Act, as those provisions read immediately before May 14, 1997,

(*c*) an offence under Part I of the Controlled Drugs and Substances Act, except subsection 4(1), or

(*d*) a conspiracy or an attempt to commit, being an accessory after the fact in relation to, or any counselling in relation to, an offence referred to in any of paragraphs (*a*) to (*c*); (infraction désignée en matière de drogue)

“label” has the same meaning as in section 2 of the Food and Drugs Act. (étiquette)

“package” has the same meaning as in section 2 of the Food and Drugs Act. (emballage)

“Security Directive” means the Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances) published by the Department, as amended from time to time. (Directive en matière de sécurité)

(3) Unless otherwise provided, the definitions in subsection 2(1) of the Controlled Drugs and Substances Act apply in this Part and Part J.

SOR/78-220, s. 1; SOR/85-550, s. 1; SOR/86-91, s. 1; SOR/90-261, s. 1(F); SOR/92-386, s. 1; SOR/97-228, s. 7; SOR/97-515, s. 2; SOR/2003-135, s. 2; SOR/2004-238, s. 1.

G.01.002. (1) A person is authorized to have a controlled drug set out in any of items 1 to 3, 8 to 10, 12 to 14, 16 or 17 of Part I of the schedule to this Part in his or her possession where the person has obtained the controlled drug under these Regulations, in the course of activities performed in connection with the enforcement or administration of an Act or regulation, or from a person who is exempt under section 56 of the Controlled Drugs and Substances Act from the application of subsection 5(1) of that Act with respect to that controlled drug, and the person

(*a*) requires the controlled drug for his business or profession and is

(i) a licensed dealer,

(ii) a pharmacist, or

(iii) a practitioner who is registered and entitled to practise in the province in which he has such possession;

(*b*) is a practitioner who is registered and entitled to practise in a province other than the province in which he has such possession and such possession is for emergency medical purposes only;

(*c*) is a hospital employee or a practitioner in a hospital;

(*d*) has obtained the controlled drug for his own use from a practitioner or pursuant to a prescription that is not issued or obtained in contravention of these Regulations;

(*e*) is a practitioner of medicine who received the controlled drug under subsection G.06.001(3) or (4) and whose possession is for a purpose referred to in subsection G.06.001(5);

(*f*) is an agent of a practitioner of medicine who received the controlled drug under subsection G.06.001(3) and whose possession is for the purpose of complying with subsection G.06.001(4);

(*g*) is employed as an inspector, a member of the Royal Canadian Mounted Police, a police constable, peace officer or member of the technical or scientific staff of any department of the Government of Canada or of a province or university and such possession is for the purposes of and in connection with such employment;

(*h*) is a person other than a person referred to in paragraph (*e*) or (*f*), is exempted under section 56 of the Controlled Drugs and Substances Act with respect to possession of that controlled drug and whose possession is for a purpose set out in the exemption; or

(*i*) is a person referred to in paragraph G.06.001(5)(*b*).

(2) A person is authorized to have a controlled drug referred to in subsection (1) in his possession where the person is acting as the agent for any person referred to in paragraph (1)(*a*) to (*e*), (*h*) or (*i*).

(3) A person is authorized to have a controlled drug referred to in subsection (1) in his possession where

(*a*) the person is acting as the agent for a person he has reasonable grounds to believe is a person referred to in paragraph (1)(*g*); and

(*b*) the possession of the controlled drug is for the purpose of assisting that person in the enforcement or administration of an Act or a regulation.

SOR/97-515, s. 3; SOR/99-125, s. 1; SOR/2003-34, s. 1; SOR/2003-413, s. 1.

G.01.002.1. Section C.01.004 does not apply to a test kit that contains a controlled drug where a registration number has been issued for the test kit pursuant to section G.06.002.3 and has not been cancelled pursuant to section G.06.002.4.

SOR/80-543, s. 11.

G.01.003. In the case of a controlled drug that is dispensed by a pharmacist pursuant to a prescription, section C.01.004 does not apply but the label of the package in which the controlled drug is contained shall carry the following:

(*a*) the name and address of the pharmacy or pharmacist;

(*b*) the date and number of the prescription;

(*c*) the name of the person for whom the controlled drug is dispensed;

(*d*) the name of the practitioner;

(*e*) directions for use; and

(*f*) any other information that the prescription requires be shown on the label.

SOR/80-543, s. 11; SOR/2004-238, s. 2(F).

G.01.004. The Controlled Drugs and Substances Act and this Part do not apply in respect of a controlled drug that is contained in an agricultural implant and set out in Part III of the schedule to this Part, but nothing in this section exempts such a drug from the requirements of Part C.

SOR/92-386, s. 2; SOR/97-228, s. 8.

G.01.005. [Repealed, SOR/80-543, s. 12]

G.01.006. Except as otherwise provided in this Part, no person shall sell a controlled drug or preparation that does not comply with all provisions of Parts C and D applicable to it.

G.01.007. No person shall

(*a*) advertise a controlled drug to the general public; or

(*b*) issue or publish any other written advertisement respecting a controlled drug unless that advertisement carries the symbol  in a clear and conspicuous colour and size in the upper left quarter of the first page of the advertisement.

G.01.008. [Repealed, SOR/80-543, s. 12]

## Prescribed Manner of Notice of Application for an Order of Restoration

G.01.010. (1) For the purpose of subsection 24(1) of the Controlled Drugs and Substances Act, notice of application for an order of restoration shall be given in writing to the Attorney General by registered mail.

(2) The notice referred to in subsection (1) shall be mailed not less than 15 clear days prior to the date the application for an order of restoration is to be made to the magistrate and shall specify

(*a*) the magistrate to whom the application is to be made;

(*b*) the time and place where the application is to be heard;

(*c*) the controlled drug or other thing in respect of which the application is to be made; and

(*d*) the evidence upon which the applicant intends to rely to establish that he is entitled to possession of the controlled drug or other thing referred to in paragraph (*c*).

SOR/97-228, s. 9.

# Division 2

# Licences And Licensed Dealers

G.02.001. Subject to this Part, no person except a licensed dealer shall produce, make, assemble, import, export, sell, provide, transport, send or deliver a controlled drug.

SOR/2004-238, s. 3.

G.02.001.1. To be eligible for a dealer's licence, a person must be

(*a*) an individual who ordinarily resides in Canada;

(*b*) a corporation that has its head office in Canada or operates a branch office in Canada; or

(*c*) the holder of a position that includes responsibility for controlled drugs on behalf of a department of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada.

SOR/2004-238, s. 3.

G.02.001.2. (1) A licensed dealer

(*a*) shall designate one qualified person in charge, who may be the licensed dealer if the licensed dealer is an individual, who must work at the premises specified in the licence, have responsibility for supervising activities with respect to controlled drugs specified in the licence and for ensuring, on behalf of the licensed dealer, that those activities comply with these Regulations; and

(*b*) may designate an alternate qualified person in charge who must work at the premises specified the licence and have authority to replace the qualified person in charge when that person is absent.

(2) The qualified person in charge and, if applicable, the alternate qualified person in charge

(*a*) shall be familiar with the provisions of the Act and the regulations under it that apply to the licence of the licensed dealer who designated them and have knowledge of chemistry and pharmacology and experience in those fields to properly carry out their duties;

(*b*) shall be a pharmacist or a practitioner registered with a provincial professional licensing authority or possess a degree in an applicable science — such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, organic chemistry or chemical engineering — that is awarded by a Canadian university or, if awarded by a foreign university, that is recognized by a Canadian university or a Canadian professional association; and

(*c*) shall not have been convicted, as an adult, within the preceding 10 years, of

(i) a designated drug offence,

(ii) a designated criminal offence, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii).

SOR/2004-238, s. 3; SOR/2010-222, ss. 1(E), 34.

Previous Version

G.02.002. No licensed dealer may import or export a controlled drug without a permit.

G.02.002.1 A licensed dealer is authorized to have a controlled drug in his possession for the purpose of exporting the controlled drug from Canada if he has obtained the controlled drug pursuant to these Regulations.

SOR/97-515, s. 4.

G.02.003. (1) To apply for a dealer's licence, a person shall submit an application to the Minister containing

(*a*) if the licence is sought for

(i) an individual, the individual's name,

(ii) a corporation, the corporation's name and any other name registered with a province, under which it intends to carry out the activities specified in its dealer's licence or intends to identify itself; and

(iii) the holder of a position mentioned in paragraph G.02.001.1(*c*), the applicant's name and the title of the position;

(*b*) the address, telephone number and, if applicable, the facsimile number and e-mail address for the premises to which the dealer's licence would apply and, if different, the mailing address for the premises;

(*c*) the name, date of birth and gender of the individual in charge of the premises;

(*d*) with respect to the proposed qualified person in charge and, if applicable, the alternate proposed qualified person in charge,

(i) their name, date of birth and gender,

(ii) their academic qualifications, training and work experience relevant to their duties,

(iii) their hours of work at the premises,

(iv) their title at the premises,

(v) the name and title of their immediate supervisor at the premises, and

(vi) in the case of a pharmacist or a practitioner, the name of the province in which the person's current professional licence, certification or authorization was issued and the professional licence, certification or authorization number;

(*e*) the name and gender of the individuals authorized to place an order for a controlled drug on behalf of the applicant;

(*f*) in the case of a product or compound that contains a controlled drug but is not a test kit and that would be made or assembled for or by the applicant, a list that sets out

(i) the brand name, if any, of each product or compound,

(ii) the controlled drug in each product or compound,

(iii) the strength per unit of the controlled drug in each product or compound,

(iv) the quantity or package sizes of each product or compound, and

(v) if the product or compound would be made or assembled by or for another licensed dealer under a custom order, the name, address and the dealer's licence number of the other dealer;

(*g*) the activities referred to in section G.02.001 for which the licence is sought that would be carried out at the premises to which the dealer's licence would apply;

(*h*) if the licence is sought to produce a controlled drug other than a product or compound that contains a controlled drug,

(i) the name of the controlled drug to be produced,

(ii) the quantity that the applicant expects to produce under the dealer's licence and the period during which that quantity would be produced, and

(iii) if the controlled drug would be produced for another licensed dealer under a custom order, the name, address and dealer's licence number of the other dealer;

(*i*) a detailed description of the security measures at the premises, determined in accordance with the Security Directive;

(*j*) a detailed description of the method that the applicant proposes to use for recording their controlled drug transactions; and

(*k*) for any activity referred to in section G.02.001, other than the activities described in paragraphs (*f*) and (*h*), the controlled drug and the purpose for carrying out the activity.

(2) An application for a dealer's licence must

(*a*) be signed by the individual in charge of the premises to which the licence would apply; and

(*b*) be accompanied by a statement signed by the individual in charge indicating that

(i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) the individual has the authority to bind the applicant.

(3) An application for a dealer's licence must be accompanied by

(*a*) declarations signed by the individual in charge of the premises to which the application applies, the proposed qualified person in charge and, if applicable, the alternate proposed qualified person in charge, stating that they have not been convicted, as an adult, within the previous 10 years, of

(i) a designated drug offence,

(ii) a designated criminal offence, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(*b*) a document issued by a Canadian police force with respect to each of the persons referred to in paragraph (*a*), stating whether the person has or has not been convicted, as an adult, during the preceding 10 years, of a designated drug offence or a designated criminal offence;

(*c*) if any of the persons referred to in paragraph (*a*) has ordinarily resided in a country other than Canada during the preceding 10 years, a document issued by a police force of that country stating whether the person has or has not been convicted in that country, as an adult, during the preceding 10 years, of an offence that would have constituted a designated drug offence or a designated criminal offence if committed in Canada;

(*d*) a statement, signed and dated by the individual in charge of the premises to which the application applies, stating that the proposed qualified person in charge and, if applicable, the alternate proposed qualified person in charge have the knowledge and experience required under paragraph G.02.001.2(2)(*a*);

(*e*) if the proposed qualified person in charge or, if applicable, the alternate proposed qualified person in charge is not a pharmacist or a practitioner registered with a provincial professional licensing authority, a copy of the person's degree required under paragraph G.02.001.2(2)(*b*) and a copy of the course transcript for that degree;

(*f*) if the applicant's name appears on the label of a product or compound that contains a controlled drug, a copy of the inner label, as defined in section A.01.010, for each product or compound to which the licence would apply; and

(*g*) if the applicant is a corporation, a copy of

(i) the certificate of incorporation or other constituting instrument, and

(ii) any document filed with the province in which the premises to which the licence would apply are located that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.

(4) The method proposed by the applicant under paragraph (1)(*j*) must

(*a*) allow for the recording of controlled drug transactions in accordance with section G.02.014; and

(*b*) permit the Minister to audit the activities of the licensed dealer with respect to controlled drugs.

(5) The documents referred to in paragraphs (3)(*b*) and (*c*) are not required if the persons referred to in those paragraphs consent in writing

(*a*) to having a criminal record check carried out for them, as an adult, in respect of the offences referred to in those paragraphs during the preceding 10 years;

(*b*) to provide all necessary information and to submit to any means of identification required to obtain the criminal record check; and

(*c*) to pay the fee established by the Royal Canadian Mounted Police, Criminal Record Verification for Civil Purposes Fee Regulations.

SOR/2004-238, s. 4; SOR/2010-222, s. 2.

Previous Version

G.02.003.1. The Minister may, on receiving an application made under this Part, require the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to process the application.

SOR/2004-238, s. 4.

G.02.003.2. Subject to section G.02.003.3, the Minister shall, after examining the information and documents required under sections G.02.003 and G.02.003.1, issue a dealer's licence that contains

(*a*) the licence number;

(*b*) the name of the holder of the licence or the title of the position they hold, as the case may be, or, if the holder is a corporation, its corporate name;

(*c*) a list of the activities that are permitted;

(*d*) the address of the premises at which the licensed dealer may carry on the permitted activities;

(*e*) the name of the controlled drug for which the activities are permitted;

(*f*) the security level at the premises, determined in accordance with the Security Directive;

(*g*) the effective date of the licence;

(*h*) the expiry date of the licence, which may not be later than three years after its effective date;

(*i*) any conditions to be met by the holder of the licence to

(i) ensure that an international obligation is respected,

(ii) provide the security level referred to in paragraph (*f*), or

(iii) reduce the potential security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use;

(*j*) in the case of a producer of a controlled drug, the quantity of the controlled drug that may be produced under the licence and the period during which that quantity may be produced; and

(*k*) in the case of the maker or assembler of a product or compound that contains a controlled drug but is not a test kit, an annexed list that sets out the following information for each type of product or compound that may be made or assembled under the licence:

(i) the licence number,

(ii) the brand name, if any, of each product or compound,

(iii) the controlled drug in each product or compound,

(iv) the strength per unit of the controlled drug in each product or compound, and

(v) the quantity or package sizes of each product or compound.

SOR/2004-238, s. 4; SOR/2010-222, ss. 3, 35(F).

Previous Version

G.02.003.3. (1) The Minister shall refuse to issue, renew or amend a dealer's licence if

(*a*) the applicant is not an eligible person under section G.02.001.1;

(*b*) an inspector who has requested an inspection has not been given the opportunity by the applicant to conduct an inspection under section G.02.015;

(*c*) false or misleading information or false or falsified documents were submitted in or with the application;

(*d*) an activity for which the licence is requested would not be in compliance with an international obligation;

(*e*) information received from a competent authority or the United Nations raises a reasonable belief that the applicant has been involved in the diversion of a controlled drug to an illicit market or use or has been involved in an activity that was not in compliance with an international obligation;

(*f*) the applicant does not have in place the security measures set out in the Security Directive in respect of an activity for which the licence is requested;

(*g*) the applicant is in contravention of or has contravened during the preceding 10 years

(i) a provision of the Act or the regulations made or continued under it, or

(ii) a term or condition of another dealer's licence or of an import or export permit issued to the applicant under any regulations made or continued under the Act;

(*h*) the issuance, amendment or renewal of the licence would likely create a risk to public health, safety or security, including the risk of a controlled drug being diverted to an illicit market or use;

(*i*) the individual in charge of the premises, the proposed qualified person in charge or, if applicable, the alternate proposed qualified person in charge has been convicted, as an adult, within the preceding 10 years, of

(i) a designated drug offence,

(ii) a designated criminal offence, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(*j*) the proposed method referred to in paragraph G.02.003(1)(*j*) is not capable of recording controlled drug transactions as required under section G.02.014 or permitting the Minister to audit the applicant's activities with respect to controlled drugs in a timely manner; or

(*k*) the additional information required under section G.02.003.1 has not been provided or is insufficient to process the application.

(2) Unless it is necessary to do so to protect public health, safety or security, including preventing a controlled drug from being diverted to an illicit market or use, the Minister shall not refuse to issue, renew or amend a licence under paragraph (1)(*c*) or (*g*) if the applicant

(*a*) does not have a history of non compliance with the Act or any regulation made or continued under it; and

(*b*) has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act and these Regulations.

SOR/2004-238, s. 4; SOR/2010-222, ss. 4, 35(F).

Previous Version

G.02.003.4. (1) To apply to renew a dealer's licence, a licensed dealer shall submit to the Minister

(*a*) the information referred to in paragraphs G.02.003(1)(*a*) to (*k*); and

(*b*) the following documents, namely,

(i) the documents referred to in paragraphs G.02.003(3)(*a*) and (*d*) and, subject to subsection G.02.003(5), the document referred to in paragraph G.02.003(3)(*b*),

(ii) if applicable and if not previously submitted in respect of the dealer's licence that is being renewed, the document referred to in paragraph G.02.003(3)(*e*), and

(iii) the original dealer's licence that is to be renewed.

(2) An application for renewal must

(*a*) be signed by the individual in charge of the premises to which the renewed dealer's licence would apply; and

(*b*) be accompanied by a statement signed by the individual in charge indicating that

(i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section G.02.003.3, the Minister shall, after examining the information and documents required under subsections (1) and (2) and section G.02.003.1, issue a renewed dealer's licence that contains the information specified in paragraphs G.02.003.2(*a*) to (*k*).

SOR/2004-238, s. 4.

G.02.003.5. (1) To have its dealer's licence amended, a licensed dealer shall submit to the Minister

(*a*) an application in writing describing the proposed amendment, accompanied by the supporting documents referred to in section G.02.003 that are relevant to the proposed amendment; and

(*b*) the original dealer's licence.

(2) An application for amendment must

(*a*) be signed by the individual in charge of the premises to which the amended dealer's licence would apply; and

(*b*) be accompanied by a statement signed by the individual in charge indicating that

(i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section G.02.003.3, the Minister shall, after examining the application for amendment and the supporting documentation, amend the dealer's licence in accordance with the application and may add any conditions to be met by the holder of the licence to

(*a*) ensure that an international obligation is respected;

(*b*) provide for the security level referred to in paragraph G.02.003.2(*f*) or the new level required as a result of the amendment being implemented; or

(*c*) reduce the potential security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use.

SOR/2004-238, s. 4; SOR/2010-222, ss. 5(F), 35(F).

Previous Version

G.02.003.6. (1) A licensed dealer shall

(*a*) obtain the Minister's approval before making any of the following changes, namely,

(i) a change relating to the security at the premises referred to in the dealer's licence, or

(ii) the replacement or addition of

(A) the individual in charge of the premises to which the dealer's licence applies,

(B) the qualified person in charge and, if applicable, the alternate qualified person in charge at the premises to which the dealer's licence applies, and

(C) an individual authorized to place an order for a controlled drug on behalf of the licensed dealer;

(*b*) notify the Minister, not later than 10 days after the change, when a person referred to in clause (*a*)(ii)(A) or (C) ceases to carry out their duties as specified in

(i) the application for the dealer's licence under section G.02.003,

(ii) the application to renew the dealer's licence under section G.02.003.4, or

(iii) the request for approval under paragraph (*a*); and

(*c*) notify the Minister, not later than the next business day after the change, when a person referred to in clause (*a*)(ii)(B) ceases to carry out their duties as specified in

(i) the application for the dealer's licence under section G.02.003,

(ii) the application to renew the dealer's licence under section G.02.003.4, or

(iii) the request for approval under paragraph (*a*).

(2) The licensed dealer shall, with the request for approval referred to in subparagraph (1)(*a*)(ii), provide the Minister with the following information and documents with respect to the new person:

(*a*) in the case of the replacement of the individual in charge of the premises to which the dealer's licence applies,

(i) the information specified in paragraph G.02.003(1)(*c*), and

(ii) the declarations specified in paragraph G.02.003(3)(*a*) and, subject to subsection G.02.003(5), the documents specified in paragraphs G.02.003(3)(*b*) and (*c*);

(*b*) in the case of the replacement of the qualified person in charge or the replacement or addition of the alternate qualified person in charge at the premises to which the dealer's licence applies,

(i) the information specified in paragraph G.02.003(1)(*d*), and

(ii) the documents specified in paragraphs G.02.003(3)(*a*), (*d*) and (*e*) and, subject to section G.02.003(5), the documents specified in paragraphs G.02.003(3)(*b*) and (*c*); and

(*c*) in the case of the replacement or addition of an individual who is authorized to place an order for a controlled drug on behalf of the licensed dealer, the individual's name and gender.

SOR/2004-238, s. 4.

G.02.003.7. The Minister shall revoke a dealer's licence at the request of the licensed dealer or on being notified by the licensed dealer that the licence has been lost or stolen.

SOR/2004-238, s. 4.

G.02.003.8. (1) Subject to subsection (2), the Minister shall revoke a dealer's licence in accordance with section G.02.003.91 if

(*a*) the licence was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application;

(*b*) the licensed dealer has failed to comply with a provision of the Act, a regulation under it or a term or condition of the licence or of an import or export permit issued under this Part;

(*c*) the licensed dealer is no longer an eligible person under section G.02.001.1;

(*d*) it is discovered that the individual in charge of the premises to which the licence applies, the qualified person in charge or, if applicable, the alternate qualified person in charge at those premises, has been convicted, as an adult, within the preceding 10 years, of

(i) a designated drug offence,

(ii) a designated criminal offence, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii); or

(*e*) information received from a competent authority or the United Nations raises a reasonable belief that the licensed dealer has been involved in the diversion of a controlled drug to an illicit market or use.

(2) Unless it is necessary to do so to protect public health, safety or security, including preventing a controlled drug from being diverted to an illicit market or use, the Minister shall not revoke a dealer's licence under paragraph (1)(*a*) or (*b*) if the licensed dealer

(*a*) has no history of non-compliance with the Act and the regulations made or continued under it; and

(*b*) has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act and these Regulations.

SOR/2004-238, s. 4; SOR/2010-222, ss. 6, 35(F).

Previous Version

G.02.003.9. The Minister shall suspend a dealer's licence without prior notice if it is necessary to do so to protect security, public health or safety, including preventing a controlled drug from being diverted to an illicit market or use.

SOR/2004-238, s. 4; SOR/2010-222, s. 35(F).

Previous Version

G.02.003.91. (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a dealer's licence under this Part, the Minister shall

(*a*) send a notice to the applicant or to the holder of the licence, together with a written report that sets out the reasons for the proposed refusal or revocation; and

(*b*) give the applicant or holder an opportunity to be heard in respect of the proposed refusal or revocation.

(2) The suspension of a dealer's licence under this Part takes effect as soon as the Minister notifies the holder of the licence of the decision to suspend and provides a written report that sets out the reasons for the suspension.

(3) A person who receives a notice of suspension referred to in subsection (2) may, within 10 days after receiving the notice, provide the Minister with reasons why the suspension of the licence is unfounded.

SOR/2004-238, s. 4.

G.02.004. A licensed dealer may, subject to the terms and conditions of their licence, produce, make, assemble, sell, provide, transport, send or deliver only the controlled drugs specified in their dealer's licence.

SOR/2004-238, s. 4.

G.02.005. to G.02.007 [Repealed, SOR/2004-238, s. 4]

G.02.008. The Minister may, upon application therefor, issue a permit to any licensed dealer for the importation or exportation of a controlled drug.

G.02.009. An application for a permit shall be in a form approved by the Minister.

G.02.010. Every licence or permit issued under this Part is subject to the condition that the licensed dealer will comply with the provisions of this Part.

G.02.011. The Minister shall revoke a permit at the request of the holder or if the holder informs the Minister that the permit has been lost or stolen.

SOR/2004-238, s. 5; SOR/2010-222, s. 7.

Previous Version

G.02.011.1. (1) Subject to subsection (2), the Minister shall revoke a permit by taking the same measures as those set out in subsection G.02.003.91(1) if

(*a*) any of paragraphs G.02.003.8(1)(*a*) to (*e*) applies with respect to the dealer's licence as it pertains to the controlled drug to be imported or exported; or

(*b*) the import or export permit was issued on the basis of false or misleading information or false or falsified documents submitted in support of the application.

(2) Unless it is necessary to do so to protect public health, safety or security, including preventing a controlled drug from being diverted to an illicit market or use, the Minister shall not revoke a permit under paragraph G.02.003.8(1)(*a*) or (*b*) or G.02.011.1(1)(*b*) if the holder meets the conditions set out in paragraphs G.02.003.8(2)(*a*) and (*b*).

(3) The Minister may revoke a permit if the holder fails to comply with the decision of the Minister to suspend the permit under section G.02.011.2 or if the situation giving rise to the suspension is not rectified.

SOR/2010-222, s. 7.

G.02.011.2. (1) The Minister shall suspend a permit without prior notice if

(*a*) the dealer's licence as it pertains to the controlled drug to be imported or exported has expired or has been suspended or revoked;

(*b*) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health, safety or security;

(*c*) the Minister has reasonable grounds to believe that the continuation of the permit would present a risk of a controlled drug being diverted to an illicit market or use; or

(*d*) the import or export would contravene the laws of the country of export or import or a country of transit or transhipment.

(2) A decision of the Minister to suspend a permit takes effect as soon as the Minister notifies the holder of the decision and provides a written report of the reasons for the suspension.

(3) A person whose permit is suspended under subsection (1) may, within 10 days after receiving the notice of suspension, provide the Minister with reasons why the suspension is unfounded.

SOR/2010-222, s. 7.

G.02.012. A dealer’s licence is valid until the earlier of

(*a*) the expiry date set out in the licence, and

(*b*) the revocation or suspension of the licence under section G.02.003.7, G.02.003.8 or G.02.003.9.

SOR/2004-238, s. 5.

G.02.013. A permit issued under section G.02.008 is valid only for the particular importation or exportation in respect of which it was issued.

G.02.014. (1) Every licensed dealer shall keep a record of the following:

(*a*) the name and quantity of any controlled drug received by the licensed dealer, the name and address of the person who sold or provided it and the date it was received;

(*b*) the name, quantity and form of any controlled drug sold or provided by the licensed dealer, the name and address of the person to whom it was sold or provided and the date it was sold or provided;

(*c*) the name and quantity of any controlled drug used in the making or assembling of a product or compound containing that controlled drug, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;

(*c.1*) the name and quantity of any controlled drug produced and the date on which it was placed in stock; and

(*d*) the name and quantity of any controlled drug he had in stock at the end of each month.

(2) The record of information referred to in subsection (1) shall be kept

(*a*) in a manner that permits an audit to be made;

(*b*) subject to subsection (3), in a book, register or similar record maintained exclusively for controlled drugs; and

(*c*) for any period of at least two years on the premises described in the licence of the licensed dealer.

(3) The record of information referred to in paragraphs (1)(*a*), (*b*) and (*d*) may, with respect to a controlled drug listed in Part II or III of the schedule to this Part, be kept in a form other than that specified in paragraph (2)(*b*).

SOR/78-427, s. 1; SOR/97-228, s. 10; SOR/2004-238, s. 6; SOR/2010-222, s. 8(E).

Previous Version

G.02.015. (1) The Minister may, in respect of an applicant for a dealer’s licence or a licensed dealer, require an inspection, at any reasonable time, of

(*a*) the premises used or intended to be used in producing, making, assembling or storing a controlled drug; and

(*b*) the process and conditions of the producing, making, assembling or storing.

(2) [Repealed, SOR/2010-222, s. 9]

SOR/78-427, s. 2; SOR/2004-238, s. 7; SOR/2010-222, s. 9.

Previous Version

G.02.016. Every licensed dealer shall

(*a*) furnish such information respecting the dealings of such person in any controlled drug in such form and at such times as the Minister may require;

(*b*) produce to an inspector any books, records or documents required to be kept by this Part;

(*c*) permit an inspector to make copies of or to take extracts from such books, records and documents; and

(*d*) permit an inspector to check all stock of controlled drugs located on the premises described in the licence of the licensed dealer.

G.02.017. [Repealed, SOR/78-427, s. 3]

G.02.018. Every licensed dealer shall notify the Minister promptly of changes in the following:

(*a*) [Repealed, SOR/2010-222, s. 10]

(*b*) the premises in which a controlled drug is produced, made, assembled or stored; and

(*c*) the process and conditions of the producing, making, assembling or storing.

SOR/2004-238, s. 8; SOR/2010-222, s. 10.

Previous Version

G.02.019. Every licensed dealer shall

(*a*) provide such protection against loss or theft of any controlled drug in his possession as may be required by the Minister;

(*b*) report to the Minister any loss or theft of a controlled drug within 10 days of his discovery thereof; and

(*c*) securely pack a controlled drug in its immediate container and seal it in such a manner that it cannot be opened without breaking the seal.

SOR/88-482, s. 2(F).

G.02.020. A licensed dealer may only import into or export out of Canada a controlled drug at the place specified in his permit.

G.02.021. A licensed dealer shall securely pack in a package sealed in such a manner that it cannot be opened without breaking the seal any controlled drug intended for export out of Canada.

G.02.022. A licensed dealer shall in taking delivery of a controlled drug imported by him or in making delivery of a controlled drug

(*a*) take such steps as are necessary to ensure the safekeeping of the drug during transit; and

(*b*) use such method of transportation as will ensure an accurate record being kept of the drug and of the signatures of any persons having charge of the drug until it is delivered to the consignee.

G.02.023. Notwithstanding section G.02.022, a preparation may be delivered by common carrier.

G.02.024. A licensed dealer shall not sell or provide a controlled drug to any person other than a

(*a*) licensed dealer;

(*b*) pharmacist;

(*c*) practitioner;

(*d*) hospital employee or a practitioner in a hospital;

(*e*) [Repealed, SOR/2010-222, s. 11]

(*f*) a person who has been granted an exemption under section 56 of the Controlled Drugs and Substances Act with respect to the possession of a controlled drug.

SOR/78-220, s. 3; SOR/85-550, s. 2; SOR/99-125, s. 2; SOR/2004-238, s. 9; SOR/2010-222, s. 11.

Previous Version

G.02.024.1. Subject to section G.02.024.2 and notwithstanding sections G.02.024 and G.02.025, no licensed dealer shall

(*a*) sell or provide a controlled drug, other than a preparation, to a pharmacist named in a notice given by the Minister under section G.03.017.2;

(*b*) sell or provide a preparation to a pharmacist named in a notice given by the Minister under section G.03.017.2;

(*c*) sell or provide a controlled drug, other than a preparation, to a practitioner named in a notice given by the Minister under section G.04.004.2; or

(*d*) sell or provide a preparation to a practitioner named in a notice given by the Minister under section G.04.004.2.

SOR/2003-135, ss. 7, 8; SOR/2004-238, s. 10.

G.02.024.2. Section G.02.024.1 does not apply to a licensed dealer to whom the Minister has issued a notice of retraction of the notice

(*a*) under section G.03.017.3, in respect of a pharmacist named in a notice issued by the Minister under section G.03.017.2; or

(*b*) under section G.04.004.3, in respect of a practitioner named in a notice issued by the Minister under section G.04.004.2.

SOR/2003-135, s. 3.

G.02.025. (1) Subject to this section, a licensed dealer may, in accordance with the terms and conditions of their dealer's licence, sell or provide a controlled drug to a person referred to in section G.02.024 if

(*a*) [Repealed, SOR/2010-222, s. 12]

(*b*) the licensed dealer has received, on the premises described in the licence,

(i) a written order,

(ii) an order sent through a computer from a remote input device, or

(iii) a verbal order for a controlled drug listed in Part II or III of the schedule to this Part

that specifies the name and quantity of the drug to be supplied.

(2) A licensed dealer who has received an order referred to in subparagraph (1)(*b*)(i) and verified the signature on the order may sell or provide a controlled drug to a person referred to in section G.02.024, if the order is signed and dated by one of the following persons:

(*a*) if the controlled drug is to be sold or provided to a person referred to in paragraph G.02.024(*a*), (*b*), (*c*) or (*f*), by that person; or

(*b*) if the controlled drug is to be provided to a hospital employee or a practitioner in a hospital, by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to sign the order.

(3) A licensed dealer may sell or provide a controlled drug pursuant to an order received from a remote input device through a computer if the computer program and the remote input device meet the requirements of subsections (5) and (6).

(3.1) A licensed dealer who has received an order sent through a computer from a remote input device referred to in subparagraph (1)(*b*)(ii) may provide a controlled drug to a hospital employee or to a practitioner in a hospital if the order has been placed by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to place the order.

(3.2) A licensed dealer who has received a verbal order referred to in subparagraph (1)(*b*)(iii) may provide a controlled drug listed in Part II or III of the schedule to this Part to a hospital employee or to a practitioner in a hospital if the order has been placed by the pharmacist in charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to place the order.

(4) A licensed dealer who has received a verbal order referred to in subparagraph (1)(*b*)(iii), and has provided a controlled drug listed in Part II or III of the schedule to this Part to a person referred to in paragraphs G.02.024(*b*) to (*d*), shall immediately record

(*a*) the name of the person to whom the controlled drug was sold or provided;

(*b*) if the drug was provided to a hospital employee or a practitioner in a hospital, the name of the pharmacist in charge of the dispensary of the hospital or the name of the practitioner authorized by the person in charge of the hospital to sign the order; and

(*c*) the date that the order is received.

(5) For the purposes of this section, a remote input device shall be a device for transmitting electronically orders for drugs, other than by voice communication, that

(*a*) contains a unique identifying code that can be related to the device and the pharmacist or practitioner in whose possession and care the remote input device has been placed;

(*b*) is in the possession and care of that pharmacist or practitioner; and

(*c*) is designed in such a way that the unique identifying code for the remote input device is an integral part of the circuitry and can only be modified by the dismantling of the device.

(6) For the purposes of this section, a computer program shall be able to

(*a*) identify the remote input device, the name and address of the pharmacist or practitioner in whose possession and care the remote input device has been placed;

(*b*) identify the pharmacist or practitioner placing the order by means of an identifying code unique to that pharmacist or practitioner;

(*c*) process separately and identify controlled drugs by the segregation of the orders for those drugs;

(*d*) detect unusual orders and thereby necessitate manual intervention by the licensed dealer; and

(*e*) necessitate manual intervention by the licensed dealer if one or more of the check procedures fails.

(7) Where a licensed dealer has received, from a pharmacist or practitioner, an order sent through a computer from a remote input device referred to in subparagraph (1)(*b*)(ii) or a verbal order referred to in subparagraph (1)(*b*)(iii), he shall, within five working days of filling the order for a controlled drug, obtain and keep a receipt that includes

(*a*) the signature of the pharmacist or the practitioner who received the controlled drug;

(*b*) the date the pharmacist or practitioner received the controlled drug; and

(*c*) the name and the quantity of the controlled drug.

(8) If a licensed dealer has not received a receipt from a pharmacist or practitioner under subsection (7) within the time prescribed by that subsection, the dealer shall not, until after receiving the receipt, sell or provide a controlled drug to the pharmacist or practitioner pursuant to a further

(*a*) order sent through a computer from a remote input device referred to in subparagraph (1)(*b*)(ii); or

(*b*) verbal order referred to in subparagraph (1)(*b*)(iii).

from that pharmacist or practitioner.

SOR/78-220, s. 4; SOR/78-427, s. 4; SOR/85-550, s. 3; SOR/88-482, s. 3(F); SOR/90-261, s. 2(F); SOR/97-228, s. 11; SOR/2004-238, s. 11; SOR/2010-222, s. 12.

Previous Version

G.02.026. A licensed dealer shall not sell or provide a controlled drug more than once in respect of one order unless

(*a*) the order for the drug states that the quantity of the drug is to be sold or provided

(i) in specified portions,

(ii) in separate deliveries not exceeding four deliveries, and

(iii) at specified intervals; or

(*b*) at the time of receipt of the order the licensed dealer temporarily does not have in stock the quantity of the drug ordered, in which case the dealer may sell or provide against the order the quantity of the drug that the dealer has available and deliver the balance later in accordance with the order.

SOR/2004-238, s. 12; SOR/2010-222, s. 13(F).

Previous Version

G.02.027. [Repealed, SOR/80-543, s. 12]

# Division 3

# Pharmacists

G.03.001. (1) A pharmacist, on receipt of a controlled drug from a licensed dealer or from another pharmacist, shall keep a record of the name and quantity of the controlled drug received by them, the name and address of the person who sold or provided it and the date it was received.

(2) The record of information referred to in subsection (1) shall be kept

(*a*) in a manner that permits an audit to be made; and

(*b*) subject to subsection (3), in a book, register or similar record maintained exclusively for controlled drugs.

(3) The record of information referred to in subsection (1) may, with respect to a controlled drug listed in Part II or III of the schedule to this Part, be kept in a form other than that specified in paragraph (2)(*b*).

SOR/78-427, s. 5; SOR/85-550, s. 4; SOR/86-91, s. 2(F); SOR/90-261, s. 3(F); SOR/97-228, s. 12; SOR/2004-238, s. 13; SOR/2010-222, s. 14(E).

Previous Version

G.03.002. No pharmacist shall, except as otherwise provided in this Part, sell or provide a controlled drug to any person unless the pharmacist has first been provided with a prescription for it, and

(*a*) if the prescription is in writing, it has been signed and dated by the practitioner issuing the same and the signature of the practitioner where not known to the pharmacist, has been verified by him; or

(*b*) if the prescription is given verbally, the pharmacist has taken reasonable precaution to satisfy himself that the person giving the prescription is a practitioner.

SOR/2004-238, s. 14.

G.03.002.1. Subject to section G.03.002.2 and notwithstanding sections G.03.002, G.03.003 and G.03.005, no pharmacist shall

(*a*) sell or provide a controlled drug, other than a preparation, to a pharmacist named in a notice given by the Minister under section G.03.017.2;

(*b*) sell or provide a preparation to a pharmacist named in a notice given by the Minister under section G.03.017.2;

(*c*) dispense, sell or provide a controlled drug, other than a preparation, to, or pursuant to a prescription or order given by, a practitioner named in a notice given by the Minister under section G.04.004.2; or

(*d*) dispense, sell or provide a preparation to a practitioner or pursuant to a prescription or order given by a practitioner named in a notice given by the Minister under section G.04.004.2.

SOR/2003-135, ss. 7, 8; SOR/2004-238, s. 15.

G.03.002.2. Section G.03.002.1 does not apply to a pharmacist to whom the Minister has issued a notice of retraction of the notice

(*a*) under section G.03.017.3, in respect of a pharmacist named in a notice issued by the Minister under section G.03.017.2; or

(*b*) under section G.04.004.3, in respect of a practitioner named in a notice issued by the Minister under section G.04.004.2.

SOR/2003-135, s. 4.

G.03.003. A pharmacist may sell or provide a controlled drug to a practitioner for use in their practice

(*a*) upon a written order, signed and dated by that practitioner, that has been verified if the signature of the practitioner is unknown to the pharmacist; or

(*b*) upon a verbal order specifying the name and quantity of the drug if the pharmacist has taken reasonable precautions to satisfy themself that the person making the order is a practitioner.

SOR/85-550, s. 5; SOR/2004-238, s. 16.

G.03.004. A pharmacist shall, in respect of controlled drugs sold or provided to a practitioner under section G.03.003, keep in a special prescription file a record showing the date, the name and address of the practitioner, and the quantity and kind of controlled drug sold or provided.

SOR/2004-238, s. 17.

G.03.005. A pharmacist may provide a controlled drug to a hospital employee or to a practitioner in a hospital on receipt of a written order signed and dated by the pharmacist in

charge of the dispensary of the hospital or by a practitioner authorized by the person in charge of the hospital to sign the order, if the signature of that pharmacist or practitioner is known to the pharmacist or, if unknown, has been verified.

SOR/85-550, s. 6; SOR/2004-238, s. 18(E).

G.03.006. A pharmacist shall not refill a prescription for a controlled drug unless

(*a*) the practitioner, at the time that he issued the prescription, directed in writing, in the case of a controlled drug listed in Part I of the schedule to this Part, or directed in writing or orally, in the case of a controlled drug listed in Part II or III of the schedule to this Part, that the prescription be refilled, the number of times that it may be refilled and the dates for or the intervals between refills; and

(*b*) the pharmacist keeps a record of each refilling of a prescription.

SOR/78-427, s. 6; SOR/97-228, s. 13.

G.03.007 A pharmacist who dispenses, pursuant to an order or prescription, a controlled drug listed in Part I of the schedule to this Part, other than a preparation, shall forthwith enter in a book, register or similar record maintained for such purposes

(*a*) the name and address of the person named in the order or prescription;

(*b*) the name, initials and address of the practitioner who issued the order or prescription;

(*c*) the name or initials of the pharmacist who dispensed the controlled drug;

(*d*) the name, quantity and form of the controlled drug dispensed;

(*e*) the date on which the controlled drug was sold or provided; and

(*f*) the number assigned to the order or prescription.

SOR/78-427, s. 7; SOR/81-359, s. 1(F); SOR/97-228, s. 14; SOR/2004-238; s. 19.

G.03.008. A pharmacist shall, before dispensing a controlled drug pursuant to a prescription given orally or a verbal order, make a written record thereof, setting forth,

(*a*) the name and address of the person named in the prescription;

(*b*) the name, quantity and form of such controlled drug;

(*c*) the directions for use given therewith;

(*d*) the name, initials and address of the practitioner who issued the prescription;

(*e*) the name or initials of the pharmacist who dispensed such controlled drug;

(*f*) the date on which the controlled drug was sold or provided; and

(*g*) the number assigned to the prescription.

SOR/85-550, s. 7; SOR/2004-238, s. 20.

G.03.009. A pharmacist shall maintain a special prescription file in which shall be filed in sequence as to date and number all written orders or prescriptions in writing for controlled

drugs dispensed and the written record of all controlled drugs dispensed pursuant to a prescription or order verbally given.

G.03.010. A pharmacist shall retain in his possession for a period of at least two years, any records which he is required to keep by this Part.

G.03.011. A pharmacist shall

(*a*) furnish such information respecting the dealings of the pharmacist in any controlled drug in such form and at such times as the Minister may require;

(*b*) make available and produce to an inspector upon request his special prescription file together with any books, records or documents which he is required to keep;

(*c*) permit an inspector to make copies of or to take extracts from such files, books, records or documents; and

(*d*) permit an inspector to check all stocks of controlled drugs on his premises.

G.03.012. A pharmacist shall take all reasonable steps that are necessary to protect controlled drugs on his premises or under his control against loss or theft.

SOR/85-550, s. 8.

G.03.013. A pharmacist shall report to the Minister any loss or theft of a controlled drug within 10 days of his discovery thereof.

G.03.014. A pharmacist may, upon receiving a written order for a controlled drug signed and dated by

(*a*) the licensed dealer who sold or provided that drug to them, return that drug to that dealer;

(*b*) another pharmacist, sell or provide any quantity of that drug to that other pharmacist that is specified in the order as being required for emergency purposes;

(*c*) a Regional Director of the Department, sell or provide to or in accordance with the order of that Director any quantity of that drug, specified in the order, that is required by the Director in connection with their duties; and

(*d*) a person exempted under section 56 of the Controlled Drugs and Substances Act with respect to that controlled drug, sell or provide to that person any quantity of that drug that is specified in the order.

SOR/81-359, s. 2; SOR/85-550, s. 9; SOR/99-125, s. 3; SOR/2004-238, s. 21.

G.03.015. A pharmacist shall immediately after receiving, selling or providing a controlled drug under paragraph G.03.014(*b*) or (*c*) or subsection G.05.003(4) enter the details of the transaction in a book, register or other record maintained for the purpose of recording such transactions.

SOR/85-550, s. 10; SOR/2004-238, s. 22.

G.03.016. A pharmacist shall forthwith after removing, transporting or transferring a controlled drug from his place of business to any other place of business operated by him notify the Minister, setting out the details.

G.03.017. The Minister shall provide in writing any factual information about a pharmacist that has been obtained under the Act or these Regulations to the provincial professional licensing authority responsible for the registration or authorization of the person to practise their profession

(*a*) in the province in which the pharmacist is registered or entitled to practise if

(i) the authority submits a written request that states the name and address of the pharmacist, a description of the information being sought and a statement that the information is required for the purpose of assisting a lawful investigation by the authority, or

(ii) the Minister has reasonable grounds to believe that the pharmacist has

(A) contravened a rule of conduct established by the authority,

(B) been found guilty in a court of law of a designated drug offence or of a contravention of this Part, or

(C) contravened a provision of this Part; or

(*b*) in a province in which the pharmacist is not registered or entitled to practise, if the authority submits to the Minister

(i) a written request for information that states

(A) the name and address of the pharmacist, and

(B) a description of the information being sought, and

(ii) documentation that shows that the pharmacist has applied to that authority to practise in that province.

SOR/86-881, s. 1; SOR/97-228, s. 15; SOR/2003-135, s. 5; SOR/2010-222, s. 15.

Previous Version

G.03.017.1. A pharmacist may make a written request to the Minister to send to the persons and authorities specified in subsection G.03.017.2(3) a notice, issued under section G.03.017.2, advising them that recipients of the notice must not sell or provide a controlled drug other than a preparation, a preparation, or both, to that pharmacist.

SOR/2003-135, s. 5.

G.03.017.2. (1) In the circumstances described in subsection (2), the Minister must issue a notice to the persons and authorities specified in subsection (3) advising them that licensed dealers and pharmacists practising in the notified pharmacies must not sell or provide to the pharmacist named in the notice a controlled drug other than a preparation, a preparation, or both.

(2) The notice must be issued if the pharmacist named in the notice has

(*a*) made a request to the Minister in accordance with section G.03.017.1 to issue the notice;

(*b*) contravened a rule of conduct established by the provincial professional licensing authority of the province in which the pharmacist is practising and that authority has requested the Minister in writing to issue the notice; or

(*c*) been found guilty in a court of law of a designated drug offence or of an offence under this Part.

(3) The notice must be issued to

(*a*) all licensed dealers;

(*b*) all pharmacies within the province in which the pharmacist named in the notice is registered and practising;

(*c*) the provincial professional licensing authority of the province in which the pharmacist named in the notice is registered or entitled to practise; and

(*d*) any interested provincial professional licensing authority in another province that has made a request to the Minister to issue the notice.

(4) Subject to subsection (5), the Minister may issue the notice described in subsection (1) to the persons and authorities specified in subsection (3), if the Minister, on reasonable grounds, believes that the pharmacist named in the notice

(*a*) has contravened any of the provisions of sections G.03.001 to G.03.016;

(*b*) has, on more than one occasion, self-administered a controlled drug, other than a preparation, contrary to accepted pharmaceutical practice;

(*c*) has, on more than one occasion, self-administered a preparation, contrary to accepted pharmaceutical practice;

(*d*) has, on more than one occasion, provided or administered a controlled drug, other than a preparation, to a person who is a spouse, common-law partner, parent or child of the pharmacist, including a child adopted in fact, contrary to accepted pharmaceutical practice;

(*e*) has, on more than one occasion, provided or administered a preparation to a person who is a spouse, common-law partner, parent or child of the pharmacist, including a child adopted in fact, contrary to accepted pharmaceutical practice; or

(*f*) is unable to account for the quantity of controlled drug for which the pharmacist was responsible under this Part.

(5) In the circumstances described in subsection (4), the Minister must not issue the notice referred to in subsection (1) until the Minister has

(*a*) consulted with the provincial professional licensing authority of the province in which the pharmacist to whom the notice relates is registered or entitled to practise;

(*b*) given that pharmacist an opportunity to present reasons why the notice should not be issued and considered those reasons; and

(*c*) considered

(i) the compliance history of the pharmacist in respect of the Act and the regulations made or continued under it, and

(ii) whether the actions of the pharmacist pose a significant security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use.

SOR/2003-135, s. 5; SOR/2010-222, ss. 16, 35(F).

Previous Version

G.03.017.3. The Minister must provide the licensed dealers, pharmacies and provincial professional licensing authorities who were issued a notice under subsection G.03.017.2(1) with a notice of retraction of that notice if

(*a*) in the circumstance described in paragraph G.03.017.2(2)(*a*), the requirements set out in subparagraphs (*b*)(i) and (ii) have been met and one year has elapsed since the notice was issued by the Minister; or

(*b*) in a circumstance described in any of paragraphs G.03.017.2(2)(*b*) and (*c*) and (4)(*a*) to (*f*), the pharmacist named in the notice has

(i) requested in writing that a retraction of the notice be issued, and

(ii) provided a letter from the provincial professional licensing authority of the province in which the pharmacist is registered or entitled to practise, in which the authority consents to the retraction of the notice.

SOR/2003-135, s. 5; SOR/2010-222, s. 17.

Previous Version

G.03.017.4. and G.03.017.5. [Repealed, SOR/2003-135, s. 5]

# Division 4

# Practitioners

G.04.001. (1) In this section,

“administer” includes to prescribe, sell or provide; (administrer)

“designated drug” means any of the following controlled drugs:

(*a*) amphetamine and its salts,

(*b*) benzphetamine and its salts,

(*c*) methamphetamine and its salts,

(*d*) phenmetrazine and its salts, or

(*e*) phendimetrazine and its salts. (drogue désignée)

(2) Subject to subsections (3) and (4) and to an exemption granted under section 56 of the Controlled Drugs and Substances Act with respect to the administration of the controlled drug specified in the exemption, no practitioner shall administer a controlled drug to any person or animal.

(3) A practitioner may administer a controlled drug, other than a designated drug, to a person or to an animal, if

(*a*) that person or animal is a patient under his professional treatment; and

(*b*) the controlled drug is required for the condition for which the patient is receiving treatment.

(4) A practitioner may administer a designated drug to an animal or a person who is a patient under his professional treatment where the designated drug is for the treatment of any of the following conditions:

(*a*) in humans

(i) narcolepsy,

(ii) hyperkinetic disorders in children,

(iii) mental retardation (minimal brain dysfunction),

(iv) epilepsy,

(v) parkinsonism, or

(vi) hypotensive states associated with anesthesia; or

(*b*) in animals, depression of cardiac and respiratory centres.

SOR/99-125, s. 4; SOR/2004-238, s. 23.

G.04.002. (1) A practitioner who sells or provides a controlled drug to a person for self-administration or for administration to an animal shall, whether or not the practitioner charges for the drug, keep a record showing the name and quantity of the controlled drug sold or provided, the name and address of the person to whom it was sold or provided and the date on which it was sold or provided if the quantity of the controlled drug exceeds

(*a*) three times the maximum daily dosage recommended by the producer, maker or assembler of the controlled drug; or

(*b*) three times the generally recognized maximum daily therapeutic dosage for that controlled drug if the producer, maker or assembler has not recommended a maximum daily dosage.

(2) A practitioner who is required by this section to keep a record shall keep the record in a place, form and manner that will permit an inspector readily to examine and obtain information from it.

SOR/88-482, s. 4(F); SOR/2004-238, s. 24.

G.04.002A. A practitioner shall

(*a*) furnish to the Minister on request such information respecting

(i) the use by the practitioner of controlled drugs received — including the administering, selling or providing of the drugs to a person — , and

(ii) the prescriptions for controlled drugs issued by the practitioner,

as the Minister may require;

(*b*) produce to an inspector on request any records that these Regulations require the practitioner to keep;

(*c*) permit an inspector to make copies of such records or to take extracts therefrom;

(*d*) permit an inspector to check all stocks of controlled drugs on the practitioner's premises;

(*e*) retain in his possession for at least two years any record that these Regulations require him to keep;

(*f*) take adequate steps to protect controlled drugs in his possession from loss or theft; and

(*g*) report to the Minister any loss or theft of a controlled drug within 10 days of the practitioner's discovery of the loss or theft.

SOR/2004-238, s. 25.

G.04.003. [Repealed, SOR/2010-222, s. 18]

Previous Version

G.04.004. The Minister shall provide in writing any factual information about a practitioner that has been obtained under the Act or these Regulations to the provincial professional licensing authority responsible for the registration or authorization of the person to practise their profession

(*a*) in the province in which the practitioner is registered or entitled to practise if

(i) the authority submits a written request that states the name and address of the practitioner, a description of the information being sought and a statement that the information is required for the purpose of assisting a lawful investigation by the authority, or

(ii) the Minister has reasonable grounds to believe that the practitioner has

(A) contravened a rule of conduct established by the authority,

(B) been found guilty in a court of law of a designated drug offence or of a contravention of this Part, or

(C) contravened a provision of this Part; or

(*b*) in a province in which the practitioner is not registered or entitled to practise, if the authority submits to the Minister

(i) a written request for information that states

(A) the name and address of the practitioner, and

(B) a description of the information being sought, and

(ii) documentation that shows that the practitioner has applied to that authority to practise in that province.

SOR/86-881, s. 2; SOR/97-228, s. 17; SOR/2003-135, s. 6; SOR/2010-222, s. 19.

Previous Version

G.04.004.1. A practitioner may make a written request to the Minister to send to licensed dealers and pharmacies a notice, issued under section G.04.004.2, advising them of one or more of the following requirements:

(*a*) recipients of the notice must not sell or provide a controlled drug, other than a preparation, to that practitioner;

(*b*) recipients of the notice must not sell or provide a preparation to that practitioner;

(*c*) pharmacists practising in the notified pharmacies must not fill a prescription or order for a controlled drug, other than a preparation, from that practitioner; and

(*d*) pharmacists practising in the notified pharmacies must not fill a prescription or order for a preparation from that practitioner.

SOR/2003-135, s. 6.

G.04.004.2. (1) In the circumstances described in subsection (2), the Minister must issue a notice to the persons and authorities specified in subsection (3) advising them that

(*a*) licensed dealers and pharmacists practising in the notified pharmacies must not sell or provide to the practitioner named in the notice a controlled drug other than a preparation, a preparation, or both; or

(*b*) pharmacists practising in the notified pharmacies must not fill a prescription or order from the practitioner named in the notice for a controlled drug other than a preparation, a preparation, or both.

(2) The notice must be issued if the practitioner named in the notice has

(*a*) made a request to the Minister in accordance with section G.04.004.1 to issue the notice;

(*b*) contravened a rule of conduct established by the provincial professional licensing authority of the province in which the practitioner is practising and that authority has requested the Minister in writing to issue the notice; or

(*c*) been found guilty in a court of law of a designated drug offence or of an offence under this Part.

(3) The notice must be issued to

(*a*) all licensed dealers;

(*b*) all pharmacies within the province in which the practitioner named in the notice is registered and practising;

(*c*) the provincial professional licensing authority of the province in which the practitioner named in the notice is registered or entitled to practise;

(*d*) any interested provincial professional licensing authority in another province that has made a request to the Minister to issue the notice; and

(*e*) all pharmacies in an adjacent province in which a prescription or order from the practitioner named in the notice may be filled.

(4) Subject to subsection (5), the Minister may issue the notice described in subsection (1) to the persons and authorities specified in subsection (3), if the Minister, on reasonable grounds, believes that the practitioner named in the notice

(*a*) has contravened any of the provisions of sections G.04.001 to G.04.002A;

(*b*) has, on more than one occasion, self-administered a controlled drug, other than a preparation, under a self-directed prescription or order or, in the absence of a prescription or order, contrary to accepted medical, dental or veterinary practice;

(*c*) has, on more than one occasion, self-administered a preparation, under a self-directed prescription or order or, in the absence of a prescription or order, contrary to accepted medical, dental or veterinary practice;

(*d*) has, on more than one occasion, prescribed, provided or administered a controlled drug, other than a preparation, to a person who is a spouse, common-law partner, parent or child of the practitioner, including a child adopted in fact, contrary to accepted medical, dental or veterinary practice;

(*e*) has, on more than one occasion, prescribed, provided or administered a preparation to a person who is a spouse, common-law partner, parent or child of the practitioner, including a child adopted in fact, contrary to accepted medical, dental or veterinary practice; or

(*f*) is unable to account for the quantity of controlled drug for which the practitioner was responsible under this Part.

(5) In the circumstances described in subsection (4), the Minister must not issue the notice referred to in subsection (1) until the Minister has

(*a*) consulted with the provincial professional licensing authority of the province in which the practitioner to whom the notice relates is registered or entitled to practise;

(*b*) given that practitioner an opportunity to present reasons why the notice should not be issued and considered those reasons; and

(*c*) considered

(i) the compliance history of the practitioner in respect of the Act and the regulations made or continued under it, and

(ii) whether the actions of the practitioner pose a significant security, public health or safety hazard, including the risk of the controlled drug being diverted to an illicit market or use.

SOR/2003-135, s. 6; SOR/2010-222, ss. 20, 35(F).

Previous Version

G.04.004.3. The Minister must provide the licensed dealers, pharmacies and provincial professional licensing authorities who were issued a notice under subsection G.04.004.2(1) with a notice of retraction of that notice if

(*a*) in the circumstance described in paragraph G.04.004.2(2)(*a*), the requirements set out in subparagraphs (*b*)(i) and (ii) have been met and one year has elapsed since the notice was issued by the Minister; or

(*b*) in a circumstance described in any of paragraphs G.04.004.2(2)(*b*) and (*c*) and (4)(*a*) to (*f*), the practitioner named in the notice has

(i) requested in writing that a retraction of the notice be issued, and

(ii) provided a letter from the provincial professional licensing authority of the province in which the practitioner is registered or entitled to practise, in which the authority consents to the retraction of the notice.

SOR/88-482, s. 5(F); SOR/2003-135, s. 6; SOR/2010-222, s. 21.

Previous Version

G.04.004.4. and G.04.004.5. [Repealed, SOR/2003-135, s. 6]

# Division 5

# Hospitals

G.05.001. (1) A person who is in charge of a hospital shall keep or cause to be kept a record of the following information:

(*a*) the name and quantity of any controlled drug received for the hospital by a hospital employee or a practitioner in the hospital;

(*b*) the name and address of the person from whom any controlled drug was received and the date on which it was received;

(*c*) the name and quantity of any controlled drug used in the making or assembling of a product or compound containing that controlled drug, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;

(*c.1*) the name and quantity of any controlled drug produced and the date on which it was placed in stock;

(*d*) the name of the patient for whom a controlled drug was dispensed;

(*e*) the name of the practitioner ordering or prescribing a controlled drug; and

(*f*) the date on which a controlled drug was ordered or prescribed and the form and quantity thereof.

(2) Subject to subsections (3) and (4), the record of information referred to in subsection (1) shall be kept

(*a*) in a manner that permits an audit to be made;

(*b*) in a book, register or similar record maintained exclusively for controlled drugs; and

(*c*) for a period of at least two years.

(3) The information referred to in paragraphs (1)(*d*) to (*f*) may, with respect to a preparation, be kept in a form other than that specified in paragraph (2)(*b*).

(4) The information referred to in subsection (1) may, with respect to a controlled drug listed in Part II or III of the schedule to this Part, be kept in a form other than that specified in paragraph (2)(*b*).

SOR/78-427, s. 8; SOR/85-550, s. 11; SOR/88-482, s. 6; SOR/97-228, s. 18; SOR/2004-238, s. 27.

G.05.002. A person who is in charge of a hospital shall

(*a*) furnish such information respecting the use of controlled drugs therein, in such form and at such times as the Minister may require;

(*b*) produce to an inspector any books, records or documents required by these Regulations to be kept;

(*c*) permit an inspector to make copies thereof or take extracts from such books, records and documents; and

(*d*) permit an inspector to check all stocks of controlled drugs in the hospital.

G.05.003. (1) No person in charge of a hospital shall permit a controlled drug to be sold, provided or administered except in accordance with this section.

(2) On receipt of a prescription or a written order signed and dated by a practitioner, the person in charge of a hospital may permit a controlled drug to be administered to a person or an animal under treatment as an in-patient or out-patient of the hospital, or to be sold or provided to the person or to the person in charge of the animal.

(3) Subject to subsection (6), the person in charge of a hospital may permit a controlled drug to be provided, for emergency purposes, to a hospital employee or a practitioner in another hospital on receipt of a written order signed and dated by a pharmacist in the other hospital or a practitioner authorized by the person in charge of the other hospital to sign the order.

(4) Subject to subsection (6), the person in charge of a hospital may permit a controlled drug to be sold or provided, for emergency purposes, to a pharmacist on receipt of a written order signed and dated by the pharmacist.

(5) The person in charge of a hospital may permit a controlled drug to be provided to a person employed in a research laboratory in that hospital for the purpose of research.

(6) No person in charge of a hospital shall permit a controlled drug to be sold or provided under subsection (3) or (4) unless the signature of the pharmacist in the other hospital or of the practitioner authorized by the person in charge of the other hospital to sign an order is known to the person who sells or provides the controlled drug or has been verified.

SOR/85-550, s. 12; SOR/88-482, s. 7; SOR/2004-238, s. 28; SOR/2010-222, s. 22(F).

Previous Version

G.05.004. A person who is in charge of a hospital shall take all steps necessary to protect controlled drugs in the hospital against loss or theft and shall report to the Minister any loss or theft of a controlled drug within 10 days of his discovery thereof.

SOR/78-427, s. 9.

# Division 6

## Authority and Penalty

G.06.001. (1) and (2) [Repealed, SOR/99-125, s. 5]

(3) Despite anything in these Regulations, a person may, for the purpose of identification or analysis of a controlled drug in their possession, provide or deliver the drug to

(*a*) a practitioner of medicine; or

(*b*) an agent of a practitioner of medicine, where the agent has been exempted under section 56 of the Controlled Drugs and Substances Act with respect to the possession of that controlled drug.

(4) If an agent of a practitioner of medicine receives a controlled drug under subsection (3), they shall immediately provide or deliver it

(*a*) to the practitioner of whom he is the agent; or

(*b*) to the Minister or his agent.

(5) A practitioner of medicine who receives a controlled drug under subsection (3) or (4) shall immediately provide or deliver it

(*a*) for the purpose of identification or analysis thereof, to a person exempted under section 56 of the Controlled Drugs and Substances Act with respect to the possession of that controlled drug for that purpose; or

(*b*) to the Minister or his agent.

SOR/99-125, s. 5; SOR/2004-238, s. 29.

G.06.002. Every person who is exempted under section 56 of the Controlled Drugs and Substances Act with respect to the possession or administration, as the case may be, of a controlled drug shall

(*a*) keep and retain for a period of two years from the date of the making of the record, a record of

(i) the kind, date and quantity of any controlled drug purchased or received by him,

(ii) the name and address of the person from whom the controlled drug was received, and

(iii) particulars of the use to which the controlled drug was put; and

(*b*) furnish such information respecting such controlled drugs as the Minister may require, and shall permit access to the records required to be kept by this Part.

SOR/85-550, s. 13; SOR/88-482, s. 8(F); SOR/99-125, s. 6.

## Test Kits Containing Controlled Drugs

G.06.002.1. Any person may sell, possess or otherwise deal in a test kit that contains a controlled drug if

(*a*) a registration number has been issued for the test kit pursuant to section G.06.002.3;

(*b*) the test kit bears, on its external surface,

(i) the name of the producer, maker or assembler,

(ii) the trade name or trade mark, and

(iii) the registration number issued therefor pursuant to section G.06.002.3;

(*c*) the test kit is sold, possessed or otherwise dealt in for the purpose of medical, laboratory, industrial, educational or research use; and

(*d*) the registration number has not been cancelled pursuant to section G.06.002.4.

SOR/2004-238, s. 30.

G.06.002.2. The manufacturer of a test kit that contains a controlled drug may apply for a registration number therefor by submitting to the Director an application containing

(*a*) particulars of the design and construction of the test kit;

(*b*) a detailed description of the controlled drug and other substances, if any, contained in the test kit, including the qualitative and quantitative composition of each component;

(*c*) a statement of the proposed use of the test kit; and

(*d*) any further information and material that the Minister may require in order to satisfy himself that the test kit is one for which a registration number may be issued.

G.06.002.3. Where, on application under section G.06.002.2, the Minister is satisfied that the test kit to which the application applies will only be used for medical, laboratory, industrial, educational or research use and that it

(*a*) contains a controlled drug and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion or concentration that the preparation or mixture has no significant drug abuse potential, or

(*b*) contains such small quantities or concentrations of any controlled drug as to have no significant drug abuse potential,

the Minister may issue a registration number for the test kit, which shall be a number preceded by the letters “TK”.

SOR/81-21, ss. 1, 2; SOR/86-91, s. 3(F).

G.06.002.4. The Minister may cancel the registration number for a test kit if the test kit is removed from the market by the manufacturer or if, in the Minister’s opinion,

(*a*) it is necessary to cancel the registration number in the interest of public health; or

(*b*) the test kit is used or is likely to be used for any purpose other than medical, laboratory, industrial, educational or research use.

G.06.003. Any person who violates any provision of this Part is guilty of an offence and is liable on summary conviction to a fine not exceeding $500 or to a term of imprisonment not exceeding six months, or to both such fine and imprisonment.

# Division 7

## General

G.07.001. (1) In this section,

“member” means any person who is registered, certified or otherwise licensed by a nursing statutory body for the practice of nursing; (membre)

“nursing statutory body” means any provincial professional licensing authority that, pursuant to the laws of that province, registers, certifies or otherwise licenses a person for the practice of nursing. (organisme de nursing)

(2) The Minister may provide to a nursing statutory body any information obtained under the Controlled Drugs and Substances Act, the Food and Drugs Act or these Regulations that involves any member of that body.

SOR/82-120, s. 1; SOR/97-228, s. 19.

G.07.002 Where, pursuant to the Controlled Drugs and Substances Act (Police Enforcement) Regulations, a member of a police force or a person acting under the direction and control of the member is, in respect of the conduct of the member or person, exempt from the application of subsection 4(2) or section 5, 6 or 7 of the Controlled Drugs and Substances Act, the member or person is, in respect of that conduct, exempt from the application of this Part.

SOR/97-228, s. 20.

SCHEDULE

(Sections G.01.001 and G.01.004, subsection G.02.014(3), subparagraph G.02.025(1)(b)(iii), subsections G.02.025(3.2) and (4) and G.03.001(3), paragraph G.03.006(a), section G.03.007 and subsection G.05.001(4))

# PART I

1. Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues, excluding those substances set out in item 1 of the schedule to Part J but including:
   (1) amphetamine (*α*-methylbenzeneethanamine)
   (2) methamphetamine (N,*α*-dimethylbenzeneethanamine)
   (3) Benzphetamine (N-benzyl-N,*α*-dimethylbenzeneethanamine)
2. Methylphenidate (*α*-phenyl-2-piperidineacetic acid methyl ester) and any salt thereof
3. Methaqualone (2-methyl-3-(2-methylphenyl)-4(3H)quinazolinone) and any salt thereof
4. Phendimetrazine (d-3,4-dimethyl-2-phenylmorpholine) and any salt thereof
5. Phenmetrazine (3-methyl-2-phenylmorpholine) and any salt thereof
6. Pentobarbital (5-ethyl-5-(1-methylbutyl)barbituric acid)
7. Secobarbital (5-allyl-5-(1-methylbutyl)barbituric acid)
8. 4-hydroxybutanoic acid (GHB) and any salt thereof
9. Aminorex (4,5-dihydro-5-phenyl-2-oxazolamine) and any salt thereof
10. Fenetylline (d,l-3,7-dihydro-1,3-dimethyl-7-(2-[(1-methyl-2-phenethyl)amino]ethyl)-1H-purine-2,6-dione) and any salt thereof

11. Glutethimide (2-ethyl-2-phenylglutarimide)
12. Lefetamine ((-)-N,N-dimethyl-$\alpha$-phenylbenzeneethanamine) and any salt thereof
13. Mecloqualone (2-methyl-3-(2-chlorophenyl)-4(3H)-quinazolinone) and any salt thereof
14. Mesocarb (3-($\alpha$-methylphenethyl)-N-(phenylcarbamoyl)sydnone imine) and any salt thereof
15. Pemoline (2-amino-5-phenyl-oxazolin-4-one) and any salt thereof
16. Zipeprol (4-(2-methoxy-2-phenylethyl)-$\alpha$-(methoxyphenylmethyl)-1-piperazineethanol) and any salt thereof
17. Amineptine (7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid) and any salt thereof

# PART II

1. Barbiturates, their salts and derivatives, excluding the substances set out in items 6 and 7 of Part I but including:
   (1) Allobarbital (5,5-diallylbarbituric acid)
   (2) Alphenal (5-allyl-5-phenylbarbituric acid)
   (3) Amobarbital (5-ethyl-5-(3-methylbutyl)barbituric acid)
   (4) Aprobarbital (5-allyl-5-isopropylbarbituric acid)
   (5) Barbital (5,5-diethylbarbituric acid)
   (6) Barbituric Acid (2,4,6(1H,3H,5H)-pyrimidinetrione)
   (7) Butabarbital (5-sec-butyl-5-ethylbarbituric acid)
   (8) Butalbital (5-allyl-5-isobutylbarbituric acid)
   (9) Butallylonal (5-(2-bromoallyl)-5-sec-butylbarbituric acid)
   (10) Butethal (5-butyl-5-ethylbarbituric acid)
   (11) Cyclobarbital (5-(1-cyclohexen-1-yl)-5-ethylbarbituric acid)
   (12) Cyclopal (5-allyl-5-(2-cyclopenten-1-yl)barbituric acid)
   (13) Heptabarbital (5-(1-cyclohepten-1-yl)-5-ethylbarbituric acid)
   (14) Hexethal (5-ethyl-5-hexylbarbituric acid)
   (15) Hexobarbital (5-(1-cyclohexen-1-yl)-1,5-dimethylbarbituric acid)
   (16) Mephobarbital (5-ethyl-1-methyl-5-phenylbarbituric acid)
   (17) Methabarbital (5,5-diethyl-1-methylbarbituric acid)
   (18) Methylphenobarbital (5-ethyl-1-methyl-5-phenylbarbituric acid)
   (19) Propallylonal (5-(2-bromoallyl)-5-isopropyl-barbituric acid)
   (20) Phenobarbital (5-ethyl-5-phenylbarbituric acid)
   (21) Probarbital (5-ethyl-5-isopropylbarbituric acid)
   (22) Phenylmethylbarbituric Acid (5-methyl-5-phenylbarbituric acid)
   (23) Sigmodal(5-(2-bromoallyl)-5-(1-methylbutyl)- barbituric acid)
   (24) Talbutal (5-allyl-5-sec-butylbarbituric acid)
   (25) Vinbarbital (5-ethyl-5-(1-methyl-1-butenyl)barbituric acid)
   (26) Vinylbital (5-(1-methylbutyl)-5-vinylbarbituric acid)
2. Thiobarbiturates, their salts and derivatives, including:
   (1) Thialbarbital (5-allyl-5-(2-cyclohexen-1-yl)-2-thiobarbituric acid)

(2) Thiamylal (5-allyl-5-(1-methylbutyl)-2-thiobarbituric acid)
(3) Thiobarbituric Acid (2-thiobarbituric acid)
(4) Thiopental(5-ethyl-5-(1-methylbutyl)-2- thiobarbituric acid)

3. Chlorphentermine (1-(p-chlorophenyl)-2-methyl-2-aminopropane) and any salt thereof
4. Diethylpropion (2-(diethylamino)propiophenone) and any salt thereof
5. Phentermine (*α*,*α*-dimethylbenzeneethanamine) and any salt thereof
6. Butorphanol (1-N-cyclobutylmethyl-3,14-dihydroxy-morphinan) and any salt thereof
7. Nalbuphine (N-cyclobutylmethyl-4,5-epoxy-morphinan-3,6,14-triol) and any salt thereof
8. Pyrovalerone (4′-methyl-2-(1-pyrrolidinyl)valerophenone) and any salt thereof

# PART III

1. Anabolic steroids and their derivatives, including:
(1) Androisoxazole (17ß-hydroxy-17*α*-methylandrostano[3,2-c]isoxazole)
(2) Androstanolone (17ß-hydroxy-5*α*-androstan-3-one)
(3) Androstenediol (androst-5-ene-3ß,17ß-diol)
(4) Bolandiol (estr-4-ene-3b,17ß-diol)
(5) Bolasterone (17ß-hydroxy-7*α*,17-dimethylandrost-4-en-3-one)
(6) Bolazine (17ß-hydroxy-2*α*-methyl-5*α*-androstan-3-one azine)
(7) Boldenone (17ß-hydroxyandrosta-1,4-dien-3-one)
(8) Bolenol (19-nor-17*α*-pregn-5-en-17-ol)
(9) Calusterone (17ß-hydroxy-7b,17-dimethylandrost-4-en-3-one)
(10) Clostebol (4-chloro-17ß-hydroxyandrost-4-en-3-one)
(11) Drostanolone (17ß-hydroxy-2*α*-methyl-5*α*-androstan-3-one)
(12) Enestebol (4,17ß-dihydroxy-17-methylandrosta-1,4-dien-3-one)
(13) Epitiostanol (2*α*, 3*α*-epithio-5*α*-androstan-17ß-ol)
(14) Ethylestrenol (19-nor-17*α*-pregn-4-en-17-ol)
(15) 4-Hydroxy-19-nor testosterone
(16) Fluoxymesterone (9-fluoro-11ß,17ß-dihydroxy—17-methylandrost-4-en-3-one)
(17) Formebolone (11*α*,17ß-dihydroxy-17-methyl-3-oxoandrosta-1,4-dien-2-carboxaldehyde)
(18) Furazabol (17-methyl-5*α*-androstano[2,3-c]furazan-17ß-ol)
(19) Mebolazine (17ß-hydroxy-2*α*,17-dimethyl-5*α*-androstan-3-one azine)
(20) Mesabolone (17ß-[(1-methoxycyclohexyl)oxy]-5*α*-androst-1-en-3-one)
(21) Mesterolone (17ß-hydroxy-1*α*-methyl-5*α*-androstan-3-one)
(22) Metandienone (17ß-hydroxy-17-methylandrosta-1,4-dien-3-one)
(23) Metenolone (17ß-hydroxy-1-methyl-5*α*-androst-1-en-3-one)
(24) Methandriol (17*α*-methylandrost-5-ene-3ß,17ß-diol)
(25) Methyltestosterone (17ß-hydroxy-17-methyl-androst-4-en-3-one)
(26) Metribolone (17ß-hydroxy-17-methylestra-4,9,11-trien-3-one)
(27) Mibolerone (17ß-hydroxy-7*α*,17-dimethylestr-4-en-3-one)
(28) Nandrolone (17ß-hydroxyestr-4-en-3-one)

(29) Norboletone (13-ethyl-17ß-hydroxy-18,19-dinorpregn-4-en-3-one)
(30) Norclostebol (4-chloro-17ß-hydroxyestr-4-en-3-one)
(31) Norethandrolone (17*α*-ethyl-17ß-hydroxyestr-4-en-3-one)
(32) Oxabolone (4,17ß-dihydroxyestr-4-en-3-one)
(33) Oxandrolone (17ß-hydroxy-17-methyl-2-oxa-5*α*-androstan-3-one)
(34) Oxymesterone (4,17ß-dihydroxy-17-methylandrost-4-en-3-one)
(35) Oxymetholone (17ß-hydroxy-2-(hydroxymethylene)-17-methyl-5*α*-androstan-3-one)
(36) Prasterone (3ß-hydroxyandrost-5-en-17-one)
(37) Quinbolone (17ß-(1-cyclopenten-1-yloxy)androsta-1,4-dien-3-one)
(38) Stanozolol (17ß-hydroxy-17-methyl-5*α*-androstano[3,2-c]pyrazole)
(39) Stenbolone (17ß-hydroxy-2-methyl-5*α*-androst-1-en-3-one)
(40) Testosterone (17ß-hydroxyandrost-4-en-3-one)
(41) Tibolone ((7*α*,17*α*)-17-hydroxy-7-methyl-19-norpregn-5(10)en-20-yn-3-one)
(42) Tiomesterone (1*α*,7*α*-bis(acetylthio)-17ß-hydroxy-17-methylandrost-4-en-3-one)
(43) Trenbolone (17ß-hydroxyestra-4,9,11-trien-3-one)

2. Zeranol (3,4,5,6,7,8,9,10,11,12-decahydro-7,14,16-trihydroxy-3-methyl-1H-2-benzoxacyclotetradecin-1-one)

SOR/78-427, s. 10; SOR/79-753, s. 1; SOR/81-84, s. 1; SOR/85-550, s. 14(F); SOR/86-678, s. 1; SOR/89-381, s. 1; SOR/92-386, s. 3; SOR/97-228, s. 21; SOR/99-425, s. 1; SOR/2003-34, ss. 2, 3; SOR/2003-413, s. 2.

# PART J

# RESTRICTED DRUGS

## Division 1

### General

J.01.001. In this Part,

“competent authority” means a public authority of a foreign country that is authorized under the laws of the country to approve the importation or exportation of restricted drugs into or from the country; (autorité compétente)

“institution” means any institution engaged in research on drugs and includes a hospital that is licensed by a province, a university, a department or agency of the Government of Canada or of a province or any part thereof; (établissement)

“international obligation” means an obligation in respect of a restricted drug set out in a convention, treaty or other multilateral or bilateral instrument that Canada has ratified or to which Canada adheres; (obligation internationale)

“licence”[Repealed, SOR/2004-238, s. 31]

“licensed dealer” means the holder of a licence issued under section J.01.007.2; (distributeur autorisé)

“permit” means a permit issued under section J.01.005; (permis)

“practitioner” means a person who is registered and entitled under the laws of a province to practise the profession of medicine; (praticien)

“qualified investigator” means, in respect to a restricted drug, a person who

(*a*) is employed by or is connected with an institution, or

(*b*) is engaged in research in an institution in respect of that drug,

and whose use and possession of that drug is authorized by the Minister pursuant to section J.01.018; (chercheur compétent)

“qualified person in charge” means the individual with the qualifications specified in subsection J.01.003.2(2) who is responsible for supervising the activities carried out by a licensed dealer under their licence at the premises specified in the licence; (personne qualifiée responsable)

“restricted drug” means a drug set out in the schedule to this Part; (drogue d’usage restreint)

“test kit” means an apparatus

(*a*) that contains reagent systems or buffering agents or both,

(*b*) that is used in the course of a chemical or analytical procedure for medical, laboratory, industrial, educational or research purposes, and

(*c*) the contents of which are not intended for administration to humans. (nécessaire d’essai)

SOR/97-228, s. 22; SOR/2004-238, s. 31.

## Possession

J.01.002. (1) The following persons may have a restricted drug in their possession:

(*a*) a licensed dealer;

(*b*) a qualified investigator if he has possession for the purpose of and in connection with research in an institution;

(*c*) an analyst, inspector, member of the Royal Canadian Mounted Police, constable, peace officer, member of the staff of the Department of Health or officer of a court, if such person has possession for the purpose of and in connection with his employment; and

(d) a person exempted under section 56 of the Controlled Drugs and Substances Act with respect to that restricted drug.

(2) A person is authorized to have a restricted drug in his possession if the person is acting as the agent for a person referred to in paragraph (1)(*a*), (*b*) or (*d*).

(2.1) A person is authorized to have a restricted drug in his possession where

(*a*) the person is acting as the agent for a person he has reasonable grounds to believe is a person referred to in paragraph (1)(*c*); and

(*b*) the possession of the restricted drug is for the purpose of assisting that person in the enforcement or administration of an Act or regulation.

SOR/97-228, s. 23; SOR/99-125, s. 7; SOR/2010-222, s. 23.

Previous Version

## Licences, Permits and Licensed Dealers

J.01.003. Subject to this Part, no person except a licensed dealer shall produce, make, assemble, import, export, sell, provide, transport, send or deliver a restricted drug.

SOR/2004-238, s. 32.

J.01.003.1. To be eligible for a dealer's licence, a person must be

(*a*) an individual who ordinarily resides in Canada;

(*b*) a corporation that has its head office in Canada or operates a branch office in Canada; or

(*c*) the holder of a position that includes responsibility for restricted drugs on behalf of a department of the Government of Canada or of a government of a province, a police force, a hospital or a university in Canada.

SOR/2004-238, s. 32.

J.01.003.2. (1) A licensed dealer

(*a*) shall designate one qualified person in charge, who may be the licensed dealer if the licensed dealer is an individual, who must work at the premises specified in the licence, have responsibility for supervising activities with respect to restricted drugs specified in the licence and for ensuring, on behalf of the licensed dealer, that those activities comply with these Regulations; and

(*b*) may designate an alternate qualified person in charge who must work at the premises set out in the licence and have authority to replace the qualified person in charge when that person is absent.

(2) The qualified person in charge and, if applicable, the alternate qualified person in charge

(*a*) shall be familiar with the provisions of the Act and the regulations under it that apply to the licence of the licensed dealer who designated them and have knowledge of chemistry and pharmacology and experience in those fields to properly carry out their duties;

(*b*) shall be a pharmacist or a practitioner registered with a provincial professional licensing authority or possess a degree in an applicable science — such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, organic chemistry or chemical engineering — that is awarded by a Canadian university or, if awarded by a foreign university, that is recognized by a Canadian university or a Canadian professional association; and

(*c*) shall not have been convicted, as an adult, within the previous 10 years, of

(i) a designated drug offence,

(ii) a designated criminal offence, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii).

SOR/2004-238, s. 32; SOR/2010-222, ss. 24(E), 34.

Previous Version

J.01.004. No licensed dealer shall import or export a restricted drug without a permit.

J.01.004.1 A licensed dealer is authorized to have a restricted drug in his possession for the purpose of exporting the restricted drug from Canada if he has obtained the restricted drug pursuant to these Regulations.

SOR/97-515, s. 5.

J.01.005. The Minister may, upon application therefor, after such investigation as he deems proper and subject to such terms and conditions as he deems proper, issue to any licensed dealer a permit for the importation or exportation of a restricted drug.

J.01.006. An application for a permit shall be in a form approved by the Minister.

J.01.007. (1) To apply for a dealer's licence, a person shall submit an application to the Minister containing

(*a*) if the licence is sought for

(i) an individual, the individual's name,

(ii) a corporation, the corporation's name and any other name registered with a province, under which it intends to carry out the activities specified in its dealer's licence or intends to identify itself; and

(iii) the holder of a position mentioned in paragraph J.01.003.1(*c*), the applicant's name and the title of the position;

(*b*) the address, telephone number and, if applicable, the facsimile transmission number and e-mail address for the premises to which the dealer's licence would apply and, if different, the mailing address for the premises;

(*c*) the name, date of birth and gender of the individual in charge of the premises;

(*d*) with respect to the proposed qualified person in charge and, if applicable, the alternate proposed qualified person in charge,

(i) their name, date of birth and gender,

(ii) their academic qualifications, training and work experience relevant to their duties,

(iii) their hours of work, at the premises,

(iv) their title at the premises,

(v) the name and title of their immediate supervisor at the premises, and

(vi) in the case of a pharmacist or a practitioner, the name of the province in which the person's current professional licence, certification or authorization was issued and the professional licence, certification or authorization number;

(*e*) the name and gender of the individuals authorized to place an order for a restricted drug on behalf of the applicant;

(*f*) the activities referred to in section J.01.003 for which the licence is sought that would be carried out at the premises to which the dealer's licence would apply;

(*g*) in the case of a product or compound that contains a restricted drug but is not a test kit and that would be made or assembled for or by the applicant, a list that sets out

(i) the name, number or identifying mark, if any, of each product or compound,

(ii) the restricted drug in each product or compound,

(iii) the strength per unit of the restricted drug in each product or compound,

(iv) the quantity or package sizes of each product or compound, and

(v) if the product or compound would be made or assembled by or for another licensed dealer under a custom order, the name, address and the dealer's licence number of the other dealer;

(*h*) if the licence is sought to produce a restricted drug other than a product or compound that contains a restricted drug

(i) the restricted drug to be produced,

(ii) the quantity that the applicant expects to produce under the dealer's licence and the period during which that quantity would be produced, and

(iii) if the restricted drug would be produced for another licensed dealer under a custom order, the name, address and licence number of the other dealer;

(*i*) a detailed description of the security measures at the premises, determined in accordance with the Security Directive;

(*j*) a detailed description of the method that the applicant proposes to use for recording their restricted drug transactions; and

(*k*) for any activity referred to in section J.01.003, other than the activities described in paragraphs (*g*) and *h*), the restricted drug and the purpose for carrying out the activity.

(2) An application for a dealer's licence must

(*a*) be signed by the individual in charge of the premises to which the licence would apply; and

(*b*) be accompanied by a statement signed by the individual in charge indicating that

(i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) the individual in charge has the authority to bind the applicant.

(3) An application for a dealer's licence must be accompanied by

(*a*) declarations signed by the individual in charge of the premises to which the application applies, the proposed qualified person in charge and, if applicable, the alternate proposed qualified person in charge, stating that they have not been convicted, as an adult, within the preceding 10 years of

(i) a designated drug offence,

(ii) a designated criminal offence, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(*b*) a document issued by a Canadian police force with respect to each of the persons referred to in paragraph (*a*), stating whether the person has or has not been convicted, as an adult, during the preceding 10 years of a designated drug offence or a designated criminal offence;

(*c*) if any of the persons referred to in paragraph (*a*) has ordinarily resided in a country other than Canada during the preceding 10 years, a document issued by a police force of that country stating whether the person has or has not been convicted in that country, as an adult, during the preceding 10 years, of an offence that would have constituted a designated drug offence or a designated criminal offence if committed in Canada;

(*d*) a statement, signed and dated by the individual in charge of the premises to which the application applies, stating that the proposed qualified person in charge and, if applicable, the alternate proposed qualified person in charge have the knowledge and experience required under paragraph J.01.003.2(2)(*a*);

(*e*) if the proposed qualified person in charge or, if applicable, the alternate proposed qualified person in charge is not a pharmacist or a practitioner registered with a provincial professional licensing authority, a copy of the person's degree required under paragraph J.01.003.2(2)(*b*) and a copy of the course transcript for that degree;

(*f*) if the applicant's name appears on the label of a product or compound that contains a restricted drug, a copy of the inner label, as defined in section A.01.010, for each product or compound to which the licence would apply; and

(*g*) if the applicant is a corporation, a copy of

(i) the certificate of incorporation or other constituting instrument, and

(ii) any document filed with the province in which the premises to which the licence would apply are located that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.

(4) The method proposed by the applicant under paragraph (1)(*j*) must

(*a*) allow for the recording of restricted drug transactions in accordance with section J.01.021; and

(*b*) permit the Minister to audit the activities of the licensed dealer with respect to restricted drugs.

(5) The documents referred to in paragraphs (3)(*b*) and (*c*) are not required if the persons referred to in those paragraphs consent in writing

(*a*) to having a criminal record check carried out for them, as an adult, in respect of the offences referred to in those paragraphs during the preceding 10 years;

(*b*) to provide all necessary information and to submit to any means of identification required to obtain the criminal record check; and

(*c*) to pay the fee established by the Royal Canadian Mounted Police, Criminal Record Verification for Civil Purposes Fee Regulations.

SOR/2004-238, s. 33; SOR/2010-222, s. 25.

Previous Version

J.01.007.1. The Minister may, on receiving an application made under this Part, require the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to process the application.

SOR/2004-238, s. 33.

J.01.007.2. Subject to section J.01.007.3, the Minister shall, after examining the information and documents required under sections J.01.007 and J.01.007.1, issue a dealer's licence that contains

(*a*) the licence number;

(*b*) the name of the holder of the licence or the title of the position they hold, as the case may be, or, if the holder is a corporation, its corporate name;

(*c*) a list of the activities that are permitted;

(*d*) the address of the premises at which the licensed dealer may carry on the permitted activities;

(*e*) the name of the restricted drug for which the activities are permitted;

(*f*) the security level at the premises, determined in accordance with the Security Directive;

(*g*) the effective date of the licence;

(*h*) the expiry date of the licence, which may not be later than three years after its effective date;

(*i*) any conditions to be met by the holder of the licence to

(i) ensure that an international obligation is respected,

(ii) provide the security level referred to in paragraph (*f*), or

(iii) reduce the potential security, public health or safety hazard, including the risk of the restricted drug being diverted to an illicit market or use;

(*j*) in the case of a producer of a restricted drug, the quantity of the restricted drug that may be produced under the licence and the period during which that quantity may be produced; and

(*k*) in the case of the maker or assembler of a product or compound that contains a restricted drug but is not a test kit, an annexed list that sets out the following information for each type of product or compound that may be made or assembled under the licence:

(i) the licence number,

(ii) the name, number or identifying mark, if any, of each product or compound,

(iii) the restricted drug in each product or compound,

(iv) the strength per unit of the restricted drug in each product or compound, and

(v) the quantity or package sizes of each product or compound.

SOR/2004-238, s. 33; SOR/2010-222, ss. 26, 35(F).

Previous Version

J.01.007.3. (1) The Minister shall refuse to issue, renew or amend a dealer's licence if

(*a*) the applicant is not eligible under section J.01.003.1;

(*b*) an inspector who has requested an inspection has not been given the opportunity by the applicant to conduct an inspection under section J.01.025;

(*c*) false or misleading information or false or falsified documents were submitted in or with the application;

(*d*) an activity for which the licence is requested would not be in compliance with an international obligation;

(*e*) information received from a competent authority or the United Nations raises a reasonable belief that the applicant has been involved in the diversion of a restricted drug to an illicit market or use or has been involved in an activity that was not in compliance with an international obligation;

(*f*) the applicant does not have in place the security measures set out in the Security Directive in respect of an activity for which the licence is requested;

(*g*) the applicant is in contravention of or has contravened during the preceding 10 years

(i) a provision of the Act or any regulations made or continued under the Act, or

(ii) a term or condition of another dealer's licence or of an import or export permit issued to the applicant under any regulations made or continued under the Act;

(*h*) the issuance, amendment or renewal of the licence would likely create a risk to public health, safety or security, including the risk of a restricted drug being diverted to an illicit market or use;

(*i*) the individual in charge of the premises, the proposed qualified person in charge or, if applicable, the alternate proposed qualified person in charge has been convicted, as an adult, within the preceding 10 years, of

(i) a designated drug offence,

(ii) a designated criminal offence, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii);

(*j*) the proposed method referred to in paragraph J.01.007(1)(j) is not capable of recording the applicant's restricted drug transactions as required under section J.01.023 or permitting the Minister to audit the applicant's activities with respect to restricted drugs in a timely manner; or

(*k*) the additional information required under section J.01.007.1 has not been provided or is insufficient to process the application.

(2) Unless it is necessary to do so to protect public health, safety, or security, including preventing a restricted drug from being diverted to an illicit market or use, the Minister shall not refuse to issue, renew or amend a licence under paragraph (1)(*c*) or (*g*) if the applicant

(*a*) does not have a history of non compliance with the Act or any regulation made or continued under it; and

(*b*) has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act and these Regulations.

SOR/2004-238, s. 33; SOR/2010-222, ss. 27, 35(F).

Previous Version

J.01.007.4. (1) To apply to renew a dealer's licence, a licensed dealer must submit to the Minister

(*a*) the information required under paragraphs J.01.007(1)(*a*) to (*k*); and

(*b*) the following documents, namely,

(i) the documents referred to in paragraphs J.01.007(3)(*a*) and (*d*) and, subject to subsection J.01.007(5), the document specified in paragraph J.01.007(3)(*b*),

(ii) if applicable and if not previously submitted in respect of the dealer's licence that is being renewed, the document referred to in paragraph J.01.007(3)(*e*), and

(iii) the original dealer's licence that is to be renewed.

(2) An application for renewal must

(*a*) be signed by the individual in charge of the premises to which the renewed dealer's licence would apply; and

(*b*) be accompanied by a statement signed by the individual in charge indicating that

(i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section J.01.007.3, the Minister shall, after examining the information and documents required under subsections (1) and (2) and section J.01.007.1, issue a renewed dealer's licence that contains the information specified in paragraphs J.01.007.2(*a*) to (*k*).

SOR/2004-238, s. 33.

J.01.007.5. (1) To have its dealer's licence amended, a licensed dealer shall submit to the Minister

(*a*) an application in writing describing the proposed amendment, accompanied by the supporting documents referred to in section J.01.007 that are relevant to the proposed amendment; and

(*b*) the original dealer's licence.

(2) An application for amendment must

(*a*) be signed by the individual in charge of the premises to which the amended dealer's licence would apply; and

(*b*) be accompanied by a statement signed by the individual in charge indicating that

(i) all information and documents submitted in support of the application are correct and complete to the best of their knowledge, and

(ii) the individual in charge has the authority to bind the applicant.

(3) Subject to section J.01.007.3, the Minister shall, after examining the request for amendment and the supporting documentation, amend the dealer's licence in accordance with the request and may add any conditions to be met by the holder of the licence to

(*a*) ensure that an international obligation is respected;

(*b*) provide for the security level referred to in paragraph J.01.007.2(*f*) or the new level required as a result of the amendment being implemented; or

(*c*) reduce the potential security, public health or safety hazard, including the risk of the restricted drug being diverted to an illicit market or use.

SOR/2004-238, s. 33; SOR/2010-222, ss. 28(F), 35(F).

Previous Version

J.01.007.6. (1) A licensed dealer shall

(*a*) obtain the Minister's approval before making any of the following changes, namely,

(i) a change relating to the security at the premises referred to in the dealer's licence, or

(ii) the replacement or the addition of

(A) an individual in charge of the premises to which the dealer's licence applies,

(B) a qualified person in charge and, if applicable, an alternate qualified person in charge at the premises to which the dealer's licence applies, and

(C) an individual authorized to place an order for a restricted drug on behalf of the licensed dealer;

(*b*) notify the Minister, not later than 10 days after the change, when a person referred to in clause (*a*)(ii)(A) or (C) ceases to carry out their duties as specified in

(i) the application for a dealer's licence under section J.01.007,

(ii) the application to renew a dealer's licence under section J.01.007.4, or

(iii) the request for approval under paragraph (*a*); and

(*c*) notify the Minister, not later than the next business day after the change, when a person referred to in clause (*a*)(ii)(B) ceases to carry out their duties as specified in

(i) the application for a dealer's licence under section J.01.007,

(ii) the application to renew a dealer's licence under section J.01.007.4, or

(iii) the request for approval under paragraph (*a*).

(2) The licensed dealer shall, with the request for approval referred to in subparagraph (1)(*a*)(ii), provide the Minister with the following information and documents with respect to the new person:

(*a*) in the case of the replacement of the individual in charge of the premises to which the dealer's licence applies,

(i) the information specified in paragraph J.01.007(1)(*c*), and

(ii) the declarations specified in paragraph J.01.007(3)(*a*) and, subject to subsection J.01.007(5), the documents specified in paragraphs J.01.007(3)(*b*) and (*c*);

(*b*) in the case of the replacement of the qualified person in charge or the replacement or addition of the alternate qualified person in charge at the premises to which the dealer's licence applies,

(i) the information specified in paragraph J.01.007(1)(*d*), and

(ii) the documents specified in paragraphs J.01.007(3)(*a*), (*d*) and (*e*) and, subject to subsection J.01.007(5), the documents specified in paragraphs J.01.007(3)(*b*) and (*c*); and

(*c*) in the case of the replacement or addition of an individual who is authorized to place an order for a restricted drug on behalf of the licensed dealer, the individual's name and gender.

SOR/2004-238, s. 33.

J.01.007.7. The Minister shall revoke a dealer's licence at the request of the licensed dealer or on being notified by the licensed dealer that the licence has been lost or stolen.

SOR/2004-238, s. 33.

J.01.007.8. (1) Subject to subsection (2), the Minister shall revoke a dealer's licence in accordance with section J.01.007.91 if

(*a*) the licence was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application;

(*b*) the licensed dealer has failed to comply with a provision of the Act, a regulation under it or a term or condition of the licence or of an import or export permit issued under this Part;

(*c*) the licensed dealer is no longer an eligible person under section J.01.003.1;

(*d*) it is discovered that the individual in charge of the premises to which the licence applies, the qualified person in charge or, if applicable, the alternate qualified person in charge at those premises, has been convicted, as an adult, within the previous 10 years, of

(i) a designated drug offence,

(ii) a designated criminal offence, or

(iii) an offence committed outside Canada that, if committed in Canada, would have constituted an offence referred to in subparagraph (i) or (ii); or

(*e*) information received from a competent authority or the United Nations raises a reasonable belief that the licensed dealer has been involved in the diversion of a restricted drug to an illicit market or use.

(2) Unless it is necessary to do so to protect public health, safety, or security, including preventing a restricted drug from being diverted to an illicit market or use, the Minister shall not revoke a dealer's licence under paragraph (1)(*a*) or (*b*) if the licensed dealer

(*a*) has no history of non-compliance with the Act and the regulations made or continued under it; and

(*b*) has carried out, or signed an undertaking to carry out, the necessary corrective measures to ensure compliance with the Act and these Regulations.

SOR/2004-238, s. 33; SOR/2010-222, ss. 29, 35(F).

Previous Version

J.01.007.9. The Minister shall suspend a dealer's licence without prior notice if it is necessary to do so to protect security, public health or safety, including preventing a restricted drug from being diverted to an illicit market or use.

SOR/2004-238, s. 33; SOR/2010-222, s. 35(F).

Previous Version

J.01.007.91. (1) If the Minister proposes to refuse to issue, amend or renew, or proposes to revoke, a licence under this Part, the Minister shall

(*a*) send a notice to the applicant or to the holder of the licence, together with a written report that sets out the reasons for the proposed refusal or revocation; and

(*b*) give the applicant or holder an opportunity to be heard in respect of the proposed refusal or revocation.

(2) The suspension of a licence under this Part takes effect as soon as the Minister informs the holder of the licence of the decision to suspend and provides a written report that sets out the reasons for the suspension.

(3) A person who receives a notice of suspension referred to in subsection (2) may, in the 10 days following the receipt of the notice, provide the Minister with reasons why the suspension of the licence is unfounded.

SOR/2004-238, s. 33.

J.01.008. [Repealed, SOR/2004-238, s. 33]

J.01.009. The Minister may impose such restrictions and conditions on a licensed dealer as he deems necessary for the control of a restricted drug.

J.01.010. A licensed dealer may at any time make an application to the Minister to amend his licence in order to become a licensed dealer in respect of a restricted drug other than a restricted drug specified in his licence or to change the terms or conditions of his licence.

J.01.011. A licensed dealer may, subject to the terms and conditions of their licence, produce, make, assemble, sell, provide, transport, send or deliver only the restricted drugs specified in their dealer's licence.

SOR/2004-238, s. 34.

J.01.012. The Minister shall revoke a permit at the request of the holder or if the holder informs the Minister that the permit has been lost or stolen.

SOR/2004-238, s. 34; SOR/2010-222, s. 30.

Previous Version

J.01.012.1. (1) Subject to subsection (2), the Minister shall revoke a permit by taking the same measures as those set out in subsection J.01.007.91(1) if

(*a*) any of paragraphs J.01.007.8(1)(*a*) to (*e*) applies with respect to the dealer's licence as it pertains to the restricted drug to be imported or exported; or

(*b*) the import or export permit was issued on the basis of false or misleading information or false or falsified documents submitted in or with the application.

(2) Unless it is necessary to do so to protect public health, safety, or security, including preventing a restricted drug from being diverted to an illicit market or use, the Minister shall not revoke a permit under paragraph J.01.007.8(1)(*a*) or (*b*) or J.01.012.1(1)(*b*) if the holder meets the conditions set out in paragraphs J.01.007.8(2)(*a*) and (b).

(3) The Minister may revoke a permit if the holder fails to comply with the decision of the Minister to suspend the permit under section J.01.012.2 or if the situation giving rise to the suspension is not rectified.

SOR/2010-222, s. 30.

J.01.012.2. (1) The Minister shall suspend a permit without prior notice if

(*a*) the dealer's licence as it pertains to the restricted drug to be imported or exported has expired or has been suspended or revoked;

(*b*) the Minister has reasonable grounds to believe that the suspension is necessary to protect public health, safety, or security;

(*c*) the Minister has reasonable grounds to believe that the continuation of the permit would present a risk of a restricted drug being diverted to an illicit market or use; or

(*d*) the import or export would contravene the laws of the country of export or import or a country of transit or transhipment.

(2) A decision of the Minister to suspend a permit takes effect as soon as the Minister notifies the holder of the decision and provides a written report of the reasons for the suspension.

(3) A person whose permit is suspended under subsection (1) may, within 10 days after receiving the notice of suspension, provide the Minister with reasons why the suspension is unfounded.

SOR/2010-222, s. 30.

J.01.013. A dealer's licence is valid until the earlier of

(*a*) the expiry date set out in the licence, and

(*b*) the revocation or suspension of the licence under section J.01.007.7, J.01.007.8 or J.01.007.9.

SOR/2004-238, s. 34.

J.01.014. A permit is valid only for the particular importation or exportation in respect of which it was issued.

## Sale of a Restricted Drug

J.01.015. An institution may, in a form approved by the Minister, make an application to a licensed dealer or to the Minister with respect to the purchase of a restricted drug

(*a*) for clinical use in the institution by qualified investigators for the purpose of determining the hazards and efficacy of the drug; or

(*b*) for laboratory research in the institution by qualified investigators.

J.01.016. Where a licensed dealer receives an application made pursuant to section J.01.015, he shall, before selling a restricted drug to the institution that made the application

(*a*) supply the Minister with a copy of the application; and

(*b*) obtain the written authority of the Minister to make the proposed sale of the restricted drug.

J.01.017. An application made pursuant to section J.01.015 shall contain

(*a*) the name and the address of the institution seeking to purchase the drug;

(*b*) the names and qualifications of the qualified investigators who will use and be in possession of the drug;

(*c*) the details of the proposed use of the drug;

(*d*) the quantity of the drug required;

(*e*) the dosage form of the drug required by the institution; and

(*f*) the name of the licensed dealer from whom the purchase of the drug will be made.

J.01.018. Where the Minister receives from an institution an application or a copy of an application made pursuant to section J.01.015, he may, subject to such qualifications and limitations as he deems proper, authorize

(*a*) the sale to the institution by a licensed dealer of the restricted drug applied for in such quantity and such dosage form as he deems proper; and

(*b*) qualified investigators to make clinical use of the restricted drug in the institution or to carry out laboratory research with the restricted drug in the institution and to possess the restricted drug for the purposes of such use or research.

J.01.019. An institution shall use a restricted drug only for the purpose and in accordance with the protocol therefor set out in the application respecting that restricted drug made pursuant to section J.01.015.

J.01.020. Where a licensed dealer is authorized under section J.01.018 to sell a restricted drug, he may, notwithstanding section C.08.002, sell that drug subject to any qualifications or limitations imposed by the Minister.

## Records and Inspection

J.01.021. Every institution shall keep and retain for a period of two years from the date of the making of the record, a record of

(*a*) the amount of every restricted drug received by the institution;

(*b*) details of the use of restricted drugs in the institution;

(*c*) the names and qualifications of every person who makes use of a restricted drug in the institution; and

(*d*) full clinical data with respect to the use of every restricted drug received by the institution.

SOR/85-550, s. 15.

J.01.022. Every institution shall make its records referred to in section J.01.021 available to the Minister upon his request and shall permit such inspection of the institution, respecting its use of restricted drugs, as the Minister may require.

J.01.023. Every licensed dealer shall maintain a record of

(*a*) the name, quantity and form of any restricted drug received by them, the name and address of the person who sold or provided it and the date it was received;

(*b*) the name, quantity and form of any restricted drug sold or provided by them, the name and address of the person to whom it was sold or provided and the date it was sold or provided;

(*c*) the name, quantity and form of any restricted drug they have used in making or assembling a product or compound containing that restricted drug, the name and quantity of the product or compound made or assembled and the date on which the product or compound was placed in stock;

(*d*) the name and quantity of any restricted drug produced and the date on which it was placed in stock; and

(*e*) the name, quantity and form of any restricted drug he has in stock.

SOR/2004-238, s. 35; SOR/2010-222, s. 31(F).

Previous Version

J.01.024. Every licensed dealer and every person who has been a licensed dealer shall keep the record referred to in section J.01.023 on the premises described in the licence that was issued to him or in such other place as may be approved by the Minister for a period of at least two years and shall keep such record in a form that will facilitate an audit thereof being made at any time.

J.01.025. (1) The Minister may, in respect of an applicant for a dealer's licence or a licensed dealer, require an inspection, at any reasonable time, of

(*a*) the premises used or intended to be used in producing, making, assembling or storing a restricted drug; and

(*b*) the process and conditions of the producing, making, assembling or storing.

(2) [Repealed, SOR/2010-222, s. 32]

SOR/2004-238, s. 36; SOR/2010-222, s. 32.

Previous Version

J.01.026. Every person who sells or provides a restricted drug shall

(*a*) supply such information in such form as the Minister may require respecting the dealings of any person in the restricted drug;

(*b*) produce to an inspector any books, records or documents required to be kept under this Part;

(*c*) permit an inspector to make copies of or to take extracts from any books, records and documents; and

(*d*) permit an inspector to check all stocks of restricted drugs located on the premises described in his licence.

SOR/2004-238, s. 37.

J.01.027. Every licensed dealer shall notify the Minister forthwith of any change

(*a*) [Repealed, SOR/2010-222, s. 33]

(*b*) in the premises in which a restricted drug is produced, made, assembled or stored; and

(*c*) in the process and conditions of producing, making, assembly or storage of a restricted drug.

SOR/2004-238, s. 38; SOR/2010-222, s. 33.

Previous Version

J.01.028. Every person who is in possession of a restricted drug and every institution to which the sale of a restricted drug has been authorized by the Minister shall

(*a*) provide such protection against loss or theft of the restricted drug as may be required by the Minister; and

(*b*) report forthwith to the Minister and to local law enforcement authorities any loss or theft of a restricted drug.

J.01.029. Where a licensed dealer delivers a restricted drug, he shall

(*a*) take such steps as are necessary to ensure the safekeeping of the drug during transit; and

(*b*) use such methods of transportation as will ensure that an accurate record is kept of the drug while in transit and of the signatures of any persons having charge of the drug until it is delivered to the consignee.

## Packaging and Labelling

J.01.030. Every restricted drug that is sold to an institution shall be securely packed by the licensed dealer who sells the drug in such a manner that the package cannot be opened without breaking the seal.

J.01.031. The provisions of section C.01.004 do not apply to a restricted drug.

J.01.032. Every package that contains a restricted drug shall be labelled so that the inner and outer labels thereon show

(*a*) the proper name or, if there is no proper name, the common name of the drug;

(*b*) the net contents of the package;

(*c*) the unit strength of the drug where it is in unit form;

(*d*) the lot number of the drug;

(*e*) the words “Restricted Drug”; and

(*f*) the name and address of the producer, maker or assembler of the drug.

SOR/2004-238, s. 39.

J.01.032.1. Section J.01.032 does not apply to a test kit that contains a restricted drug where a registration number has been issued for the test kit pursuant to section J.01.033.3 and has not been cancelled pursuant to section J.01.033.4.

J.01.033. (1) and (2) [Repealed, SOR/99-125, s. 8]

(3) Despite anything in these Regulations, a person may, for the purpose of identification or analysis of a restricted drug, provide or deliver the restricted drug that they have in their possession to

(*a*) a practitioner; or

(*b*) an agent of a practitioner, where the agent has been exempted under section 56 of the Controlled Drugs and Substances Act with respect to the possession of that restricted drug for that purpose.

(4) if an agent of a practitioner has received a restricted drug under subsection (3), the agent shall immediately provide or deliver it

(*a*) to the practitioner of whom he is the agent; or

(*b*) to the Minister or his agent.

(5) A practitioner who has received a restricted drug under subsection (3) or (4) shall immediately provide or deliver it

(*a*) for the purpose of identification or analysis thereof, to a person exempted under section 56 of the Controlled Drugs and Substances Act with respect to the possession of that restricted drug for that purpose; or

(*b*) to the Minister.

(6) Sections J.01.021 and J.01.022 apply with such modifications as the circumstances may require to every person who has received a restricted drug pursuant to this section other than a person to whom a restricted drug has been administered pursuant to an exemption granted under section 56 of the Controlled Drugs and Substances Act with respect to the administration of that drug.

SOR/99-125, s. 8; SOR/2004-238, s. 40.

## Test Kits Containing Restricted Drugs

J.01.033.1. Any person may sell, possess or otherwise deal in a test kit that contains a restricted drug if

(*a*) a registration number has been issued for the test kit pursuant to section J.01.033.3;

(*b*) the test kit bears, on its external surface,

(i) the name of the producer, maker or assembler,

(ii) the trade name or trade mark, and

(iii) the registration number issued therefor pursuant to section J.01.033.3;

(*c*) the test kit is sold, possessed or otherwise dealt in for the purpose of medical, laboratory, industrial, educational or research use; and

(*d*) the registration number has not been cancelled pursuant to section J.01.033.4.

SOR/2004-238, s. 41.

J.01.033.2. The manufacturer of a test kit that contains a restricted drug may apply for a registration number therefor by submitting to the Director an application containing

(*a*) particulars of the design and construction of the test kit;

(*b*) a detailed description of the restricted drug and other substances, if any, contained in the test kit, including the qualitative and quantitative composition of each component;

(*c*) a statement of the proposed use of the test kit; and

(*d*) any further information and material that the Minister may require in order to satisfy himself that the test kit is one for which a registration number may be issued.

J.01.033.3. Where, on application under section J.01.033.2, the Minister is satisfied that the test kit to which the application applies will only be used for medical, laboratory, industrial, educational or research use and that it

(*a*) contains a restricted drug and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion or concentration that the preparation or mixture has no significant drug abuse potential, or

(*b*) contains such small quantities or concentrations of any restricted drug as to have no significant drug abuse potential,

the Minister may issue a registration number for the test kit, which shall be a number preceded by the letters "TK".

SOR/81-21, ss. 3, 4; SOR/86-91, s. 4(F).

J.01.033.4. The Minister may cancel the registration number for a test kit if the test kit is removed from the market by the manufacturer or if, in the Minister's opinion,

(*a*) it is necessary to cancel the registration number in the interest of public health; or

(*b*) the test kit is used or is likely to be used for any purpose other than medical, laboratory, industrial, educational or research use.

## Prescribed Manner of Notice of Application for an Order of Restoration

J.01.035. (1) For the purpose of subsection 24(1) of the Controlled Drugs and Substances Act, notice of application for an order of restoration shall be given in writing to the Attorney General by registered mail.

(2) The notice referred to in subsection (1) shall be mailed not less than 15 clear days prior to the date the application is to be made to the magistrate and shall specify

(*a*) the magistrate to whom the application is to be made;

(*b*) the time and place where the application is to be heard;

(*c*) the restricted drug or other thing in respect of which the application is to be made; and

(*d*) the evidence upon which the applicant intends to rely to establish that he is entitled to possession of the restricted drug or other thing referred to in paragraph (*c*).

SOR/97-228, s. 24.

J.01.036 Where, pursuant to the Controlled Drugs and Substances Act (Police Enforcement) Regulations, a member of a police force or a person acting under the direction and control of the member is, in respect of the conduct of the member or person, exempt from the application of subsection 4(2) or section 5, 6 or 7 of the Controlled Drugs and Substances Act, the member or person is, in respect of that conduct, exempt from the application of this Part.

SOR/97-228, s. 25.

SCHEDULE

(Section J.01.001)

1. The following amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues:
   (1) N-ethylamphetamine (N-ethyl-α-methylbenzeneethanamine)

(2) 4-methyl-2,5-dimethoxyamphetamine (STP) (2,5-dimethoxy-4,α-dimethylbenzeneethanamine)

(3) 3,4-methylenedioxyamphetamine (MDA) (α-methyl-1,3-benzodioxole-5-ethanamine)

(4) 2,5-dimethoxyamphetamine(2,5-dimethoxy-α-methylbenzeneethanamine)

(5) 4-methoxyamphetamine (4-methoxy-α-methylbenzeneethanamine)

(6) 2,4,5-trimethoxyamphetamine (2,4,5-trimethoxy-α-methylbenzeneethanamine)

(7) N-methyl-3,4-methylenedioxyamphetamine (N,α-dimethyl-1,3-benzodioxole-5-ethanamine)

(8) 4-ethoxy-2,5-dimethoxyamphetamine (4-ethoxy-2,5-dimethoxy-α-methylbenzeneethanamine)

(9) 5-methoxy-3,4-methylenedioxyamphetamine (7-methoxy-α-methyl-1,3-benzodioxole-5-ethanamine)

(10) N,N-dimethyl-3,4-methylenedioxyamphetamine (N,N, α-trimethyl-1,3-benzodioxole-5-ethanamine)

(11) N-ethyl-3,4-methylenedioxyamphetamine (N-ethyl-α-methyl-1,3-benzodioxole-5-ethanamine)

(12) 4-ethyl-2,5-dimethoxyamphetamine (DOET) (4-ethyl-2,5-dimethoxy-α-methylbenzeneethanamine)

(13) 4-bromo-2,5-dimethoxyamphetamine (4-bromo-2,5-dimethoxy-α-methylbenzeneethanamine)

(14) 4-chloro-2,5-dimethoxyamphetamine (4-chloro-2,5-dimethoxy-α-methylbenzeneethanamine)

(15) 4-ethoxyamphetamine (4-ethoxy-α-methyl-benzeneethanamine)

(16) N-Propyl-3,4-methylenedioxyamphetamine (α-methyl-N-propyl-1,3-benzodioxole-5-ethanamine)

(17) N-hydroxy-3,4-methylenedioxyamphetamine (N-[α-methyl-3,4-(methylenedioxy)phenethyl]hydroxylamine)

(18) 3,4,5-trimethoxyamphetamine (3,4,5-trimethoxy-α-methylbenzeneethanamine)

2. Lysergic acid diethylamide (LSD) (N,N-diethyllysergamide) and any salt thereof
3. N,N-Diethyltryptamine (DET) (3-[(2-diethylamino)ethyl]indole) and any salt thereof
4. N,N-Dimethyltryptamine (DMT) (3-[(2-dimethylamino)ethyl]indole) and any salt thereof
5. N-Methyl-3-piperidyl benzilate (LBJ) (3-[(hydroxydiphenylacetyl)oxy]-1-methylpiperidine) and any salt thereof
6. Harmaline (4,9-dihydro-7-methoxy-1-methyl-3H-pyrido(3,4-b)indole) and any salt thereof
7. Harmalol (4,9-dihydro-1-methyl-3H-pyrido(3,4-ß)indol-7-ol) and any salt thereof
8. Psilocin (3-[2-(dimethylamino)ethyl]-4-hydroxyindole) and any salt thereof
9. Psilocybin (3-[2-(dimethylamino)ethyl]-4-phosphoryloxyindole) and any salt thereof
10. N-(1-phenylcyclohexyl)ethylamine (PCE) and any salt thereof
11. 1-[1-(2-Thienyl)cyclohexyl]piperidine (TCP) and any salt thereof
12. 1-Phenyl-N-propylcyclohexanamine and any salt thereof
13. Mescaline (3,4,5-trimethoxybenzeneethanamine) and any salt thereof, but not peyote (lophophora)
14. 4-Methylaminorex (4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) and any salt thereof

15. 2-Methylamino-1-phenyl-1-propanone and any salt thereof
16. 1-[1-(Phenylmethyl)cyclohexyl]piperidine and any salt thereof
17. 1-[1-(4-Methylphenyl)cyclohexyl]piperidine and any salt thereof
18. Etryptamine (3-(2-aminobutyl)indole) and any salt thereof
19. Rolicyclidine (1-(1-phenylcyclohexyl) pyrrolidine) and any salt thereof

SOR/97-228, s. 25; SOR/2003-34, ss. 4, 5.

SCHEDULE F

(Sections C.01.001, C.01.041 to C.01.047, C.01.601 and C.10.005)

# PART I

Abacavir and its salts

Abacavir et ses sels

Abatacept

Abatacept

Abciximab

Abciximab

Acamprosate and its salts

Acamprosate et ses sels

Acarbose and its derivatives

Acarbose et ses dérivés

Acebutolol and its salts

Acébutolol et ses sels

Acetazolamide

Acétazolamide

Acetohexamide

Acétohexamide

Acetylcarbromal

Acétylcarbromal

Acetylcholine Chloride

Acétylcholine (chlorure d’)

Acitretin and its salts and derivatives

Acitrétine, ses sels et dérivés

Aconiazide and its salts

Aconiazide et ses sels

Acyclovir and its salts

Acyclovir et ses sels

Adalimumab

Adalimumab

Adapalene and its salts and derivatives

Adapalène, ses sels et dérivés

Adefovir and its salts and derivatives

Adéfovir, ses sels et dérivés

Adenosine and its salts, when sold or recommended for administration by intravenous injection

Adénosine et ses sels, s’il est vendu ou recommandé pour administration par injection intraveineuse

Agalsidase alfa

Agalsidase alfa

Alatrofloxacin and its salts and derivatives

Alatrofloxacine et ses sels et dérivés

Aldesleukin

Aldésleukine

Alefacept

Aléfacept

Alemtuzumab

Alemtuzumab

Alendronic acid and its salts

Alendronique (acide) et ses sels

Alfacalcidol

Alfacalcidol

Alfuzosin and its salts

Alfuzosine et ses sels

Alglucosidase alfa

Alglucosidase alfa

Aliskiren and its salts

Aliskirène et ses sels

Alkyl nitrites

Alkyle (nitrites d’)

Allopurinol

Allopurinol

Allylisopropylacetylurea

Allylisopropylacétylurée

Almotriptan and its salts

Almotriptan et ses sels

Alpha-chloralose

Alpha-chloralose

Alphadolone and its salts

Alphadolone et ses sels

Alphaxalone

Alfaxalone

Alteplase and its salts and derivatives

Altéplase, ses sels et dérivés

Altrenogest

Altrénogest

Altretamine

Altrétamine

Amantadine and its salts

Amantadine et ses sels

Ambenonium Chloride

Ambénonium (chlorure d’)

Ambrisentan

Ambrisentan

Amifostine and its salts

Amifostine et ses sels

Amikacin and its salts and derivatives

Amikacine, ses sels et dérivés

Amiloride and its salts

Amiloride et ses sels

Aminocaproic acid

Aminocaproïque (acide)

Aminoglutethimide

Aminoglutéhimide

Aminolevulinic acid and its salts and derivatives

Aminolévulinique (acide), ses sels et dérivés

Aminophylline

Aminophylline

Aminopterin and its salts

Aminoptérine et ses sels

4-Amino-pteroyl aspartic acid and its salts

Amino-4-ptéroyl aspartique (acide) et ses sels

5-Aminosalicylic acid

Amino-5-salicylique (acide)

4-Aminosalicylic Acid and its salts

Amino-4 salicylique (acide) et ses sels

Amiodarone and its salts

Amiodarone et ses sels

Amitraz

Amitraz

Amitriptyline and its salts

Amitriptyline et ses sels

Amlexanox and its salts and derivatives

Amlexanox, ses sels et dérivés

Amlodipine and its salts

Amlodipine et ses sels

Ammonium bromide

Bromure d’ammonium

Amoxapine

Amoxapine

Amoxicillin and its salts and derivatives

Amoxicilline, ses sels et dérivés

Amphotericin B and its salts and derivatives

Amphotéricine B, ses sels et dérivés

Ampicillin and its salts and derivatives

Ampicilline, ses sels et dérivés

Amprenavir and its salts and derivatives

Amprénavir et ses sels et dérivés

Amrinone and its salts

Amrinone et ses sels

Amsacrine and its salts

Amsacrine et ses sels

Anagrelide and its salts

Anagrélide et ses sels

Anakinra and its salts and derivatives

Anakinra, ses sels et dérivés

Anastrozole

Anastrozole

Ancestim

Ancestim

Anidulafungin

Anidulafungine

Anti-thymocyte globulin

Sérum antithymocytes

Apiol, oil of

Apiol (huile d’)

Apraclonidine and its salts

Apraclonidine et ses sels

Aprepitant and its derivatives

Aprépitant et ses dérivés

Aprotinin

Aprotinine

Argatroban and its salts and derivatives

Argatroban, ses sels et dérivés

L-Asparaginase

L-Asparaginase

Astemizole and its salts

Astémizole et ses sels

Atazanavir and its salts

Atazanavir et ses sels

Atenolol and its salts

Aténolol et ses sels

Atipamezole and its salts

Atipamézole et ses sels

Atomoxetine and its salts

Atomoxétine et ses sels

Atorvastatin and its salts

Atorvastatine et ses sels

Atovaquone

Atovaquone

Atracurium besilate

Atracurium (bésilate d’)

Atropine and its salts in ophthalmic or parenteral preparations only

Atropine et ses sels dans les préparations pour usage ophtalmique ou parentéral seulement

Auranofin

Auranofine

Aurothioglucose

Aurothioglucose

Azacyclonol and its salts

Azacyclonol et ses sels

Azaribine

Azaribine

Azathioprine and its salts

Azathioprine et ses sels

Azatidine and its salts

Azatadine et ses sels

Azelaic acid

Acide azélaïque

Azlocillin and its salts and derivatives

Azlocilline, ses sels et dérivés

Aztreonam and its salts

Aztréonam et ses sels

Baclofen and its salts

Baclofène et ses sels

Bambuterol and its salts

Bambutérol et ses sels

Becaplermin

Bécaplermine

Basiliximab

Basiliximab

Bemegride

Bémégride

Benactyzine and its salts

Benactyzine et ses sels

Benazepril and its salts and derivatives

Bénazépril, ses sels et dérivés

Bendazac and its salts

Bendazac et ses sels

Benoxaprofen and its salts

Benoxaprofène et ses sels

Benserazide and its salts

Bensérazide et ses sels

Benzathine penicillin and its salts and derivatives

Benzathine pénicilline, ses sels et dérivés

Benzoyl peroxide in concentrations greater than 5 per cent or when sold in combination with another medicinal ingredient

Benzoyle (peroxyde de) lorsqu'il constitue plus de cinq pour cent d'un mélange ou qu'il est vendu en association avec un autre ingrédient médicinal

Benztropine and its salts

Benzatropine et ses sels

Benzydamine and its salts

Benzydamine et ses sels

Beractant

Béractant

Betahistine and its salts

Bétahistine et ses sels

Betaine and its salts when sold or recommended for the treatment of homocystinuria

Bétaïne et ses sels s'ils sont vendus ou recommandés pour le traitement de l'homocystinurie

Betaxolol and its salts

Betaxolol et ses sels

Bethanechol chloride

Béthanéchol (chlorure de)

Bethanidine and its salts

Béthanidine et ses sels

Bevacizumab

Bévacizumab

Bezafibrate and its salts and derivatives

Bezafibrate, ses sels et dérivés

Bicalutamide

Bicalutamide

Bimatoprost and its derivatives

Bimatoprost et ses dérivés

Biperiden and its salts

Bipéridène et ses sels

Bishydroxycoumarin and its salts and derivatives

Bishydroxycoumarine, ses sels et dérivés

Bisoprolol and its salts

Bisoprolol et ses sels

Bitolterol and its salts

Bitoltérol et ses sels

Bivalirudin

Bivalirudine

Bleomycin

Bléomycine

Bortezomib

Bortézomib

Bosentan and its salts and derivatives

Bosentan et ses sels et dérivés

Botulinum toxin Type A

Toxine botulinique, type A

Botulinum Toxin Type B

Toxine botulinique, type B

Bretylium tosylate

Brétylium (tosylate de)

Brimonidine and its salts

Brimonidine et ses sels

Bromal

Bromal

Bromal hydrate

Bromal (hydrate de)

Brometone

Brométone

Bromisoval

Bromisoval

Bromocriptine and its salts

Bromocriptine et ses sels

Bromoform

Bromoforme

Bumetanide and its salts and derivatives

Bumétanide, ses sels et dérivés

Buproprion and its salts

Buproprione et ses sels

Buserelin and its salts

Busséréline et ses sels

Buspirone and its salts

Buspirone et ses sels

Busulfan

Busulfan

Butaperazine and its salts

Butapérazine et ses sels

Butoconazole and its salts

Butoconazole et ses sels

Butyl chloral hydrate

Butylchloral (hydrate de)

Cabergoline and its salts

Cabergoline et ses sels

Calcipotriol

Calcipotriol

Calcitonin

Calcitonine

Calcitriol

Calcitriol

Calcium bromide

Bromure de calcium

Calcium bromolactobionate

Bromolactobionate de calcium

Calcium carbimide

Calcium (carbimide de)

Candesartan and its salts and derivatives

Candésartan et ses sels et dérivés

Candicidin and its salts and derivatives

Candicidine, ses sels et dérivés

Capecitabine and its salts and derivatives

Capécitabine et ses sels et dérivés

Capreomycin and its salts and derivatives

Capréomycine, ses sels et dérivés

Captodiamine and its salts

Captodiamine et ses sels

Captopril and its salts

Captopril et ses sels

Carbachol

Carbachol

Carbamazepine

Carbamazépine

Carbenicillin and its salts and derivatives

Carbénicilline, ses sels et dérivés

Carbenoxolone and its salts

Carbenoxolone et ses sels

Carbetocin and its salts

Carbétocine et ses sels

Carbidopa and its salts

Carbidopa et ses sels

Carbimazole

Carbimazole

Carbocisteine

Carbocistéine

Carbomycin and its salts and derivatives

Carbomycine, ses sels et dérivés

Carboplatin

Carboplatine

Carbromal

Carbromal

Carisoprodol

Carisoprodol

Carmustine

Carmustine

Carphenazine and its salts

Carphénazine et ses sels

Carprofen and its salts and derivatives

Carprofène, ses sels et dérivés

Carvedilol and its salts

Carvédilol et ses sels

Caspofungin and its salts and derivatives

Caspofungine et ses sels et dérivés

Cefdinir and its salts and derivatives

Cefdinir et ses sels et dérivés

Cefepime and its salts and derivatives

Céfépime, ses sels et dérivés

Cefonicide and its salts

Céfonicide et ses sels

Cefoperazone and its salts and derivatives

Céfopérazone, ses sels et dérivés

Cefprozil and its salts and derivatives

Cefprozil, ses sels et dérivés

Ceftibuten and its salts and derivatives

Ceftibutène, ses sels et dérivés

Celecoxib and its salts

Célécoxib et ses sels

Cephalosporin C and its salts and derivatives

Céphalosporine C, ses sels et dérivés

Cerivastatin and its salts

Cérivastatine et ses sels

Cetirizine and its salts when sold in concentrations greater than 8.5 mg cetirizine per unit dose

Cétirizine et ses sels lorsque vendues en concentration supérieure à 8,5 mg de cétirizine par unité posologique

Cetrorelix and its salts

Cétrorélix et ses sels

Cetuximab

Cétuximab

Chloral

Chloral

Chloral hydrate

Chloral (hydrate de)

Chloralformamide

Chloralformamide

Chloralimide

Chloralimide

Chlorambucil and its salts and derivatives

Chlorambucil, ses sels et dérivés

Chloramphenicol and its salts and derivatives

Chloramphénicol, ses sels et dérivés

Chlorcyclizine and its salts (except in preparations for external use only)

Chlorcyclizine et ses sels (sauf dans les préparations pour usage externe seulement)

Chlorisondamine and its salts

Chlorisondamine et ses sels

Chlormezanone

Chlormézanone

Chloroquine and its salts

Chloroquine et ses sels

Chlorpropamide

Chlorpropamide

Chlorprothixene and its salts

Chlorprothixène et ses sels

Choline salicylate, when sold in combination with magnesium salicylate

Choline (salicylate de) s’il est vendu en association avec le salicylate de magnésium

Choline theophyllinate

Choline (théophyllinate de)

Choriogonadotropin alfa

Choriogonadotropine alfa

Ciclopirox and its salts

Ciclopirox et ses sels

Cilastatin and its salts

Cilastatine et ses sels

Cilazapril and its salts and derivatives

Cilazapril, ses sels et dérivés

Cimetidine and its salts, except when sold in concentrations of 200 mg or less per oral dosage unit and indicated for the treatment of heartburn

Cimétidine et ses sels, sauf s’ils sont vendus en une concentration de 200 mg ou moins par unité posologique orale pour le traitement des brûlures d’estomac

Cinacalcet and its salts

Cinacalcet et ses sels

Cinchophene and its salts

Cinchophène et ses sels

Cinoxacin

Cinoxacine

Ciprofloxacin and its salts

Ciprofloxacine et ses sels

Cisapride and its salts

Cisapride et ses sels

Cisatracurium besilate

Cisatracurium (bésilate de)

Cisplatin

Cisplatine

Citalopram and its salts

Citalopram et ses sels

Cladribine and its salts

Cladribine et ses sels

Clenbuterol and its salts

Clenbutérol et ses sels

Clindamycin and its salts and derivatives

Clindamycine et ses sels et dérivés

Clodronic acid and its salts

Clodronique (acide) et ses sels

Clofibrate

Clofibrate

Clomiphene and its salts

Clomiphène et ses sels

Clomipramine and its salts

Clomipramine et ses sels

Clonidine and its salts

Clonidine et ses sels

Clopidogrel and its salts

Clopidogrel et ses sels

Cloprostenol and its salts and derivatives

Cloprosténol, ses sels et dérivés

Clorazepic acid and its salts

Clorazépique (acide) et ses sels

Clotrimazole and its salts (except in preparations for topical and vaginal use)

Clotrimazole et ses sels (sauf dans les préparations pour usage topique et vaginal)

Cloxacillin and its salts and derivatives

Cloxacilline, ses sels et dérivés

Clozapine and its salts

Clozapine et ses sels

Colchicine

Colchicine

Colestipol and its salts

Colestipol et ses sels

Colfosceril and its derivatives

Colfoscéril et ses dérivés

Colistin and its salt and derivatives

Colistine, ses sels et dérivés

Cromoglicic acid and its salts (except sodium cromoglicate in solutions for ophthalmic or nasal use in concentrations of 2% or less)

Cromoglicique (acide) et ses sels (sauf le cromoglicate de sodium dans les solutions pour usage ophtalmique ou nasal en concentration de 2 % ou moins)

Cyclobenzaprine and its salts

Cyclobenzaprine et ses sels

Cyclopentolate and its salts in preparations for parenteral or ophthalmic use, except when sold for use in diagnostic procedures to an optometrist registered in a province of Canada

Cyclopentolate et ses sels dans les préparations pour usage parentéral ou ophtalmique, sauf lorsqu'ils sont vendus pour usage diagnostique à un optométriste agréé dans une province du Canada

Cyclophosphamide

Cyclophosphamide

Cycloserine

Cyclosérine

Cyclosporine

Cyclosporine

Cyproterone acetate

Cyprotérone (acétate de)

Cytarabine and its salts

Cytarabine et ses sels

Dabigatran and its salts and derivatives

Dabigatran et ses sels et dérivés

Dacarbazine

Dacarbazine

Daclizumab

Daclizumab

Dactinomycin

Dactinomycine

Dalfopristin and its salts

Dalfopristine et ses sels

Dalteparin and its salts

Daltéparine et ses sels

Danaparoid and its salts and derivatives

Danaparoïde, ses sels et dérivés

Danazol

Danazol

Danofloxacin and its salts

Danofloxacine et ses sels

Dantrolene and its salts

Dantrolène et ses sels

Dapiprazole and its salts

Dapiprazole et ses sels

Daptomycin

Daptomycine

Darifenacin and its salts

Darifénacine et ses sels

Darunavir

Darunavir

Dasatinib

Dasatinib

Daunorubicin and its salts

Daunorubicine et ses sels

Deanol, and its salts and derivatives

Déanol, ses sels et dérivés

Debrisoquin and its salts

Debrisoquine et ses sels

Deferasirox

Déférasirox

Deferoxamine and its salts

Déféroxamine et ses sels

Delavirdine and its salts

Délavirdine et ses sels

Deracoxib

Déracoxib

Deserpidine and its alkaloids and salts

Déserpidine, ses alcaloïdes et sels

Desflurane

Desflurane

Desipramine and its salts

Désipramine et ses sels

Desmopressin and its salts

Desmopressin et ses sels

Detomidine and its salts

Détomidine et ses sels

Dexfenfluramine and its salts

Dexfenfluramine et ses sels

Dexrazoxane and its salts

Dexrazoxane et ses sels

Diazoxide and its salts

Diazoxide et ses sels

Dichloroacetic Acid

Dichloroacétique (acide)

Diclofenac and its salts, except when sold as a single medicinal ingredient in a concentration equivalent to 1% or less diclofenac in preparations for topical use on the skin

Diclofénac et ses sels sauf s'ils sont vendus comme ingrédient médicinal unique en une concentration maximale de 1 % dans les préparations pour usage topique sur la peau

Dicloxacillin and its salts and derivatives

Dicloxacilline, ses sels et dérivés

Didanosine and its salts and derivatives

Didanosine, ses sels et dérivés

Diethylbromacetamide

Diéthylbromacétamide

Diethylcarbamazine and its salts

Diéthylcarbamazine et ses sels

Diethylstilbestrol and its salts and derivatives

Diéthylstilbestrol, ses sels et dérivés

Difloxacin and its salts and derivatives

Difloxacine et ses sels et dérivés

Diflunisal and its salts

Diflunisal et ses sels

Digitalis lanata and its glycosides

Digitalis lanata et ses glycosides

Digitalis purpurea and its glycosides

Digitalis purpurea et ses glycosides

Digoxin immune Fab (ovine)

Digoxine [Fragments d'anticorps spécifiques de la digoxine Fab (ovins)]

Dihydrotachysterol

Dihydrotachystérol

Diiodohydroxyquin (except in preparations for topical use on the skin)

Diiodohydroxyquinoléine (sauf dans les préparations pour usage topique sur la peau)

Diltiazem and its salts

Diltiazem et ses sels

Dimercaprol

Dimercaprol

Dimethyl sulfoxide

Diméthylsulfoxide

2,4-Dinitrophenol and its salts and derivatives

Dinitro-2,4-phénol, ses sels et dérivés

Dinoprostone and its salts and derivatives

Dinoprostone, ses sels et dérivés

Diphenidol and its salts

Diphénidol et ses sels

Diphenylhydantoin (phenytoin) and its salts

Diphénylhydantoine (phénytoïne) et ses sels

Dipivefrin and its salts

Dipivefrine et ses sels

Diprophylline and its salts

Diprophylline et ses sels

Dipyridamole

Dipyridamole

Disopyramide and its salts

Disopyramide et ses sels

Disulfiram

Disulfirame

Dobutamine and its salts

Dobutamine et ses sels

Docetaxel and its derivatives

Docétaxel et ses dérivés

Dolasetron and its salts

Dolasétron et ses sels

Domperidone

Dompéridone

Donepezil and its salts

Donépézil et ses sels

Dopamine and its salts

Dopamine et ses sels

Dornase alfa

Dornase alfa

Dorzolamide and its salts

Dorzolamide et ses sels

Doxacurium chloride

Doxacurium (cholure de)

Doxapram

Doxapram

Doxazosin and its salts

Doxazosine et ses sels

Doxepin and its salts

Doxépine et ses sels

Doxercalciferol and its derivatives

Doxercalciférol et ses dérivés

Doxorubicin and its salts

Doxorubicine et ses sels

Doxycycline and its salts and derivatives, when sold for intramuscular administration in caged birds

Doxycycline, ses sels et dérivés, lorsque vendue pour administration intramusculaire aux oiseaux en cage

Doxylamine and its salts, when sold or recommended for use in the nausea or vomiting of pregnancy

Doxylamine et ses sels lorsque vendus ou recommandés contre les nausées ou vomissements de la grossesse

Droperidol and its salts

Dropéridol et ses sels

Drotrecogin

Drotrécogine

Duloxetine and its salts

Duloxétine et ses sels

Dutasteride

Dutastéride

Econazole and its salts

Éconazole et ses sels

Ecothiophate and its salts

Écothiophate et ses sels

Ectylurea and its salts

Ectylurée et ses sels

Eculizumab

Éculizumab

Edrophonium chloride

Édrophonium (chlorure d’)

Efalizumab

Éfalizumab

Efavirenz

Éfavirenz

Eflornithine and its salts and derivatives

Éflornithine, ses sels et dérivés

Eletriptan and its salts

Élétriptan et ses sels

Embutramide

Embutramide

Emedastine and its salts

Émédastine et ses sels

Emtricitabine

Emtricitabine

Emylcamate

Émylcamate

Enalaprilat and its salts and derivatives

Énalaprilate, ses sels et dérivés

Enflurane

Enflurane

Enfuvirtide

Enfuvirtide

Enoxaparin and its salts

Énoxaparine et ses sels

Enrofloxacin

Enrofloxacine

Entacapone

Entacapone

Entecavir

Entécavir

Epirubicine and its salts

Épirubicine et ses sels

Epoprostenol and its salts

Époprosténol et ses sels

Eprosartan and its salts and derivatives

Éprosartan et ses sels et dérivés

Epsiprantel

Epsiprantel

Eptifibatide and its salts

Eptifibatide et ses sels

Erlotinib and its salts

Erlotinib et ses sels

Ertapenem and its salts

Ertapénem et ses sels

Erythropoietin

Érythropoiétine

Escitalopram and its salts

Escitalopram et ses sels

Esmolol and its salts

Esmolol et ses sels

Esomeprazole and its salts

Ésoméprazole et ses sels

Estramustine and its salts

Estramustine et ses sels

Etanercept

Étanercept

Ethacrynic acid

Étacrynique (acide)

Ethambutol and its salts

Éthambutol et ses sels

Ethionamide and its salts

Éthionamide et ses sels

Ethomoxane and its salts

Éthomoxane et ses sels

Ethotoin and its salts

Éthotoine et ses sels

Ethyl trichloramate

Éthyle (trichloramate d’)

Etidronic acid and its salts

Étidronique (acide) et ses sels

Etodolac and its salts and derivatives

Étodolac, ses sels et dérivés

Etoposide and its derivatives

Étoposide et ses dérivés

Etravirine and its salts

Étravirine et ses sels

Etretinate

Étrétinate

Etymemazine and its salts

Étymémazine et ses sels

Exemestane

Exémestane

Ezetimibe

Ézétimibe

Famciclovir and its salts

Famciclovir et ses sels

Famotidine and its salts, except when sold in concentrations of 20 mg or less per oral dosage unit and indicated for the treatment of heartburn

Famotidine et ses sels, sauf s’ils sont vendus en une concentration de 20 mg ou moins par unité posologique orale et indiqués pour le traitement des brûlures d’estomac

Felodipine and its salts

Félodipine et ses sels

Fenfluramine and its salts

Fenfluramine et ses sels

Fenofibrate

Fénofibrate

Fenoprofen and its salts

Fénoprofène et ses sels

Fenoterol and its salts

Fénotérol et ses sels

Filgrastim

Filgrastime

Finasteride

Finastéride

Flavoxate and its salts

Flavoxate et ses sels

Flecainide and its salts

Flécaïnide et ses sels

Fleroxacin and its salts and derivatives

Fléroxacine, ses sels et dérivés

Floctafenine

Floctafénine

Florfenicol and its derivatives

Florfénicol et ses dérivés

Fluconazole, except when sold in a concentration of 150 mg per oral dosage unit and indicated for the treatment of vaginal candidiasis

Fluconazole, sauf s'il est vendu en une concentration de 150 mg par unité posologique orale pour le traitement des candidoses vaginales

Flucytosine

Flucytosine

Fludarabine and its salts and derivatives

Fludarabine, ses sels et dérivés

Flunarizine and its salts

Flunarizine et ses sels

Flunixin and its salts and derivatives

Flunixine, ses sels et dérivés

Fluorouracil and its derivatives

Fluorouracile et ses dérivés

Fluoxetine and its salts

Fluoxétine et ses sels

Flupentixol and its salts and derivatives

Flupentixol, ses sels et dérivés

Fluphenazine and its salts

Fluphénazine et ses sels

Fluprostenol and its salts and derivatives

Fluprosténol, ses sels et dérivés

Flurbiprofen and its salts

Flurbiprofène et ses sels

Fluspirilene

Fluspirilène

Flutamide

Flutamide

Fluvastatin and its salts and derivatives

Fluvastatine, ses sels et dérivés

Fluvoxamine and its salts

Fluvoxamine et ses sels

Folic acid in oral dosage form containing more than 1.0 mg of folic acid per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by that person of more than 1.0 mg of folic acid

Acide folique présenté en unités posologiques orales contenant chacune plus de 1,0 mg d’acide folique ou dont la plus forte dose quotidienne recommandée sur l’étiquette résulte en l’ingestion, par une personne, de plus de 1,0 mg d’acide folique

Follicle stimulating hormone

Folliculo-stimulante (hormone)

Fomepizole and its salts

Fomépizole et ses sels

Fondaparinux sodium

Fondaparinux sodique

Formestane and its derivatives

Formestane et ses dérivés

Formoterol and its salts

Formotérol et ses sels

Foscarnet sodium

Foscarnet sodique

Fosfomycin and its salts

Fosfomycine et ses sels

Fosinopril and its salts

Fosinopril et ses sels

Fosphenytoin and its salts

Fosphénytoïne et ses sels

Frovatriptan and its salts

Frovatriptan et ses sels

Fulvestrant

Fulvestrant

Fusidic acid and its salts

Fusidique (acide) et ses sels

Gabapentin and its salts and derivatives

Gabapentin, ses sels et dérivés

Galantamine and its salts and derivatives

Galantamine et ses sels et dérivés

Gallamine triethiodide

Gallamine (triéthiodure de)

Gallium and its salts

Gallium et ses sels

Ganciclovir and its salts

Ganciclovir et ses sels

Ganirelix and its salts and derivatives

Ganirélix, ses sels et dérivés

Gatifloxacin and its salts and derivatives

Gatifloxacine, ses sels et dérivés

Gefitinib

Géfitinib

Gemcitabine and its salts

Gemcitabine et ses sels

Gemfibrozil and its salts

Gemfibrozil et ses sels

Gemifloxacin and its salts

Gémifloxacine et ses sels

Gentamicin and its salts and derivatives

Gentamicine, ses sels et dérivés

Glatiramer and its salts

Glatiramère et ses sels

Gliclazide

Gliclazide

Glimepiride

Glimépiride

Glipizide

Glipizide

Glyburide and its salts and derivatives

Glyburide, ses sels et dérivés

Gold and its salts

Or et ses sels

Golimumab

Golimumab

Gonadorelin and its salts

Gonadoréline et ses sels

Gonadotropin, chorionic (human)

Gonadotropine chorionique (humain)

Gonadotropins, serum (human)

Gonadotropines sériques (humains)

Goserelin and its salts

Gosséréline et ses sels

Granisetron and its salts

Granisetron et ses sels

Grepafloxacin and its salts and derivatives

Grépafloxacine et ses sels et dérivés

Guanethidine and its salts

Guanéthidine et ses sels

Halofantrine and its salts

Halofantrine et ses sels

Haloperidol

Halopéridol

Halothane

Halothane

Hetacillin and its salts and derivatives

Hétacilline, ses sels et dérivés

Hetastarch and its derivatives

Hetastarch et ses dérivés

Hexachlorophene and its salts

Hexachlorophène et ses sels

Hexacyclonate sodium

Hexacyclonate sodique

Hexamethonium and its salts

Hexaméthonium et ses sels

Histrelin and its salts

Histréline et ses sels

Hyaluronic acid and its salts, when sold or recommended for administration by intra-articular injection to horses

Hyaluronique (acide) et ses sels, s’il est vendu ou recommandé pour administration par injection intra-articulaire aux chevaux

Hydralazine and its salts

Hydralazine et ses sels

Hydroxychloroquine and its salts

Hydroxychloroquine et ses sels

4-Hydroxycoumarin and its derivatives when sold or recommended as anticoagulants

Hydroxy-4 coumarine et ses dérivés, s’ils sont vendus ou recommandés comme anticoagulants

Hydroxyurea

Hydroxyurée

Hydroxyzine and its salts and derivatives

Hydroxyzine, ses sels et dérivés

Ibandronic acid and its salts

Acide ibandronique et ses sels

Ibuprofen and its salts except when sold for oral administration in a concentration of 400 mg or less per dosage unit.

Ibuprofène et ses sels, sauf s’ils sont vendus pour administration par voie orale en une concentration de 400 mg ou moins par unité posologique

Ibutilide and its salts and derivatives

Ibutilide et ses sels et dérivés

Idarubicin and its salts

Idarubicine et ses sels

Idoxuridine

Idoxuridine

Ifosfamide

Ifosfamide

Imatinib and its salts

Imatinib et ses sels

Imiglucerase

Imiglucérase

Imipenem and its salts and derivatives

Imipénem, ses sels et dérivés

Imipramine and its salts

Imipramine et ses sels

Imiquimod and its salts

Imiquimod et ses sels

Indapamide and its salts

Indapamide et ses sels

Indinavir and its salts

Indinavir et ses sels

Indomethacin

Indométhacine

Infliximab

Infliximab

Inhaled human insulin

Insuline humaine inhalée

Inosiplex

Inosiplex

Interferon

Interféron

Iodochlorohydroxyquin (except in preparations for topical use on the skin)

Iodochlorhydroxyquinoléine (sauf dans les préparations pour usage topique sur la peau)

Ipratropium and its salts

Ipratropium et ses sels

Iproniazid and its salts

Iproniazide et ses sels

Irbesartan and its salts

Irbésartan et ses sels

Irinotecan and its salts

Irinotécan et ses sels

Isocarboxazid and its salts

Isocarboxazide et ses sels

Isoflurane

Isoflurane

Isoniazid

Isoniazide

Isoproterenol (Isoprenaline) and its salts

Isoprotérénol (Isoprénaline) et ses sels

Isotretinoin and its salts

Isotrétinoïne et ses sels

Isoxsuprine and its salts

Isoxsuprine et ses sels

Isradipine and its salts

Isradipine et ses sels

Itraconazole and its salts

Itraconazole et ses sels

Ivermectin and its derivatives, for human use or for veterinary use when sold for intramuscular injection into horses or for oral administration to dogs and cats

Ivermectine et ses dérivés, destinés à l’usage humain ou à l’usage vétérinaire, s’ils sont vendus pour injection intramusculaire aux chevaux ou pour administration par voie orale aux chiens et aux chats

Ketanserin and its salts

Kétansérine et ses sels

Ketoconazole and its salts (except in preparations for topical use as a shampoo)

Kétoconazole et ses sels (excepté pour les préparations pour usage topique sous la forme d’un shampooing)

Ketoprofene and its salts

Kétoprofène et ses sels

Ketorolac and its salts

Kétorolac et ses sels

Ketotifen and its salts

Kétotifène et ses sels

Labetalol and its salts

Labétalol et ses sels

Lactic acid, when recommended for parenteral use as a tissue sclerosing agent

Acide lactique, s’il est recommandé pour usage parentéral comme agent sclérosant

Lamivudine and its salts

Lamivudine et ses sels

Lamotrigine and its salts

Lamotrigue et ses sels

Lanreotide and its salts

Lanréotide et ses sels

Lansoprazole and its salts

Lansoprazole et ses sels

Lanthanum salts, when sold for the treatment of hyperphosphatemia

Sels de lanthane vendus pour le traitement de l’hyperphosphatémie

Lapatinib and its salts

Lapatinib et ses sels

Laronidase

Laronidase

Latanoprost

Latanoprost

Leflunomide and its salts

Léflunomide et ses sels

Lenalidomide

Lénalidomide

Letrozole

Létrozole

Leucovorin and its salts

Acide folinique et ses sels

Leuprolide and its salts

Leuproréline et ses sels

Levetiracetam

Lévétiracétam

Levobunolol and its salts

Levobunolol et ses sels

Levocabastine and its salts and derivatives

Lévocabastine, ses sels et dérivés

Levocarnitine and its salts and derivatives

Lévocarnitine et ses sels et dérivés

Levodopa and its salts

Lévodopa et ses sels

Linezolid and its salts

Linézolide et ses sels

Lisinopril and its salts and derivatives

Lisinopril, ses sels et dérivés

Lithium and its salts

Lithium et ses sels

Lodoxamide and its salts and derivatives

Lodoxamide, ses sels et dérivés

Lomefloxacin and its salts

Loméfloxacine et ses sels

Lomustine

Lomustine

Lopinavir

Lopinavir

Loracarbef and its salts and derivatives

Loracarbef, ses sels et dérives

Losartan and its salts

Losartan et ses sels

Losoxantrone and its salts

Losoxantrone et ses sels

Lovastatin

Lovastatine

Loxapine and its salts

Loxapine et ses sels

Lumiracoxib

Lumiracoxib

Lutropin alfa

Lutropine alfa

Magnesium glutamate hydrobromide

Bromhydrate de glutamate de magnésium

Maprotiline and its salts

Maprotiline et ses sels

Maraviroc

Maraviroc

Marbofloxacin and its salts and derivatives

Marbofloxacine et ses sels et dérivés

Mecamylamine and its salts

Mécamylamine et ses sels

Mechlorethamine and its salts

Méchloréthamine et ses sels

Mecillinam and its salts and derivatives

Mécillinam, ses sels et dérivés

Meclofenamic acid and its salts

Méclofénamique (acide) et ses sels

Medetomidine and its salts

Médétomidine et ses sels

Mefenamic acid and its salts

Méfénamique (acide) et ses sels

Mefloquine and its salts and derivatives

Méfloquine, ses sels et dérivés

Megestrol and its salts

Mégestrol et ses sels

Melanoma therapeutic vaccine

Vaccin thérapeutique contre le mélanome

Melarsomine and its salts, when sold for the treatment of heartworm in dogs

Mélarsomine et ses sels, s’ils sont vendus pour le traitement du ver du coeur chez le chien

Meloxicam and its salts and derivatives

Méloxicam et ses sels et dérivés

Melphalan

Melphalan

Memantine and its salts

Mémantine et ses sels

Menotropins (human)

Ménotropines (humains)

Mepacrine and its salts

Mépacrine et ses sels

Mepazine and its salts

Mépazine et ses sels

Mephenoxalone

Méphenoxalone

Mephentermine and its salts

Méphentermine et ses sels

Mercaptopurine

Mercaptopurine

Meropenem and its salts and derivatives

Méropénem, ses sels et dérivés

Mesna

Mesna

Mesoridazine and its salts

Mésoridazine et ses sels

Metaldehyde

Métaldéhyde

Metformin and its salts and derivatives

Metformine, ses sels et dérivés

Methacholine chloride

Méthacholine (chlorure de)

Methazolamide and its salts

Méthazolamide et ses sels

Methicillin and its salts and derivatives

Méthicilline, ses sels et dérivés

Methimazole

Méthimazole

Methisazone

Méthisazone

Methoin (Mephenytoin) and its salts

Méthoïne (méphénytoine) et ses sels

Methotrexate and its salts

Méthotrexate et ses sels

Methotrimeprazine and its salts

Méthotriméprazine et ses sels

Methoxamine and its salts

Méthoxamine et ses sels

Methoxsalen

Méthoxsalène

Methoxy polyethylene glycol-epoetin beta

Méthoxy polyéthylèneglycol-époétine bêta

Methyldopa and its salts

Méthyldopa et ses sels

Methylparafynol

Méthylparafynol

Methysergide and its salts and derivatives

Méthysergide, ses sels et dérivés

Metoclopramide

Métoclopramide

Metolazone and its salts

Métolazone et ses sels

Metomidate and its salts

Métomidate et ses sels

Metopimazine and its salts

Métopimazine et ses sels

Metoprolol and its salts

Métoprolol et ses sels

Metronidazole

Métronïdazole

Metyrapone and its salts

Métyrapone et ses sels

Mexiletine and its salts

Mésiletine et ses sels

Mezlocillin and its salts and derivatives

Mézlocilline, ses sels et dérivés

Micafungin and its salts

Micafungine et ses sels

Miconazole and its salts (except in preparations for topical and vaginal use)

Miconazole et ses sels (sauf dans les préparations pour usage topique et vaginal)

Midodrine and its salts

Midodrine et ses sels

Miglustat

Miglustat

Milbemycin and its derivatives

Milbémycine et ses dérivés

Milrinone and its salts

Milrinone et ses sels

Minoxidil (except in solutions for topical use in concentrations of 2% or less)

Minoxidil (sauf dans les solutions pour usage topique où sa concentration est de 2 % ou moins)

Mirtazapine and its salts

Mirtazapine et ses sels

Mitomycin and its salts

Mitomycine et ses sels

Mitotane (o,p’-DDD)

Mitotane (o,p’-DDD)

Mitoxantrone and its salts

Mitoxantrone et ses sels

Mivacurium chloride

Mivacurium (chlorure de)

Modafinil and its salts

Modafinil et ses sels

Molgramostim

Molgramostim

Montelukast and its salts

Montélukast et ses sels

Moxidectin and its derivatives, when sold for the prevention of heartworm in dogs

Moxidectine et ses dérivés, s’ils sont vendus pour la prévention du ver du coeur chez le chien

Moxifloxacin and its salts and derivatives

Moxifloxacine, ses sels et dérivés

Muromonab-CD3

Muromonab-CD3

Mycophenolic acid and its salts and derivatives

Mycophénolique (acide) et ses sels et dérivés

Nabumetone

Nabumétone

Nadolol and its salts

Nadolol et ses sels

Nadroparin and its salts

Nadroparine et ses sels

Nafarelin and its salts and derivatives

Nafaréline, ses sels et dérivés

Nafcillin and its salts and derivatives

Nafcilline, ses sels et dérivés

Nalidixic acid

Nalidixique (acide)

Nalmefene and its salts

Nalméfène et ses sels

Naloxone and its salts

Naloxone et ses sels

Naltrexone and its salts and derivatives

Naltrexone, ses sels et ses dérivés

Naproxen and its salts, except when sold for oral use with a daily dosage of 440 mg

Naproxène et ses sels,sauf lorsque vendu pour administration par voie orale en dose quotidienne de 440 mg

Naratriptan and its salts

Naratriptan et ses sels

Natalizumab

Natalizumab

Nateglinide and its salts and derivatives

Natéglinide et ses sels et dérivés

Nedocromil and its salts

Nédocromil et ses sels

Nefazodone and its salts

Néfazodone et ses sels

Nelarabine

Nélarabine

Nelfinavir and its salts

Nelfinavir et ses sels

Neocinchophen and its salts

Néocinchophène et ses sels

Neostigmine salts

Néostigmine (les sels de)

Nepafenac

Népafénac

Netilmicin and its salts and derivatives

Nétilmicine, ses sels et dérivés

Nevirapine and its salts

Névirapine et ses sels

Nialamide and its salts

Nialamide et ses sels

Nicardipine and its salts

Nicardipine et ses sels

Nicotine and its salts, for human use, except

(*a*) in natural substances;

(*b*) in the form of a chewing gum containing 4 mg or less of nicotine per dosage unit;

(*c*) in the form of a transdermal patch with a delivery rate of 22 mg or less of nicotine per day;

(*d*) in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit; or

(*e*) in the form of a lozenge containing 4 mg or less of nicotine per dosage unit

*Nicotine et ses sels, destinés à l'usage humain, sauf :*

*a*) *dans les substances naturelles;*

*b*) *sous forme de gomme à mâcher contenant 4 mg ou moins de nicotine par unité posologique;*

*c*) *sous forme de timbre cutané ayant un taux de libération de 22 mg ou moins de nicotine par jour;*

*d*) *sous une forme destinée à être administrée par voie orale au moyen d'un inhalateur libérant 4 mg ou moins de nicotine par unité posologique;*

*e*) *sous forme de pastille contenant 4 mg ou moins de nicotine par unité posologique*

Nicotinic acid when sold in

(*a*) a modified-release oral dosage form that provides 500 mg or more per dosage unit or per daily dose; or

(*b*) an immediate-release oral dosage form that provides more than 500 mg per dosage unit or per daily dose

*Acide nicotinique vendu sous l'une des forme suivantes :*

*a*) *en forme posologique à libération modifiée fournissant, par unité posologique ou par dose quotidienne, 500 mg ou plus d'acide nicotinique administré par voie orale;*

*b*) *en forme posologique à libération immédiate fournissant, par unité posologique ou par dose quotidienne, plus de 500 mg d'acide nicotinique administré par voie orale*

Nifedipine

Nifédipine

Nilotinib and its salts

Nilotinib et ses sels

Nilutamide

Nilutamide

Nimodipine and its salts

Nimodipine et ses sels

Nitric oxide

Oxyde nitrique

Nitroscanate

Nitroscanate

Nizatidine and its salts (except when sold in an oral dosage form containing not more than the equivalent of 75 mg of nizatidine)

Nizatidine et ses sels (sauf lorsque vendue sous une forme posologique orale contenant au plus l’équivalent de 75 mg de nizatidine)

Nomifensine and its salts

Nomifensine et ses sels

Norfloxacin

Norfloxacine

Nortriptyline and its salts

Nortriptyline et ses sels

Nylidrin and its salts

Nylidrine et ses sels

Octatropine methylbromide

Octatropine (méthylbromure d’)

Octreotide

Octréotide

Ofloxacin and its salts

Ofloxacine et ses sels

Olanzapine and its salts

Olanzapine et ses sels

Olmesartan and its salts and derivatives

Olmésartan, ses sels et dérivés

Olopatadine and its salts

Olopatadine et ses sels

Olsalazine and its salts

Olsalazine et ses sels

Omalizumab

Omalizumab

Omeprazole and its salts

Oméprazole et ses sels

Ondansetron and its salts

Ondansétron et ses sels

Orbifloxacin and its salts and derivatives

Orbifloxacine, ses sels et dérivés

Orciprenaline (Metaproterenol) and its salts

Orciprénaline (Métaprotérénol) et ses sels

Orlistat

Orlistat

Ormetoprim and its salts

Ormétoprime et ses sels

Ornidazole

Ornidazole

Oseltamivir and its salts

Oséltamivir et ses sels

Oxacillin, and its salts and derivatives

Oxacilline, ses sels et dérivés

Oxaliplatin

Oxaliplatine

Oxanamide

Oxanamide

Oxaprozin and its salts and derivatives

Oxaprozine, ses sels et dérivés

Oxcarbazepine

Oxcarbazépine

Oxolinic acid and its salts

Oxolinique (acide) et ses sels

Oxprenolol and its salts

Oxprénolol et ses sels

Oxybutynin and its salts

Oxybutynine et ses sels

Oxyphenbutazone and its salts

Oxyphenbutazone et ses sels

Oxytocin

Oxytocine

Paclitaxel and its derivatives

Paclitaxel et ses dérivés

Palifermin

Palifermine

Paliperidone and its salts and derivatives

Palipéridone, ses sels et ses dérivés

Palivizumab

Palivizumab

Pamidronic acid and its salts

Pamidronique (acide) et ses sels

Pancuronium and its salts

Pancuronium et ses sels

Panitumumab

Panitumumab

Pantoprazole and its salts

Pantoprazole et ses sels

Paraldehyde

Paraldéhyde

Paramethadione

Paraméthadione

Pargyline and its salts

Pargyline et ses sels

Paricalcitol

Paricalcitol

Paroxetine and its salts

Paroxétine et ses sels

Pegaptanib and its salts

Pegaptanib et ses sels

Pegfilgrastim

Pegfilgrastim

Pegvisomant

Pegvisomant

Pemetrexed and its salts

Pémétrexed et ses sels

Penciclovir and its salts

Penciclovir et ses sels

Penicillamine

Pénicillamine

Pentamidine and its salts

Pentamidine et ses sels

Pentolinium tartrate

Pentolinium (tartrate de)

Pentosan polysulfate and its salts

Pentosane polysulfate et ses sels

Pentostatin and its salts

Pentostatine et ses sels

Pentoxifylline and its salts

Pentoxifylline et ses sels

Perflutren

Perflutrène

Pergolide and its salts

Pergolide et ses sels

Pericyazine and its salts

Péricyazine et ses sels

Perindopril and its salts

Périndopril et ses sels

Perphenazine and its salts

Perphénazine et ses sels

Phacetoperane and its salts

Phacétopérane et ses sels

Phenacemide

Phénacémide

Phenacetin

Phénacétine

Phenaglycodol

Phénaglycodol

Phenazopyridine and its salts

Phénazopyridine et ses sels

Phenelzine and its salts

Phénelzine et ses sels

Phenformin and its salts

Phenformine et ses sels

Pheniprazine and its salts

Phéniprazine et ses sels

Phenthoxate and its salts

Phentoxate et ses sels

Phentolamine and its salts

Phentolamine et ses sels

Phenylbutazone and its salts

Phénylbutazone et ses sels

Phenylephrine and its salts in preparations for ophthalmic or parenteral use in concentrations greater than 2.5%

Phényléphrine et ses sels dans les préparations pour usage ophtalmique ou parentéral lorsqu'il constitue plus de 2,5% d'un mélange

Phenylindanedione and its derivatives

Phénylindanédione et ses dérivés

Phenylpropanolamine and its salts and derivatives for veterinary use

Phénylpropanolamine, ses sels et dérivés, destinés à l'usage vétérinaire

Pilocarpine and its salts

Pilocarpine et ses sels

Pimecrolimus

Pimécrolimus

Pimobendan

Pimobendan

Pimozide

Pimozide

Pinaverium bromide

Pinavérium (bromure de)

Pindolol and its salts

Pindolol et ses sels

Pioglitazone and its salts

Pioglitazone et ses sels

Pipecuronium bromide

Pipécuronium (bromure de)

Piperacetazine and its salts

Pipéracétazine et ses sels

Piperilate and its salts

Pipérilate et ses sels

Pipotiazine and its salts

Pipotiazine et ses sels

Pipobroman

Pipobroman

Pirbuterol and its salts

Pirbutérol et ses sels

Pirenzepine and its salts

Pirenzépine et ses sels

Pirlimycin and its salts

Pirlimycine et ses sels

Piroxicam and its salts

Piroxicam et ses sels

Pizotyline and its salts

Pizotyline et ses sels

Podophyllum and the following extracts and active principles, when sold or recommended for topical use:

(*a*) podophyllotoxin

(*b*) podophyllum resin

*Podophyllum, ses extraits et principes actifs suivants lorsque vendus ou recommandés pour usage topique :*

*a) podophyllotoxine*

*b) podophyllum (résine de)*

Polysulfated glycosaminoglycan

Glycosaminoglycan polysulfaté

Ponazuril

Ponazuril

Poractant alfa

Poractant alfa

Porfimer and its salts

Porfimère et ses sels

Posaconazole

Posaconazole

Potassium bromide

Bromure de potassium

Potassium gluconate, when sold or recommended for administration to cats

Potassium (gluconate de), lorsqu’il est vendu ou recommandé pour administration aux chats

Potassium para-aminobenzoate (except in preparations for topical use on the skin)

Potassium (para-aminobenzoate de) (sauf dans les préparations pour usage topique sur la peau)

Pralidoxime and its salts

Pralidoxime et ses sels

Pramipexole and its salts

Pramipexole et ses sels

Pravastatin and its salts

Pravastatine et ses sels

Praziquantel, except when sold for the treatment of the tapeworm Anoplocephala perfoliata in horses

Praziquantel, sauf s’il est vendu pour le traitement du ver solitaire Anoplocephala perfoliata chez les chevaux

Prazosin and its salts

Prazosine et ses sels

Pregabalin and its salts and derivatives

Prégabaline, ses sels et ses dérivés

Prenylamine and its salts

Prénylamine et ses sels

Primaquine and its salts

Primaquine et ses sels

Probenecid and its salts

Probénécide et ses sels

Probucol

Probucol

Procainamide and its salts

Procainamide et ses sels

Procarbazine and its salts

Procarbazine et ses sels

Procaterol and its salts

Procatérol et ses sels

Prochlorperazine and its salts

Prochlorpérazine et ses sels

Procyclidine and its salts

Procyclidine et ses sels

Prodilidine and its salts

Prodilidine et ses sels

Profenamine and its salts

Profénamine et ses sels

Proguanil and its salts

Proguanil et ses sels

Propafenone and its salts

Propafénone et ses sels

Propofol

Propofol

Propranolol and its salts

Propranolol et ses sels

Prostaglandins and their salts and derivatives

Prostaglandines, leurs sels et dérivés

Prothipendyl hydrochloride

Prothipendyl (chlorhydrate de)

Protirelin

Protireline

Protriptyline and its salts

Protriptyline et ses sels

Pyrazinamide

Pyrazinamide

Pyridostigmine bromide

Pyridostigmine (bromure de)

Pyrimethamine and its salts

Pyriméthamine et ses sels

Quetiapine and its salts

Quétiapine et ses sels

Quinagolide and its salts

Quinagolide et ses sels

Quinapril and its salts and derivatives

Quinapril, ses sels et dérivés

Quinupristin and its salts

Quinupristine et ses sels

Rabeprazole and its salts

Rabéprazole et ses sels

Raloxifene and its salts

Raloxifène et ses sels

Raltegravir and its salts

Raltégravir et ses sels

Raltitrexed and its salts and derivatives

Raltitrexed, ses sels et dérivés

Ramipril and its salts and derivatives

Ramipril, ses sels et dérivés

Ranibizumab

Ranibizumab

Ranitidine and its salts, except when sold in concentrations of 150 mg or less per oral dosage unit and indicated for the treatment of heartburn

Ranitidine et ses sels, sauf s’ils sont vendus en une concentration de 150 mg ou moins par unité posologique orale et indiqués pour le traitement des brûlures d’estomac

Rasagiline and its salts

Rasagiline et ses sels

Rasburicase

Rasburicase

Raubasine and its salts

Raubasine et ses sels

Rauwolfia

Rauwolfia

Remoxipride and its salts

Rémoxipride et ses sels

Repaglinide and its salts and derivatives

Répaglinide et ses sels et dérivés

Rescinnamine and its salts

Rescinnamine et ses sels

Resocortol and its derivatives

Résocortol et ses dérivés

Retapamulin

Rétapamuline

Reviparin and its salts

Réviparine et ses sels

Ribavirin

Ribavirine

Rifabutin and its salts

Rifabutine et ses sels

Rifampin and its salts and derivatives

Rifampine, ses sels et dérivés

Riluzole and its salts

Riluzole et ses sels

Risedronic acid and its salts

Acide risédronique et ses sels

Risperidone and its salts

Rispéridone et ses sels

Ritodrine and its salts

Ritodrine et ses sels

Ritonavir

Ritonavir

Rituximab

Rituximab

Rivaroxaban

Rivaroxaban

Rivastigmine and its salts

Rivastigmine et ses sels

Rizatriptan and its salts

Rizatriptan et ses sels

Rocuronium bromide

Rocuronium (bromure de)

Rofecoxib

Rofécoxib

Romifidine and its salts

Romifidine et ses sels

Romiplostim

Romiplostim

Ropinirole and its salts

Ropinirole et ses sels

Rosiglitazone and its salts

Rosiglitazone et ses sels

Rosoxacin and its salts

Rosoxacine et ses sels

Rosuvastatin and its salts

Rosuvastatine et ses sels

Salbutamol and its salts

Salbutamol et ses sels

Salmeterol and its salts

Salmetérol et ses sels

Salsalate and its salts and derivatives

Salsalate, ses sels et dérivés

Saquinavir and its salts and derivatives

Saquinavir, ses sels et dérivés

Saralasin and its salts

Saralasine et ses sels

Sargramostim

Sargramostim

Selegiline and its salts

Sélégiline et ses sels

Sermorelin and its salts

Sermoréline et ses sels

Sertraline and its salts

Sertraline et ses sels

Sevelamer and its salts

Sévélamer et ses sels

Sibutramine and its salts

Sibutramine et ses sels

Sildenafil and its salts

Sildénafil et ses sels

Simvastatin

Simvastatine

Sirolimus and its derivatives

Sirolimus et ses dérivés

Sitagliptin and its salts

Sitagliptine et ses sels

Sitaxentan and its salts

Sitaxentan et ses sels

Sodium aurothiomalate

Aurothiomalate de sodium

Sodium bromide

Bromure de sodium

Sodium nitroprusside and its salts

Sodium (nitroprussiate de) et ses sels

Sodium polystyrene sulfonate

Sulfonate de polystyrène de sodium

Solifenacin and its salts

Solifénacine et ses sels

Somatostatin

Somatostatine

Somatrem

Somatrem

Somatropin

Somatropine

Sorafenib and its salts

Sorafénib et ses sels

Sotalol and its salts

Sotalol et ses sels

Spironolactone

Spironolactone

Stavudine

Stavudine

Streptozocin

Streptozocine

Strontium bromide

Bromure de strontium

Succinimide and its salts and derivatives (except those compounds used for decontaminating water)

Succinimide, ses sels et dérivés (sauf les produits utilisés pour décontaminer l’eau)

Sucralfate

Sucralfate

Sulconazole and its salts

Sulconazole et ses sels

Sulfinpyrazone and its salts

Sulfinpyrazone et ses sels

Sulindac and its salts

Sulindac et ses sels

Sulphones and their derivatives

Sulphones et leurs dérivés

Sumatriptan and its salts

Sumatriptan et ses sels

Sunitinib and its salts

Sunitinib et ses sels

Suprofen and its salts

Suprofène et ses sels

Suxamethonium chloride

Suxaméthonium (chlorure de)

Tacrolimus and its derivatives

Tacrolimus et ses dérivés

Tadalafil and its salts

Tadalafil et ses sels

Tamoxifen and its salts

Tamoxifène et ses sels

Tamsulosin and its salts

Tamsulosine et ses sels

Tazarotene

Tazarotène

Tazobactam and its salts and derivatives

Tazobactam, ses sels et dérivés

Teflubenzuron

Teflubenzuron

Tegafur and its salts

Tégafur et ses sels

Tegaserod and its salts

Tégasérod et ses sels

Telbivudine

Telbivudine

Telithromycin and its salts and derivatives

Télithromycine et ses sels et dérivés

Telmisartan and its salts and derivatives

Telmisartan et ses sels et dérivés

Temozolomide and its salts

Témozolomide et ses sels

Tenecteplase and its salts and derivatives

Ténectéplase et ses sels et dérivés

Teniposide

Téniposide

Tenofovir and its salts and derivatives

Ténofovir et ses sels et dérivés

Tenoxicam and its salts

Ténoxicam et ses sels

Terazosin and its salts

Térazosine et ses sels

Terbinafine and its salts

Terbinafine et ses sels

Terbutaline and its salts

Terbutaline et ses sels

Terconazole and its salts

Terconazole et ses sels

Terfenadine and its salts

Terfénadine et ses sels

Teriparatide and its salts

Tériparatide et ses sels

Terlipressin and its salts

Terlipressine et ses sels

Tetrabenazine and its salts

Tétrabénazine et ses sels

Thalidomide

Thalidomide

Theobromine and its salts

Théobromine et ses sels

Theophylline and its salts

Théophylline et ses sels

Thiethylperazine and its salts

Thiéthylpérazine et ses sels

Thiocarlide

Thiocarlide

Thioguanine

Thioguanine

Thiopropazate and its salts

Thiopropazate et ses sels

Thioproperazine and its salts

Thiopropérazine et ses sels

Thioridazine and its salts

Thioridazine et ses sels

Thiotepa

Thiotépa

Thiothixene and its salts

Thiothixène et ses sels

Thiouracil and its derivatives

Thiouracile et ses dérivés

Thyrotropin alfa

Thyrotropine alfa

Thyroxin and its salts

Thyroxine et ses sels

Tiaprofenic acid and its salts

Tiaprofénique (acide) et ses sels

Ticarcillin and its salts and derivatives

Ticarcilline, ses sels et dérivés

Ticlopidine and its salts

Ticlopidine et ses sels

Tigecycline

Tigécycline

Tilmicosin, except in preparations for veterinary use to be administered orally

Tilmicosine, sauf dans les préparations pour usage vétérinaire destinées à être administrées par voie orale

Tiludronic acid and its salts

Tiludronique (acide) et ses sels

Timolol and its salts

Timolol et ses sels

Tinidazole

Tinidazole

Tinzaparin and its salts

Tinzaparine et ses sels

Tioconazole and its salts (except in preparations for topical and vaginal use)

Tioconazole et ses sels (sauf dans les préparations pour usage topique et vaginal)

Tiotropium bromide

Tiotropium (bromure de)

Tipranavir and its salts

Tipranavir et ses sels

Tirofiban and its salts and derivatives

Tirofiban et ses sels et dérivés

Tizanidine and its salts

Tizanidine et ses sels

Tobramycin and its salts and derivatives

Tobramycine, ses sels et dérivés

Tocainide and its salts

Tocaïnide et ses sels

Tolazamide

Tolazamide

Tolazoline and its salts

Tolazoline et ses sels

Tolbutamide

Tolbutamide

Tolcapone

Tolcapone

Tolfenamic acid and its salts and derivatives

Tolfénamique (acide), ses sels et dérivés

Tolmetin and its salts

Tolmétine et ses sels

Tolterodine and its salts

Toltérodine et ses sels

Topiramate

Topiramate

Topotecan and its salts

Topotécane et ses sels

Torasemide and its salts

Torasémide et ses sels

Toremifene and its salts

Torémifène et ses sels

Trandolaprilat and its salts and derivatives

Trandolaprilat et ses sels et dérivés

Tranexamic acid

Tranexamique (acide)

Tranylcypromine

Tranylcypromine

Trastuzumab

Trastuzumab

Trazodone and its salts

Trazodone et ses sels

Treosulfan

Tréosulfan

Treprostinil and its salts

Tréprostinil et ses sels

Tretamine

Trétamine

Tretinoin and its salts and derivatives

Trétinoïne, ses sels et dérivés

Tretinoin (Vitamin A acid)

Trétinoïne (acide de vitamine A)

Triamterene and its salts

Triamtérène et ses sels

Tricaine and its salts

Tricaïne et ses sels

Trifluoperazine and its salts

Trifluopérazine et ses sels

Triflupromazine and its salts

Triflupromazine et ses sels

Trifluridine

Trifluridine

Trihexyphenidyl and its salts

Trihexyphénidyle et ses sels

Triiodothyropropionic acid

Triiodothyropropionique (acide)

Trilostane

Trilostane

Trimebutine and its salts

Trimébutine et ses sels

Trimethadione

Triméthadione

Trimethaphan camsylate

Trimétaphan (camsilate de)

Trimethoprim and its salts

Triméthoprime et ses sels

Trimetrexate and its salts

Trimétrexate et ses sels

Trimipramine and its salts

Trimipramine et ses sels

Trioxsalen

Trioxysalène

Troglitazone

Troglitazone

Tropicamide and its salts in preparations for parenteral or ophthalmic use, except when sold for use in diagnostic procedures to an optometrist registered in a province of Canada

Tropicamide et ses sels dans les préparations pour usage ophtalmique ou parentéral, sauf lorsque vendu pour usage diagnostique à un optométriste enregistré dans une province du Canada

Trospium chloride

Trospium (chlorure de)

Trovafloxacin and its salts and derivatives

Trovafloxacine et ses sels et dérivés

L-Tryptophan, when sold as a single ingredient

L-Tryptophane, s'il est vendu comme seul ingrédient

Tubocurarine chloride

Tubocurarine (chlorure de)

Tybamate

Tybamate

Tylosin and its salts and derivatives, when sold for the treatment of chronic colitis in dogs

Tylosine, ses sels et dérivés, lorsque vendu pour le traitement de la colite chronique chez le chien

Unoprostone and its salts and derivatives

Unoprostone, ses sels et dérivés

Uracil and its salts

Uracile et ses sels

Uracil mustard and its salts

Uracile (moutarde à l') et ses sels

Ursodeoxycholic acid and its salts

Ursodéoxycholique (acide) et ses sels

Ustekinumab

Ustekinumab

Valaciclovir and its salts

Valaciclovir et ses sels

Valdecoxib and its salts

Valdécoxib et ses sels

Valganciclovir and its salts and derivatives

Valganciclovir, ses sels et dérivés

Valproic acid and its salts

Valproïque (acide) et ses sels

Valrubicin and its derivatives

Valrubicine et ses dérivés

Valsartan and its salts and derivatives

Valsartan et ses sels et dérivés

Vancomycin and its salts and derivatives

Vancomycine, ses sels et dérivés

Vardenafil and its salts

Vardénafil et ses sels

Varenicline and its salts

Varénicline et ses sels

Vasopressin and its salts

Vasopressine et ses sels

Vecuronium bromide

Vecuronium (bromure de)

Vedaprofen and its salts and derivatives

Védaprofène et ses sels et dérivés

Venlafaxine and its salts

Venlafaxine et ses sels

Verapamil and its salts

Vérapamil et ses sels

Verteporfin and its salts and derivatives

Vertéporfine et ses sels et dérivés

Vidarabine

Vidarabine

Vigabatrin and its salts and derivatives

Vigabatrine, ses sels et dérivés

Vinblastine and its salts

Vinblastine et ses sels

Vincristine and its salts

Vincristine et ses sels

Vindesine and its salts

Vindésine et ses sels

Vinorelbine and its salts

Vinorelbine et ses sels

Viomycin and its salts and derivatives

Viomycine, ses sels et dérivés

Vitamin A in oral dosage form containing more than 10,000 International Units of Vitamin A per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by that person of more than 10,000 International Units ofVitamin A

Vitamine A présentée en unités posologiques orales contenant chacune plus de 10 000 unités internationales de vitamine A ou dont la plus forte dose quotidienne recommandée sur l’étiquette résulte en l’ingestion,par une personne, de plus de 10 000 unités internationales de vitamine A

Vitamin B12 with Intrinsic Factor Concentrate

Vitamine B12 avec concentré de facteur intrinsèque

Vitamin D in oral dosage form containing more than 1,000 International Units of Vitamin D per dosage form or, where the largest recommended daily dosage shown on the label would, if consumed by a person, result in the daily intake by that person of more than 1,000 International Units ofVitamin D

Vitamine D présentée en unités posologiques orales contenant chacune plus de 1 000 unités internationales de vitamine D ou dont la plus forte dose quotidienne recommandée sur

l’étiquette résulte en l’ingestion,par une personne, de plus de 1 000 unités internationales de vitamine D

Voriconazole

Voriconazole

Vorinostat

Vorinostat

Xanthinol nicotinate

Xantinol (nicotinate de)

Xylazine and its salts

Xylazine et ses sels

Yohimbine and its salts

Yohimbine et ses sels

Zafirlukast and its salts

Zafirlukast et ses sels

Zalcitabine and its salts

Zalcitabine et ses sels

Zanamivir and its salts and derivatives

Zanamivir et ses sels et dérivés

Zidovudine

Zidovudine

Ziprasidone and its salts

Ziprasidone et ses sels

Zoledronic acid and its salts and derivatives

Acide zolédronique et ses sels et dérivés

Zomepirac and its salts

Zomépirac et ses sels

Zopiclone and its salts

Zopiclone et ses sels

Zuclopenthixol and its salts and derivatives

Zuclopenthixol, ses sels et dérivés

# PART II

Acepromazine and its salts

Acépromazine et ses sels

Acetanilide

Acétanilide

Adrenocortical hormones and their salts and derivatives, except

(*a*) hydrocortisone or hydrocortisone acetate, when sold as a single medicinal ingredient in a concentration that provides 0.5% hydrocortisone in preparations for topical use on the skin; and

(*b*) clobetasone butyrate, when sold in a concentration of 0.05% clobetasone butyrate in cream preparations for topical use on the skin

*Hormones corticosurrénales, leurs sels et dérivés sauf les suivants :*

(*a*) *l'hydrocortisone et l'acétate d'hydrocortisone vendus en tant qu'ingrédient médicinal unique dont la concentration permet un apport en hydrocortisone de 0,5 % dans les préparations pour usage topique sur la peau;*

(*b*) *le butyrate de clobétasone vendu sous forme de crème contenant 0,05 % de butyrate de clobétasone pour usage topique sur la peau*

Aminopyrine and its derivatives

Aminopyrine et ses dérivés

Amprolium and its salts

Amprolium et ses sels

Antipyrine (except preparations for topical use)

Antipyrine (sauf dans les préparations pour usage topique)

Apramycin and its salts

Apramycine et ses sels

Azithromycin and its salts and derivatives

Azithromycine, ses sels et dérivés

Calcium salts when sold for the treatment of hyperphosphatemia

Calcium (sels de) vendus pour le traitement de l'hyperphosphatémie

Centella asiatica extract and active principles thereof

Centella asiatica (extrait de) et ses principes actifs

Chlorhexidine and its salts, when used as a topical oral preparation

Chlorhexidine et ses sels, dans les préparations pour usage oral topique

Chlorothiazide and its salts and derivatives

Chlorothiazide, ses sels et dérivés

Chlorpromazine and its salts

Chlorpromazine et ses sels

Cholestyramine resin

Colestyramine (résine de)

Clarithromycin and its salts and derivatives

Clarithromycine, ses sels et dérivés

Cyclizine

Cyclizine

Dihydrostreptomycin and its salts and derivatives

Dihydrostreptomycine, ses sels et dérivés

Dirithromycin

Dirithromycine

Ergot alkaloids and their salts

Ergot (alcaloïdes d’) et leurs sels

Erythromycin and its salts and derivatives

Érythromycine, ses sels et dérivés

Folic acid

Acide folique

Framycetin and its salts and derivatives

Framycétine, ses sels et dérivés

Furaltadone and its salts

Furaltadone et ses sels

Furazolidone and its salts

Furazolidone et ses sels

Furosemide

Furosémide

Griseofulvin and its salts and derivatives

Griséofulvine, ses sels et dérivés

Iron derivatives for parenteral use only

Fer, ses dérivés pour usage parentéral seulement

Kanamycin and its salts and derivatives

Kanamycine, ses sels et dérivés

Levamisole and its salts

Lévamisole et ses sels

Lincomycin and its salts and derivatives

Lincomycine, ses sels et dérivés

Liothyronine and its salts

Liothyronine et ses sels

Mebendazole

Mébendazole

Meclizine and its salts when sold in concentrations greater than 25 mg per dosage unit

Méclizine et ses sels s'ils sont vendus en une concentration supérieure à 25 mg par unité posologique

Neomycin and its salts and derivatives

Néomycine, ses sels et dérivés

Nicarbazin

Nicarbazin

Nitrofurantoin and its salts

Nitrofurantoine et ses sels

Novobiocin and its salts and derivatives

Novobiocine, ses sels et dérivés

Nystatin (except preparations for topical use on the skin) and its salts and derivatives

Nystatine (sauf dans les préparations pour usage topique sur la peau), ses sels et dérivés

Oleandomycin and its salts and derivatives

Oléandomycine, ses sels et dérivés

Penicillin and its salts and derivatives, (except amoxicillin, ampicillin, azlocillin, benzathine penicillin, carbenicillin, cloxacillin, dicloxacillin, hetacillin, mecillinam, methicillin, mezlocillin, nafcillin, oxacillin and ticarcillin and their salts and derivatives)

Pénicilline, ses sels et dérivés, (sauf amoxicilline, ampicilline, azlocilline, benzathine pénicilline, carbénicilline, cloxacilline, dicloxacilline, hétacilline, mécillinam, méthicilline, mezlocilline, nafcilline, oxacilline et ticarcilline, leurs sels et dérivés)

Physostigmine salicylate (except preparations for oral or topical use only)

Physostigmine (salicylate de), (sauf dans les préparations pour usage oral et topique seulement)

Polymyxin B and its salts and derivatives, (except for topical use or for local action in the oral cavity or nasal passages)

Polymyxine B, ses sels et dérivés, (sauf pour usage topique ou local dans la cavité buccale ou dans les voies nasales)

Primidone

Primidone

Promazine and its salts

Promazine et ses sels

Reserpine and its salts

Réserpine et ses sels

Ronidazole and its salts and derivatives

Ronidazole, ses sels et dérivés

Sex hormones, except the following:

Hormones sexuelles, sauf :

Androisoxazole

Androisoxazole

Androstanolone

Androstanolone

Androstenediol and its derivatives

Androstènediol et ses dérivés

Bolandiol and its derivatives

Bolandiol et ses dérivés

Bolasterone

Bolastérone

Bolazine

Bolazine

Boldenone and its derivatives

Boldénone et ses dérivés

Bolenol

Bolénol

Calusterone

Calustérone

Clostebol and its derivatives

Clostébol et ses dérivés

Cyproterone and its derivatives

Cyprotérone et ses dérivés

Diethylstilbestrol and its derivatives

Diéthylstilbestrol et ses dérivés

Drostanolone and its derivatives

Drostanolone et ses dérivés

Enestebol

Énestébol

Epitiostanol

Épitiostanol

Ethylestrenol

Éthylestrénol

Fluoxymesterone

Fluoxymestérone

Formebolone

Formébolone

Furazabol

Furazabol

4-Hydroxy-19-nortestosterone and its derivatives

Hydroxy-4-nor-19 testostérone et ses dérivés

Levonorgestrel, when sold in concentrations of 0.75 mg per oral dosage unit

Lévonorgestrel, s’il est vendu en une concentration de 0,75 mg par unité posologique orale

Mebolazine

Mébolazine

Megestrol and its derivatives

Mégestrol et ses dérivés

Mesabolone

Mésabolone

Mesterolone

Mestérolone

Metandienone

Métandiénone

Metenolone and its derivatives

Méténolone et ses dérivés

Methandriol

Méthandriol

Methyltestosterone and its derivatives

Méthyltestostérone et ses dérivés

Metribolone

Métribolone

Mibolerone

Mibolérone

Nandrolone and its derivatives

Nandrolone et ses dérivés

Norboletone

Norbolétone

Norclostebol and its derivatives

Norclostébol et ses dérivés

Norethandrolone

Noréthandrolone

Oxabolone and its derivatives

Oxabolone et ses dérivés

Oxandrolone

Oxandrolone

Oxymesterone

Oxymestérone

Oxymetholone

Oxymétholone

Prasterone

Prastérone

Quinbolone

Quinbolone

Stanozolol

Stanozolol

Stenbolone and its derivatives

Stenbolone et ses dérivés

Testosterone and its derivatives

Testostérone et ses dérivés

Tibolone

Tibolone

Tiomesterone

Tiomestérone

Trenbolone and its derivatives

Trenbolone et ses dérivés

Zeranol

Zéranol

Sodium fluoride (in solid oral dosage forms containing more than one milligram of fluoride ion)

Sodium (fluorure de) (sous forme posologique solide orale contenant plus d’un milligramme d’ion fluor)

Spectinomycin and its salts and derivatives

Spectinomycine, ses sels et dérivés

Spiramycin and its salts and derivatives

Spiramycine, ses sels et dérivés

Streptomycin and its salts and derivatives

Streptomycine, ses sels et dérivés

Sulphonamides and their salts and derivatives

Sulfamides, leurs sels et dérivés

Tetracycline and its salts and derivatives (except doxycycline when sold for intramuscular administration in caged birds)

Tétracycline, ses sels et dérivés (sauf doxycycline si elle est vendue pour administration intramusculaire aux oiseaux en cage)

Thiabendazole

Thiabendazole

Thyroid

Thyroïde

Tioconazole and its salts

Tioconazole et ses sels

Trimeprazine and its salts

Triméprazine et ses sels

Tylosin and its salts and derivatives (except when sold for the treatment of chronic colitis in dogs)

Tylosine, ses sels et dérivés (sauf lorsque vendu pour le traitement de la colite chronique chez le chien)

Veratrum album and its alkaloids and their salts

Veratrum album, ses alcaloïdes et leurs sels

Veratrum viride and its alkaloids and their salts

Veratrum viride, ses alcaloïdes et leurs sels

Virginiamycin and its salts and derivatives

Virginiamycine, ses sels et dérivés

Vitamin A

Vitamine A

Vitamin D

Vitamine D

Vitamin K, except Vitamin K1 and Vitamin K2 sold

(*a*) for external use in humans; or

(*b*) in an oral dosage form for use in humans if the maximum recommended daily dose is 0.120 mg or less

*Vitamine K, sauf la vitamine K1 et la vitamine K2 vendues :*

(*a*) *soit pour usage externe destiné aux humains;*

(*b*) *soit sous une forme posologique orale destinée aux humains si la dose quotidienne maximale recommandée est de 0,120 mg ou moins*

SOR/78-423, s. 5; SOR/78-427, s. 11; SOR/79-754, s. 1; SOR/80-279, s. 1; SOR/81-334, s. 6; SOR/81-358, s. 2; SOR/82-1072, s. 1; SOR/85-551, s. 2; SOR/86-91, s. 5; SOR/86-955, s. 1; SOR/87-332, s. 1; SOR/87-447, s. 1; SOR/87-496, ss. 1 to 18; SOR/87-669, ss. 1, 2; SOR/88-351, ss. 1 to 11; SOR/88-511, ss. 1 to 11; SOR/89-195, s. 1; SOR/89-454, ss. 1 to 4; SOR/89-504, ss. 1 to 4; SOR/89-572, ss. 1 to 45; SOR/90-119, ss. 1 to 10; SOR/90-173, s. 2(F); SOR/90-443, ss. 1(F) to 4 (F), 5, 6(F) to 15(F); SOR/90-585, ss. 1 to 5; SOR/91-197, ss. 1, 2(F); SOR/91-521, ss. 1 to 15; SOR/92-95, ss. 1 to 9; SOR/92-386, ss. 4 to 8; SOR/92-591, s. 2; SOR/92-647, ss. 1 to 15; SOR/92-724, s. 1; SOR/93-110, ss. 1 to 3, 4(E), 5(E), 6 to 11; SOR/93-243, s. 2; SOR/93-435, ss. 1 to 38; SOR/94-166, ss. 1 to 17, 18(E), 19 to 30; SOR/94-286, ss. 1, 2; SOR/94-458, ss. 1 to 13; SOR/94-462, s. 1; SOR/94-557, ss. 1 to 9; SOR/94-461, s. 1; SOR/95-59, s. 1; SOR/95-172, s. 2; SOR/95-201, s. 1; SOR/95-546, s. 1; SOR/96-253, ss. 1, 2; SOR/96-306, s. 1; SOR/97-140, s. 1; SOR/97-407, s. 1; SOR/97-410, ss. 1, 2; SOR/97-414, s. 1; SOR/97-543, ss. 8, 9; SOR/97-544, s. 1; SOR/97-567, s. 1; SOR/98-291, ss. 1 to 7; SOR/98-292, s. 1; SOR/98-293, s. 1; SOR/98-294, s. 1; SOR/99-370, ss. 1, 2(F), 3, 4(F); SOR/99-373, s. 1; SOR/99-374, ss. 1(F), 2; SOR/99-412, s. 1; SOR/2000-119, s. 1; SOR/2000-124, s. 1; SOR/2000-197, ss. 1, 2; SOR/2000-219, s. 2; SOR/2000-403, ss. 1, 2; SOR/2001-95, s. 1; SOR/2001-531, s. 1; SOR/2002-53, s. 1; SOR/2002-418, s. 1; SOR/2003-34, ss. 6 to 8; SOR/2003-36, s. 1; SOR/2003-80, ss. 1, 2; SOR/2003-248, s. 1; SOR/2003-327, s. 1; SOR/2004-108, ss. 1 to 6; SOR/2005-105, s. 1; SOR/2005-167, s. 1; SOR/2005-270, s. 1; SOR/2005-307, s. 1; SOR/2006-143, s. 1; SOR/2006-144, ss. 1, 2; SOR/2006-211, s. 1; SOR/2006-212, s. 1; SOR/2006-213, s. 1; SOR/2006-214, s. 1; SOR/2006-215, s. 1; SOR/2006-251, s. 1; SOR/2007-36, s. 1; SOR/2007-37, s. 1; SOR/2007-38, s. 1; SOR/2007-39, s. 1; SOR/2007-40, s. 1; SOR/2007-41, s. 1; SOR/2007-42, ss. 1, 2; SOR/2007-83, s. 1; SOR/2007-224, s. 1; SOR/2007-234, s. 1; SOR/2008-35, s. 1; SOR/2008-100, s. 1; SOR/2008-101, ss. 1, 2; SOR/2008-108, s. 1; SOR/2008-204, s. 1; SOR/2008-205, s. 1; SOR/2008-206, s. 1; SOR/2008-207, s. 1; SOR/2008-260, s. 1; SOR/2009-116, s. 1; SOR/2009-117, s. 1; SOR/2009-118, s. 1; SOR/2009-119, s. 1; SOR/2009-120, s. 1;

SOR/2009-279, ss. 1, 2; SOR/2009-305, s. 1; SOR/2010-114, s. 1; SOR/2011-58, s. 1; SOR/2011-93, s. 1.

Previous Version

SCHEDULE K

REASONABLE DAILY INTAKE FOR VARIOUS FOODS

| | Column I | | Column II |
|---|---|---|---|
| Item No. | Name and Description | | R.D.I. |
| 1. | Alimentary Pastes, dry ..... | 3.0 oz. | 85 g |
| 2. | Bacon (side) simulated meat product that resembles side bacon, (cooked) ..... | 1.0 oz. | 28 g |
| 3. | Beverage Bases and Mixes, Flavoured, for Addition to Milk (ready to serve) ..... | 16.0 fl.oz. | 454 ml |
| 4. | Bread, 5 slices ..... | 5.3 oz. | 150 g |
| 5. | Butter ..... | 2.0 oz. | 57 g |
| 6. | Buttermilk ..... | 30.0 fl.oz. | 852 ml |
| 7. | Cereals, Breakfast or Infant ..... | 1.0 oz. | 28 g |
| 8. | Cereals, puffed ..... | 0.5 oz. | 14 g |
| 9. | Cheese (other than Cottage Cheese) ..... | 2.0 oz. | 57 g |
| 10. | Cheese, Cottage ..... | 3.5 oz. | 100 g |
| 11. | Condensed Milk ..... | 15.0 fl.oz. | 426 ml |
| 12. | Cream, whipping ..... | 2.0 oz. | 57 g |
| 13. | Egg, yolk-replaced egg ..... | 3.5 oz. | 100 g |
| 14. | Evaporated Milk, Evaporated Skim Milk, Evaporated Partly Skimmed Milk ..... | 15.0 fl.oz.<br>30.0 fl.oz.<br>(reconstituted to original volume) | 852 ml |
| 15. | Fish, Shell Fish ..... | 3.5 oz. | 100 g |
| 16. | Fruits, dried ..... | 2.0 oz. | 57 g |
| 17. | Fruits, (other than banana, lemon, lime, watermelon) ..... | 3.5 oz. | 100 g |
| 18. | Fruits, Banana ..... | 5.3 oz. | 150 g |
| 19. | Fruits, Lemon ..... | 1.8 oz. | 50 g |
| 20. | Fruits, Lime ..... | 1.8 oz. | 50 g |
| 21. | Fruits, Watermelon ..... | 7.0 oz. | 200 g |
| 22. | Fruit Drinks, Fruit Nectars (ready to serve) ..... | 4.0 fl.oz. | 114 ml |
| 23. | Fruit Drink Bases, Mixes and Concentrates (ready to serve) ..... | 4.0 fl.oz. | 114 ml |
| 24. | Fruit Juices (other than lemon juice and lime juice) ..... | 4.0 fl.oz. | 114 ml |

| Item No. | Column I<br>Name and Description | | Column II<br>R.D.I. |
|---|---|---|---|
| 25. | Fruit Juices, Lemon ..... | 1.0 fl.oz. | 28 ml |
| 26. | Fruit Juices, Lime ..... | 1.0 fl.oz. | 28 ml |
| 27. | Ice Cream, Ice Milk ..... | 3.5 oz. | 100 g |
| 28. | Infant Formulas, Prepared (ready to serve) ..... | As directed by Label | |
| 29. | Instant Breakfast, Ready Breakfast (ready to serve) ..... | As directed by Label | |
| 30. | Margarine ..... | 2.0 oz. | 57 g |
| 31. | Meat Products ..... | 3.5 oz. | 100 g |
| 32. | Meat Product Extenders ..... | 3.5 oz. | 100 g |
| 33. | Extended Meat Products ..... | 3.5 oz. | 100 g |
| 34. | Milk, whole ..... | 30.0 fl.oz. | 852 ml |
| 35. | Milk Powder (reconstituted and ready to serve) ..... | 30.0 fl.oz. | 852 ml |
| 36. | (naming the flavour) Milk ..... | 30.0 fl.oz. | 852 ml |
| 37. | Molasses ..... | 1.5 oz. | 43 g |
| 38. | Nuts ..... | 1.0 oz. | 28 g |
| 39. | Peanut Butter ..... | 1.0 oz. | 28 g |
| 40. | Poultry Products ..... | 3.5 oz. | 100 g |
| 41. | Extended Poultry Products ..... | 3.5 oz. | 100 g |
| 42. | Poultry Product Extenders ..... | 3.5 oz. | 100 g |
| 43. | Simulated Meat Products excluding a simulated meat product that resembles side bacon ..... | 3.5 oz. | 100 g |
| 44. | Simulated Poultry Products ..... | 3.5 oz. | 100 g |
| 45. | Skim Milk, Partly Skimmed Milk ..... | 30.0 fl.oz. | 852 ml |
| 46. | (naming the flavour) Skim Milk, (naming the flavour) Partly Skimmed Milk ..... | 30.0 fl.oz. | 852 ml |
| 47. | Skim Milk Powder, Partly Skimmed Milk Powder (reconstituted and ready to serve) ..... | 30.0 fl.oz. | 852 ml |
| 48. | Skim Milk with Added Milk Solids, Partly Skimmed Milk with Added Milk Solids ..... | 30.0 fl.oz. | 852 ml |
| 49. | (naming the flavour) Skim Milk with Added Milk Solids, (naming the flavour) Partly Skimmed Milk with Added Milk Solids ..... | 30.0 fl.oz. | 852 ml |
| 50. | Soup (ready to serve) ..... | 7.0 fl.oz. | 200 ml |
| 51. | Sterilized Milk ..... | 30.0 fl.oz. | 852 ml |
| 52. | Vegetable Juices ..... | 4.0 fl.oz. | 114 ml |
| 53. | Vegetable Drinks ..... | 4.0 fl.oz. | 114 ml |

| | Column I | | Column II |
|---|---|---|---|
| Item No. | Name and Description | | R.D.I. |
| 54. | Vegetable Drink Concentrates, Mixes and Bases (ready to serve) ..... | 4.0 fl.oz. | 114 ml |
| 55. | Vegetable (other than baked beans and cooked potatoes) ..... | 3.5 oz. | 100 g |
| 56. | Vegetables, baked beans ..... | 8.5 oz. | 250 g |
| 57. | Vegetables, cooked potatoes ..... | 7.0 oz. | 200 g |
| 58. | Yeast ..... | 0.5 oz. | 14 g |
| 59. | Yogurt, plain ..... | 5.0 oz. | 150 g |

SOR/78-64, s. 10; SOR/84-300, s. 63(E).

# APPENDICES I AND II

# [Repealed, SOR/81-935, s. 2]

# APPENDIX III

# FORMS

## Export Certificate

(Under the Food and Drugs Act*—R.S.C. 1970, c. F-27)

The undersigned exporter hereby certifies that the (description of article)

_____

packaged and labelled as follows: _____

and marked in distinct overprinting with the word “Export”

1. is not manufactured for consumption in Canada,

2. is not sold for consumption in Canada, and

3. packages and the contents of such packages do not contravene any known requirement of the law of

to which it is or is about to be consigned.

(name of country or countries)

Dated at the day of 19 .

Canada : In the matter of an Export Certificate under the Food and Drugs Act,

Province of

To
Wit : I, _____

of the of _____

in the of _____

do solemnly declare:

1. that I am the “Exporter” issuing the certificate above set out and have a knowledge of the matters and facts herein declared to by me,

or

I am the of _____

_____

the “Exporter” issuing the certificate above set out and have a knowledge of the matters and facts herein declared to by me (describe position of declarant as the agent of the “Exporter” in case of a Corporation issuing the certificate),

2. that the information set out in the said certificate is true,

3. that all information relevant to the purpose of the said certificate is set out herein and no information relevant thereto has knowingly been withheld.

And I make this solemn declaration conscientiously believing it to be true, and knowing that it is of the same force and effect as if made under oath, and by virtue of The Canada Evidence Act.

Declared before me at this _____

day of 19 .

A Commissioner for Taking Oaths

[*]See section 32 of the Food and Drugs Act and Appendix III of the Food and Drug Regulations

SOR/80-318, s. 2.

SCHEDULE L

(Sections B.01.402, B.01.403, B.01.450 and B.01.454 to B.01.465)

NUTRITION FACTS TABLE FORMATS

GRAPHICS ARE NOT DISPLAYED, SEE SOR/2003-11, S. 37; ERR., VOL. 137, NO. 5

SOR/2003-11, s. 37; err., Vol. 137, No. 5.

SCHEDULE M

(Sections B.01.001, B.01.002A and D.01.001)

REFERENCE AMOUNTS

| | Column 1 | Column 2 |
|---|---|---|
| Item | Food | Reference amount[1] |
| | ***Bakery Products*** | |
| 1. | Bread, excluding sweet quick-type rolls | 50 g |
| 2. | Bagels, tea biscuits, scones, rolls, buns, croissants, tortillas, soft bread sticks, soft pretzels and corn bread | 55 g |
| 3. | Brownies | 40 g |
| 4. | Heavy weight cake: 10 g or more per 2.5 cm cube, such as cheese cake, pineapple upside-down cake, cake with at least 35% of the finished weight as fruit, nuts or vegetables, or any of these combined | 125 g |
| 5. | Medium weight cake: 4 g or more per 2.5 cm cube but less than 10 g per 2.5 cm cube, such as cake with or without icing or filling, cake with less than 35% of the finished weight as fruit, nuts or vegetables or any of these combined, light weight cake with icing, Boston cream pie, cupcakes, eclairs or cream puffs | 80 g |
| 6. | Light weight cake: less than 4 g per 2.5 cm cube, such as angel food, chiffon or sponge cake, without icing or filling | 55 g |
| 7. | Coffee cakes, doughnuts, danishes, sweet rolls, sweet quick-type breads and muffins | 55 g |
| 8. | Cookies, with or without coating or filling, and graham wafers | 30 g |
| 9. | Crackers, hard bread sticks and melba toast | 20 g |
| 10. | Dry breads, matzo and rusks | 30 g |
| 11. | Flaky type pastries, with or without filling or icing | 55 g |
| 12. | Toaster pastries | 55 g |
| 13. | Ice cream cones | 5 g |
| 14. | Croutons | 7 g |
| 15. | French toast, pancakes and waffles | 75 g |
| 16. | Grain-based bars, with filling or partial or full coating | 40 g |
| 17. | Grain-based bars, without filling or coating | 30 g |
| 18. | Rice cakes and corn cakes | 15 g |
| 19. | Pies, tarts, cobblers, turnovers and other pastries | 110 g |
| 20. | Pie crust | 1/6 of 20 cm |

| Item | Column 1<br>Food | Column 2<br>Reference amount[1] |
|---|---|---|
| | | crust or 1/8 of 23 cm crust |
| 21. | Pizza crust | 55 g |
| 22. | Taco shell, hard | 30 g |
| | ***Beverages*** | |
| 23. | Carbonated and non-carbonated beverages, iced tea and wine coolers | 355 mL |
| 24. | Sports drinks and water | 500 mL |
| 25. | Coffee: regular, instant and specialty, including espresso, café au lait, flavoured and sweetened | 175 mL |
| 26. | Tea and herbal tea | |
| | (*a*) regular and instant (hot) | 175 mL |
| | (*b*) flavoured and sweetened, prepared from mixes | 250 mL |
| 27. | Cocoa and chocolate beverages (hot) | 175 mL |
| | ***Cereals and Other Grain Products*** | |
| 28. | Hot breakfast cereals, such as oatmeal or cream of wheat | 40 g dry<br>250 mL prepared |
| 29. | Ready-to-eat breakfast cereals, puffed and uncoated (less than 20 g per 250 mL) | 15 g |
| 30. | Ready-to-eat breakfast cereals, puffed and coated, flaked, extruded, without fruit or nuts (20 g to 42 g per 250 mL), very high fibre cereals (with 28 g or more fibre per 100 g) | 30 g |
| 31. | Ready-to-eat breakfast cereals, fruit and nut type, granola (43 g or more per 250 mL) and biscuit type cereals | 55 g |
| 32. | Bran and wheat germ | 15 g |
| 33. | Flours, including cornmeal | 30 g |
| 34. | Grains, such as rice or barley | 45 g dry<br>140 g cooked |
| 35. | Pastas without sauce | 85 g dry<br>215 g cooked |
| 36. | Pastas, dry and ready-to-eat, such as fried canned chow mein noodles | 25 g |
| 37. | Starch, such as cornstarch, potato starch, tapioca starch or wheat starch | 10 g |
| 38. | Stuffing | 100 g |
| | ***Dairy Products and Substitutes*** | |
| 39. | Cheese, including cream cheese and cheese spread, except those listed as a separate item | 30 g |
| 40. | Cottage cheese | 125 g |
| 41. | Cheese used as an ingredient, such as dry cottage cheese or ricotta cheese | 55 g |
| 42. | Hard cheese, grated, such as parmesan or romano | 15 g |

| Item | Column 1<br>Food | Column 2<br>Reference amount[1] |
|---|---|---|
| 43. | Quark, fresh cheese and fresh dairy desserts | 100 g |
| 44. | Cream and cream substitute, except those listed as a separate item | 15 mL |
| 45. | Cream and cream substitute, powder | 2 g |
| 46. | Cream and cream substitute, aerosol or whipped | 15 g |
| 47. | Eggnog | 125 mL |
| 48. | Milk, evaporated or condensed | 15 mL |
| 49. | Plant-based beverages, milk, buttermilk and milk-based drinks, such as chocolate milk | 250 mL |
| 50. | Shakes and shake substitutes, such as dairy shake mix | 250 mL |
| 51. | Sour cream | 30 mL |
| 52. | Yogurt | 175 g |
| | ***Desserts*** | |
| 53. | Ice cream, ice milk, frozen yogurt and sherbet | 125 mL |
| 54. | Dairy desserts, frozen, such as cakes, bars, sandwiches or cones | 125 mL |
| 55. | Non-dairy desserts, frozen, such as flavoured and sweetened ice or pops, or frozen fruit juices in bars or cups | 75 mL |
| 56. | Sundaes | 250 mL |
| 57. | Custard, gelatin and pudding | 125 mL |
| | ***Dessert Toppings and Fillings*** | |
| 58. | Dessert toppings, such as maple butter and marshmallow cream | 30 g |
| 59. | Cake frostings and icings | 35 g |
| 60. | Pie fillings | 75 mL |
| | ***Eggs and Egg Substitutes*** | |
| 61. | Egg mixtures, such as egg foo young, scrambled eggs or omelets | 110 g |
| 62. | Eggs | 50 g |
| 63. | Egg substitutes | 50 g |
| | ***Fats and Oils*** | |
| 64. | Butter, margarine, shortening and lard | 10 g |
| 65. | Vegetable oil | 10 mL |
| 66. | Butter replacement, powder | 2 g |
| 67. | Dressings for salad | 30 mL |
| 68. | Mayonnaise, sandwich spread and mayonnaise-type dressing | 15 mL |
| 69. | Oil, spray type | 0.5 g |
| | ***Marine and Fresh Water Animals*** | |
| 70. | Canned anchovies, anchovy paste and caviar | 15 g[2] |
| 71. | Marine and fresh water animals with sauce, such as fish with cream sauce or shrimp with lobster sauce | 140 g cooked |
| 72. | Marine and fresh water animals without sauce, such as plain or fried fish or shellfish, or fish or shellfish cakes, with or without breading or | 125 g raw<br>100 g cooked |

| Item | Column 1<br>Food | Column 2<br>Reference amount[1] |
|---|---|---|
| | batter | |
| 73. | Marine and fresh water animals, canned | 55 g[2] |
| 74. | Marine and fresh water animals, smoked or pickled, or spreads | 55 g[2] |
| | ***Fruit and Fruit Juices*** | |
| 75. | Fruit, fresh, canned or frozen, except those listed as a separate item | 140 g<br>150 mL canned[2] |
| 76. | Candied or pickled fruit | 30 g[2] |
| 77. | Dried fruit, such as raisins, dates or figs | 40 g |
| 78. | Fruit for garnish or flavour, such as maraschino cherries | 4 g[2] |
| 79. | Fruit relishes | 60 mL |
| 80. | Avocado, used as an ingredient | 30 g |
| 81. | Cranberries, lemons and limes, used as ingredients | 55 g |
| 82. | Watermelon, cantaloupe, honeydew and other melons | 150 g |
| 83. | Juices, nectars and fruit drinks represented for use as substitutes for fruit juices | 250 mL |
| 84. | Juices, used as ingredients, such as lemon juice or lime juice | 5 mL |
| | ***Legumes*** | |
| 85. | Bean curd (tofu) and tempeh | 85 g[2] |
| 86. | Beans, peas and lentils, such as white beans, kidney beans, romano beans, soybeans or chick peas | 100 g dry<br>250 mL cooked or canned[2] |
| | ***Meat, Poultry, Their Products and Substitutes***[3] | |
| 87. | Pork rinds and bacon | 54 g uncooked<br>15 g cooked |
| 88. | Beef, pork and poultry breakfast strips | 30 g uncooked<br>15 g cooked |
| 89. | Dried meat and poultry, such as jerky, dried beef or parma ham, as well as sausage products with a water activity of 0.90 or less, such as salami, dried thuringer or cervelat | 30 g |
| 90. | Luncheon meats, such as bologna, blood pudding, minced luncheon roll, liver sausage, mortadella, ham and cheese loaf or headcheese; pâté; sandwich spread; potted meat food product; taco fillings; meat pie fillings and cretons | 75 g uncooked<br>55 g cooked |
| 91. | Sausage products, such as linked sausage, Vienna sausage, wieners, breakfast sausage, frankfurters, pork sausage, bratwurst, kielbasa, Polish sausage, summer sausage, smoked sausage, smoked country sausage, pepperoni, knackwurst, thuringer or cervelat | 75 g uncooked<br>55 g cooked |
| 92. | Cuts of meat and poultry without sauce, and ready-to-cook cuts, with or without breading or batter, including marinated, tenderized and injected cuts | 125 g raw<br>100 g cooked |

| Item | Column 1<br>Food | Column 2<br>Reference amount[1] |
|---|---|---|
| 93. | Patties, cutlettes, chopettes, steakettes, meatballs, sausage meat and ground meat, with or without breading or batter | 100 g raw<br>60 g cooked |
| 94. | Cured meat products, such as cured ham, dry cured ham, back bacon, cured pork back, dry cured cappicolo, corned beef, pastrami, country ham, cured pork shoulder picnic, cured poultry ham products, smoked meat or pickled meat | 85 g raw<br>55 g cooked |
| 95. | Canned meat and poultry | 55 g[2] |
| 96. | Meat and poultry with sauce, such as meat in barbecue sauce or turkey with gravy, but excluding combination dishes | 140 g |
| | ***Miscellaneous*** | |
| 97. | Baking powder, baking soda and pectin | 0.6 g |
| 98. | Baking decorations, such as coloured sugars or sprinkles for cookies | 4 g |
| 99. | Bread crumbs and batter mixes | 30 g |
| 100. | Cooking wine | 30 mL |
| 101. | Cocoa powder | 5 g |
| 102. | Non-alcoholic drink mixers, such as pina colada or daiquiri | 250 mL |
| 103. | Chewing gum | 3 g |
| 104. | Salad and potato toppers, such as salad crunchies, salad crispins or substitutes for bacon bits | 7 g |
| 105. | Salt and salt substitutes, as well as seasoned salt, such as garlic salt | 1 g |
| 106. | Spices and herbs | 0.5 g |
| | ***Combination Dishes*** | |
| 107. | Measurable with a cup, such as casserole, hash, macaroni and cheese with or without meat, pot pie, spaghetti with sauce, stir fry, meat or poultry casserole, baked or refried beans, wieners and beans, meat chili, chili with beans, creamed chipped beef, beef or poultry ravioli in sauce, beef stroganoff, poultry à la king, Brunswick stew, goulash, stew, ragout or poutine | 250 mL |
| 108. | Not measurable with a cup, such as burritos, egg rolls, enchiladas, pizza, pizza rolls, sausage rolls, pastry rolls, cabbage rolls, quiche, sandwiches, crackers and meat or poultry lunch-type packages, gyros, burger on a bun, frank on a bun, calzones, tacos, pockets stuffed with meat, lasagna, chicken cordon bleu, stuffed vegetables with meat or poultry, shish kabobs, empanadas, fajitas, souvlaki, meat pie or tourtière | 140 g without gravy or sauce<br>195 g with gravy or sauce |
| 109. | Hors d’oeuvres | 50 g |
| | ***Nuts and Seeds*** | |
| 110. | Nuts and seeds, not for use as snacks: whole, chopped, sliced, slivered or ground | 30 g shelled |
| 111. | Butters, pastes and creams, other than peanut butter | 30 g |
| 112. | Peanut butter | 15 g |

| Item | Column 1<br>Food | Column 2<br>Reference amount[1] |
|---|---|---|
| 113. | Flours, such as coconut flour | 15 g |
| | ***Potatoes, Sweet Potatoes and Yams*** | |
| 114. | French fries, hash browns, skins and pancakes | 85 g frozen French fries<br>70 g prepared |
| 115. | Mashed, candied, stuffed or with sauce | 140 g |
| 116. | Plain, fresh, canned or frozen | 110 g fresh or frozen<br>125 g vacuum packed<br>160 g canned[2] |
| | ***Salads*** | |
| 117. | Salads, such as egg, fish, shellfish, bean, fruit, vegetable, meat, ham or poultry salad, except those listed as a separate item | 100 g |
| 118. | Gelatin salad | 120 g |
| 119. | Pasta or potato salad | 140 g |
| | ***Sauces, Dips, Gravies and Condiments*** | |
| 120. | Sauces for dipping, such as barbecue, hollandaise, tartar, mustard or sweet and sour sauce | 30 mL |
| 121. | Dips, such as legume or dairy-based | 30 g |
| 122. | Major main entree sauce, such as spaghetti sauce | 125 mL |
| 123. | Minor main entree sauce, such as pizza sauce, pesto sauce or other sauces used as toppings, such as white sauce, cheese sauce, salsa, cocktail sauce or gravy | 60 mL |
| 124. | Major condiments, such as ketchup, steak sauce, soy sauce, vinegar, teriyaki sauce or marinades | 15 mL |
| 125. | Minor condiments, such as horseradish, hot sauce, mustard or worcestershire sauce | 5 mL |
| | ***Snacks*** | |
| 126. | Chips, pretzels, popcorn, extruded snacks, grain-based snack mixes and fruit-based snacks, such as fruit chips | 50 g |
| 127. | Nuts or seeds for use as snacks | 50 g shelled |
| 128. | Meat or poultry snack food sticks | 20 g |
| | ***Soups*** | |
| 129. | All varieties | 250 mL |
| | ***Sugars and Sweets*** | |
| 130. | Candies, including chocolate bars and other chocolate products, except those listed as a separate item | 40 g |
| 131. | Hard candies, except those listed as a separate item | 15 g |
| 132. | Baking candies, such as chocolate chips | 15 g |

| Item | Column 1<br>Food | Column 2<br>Reference amount[1] |
|---|---|---|
| 133. | Breath mints | 2 g |
| 134. | Roll-type hard candies and mini size hard candies in dispenser packages | 5 g |
| 135. | Confectioner’s or icing sugar | 30 g |
| 136. | Bread spreads, except those listed as a separate item, honey and molasses | 20 g |
| 137. | Jams, jellies, marmalades, fruit butters and spreads | 15 mL |
| 138. | Marshmallows | 30 g |
| 139. | Sugars, except those listed as a separate item | 4 g |
| 140. | Sugar substitute | amount equivalent in sweetness to 4 g of sugar |
| 141. | Syrups, including chocolate, maple and corn syrup | 30 mL as ingredient<br>60 mL other uses |
| | ***Vegetables*** | |
| 142. | Vegetables without sauce, including cream style corn and stewed tomatoes, but not including vegetables without sauce listed as a separate item | 85 g fresh or frozen<br>125 mL canned[2] |
| 143. | Vegetables with sauce | 110 g fresh or frozen<br>125 mL canned |
| 144. | Vegetables primarily used for garnish or flavouring, fresh, canned or frozen, but not dried, such as parsley or garlic | 4 g |
| 145. | Chili pepper and green onion | 30 g |
| 146. | Seaweed | 15 g |
| 147. | Lettuce and sprouts | 65 g |
| 148. | Vegetable juice and vegetable drink | 250 mL |
| 149. | Olives | 15 g[2] |
| 150. | Pickles | 30 g[2] |
| 151. | Relish | 15 mL |
| 152. | Vegetable pastes, such as tomato paste | 30 mL |
| 153. | Vegetable sauce or purée, such as tomato sauce or tomato purée | 60 mL |

[1]Unless otherwise noted, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the food. If not listed separately, the reference amount for the unprepared form, such as dry mixes, concentrates, dough, batter, and fresh or frozen pasta, is the amount required to make one reference amount of the prepared form.

[2]Excludes any liquid in which the solid food may be packed or canned, unless the liquid is customarily consumed with the solid food.

[3]Meat and poultry substitutes include extended and simulated meat and poultry products.

SOR/2003-11, s. 37; SOR/2010-94, s. 7(F).

Previous Version

RELATED PROVISIONS

- — SOR/97-12

  66. Packages of drugs that are labelled in accordance with Part C of the Food and Drug Regulations, as those Regulations read on December 31, 1996, are not required to comply with the labelling requirements in these Regulations until January 1, 1999.

- — SOR/98-423

  10. For the purposes of sections 11 to 13, “Director” has the same meaning as in section A.01.010 of the Food and Drugs Regulations.

- — SOR/98-423

  11. Despite sections 1 and 7 to 9, if a numbered certificate of registration has been issued in respect of a drug but a drug identification number has not been assigned under section C.01.014.2 of the Food and Drug Regulations, as amended by section 4 of these Regulations, or under section 12 of these Regulations, then section C.01.001A, paragraphs C.01.015(2)(*b*) and C.01.062(5)(*b*) and Division 10 and the schedule and the table to Division 10 of Part C of the Food and Drug Regulations, as they read immediately before the coming into force of these Regulations, remain in force in respect of that drug until October 1, 1998, except to the extent that they require information that is not required by those provisions as amended by these Regulations.

- — SOR/98-423

  12. (1) Despite these Regulations and subject to subsection (3), if the conditions set out in subsection (2) are satisfied, the Director shall, until October 1, 1998, provide to a manufacturer or importer referred to in paragraph (2)( *c*),

  (*a*) if the information referred to in section C.01.014.3 of the Food and Drug Regulations as amended by section 5 of these Regulations has not been submitted in respect of the drug, the document referred to in subsection C.01.014.2(1) of the Food and Drug Regulations, as amended by section 4 of these Regulations; or

  (*b*) in any other case,

  (i) a drug identification number for the drug preceded by the letters “DIN”, or

  (ii) where there are two or more brand names for the drug, the drug identification numbers assigned by the Director for the drug, each of which pertains to one of the brand names and is preceded by the letters “DIN”.

  (2) The conditions referred to in subsection (1) are:

(*a*) a numbered certificate of registration has been issued for the drug under subsection C.10.004(1) of the Food and Drug Regulations as it read before the coming into force of these Regulations;

(*b*) the numbered certificate of registration has not been cancelled under section C.10.008 of the Food and Drug Regulations as it read immediately before the coming into force of these Regulations; and

(*c*) prior to September 1, 1998, the manufacturer or importer has submitted to the Director

(i) the name of the drug for which a drug identification number is to be issued, and

(ii) the information referred to in subsection C.01.014.1(2) of the Food and Drug Regulations.

(3) If more than one numbered certificate of registration has been issued for a drug on the sole basis of a difference in colour, flavour or fragrance, a single drug identification number shall be assigned in respect of the drug.

- — SOR/98-423

  13. Despite section 4 of these Regulations and subject to section C.10.005 of the Food and Drug Regulations as that section read immediately before the coming into force of these Regulations, the Director may, until September 30, 1998, issue a numbered certificate of registration, if

  (*a*) the manufacturer expressly requests that a numbered certificate of registration be issued for the drug; and

  (*b*) its application was accepted by the Director for review before the coming into force of these Regulations.

- — SOR/98-423

  14. Despite section 2, a manufacturer may, until September 30, 2000, label a drug with the label that was in use on September 30, 1998.

- — SOR/2001-203

  11. An application concerning the sale of a drug for human use for the purposes of a clinical trial that is received under Division 8 of the Food and Drug Regulations before September 1, 2001 is subject to those Regulations and any procedures established under those Regulations as they read at the time the application was received.

- — SOR/2003-11

  38. (1) The following definitions apply in this section.

  “former Regulations” means the Food and Drug Regulations as they read immediately before the day on which these Regulations come into force. (règlement antérieur)

  “manufacturer” has the same meaning as in section A.01.010 of the Food and Drug Regulations. (fabricant)

“prepackaged product” has the same meaning as in section B.01.001 of the Food and Drug Regulations. (produit préemballé)

(2) Despite sections 1 to 37 and subject to subsection (3), the former Regulations continue to apply to a prepackaged product that is labelled in accordance with the former Regulations until the day that is three years after the day on which these Regulations come into force, unless the label of the product, or any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product, contains

(*a*) a statement or claim set out in column 4 of any of items 15, 16 and 22 to 26 of the table following section B.01.513 of the Food and Drug Regulations, as enacted by section 20 of these Regulations;

(*b*) a statement or claim set out in column 1 of the table following section B.01.603 of the Food and Drug Regulations, as enacted by section 20 of these Regulations; or

(*c*) the expression “nutrition facts”, “valeur nutritive” or “valeurs nutritives”.

(3) In applying subsection (2) to a prepackaged product that is sold by a manufacturer who had gross revenues from sales in Canada of food of less than $1,000,000 for the 12-month period immediately prior to the day on which these Regulations come into force, the reference to “three years” in that subsection shall be read as a reference to “five years”.

- — SOR/2006-241

2. Section C.08.004.1 of the Food and Drug Regulations, as it read immediately before the coming into force of these Regulations, applies to a drug in respect of which a notice of compliance was issued before June 17, 2006.

- — SOR/2007-302, s. 12

12. Sections 1 to 6 and 11 of these Regulations do not apply to cheese that is made before these Regulations come into force.

AMENDMENTS NOT IN FORCE

- — SOR/2010-105, s. 1

1. Subsection C.01.001(1) of the Food and Drug Regulations[1] is amended by adding the following in alphabetical order:

[1]C.R.C., c. 870

“flavour” means a non-medicinal ingredient or combination of non-medicinal ingredients added to a drug solely to produce or mask a particular taste. It does not include an ingredient or combination of ingredients that impart only a sweet taste to the drug; (saveur)

“fragrance” means a non-medicinal ingredient or combination of non-medicinal ingredients added to a drug to produce or mask a particular odour; (parfum)

“non-medicinal ingredient” means a substance — other than the pharmacologically active drug — that is added during the manufacturing process and that is present in the finished drug product; (ingrédient non médicinal)

“pharmaceutical ink” means a non-medicinal ingredient or combination of non-medicinal ingredients used to imprint the drug with marks or symbols; (encre pharmaceutique)

- — SOR/2010-105, s. 2

2. (1) Section C.01.004 of the Regulations is amended by adding the following after subsection (1):

(1.1) In addition to the requirements of subsection (1), when a drug is intended for human use, its outer label must contain a list of all non-medicinal ingredients, or, if the outer label is too small, the list must appear on a tag, tape or card that is attached to the package.

(1.2) The non-medicinal ingredients must be listed in alphabetical order or in descending order of predominance by their proportion in the drug, preceded by words that clearly distinguish them from the medicinal ingredients.

(1.3) In the case of flavour, fragrance or pharmaceutical ink, the expressions “flavour/saveur”, “fragrance/parfum” and “pharmaceutical ink/encre pharmaceutique”, respectively, may be included in the list to indicate that such ingredients have been added to the drug, instead of listing those ingredients or combinations of them individually.

(1.4) When the composition of the drug varies from one lot to another, the outer label must include a reference to all non-medicinal ingredient alternatives that may be present in the drug, preceded by the symbol “+/–” or “±” or the expression “or/ou” or “may contain/peut contenir”.

(1.5) Subsections (1.1) to (1.4) do not apply to

(*a*) a drug that is required to be sold pursuant to a prescription;

(*b*) a drug that is not required to be sold pursuant to a prescription but is administered only under the supervision of a practitioner;

(*c*) a drug that is represented as being solely for use as a disinfectant on hard non-porous surfaces; or

(*d*) a drug for veterinary use.

(2) The portion of subsection C.01.004(2) of the Regulations before paragraph (*a*) is replaced by the following:

(2) In addition to the requirements of subsection (1) and, if applicable, subsections (1.1) to (1.4), the outer label of a drug must show all of the following information:

- — SOR/2011-28, s. 1

1. Paragraph B.01.008(5)(*a*) of the Food and Drug Regulations[1] is replaced by the following:

[1]C.R.C., c. 870

(*a*) immediately after the ingredient of which they are components in such a manner as to indicate that they are components of the ingredient, except that if a source of a food allergen or gluten is required by paragraph B.01.010.1(8)(*a*) to be shown immediately after that ingredient, they shall instead be shown immediately after that source; and

- — SOR/2011-28, s. 2

2. (1) Item 30 of the table to subsection B.01.009(1) of the English version of the Regulations is replaced by the following:

| Item | Ingredient |
|---|---|
| 30. | hydrolyzed plant protein |

(2) Paragraph B.01.009(3)(*c*) of the Regulations is replaced by the following:

(*c*) hydrolyzed plant protein;

(3) Subsection B.01.009(5) of the Regulations is repealed.

- — SOR/2011-28, s. 3

3. (1) Item 8 of the table to paragraph B.01.010(3)(*a*) of the Regulations is replaced by the following:

| | Column I | Column II |
|---|---|---|
| **Item** | **Ingredient or Component** | **Common Name** |
| 8. | hydrolyzed plant protein | hydrolyzed plus the name of the plant plus protein or hydrolysed plus the name of the plant plus protein |

(2) The table to paragraph B.01.010(3)(*a*) of the Regulations is amended by adding the following after item 19:

| | Column I | Column II |
|---|---|---|
| **Item** | **Ingredient or Component** | **Common Name** |
| 20. | starch | the name of the plant plus starch |
| 21. | modified starch | modified plus the name of the plant plus starch |
| 22. | lecithin | the name of the source of the lecithin plus lecithin |
| 23. | crustacean | the name of the crustacean |
| 24. | shellfish | the name of the shellfish |

(3) Item 21 of the table to paragraph B.01.010(3)(*b*) of the Regulations is replaced by the following:

| | Column I | Column II |
|---|---|---|
| **Item** | **Ingredient or Component** | **Common Name** |
| 21. | one or more of the following food additives, namely, potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium dithionite, sodium metabisulphite, sodium sulphite, sulphur dioxide and sulphurous acid | sulfites, sulfiting agents, sulphites or sulphiting agents |

- — SOR/2011-28, s. 4

  4. The Regulations are amended by adding the following after section B.01.010:

  B.01.010.1 (1) The following definitions apply in this section and in section B.01.010.3.

  “food allergen” means any protein from any of the following foods, or any modified protein, including any protein fraction, that is derived from any of the following foods:

  (*a*) almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts;

  (*b*) peanuts;

  (*c*) sesame seeds;

  (*d*) wheat or triticale;

  (*e*) eggs;

  (*f*) milk;

  (*g*) soybeans;

  (*h*) crustaceans;

  (*i*) shellfish;

  (*j*) fish; or

  (*k*) mustard seeds. (allergène alimentaire)

  “gluten” means

  (*a*) any gluten protein from the grain of any of the following cereals or from the grain of a hybridized strain that is created from at least one of the following cereals:

  (i) barley,

  (ii) oats,

  (iii) rye,

  (iv) triticale,

  (v) wheat; or

  (*b*) any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of the cereals referred to in paragraph (*a*) or from the grain of a hybridized strain referred to in that paragraph. (gluten)

  (2) If a food allergen or gluten is present in a prepackaged product, the source of the food allergen or gluten, as the case may be, must be shown on the label of the product in

  (*a*) the list of ingredients; or

(*b*) in a statement entitled “Contains” that complies with the requirements of subsection B.01.010.3(1).

(3) Subsection (2) does not apply to a food allergen or gluten that is present in a prepackaged product as a result of cross-contamination.

(4) Subsection (2) does not apply to a to a food allergen or gluten that is present in a prepackaged product referred to in paragraphs B.01.008(2)(*a*) to (*e*) unless a list of ingredients is shown on the product’s label.

(5) Subsection (2) does not apply to a food allergen or gluten that is present in a prepackaged product for which a standard is prescribed by section B.02.130 or B.02.131 unless a list of ingredients is shown on the product’s label.

(6) The source of a food allergen required to be shown under subsection (2) must be shown

(*a*) for a food allergen from a food referred to in one of paragraphs (*a*), (*b*) and (*e*) of the definition “food allergen” in subsection (1) or derived from that food, by the name of the food as shown in the applicable paragraph, expressed in the singular or plural;

(*b*) for a food allergen from the food referred to in paragraph (*c*) of the definition “food allergen” in subsection (1) or derived from that food, by the name “sesame”, “sesame seed” or “sesame seeds”;

(*c*) for a food allergen from a food referred to in one of paragraphs (*d*) and (*f*) of the definition “food allergen” in subsection (1) or derived from that food, by the name of the food as shown in the applicable paragraph;

(*d*) for a food allergen from the food referred to in paragraph (*g*) of the definition “food allergen” in subsection (1) or derived from that food, by the name “soy”, “soya”, “soybean” or “soybeans”;

(*e*) for a food allergen from a food referred to in one of paragraphs (*h*) to (*j*) of the definition “food allergen” in subsection (1) or derived from that food, by the common name of the food referred to in column II of item 6, 23 or 24 of the table to paragraph B.01.010(3)(*a*), whichever is applicable; and

(*f*) for a food allergen from the food referred to in paragraph (*k*) of the definition “food allergen” in subsection (1) or derived from that food, by the name “mustard”, “mustard seed” or “mustard seeds”.

(7) The source of gluten required to be shown under subsection (2) must be shown

(*a*) for gluten from the grain of a cereal referred to in one of subparagraphs (*a*)(i) to (v) of the definition “gluten” in subsection (1) or derived from that grain, by the name of the cereal as shown in the applicable subparagraph; and

(*b*) for gluten from the grain of a hybridized strain created from one or more of the cereals referred to in subparagraphs (*a*)(i) to (v) of the definition “gluten” in subsection (1) or derived from that grain, by the names of the cereals as shown in the applicable subparagraphs.

(8) For the purpose of paragraph (2)(*a*), the source of the food allergen or gluten must be shown in the list of ingredients, in parentheses, as follows:

(*a*) immediately after the ingredient that is shown in that list, if the food allergen or gluten

(i) is that ingredient,

(ii) is present in that ingredient, but is not a component of or present in a component of that ingredient, or

(iii) is, or is present in, a component of that ingredient and the component is not shown in the list of ingredients; or

(*b*) immediately after the component that is shown in the list of ingredients, if the food allergen or gluten is that component or is present in that component.

(9) Despite subsection (2), the source of the food allergen or gluten must be shown on the label of the product in the "Contains" statement if the food allergen or gluten

(*a*) is, or is present in, an ingredient that is not shown in the list of ingredients, but is not a component of that ingredient or present in a component of that ingredient; or

(*b*) is, or is present in, a component and neither the component nor the ingredient in which it is present is shown in the list of ingredients.

(10) Despite subsection (8), the source of the food allergen or gluten is not required to be shown in parentheses immediately after the ingredient or component, as the case may be, if the source of the food allergen or gluten appears

(*a*) in the list of ingredients

(i) as part of the common name of the ingredient or component, or

(ii) in parentheses, under subsection (8), immediately after another ingredient or component; or

(*b*) in the "Contains" statement.

(11) For greater certainty, nothing in subsection (8) affects how an ingredient or component may be shown in the list of ingredients under paragraph B.01.010(3)(*b*).

B.01.010.2 (1) In this section and in section B.01.010.3, "sulphites" means one or more food additives that are listed exclusively in column I of item 21 of the table to paragraph B.01.010(3)(*b*) and are present in a prepackaged product.

(2) For greater certainty, the definition "sulphites" in subsection (1) includes only sulphites that are present in the prepackaged product as a result of being added.

(3) If sulphites are present in a prepackaged product in a total amount of 10 parts per million or more and none are required to be shown in the list of ingredients under section B.01.008 or B.01.009, the sulphites must be shown on the label of the product in

(*a*) the list of ingredients; or

(*b*) a statement entitled “Contains” that complies with the requirements of subsection B.01.010.3(1).

(4) Subsection (3) does not apply to sulphites present in the prepackaged products referred to in paragraphs B.01.008(2)(*a*) to (*e*) unless a list of ingredients is shown on the product’s label.

(5) Subsection (3) does not apply to sulphites present in a prepackaged product for which a standard is prescribed by section B.02.130 or B.02.131 unless a list of ingredients is shown on the product’s label.

(6) Sulphites that are shown on a label of the product under subsection (3) must be shown as follows:

(*a*) if the sulphites are shown in the list of ingredients,

(i) by one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents”, or

(ii) individually by the applicable name set out in column I of item 21 of the table to paragraph B.01.010(3)(*b*), except that the name “sodium dithionite”, “sulphur dioxide” or “sulphurous acid” must be followed, in parentheses, by one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents”; or

(*b*) if the sulphites are shown in a “Contains” statement, by one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents”.

(7) Sulphites that are shown in the list of ingredients under paragraph (6)(*a*) must be shown as follows:

(*a*) sulphites that are a component of an ingredient that is shown in the list of ingredients must be shown either in parentheses immediately after the ingredient or at the end of that list where they may be shown in any order with the other ingredients that are shown at the end of that list under subsection B.01.008(4);

(*b*) in all other cases, the sulphites must be shown at the end of the list of ingredients where they may be shown in any order with the other ingredients that are shown at the end of that list under subsection B.01.008(4).

(8) If sulphites are present in a prepackaged product in a total amount of 10 parts per million or more and any of them are required to be shown in the list of ingredients under section B.01.008 or B.01.009, in the case of sulphites shown individually by the name “sodium dithionite”, “sulphur dioxide” or “sulphurous acid”, that name must be followed, in parentheses, by one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents”.

(9) If the total amount of sulphites present in the prepackaged product is 10 parts per million or more, sulphites that are required to be shown in a list of ingredients under section B.01.008 or B.01.009 may also be shown on the label of the product in a “Contains” statement that complies with the requirements of subsection B.01.010.3(1).

(10) Despite subparagraph (6)(*a*)(ii) and subsection (8), if sulphites are shown individually in a list of ingredients, by the name “sodium dithionite”, “sulphur dioxide” or “sulphurous acid”, that name is not required to be followed, in

parentheses, by one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents” if

(*a*) in the list of ingredients,

(i) the term “sulfite” or “sulphite” appears in the common name of another sulphite, or

(ii) one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents” is shown in parentheses following another sulphite; or

(*b*) one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents” is shown in a “Contains” statement on the label of the product.

B.01.010.3 (1) If a “Contains” statement is included on the label of a prepackaged product under any of subsections B.01.010.1(2), B.01.010.1(9), B.01.010.2(3) or B.01.010.2(9), that statement must

(*a*) appear after the list of ingredients for the product, if any, without any intervening printed, written or graphic material; and

(*b*) include all of the following information, even if all or part of that information is also shown in the list of ingredients for the product:

(i) the source for each food allergen that is present in the product,

(ii) each source for the gluten that is present in the product, and

(iii) one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents”, if the total amount of sulphites present in the product is 10 parts per million or more.

(2) Despite paragraph (1)(*b*), the following information is not required to be shown in the statement more than once:

(*a*) the same source of a food allergen;

(*b*) the same source of gluten; and

(*c*) one of the common names “sulfites”, “sulfiting agents”, “sulphites” or “sulphiting agents”.

- — SOR/2011-28, s. 5

  5. Section B.13.011 of the Regulations is replaced by the following:

  B.13.011. **[S]. Corn starch** shall be starch made from maize and shall contain not less than 84% starch.

- — SOR/2011-28, s. 6

  6. Section B.24.018 of the Regulations is replaced by the following:

  B.24.018. It is prohibited to label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food if the food contains any gluten protein or modified gluten protein, including any gluten protein fraction, referred to in the definition “gluten” in subsection B.01.010.1(1).

- — SOR/2011-28, s. 7

  7. Paragraph D.01.007(1)(*a*) of the Regulations is replaced by the following:

  (*a*) despite subsection B.01.008(6), the vitamin is declared by its common name, and that common name is shown immediately after the ingredient in such a manner as to indicate that the vitamin is a component of that ingredient, except that if a source of a food allergen or gluten is required by paragraph B.01.010.1(8)(*a*) to be shown immediately after that ingredient, the common name of the vitamin is instead shown immediately after that source; and

- — SOR/2011-28, s. 8

  8. Paragraph D.02.005(1)(*a*) of the Regulations is replaced by the following:

  (*a*) despite subsection B.01.008(6), the mineral nutrient is declared by its common name, and that common name is shown immediately after the ingredient in such a manner as to indicate that the mineral nutrient is a component of that ingredient, except that if a source of a food allergen or gluten is required by paragraph B.01.010.1(8)(*a*) to be shown immediately after that ingredient, the common name of the mineral nutrient is instead shown immediately after that source; and