Food and Drugs Act (R.S., 1985, c. F-27)
Act current to January 25th, 2011
Attention: See coming into force provision and notes, where applicable.

Food and Drugs Act

F-27

An Act respecting food, drugs, cosmetics and therapeutic devices

SHORT TITLE

Short title

1. This Act may be cited as the *Food and Drugs Act*.

R.S., c. F-27, s. 1.

INTERPRETATION

Definitions

2. In this Act,

“advertisement”
« *publicité* » ou « *annonce* »

“advertisement” includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device;

“analyst”
« *analyste* »

“analyst” means a person designated as an analyst for the purpose of the enforcement of this Act under section 28 or under section 13 of the *Canadian Food Inspection Agency Act*;

“contraceptive device”
« *moyen anticonceptionnel* »

“contraceptive device” means any instrument, apparatus, contrivance or substance other than a drug, that is manufactured, sold or represented for use in the prevention of conception;

“cosmetic”
« *cosmétique* »

“cosmetic” includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes;

“Department”
« *ministère* »

“Department” means the Department of Health;

“device”
« *instrument* »

“device” means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in
(*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
(*b*) restoring, correcting or modifying a body function or the body structure of human beings or animals,
(*c*) the diagnosis of pregnancy in human beings or animals, or
(*d*) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug;

“drug”
« *drogue* »

“drug” includes any substance or mixture of substances manufactured, sold or represented for use in
(*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
(*b*) restoring, correcting or modifying organic functions in human beings or animals, or
(*c*) disinfection in premises in which food is manufactured, prepared or kept;

“food”
« *aliment* »

“food” includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever;

“inspector”
« *inspecteur* »

“inspector” means any person designated as an inspector for the purpose of the enforcement of this Act under subsection 22(1) or under section 13 of the *Canadian Food Inspection Agency Act*;

“label”
« *étiquette* »

“label” includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package;

“Minister”
« *ministre* »

“Minister” means the Minister of Health;

“package”
« *emballage* »

“package” includes any thing in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed;

“prescribed”
« *Version anglaise seulement* »

“prescribed” means prescribed by the regulations;

“sell”
« *vente* »

“sell” includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration;

“unsanitary conditions”
« *conditions non hygiéniques* »

“unsanitary conditions” means such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health, a food, drug or cosmetic.

R.S., 1985, c. F-27, s. 2; R.S., 1985, c. 27 (1st Supp.), s. 191; 1992, c. 1, s. 145(F); 1993, c. 34, s. 71; 1994, c. 26, s. 32(F), c. 38, s. 18; 1995, c. 1, s. 63; 1996, c. 8, ss. 23.1, 32, 34; 1997, c. 6, s. 62.

PART I

FOODS, DRUGS, COSMETICS AND DEVICES

GENERAL

Prohibited advertising

3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Prohibited label or advertisement where sale made

(2) No person shall sell any food, drug, cosmetic or device
(*a*) that is represented by label, or
(*b*) that the person advertises to the general public
as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

Unauthorized advertising of contraceptive device prohibited

(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception.

R.S., 1985, c. F-27, s. 3; 1993, c. 34, s. 72(F).

Prohibited sales of food

4. (1) No person shall sell an article of food that
(*a*) has in or on it any poisonous or harmful substance;
(*b*) is unfit for human consumption;
(*c*) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
(*d*) is adulterated; or
(*e*) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

Exemptions

(2) A food is not adulterated for the purposes of paragraph (1)(*d*)
(*a*) by an agricultural chemical or its components or derivatives, if the sale of the food is subject to an interim marketing authorization issued under subsection 30.2(1) and the amount of the agricultural chemical and the components or derivatives, singly or in any combination, in or on the food does not exceed the maximum residue limit that is set out in the authorization;
(*b*) by a veterinary drug or its metabolites, if the sale of the food is subject to an interim marketing authorization issued under subsection 30.2(1) and the amount of the veterinary drug and the metabolites, singly or in any combination, in the food does not exceed the maximum residue limit that is set out in the authorization; and
(*c*) by a pest control product as defined in subsection 2(1) of the *Pest Control Products Act*, chapter 28 of the Statutes of Canada, 2002, or its components or derivatives, if the amount of the pest control product or the components or derivatives in or on the food being sold does not exceed the maximum residue limit specified under section 9 or 10 of that Act.

R.S., 1985, c. F-27, s. 4; 2005, c. 42, s. 1.

Deception, etc., regarding food

5. (1) No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Food labelled or packaged in contravention of regulations

(2) An article of food that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

R.S., c. F-27, s. 5.

Importation and interprovincial movement of food

6. (1) Where a standard for a food has been prescribed, no person shall
(*a*) import into Canada,
(*b*) send, convey or receive for conveyance from one province to another, or
(*c*) have in possession for the purpose of sending or conveying from one province to another

any article that is intended for sale and that is likely to be mistaken for that food unless the article complies with the prescribed standard.

Not applicable to carriers

(2) Paragraphs (1)(*b*) and (*c*) do not apply to an operator of a conveyance that is used to carry an article or to a carrier of an article whose sole concern, in respect of the article, is the conveyance of the article unless the operator or carrier could, with reasonable diligence, have ascertained that the conveying or receiving for conveyance of the article or the possession of the article for the purpose of conveyance would be in contravention of subsection (1).

Labelling, etc., of food that is imported or moved interprovincially

(3) Where a standard for a food has been prescribed, no person shall label, package, sell or advertise any article that
(*a*) has been imported into Canada,
(*b*) has been sent or conveyed from one province to another, or
(*c*) is intended to be sent or conveyed from one province to another
in such a manner that it is likely to be mistaken for that food unless the article complies with the prescribed standard.

R.S., 1985, c. F-27, s. 6; R.S., 1985, c. 27 (3rd Supp.), s. 1.

Governor in Council may identify standard or portion thereof

6.1 (1) The Governor in Council may, by regulation, identify a standard prescribed for a food, or any portion of the standard, as being necessary to prevent injury to the health of the consumer or purchaser of the food.

Where standard or portion thereof is identified

(2) Where a standard or any portion of a standard prescribed for a food is identified by the Governor in Council pursuant to subsection (1), no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that food unless the article complies with the standard or portion of a standard so identified.

R.S., 1985, c. 27 (3rd Supp.), s. 1.

Unsanitary manufacture, etc., of food

7. No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions.

R.S., c. F-27, s. 7.

DRUGS

Prohibited sales of drugs

8. No person shall sell any drug that
(*a*) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or
(*b*) is adulterated.

R.S., c. F-27, s. 8.

Deception, etc., regarding drugs

9. (1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

Drugs labelled or packaged in contravention of regulations

(2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

R.S., c. F-27, s. 9.

Where standard prescribed for drug

10. (1) Where a standard has been prescribed for a drug, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the prescribed standard.

Trade standards

(2) Where a standard has not been prescribed for a drug, but a standard for the drug is contained in any publication referred to in Schedule B, no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that drug, unless the substance complies with the standard.

Where no prescribed or trade standard

(3) Where a standard for a drug has not been prescribed and no standard for the drug is contained in any publication referred to in Schedule B, no person shall sell the drug unless
(*a*) it is in accordance with the professed standard under which it is sold; and
(*b*) it does not resemble, in a manner likely to deceive, any drug for which a standard has been prescribed or is contained in any publication referred to in Schedule B.

R.S., c. F-27, s. 10.

Unsanitary manufacture, etc., of drug

11. No person shall manufacture, prepare, preserve, package or store for sale any drug under unsanitary conditions.

R.S., c. F-27, s. 11.

Drugs not to be sold unless safe manufacture indicated

12. No person shall sell any drug described in Schedule C or D unless the Minister has, in prescribed form and manner, indicated that the premises in which the drug was manufactured and the process and conditions of manufacture therein are suitable to ensure that the drug will not be unsafe for use.

R.S., c. F-27, s. 12.

Drugs not to be sold unless safe batch indicated

13. No person shall sell any drug described in Schedule E unless the Minister has, in prescribed form and manner, indicated that the batch from which the drug was taken is not unsafe for use.

R.S., c. F-27, s. 13.

Samples

14. (1) No person shall distribute or cause to be distributed any drug as a sample.

Exception

(2) Subsection (1) does not apply to the distribution, under prescribed conditions, of samples of drugs to physicians, dentists, veterinary surgeons or pharmacists.

R.S., c. F-27, s. 14.

Schedule F drugs not to be sold

15. No person shall sell any drug described in Schedule F.

R.S., c. F-27, s. 15.

COSMETICS

Prohibited sales of cosmetics

16. No person shall sell any cosmetic that

(*a*) has in or on it any substance that may cause injury to the health of the user when the cosmetic is used,

(i) according to the directions on the label or accompanying the cosmetic, or

(ii) for such purposes and by such methods of use as are customary or usual therefor;

(*b*) consists in whole or in part of any filthy or decomposed substance or of any foreign matter; or

(*c*) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

R.S., c. F-27, s. 16.

Where standard prescribed for cosmetic

17. Where a standard has been prescribed for a cosmetic, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that cosmetic, unless the article complies with the prescribed standard.

R.S., c. F-27, s. 17.

Unsanitary conditions

18. No person shall manufacture, prepare, preserve, package or store for sale any cosmetic under unsanitary conditions.

R.S., c. F-27, s. 18.

DEVICES

Prohibited sales of devices

19. No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.

R.S., c. F-27, s. 19.

Deception, etc., regarding devices

20. (1) No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

Devices labelled or packaged in contravention of regulations

(2) A device that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).

R.S., c. F-27, s. 20; 1976-77, c. 28, s. 16.

Where standard prescribed for device

21. Where a standard has been prescribed for a device, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that device, unless the article complies with the prescribed standard.

R.S., c. F-27, s. 21.

PART II

ADMINISTRATION AND ENFORCEMENT

INSPECTION, SEIZURE AND FORFEITURE

Inspectors

22. (1) The Minister may designate any person as an inspector for the purpose of the enforcement of this Act.

Certificate to be produced

(2) An inspector shall be given a certificate in a form established by the Minister or the President of the Canadian Food Inspection Agency attesting to the inspector's designation and, on entering any place pursuant to subsection 23(1), an inspector shall, if so required, produce the certificate to the person in charge of that place.

R.S., 1985, c. F-27, s. 22; 1997, c. 6, s. 63.

Powers of inspectors

23. (1) Subject to subsection (1.1), an inspector may at any reasonable time enter any place where the inspector believes on reasonable grounds any article to

which this Act or the regulations apply is manufactured, prepared, preserved, packaged or stored, and may
(*a*) examine any such article and take samples thereof, and examine anything that the inspector believes on reasonable grounds is used or capable of being used for that manufacture, preparation, preservation, packaging or storing;
(*a.1*) enter any conveyance that the inspector believes on reasonable grounds is used to carry any article to which section 6 or 6.1 applies and examine any such article found therein and take samples thereof;
(*b*) open and examine any receptacle or package that the inspector believes on reasonable grounds contains any article to which this Act or the regulations apply;
(*c*) examine and make copies of, or extracts from, any books, documents or other records found in any place referred to in this subsection that the inspector believes on reasonable grounds contain any information relevant to the enforcement of this Act with respect to any article to which this Act or the regulations apply; and
(*d*) seize and detain for such time as may be necessary any article by means of or in relation to which the inspector believes on reasonable grounds any provision of this Act or the regulations has been contravened.

Warrant required to enter dwelling-house

(1.1) Where any place mentioned in subsection (1) is a dwelling-house, an inspector may not enter that dwelling-house without the consent of the occupant except under the authority of a warrant issued under subsection (1.2).

Authority to issue warrant

(1.2) Where on *ex parte* application a justice of the peace is satisfied by information on oath
(*a*) that the conditions for entry described in subsection (1) exist in relation to a dwelling-house,
(*b*) that entry to the dwelling-house is necessary for any purpose relating to the administration or enforcement of this Act, and
(*c*) that entry to the dwelling-house has been refused or that there are reasonable grounds for believing that entry thereto will be refused,
the justice of the peace may issue a warrant under his hand authorizing the inspector named therein to enter that dwelling-house subject to such conditions as may be specified in the warrant.

Use of force

(1.3) In executing a warrant issued under subsection (1.2), the inspector named therein shall not use force unless the inspector is accompanied by a peace officer and the use of force has been specifically authorized in the warrant.

Definition of “article to which this Act or the regulations apply”

(2) In subsection (1), “article to which this Act or the regulations apply” includes
(*a*) any food, drug, cosmetic or device;
(*b*) anything used for the manufacture, preparation, preservation, packaging or storing thereof; and
(*c*) any labelling or advertising material.

Assistance and information to be given inspector

(3) The owner or person in charge of a place entered by an inspector pursuant to subsection (1) and every person found therein shall give the inspector all reasonable assistance and furnish the inspector with any information he may reasonably require.

R.S., 1985, c. F-27, s. 23; R.S., 1985, c. 31 (1st Supp.), s. 11, c. 27 (3rd Supp.), s. 2.

Obstruction and false statements

24. (1) No person shall obstruct or hinder, or knowingly make any false or misleading statement either orally or in writing to, an inspector while the inspector is engaged in carrying out his duties or functions under this Act or the regulations.

Interference

(2) Except with the authority of an inspector, no person shall remove, alter or interfere in any way with anything seized under this Part.

R.S., c. F-27, ss. 22, 37.

Storage and removal

25. Any article seized under this Part may, at the option of an inspector, be kept or stored in the building or place where it was seized or, at the direction of an inspector, the article may be removed to any other proper place.

R.S., c. F-27, ss. 22, 37.

Release of seized articles

26. An inspector who has seized any article under this Part shall release it when he is satisfied that all the provisions of this Act and the regulations with respect thereto have been complied with.

R.S., c. F-27, ss. 23, 37.

Destruction with consent

27. (1) Where an inspector has seized an article under this Part and its owner or the person in whose possession the article was at the time of seizure consents to its destruction, the article is thereupon forfeited to Her Majesty and may be destroyed or otherwise disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Forfeiture

(2) Where a person has been convicted of a contravention of this Act or the regulations, the court or judge may order that any article by means of or in relation to which the offence was committed, and any thing of a similar nature belonging to or in the possession of the person or found with the article, be forfeited. On the making of the order, the article and thing are forfeited to Her Majesty and may be disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

Order for forfeiture on application of inspector

(3) Without prejudice to subsection (2), a judge of a superior court of the province in which any article is seized under this Part may, on the application of an inspector and on such notice to such persons as the judge directs, order that the article and any thing of a similar nature found with it be forfeited to Her Majesty, if the judge finds, after making such inquiry as the judge considers necessary, that the article is one by means of or in relation to which any of the provisions of this Act or the regulations have been contravened. On the making of the order, the article or thing may be disposed of as the Minister or the Minister of Agriculture and Agri-Food may direct.

R.S., 1985, c. F-27, s. 27; 1992, c. 1, s. 145(F); 1994, c. 38, s. 19; 1995, c. 1, s. 62; 1996, c. 8, s. 23.2; 1997, c. 6, s. 64.

ANALYSIS

Analysts

28. The Minister may designate any person as an analyst for the purpose of the enforcement of this Act.

1980-81-82-83, c. 47, s. 19.

Analysis and examination

29. (1) An inspector may submit to an analyst, for analysis or examination, any article seized by the inspector, any sample therefrom or any sample taken by the inspector.

Certificate or report

(2) An analyst who has made an analysis or examination may issue a certificate or report setting out the results of the analysis or examination.

R.S., c. F-27, s. 24.

REGULATIONS

Regulations

30. (1) The Governor in Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but without restricting the generality of the foregoing, may make regulations

(*a*) declaring that any food or drug or class of food or drugs is adulterated if any prescribed substance or class of substances is present therein or has been added thereto or extracted or omitted therefrom;

(*b*) respecting

(i) the labelling and packaging and the offering, exposing and advertising for sale of food, drugs, cosmetics and devices,

(ii) the size, dimensions, fill and other specifications of packages of food, drugs, cosmetics and devices,

(iii) the sale or the conditions of sale of any food, drug, cosmetic or device, and

(iv) the use of any substance as an ingredient in any food, drug, cosmetic or device,

to prevent the purchaser or consumer thereof from being deceived or misled in respect of the design, construction, performance, intended use, quantity, character, value, composition, merit or safety thereof, or to prevent injury to the health of the purchaser or consumer;
(*c*) prescribing standards of composition, strength, potency, purity, quality or other property of any article of food, drug, cosmetic or device;
(*d*) respecting the importation of foods, drugs, cosmetics and devices in order to ensure compliance with this Act and the regulations;
(*e*) respecting the method of manufacture, preparation, preserving, packing, storing and testing of any food, drug, cosmetic or device in the interest of, or for the prevention of injury to, the health of the purchaser or consumer;
(*f*) requiring persons who sell food, drugs, cosmetics or devices to maintain such books and records as the Governor in Council considers necessary for the proper enforcement and administration of this Act and the regulations;
(*g*) respecting the form and manner of the Minister's indication under section 12, including the fees payable therefor, and prescribing what premises or what processes or conditions of manufacture, including qualifications of technical staff, shall or shall not be deemed to be suitable for the purposes of that section;
(*h*) requiring manufacturers of any drugs described in Schedule E to submit test portions of any batch of those drugs and respecting the form and manner of the Minister's indication under section 13, including the fees payable therefor;
(*i*) respecting the powers and duties of inspectors and analysts and the taking of samples and the seizure, detention, forfeiture and disposition of articles;
(*j*) exempting any food, drug, cosmetic or device from all or any of the provisions of this Act and prescribing the conditions of the exemption;
(*k*) prescribing forms for the purposes of this Act and the regulations;
(*l*) providing for the analysis of food, drugs or cosmetics other than for the purposes of this Act and prescribing a tariff of fees to be paid for that analysis;
(*l.1*) respecting the assessment of the effect on the environment or on human life and health of the release into the environment of any food, drug, cosmetic or device, and the measures to take before importing or selling any such food, drug, cosmetic or device;
(*m*) adding anything to any of the schedules, in the interest of, or for the prevention of injury to, the health of the purchaser or consumer, or deleting anything therefrom;
(*n*) respecting the distribution or the conditions of distribution of samples of any drug;
(*o*) respecting
    (i) the method of manufacture, preparation, preserving, packing, labelling, storing and testing of any new drug, and
    (ii) the sale or the conditions of sale of any new drug,
and defining for the purposes of this Act the expression "new drug";
(*p*) authorizing the advertising to the general public of contraceptive devices and drugs manufactured, sold or represented for use in the prevention of conception and prescribing the circumstances and conditions under which, and the persons by whom, those devices and drugs may be so advertised;
(*q*) defining "agricultural chemical", "food additive", "mineral nutrient", "veterinary drug" and "vitamin" for the purposes of this Act; and
(*r*) respecting interim marketing authorizations, including applications for authorizations.

Regulations respecting drugs manufactured outside Canada

(2) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations governing, regulating or prohibiting
(*a*) the importation into Canada of any drug or class of drugs manufactured outside Canada, or
(*b*) the distribution or sale in Canada, or the offering, exposing or having in possession for sale in Canada, of any drug or class of drugs manufactured outside Canada,
as the Governor in Council deems necessary for the protection of the public in relation to the safety and quality of any such drug or class of drugs.

Regulations re the North American Free Trade Agreement and WTO Agreement

(3) Without limiting or restricting the authority conferred by any other provisions of this Act or any Part thereof for carrying into effect the purposes and provisions of this Act or any Part thereof, the Governor in Council may make such regulations as the Governor in Council deems necessary for the purpose of implementing, in relation to drugs, Article 1711 of the North American Free Trade Agreement or paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement.

Definitions

(4) In subsection (3),

“North American Free Trade Agreement”
« *Accord de libre-échange nord-américain* »

“North American Free Trade Agreement” has the meaning given to the word “Agreement” by subsection 2(1) of the *North American Free Trade Agreement Implementation Act*;

“WTO Agreement”
« *Accord sur l’OMC* »

“WTO Agreement” has the meaning given to the word “Agreement” by subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.

Regulations to implement the General Council Decision

(5) Without limiting or restricting the authority conferred by any other provisions of this Act or any of its Parts for carrying into effect the purposes and provisions of this Act or any of its Parts, the Governor in Council may make any regulations that the Governor in Council considers necessary for the purpose of implementing the General Council Decision.

Definitions

(6) The definitions in this subsection apply in this subsection and in subsection (5).

“General Council”
« *Conseil général* »

“General Council” means the General Council of the WTO established by paragraph 2 of Article IV of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

“General Council Decision”
« *décision du Conseil général* »

“General Council Decision” means the decision of the General Council of August 30, 2003 respecting Article 31 of the TRIPS Agreement, including the interpretation of that decision in the General Council Chairperson’s statement of that date.

“TRIPS Agreement”
« *Accord sur les ADPIC* »

“TRIPS Agreement” means the Agreement on Trade-Related Aspects of Intellectual Property Rights, being Annex 1C of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

“WTO”
« *OMC* »

“WTO” means the World Trade Organization established by Article I of the Agreement Establishing the World Trade Organization, signed at Marrakesh on April 15, 1994.

R.S., 1985, c. F-27, s. 30; 1993, c. 44, s. 158; 1994, c. 47, s. 117; 1999, c. 33, s. 347; 2004, c. 23, s. 2; 2005, c. 42, s. 2.

INTERIM ORDERS

Interim orders

30.1 (1) The Minister may make an interim order that contains any provision that may be contained in a regulation made under this Act if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment.

Cessation of effect

(2) An interim order has effect from the time that it is made but ceases to have effect on the earliest of
(*a*) 14 days after it is made, unless it is approved by the Governor in Council,
(*b*) the day on which it is repealed,
(*c*) the day on which a regulation made under this Act, that has the same effect as the interim order, comes into force, and
(*d*) one year after the interim order is made or any shorter period that may be specified in the interim order.

Contravention of unpublished order

(3) No person shall be convicted of an offence consisting of a contravention of an interim order that, at the time of the alleged contravention, had not been published

in the *Canada Gazette* unless it is proved that, at the time of the alleged contravention, the person had been notified of the interim order or reasonable steps had been taken to bring the purport of the interim order to the notice of those persons likely to be affected by it.

Exemption from *Statutory Instruments Act*

(4) An interim order
(*a*) is exempt from the application of sections 3, 5 and 11 of the *Statutory Instruments Act*; and
(*b*) shall be published in the *Canada Gazette* within 23 days after it is made.

Deeming

(5) For the purpose of any provision of this Act other than this section, any reference to regulations made under this Act is deemed to include interim orders, and any reference to a regulation made under a specified provision of this Act is deemed to include a reference to the portion of an interim order containing any provision that may be contained in a regulation made under the specified provision.

Tabling of order

(6) A copy of each interim order must be tabled in each House of Parliament within 15 days after it is made.

House not sitting

(7) In order to comply with subsection (6), the interim order may be sent to the Clerk of the House if the House is not sitting.

2004, c. 15, s. 66.

INTERIM MARKETING AUTHORIZATIONS

Interim marketing authorization

30.2 (1) The Minister may issue an interim marketing authorization for a food that provides for any matter referred to in subsection (2), and may exempt the food from the application, in whole or in part, of sections 5 to 6.1 and the applicable requirements of the regulations, if the Minister determines that the food would not be harmful to the health of the purchaser or consumer.

Types of authorization

(2) An authorization may provide for any of the following that are applicable to the food:
(*a*) the maximum residue limit in respect of an agricultural chemical and its components or derivatives, singly or in any combination;
(*b*) the maximum residue limit in respect of a veterinary drug and its metabolites, singly or in any combination;
(*c*) the maximum level of use in respect of a food additive; and
(*d*) the minimum or maximum level, or both, in respect of a vitamin, a mineral nutrient or an amino acid.

Limitation

(3) An authorization may provide for a maximum residue limit in respect of an agricultural chemical or veterinary drug, or a maximum level of use in respect of a food additive, only if
(*a*) in the case of an agricultural chemical, the regulations allow the agricultural chemical and its components or derivatives, singly or in any combination, to be present in or on a food at or below a prescribed maximum residue limit and the authorization would allow the agricultural chemical and its components or derivatives, singly or in any combination, to be present in or on the food in an amount that exceeds that limit, or to be present in or on a different food;
(*b*) in the case of a veterinary drug, the regulations allow the veterinary drug and its metabolites, singly or in any combination, to be present in a food at or below a prescribed maximum residue limit and the authorization would allow the veterinary drug and its metabolites, singly or in any combination, to be present in the food in an amount that exceeds that limit, or to be present in a different food; and
(*c*) in the case of a food additive, the regulations allow the food additive to be present in or on a food at or below a prescribed maximum level of use and the authorization would allow it to be used in or on the food in an amount that exceeds that level of use, or would allow it to be used in or on a different food.

Terms and conditions

(4) An authorization may contain any terms and conditions specified by the Minister.

Exemption from *Statutory Instruments Act*

(5) An authorization and any notice cancelling the authorization
(*a*) are exempt from the application of sections 3, 5 and 11 of the *Statutory Instruments Act*; and
(*b*) shall be published in the *Canada Gazette*.

When effective

(6) An authorization has effect beginning on the day on which it is published in the *Canada Gazette*, and ceases to have effect on the earliest of
(*a*) the day on which a notice cancelling the authorization is published in the *Canada Gazette*,
(*b*) the day on which a regulation made under this Act, that has the same effect as the authorization, comes into force, and
(*c*) two years after the day on which the authorization is published.

2005, c. 42, s. 3.

Offences and Punishment

Contravention of Act or regulations

31. Subject to section 31.1, every person who contravenes any of the provisions of this Act or of the regulations made under this Part is guilty of an offence and liable
(*a*) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both and, for

a subsequent offence, to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months or to both; and
(*b*) on conviction on indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both.

R.S., 1985, c. F-27, s. 31; 1996, c. 19, s. 77; 1997, c. 6, ss. 65, 91.

Offences relating to food

31.1 Every person who contravenes any provision of this Act or the regulations, as it relates to food, is guilty of an offence and liable
(*a*) on summary conviction, to a fine not exceeding $50,000 or to imprisonment for a term not exceeding six months or to both; or
(*b*) on conviction by indictment, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding three years or to both.

1997, c. 6, s. 66.

Limitation period

32. (1) A prosecution for a summary conviction offence under this Act may be instituted at any time within two years after the time the subject-matter of the prosecution becomes known to the Minister or, in the case of a contravention of a provision of the Act that relates to food, to the Minister of Agriculture and Agri-Food.

Minister's certificate

(2) A document purporting to have been issued by the Minister referred to in subsection (1), certifying the day on which the subject-matter of any prosecution became known to the Minister, is admissible in evidence without proof of the signature or official character of the person appearing to have signed the document and is evidence of the matters asserted in it.

R.S., 1985, c. F-27, s. 32; 1997, c. 6, s. 66.

Venue

33. A prosecution for a contravention of this Act or the regulations may be instituted, heard, tried or determined in the place in which the offence was committed or the subject-matter of the prosecution arose or in any place in which the accused is apprehended or happens to be.

R.S., c. F-27, s. 28.

Want of knowledge

34. (1) Subject to subsection (2), in a prosecution for the sale of any article in contravention of this Act, except Parts III and IV, or of the regulations made under this Part, if the accused proves to the satisfaction of the court or judge that
(*a*) the accused purchased the article from another person in packaged form and sold it in the same package and in the same condition the article was in at the time it was so purchased, and
(*b*) that the accused could not with reasonable diligence have ascertained that the sale of the article would be in contravention of this Act or the regulations,
the accused shall be acquitted.

Notice of reliance on want of knowledge

(2) Subsection (1) does not apply in any prosecution unless the accused, at least ten days before the day fixed for the trial, has given to the prosecutor notice in writing that the accused intends to avail himself of the provisions of subsection (1) and has disclosed to the prosecutor the name and address of the person from whom the accused purchased the article and the date of purchase.

R.S., c. F-27, ss. 29, 39, 46.

Certificate of analyst

35. (1) Subject to this section, in any prosecution for an offence under section 31, a certificate purporting to be signed by an analyst and stating that an article, sample or substance has been submitted to, and analysed or examined by, the analyst and stating the results of the analysis or examination is admissible in evidence and, in the absence of evidence to the contrary, is proof of the statements contained in the certificate without proof of the signature or official character of the person appearing to have signed it.

Requiring attendance of analyst

(2) The party against whom a certificate of an analyst is produced pursuant to subsection (1) may, with leave of the court, require the attendance of the analyst for the purposes of cross-examination.

Notice of intention to produce certificate

(3) No certificate shall be admitted in evidence pursuant to subsection (1) unless, before the trial, the party intending to produce the certificate has given reasonable notice of that intention, together with a copy of the certificate, to the party against whom it is intended to be produced.

Proof of service

(4) For the purposes of this Act, service of any certificate referred to in subsection (1) may be proved by oral evidence given under oath by, or by the affidavit or solemn declaration of, the person claiming to have served it.

Attendance for examination

(5) Notwithstanding subsection (4), the court may require the person who appears to have signed an affidavit or solemn declaration referred to in that subsection to appear before it for examination or cross-examination in respect of the issue of proof of service.

R.S., 1985, c. F-27, s. 35; R.S., 1985, c. 27 (1st Supp.), s. 192; 1996, c. 19, s. 78.

Proof as to manufacturer or packager

36. (1) In a prosecution for a contravention of this Act or of the regulations made under this Part, proof that a package containing any article to which this Act or the regulations apply bore a name or address purporting to be the name or address of the person by whom it was manufactured or packaged is, in the absence of evidence

to the contrary, proof that the article was manufactured or packaged, as the case may be, by the person whose name or address appeared on the package.

Offence by employee or agent

(2) In a prosecution for a contravention described in subsection (1), it is sufficient proof of the offence to establish that it was committed by an employee or agent of the accused whether or not the employee or agent is identified or has been prosecuted for the offence.

Certified copies and extracts

(3) In a prosecution for a contravention described in subsection (1), a copy of a record or an extract therefrom certified to be a true copy by the inspector who made it pursuant to paragraph 23(1)(*c*) is admissible in evidence and is, in the absence of evidence to the contrary, proof of its contents.

Where accused had adulterating substances

(4) Where a person is prosecuted under this Part for having manufactured an adulterated food or drug for sale, and it is established that the person had in his possession or on his premises any substance the addition of which to that food or drug has been declared by regulation to cause the adulteration of the food or drug, the onus of proving that the food or drug was not adulterated by the addition of that substance lies on the accused.

R.S., 1985, c. F-27, s. 36; 1996, c. 19, s. 79.

EXPORTS

Conditions under which exports exempt

37. (1) This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word “Export” or “Exportation” and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner.

Exception - General Council Decision

(2) Despite subsection (1), this Act applies in respect of any drug or device to be manufactured for the purpose of being exported in accordance with the General Council Decision, as defined in subsection 30(6), and the requirements of the Act and the regulations apply to the drug or device as though it were a drug or device to be manufactured and sold for consumption in Canada, unless the regulations provide otherwise.

R.S., 1985, c. F-27, s. 37; 1993, c. 34, s. 73; 1996, c. 19, s. 80; 2004, c. 23, s. 3.

PARTS III AND IV

[Repealed, 1996, c. 19, s. 81]

SCHEDULE A

(Section 3)

Acute alcoholism
Alcoolisme aigu

Acute anxiety state
État anxieux aigu

Acute infectious respiratory syndromes
Syndromes respiratoires infectieux aigus

Acute, inflammatory and debilitating arthritis
Arthrite aiguë, inflammatoire et débilitante

Acute psychotic conditions
Troubles psychotiques aigus

Addiction (except nicotine addiction)
Dépendance (sauf la dépendance à la nicotine)

Appendicitis
Appendicite

Arteriosclerosis
Artériosclérose

Asthma
Asthme

Cancer
Cancer

Congestive heart failure
Insuffisance cardiaque congestive

Convulsions
Convulsions

Dementia
Démence

Depression
Dépression

Diabetes
Diabète

Gangrene
Gangrène

Glaucoma
Glaucome

Haematologic bleeding disorders
Affections hématologiques hémorragiques

Hepatitis
Hépatite

Hypertension
Hypertension

Nausea and vomiting of pregnancy

Nausées et vomissements de la grossesse

Obesity

Obésité

Rheumatic fever

Rhumatisme articulaire aigu

Septicemia

Septicémie

Sexually transmitted diseases

Maladies transmises sexuellement

Strangulated hernia

Hernie étranglée

Thrombotic and Embolic disorders

Maladies thrombotiques et embolies

Thyroid disease

Glande thyroïdienne (affections)

Ulcer of the gastro-intestinal tract

Ulcères des voies gastro-intestinales

R.S., 1985, c. F-27, Sch. A; SOR/88-252; SOR/89-503; SOR/90-655; SOR/92-198; SOR/94-287; SOR/99-413, 414; SOR/2007-289, ss. 1, 2.

SCHEDULE B

(Section 10)

The most recent editions, including all errata, supplements, revisions and addenda, of the following standards:

Item	Column I Name	Column II Abbreviation
1.	European Pharmacopoeia	(Ph.Eur.)
2.	Pharmacopée française	(Ph.F.)
3.	Pharmacopoeia Internationalis	(Ph.I.)
4.	The British Pharmacopoeia	(B.P.)
5.	The Canadian Formulary	(C.F.)
6.	The National Formulary	(N.F.)
7.	The Pharmaceutical Codex: Principles and Practices of Pharmaceuticals	
8.	The United States Pharmacopoeia	(U.S.P.)

R.S., 1985, c. F-27, Sch. B; SOR/85-276; SOR/89-315; SOR/90-160; SOR/94-288; SOR/95-530, s. 2; SOR/96-96.

SCHEDULE C

(Section 12)

Drugs, other than radionuclides, sold or represented for use in the preparation of radiopharmaceuticals

Drogues...

Radiopharmaceuticals

Produits pharmaceutiques radioactifs

R.S., c. F-27, Sch. C; SI/72-44; SI/76-1; SOR/79-237; SOR/81-195, 332; SOR/82-769.

SCHEDULE D

(Section 12)

Allergenic substances used for the treatment or diagnosis of allergic or immunological diseases
Substances...

Anterior pituitary extracts
Extraits hypophysaires (lobe antérieur)

Aprotinin
Aprotinine

Blood and blood derivatives, except cord blood and peripheral blood that are a source of lymphohematopoietic cells for transplantation
Sang et dérivés du sang...

Cholecystokinin
Cholécystokinine

Drugs obtained by recombinant DNA procedures
Drogues obtenues...

Drugs, other than antibiotics, prepared from micro-organisms
Drogues, sauf...

Glucagon
Glucagon

Gonadotrophins
Gonadotrophines

Human plasma collected by plasmapheresis
Plasma...

Immunizing agents
Agents immunisants

Insulin
Insuline

Interferon
Interféron

Monoclonal antibodies, their conjugates and derivatives
Anticorps monoclonaux et leurs dérivés et conjugués

Secretin
Sécrétine

Snake Venom
Venin de serpent

Urokinase
Urokinase

R.S., 1985, c. F-27, Sch. D; SOR/85-715, s. 1; SOR/89-177; SOR/93-64; SOR/97-560; SOR/2007-120.

SCHEDULE E

(Section 13)

R.S., c. F-27, Sch. E; SOR/77-824; SOR/82-769.

SCHEDULE F

(Section 15)

R.S., c. F-27, Sch. F; SOR/84-566.

SCHEDULES G AND H
[Repealed, 1996, c. 19, s. 82]

RELATED PROVISIONS

— R.S., 1985, c. 27 (1st Supp.), s. 208:

Writs of Assistance

208. Nothing in sections 190, 195, 199 and 200 of this Act shall be construed as rendering invalid or inadmissible in any proceedings any evidence obtained by the exercise of a writ of assistance prior to the coming into force of those sections.

— 1997, c. 6, s. 66(2):

Transitional

(2) For greater certainty, the two year limitation period provided for in subsection 32(1) of the Act, as amended by subsection (1), only applies in respect of offences committed after the coming into force of that subsection.

— 2005, c. 42, s. 4:

Deeming provision

4. A Notice of Interim Marketing Authorization that is issued under the *Food and Drug Regulations* before the day on which this section comes into force, in respect of any matter referred to in subsection 30.2(2) of the *Food and Drugs Act*, as enacted by section 3 of this Act, and that is in effect on the day on which this section comes into force, is deemed to be an interim marketing authorization issued under subsection 30.2(1) of that Act.

— 2005, c. 42, s. 5(1):

Pest control products

5. (1) The maximum residue limit established for an agricultural chemical and its derivatives under the *Food and Drug Regulations*, as those regulations read immediately before the coming into force of this subsection, is deemed, if the agricultural chemical is a pest control product as defined in subsection 2(1) of the *Pest Control Products Act*, chapter 28 of the Statutes of Canada, 2002, to have been specified by the Minister under section 9 or 10 of that Act as the maximum residue limit for that agricultural chemical and its derivatives.

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