

Tobacco Reporting Regulations

SOR/2000-273

TOBACCO ACT

Registration 2000-06-26

Tobacco Reporting Regulations

P.C. 2000-1040 2000-06-21

Whereas, pursuant to section 42.1 of the *Tobacco Act*^a, the Minister of Health laid a copy of the proposed *Tobacco Reporting Regulations*, substantially in the annexed form, before the House of Commons on May 12, 2000 and the House of Commons concurred on June 8, 2000 in a report from the Standing Committee on Health approving the proposed Regulations;

Therefore, Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to sections 7 and 33 of the *Tobacco Act*^a, hereby makes the annexed *Tobacco Reporting Regulations*.

^aS.C. 1997, c. 13

INTERPRETATION

Definitions

1. The definitions in this section apply in these Regulations.

"accredited representative"
« *représentant accrédité* »

"accredited representative" means a person who is entitled to the tax exemptions specified in Article 34 of the Convention set out in Schedule I to the *Foreign Missions and International Organizations Act* or Article 49 of the Convention set out in Schedule II to that Act.
(*représentant accrédité*)

"Act"
« *Loi* »

"Act" means the *Tobacco Act*. (*Loi*)

"brand"
« *marque* »

"brand" means all of the brand elements that as a whole are used by a manufacturer to identify to a consumer a tobacco product made by the manufacturer. (*marque*)

"cigar"
« *cigare* »

"cigar" includes

(a) a cigarillo or cheroot; and

(b) any roll or tubular construction intended for smoking that consists of a filler composed of pieces of natural or reconstituted leaf tobacco, a binder of natural or reconstituted leaf tobacco in which the filler is wrapped, and a wrapper of natural or reconstituted leaf tobacco. (*cigare*)

"cigarette"
« *cigarette* »

"cigarette" includes any roll or tubular construction that contains tobacco and is intended for smoking, other than a bidi, cigar, kretek or tobacco stick. (*cigarette*)

"constituent"
« *constituant* »

"constituent" means a constituent listed in column 1 of Schedule 1. (*constituant*)

"consumer tobacco product"
« *produit du tabac pour consommation* »

"consumer tobacco product" means any of the following types of tobacco product that is for use by a consumer:

- (a) cigarettes;
- (b) cigarette tobacco;
- (c) leaf tobacco;
- (d) cigars;
- (e) pipe tobacco;
- (f) tobacco sticks;
- (g) smokeless tobacco;
- (h) kreteks;
- (i) bidis; and
- (j) any kit. (*produit du tabac pour consommation*)

"designated tobacco product"
« *produit du tabac désigné* »

"designated tobacco product" means any of the following types of consumer tobacco product:

- (a) cigarettes;
- (b) cigarette tobacco;
- (c) leaf tobacco;
- (d) tobacco sticks; and
- (e) kreteks. (*produit du tabac désigné*)

"duty free shop"
« *boutique hors taxes* »

"duty free shop" has the same meaning as in subsection 2(1) of the *Customs Act*. (*boutique hors taxes*)

"emission"
« *émission* »

"emission" means, in the case of an emission contained in mainstream smoke, an emission listed in column 1 of Schedule 2 and, in the case of an emission contained in sidestream smoke, an emission listed in column 1 of Schedule 3. (*émission*)

"equivalent unit"
« *unité équivalente* »

"equivalent unit" means

(a) in respect of cigarette tobacco, a cigarette prepared in accordance with the method set out in the Canadian General Standards Board standard CAN/CGSB-176.1-92, entitled *Preparation of Cigarettes from Cigarette Tobacco for Testing*, dated December 1992; and

(b) in respect of leaf tobacco, a cigarette prepared in accordance with Official Method T-401, entitled *Preparation of Cigarettes from Leaf Tobacco for Testing*, made by the Department of Health, dated December 31, 1999. (*unité équivalente*)

"identical products"
« *produits identiques* »

"identical products" means tobacco products that

(a) contain identical ingredients;

(b) are manufactured in an identical manner;

(c) have identical dimensions; and

(d) perform in an identical manner under the same conditions. (*produits identiques*)

"ingredient"
« *ingrédient* »

"ingredient" means any substance or material used in the manufacture of a tobacco product, and includes an additive. (*ingrédient*)

"kit"
« *trousse* »

"kit" means a package that includes a tobacco product referred to in any of paragraphs (a) to (j) of the definition "consumer tobacco product" together with another tobacco product, which products are intended to be assembled by a consumer for their use. (*trousse*)

"mainstream smoke"
« *fumée principale* »

"mainstream smoke" means the smoke that is drawn through the port of a smoking machine when a tobacco product is placed in the machine and combusted. (*fumée principale*)

"manufacturer"
« *fabricant* »

"manufacturer" includes an importer of tobacco products. It does not include a manufacturer that only packages or that only distributes tobacco products on behalf of another manufacturer. (*fabricant*)

"sidestream smoke"
« *fumée latérale* »

"sidestream smoke" means the smoke, other than mainstream smoke, that leaves a tobacco product when the product is placed in a smoking machine and combusted. (*fumée latérale*)

"smokeless tobacco"
« *tabac sans fumée* »

"smokeless tobacco" means chewing tobacco and snuff. (*tabac sans fumée*)

"type of package"
« *type d'emballage* »

"type of package" includes each size of the following types of packages:

(a) in respect of bidis, cigarettes, kreteks and tobacco sticks,

(i) a slide and shell package,

- (ii) a flip-top package, and
 - (iii) a soft package;
- (b) in respect of cigarette tobacco and pipe tobacco,

- (i) a pouch,
- (ii) a can, and
- (iii) a tub;

(c) in respect of cigars,

- (i) a tube,
- (ii) a flip-top box,
- (iii) a soft package, and
- (iv) a bundle; and

(d) in respect of smokeless tobacco, a plastic or metal container. (*type d'emballage*)

"type of tobacco"
« *type de tabac* »

"type of tobacco" includes the following types of tobacco commonly known as

- (a) Virginia flue-cured;
- (b) Maryland;
- (c) Burley; and
- (d) Oriental. (*type de tabac*)

"unit"
« *unité* »

"unit" means

- (a) a cigarette;
- (b) a cigar;
- (c) a tobacco stick;
- (d) a kretek; and
- (e) a bidi. (*unité*)

APPLICATION

Application

1.1 Every provision of these Regulations that applies to a brand of tobacco product also applies to every size of that brand.

SOR/2005-179, s. 2.

REPORTS

Content and form

2. (1) Every report made under these Regulations must be submitted to the Minister in writing or in an electronic format and must set out, in addition to the information required by these Regulations, the following information:

- (a) the name, street address and telephone number of
 - (i) the manufacturer on whose behalf the report is made, and
 - (ii) the person who makes the report;
- (b) the street address of the manufacturer's principal place of business in Canada;
- (c) the street address of the place of business where the tobacco product that is the subject of the report was manufactured;
- (d) the date of the report;
- (e) the period covered by the report;
- (f) in respect of any tobacco product that is to be reported, its type and brand; and
- (g) the section of these Regulations under which the report is made.

Information gathering analysis

- (2) Every report made under Parts 2, 3, 4 and 5 shall be based
- (a) on data obtained from the analyses of tobacco products performed during the period to be reported on; or
 - (b) on activities undertaken by or on behalf of the manufacturer during that period.

Reports under Part 3.1

(3) Despite subsection (1), the results of the tests referred to in subsection 14.2(6) must be submitted to the Minister in an electronic format that is acceptable to the Minister, based on the following criteria:

- (a) the Minister must have access to the test results;

(b) the Minister must be able to electronically process the test results without having to re-copy or re-enter them; and

(c) the Minister must be able to clearly identify the test result data.

SOR/2005-179, s. 3.

ATTESTATION

By person reporting

3. Any person who makes a report under these Regulations shall attach to the report an attestation that states that the information in the report is true and complete to the best of the knowledge and belief of that person and is provided in good faith.

LABORATORIES

Accreditation

4. (1) Any laboratory that performs an analysis on which a manufacturer relies for the purposes of these Regulations shall be accredited under the International Organization for Standardization standard ISO/IEC 17025, first edition, dated December 15, 1999, entitled *General Requirements for the Competence of Testing and Calibration Laboratories*.

Scope of Accreditation

(2) The document entitled *Scope of Accreditation* issued by the Standards Council of Canada to the laboratory referred to in subsection (1) or any other equivalent document that is evidence of the laboratory's accreditation shall specify the method used to perform the analysis referred to in subsection (1).

SOR/2005-179, s. 4.

ALTERNATIVE METHODS

Conditions of use

5. Despite sections 12 and 14, a laboratory may use a method that is not provided for in these Regulations (in this section referred to as an "alternative method") to collect information if

(a) the use of the alternative method results in information that is at least as accurate and precise as the information that would be produced if the method provided were used; and

(b) the laboratory submits a description of the alternative method to the Minister together with data that demonstrate that the requirements of paragraph (a) have been met.

PART 1
GENERAL INFORMATION

SPECIAL REQUESTS

Urgent Requests

6. Where any information to be provided in a report made under Parts 2 to 5 is urgently required for any of the purposes set out in section 4 of the Act, the Minister may, in writing and with reasons, request that a manufacturer provide the information before the day on which the report is required to be submitted.

Requests for additional information

7. Where additional information is required for any of the purposes set out in section 4 of the Act, the Minister may, in writing and with reasons, request that a manufacturer provide any additional information that is related to information provided in a report made under these Regulations, including

(a) any report made by a laboratory that is the basis for a report made under these Regulations; and

(b) any information relating to a research activity reported under Part 4, including a copy of any document for which a cover page was included.

Time to provide additional information

8. For the purposes of sections 6 and 7, the manufacturer shall provide any additional information within 30 days after the Minister's request is sent or at such later date as may be fixed by the Minister if the Minister determines that more time to comply with the request is necessary because of the complexity of the request or because new analyses or calculations are required to satisfy the request.

PERMANENT REPORTS

Content

9. (1) Every manufacturer shall report the following information:

(a) their name, street address and telephone number;

(b) the street address of each establishment where they manufacture a tobacco product;

(c) a list of every consumer tobacco product that they manufacture, by brand and by each type of package and carton of the brand, and, in the case of a kit, a list of every tobacco product contained in it; and

(d) a list of consumer tobacco products that they manufacture that are identical products sold under different brands, including an indication of which of the products are identical.

Samples of packages, cartons, and kits

(2) Every manufacturer shall provide to the Minister, for each brand of a consumer tobacco product that they manufacture, a sample or reasonable facsimile of each type of package, carton and kit.

Initial report

(3) Every manufacturer of a consumer tobacco product shall, within 90 days after the coming into force of these Regulations, provide the following to the Minister:

- (a) the information described in subsection (1); and
- (b) the samples or facsimiles described in subsection (2).

Notice of changes

(4) If the information reported under subsection (1), or anything provided under subsection (2), is changed by the manufacturer, the manufacturer shall, within 30 days after the change is made,

- (a) advise the Minister of the change in the information; and
- (b) provide the Minister with a copy of the changed package, carton or kit.

MANUFACTURING PROCEDURES

Requirement to provide

10. (1) Every manufacturer shall provide to the Minister, by brand, their manufacturing procedures for each of their consumer tobacco products.

Time to provide procedures

- (2) The manufacturing procedures shall be provided
 - (a) in the case of a consumer tobacco product being manufactured at the time these Regulations come into force, within 90 days after that coming into force date; and
 - (b) in the case of any other consumer tobacco product, on or before the day on which the manufacturer begins to manufacture that consumer tobacco product.

Change in information

(3) If a manufacturer changes a manufacturing procedure, the manufacturer shall provide the new procedure to the Minister within 30 days after the change is made.

PART 2
REPORTS
INGREDIENTS

Quarterly report

11. (1) Every manufacturer of a consumer tobacco product, a paper, a tube or a filter shall report, quarterly, by brand and type of tobacco, the information described in subsections (2) and (3).

Inventory

- (2) The report shall set out the total quantity and cost of every ingredient
- (a) purchased in the quarter;
 - (b) used in the quarter; and
 - (c) stored, on the date the report is made.

Content of report

- (3) The report shall set out the following information:
- (a) in the case of a bidi, cigarette, cigar, tobacco stick, or kretek, its weight in milligrams per unit;
 - (b) in respect of each ingredient in a consumer tobacco product, a paper, a tube or a filter,
 - (i) its common, chemical and commercial names,
 - (ii) if applicable, its biological origin, in standard Latin nomenclature,
 - (iii) if applicable, the registry number assigned to it in accordance with the Chemical Abstracts Service of the American Chemical Society,
 - (iv) the mean, standard deviation and 95% confidence limit of the amount of it in milligrams
 - (A) per gram of the consumer tobacco product, paper, tube or filter, and
 - (B) in the case of a bidi, cigarette, cigar, tobacco stick or kretek, per unit of the product,
 - (v) the name and street address of its supplier,
 - (vi) its country of origin,
 - (vii) in the case of tobacco, its type,

(viii) in the case of a paper, its type and specifications, and

(ix) in the case of a filter, a description of it, its specifications and pressure drop and, with respect to nicotine for those brands analyzed pursuant to subsection 14(13), its efficiency, determined in accordance with Official Method T-106, entitled *Determination of Filter Efficiency in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999; and

(c) in respect of each component of an ingredient in a consumer tobacco product, a paper, a tube or a filter

(i) its commercial, common and chemical names,

(ii) if applicable, its biological origin, in standard Latin nomenclature,

(iii) if applicable, the registry number assigned to it in accordance with the Chemical Abstracts Service of the American Chemical Society,

(iv) the mean, standard deviation and 95% confidence limit of the amount of it in milligrams

(A) per gram of the ingredient and of the consumer tobacco product, paper, tube or filter, and

(B) in the case of a bidi, cigarette, cigar, tobacco stick or kretek, per unit of the tobacco product,

(v) the name and street address of its supplier, and

(vi) its country of origin.

When report to be submitted

(4) The report shall be submitted

(a) for the period beginning on January 1 and ending on March 31 of a year, on or before April 30 of that year;

(b) for the period beginning on April 1 and ending on June 30 of a year, on or before July 31 of that year;

(c) for the period beginning on July 1 and ending on September 30 of a year, on or before October 31 of that year; and

(d) for the period beginning on October 1 and ending on December 31 of a year, on or before January 31 of the following year.

Exception — identical products

(5) The report is not required for a consumer tobacco product if

(a) the product is one of identical products of the manufacturer sold under different brands; and

(b) a report under this section is submitted in respect of another of those identical products.

CONSTITUENTS

Annual report

12. (1) Every manufacturer of a consumer tobacco product shall report annually, by brand and type of tobacco, the information described in subsection (7) for the consumer tobacco product. The report shall, subject to subsection (2), be submitted on or before January 31 of the year following the year to be reported on.

Initial report

(2) The initial report, relating to the portion of the year remaining of the year in which these Regulations come into force, shall be submitted within the later of

(a) January 31 of the year following the year these Regulations come into force, or

(b) 180 days after these Regulations come into force.

Method of collecting information

(3) Every manufacturer shall use the applicable method listed in column 2 of Schedule 1 to collect information about a constituent.

Sampling

(4) A sample used for the purpose of determining the amount of a constituent must be

(a) selected in accordance with the procedures described in items A and B of Table 1 of the International Organization for Standardization standard ISO 8243, second edition, dated 1991-10-15 and entitled *Cigarettes — Sampling*; and

(b) prepared in accordance with Official Method T-402, entitled *Preparation of Cigarettes, Cigarette Tobacco, Cigars, Kreteks, Bidis, Packaged Leaf Tobacco, Pipe Tobacco and Smokeless Tobacco for Testing*, made by the Department of Health, dated December 31, 1999.

Replicates

(5) The mean, standard deviation and 95% confidence limit of the amount of each constituent must be based on three replicates of a sample.

Adjustment for moisture

(6) The amount of each constituent must be corrected for moisture in accordance with AOAC Official Method 966.02, entitled *Moisture in Tobacco, Gravimetric Method*, made in 1968.

Content of report

(7) The report shall set out the following information:

(a) in the case of bidis, cigarettes, cigars, tobacco sticks and kreteks, the weight in milligrams per unit;

(b) the name of each constituent in the consumer tobacco product;

(c) the mean, standard deviation and 95% confidence limit of the amount of each constituent in milligrams, micrograms, or nanograms

(i) per gram of the consumer tobacco product, and

(ii) in the case of bidis, cigarettes, cigars, tobacco sticks and kreteks, per unit; and

(d) the pH of the consumer tobacco product, determined in accordance with Official Method T-310, entitled *Determination of Whole Tobacco pH*, made by the Department of Health, dated December 31, 1999.

Exception — identical products

(8) The report is not required for a consumer tobacco product if

(a) the product is one of identical products of the manufacturer sold under different brands; and

(b) a report under this section is submitted in respect of another of those identical products.

Exception — sales volume

(9) The report is not required for the following tobacco products where the total sales of the manufacturer for the year preceding to the year covered by the report are less than

(a) in the case of cigars, 1,000,000 units per brand; and

(b) in the case of pipe tobacco, 8000 kg per brand.

Exception — short report

(10) A manufacturer may, instead of submitting the report described in subsection (1) or (2) for a consumer tobacco product, submit a report on the amount of nicotine, nitrosamines, nickel, lead, cadmium, chromium, arsenic, selenium and mercury in the product if

(a) in respect of cigarettes, cigarette tobacco and tobacco sticks, including any cigarettes, cigarette tobacco or tobacco sticks sold in kits, the manufacturer's total sales for that product in the year preceding the period covered by the report is less than 1% of the total sales of that product in that year in Canada; and

(b) in respect of leaf tobacco, bidis and kreteks, the manufacturer's total sales for that product in the year preceding the period covered by the report is less than 5% of the total sales of that product in that year in Canada.

Exception — eugenol

(11) If clove, clove extract or eugenol has not been added to a consumer tobacco product, the manufacturer of the product need not analyze it for the constituent of eugenol.

SALES

Report

13. (1) Every manufacturer of a consumer tobacco product shall report the information described in subsection (3) in respect of the following categories, by brand and by each type of package of the brand:

- (a) in Canada;
- (b) in each province;
- (c) in each duty free trade customer and operator;
- (d) as ships' stores in accordance with the *Ships' Stores Regulations*;
- (e) to accredited representatives; and
- (f) for export, by country of destination.

Duty free shop importers

(2) Every importer of a consumer tobacco product to be sold at a duty free shop shall report, by province, the information described in subsection (3) by brand and by each type of package of the brand in respect of each duty free shop.

Manner of reporting

(3) The information in respect of the sales of a consumer tobacco product for each category described in subsection (1) and (2) shall be reported as follows:

- (a) in respect of bidis, cigarettes, cigars, tobacco sticks and kreteks,
 - (i) by unit, and
 - (ii) by number of packages sold, specifying the type of package, the number of units in a package, and the dollar value of the total sales of each type of package;
- (b) in respect of kits
 - (i) by number sold,
 - (ii) by weight, in kilograms, of tobacco contained in each kit,
 - (iii) if applicable, by the number of papers, tubes or filters included in each kit, and
 - (iv) by the number of units intended to be made;

(c) in respect of cigarette tobacco, by weight in kilograms of tobacco in each specified type of package; and

(d) in respect of any other consumer tobacco product

(i) by weight in kilograms of the consumer tobacco product, and

(ii) by number of packages sold, specifying the type of package, the weight of the tobacco product in the package and the dollar value of the total sales of each type of package.

Time to report

(4) The report shall be submitted

(a) for cigarettes, cigarette tobacco or tobacco sticks, on or before the 15th day of each month, for the previous month; and

(b) for every other consumer tobacco product,

(i) for the period beginning on January 1 and ending on March 31 of a year, on or before April 30 of that year,

(ii) for the period beginning on April 1 and ending on June 30 of a year, on or before July 31 of that year,

(iii) for the period beginning on July 1 and ending on September 30 of a year, on or before October 31 of that year, and

(iv) for the period beginning on October 1 and ending on December 31 of a year, on or before January 31 of the following year.

PART 3

EMISSIONS FROM DESIGNATED TOBACCO PRODUCTS

Report

14. (1) Every manufacturer of a designated tobacco product shall report the information described in subsections (2) and (7), by brand and type of designated tobacco product, in respect of

(a) the emissions contained in the mainstream smoke produced from the combustion of the designated tobacco product; and

(b) the emissions contained in the sidestream smoke produced from the combustion of the designated tobacco product.

Content of report

(2) The report shall, in respect of the emissions contained in the mainstream and sidestream smoke produced from a cigarette, tobacco stick, kretek or equivalent unit of a designated tobacco product that is placed in a smoking machine and combusted, identify the emission and set out the mean, standard deviation and 95% confidence limit

(a) of the number of puffs;

(b) of each emission, expressed in milligrams, micrograms or nanograms per unit or equivalent unit; and

(c) of the weight of tobacco contained in the designated tobacco product expressed in milligrams per unit or equivalent unit.

Sampling

(3) A sample to be used for the purpose of determining the amount of an emission must be

(a) selected in accordance with the procedures described in items A and B of Table 1 of the International Organization for Standardization standard ISO 8243, second edition, dated 1991-10-15 and entitled *Cigarettes — Sampling*; and

(b) conditioned and smoked in an environment as described in the International Organization for Standardization standard ISO 3402, third edition, dated 1991-07-01 and entitled *Tobacco and Tobacco Products — Atmosphere for Conditioning and Testing*.

Replicates

(4) The mean, standard deviation and 95% confidence limit of the amount of each emission must be based

(a) in the case of tar, nicotine and carbon monoxide, on 20 replicates of a sample; and

(b) in every other case, on 7 replicates of a sample.

Method of collecting data

(5) Every manufacturer shall use the following methods to collect data for an emission:

(a) in the case of mainstream smoke, the applicable official method set out in column 2 of Schedule 2; and

(b) in the case of sidestream smoke, the applicable official method set out in column 2 of Schedule 3.

Conditions for the collection of data

(6) For the purpose of subsection (2), both of the following conditions are to be used to determine the amount of an emission:

(a) the conditions set out in the International Organization for Standardization standard ISO 3308, Third Edition 1991-10-15, entitled *Routine analytical cigarette-smoking machine — Definitions and standard conditions*, 1991 (E); and

(b) the conditions referred to in paragraph (a), but modified in the following manner:

(i) puff volume must be increased from 35 mL to 55 mL,

(ii) puff interval must be decreased from 60 s to 30 s, and

(iii) all ventilation holes must be blocked by placing over them a strip of Mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape, and the tape must be cut so that it covers the circumference and is tightly secured from the end of the filter to the tipping overwrap seam, or by another method of equivalent efficiency.

pH levels

(7) The report shall also set out the pH level of the mainstream smoke, determined in accordance with Official Method T-113, entitled *Determination of Mainstream Tobacco Smoke pH*, made by the Department of Health, dated December 31, 1999.

When report to be submitted

(8) The report shall be submitted

(a) in the case of a report in respect of the emissions of tar, nicotine and carbon monoxide in the mainstream and sidestream smoke produced from the combustion of a cigarette or an equivalent unit of cigarette tobacco

(i) in relation to the conditions set out in paragraph (6)(b), for the period beginning on January 1 and ending on June 30 of a year, on or before July 31 of that year, and

(ii) in relation to the conditions set out in paragraph (6)(a), for the period beginning on July 1 and ending on December 31 of a year, on or before January 31 of the following year; and

(b) in the case of the report in respect of all other emissions in the mainstream and sidestream smoke or the short report referred to in subsection (9), annually on or before January 31 of the year following the year covered by the report.

Exception — short report

(9) A manufacturer may, instead of submitting the report described in subsection (1) for a designated tobacco product, submit, every two years, a report on the amount of tar, nicotine, carbon monoxide, benzene, hydrogen cyanide and formaldehyde emissions contained in the smoke produced from the designated tobacco product if

(a) in respect of cigarettes, cigarette tobacco and tobacco sticks, including any cigarettes, cigarette tobacco or tobacco sticks sold in kits, the manufacturer's total sales for that product in the year preceding the period covered by the report is less than 1% of the total sales of that product in that year in Canada; and

(b) in respect of leaf tobacco and kreteks, the manufacturer's total sales of that product in the year preceding the period covered by the report is less than 5% of the total sales of that product in that year in Canada.

Exception

(10) The report, other than a report in respect of the emissions of tar, nicotine and carbon monoxide, is not required for a designated tobacco product if

(a) the product is one of identical products of the manufacturer sold under different brands; and

(b) a report under this section is submitted in respect of another of those identical products.

Exemption — functional relationship of certain emissions

(11) A manufacturer may, on or before December 1 of the year preceding the year for which the exemption is sought, apply to the Minister for an exemption from the requirement to submit a report under subsection (1) in respect of the emissions for mainstream or sidestream smoke of a brand of a designated tobacco product specified by the manufacturer, if the manufacturer provides to the Minister the content and results of a statistical analysis done under the conditions referred to in subsection (12), that demonstrates, within a 95% confidence limit and in relation to the type of emission exemption sought, the existence of a functional linear relationship

(a) between tar and each of the other emissions, other than nicotine, produced from the combustion of the designated tobacco product

(i) by using the following formula:

$$y=mx+b$$

where

y

is the amount of the other emission,

m

is the slope,

x

is the mean amount of tar as determined by 7 replicates, and

b

is the intercept,

(ii) by applying a regression analysis to the results obtained under subparagraph (i), and

(iii) by applying an F-test to the results obtained under that subparagraph; and

(b) between nicotine and the other emissions produced from the combustion of the designated tobacco product, by making the calculation and applying the analysis and test described in paragraph (a), except that the references to "tar" in subparagraph (i), other than in the description of "y", shall be read as references to "nicotine".

Conditions

(12) The conditions under which the statistical analysis to be provided in subsection (11) are as follows:

(a) in the case of mainstream smoke, under the conditions set out in paragraphs (6)(a) and (b); and

(b) in the case of sidestream smoke, under the conditions set out in paragraph (6)(a).

Sample size

(13) To qualify for an exemption under subsection (11), the manufacturer must submit to the Minister

(a) a sample that must be composed of at least 28 different brands and 2 standard samples of a type of the designated tobacco product that represent the range of tar and nicotine deliveries for that type of designated tobacco product as determined

(i) in the case of mainstream smoke, in accordance with Official Method T-115, entitled *Determination of "Tar", Nicotine and Carbon Monoxide in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999, and

(ii) in the case of sidestream smoke, in accordance with Official Method T-212 entitled *Determination of "Tar" and Nicotine in Sidestream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999;

(b) a list of the brands of the designated tobacco product for which the application for exemption is made; and

(c) a list of the properties of the designated tobacco product, such as the type of tobacco, type of filter and characteristics of a cigarette paper, which demonstrate the functional linear relationship between

(i) the brands of the designated tobacco product that form the sample, and

(ii) one or more of the brands of the designated tobacco product for which the application for exemption is made.

Joint Sample

(14) For the purpose of subsection (13), two or more manufacturers may combine their designated tobacco products to produce a joint sample for the purpose of analyzing the sample in accordance with that subsection.

Decision of the Minister

(15) The Minister shall, without delay, decide to accept or reject

(a) an application made under subsection (11), based on the

(i) methodology used, and

(ii) the demonstration of a satisfactory functional linear relationship based on

(A) the mean and standard deviations of the amount of each of the emissions, other than tar and nicotine,

(B) the estimates and 95% confidence limits for the slope "m" and the intercept "b" referred to in subparagraph (11)(a)(i),

(C) regression statistics, including the degree of freedom for error, degree of freedom for regression, mean square regression, mean square error and the F statistic, and

(D) the fact that the data must fall under a 95% prediction interval; and

(b) a sample made in accordance with subsection (13) or (14), based on the methodology used and the representativeness of the sample.

Satisfactory functional relationship

(16) For the purposes of paragraph (15)(a), a satisfactory functional linear relationship exists if a linear model demonstrates a significant portion of the variation of the other emissions about the mean of those other emissions, with a statistical significance of less than 0.01.

PART 3.1

TOXICITY OF CIGARETTE EMISSIONS

INTERPRETATION

Definitions

14.1 The following definitions apply in this Part.

"cigarette"
« *cigarette* »

"cigarette" means any roll or tubular construction that contains tobacco, has a wrapper or cover made of paper and is consumed through the inhalation of the products of combustion but does not include a bidi, cigar, kretek or tobacco stick. (*cigarette*)

"identical cigarettes"
« *cigarettes identiques* »

"identical cigarettes" means cigarettes that

(a) contain identical ingredients;

(b) are manufactured in an identical manner;

(c) have identical dimensions; and

(d) perform in an identical manner under the same conditions. (*cigarettes identiques*)

SOR/2005-179, s. 5.

TOXICITY TESTING AND REPORT REQUIREMENTS

Initial testing

14.2 (1) Every manufacturer shall perform toxicity testing in accordance with subsection (6) on every brand of cigarettes that it manufactures after December 31, 2004 and before October 1, 2005.

Annual testing

(2) After September 30, 2005, for every period beginning on January 1 of a year and ending on December 31 of the same year, every manufacturer shall perform toxicity testing in accordance with subsection (6) on every brand of cigarettes that it manufactures during that period.

Report

(3) The manufacturer shall submit a report of the test results to the Minister on or before January 31 of the year following the year in which the tested cigarettes were manufactured.

Presentation of results

(4) The report shall include

(a) the date of manufacture of the cigarettes tested, the name of the testing laboratory, the start and end dates of the tests, the results of the tests and the name of the applicable Department of Health official method used for the tests;

(b) in the case of a report on the initial testing required by subsection (1), the results, if known, of the ignition propensity tests conducted on cigarettes of the same brand using ASTM International method E2187 — 04, dated July 1, 2004 and entitled *Standard Test Method for Measuring the Ignition Strength of Cigarettes*; and

(c) a copy of all laboratory reports.

Number of replicates of a sample

(5) The results of the tests performed in accordance with paragraph (6)(a) or (b) shall be based on three replicates of a sample.

Method of collecting data

(6) The toxicity data shall be collected using the following test methodologies:

(a) Department of Health Official Method T-501, entitled *Bacterial Reverse Mutation Assay for Mainstream Tobacco Smoke*, as amended from time to time;

(b) Department of Health Official Method T-502, entitled *Neutral Red Uptake Assay for Mainstream Tobacco Smoke*, as amended from time to time; and

(c) Department of Health Official Method T-503, entitled *In Vitro Micronucleus Assay for Mainstream Tobacco Smoke*, as amended from time to time.

Sampling

(7) The sampling of cigarettes for the toxicity testing shall be performed in accordance with the procedures described in items A and B of Table 1 of the International Organization for Standardization standard ISO 8243, second edition, dated October 15, 1991 and entitled *Cigarettes — Sampling*.

Conditioning

(8) The cigarettes to be used in the toxicity testing shall be conditioned in an environment as described in the International Organization for Standardization standard ISO 3402, fourth edition, dated December 15, 1999 and entitled *Tobacco and Tobacco Products — Atmosphere for Conditioning and Testing*.

Exception — identical cigarettes

(9) A manufacturer is not required to perform the testing and submit the report in respect of a particular brand of cigarettes if the manufacturer

(a) sells identical cigarettes under more than one brand, including the particular brand;

(b) submits a report under this section in respect of another of those brands of identical cigarettes and that brand is specified in the report as being the "reference brand"; and

(c) specifies in the report that is submitted in respect of the reference brand the other brands of identical cigarettes that are also covered by the report, including the particular brand.

SOR/2005-179, s. 5.

PART 4 RESEARCH ACTIVITIES

Annual Report

15. (1) Every manufacturer of a consumer tobacco product shall report annually on each research activity that was undertaken, continued or completed during a year by or on behalf of the manufacturer in respect of that consumer tobacco product, including, but not limited to, research regarding

(a) its toxicity;

(b) its health effects;

(c) its ingredients;

(d) its taste and flavour;

(e) its modification;

(f) its marketing; and

(g) the manner in which it is used by consumers.

The report shall be submitted on or before January 31 of the following year.

Content of report

(2) The report shall set out the following information in respect of each research activity:

(a) the cover page of any relevant document;

(b) any progress report, synopsis or outline made in respect of the activity; and

(c) the expected duration of the activity, the date it began and the expected date of completion.

New consumer tobacco products

(3) Every manufacturer shall report annually the information described in subsection (2) in respect of each research activity related to the development of a new consumer tobacco product undertaken, continued or completed during a year by or on behalf of the manufacturer. The report shall be submitted on or before January 31 of the following year.

PART 5

PROMOTIONAL ACTIVITIES

SEMI-ANNUAL REPORTS

Promotional activities

16. (1) Every manufacturer of a consumer tobacco product shall report

(a) subject to subsection 18(2), quarterly and at the following times, the dates of release of any promotional activity in respect of that consumer tobacco product and the applicable descriptive information set out in sections 17 to 24:

(i) for the period beginning on January 1 and ending on March 31 of a year, on or before April 30 of that year;

(ii) for the period beginning on April 1 and ending on June 30 of a year, on or before July 31 of that year;

(iii) for the period beginning on July 1 and ending on September 30 of a year, on or before October 31 of that year;

(iv) for the period beginning on October 1 and ending on December 31 of a year, on or before January 31 of the following year.

(b) semi-annually, the information described in subsection (2) in respect of each promotional activity undertaken by the manufacturer or for the manufacturer for consideration in respect of that consumer tobacco product

(i) for the period beginning on January 1 and ending on June 30 of a year, on or before July 31 of that year, and

(ii) for the period beginning on July 1 and ending on December 31 of a year, on or before January 31 of the following year.

Content of report

(2) In addition to the information to be reported under sections 17 to 24, the semi-annual report mentioned in paragraph (1)(b) shall set out, for each province and specifying national totals,

(a) by brand family and, where applicable, by brand

(i) the total semi-annual costs of each of the promotional activities described in sections 17 to 24, and

(ii) by type of consumer tobacco product, the total semi-annual costs of all promotional activities; and

(b) in respect of all of the manufacturer's promotional activities for all of their consumer tobacco products, the total semi-annual costs of those promotional activities.

ADVERTISEMENTS IN PUBLICATIONS

Information about advertisements

17. (1) If a consumer tobacco product is advertised in a publication, the manufacturer of that product shall report the following information:

(a) every province in which the publication was distributed;

(b) the dates the advertisement was published; and

(c) the total cost of the advertisement.

Copy of advertisement

(2) The manufacturer shall attach to the report a copy or a reasonable facsimile with a detailed description of any advertisement reported under subsection (1).

SPONSORSHIP

Information to be provided

18. (1) If a consumer tobacco product-related brand element is displayed, before October 1, 2003, in a promotion that is used in the sponsorship of a person, entity, event, activity or permanent facility, the manufacturer of the consumer tobacco product shall report the following information:

(a) if the sponsorship is in respect of

(i) a person or an entity, the name of the person or entity and a description of any items bearing the consumer tobacco product-related brand element of the manufacturer,

(ii) an event or activity, a description of the event or activity and its date, or

(iii) a permanent facility, the name of the facility, a description of it and its street address;

(b) whether the consumer tobacco product-related brand element was displayed between January 25, 1996 and April 25, 1997 in promotional material that was used in the sponsorship of an event or activity that took place in Canada and, if so, the date of the event or activity;

(c) a copy or reasonable facsimile with a detailed description of any promotional material containing a brand element of the manufacturer, including, with respect to the promotional material,

- (i) the colours used in it,
 - (ii) its size, and
 - (iii) a copy of any text appearing in it;
- (d) the expected duration of the display of any promotional material used in the sponsorship;
- (e) if promotional material used in the sponsorship appears in a publication, the information required by section 17; and
- (f) the total cost of the sponsorship.

When required

(2) The material required in paragraph (1)(c) must be provided no later than the date of its release.

Permanent facilities

19. If a consumer tobacco product-related brand element, or the name of a manufacturer, is displayed, on or after October 1, 2003, on a permanent facility where the brand element or name is not thereby associated with a sport or cultural event or activity, the manufacturer of the consumer tobacco product shall report the following information:

- (a) the name, the street address and a description of the facility;
- (b) a description of the brand element or name displayed, including
 - (i) the colours used in it, and
 - (ii) its size;
- (c) the expected duration of the display; and
- (d) the total cost of the display.

PACKAGING

Information to be provided

20. Every manufacturer of a consumer tobacco product shall report, by brand and each type of package, carton or kit containing the brand, the cost of manufacturing the packaging of the consumer tobacco product.

SERVICES

Information to be provided

21. If a service uses a consumer tobacco product-related brand element of a manufacturer for consideration by the manufacturer, the manufacturer shall report the following information:

- (a) a detailed description of the service;
- (b) in respect of the service, the expected duration of the use of the consumer tobacco product-related brand element;
- (c) the province in which the consumer tobacco product-related brand element is used by the service; and
- (d) the consideration given by the manufacturer for the promotion of the consumer tobacco product.

DISPLAY AT RETAIL

Report

22. Every manufacturer of a consumer tobacco product that uses a sign to promote the product, specifies the manner of displaying the product at retail or pays a fee for the display of the product shall report the following information in respect of the display at retail of the product:

- (a) if a sign or display is used,
 - (i) a detailed description of the sign or display,
 - (ii) a photo or reasonable facsimile of the sign or display, and
 - (iii) the cost of providing the display or using the sign, including the cost of their production and distribution;
- (b) the total amount paid to retailers to display the product or sign, by province;
- (c) the number of retailers, by province and by each of the following categories, that have received a fee to display the product or sign:
 - (i) a convenience store, including
 - (A) an independently owned convenience store, and
 - (B) any other convenience store,
 - (ii) a grocery store,
 - (iii) a pharmacy,
 - (iv) a restaurant,

- (v) a tavern, bar or beverage room, and
 - (vi) any other establishment not described in subparagraphs (i) to (v); and
- (d) in the case of a sign,
- (i) the number of establishments, including their names and addresses, that do not permit entry to young persons and that displayed the sign; and
 - (ii) the period during which the sign was specified to be displayed.

ACCESSORIES

Information to be provided

23. If an accessory that displays a consumer tobacco product-related brand element is promoted, the manufacturer of that consumer tobacco product shall report the following information about the accessory:

- (a) photograph or reasonable facsimile of it;
- (b) a detailed description of it;
- (c) the number sold, by province; and
- (d) its cost
 - (i) of development,
 - (ii) of manufacture,
 - (iii) of distribution, and
 - (iv) of promotion.

OTHER PRODUCTS

Information to be provided

24. If a non-tobacco product, other than an accessory that displays a consumer tobacco product-related brand element, displays a consumer tobacco product-related brand element of a manufacturer, the manufacturer shall report the following information in respect of the non-tobacco product:

- (a) a photograph or reasonable facsimile of it;
- (b) a detailed description of it;
- (c) the number sold, by province; and
- (d) its cost
 - (i) of development,

- (ii) of manufacture,
- (iii) of distribution, and
- (iv) of promotion.

PART 6
REPEAL AND COMING INTO FORCE

REPEAL

25. The Tobacco Products Control Regulations¹ are repealed.

¹SOR/89-21

COMING INTO FORCE

26. These Regulations come into force on the day on which they are registered.

SCHEDULE 1

(Section 1 and subsection 12(3))

OFFICIAL METHODS FOR THE COLLECTION OF DATA ON CONSTITUENTS

Column 1	Column 2
Item Constituent	Official Method
1. (a) Nicotine (b) Nornicotine (c) Anabasine (d) Myosmine (e) Anatabine	Official Method T-301, <i>Determination of Alkaloids in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
2. Ammonia	Official Method T-302, <i>Determination of Ammonia in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
3. (a) Glycerol (b) Propylene glycol (c) Triethylene glycol	Official Method T-304, <i>Determination of Humectants in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
4. (a) Nickel (b) Lead (c) Cadmium (d) Chromium (e) Arsenic	Official Method T-306, <i>Determination of Ni, Pb, Cd, Cr, As, Se and Hg in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999

Item	Column 1 Constituent	Column 2 Official Method
	(f) Selenium	
	(g) Mercury	
5.	Benzo[a]pyrene	Official Method T-307, <i>Determination of Benzo[a]pyrene in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
6.	Nitrate	Official Method T-308, <i>Determination of Nitrate from Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
7.	(a) N-nitrosornicotine (b) 4-(N-nitrosomethylamino)-l-(3-pyridyl)-1-butanone (c) N-nitrosoanatabine (d) N-nitrosoanabasine	Official Method T-309, <i>Determination of Nitrosamines in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
8.	Triacetin	Official Method T-311, <i>Determination of Triacetin in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
9.	Sodium propionate	Official Method T-312, <i>Determination of Sodium Propionate in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
10.	Sorbic acid	Official Method T-313, <i>Determination of Sorbic Acid in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
11.	Eugenol [2- Methoxy-4-(2-propenyl)-phenol]	Official Method T-314, <i>Determination of Eugenol in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999

SCHEDULE 2

(Section 1 and subsection 14(5))

OFFICIAL METHODS FOR THE COLLECTION OF EMISSION DATA ON MAINSTREAM SMOKE

Item	Column 1 Emission	Column 2 Official Method
1.	Ammonia	Official Method T-101, <i>Determination of Ammonia in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
2.	(a) 1- aminonaphthalene (b) 2- aminonaphthalene (c) 3- amonobiphenyl and (d) 4- aminobiphenyl	Official Method T-102, <i>Determination of 1- and 2- Aminonaphthalene and 3- and 4- Aminobiphenyl in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999

3. Benzo[a]pyrene Official Method T-103, *Determination of Benzo[a]pyrene in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
4. (a) Formaldehyde
(b) Acetaldehyde
(c) Acetone
(d) Acrolein
(e) Propionaldehyde
(f) Crotonaldehyde
(g) Butyraldehyde Official Method T-104, *Determination of Selected Carbonyls in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
5. Eugenol [2-Methoxy-4-(2-propenyl)-phenol] Official Method T-105, *Determination of Eugenol in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
6. Hydrogen cyanide Official Method T-107, *Determination of Hydrogen Cyanide in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
7. Mercury Official Method T-108, *Determination of Mercury in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
8. (a) Lead
(b) Cadmium Official Method T-109, *Determination of Ni, Pb, Cd, Cr, As and Se in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
9. (a) NO
(b) NO_x Official Method T-110, *Determination of Oxides of Nitrogen in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
10. (a) *N*-nitrosonornicotine
(b) 4-(*N*-nitrosomethylamino)-1-(3-pyridyl)-1-butanone
(c) *N*-nitrosoanatabine
(d) *N*-nitrosoanabasine Official Method T-111, *Determination of Nitrosamines in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
11. (a) Pyridine
(b) Quinoline
(c) Styrene Official Method T-112, *Determination of Pyridine, Quinoline and Styrene in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
12. (a) Hydroquinone
(b) Resorcinol
(c) Cathecol
(d) Phenol
(e) *m+p*-Cresol
(f) *o*-Cresol Official Method T-114, *Determination of Phenolic Compounds in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999

13. (a) Tar
(b) Nicotine
(c) Carbon Monoxide
- Official Method T-115, *Determination of "Tar", Nicotine and Carbon Monoxide in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
14. (a) 1,3 Butadiene
(b) Isoprene
(c) Acrylonitrile
(d) Benzene
(e) Toluene
- Official Method T-116, *Determination of 1,3- Butadiene, Isoprene, Acrylonitrile, Benzene and Toluene in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999

SCHEDULE 3

(Section 1 and subsection 14(5))

OFFICIAL METHODS FOR THE COLLECTION OF EMISSION DATA ON SIDESTREAM SMOKE

Item	Column 1 Emission	Column 2 Official Method
1.	Ammonia	Official Method T-201, <i>Determination of Ammonia in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
2.	(a) 1- aminonaphthalene (b) 2- aminonaphthalene (c) 3- aminobiphenyl and (d) 4- aminobiphenyl	Official Method T-202, <i>Determination of Aminonaphthalene in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
3.	Benzo[a]pyrene	Official Method T-203, <i>Determination of Benzo[a]pyrene in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
4.	(a) Formaldehyde (b) Acetaldehyde (c) Acetone (d) Acrolein (e) Propionaldehyde (f) Crotonaldehyde (g) Butyraldehyde	Official Method T-204, <i>Determination of Carbonyls in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
5.	Hydrogen cyanide	Official Method T-205, <i>Determination of Hydrogen Cyanide in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
6.	Mercury	Official Method T-206, <i>Determination of Mercury in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated

	Column 1	Column 2
Item	Emission	Official Method
		December 31, 1999
7.	(a) Lead (b) Cadmium	Official Method T-207, <i>Determination of Ni, Pb, Cd, Cr, As, and Se in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
8.	(a) NO (b) NOx	Official Method T-208, <i>Determination of Oxides of Nitrogen in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
9.	(a) <i>N</i> -nitrosonornicotine (b) 4-(<i>N</i> -nitrosomethylamino)-1-(3-pyridyl)-1-butanone (c) <i>N</i> -nitrosoanatabine (d) <i>N</i> -nitrosoanabasine	Official Method T-209, <i>Determination of Nitrosamines in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
10.	(a) Pyridine (b) Quinoline	Official Method T-210, <i>Determination of Selected Basic Semi-Volatiles (Pyridine and Quinoline) in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
11.	(a) Hydroquinone (b) Resorcinol (c) Cathecol (d) Phenol (e) <i>m+p</i> -Cresol (f) <i>o</i> -Cresol	Official Method T-211, <i>Determination of Phenolic Compounds in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
12.	(a) Tar (b) Nicotine	Official Method T-212, <i>Determination of "Tar" and nicotine in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
13.	(a) 1,3 Butadiene (b) Isoprene (c) Acrylonitrile (d) Benzene (e) Toluene (f) Styrene	Official Method T-213, <i>Determination of Selected Volatiles (1,3 Butadiene, Isoprene, Acrylonitrile, Benzene, Toluene and Styrene) in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
14.	Carbon Monoxide	Official Method T-214, <i>Determination of Carbon Monoxide (Co) in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999