

[Home](#) > [Part II: Official Regulations](#) > [2011-10-12](#)

Vol. 145, No. 21 — October 12, 2011

Registration

SOR/2011-177 September 22, 2011

TOBACCO ACT

Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)

P.C. 2011-925 September 22, 2011

Whereas, pursuant to section 42.1 of the *Tobacco Act* ([see footnote a](#)), the Minister of Health laid a copy of the proposed *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)*, substantially in the annexed form, before the House of Commons on June 9, 2011 and the House of Commons concurred on June 22, 2011 in a report from the Standing Committee on Health approving the proposed Regulations;

Therefore, His Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to sections 17 and 33 ([see footnote b](#)) of the *Tobacco Act* ([see footnote c](#)), hereby makes the annexed *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)*.

TOBACCO PRODUCTS LABELLING REGULATIONS (CIGARETTES AND LITTLE CIGARS)

INTERPRETATION

Definitions

1. The following definitions apply in these Regulations.

“box”
« *boîte* »

“box” means a package that has rectangular sides and a lid.

“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.

“carton”
« *cartouche* »

“carton” means a package that contains two or more packages of a tobacco product.

“cigarette”
« *cigarette* »

“cigarette” includes any roll or tubular construction that contains tobacco and is intended for

smoking, other than a bidi, cigar, kretek, little cigar or tobacco stick.

“component”
« *composante* »

“component” means, with respect to a labelling element,

- (a) in the case of a health warning, the image, the title, the explanatory text or related information;
- (b) in the case of a toxic emissions statement, the text;
- (c) in the case of a health information message, the image or the text; and
- (d) the attribution of a labelling element to its source as provided for in subsection 6(1) if the attribution appears in a display area or on a leaflet, even though the attribution is not a labelling element.

“display area”
« *zone d’application* »

“display area” means a side, or part of a side, of a package specified as a display area in accordance with sections 12, 17 and 22.

“exterior surface of the slide”
« *surface extérieure du tiroir* »

“exterior surface of the slide” means, in respect of a slide and shell package, the exterior surface of the slide, other than the flaps of the slide, when the package is used in the customary manner to gain access to the tobacco product.

“health information message”
« *message d’information sur la santé* »

“health information message” means the following messages, but does not include the attribution of those messages to their source as provided for in subsection 6(1):

- (a) in respect of cigarettes, the messages set out in Part 3 of Division A of the source document; and
- (b) in respect of little cigars, the messages set out in Part 3 of Division B of the source document.

“health warning”
« *mise en garde* »

“health warning” means the following warnings, but does not include the attribution of those warnings to their source as provided for in subsection 6(1):

- (a) in respect of cigarettes, the warnings set out in Part 1 of Division A of the source document; and
- (b) in respect of little cigars, the warnings set out in Part 1 of Division B of the source document.

“labelling element”
« *élément d’étiquetage* »

“labelling element” means a health warning, toxic emissions statement or health information message.

“manufacturer”
« *fabricant* »

“manufacturer” does not include an individual or entity that only packages or only distributes tobacco products on behalf of a manufacturer.

“slide”
« *tiroir* »

“slide” means the sliding portion of a slide and shell package.

“source document”
« *document source* »

“source document” means the document entitled *Labelling Elements for Tobacco Products (Cigarettes and Little Cigars)*, published by the Department of Health, dated May 27, 2011.

“tobacco product”
« *produit du tabac* »

“tobacco product” means a cigarette or little cigar.

“top edge”
« *arête supérieure* »

“top edge” means

(a) in respect of a cylindrical package, the edge that is in the horizontal plane and that forms the upper limit of the side of the package, which side excludes the top of the package but includes the side of the lid when the side forms part of the side of the package;

(b) in respect of a package other than a cylindrical package, the edge that is in the horizontal plane and that forms the upper limit of the package when the package is used in the customary manner to gain access to the tobacco product; and

(c) in respect of an exterior surface of a slide, the edge that is in the horizontal plane and that forms the upper limit of that surface when the package is used in the customary manner to gain access to the tobacco product.

“toxic emissions statement”
« *énoncé sur les émissions toxiques* »

“toxic emissions statement” means the following statements, but does not include the attribution of those statements to their source as provided for in subsection 6(1):

(a) in respect of cigarettes, the statements set out in Part 2 of Division A of the source document; and

(b) in respect of little cigars, the statements set out in Part 2 of Division B of the source document.

“upper slide-flap”
« *rabat supérieur* »

“upper slide-flap” means, in respect of a slide and shell package, the extremity of the slide that can be folded and is concealed by the shell when the package is closed and that is visible when the package is used in the customary manner to gain access to the tobacco product.

APPLICATION

Retail sale

2. (1) These Regulations apply to packages of tobacco products that are intended for retail sale.

Overwraps

(2) These Regulations also apply to overwraps used as cartons that are intended for retail sale.

GENERAL PROVISIONS

Electronic files

3. A manufacturer must obtain from the Minister, in the form of electronic files, the labelling elements set out in the source document, including the attribution of the labelling elements to their source, and display them on packages or leaflets in accordance with these Regulations.

Printing

4. A labelling element and any attribution of its source that is displayed on a package or leaflet must be printed

(a) in colours that are as close as possible to the colours in which the labelling element and source attribution are set out in the source document; and

(b) with the greatest clarity possible taking into consideration the printing method used.

Legibility and official languages

5. Text contained in a labelling element must be legible and displayed in both official languages in the same manner.

Retention of attribution

6. (1) If a manufacturer chooses to display the attribution contained in the electronic files, they must display it in the same manner as it is presented in the source document or in accordance with section 10.

Removal of attribution

(2) If a manufacturer chooses to remove the attribution contained in the electronic files, they must only remove the phrases "Health Canada" and "Santé Canada".

Visibility

7. A labelling element, or a component of a labelling element, must not be concealed or obscured, except partially

(a) by an excise stamp in accordance with subsection 11(2); or

(b) by a tear tape required under provincial legislation.

Integrity

8. (1) The customary method of opening the package must not damage the labelling element or make it illegible.

Severed package

(2) If the customary method of opening the package severs the labelling element,

(a) the integrity of the labelling element must be restored when the package is closed; and

(b) two lines of text within the labelling element may be separated, but no letter, numeral or other character may be severed.

Non-application

(3) Subsection (1) does not apply to a package that is ordinarily torn or discarded after opening.

Permanence

9. A labelling element that is displayed on a package or a leaflet must be irremovable.

Adaptation

10. If a labelling element does not fit the portion of the display area that it must occupy or does not fit the dimensions of a leaflet that are determined in accordance with subsections 29 (1) and (2), the labelling element must be adapted in accordance with the following requirements:

(a) its components must, to the extent possible, maintain the scale of the components in the source document;

(b) the positions of the components must, to the extent possible, be maintained relative to each other;

(c) the text may only be displaced to meet the requirements of section 8 or subsection 11(2); and

(d) the number of lines of text may only be adapted to avoid distortion of a component.

Stamp

11. (1) A labelling element must not be applied on an excise stamp that is required under the *Stamping and Marking of Tobacco Products Regulations*.

Coverage

(2) A labelling element may be concealed only by an excise stamp but to the least extent possible and to a maximum surface area of 180 mm². In that case, the labelling element must be adapted in accordance with section 10 so that no component is concealed by the excise stamp.

HEALTH WARNINGS

Display areas

12. (1) Subject to subsection (2), health warnings must be displayed in respect of each type of package set out in column 1 of Schedule 1 on the display areas set out in column 2.

Other packages

(2) In respect of a type of package that is not set out in Schedule 1, health warnings must be displayed on the following display areas:

(a) in the case of a package that has at least two equal-sized sides, other than the top and bottom of the package, two of those sides that are opposite sides of the package and one of which is visible when the package is used in the customary manner to gain access to the tobacco product, including the sides of any lid if those sides are part of the sides of the package; and

(b) in the case of any other package, the largest side that is visible when the package is used in the customary manner to gain access to the tobacco product.

Portion of display area

13. (1) The portion of a display area of a package on which a health warning must be displayed is at least 75% of each display area referred to in section 12.

Determination of portion of display area

(2) The portion of a display area of a soft package is determined in accordance with subsection (3), the portion of a display area of a three-sided package is determined in accordance with subsection (4), the portion of a display area of a cylindrical package is determined in accordance with subsection (5) and the portion of a display area of all other types of packages is determined in accordance with subsections (6) and (7).

Soft packages

(3) In the case of a soft package, the portion of the display area runs along a line that is parallel to and not more than 12 mm below the top edge of the package and extends from the left edge to the right edge of the display area.

Three-sided packages

(4) In the case of a three-sided package, the portion of the display area runs along a line that is parallel to the top edge of the package and not more than 12 mm below the tear line and extends from the left edge to the right edge of the display area.

Cylindrical packages

(5) In the case of a cylindrical package, the portion of the display area runs along the line of separation between the lid and the side of the package, extends towards the bottom of the package and is bounded by the left and right limits of the display area.

Vertical

(6) If, in relation to the top edge of a package, the height to width ratio of the display area is greater than or equal to 0.5, then the portion of the display area runs along that top edge and extends from the left edge to the right edge of the display area.

Horizontal

(7) If, in relation to the top edge of a package, the height to width ratio of the display area is less than 0.5, then the portion of the display area runs along the left edge of the display area and extends from the bottom edge to the top edge of the package.

Space occupied and orientation of text

(8) A health warning must completely occupy the portion of the display area and must be oriented in such a manner that its text is readable from left to right when the package is used in the customary manner to gain access to the tobacco product.

Package — two display areas

14. (1) If a package has two display areas, the English version of a health warning set out in Set 1 of Part 1 of the source document must be displayed on one display area and the French version must be displayed on the other.

Package — one display area

(2) If a package has one display area, a health warning in English and French set out in Set 2 of Part 1 of the source document must be displayed on the display area.

Package — cartons

(3) In the case of a carton, the English version of a health warning set out in Set 1 of Part 1 of the source document must be displayed on one of the primary display areas set out in column 2 of item 10 of Schedule 1 and the French version must be displayed on the other. The English version of a different health warning set out in that Set 1 must be displayed on one of the two secondary display areas set out in the same column of the same item and the French version must be displayed on the other.

Proportional display

15. A manufacturer must, in respect of each type of package of each brand of tobacco product that they package in a year, display each health warning on between 3.25% and 9.25% of the packages of those products.

Formats

16. The format of a health warning set out in the source document that must be displayed on a package is the following:

- (a) if the height to width ratio of the portion of the display area is less than 0.5, the "Elongated Landscape" format;
- (b) if the height to width ratio of the portion of the display area is greater than or equal to 0.5 but less than or equal to 1.0, the "Landscape" format;
- (c) if the height to width ratio of the portion of the display area is greater than 1.0 but less than or equal to 2, the "Portrait" format; and
- (d) if the height to width ratio of the portion of the display area is greater than 2, the "Elongated Portrait" format.

TOXIC EMISSIONS STATEMENTS

Display areas

17. (1) Subject to subsection (2), a toxic emissions statement must be displayed in respect of each type of package set out in column 1 of Schedule 2 on the display areas set out in column 2.

Other packages

(2) In the case of a type of package that is not referred to in Schedule 2, a toxic emissions statement must be displayed on the display area that is the largest side of the package, other

than the side or sides on which a health warning is displayed.

Space occupied — small display area

18. (1) If the display area on which the toxic emissions statement is required to be displayed is less than 10 cm², the statement must completely occupy the display area.

Space occupied — large display area

(2) In any other case except for cartons, if the display area on which the toxic emissions statement is required to be displayed is equal to or greater than 10 cm², the statement must occupy the greater of 60% of the display area and 10 cm².

Surface area

(3) Except in the case of cartons, the portion of the display area on which the toxic emissions statement is required to be displayed does not have to exceed a surface area of 30 cm².

Cartons

(4) In the case of a carton, the portion of the display area on which the toxic emissions statement must be displayed is at least 50% of the display area.

Soft packages

(5) In the case of a soft package, the portion of the display area runs along a line that is parallel to and not more than 12 mm below the top edge of the package and extends from the left edge to the right edge of the display area.

Cylindrical packages

(6) In the case of a cylindrical package, the portion of the display area runs along the line of separation between the lid and the side of the package, extends towards the bottom of the package and is bounded by the left and right limits of the display area.

Space occupied

(7) For the purposes of subsections (2) to (6), the toxic emissions statement must completely occupy the portion of the display area.

Bilingual toxic emissions statement

19. A toxic emissions statement must be displayed in English and French in the display area or the portion of the display area, as the case may be.

Proportional display

20. A manufacturer must, in respect of each type of package of each brand of tobacco product that they package in a year, display each toxic emissions statement on between 22% and 28% of those products.

Formats

21. The format of a toxic emissions statement set out in the source document that must be displayed on a package is the following:

- (a) if the surface area of the display area or the portion of the display area, as the case

may be, is less than or equal to 10 cm², the "Landscape" format; and

(b) if the surface area of the display area or the portion of the display area, as the case may be, is greater than 10 cm², the "Elongated Landscape" format.

HEALTH INFORMATION MESSAGES

Display areas

22. (1) Subject to subsections (3) and (4), in the case of a slide and shell package, other than a slide and shell package with a lateral slide, a health information message must be displayed on either the two display areas of the package which are the upper slide-flap and the exterior surface of the slide or on a leaflet inserted in the package.

Orientation of health information message

(2) When the package is used in the customary manner to gain access to the tobacco product, the health information message on the upper slide-flap and on the exterior surface of the slide must be oriented in the same direction as the health warning displayed on the package.

Exception — surface area

(3) If the surface area of the exterior surface of the slide is less than 55 cm², a health information message must be displayed on a leaflet inserted in the package.

Exception — height to width ratio

(4) If, in relation to the top edge of the exterior surface of the slide, the height to width ratio of the exterior surface of the slide is greater than one, a health information message must be displayed on a leaflet inserted in the package.

Leaflet

23. Subject to section 22, a health information message must be displayed on a leaflet inserted in the package except in the case of cylindrical packages, soft packages, two-sided packages, three-sided packages and cartons other than cartons containing soft packages. In the case of cartons containing soft packages the health information message must be displayed on a leaflet inserted in the carton.

Space occupied

24. A health information message must completely occupy the two display areas of a slide and shell package or the two sides of a leaflet.

Health information message — slide and shell package

25. (1) The health information message required to be displayed on a slide and shell package must be one of those set out in section A of Part 3 of the source document.

Health information message — leaflet

(2) The health information message required to be displayed on a leaflet must be one of those set out in section B of Part 3 of the source document.

Proportional display

26. A manufacturer must, in respect of each type of package of each brand of tobacco product that they package in a year, display each health information message on between 9.5%

and 15.5% of the packages or leaflets, as the case may be.

Formats

27. The format of a health information message set out in the source document that must be displayed on a slide and shell package is the following:

- (a) if the height to width ratio of the exterior surface of the slide is less than 0.5, the "Elongated Landscape" format;
- (b) if the height to width ratio of the exterior surface of the slide is greater than or equal to 0.5 but less than 1.0, the "Landscape" format; and
- (c) if the height to width ratio of the exterior surface of the slide is greater than or equal to 1.0, the "Portrait" format.

Bilingual health information messages — slide and shell package

28. A health information message must be displayed in English and French in the display areas of a slide and shell package.

Size of leaflet

29. (1) A leaflet on which a health information message is displayed must be the largest possible size that the dimensions of the package will allow without the leaflet being folded, and must be at least 65 mm high and 43 mm wide. If the dimensions of a package will not allow the insertion of a leaflet that is at least 65 mm high and 43 mm wide, the leaflet may be folded once lengthwise to allow it to be inserted in the package and, if necessary, folded a second time.

Surface area

(2) A leaflet does not have to exceed a surface area of 224 cm² as calculated on the basis of the height and width of one side of the leaflet.

Visibility and readability

(3) A leaflet must be readily visible when the package is used in the customary manner to gain access to the tobacco product, be easily removable and be placed in the package in a manner that makes the text of the message, or some portion of the text, readable without further manipulation.

Formats

30. The format of a health information message that must be displayed on a leaflet is the following:

- (a) if the height to width ratio of the leaflet is less than or equal to 2, the "Portrait" format; and
- (b) if the height to width ratio of the leaflet is greater than 2, the "Elongated Portrait" format.

Bilingual health information messages — leaflets

31. The English version of a health information message must be displayed on one side of the leaflet and the French version on the other.

TRANSITIONAL PROVISIONS

32. (1) In this section, “former Regulations” means the *Tobacco Products Information Regulations* as they read immediately before the day on which these Regulations come into force.

(2) Despite these Regulations, if a package of a tobacco product or any accompanying leaflet displays information in accordance with the former Regulations and the product is sold or distributed by a manufacturer, the former Regulations continue to apply to the package or the leaflet during the period of 180 days after the coming into force of these Regulations.

(3) Despite these Regulations, if a package of a tobacco product or any accompanying leaflet displays information in accordance with the former Regulations and the product is sold by a re-tailer, the former Regulations continue to apply to the package or the leaflet during the period of 270 days after the coming into force of these Regulations.

COMING INTO FORCE

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

SCHEDULE 1 (Section 12 and subsection 14(3))

DISPLAY AREAS FOR HEALTH WARNINGS

	Column 1	Column 2
Item	TYPE OF PACKAGE	DISPLAY AREAS
1.	Slide and shell package	The two largest sides of the package
2.	Slide and shell package with a lateral slide	The two largest sides of the package
3.	Flip-top package	The two largest sides of the package
4.	Soft package	The two largest sides of the package
5.	Flip-top package with bevelled sides	The two largest sides of the package, including the two contiguous bevelled sides
6.	Two-sided package	One of the two sides of the package
7.	Three-sided package	The two largest sides excluding the bottom
8.	Box that is not a carton	If the two largest sides, excluding the top and bottom of the package, have a total surface area greater than the surface area of the top, the two largest sides If the two largest sides, excluding the top and bottom of the package, have a total surface area less than or equal to the surface area of the top, the top
9.	Cylindrical package	Excluding the top and bottom of the cylindrical package, any two areas each of which occupy 40% of the side and which extend from the top edge of the package to the bottom edge and which form rectangles when projected onto a flat plane
10.	Carton	The two largest sides of the package are the two primary display areas and the next two largest remaining sides are the two secondary display areas

SCHEDULE 2
(Section 17)

DISPLAY AREA FOR TOXIC EMISSIONS STATEMENTS

Item	Column 1 TYPE OF PACKAGE	Column 2 DISPLAY AREA
1.	Slide and shell package	A side, other than that on which a health warning is displayed, excluding the top and bottom of the package
2.	Slide and shell package with a lateral slide	A side, other than that on which a health warning is displayed, excluding the top and bottom of the package
3.	Soft package	A side, other than that on which a health warning is displayed, excluding the top and bottom of the package
4.	Flip-top package	A side, other than that on which a health warning is displayed, excluding the top and bottom of the package and the portion of that side that is part of the flip-top
5.	Flip-top package with bevelled sides	A side, other than that on which a health warning is displayed, excluding the top and bottom of the package and the portion of that side that is part of the flip-top
6.	Two-sided package	The side on which no health warning is displayed
7.	Three-sided package	The side on which no health warning is displayed
8.	Box that is not a carton	If the health warnings are displayed on sides other than the top of the package, one of the largest remaining sides, excluding the bottom
9.	Cylindrical package	If the health warning is displayed on the top of the package, one of the largest remaining sides, excluding the bottom Excluding the top and bottom of the package and the display areas on which a health warning is displayed, any area that occupies at least 10% of the side and which extends from the top edge of the package to the bottom edge and which forms a rectangle when projected onto a flat plane
10.	Carton	The remaining sides, other than the sides on which the health warnings are displayed

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Executive summary

Issue: Tobacco use is the leading preventable cause of illness and premature death in Canada. The provision of health-related information on tobacco products is recognized as one of the best approaches to inform users of the health risks of tobacco use. Research has shown that the health-related labelling required by the *Tobacco Products Information Regulations* (TPIR) has reached its maximum potential. The *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)* [TPLR-CLC] build on the achievements of the TPIR and embark on a new chapter in health-related tobacco labelling.

Description: The TPLR-CLC replace the labelling requirements for cigarettes and little cigars currently enshrined in the TPIR with new messages that are more memorable, noticeable, and engaging. The TPLR-CLC require the display of 16 health

warnings, 8 health information messages, and 4 toxic emissions statements. The TPLR-CLC also include a pan-Canadian toll-free quitline number and cessation Web portal to be displayed on all health warnings and on some health information messages and enhanced regulatory requirements to maximize visibility and legibility on all types and sizes of packages, including an increase in the size of the health warnings from 50% to 75% of the front and back of cigarette and little cigar packages.

Cost-benefit statement: The cost-benefit analysis estimated that the costs of the TPLR-CLC would range from \$74.1 million to \$83.3 million over a 10-year period; Government costs would be approximately \$11.7 million over a 10-year period, and industry costs would range from \$62.4 million to \$71.7 million, of which cigarette and little cigar manufacturers and importers would bear \$49.6 million to \$53.4 million, over this period.

The analysis estimated the benefits of the TPLR-CLC would range from \$3.9 billion to \$12 billion over a 10-year period. These benefits would accrue from the reduced morbidity and mortality effects on former smokers who successfully quit. Other potential beneficial impacts include reduced exposure to second-hand smoke, reduced loss of life and damage from cigarette-induced fires, and improved quality of life of former smokers. The analysis does not quantify these ancillary benefits. The estimated benefits of the TPLR-CLC are to exceed the estimated costs by a factor of 47 or more.

Business and consumer impacts: The TPLR-CLC are not expected to increase the administrative burden on industry, since they are a renewal of current Government of Canada regulations. The TPLR-CLC apply to all manufacturers, importers, and retailers of cigarettes and little cigars in Canada, and therefore are not expected to impact competition. Impacts on consumers are expected to be minimal. The analysis of costs and benefits estimates that the increased cost to consumers would be approximately \$0.05 per carton for cigarettes and possibly up to \$0.10 per carton for little cigars.

Domestic and international coordination and cooperation: The Department of Health has worked closely with the Canada Revenue Agency to coordinate regulations that affect the tobacco industry. To the extent possible, the departments are coordinating the implementation of the TPLR-CLC and the new *Regulations Amending the Stamping and Marking of Tobacco Products Regulations (2011)* in order to minimize the impacts on industry. The Department of Health is also coordinating the implementation of the TPLR-CLC with amendments to the TPIR, which remove the applicability of the TPIR to cigarettes and little cigars. This coordination should minimize business disruptions and compliance costs, as well as ensure the consistent application of health-related labels to all tobacco products. The TPLR-CLC are not expected to result in significant impacts on trade; the requirements are a renewal of current regulations, and many international trading partners have similar regulatory requirements for tobacco products.

Issue

Tobacco use is the leading preventable cause of illness and premature death in Canada. It is a known or probable cause of more than 30 debilitating and often fatal diseases of the lungs, heart, and other organs, and is responsible for more than 37 000 premature deaths each year. It is estimated that the attributable health care costs of tobacco use in Canada are more than \$4 billion a year; in a 2006 study, the Canadian Centre on Substance Abuse estimated that the societal costs of tobacco reached \$17 billion in 2002.

The Federal Tobacco Control Strategy (FTCS) is intended to reduce tobacco-related death and disease among Canadians. Built on the tenets of prevention, protection, cessation, and product regulation, the FTCS represents the most ambitious effort Canada has ever undertaken to fight the tobacco epidemic. Tobacco product labelling is a key part of the FTCS; available research indicates that the display of health-related messages and information on packages directly

influences tobacco users in their decision not to smoke.

Current labelling requirements, set out in the *Tobacco Products Information Regulations* (TPIR), require the display of health-related messages and information on tobacco product packaging in three ways: a health warning located on a display area of tobacco product packages; a health information message, required on some smoked tobacco product packages, located on an inside panel or as a leaflet; and toxic emissions information displayed on the side of tobacco product packages.

Research has shown that the health-related labels on tobacco products currently mandated through the TPIR, which have been in place since 2000, have reached their maximum potential. Research has also shown that the health-related labels, although effective overall, are not as effective at reaching people with low literacy skills, older smokers, and hard-core smokers. As well, the health information messages are not sufficiently noticed or read by smokers and, in the current format, the toxic emissions information is generally not well understood or recalled. Research, including public opinion research, has also shown that there are a number of ways in which the current labels could be improved to make them a more effective vehicle to communicate with tobacco users, including increasing the size of warnings and improved use of graphics and colour.

As a Party to the World Health Organization's *Framework Convention on Tobacco Control* (FCTC), Canada has the obligation to implement the requirements for displaying health-related information on tobacco products set out in Article 11. While most of Canada's tobacco legislation meets or exceeds these requirements, Canada is not yet fully compliant; health warnings applicable to cigars, including little cigars, do not all meet the minimum 30% of the principal display area. With the coming into force of the *Cracking Down on Tobacco Marketing Aimed at Youth Act* in October 2009, which included the requirement to package little cigars in packs of at least 20, it is particularly important to ensure new packages carry appropriate health-related labels.

Objectives

The *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)* [TPLR-CLC] are an integral part of the FTCS. The main goal of the FTCS, which was implemented in April 2001, is to reduce tobacco-related death and disease among Canadians.

The objectives of the FTCS are to

- Reduce overall smoking prevalence from 19% in 2006 to 12%;
- Reduce the prevalence of Canadian youth aged 15–17 who smoke from 15% to 9%;
- Increase the number of adult Canadians who quit smoking by 1.5 million;
- Reduce the prevalence of Canadians exposed daily to second-hand smoke from 28% to 20%;
- Examine the next generation of tobacco control policy in Canada;
- Contribute to the global implementation of the FCTC; and
- Monitor and assess contraband tobacco activities and enhance compliance.

The TPLR-CLC build on the achievements of the current labelling system while aiming to improve its overall effectiveness among different audiences and bring Canada in line with other countries whose regulatory requirements are more stringent. Through the balanced use of information on the health risks of smoking and the health benefits of quitting, the TPLR-CLC continue efforts to inform Canadians about the health hazards and health effects of using tobacco, and raise awareness of available cessation resources.

The TPLR-CLC support the FTCS through four main objectives:

- To better inform Canadians, especially tobacco users and potential users, about the health risks of tobacco use and the health benefits of quitting;
- To inform tobacco users about the availability of cessation services through the display on the health warnings of a pan-Canadian toll-free quitline number and cessation Web portal;

- To support provincial and territorial partners in their efforts to provide cessation services; and
- To bring Canada into greater compliance with the FCTC.

Description

The TPLR-CLC replace the existing requirements in the TPIR that apply to cigarettes and little cigars, and require new health-related labels to be displayed on all cigarette and little cigar packages that are intended for retail sale. Cigarettes and little cigars account for approximately 95% of the tobacco market in Canada. As in the TPIR, the TPLR-CLC use a combination of health warnings, health information messages, and toxic emissions statements to inform users. The TPLR-CLC also include enhanced regulatory requirements that distinguish it from the TPIR.

Health warnings use a combination of an image and explanatory text to inform users of the health risks associated with tobacco use. The TPLR-CLC replace the current 16 health warnings in the TPIR with 16 new, high impact warnings that are more noticeable, memorable, and engaging. In order to make them more compelling, the revised health warnings include a number of new themes, including illnesses not included in the current messages, and compelling true stories from former tobacco users whose health has been impacted by tobacco use. The messages are required to be displayed on 75% of the front and back of cigarette and little cigar packages.

While many countries have adopted pictorial health warnings since their introduction in 2000, Canada remains the only country that also requires the display of health information messages, presenting a unique venue to provide tobacco users with additional information about tobacco use and its effects on their health. The TPLR-CLC replace the current 16 textual health information messages with 8 new pictorial health information messages. Health information messages continue to be displayed on the upper slide flap and the back of the slide of slide-and-shell type packages, or on a leaflet inserted into other types of packages. The TPLR-CLC specify a minimum size for leaflets displaying health information messages.

Changes to the design of the health information messages make them more engaging and encourage users to read the information. The “teasers,” the information displayed on the upper slide flap or at the top of the leaflet, draw attention to the inside of the package or the leaflets through the use of colour and images. The health information messages focus on positive cessation messages, including a motivational true story from a former tobacco user and tips about quitting and complement the health warnings, which focus on the negative consequences of smoking. Research indicates that combining positive and negative elements is important in motivating behaviour change.

In developing the health warnings and the health information messages, emphasis was placed on how to maximize their effectiveness to communicate with tobacco users. While shocking or graphic messages were effective with some smokers, findings from public opinion research studies showed that a variety of approaches are needed to maximize the potential to reach different segments of the target audience. The importance of a balanced approach is further supported by the fact that personal relevance was consistently found to be a key determinant of effectiveness. To achieve this balanced approach, the health warnings and the health information messages include

- Messages that are intended to appeal to tobacco users of different ages, genders, socio-economic levels and literacy levels;
- A diversity of images, including photos of real people impacted by smoking, photos of organs, and other images intended to grab the attention of the user;
- A diversity of fresh approaches to communicating a message, such as short headings, catchy phrases, and causal statements; and
- A more inclusive list of the health impacts of tobacco, including bladder cancer, diseases of the eyes, pre- and post-natal effects, and mouth and throat cancers.

A key new feature of the TPLR-CLC requires the display of a pan-Canadian toll-free quitline number and cessation Web portal on all of the health warnings and on some of the health information messages. Callers to the pan-Canadian toll-free quitline number will be seamlessly

redirected to existing cessation services provided by the provinces and territories. These services provide one-on-one counselling, self-help materials, referrals to community services, and online cessation support. By placing the toll-free phone number and cessation Web portal on tobacco packages, users will be reminded of the existence of cessation services every time they look at the pack, and the information will be readily available when they are thinking about quitting.

Research has shown that the current format of the toxic emissions information, which displays a range of values for six toxic substances, is not clearly understood by some smokers and that most have little idea what the range of numbers displayed for each chemical means. The TPLR-CLC replace the numerical values currently displayed with four text-based statements that provide clear, concise and easy-to-understand information about the toxic substances found in tobacco smoke. They use plain language in order to be more accessible to a wider audience. The toxic emissions statements are displayed on the side of cigarette and little cigar packages.

Finally, the TPLR-CLC include an enhanced regulatory framework to maximize the visibility and legibility of the health-related labels on all types of cigarettes and little cigar packaging. This includes the provision of a source document, titled *Labelling Elements for Tobacco Products (Cigarettes and Little Cigars)*, which defines the shape and orientation of health warnings based on package shape and dimensions. As in the TPIR, the source document illustrates the standard expected for the display of messages on packages. The source document has been incorporated into the TPLR-CLC by reference, and is available from the Department of Health in electronic and print versions. A sample of the new health-related messages can be viewed on the Health Canada Web site at www.hc-sc.gc.ca.

Revisions to the TPLR-CLC following prepublication

Several changes have been made to the regulatory text following prepublication in response to comments received as well as to suggestions made after review of the proposed Regulations by the Department of Health. Of more significance were the following:

- Section 1 — Section 1 provides definitions for terms used elsewhere in the Regulations. The prepublished definition of “box” has been revised by deleting the term “rigid” in reference to the sides and to change the words “rectangular shape” to “rectangular sides.” The term “rigid” was considered unnecessary and the term “rectangular shape” was considered to be appropriate for a two-dimensional shape but not for a three-dimensional object.
- Section 7 — Section 7 requires that no labelling element or component of a labelling element be concealed or obscured. In the prepublication, a partial exemption is provided in subsection 11(2) for the federal excise stamp. However, provincial tax tear tapes, when required, would slightly conceal or obscure the health warnings. An exemption has been added for the provincial tax tear tapes to prevent any conflict between requirements in section 7 and provincial tax requirements.
- Section 10 — Section 10 provides the rules manufacturers must follow if it is necessary to adapt a labelling element to fit the portion of the display area it must occupy. Paragraph 10(b) in the prepublication requires that the positions of the components of a labelling element, such as the image and text, be maintained relative to each other. Instances have been identified where strict adherence to this requirement would be difficult. The phrase “to the extent possible” has been added to provide a margin of flexibility.
- Section 11 — Section 11 concerns the interaction between the federal excise stamp required by the Canada Revenue Agency and the labelling requirements. Subsection 11(2) in the prepublication allows the encroachment of a maximum of 120 mm² by the excise stamp into a labelling element. The tobacco industry has provided documentation that indicates that 120 mm² would be insufficient to accommodate excise stamp encroachment on certain types of packages. The maximum encroachment has been increased to 180 mm².
- Section 13 — Subsection 13(1) provides that a health warning must occupy exactly 75% of the display area. This language is too precise and inflexible and not consistent with a similar section for toxic emissions statements. The wording has been changed to “must be at least 75% of the display area.”
- Section 13 — Section 13 also provides special instructions for the location of the health

warnings for soft packs because the way they are opened makes the top of the display area unusable for the health warnings. A similar provision is needed for three-sided bags, which have a tear strip near the top of the package, also making the top of the display area unusable for the health warnings. A subsection for three-sided bags with wording similar to that used for soft packs has been added.

- Section 16 — Section 16 provides instructions on how to choose the most appropriate format for the health warning to be displayed on a package. The order of the formats has been changed so as to progress from the smallest height-to-width ratio to the largest.
- Section 23 — Section 23 describes the type of packages into which a health information message in the form of a leaflet must be inserted. A reference to section 22 (display areas for slide and shell packages) has been added for clarity.
- Section 26 — Section 26 sets out the requirements for the proportional display for the health information messages. The range as it appeared in the prepublication was incorrect. The range of values has been changed from “on between 9% to 15% of the packages or leaflets” to “on between 9.5% to 15.5% of the packages or leaflets.”
- Section 27 — Section 27 describes the formats required for the health information messages on slide and shell packages according to the height-to-width ratios of the slide. The introduction of a new slide and shell package, which has dimensions more associated with a flip-top package, requires an additional format to minimize adaptation. A “portrait” format has been added in addition to the current “landscape” and “elongated landscape” formats. In addition, the order of the formats has been changed so as to progress from the smallest height-to-width ratio to the largest.
- Section 29 — Section 29 describes the requirements for the size of leaflets and had, in the prepublication, a provision that allows a leaflet to be folded once for insertion into narrow packages. The Department of Health was made aware that a single fold would be insufficient to allow the leaflet to be inserted into certain narrow packages. Subsection 29 (1) has been revised to permit a leaflet to be folded lengthwise the minimum number of times to allow it to fit into the package, to a maximum of two folds.
- Section 32 — Section 32 describes the transitional provisions that allow the sale of packages with labelling in accordance with the current *Tobacco Products Information Regulations*. Manufacturers have 180 days after the new labelling regulations are in force to comply with the new labelling requirements while retailers have an additional 90 days. In the prepublication, fixed calendar dates for the end of the transitional periods were provided. This could result in shorter transitional periods if the Regulations come into force later than anticipated. The wording of the transitional period has been changed so that the dates are in terms of the number of days from the date that the TPLR-CLC come into force rather than fixed dates.
- Schedule 2 — Schedule 2 describes the display area for the toxic emissions statements. In the prepublication, it was proposed for cartons that a toxic emissions statement would appear on one of the sides not occupied by a health warning and would occupy 50% of that side. The current *Tobacco Products Information Regulations* require toxic emissions statements to appear on both remaining sides, when the option to use a toxic emissions statement is chosen. There had been some concern with respect to the new TPLR-CLC that there would be problems complying with the provincial tax stamp on cartons if both remaining sides were used. Further research demonstrated that there are no issues. Therefore, Schedule 2 was revised so that the toxic emissions statements are required on both sides of a carton.
- Source document — There have been some minor changes to the health-related messages since originally proposed. Some messages were redesigned in an effort to improve readability. Also, some minor word changes were made to some of the messages based on review by scientific experts. An image was replaced in one of the health warnings to better reflect Canada’s ethnic diversity. The Department of Health also added a health information message (“Thinking of having a baby?”) on quitting prior to pregnancy. This replaces a message (“Here are some tips to help you fight your cravings”) that did not pass the scientific review process and adds important information about the effects of smoking during pregnancy.

Regulatory and non-regulatory options considered

Option 1: Status quo

This option considered retaining the existing TPIR and the health-related messages currently

displayed on all tobacco products. This option was rejected for several reasons. Since research has shown that the current labels have reached their maximum potential and are no longer as effective as they were when they were implemented, this option would be unlikely to continue to inform tobacco users, and therefore would not yield incremental health benefits. Furthermore, this option would not meet the objectives of this proposal to introduce a pan-Canadian toll-free quitline number and cessation Web portal, nor would it allow for inclusion of specific messages for little cigar packages.

Option 2: Public education and social marketing campaign

This option considered informing users of the health hazards of tobacco use through a public education and social marketing campaign rather than by requiring the display of health-related information on tobacco packaging. This option was seen to be overlooking the potential of tobacco packaging to reach users. Research has shown that tobacco users are exposed to labels on packaging several times a day, a reach that even the most successful of media campaigns, on its own, could likely not equal. While this option was not considered to be as effective as the TPLR-CLC, it should be noted that a public education and social marketing campaign could be used to complement it.

Option 3: Amend the current TPIR to renew the labels

This option considered amending the current TPIR to renew the source document and introduce new health-related messages. This option was rejected because the TPIR was not considered to have the flexibility to deal with an evolution in tobacco packaging. In recent years a number of new types of tobacco packages have been introduced, some of which are significantly smaller than traditional slide-and-shell and flip-top type packages. In some cases, these smaller display surfaces have diluted the effectiveness of the health-related labels. While the existing TPIR could have been amended to require the features that are included in the TPLR-CLC, the amendments would have been extensive and could have led to confusion about which requirements applied to which tobacco products.

Option 4: Develop a new regulation — Selected option

This option considered developing new regulations to replace the labelling requirements in the TPIR for cigarette and little cigar packages and to display new health warnings, health information messages, and toxic emissions statements. This option was retained, as it was seen to be the most flexible option for including all of the new requirements. It allows for the integration of the pan-Canadian quitline number and cessation Web portal into the design of new messages; it allows for new regulatory requirements to be included in the regulation, including requirements for visibility and legibility; and it allowed the Department of Health to proceed with renewing the requirements for cigarettes and little cigars, which, as noted, represent 95% of the tobacco market, while still maintaining the TPIR for all other tobacco products and ensuring regulatory consistency.

Benefits and costs

A cost-benefit analysis was carried out by Industrial Economics (IEc) on behalf of the Department of Health to attempt to quantify the anticipated costs and benefits of the TPLR-CLC. This section will provide a brief summary of the analysis. The full cost-benefit analysis is available on demand.

While the scope of the scenario presented to industry that provided the basis for the analysis is broader than the scope of the TPLR-CLC, the analysis obtained from the cost-benefit analysis will be provided here. Justification for using a cost analysis based on a broader scenario is included in the Rationale section.

Benefits

In light of the inherent challenges of determining the potential impacts of the TPLR-CLC, the cost-benefit analysis notes that the estimate developed is conservative. The analysis relied on studies of how consumers process warning information and on observed trends in the way

Canadian smokers pay attention to and think about the warnings displayed under the TPIR. The resulting estimate of impacts is expressed as the number of tobacco users who would quit using tobacco each year as a result of the TPLR-CLC, which would be incremental to reductions in tobacco use that could be anticipated absent a change in labelling requirements.

Based on reported effectiveness of the health-related labels mandated under the TPIR, and the results of public opinion research, the analysis concluded that the effectiveness of the current labels peaked during the three years following their introduction, and levelled off in the following four years. As the analysis notes, a major objective of the TPLR-CLC is to inform Canadians by introducing new labels, and including such new features as increased size, design and colour changes, and the inclusion of cessation services information. A review of existing literature revealed that each of these features enhances labelling effectiveness.

The analysis used a four-step approach to quantify the potential impacts of the TPLR-CLC. Details of the steps can be found in the complete cost-benefit analysis document referred to at the end of the Benefits and costs section. The analysis concluded that the TPLR-CLC could increase the number of individuals who successfully quit smoking by 1 800 to 5 500 per year, or 13 380 to 40 740 over a 10-year period, assuming a baseline of 4.88 million smokers. Included in this estimate are the estimated impacts of the pan-Canadian quitline number and Web cessation portal. The analysis estimated that display of cessation information on health-related labels would result in a 40% increase in call volumes to cessation services. Assuming current call volumes of 80 000 individual calls per year, this increase represents an additional 32 000 calls annually, which could translate into an increase of up to 2 300 individuals who quit smoking over a 10-year period.

Benefits of reduced tobacco-related mortality

The greatest benefit of the TPLR-CLC will likely derive from reductions in the risk of premature death due to smoking. To estimate these benefits, the analysis used research on the value of preventing someone aged 24 from smoking, and valued the reductions in mortality risks associated with quitting smoking using an estimate of the value of a statistical life. Using this methodology, the analysis estimated the reduction in the risk of premature mortality gained by the average former smoker had a present value of \$413,000. The value of these benefits calculated over a 10-year period ranged from a high of \$0.7 billion to \$2.2 billion in the year following implementation, to a low of \$0.4 billion to \$1.2 billion at the end of the period. At an annual discount rate of 8%, the present value of these benefits ranges from \$3.8 billion to \$11.7 billion.

Benefits of reduced tobacco-related morbidity

An additional benefit of the TPLR-CLC is the likely reduction in illnesses attributable to smoking. In the absence of specific research, the analysis relied on a cost-of-illness approach to characterise these benefits. Cost-of-illness studies estimate the financial burden of an illness based on the actual direct and in-direct costs. For a number of reasons, including the fact that they do not capture willingness to pay to avoid pain and suffering, cost-of-illness studies are generally assumed to understate the benefits of health improvements; this analysis, therefore, is likely a conservative estimate of the benefits of reduced tobacco-related morbidity.

The analysis valued the benefits of reduced tobacco-related morbidity from a high of \$15 million to \$45 million in the year immediately following the implementation of the TPLR-CLC, to a low of \$8 million to \$25 million at the end of the analysis period. At an annual discount rate of 8%, the present value of these anticipated benefits would be \$80 million to \$240 million over a 10-year period.

Other beneficial impacts

In addition to these quantified benefits, there are a number of possible additional benefits that may accrue from the TPLR-CLC. Changes in tobacco use resulting from the TPLR-CLC may result in benefits for non-smokers, including fewer people being exposed to second-hand smoke. Reductions in smoking may also reduce the numbers of smoking-related fires and the associated risk of property damage, injury, and death. The health improvements associated with

reduced tobacco use may also result in an overall reduction in demand on the health care system. Finally, those who successfully quit smoking may enjoy an improved quality of life. These ancillary benefits have not been quantified and are not included in the monetary estimates.

Total benefits

The analysis estimated that the annual value of the incremental benefits of the TPLR-CLC ranged from a high of \$0.7 billion to \$2.2 billion in the year immediately following implementation, and a low of \$0.4 billion to \$1.2 billion at the end of the period. The analysis estimated that the overall present value of the benefits ranges from \$3.9 billion to \$12 billion over 10 years.

Distribution of benefits

Based on the distributional data reported in the Canadian Tobacco Use Monitoring Survey (CTUMS), the analysis assumed the following distribution of health benefits among Canadians:

- The age of smokers who successfully quit would mirror the distribution, by age, of Canadians who quit smoking within five years, as reported in 2008;
- Measures designed to encourage smoking cessation may offer disproportionately higher benefits to the unemployed and those with limited formal education; and
- In general, the distribution of benefits by province would be likely to mirror the distribution of smokers nationwide.

Costs

Costs to industry

The primary source of information for the cost analysis was a survey carried out for the Department of Health by PricewaterhouseCoopers LLP (PWC). In preparation for proposed changes to the TPIR, PWC surveyed tobacco products manufacturers and importers to collect data on several topics, including general information on product lines and sales, incremental costs on anticipated expenditures necessitated by the regulatory proposal, and inventory obsolescence costs. The survey requested information for two major groups of products: cigarettes, cigarette tobacco, leaf tobacco, tobacco sticks, kreteks, and little cigars; and cigars, pipe tobacco, water pipe tobacco, bidis, blunts, and smokeless tobacco products. For the purposes of the TPLR-CLC, only those costs relating to cigarettes and little cigars have been considered. The Department of Health provided the responses of tobacco products manufacturers to IEc as the foundation for the cost analysis. Only a few manufacturers responded, accounting for an important share of tobacco products sales in Canada. The base year of the analysis was 2007.

The industry survey presented two options, but respondents only provided information for option one. The scenario proposed 3 rotations of 36 months each, with a 6-month transition period between each rotation. Each rotation consisted of 16 health warnings, 6 health information messages, and 2 toxic emissions statements. All messages were to be displayed equally across each brand and package type. The responses to the survey indicated that many of the costs would be incurred in three-year cycles, consistent with the rotation period.

The cost analysis comprised five basic steps: adjusting future expenses to the current year; annualizing costs, based on a 10-year useful life for capital costs, into an equivalent annual cost to facilitate comparison to benefits and other annual measures; standardizing compliance costs per unit; scaling up the costs of the two respondents to the overall tobacco products sector; and extrapolating minor tobacco products not addressed in the responses.

The analysis indicates that the incremental costs to the tobacco industry of complying with the TPLR-CLC equates to an annualized expenditure of \$9.3 million to \$10.7 million over a 10-year period. The analysis notes that approximately \$7.4 to \$7.9 million of these annual costs would be accrued by cigarette manufacturers. This includes the costs of purchasing or modifying capital equipment, changes in operational costs, and the value of lost inventory due to

obsolescence. Assuming the TPLR-CLC would remain in effect for 10 years, roughly equivalent to the period of time that the TPIR have been in force, the present value of the industry compliance costs is \$62.4 million to \$71.7 million, with an 8% rate of discount. The present value of the costs cigarette and little cigar manufacturers and importers would incur over this period is \$49.6 to \$53.4 million. Analysis of unit costs suggests that the direct cost of complying with the TPLR-CLC would impose a limited economic burden. Based on sales in the base year, the analysis estimated a marginal unit cost increase of \$0.00025 to \$0.00027 per cigarette produced, or about \$0.05 per carton of 200 cigarettes. This translates to an increase in production costs of approximately 1% and a corresponding increase of less than 1/10 of 1% in the price of a carton of cigarettes at retail.

Prior to the introduction of the *Cracking Down on Marketing Aimed at Youth Act*, production, importation and disposition data on little cigars were reported to the Department of Health under the broader category of cigars; therefore, it was difficult to extrapolate information on this specific product group. Though the cost survey attempted to identify the compliance costs associated with the TPLR-CLC for these products, none of the completed surveys returned any data on little cigars. Given the similarities between the packaging and labelling of cigarettes and little cigar products currently on the market, the unit incremental costs of the labelling of the little cigars were calculated by assuming the costs would range from equal to double the amount estimated for cigarettes, the upper limit being reflective of the much lower production and sales volumes of little cigars.

Based on this assumption, Canadian little cigars manufacturers and importers would bear only a fraction of the total annual cost of the TPLR-CLC. Assuming sales of 403 million units in the base year, the incremental costs of compliance with the TPLR-CLC ranged from \$102,434 to \$217,172 per year. The present value of costs, over 10 years, at an 8% discount rate was \$687,338 to \$1.46 million. Unit cost of production was estimated to be twice the cigarette unit costs to account for differences in economies of scale. Lack of cost data limited further analysis on the effect of this unit cost increase on overall production costs and on retail level prices.

The estimates of industry compliance costs are based on survey responses provided by industry, with little adjustment or interpretation. Despite the fact that the estimates are derived from the responses of only a few manufacturers, the annualized unit costs were remarkably similar. This consistency increases the confidence in compliance costs for cigarettes, the major product driving overall costs.

However, the analysis identified some level of uncertainty within the cost estimates. The specific details of the TPLR-CLC are not identical to the scenario presented in the cost survey to industry. The total number of messages has been reduced, as has the number of rotations. This change suggests that the cost estimates may be overstated, although the magnitude is difficult to characterize. The cost-benefit suggests that some linear costs may be overstated by as much as 50%. The development of annualized costs assumed 10 years as the useful life of printing equipment. Given the nature of the rotations proposed in the cost survey to industry, resulting in the use of some equipment on a three-year cycle, the analysis may have understated the life of such equipment and, therefore, overstated the costs. This concern is offset to some extent by the expectation that the Department of Health may continue to revise regulatory requirements and, given the length of time the TPIR has been in force, the 10-year period may be appropriate. Finally, the analytic approach makes the simplifying assumption that all manufacturers would incur the costs associated with the TPLR-CLC, rather than institute business changes to reduce compliance costs.

Whereas most little cigar products currently on the Canadian market are imported pre-packaged, the majority of cigarettes are packaged or labelled domestically. The printing and engraving industry, which provides services to the tobacco industry, is very concentrated with only a handful of firms supplying services. Interviews with selected printers and engravers indicated that they are unlikely to absorb any significant costs due to the TPLR-CLC. Since printers and engravers supply these services to the cigarette manufacturers on a contract basis, the costs associated with the TPLR-CLC would be passed on to cigarette manufacturers. Respondents indicated, however, that business disruptions would be directly proportional to the transition time allowed for the TPLR-CLC to come into effect. A short lead time would be more disruptive to operational plans than a longer one. However, given the experience gained from the introduction of the TPIR, firms can be expected to be better prepared to handle operational

pressures. Overall, the TPLR-CLC are not expected to result in any negative financial impacts.

Costs to Government

Two anticipated incremental costs of the TPLR-CLC will be borne by Government: the costs of compliance monitoring and the costs associated with the increase in quitline calls and web counselling volumes. Compliance monitoring of the TPIR is already being carried out by departmental inspectors, and baseline expenditures, including personnel and other activities related to compliance monitoring, are not expected to change. The introduction of new requirements would require updated training for enforcement personnel; the estimated overall cost of this training is \$50,000. The analysis had originally included a budget for increased enforcement staff of \$870,000 per year for each of the first three years after implementation; it has since been determined that existing staffing resources will be adequate to monitor compliance with the TPLR-CLC, and the budgeted amount should be removed from the estimated cost to Government.

The Government has also committed to providing financial resources to the provinces and territories that will provide the cessation services linked to the toll-free pan-Canadian quitline number. The expected increase in call volume is likely to increase the number of counsellors required to handle calls, as well as administrative and management costs, and infrastructure costs. The analysis estimated that the Department of Health would provide funding of up to \$12 million to meet the additional demand for quitline services; the annual distribution of these funds were estimated to be \$3.5 million in years one and two, when the volume of calls is expected to peak, and \$2.5 million in years three and four, when the surge in volume is likely to begin to subside. The analysis assumed minimal additional costs to Government after this period, when the volume of calls would likely return to a level that could be managed with current staffing and resources.

The total incremental annual costs to Government, as calculated by the analysis, of the TPLR-CLC would be \$1.7 million. The annualized cost over a 10-year period would be approximately \$11.7 million.

Total costs

The present value of total incremental costs of the TPLR-CLC would be \$74.1 million to \$83.3 million in constant 2007 dollars over 10 years. Cigarette and little cigar manufacturers and importers would bear about 80% of the costs, primarily in the form of investments in new printing equipment, new materials, and package re-design costs. The incremental costs to Government would be \$11.7 million due to a slight increase in administrative burden and funding provided to provincial and territorial partners.

Distribution of cost impacts

Domestic versus imported products

Based on import and sales data, the analysis developed estimated that domestic products would account for 42% to 46% of compliance costs, while imported products would account for 54% to 58%. It is important to note that these estimates include all tobacco products, some of which are only imported. In the case of the TPLR-CLC, 51% of cigarettes are imported, and 49% are produced domestically. Little cigars, as mentioned previously, have until recently been classified as cigars, which are almost always imported. It is therefore likely that the costs of compliance would be borne equally among domestic manufacturers and importers of cigarettes, while little cigar importers would likely bear the compliance costs associated with this product group.

Geographic distribution of impacts

The geographic distribution of any impacts associated with an increase in compliance costs will likely be correlated with the geographic distribution of tobacco products production. Canada's largest tobacco product manufacturing facilities are located in southern Quebec, with additional significant production in southern Ontario. The firms operating these plants are all

headquartered in Ontario, with the largest two headquartered outside Toronto.

Although the analysis does not anticipate major impacts on the industry overall, small manufacturers lacking significant economies of scale may find it more difficult to comply with the labelling requirements. The headquarters and manufacturing operations of the smaller producers are concentrated in Quebec.

Disproportionately affected products

The costs of complying with TPLR-CLC are unlikely, in most cases, to lead to significant changes in production economics or product pricing. If a large share of a product is imported, however, disproportionate impacts are possible. The primary concern is that foreign producers may forgo the Canadian market rather than incur the costs of compliance. Should this occur, the impact on the market for certain products and brands could prove more substantial.

However, the potential for such impacts is confined to a limited set of products. Observations suggest that the products most vulnerable to disproportionate impacts are those with several features:

- Products for which a large share of Canadian sales rely on imports;
- Products for which the Canadian market is a small element in the foreign manufacturers' base of business; and
- Products sold in a wide variety of package sizes and types.

At least two considerations counterbalance the concerns noted above. First, market dynamics could mitigate the most severe impacts; foreign suppliers interested in remaining in the Canadian market may consolidate brands and package types to reduce compliance costs, or suppliers for which the Canadian market is significant may increase exports to Canada to meet the demand formerly met by any manufacturer who abandons the market. It is also worth noting that the current TPIR have not proved to be a significant impediment to trade. To date, the Department of Health is not aware of any significant loss in product variety due to regulatory requirements. Indeed, new products have been introduced, suggesting that regulations pose no barrier to entry for new imports.

Nonetheless, short-term economic losses are possible for manufacturers and sellers of some imported cigar brands. In the longer term, the adjustments also may lead to a redistribution of profits among Canadian importers.

Impacts on distributors and retailers

Based on interviews with stakeholders, potential impacts on distributors and retailers have been identified, including potential price increases, which may encourage the sale of illegal products, loss of inventory, and disruptions in the supply chain.

The analysis notes that these impacts would likely be most significant for retail establishments that rely heavily on tobacco sales. The impacts would not be likely to be disproportionately concentrated in any particular geographic area; they would likely mirror the distribution of tobacco product sales nationwide.

Impacts on tobacco growers

The analysis suggests that the revised labelling requirements would reduce demand for products made with domestic tobacco (cigarettes, loose tobacco, and tobacco sticks) by less than 1% over a 10-year period. Thus, the new TPLR-CLC will likely have a minimal impact on Canadian tobacco growers.

Impacts on tobacco consumers

The TPLR-CLC could adversely affect tobacco consumers in several ways. Those who continue to smoke would bear the additional costs of compliance. However, as discussed earlier, the

impact on retail prices is not expected to be significant. As a result, the impact of price increases on consumers is likely to be minimal.

The variety of tobacco products available to consumers may be reduced if manufacturers choose to consolidate brands. These impacts hinge on individual tastes and preferences and therefore are complex and difficult to analyze quantitatively. The information available, however, suggests that the impacts are not likely to be extensive.

Cost-Benefit Statement			Monetizable Impacts (Millions of \$2007 CAD)				
Stakeholders	Cost/benefit	Description	PV costs	PV benefits	Year 1	Year 10	Average annual
Canadians	Benefit	Lower costs of smoking-related illnesses		\$80 (High estimate: \$240)	\$15 (High estimate: \$45)	\$8 (High estimate: \$25)	\$11.4 (High estimate: \$34.7)
	Benefit	Avoided costs of premature death		\$3,850 (High estimate: \$11,740)	\$710 (High estimate: \$2,160)	\$390 (High estimate: \$1,200)	\$551 (High estimate: \$1,683)
Government	Cost	Incremental costs of compliance, monitoring and quitline	\$11.7		\$3.5		\$1.7
Industry — Cigarette and little cigar manufacturers	Cost	Incremental costs including materials, equipment, package re-design, and printing	\$49.6 (High estimate: \$53.4)		\$7.4 (High estimate: \$8)	\$7.4 (High estimate: \$8)	\$7.4 (High estimate: \$8)
Total PV at 8%			\$61.3 (High estimate: \$65.1)	\$3,930 (High estimate: \$11,980)			
Net benefit			\$3,869 (High estimate: \$11,915)				
B. Quantifiable impacts							
Stakeholders	Cost/Benefit	Description	Total	Total	Year 1	Year 10	Average annual
Canadians	Benefit	Increase in the number of smokers who avoid smoking-related illnesses and premature		\$13,380 (High estimate: \$40,740)	\$1,720 (High estimate: \$5,240)	\$960 (High estimate: \$2,910)	\$1,338 (High estimate: \$4,074)

		death due to smoking				
Industry — Cigarette and little cigar manufacturers	Cost (high estimate)	Reduction in number of cartons sold	\$1,249,003		\$201,113	\$124,900
C. Qualitative impacts						
Stakeholders	Impacts	Description				
Smokers	Positive impacts	<ul style="list-style-type: none"> Smokers who quit may benefit from improved quality of life and reduced disease-induced pain and suffering. 				
Canadians	Positive impacts	<ul style="list-style-type: none"> Possible reduction in smoking-related fires, and associated risks of property damage, injury and death. Non-smokers may benefit from reduced exposure to second-hand smoke. 				
General public	Positive impacts	<ul style="list-style-type: none"> Health improvements associated with reduced tobacco use may reduce the overall demand on the health care system, freeing resources to address other health issues more effectively and efficiently. 				
Industry	Negative impacts	<ul style="list-style-type: none"> Manufacturers and importers may experience short-term operational disruptions during the transition. 				

Comparison of costs and benefits

The analysis estimates that the net benefits, that is benefits minus the costs, of the TPLR-CLC range from \$3.8 billion to \$11.9 billion. Overall, the analysis estimated that the benefits of the proposal exceeded the costs by a factor of 47 or more.

The full cost-benefit analysis is available on demand.

Revised costs and benefits of the TPLR-CLC

The Department of Health has done an internal analysis of the source data to determine the overall impacts of the differences in the scenario between the cost survey to industry and the TPLR-CLC on the costs and benefits. The internal analysis showed that the changes in the scenario had some impact on the costs and benefits, but that those impacts were not significant. The analysis showed that the scenario changes reduced the costs proportionally more than the benefits, and that the benefits of the TPLR-CLC would still far outweigh the costs.

Rationale

While the proposed option to develop new regulations was retained by the Department of Health, the approach to the display of health-related information on cigarette and little cigar packages does not differ substantially from the current approach; the TPLR-CLC require additional elements and improved features, such as the increased use of graphics and colour, but the approach continues to build on the current TPIR. The TPLR-CLC continue to require the display of the same types of information, namely health warnings, health information messages, and toxic emissions statements, on the same display surfaces as are currently mandated by the TPIR. Research carried out by the Department of Health on the effectiveness of the current health-related information on tobacco products served as the basis for the decision to renew the information. Research has shown that the labels currently mandated under the TPIR have reached their maximum potential and have become less effective at informing Canadians about

the health hazards of tobacco use.

There are two aspects of the TPLR-CLC that vary from either the current TPIR or the scenario sent to industry in the cost survey: the scope of the Regulations and the size of the health warnings. Both will be discussed in this section.

The Department of Health has decided to narrow the proposal, from the broad scenario in the cost survey that was sent to industry to a narrower regulatory proposal, for two main reasons. First, the Department wants to put the TPLR-CLC in place as soon as possible. The scenario sent to industry would have required the Department to prepare three different sets of 16 health warnings, 8 health information messages, and 4 toxic emissions statements prior to publication in the *Canada Gazette*, Part I. Rather than implement the three-series approach, which would incur delays, the Department has chosen to require the display of a first series of health-related messages while subsequent series are being finalized. The Department feels that this approach will allow incremental health benefits to begin to accrue sooner. While subsequent series of messages would likely increase the effectiveness of the messages over time by increasing novelty and relevance, delaying the implementation of the proposal to include subsequent series could also delay the potential health benefits of the other enhanced features, namely the increase in the size of the health warnings, the inclusion of the quitline information, and the improved noticeability of new graphics and colour. Internal analysis of the source data on costs and benefits has also shown that narrowing the proposal will reduce the costs proportionally more than the benefits, and that the benefits of the regulatory proposal will still far outweigh the costs. The overall impacts on the costs and benefits were not significant enough to warrant a change in the Department's recommended approach.

The introduction of the requirement to display one series of new health-related labels on cigarette and little cigar packaging will also allow the Government to carry out an initial evaluation of the effectiveness of the first series. This would be done through public opinion research similar to the waves carried out to evaluate the effectiveness of the current labels mandated by the TPIR. This evaluation will allow the Department to adjust future messages based on the feedback on effectiveness. The approach adopted will also allow the Department to consider emerging science on the health hazards of tobacco use, such as the research currently being done on the links between tobacco and breast cancer. This will allow the Department to include new messages when the scientific information warrants.

The required size of the health warnings is a requirement of the TPLR-CLC that also varies from the TPIR. While the TPIR require health warnings to be displayed on 50% of the front and back of packages, the TPLR-CLC require 75% coverage. The decision to require larger health warnings is based on two key sources of information: research carried by the Department of Health that showed that larger warnings are considered more effective, and international experience that shows that the inclusion of cessation services information on tobacco packaging is an important tool in informing tobacco users of the existence of cessation services and may lead to increased information to users about the health benefits of quitting. In 2008, the Department of Health carried out two separate public opinion research studies to help determine the size of the health warnings.

The research firm Environics Research Group carried out quantitative consumer research among youth and adults on the size and format of health warnings on behalf of the Department of Health. The full reports can be found on the Library and Archives Canada Web site (www.porr-rrop.gc.ca/index-e.html.) The studies employed identical survey methods for both youth and adults in order to explore reactions to different size options for the health warnings. Face-to-face interviews were conducted to present respondents with four size options of health warnings, 50%, 75%, 90%, and 100%, on three-dimensional cigarette package mock-ups. Respondents were asked an extensive series of questions to test perceptions and smoking behaviours and were submitted to an experimental design component to test responses to various visual and size options that included questions related to the size of health warnings and their effectiveness at informing about the health effects of tobacco use and encouraging reduction in tobacco use.

A total of 1 000 youth, including 300 smokers, aged 12 to 18 were interviewed. The key findings of the research showed that

- When asked, top-of-mind, how the current health warnings could be changed to be more effective, 19% of youth responded increase their size, 29% responded change the pictures, 22% responded change the messages, and 19% suggested adding more detailed information.
- When asked specifically about possible changes that would make the health warnings more effective, 83% of youth suggested increasing the size of messages, 92% suggested using new or different pictures, 89% recommended new or different text messages, and 89% suggested making the words more closely reflect the pictures.
- When asked if increasing the size of health warnings would increase their effectiveness at informing Canadians about the health risks of tobacco use, 37% of youth responded that they would be much more effective, and 52% said they would be somewhat more effective; 32% responded that increasing the size of health warnings would make them much more effective in encouraging Canadians to reduce their tobacco use; and 48% said they would be somewhat more effective.
- When asked about the effectiveness of the four test sizes of the health warnings in informing Canadians about the health effects of tobacco, 68% of youth said the 50% size option would be very or somewhat effective. In comparison, 86% said the 75% size option would be very or somewhat effective, 89% said the 90% size option would be very or somewhat effective, and 94% said the 100% size option would be very or somewhat effective.

The research study of 1 000 adult smokers, aged 18 and older, resulted in similar findings:

- When asked, top-of-mind, how the current health warnings could be changed to be more effective, 11% responded increase their size, 29% replied use new pictures, and 22% said change the messages.
- When asked specifically about possible changes to the health warnings to make them more effective, 58% responded that increasing the size of messages would be very or somewhat effective in making the messages more noticeable, 81% suggested using new or different pictures, 78% recommended using new or different text, and 71% percent said making the words more closely reflect the pictures would be very or somewhat effective.
- When asked if increasing the size of health warnings would make them more effective in informing Canadians about the health effects of tobacco, 23% said it would make them much more effective, and 43% said it would make them somewhat more effective; 20% said increasing the size of the health warnings would make them much more effective in encouraging Canadians to reduce their tobacco use, and 44% said it would make them somewhat more effective.
- When asked about the effectiveness of the four test sizes of the health warnings in informing Canadians about the health effects of tobacco, 69% of smokers said the 50% size option would be very or somewhat effective. In comparison, 81% said the same for the 75 % size option, 84% said the same for the 90% size option, and 85% said the same for the 100% size option.

A second study was carried out by the research firm Les Études de Marché Créatec on behalf of the Department of Health to test the relationship between message effectiveness and size. The research study was carried out with both youth and adult target groups, and a report was prepared for each group. The full reports can be found on the Library and Archives Canada Web site (www.porr-rrop.gc.ca/index-e.html). The studies were designed to test the potential impact on adults' and youths' perceptions of three new increased size options, 75%, 90%, and 100%, for health warnings on cigarette packages, using the current requirement of 50% coverage as a benchmark. The methodology of the research study was identical for both youth and adult populations; the studies applied an experimental approach in which respondents were exposed to all four warning size scenarios, through face-to-face interviews, and their reactions were measured according to a pre-defined protocol. Findings were inferred by statistical analysis and not from opinions directly expressed by respondents. The experimental design was based on repeated measures with one control scenario, the current size of 50%, and three test sizes of 75%, 90% and 100%.

Through the study aimed at youth, a total of 746 current smokers and vulnerable non-smokers aged 14 to 17 were interviewed. Overall findings of the study showed that young respondents were sensitive to the size of the health warnings, and that any of the three

increased size options for health warnings on cigarette packages would make the warnings a more effective vehicle for communicating with young smokers and vulnerable non-smokers than the current requirement of 50%. The study found that impacts on the measured indicators began to be statistically significant at the smallest size increase option of 75%, compared to the 50% option, and continued to increase with the larger size options. The report concluded that if the size of the health warnings was increased from 50% to 75%, impacts on all indicators would be small, but statistically significant; two effects in particular were found to be substantial, convincing respondents to personally stay away from smoking and communicating with the public about the risks of smoking.

The study of adult smokers showed similar results. Through the study, a total of 730 hardcore smokers and potential quitters aged 18 and over were interviewed. As with young respondents, the study found that adult smokers were sensitive to the size of the health warnings, and that any of the three increased size options for health warnings on cigarette packages would make the warnings a more effective vehicle for communicating with adult smokers. Again, the study found that impacts on the measured indicators began to be statistically significant at the smallest size increase option of 75%, compared to the 50% option, and continued to increase with the larger size options. The study concluded that if the health warnings were increased from 50% to 75%, impacts on many indicators would be small but statistically significant. With health warnings at 75%, one effect was found to be substantial with adult smokers; respondents felt personally more convinced to stay away from smoking.

Given the stated objectives of the TPLR-CLC, especially the primary objective of informing Canadians of the health hazards associated with tobacco use, these public opinion research studies support the Department of Health's decision to renew the labelling requirements on cigarettes and little cigars packages. The Department used a combination of the elements that both young and adult smokers identified as factors that would increase the effectiveness of the messages: changing the texts of the health warnings, changing the images, and increasing the size of the warnings. The studies further support the decision to increase the required size of the health warnings from 50% to 75%. While both studies showed that both the 90% and 100% size options had the greatest potential to increase the effectiveness of the health warnings compared to the 50% option, particularly in communicating the health risks of tobacco use, the Department of Health chose to retain 75%; this option was seen as offering a balance between improving the effectiveness of the health warnings as a vehicle to communicate with Canadians, and providing users with product-related information.

The Department of Health tested the effectiveness of the integration of the pan-Canadian quitline and cessation Web portal into various sizes of health warnings through public opinion research. While the size of the pan-Canadian quitline number and the cessation Web portal address was not the primary focus of most of those studies, feedback from various studies on the health warnings indicated that integrating cessation services information into a health warning covering 50% of the package could detract from the overall message and make the information difficult to read. For example, respondents indicated that the information was more visible and legible and had greater overall impact when displayed prominently in the larger health warning. It was considered that the coverage of 75% of the front and back of the package was an appropriate size to include all the information, yet retain the overall effectiveness of the message in communicating with tobacco users.

Impacts of the selected option on costs

As noted in the costs and benefits section, the regulatory scenario sent to industry which served as the basis of the analysis of costs and benefits is not the same as the scenario in the TPLR-CLC. However, the Department of Health feels that it is appropriate to present the analysis of costs and benefits for several reasons. First, the scope of the scenario presented in the TPLR-CLC is much narrower than the scope of the scenario sent to industry for costing purposes. The compliance costs are therefore expected to be much lower than those presented in the costs and benefits section. Second, while the scope of the proposal has been narrowed, the fundamentals of the proposals have not changed. The main drivers of the compliance costs to industry remain unchanged, specifically the requirement to display new health warnings, health information messages, and toxic emissions statements and the requirement to display health warnings on 75% of the front and back of cigarette and little cigar packages. Finally, in the analysis of the original scenario sent to industry, the net benefits of the proposal exceeded the

costs by a factor of 47 or more. It is expected that while the exact ratio of benefits to costs may not be maintained, the benefits of the proposal would still far outweigh the costs even if the scope of the regulatory proposal was narrowed.

The selected option, particularly the decision to increase the size of the health warnings, may have some impacts on costs, both to industry and to consumers; however, those costs are not expected to be significant. Increasing the size of the health warnings from 50% to 75% may necessitate incremental costs to industry, such as package redesign costs and other possible production costs that would not have been needed had the Department chosen another option. However, as noted in the costs and benefits section, these costs to industry are not expected to be significant, and the overall costs of the proposal are expected to result in a marginal unit cost increase of \$0.00025 to \$0.00027 per cigarette produced. While it is expected that these costs would be passed on to consumers, the increased cost per carton of 200 cigarettes is expected to be \$0.05.

Impacts of the selected option on objectives

The selected option will meet all of the objectives stated above. By requiring the display of new health-related information based on the latest research, the TPLR-CLC continue to build on the achievements of the TPIR by better informing Canadians, especially cigarette and little cigar users, on the health risks of tobacco use. The health warnings and health information messages provide new information which is more noticeable, engaging, and easier to understand than the current health-related information. Groups that have been less well served by the health-related information on tobacco products in the past, including less literate smokers, older smokers, and hardcore smokers, will particularly benefit from access to information that is better suited to their circumstances. Tobacco users will also benefit from increased awareness of the existence of cessation services. While these services have been available from most of the provinces and territories for some time, advertising them in a consistent way has been a challenge. By using tobacco packaging, widely acknowledged as the best vehicle to connect with tobacco users, display of the toll-free pan-Canadian quitline number and cessation Web portal is expected to increase the use of these services. The TPLR-CLC allow the Government to support the efforts of its provincial and territorial partners to provide cessation services both by prominently displaying the toll-free pan-Canadian quitline number and cessation Web portal and by providing funds to provinces and territories to help cover the anticipated costs of infrastructure and human resources of an expected increase in call volume. Finally, the TPLR-CLC bring Canada into greater compliance with the FCTC by requiring appropriately sized messages on little cigar packages.

The selected option is proportional to the degree and type of risk posed by tobacco. The combined approach of informing tobacco users about the health risks of tobacco use and the health benefits of quitting and raising awareness of the availability of cessation services will enable users to make informed decisions regarding tobacco use and their health. This proposal should result in tobacco users who are better informed about the health hazards of tobacco use, and may also reduce the number of Canadians afflicted with the debilitating diseases caused by tobacco use, as well as reduce the overall health care burden.

Coordination and cooperation

Over the course of developing the TPLR-CLC, the Department of Health has worked closely with the Canada Revenue Agency to coordinate efforts on regulations that affect the tobacco industry. Given the linkages between the TPLR-CLC and the *Regulations Amending the Stamping and Marking of Tobacco Products Regulations (2011)*, which require an excise stamp to be displayed on the outside of tobacco packages, the Department and the Agency have worked to ensure that the coming into force of the TPLR-CLC minimizes business disruptions to the extent possible. Provisions have also been made in the TPLR-CLC to allow industry to modify the health warnings to accommodate the excise stamp to ensure that the two measures do not undermine each other.

The Department of Health has also worked internally to ensure coordination between three regulatory initiatives that affect tobacco packaging: the TPLR-CLC, amendments to the current TPIR, and the *Promotion of Tobacco Products and Accessories Regulations (Prohibited Terms)*,

which prohibit the terms “light” and “mild” on tobacco packaging. The Department has worked to coordinate the introduction and implementation of these initiatives in order to minimize costs to industry and business disruptions, as well as to ensure regulatory consistency. This is particularly the case with the TPLR-CLC and the amendments to the TPIR; while the TPLR-CLC require new health-related information on all cigarette and little cigar packages, the current TPIR will continue to apply to all other tobacco products, including cigars, pipe tobacco, and smokeless tobacco products. The regulatory processes for all three regulatory initiatives have been coordinated to the extent possible, including simultaneous pre-publication in the *Canada Gazette*, Part I, laying the regulations before the House of Commons, and final publication in the *Canada Gazette*, Part I.

Consultation

Report of the Standing Committee on Health and concurrence by the House of Commons

The TPLR-CLC were laid before the House of Commons on June 9, 2011, with the *Regulations Amending the Tobacco Products Information Regulations and the Promotion of Tobacco Products and Accessories Regulations (Prohibited Terms)*. The Standing Committee on Health held a hearing on the three regulations on June 20, 2011. In their report presented to the House of Commons on June 22, 2011, the Committee recommended adoption of the three regulations without amendment.

The House of Commons concurred with the Committee report on June 22, 2011.

Prepublication — February 19, 2011

The 75-day comment period for the three proposed tobacco regulations ended on May 5, 2011. In total, 54 organizations commented: 17 from the tobacco industry, their suppliers and various trade associations; 13 from health non-governmental organizations; 2 from governments; and 22 from individuals. This includes two campaigns launched during the consultation (counted as one submission each): the Department of Health received 155 identical emails from a stakeholder’s employees and more than 4 400 identical postcards from retailers through a trade association.

Industry

- Issue: Contraband

The tobacco industry and retailers indicated that the focus should be on the contraband problem and not on additional regulatory requirements that will affect the legitimate market and that could serve to provide a competitive advantage to illegal operators.

Department of Health response:

While the issue of contraband tobacco is important, action on contraband is the responsibility of the Minister of the Department of Public Safety and Emergency Preparedness. The Department of Health estimates of the net benefits of the TPLR-CLC justify their implementation.

- Issue: Size of health warnings

The tobacco industry stated that the evidence base used by the Department of Health to justify increasing the size of the health warnings is poor and the methodologies flawed and that the lack of substantiation has deprived the industry of any meaningful consultation. Industry also argued that there is ample room within the existing 50% design to include both renewed health warnings and cessation information services.

Department of Health response:

The Department conducts all of its public opinion research by following standards set by the

Department of Public Works and Government Services Canada (PWGSC) and ensures that its public opinion research adheres to industry standards, including those of the Marketing Research and Intelligence Association. Research carried out by the Department showed that larger warnings are considered more effective.

- Issue: Addition effect of CRA tax stamp

The tobacco industry stated that the CRA excise stamp and the new, larger health warnings combined will cover significantly more than 75% of the principal display surfaces of the package.

Department of Health response:

Over the course of developing the TPLR-CLC, the Department has worked closely with the Canada Revenue Agency to coordinate efforts on regulations that affect the tobacco industry. Given the linkages between the TPLR-CLC and the *Regulations Amending the Stamping and Marking of Tobacco Products Regulations (2011)*, which require an excise stamp to be displayed on the outside of tobacco packages, the Department and the Agency have worked to ensure that the coming into force of the TPLR-CLC minimizes business disruptions to the extent possible. Provisions have also been made in the TPLR-CLC to allow industry to modify the health warnings to a minimal extent to accommodate the excise stamp.

- Issue: Implementation schedule

The tobacco industry and their Canadian supplier of specialized printing machinery (pre-press services) have maintained that an implementation period of 6 months is too short and that at least 12–13 months would be required for full compliance. The supplier added that if current timelines are maintained, some pre-press service work may need to be outsourced to other countries and suggested that this will negatively impact future opportunities.

Department of Health response:

The comments from the tobacco industry and the supplier were noted and carefully considered. The implementation schedule remains unchanged.

- Issue: Traditional little cigars

The manufacturers and importers of little cigars argued that traditional little cigars, those with spiral wrappers, are used like cigars and should be excluded from the TPLR-CLC. In a related comment, the industry noted that the Regulatory Impact Analysis Statement (RIAS) did not distinguish between cigarettes and little cigars with respect to the lower risk to cigar smokers. The industry also commented that because of the small Canadian market, few traditional little cigar manufacturers or importers will be interested in remaining in the Canadian market once the TPLR-CLC come into effect and that the impact on importers, as reported in the section in the RIAS on "Disproportionately Affected Products," is underestimated.

Department of Health response:

The Department's research has shown that the smoke of little cigars, either with or without filters, contains the same toxic chemicals present in the smoke of cigarettes and therefore the Department considers that smoking little cigars poses the same risk of harmful health effects as smoking cigarettes. Excluding certain types of small cigars from the definition of little cigars would allow them to be once again marketed with additives and flavours that appeal to youth, which would be contrary to the objectives of the *Cracking Down on Tobacco Marketing Aimed at Youth Act*. While it is impossible to predict the precise nature of the adjustments that are likely to occur in the Canadian tobacco products marketplace due to implementation of the TPLR-CLC, the Department to date is not aware of a significant loss of product variety or of supplier departures from the market due to the implementation of the current labelling regulations in 2000.

- Issue: Technical matters

The Canadian supplier of pre-press services and tobacco industry technical experts expressed several concerns of a technical nature with respect to the images displayed in the source document, for example, an apparent lack of adherence to the standard CMYK printing process.

Department of Health response:

The Department has addressed all technical issues raised around the proposed messages to facilitate printing by manufacturers.

- Other issues

The tobacco industry was of the view that the proposal to increase the size of the health warnings would further limit their right of free expression and may constitute a violation of international trade agreements to which Canada is a party.

Health non-governmental organizations

- Issue: Overall support for regulatory proposal

The responses from the health non-governmental organizations (NGO) were generally supportive of the proposed new labelling regulations for cigarettes and little cigars, especially the increase in the size of health warning messages to 75%. They applauded the coordinated approach between federal and provincial governments in the provision of and promotion of a pan-Canadian toll-free quitline number and cessation portal. However, they also provided a number of specific comments on the health warning messages, health information messages and toxic emissions statements, including concerns with the inclusion of "blame the victim" language such as "smoking causes heart disease" as opposed to "cigarettes cause heart disease."

Department of Health response:

With respect to the specific comments on some of the labelling elements, the Department emphasizes that all health-related messages were validated by scientific experts and can report that some specific comments were addressed, such as the adjustments made to the messages to improve legibility. Other comments were noted and may be considered for the next set of health-related messages.

- Issue: Scope of the regulatory proposal

The NGOs stated that they did not support the exclusion of cigarette-type tobacco products from these Regulations, such as kreteks, tobacco sticks and cigarette tobacco and that tobacco products that are not smoked should also be addressed.

Department of Health response:

In view of the large variety of tobacco products on the market, renewing the health-related messages on packages of cigarettes and little cigars will have the most positive impact on the health of Canadians, as these products account for approximately 95% of tobacco products purchased in Canada. For all other tobacco products, current regulations continue to apply.

- Issue: Strengthen the impact of the labelling

The NGOs proposed that the impact of labelling requirements be strengthened with complementary packaging reforms such as the development of new exterior and interior messages, standardised packaging and plain packaging. The NGOs requested that information be provided on the relative risk of health outcomes and questioned the absence of a health warning specifically on breast cancer and on impotence. They also stated that there should be

16 health information messages as in the current TPIR, not 8 as proposed.

Department of Health response:

More information on the new messages is available on Health Canada's Web site in the form of fact sheets which present a summary of the scientific evidence that underlies each message, including information on relative risk. The Department is not recommending a message linking smoking to breast cancer at this time. However, as scientific evidence mounts, the Department will consider including breast cancer as a topic in the future. Even though the current health warning messages include a message on impotence, the Department has decided not to propose a message on this topic as part of the renewal. With regards to the number of health information messages, the Department focussed on improving the quality and effectiveness of those messages rather than on maintaining their current number. The new health information messages have been enhanced and made more noticeable with the use of colour and graphic elements.

Governments

The two responses received from government organizations were supportive of the regulatory proposal, including the increase in size of the health warnings to 75%.

Department of Health response:

The comments were noted.

Individuals

A wide range of opinions were received from individuals. Major themes included

- The importance of helping young people not to start smoking or to quit smoking was emphasized. It was suggested that teens would relate more to the messages if younger people were featured on the labels.
- Fear or guilt is not effective alone in communications designed to modify behaviours.
- Labels may sway a few early smokers, but the majority of older smokers already know the risk and will continue to smoke because they are addicted.

Department of Health response:

As part of a new, comprehensive approach, the health warnings on the package include a pan-Canadian toll-free quitline number and cessation Web portal and will be complemented by a multimedia social marketing campaign, including the use of social media tools such as Facebook and Twitter, to reach and engage youth and young adult smokers. While the health warnings focus on the negative health consequences of tobacco use, the health information messages complement the warnings by providing information on the health benefits of quitting, the quitting process and cessation tools. The Department sought to propose a mix of health warnings and health information messages to better reach different demographic segments of tobacco users.

Previous consultations

The Department of Health consulted widely on the proposed Regulations between July 2003 and September 2009. Consultations were held with major stakeholders, including the tobacco industry, non-governmental organizations (NGOs), provinces and territories, health experts, academics, and researchers. Tobacco users were also widely consulted through public opinion research studies. The majority of the consultations focused on the format and content of the health-related messages; however, some stakeholders were also consulted on specific requirements of the proposed Regulations.

Consultation document

In August of 2004, the Department of Health released a consultation document titled *A Proposal for New Health-related Information on Tobacco Product Labels*. The document was made available on the departmental Web site, and was distributed to members of the tobacco industry, NGOs, government organizations, academics, experts, and researchers. The document solicited comments on the proposed options to renew the tobacco labelling elements that had been introduced through the TPIR in 2000. In all, 25 comments were received: 9 from NGOs, professional organizations, and academics, 8 from the tobacco industry, 5 from the general public, and 3 from government organizations.

Most respondents expressed support for the proposal to develop new health-related information on tobacco product labels. The majority also supported the specific proposals for health warnings, health information messages, and toxic emissions/ constituents statements, but frequently had differing views about proposed options.

Responses from NGOs, government organizations, and the public addressed many aspects of the labelling requirements, with the majority of their comments targeting the approach and content of new health warnings and health information messages. Comments from the tobacco industry tended to focus on implementation aspects of the proposed changes, such as space requirements and placement of the new labels on the package.

The majority of respondents were in favour of replacing the information on toxic emissions, particularly the numerical ranges, with a simplified approach. Most NGO and government organization respondents generally supported the proposal to focus on each of eight substances in text-based statements. Comments from the tobacco industry focused on the need to ensure the accuracy and objectivity of the content of the simplified statements. Some industry respondents also indicated that they would object to any increase in the space required to display the toxic emissions information.

A full summary of the comments received can be found on the departmental Web site at www.hc-sc.gc.ca/hc-ps/consult/index-eng.php.

The Department of Health modified the proposal based on the comments received. An option to integrate a toll-free panCanadian quitline number and cessation Web portal into the health warnings was developed, and the wording of the health warnings, as well as their images, were modified over several rounds of revisions. An option to increase the size of the health warnings from 50% to 75% of the front and back of cigarette and little cigar packages was also developed.

Face-to-face meetings

Between July 2003 and September 2009, the Department of Health held approximately 30 face-to-face meetings with key stakeholders, including 10 with the tobacco industry, 2 of which also included the Canada Revenue Agency, 14 with NGOs, 4 of which included academics and experts, 2 solely with academics and experts, and 1 with a national Aboriginal organization. In all, more than 40 organizations and individuals were consulted through these meetings.

The purpose of the meetings varied; some focused on specific elements of the proposal, while others presented the results of public opinion research undertaken with tobacco users. Many of the meetings resulted in recommendations from stakeholders on specific labelling elements.

Health warnings

Non-governmental organizations supported increasing the size of the health warnings from 50% to 75% of the display area of tobacco packages, and recommended strengthening the language of the health warnings to convey the magnitude of the health hazards of tobacco use. As mentioned previously, they also recommended the use of only the strongest and most effective messages in the proposed Regulations, and suggested including additional topics, such as mouth disease, mouth cancer, and breast cancer. Some of these recommendations were made by the NGOs as a group, and others were supported by one or more organizations.

Industry has not been opposed to the renewal of the health warnings, but they have

recommended that the current TPIR requirement of 50% of the package for the health warnings be maintained and that the quitline information be incorporated into the existing space. Industry has argued that the new excise stamp for tobacco packages introduced by the Canada Revenue Agency should be incorporated within the space currently occupied by Government of Canada requirements. This comment was addressed within the TPLR-CLC by allowing the excise stamp to overlap on the health warnings to some extent, provided the information is not obscured.

Health information messages

Non-governmental organizations made several recommendations to make the health information messages more compelling, including strengthening the language, including graphics, making the teasers more persuasive, and using stronger testimonials from former tobacco users. NGOs were strongly and almost unanimously opposed to health information messages that used cartoons or humour. While some of these messages tested fairly well with users, NGOs felt that they trivialized the issue of tobacco use and recommended they be removed.

In response, the entire package of health information messages was strengthened. The language and images were all reviewed to ensure that the approach would appeal to a wide variety of users, including the use of messages that provide techniques and tips for quitting and positive messages promoting the benefits of quitting. The messages that used cartoons or humour were either revised to use a different approach and graphics, or removed completely.

Industry stakeholders generally provided little feedback on the health information messages. Only one company confirmed its understanding that the only changes to the approach of the health information messages were that the texts would be revised and graphics added.

Toxic emissions statements

Non-governmental organizations were supportive of the proposal to change the format of the toxic emissions statements. The feedback most often heard from this group was to strengthen the language and to include a universally recognized warning symbol to draw attention to the side of the package.

The tobacco industry has generally been silent on the issue of the toxic emissions statements.

Public opinion research

Given the principal objective of the TPLR-CLC to better inform Canadians on the health hazards of tobacco use, public opinion research with tobacco users has been used extensively in the development of the health-related labels.

Between July 2003 and September 2009, 10 public opinion research studies were conducted with smokers to solicit their opinions on the health warnings, health information messages, and toxic emissions statements. Focus group sessions were held with both English- and French-speaking tobacco users in 20 different locations across Canada, for a total of more than 7 400 tobacco users. While a small number of studies focused on other tobacco products such as cigars and smokeless tobacco, the majority of them surveyed cigarette smokers. In each session, participants were shown mock-ups of possible health warnings, health information messages, and/or toxic emissions statements. Participants were asked a series of questions about noticeability, memorability, and effectiveness. They were also asked to provide feedback in more open-forum discussions. The views expressed by tobacco users in these studies were highly influential in informing revisions of the messages; the messages were modified based on comments received from each round of research.

One research study also examined the display and format of the pan-Canadian quitline number and Web cessation portal address, and two studies examined the size of the health warnings. In these studies, participants were shown the relevant information in a variety of sizes and formats and were asked a series of questions to determine which were most effective. The findings from these studies helped inform the details of the TPLR-CLC.

All research was conducted by reputable research firms according to Government of Canada guidelines. These firms ensured an unbiased and fair process and results by leading each session, from recruiting candidates to facilitating the presentation of the messages and subsequent discussions. Representatives of the Department of Health, as well as some NGOs, viewed all sessions through one-way glass so as not to influence the outcomes. A report on each study can be found on the Library and Archives Canada Web site (www.porr-rop.gc.ca/index-e.html).

Implementation, enforcement and service standards

Coming into force

The TPLR-CLC come into force on the day they are registered. Manufacturers of tobacco products have a transition period of 180 days for implementation, in which they will be allowed to continue to provide retailers with packages displaying the health-related labels mandated by the TPIR. Retailers have a transition period of 270 days for implementation, in which they will be able to sell-through their inventory of products that display the health-related labels mandated by the TPIR. These transition periods should help to minimize loss of inventory.

The Department of Health has also coordinated the TPLR-CLC with the proposed amendments to the TPIR to ensure consistency in the application of the regulatory requirements. The Department of Health is ensuring that the TPLR-CLC, the amendments to the TPIR and the *Promotion of Tobacco Products and Accessories Regulations (Prohibited Terms)* follow a coordinated regulatory process, including pre-publication in the *Canada Gazette*, Part I, laying before the House of Commons, and final publication in the *Canada Gazette*, Part I.

Communication and outreach activities

Communication activities have been undertaken to make stakeholders aware of the final publication in the *Canada Gazette*, Part I. The Department of Health intends to inform stakeholders, through hard-copy and electronic mail-outs, of the final publication. The Department has made electronic and hard-copy versions of the source document available to stakeholders. International stakeholders have been notified through the WHO notification process and provided with the same access to documents as domestic stakeholders.

Enforcement of the Regulations

Compliance monitoring and enforcement activities will continue to be undertaken by the Department of Health. Training on the TPLR-CLC will be provided to Department of Health tobacco inspectors currently enforcing the TPIR. With the TPLR-CLC coming into force, these inspectors are responsible for monitoring compliance with both the TPLR-CLC and the TPIR.

The Department of Health will actively monitor compliance throughout the supply chain, including manufacturers, distributors, importers and retailers. When Department of Health tobacco inspectors have reasonable grounds to believe that the Regulations have been contravened, appropriate measures are taken. Inspectors have the authority to issue warnings, seize product, or refer cases for prosecution.

Penalties for non-compliance

Penalties for non-compliance with the TPLR-CLC are outlined in Part VI of the *Tobacco Act*.

Possible future action

At a ministerial press conference to introduce the renewal of the health-related labels on cigarettes and little cigars, the Government announced its intention to consider introducing a rotation scheme. A rotation scheme would aim to enhance novelty and relevance of the health-related information by changing the messages periodically. This feature was included in the original analysis of the costs and benefits, but is not included in the TPLR-CLC. The Government would ensure adequate notification of a regulatory amendment to all stakeholders.

Contact

Manager
Regulations Division
Office of Regulations and Compliance
Controlled Substances and Tobacco Directorate
Healthy Environments and Consumer Safety Branch
Health Canada
Address Locator: 3507C1
123 Slater Street
Ottawa, Ontario
K1A 0K9
Fax: 613-941-1551
Email: pregs@hc-sc.gc.ca

[Footnote a](#)

S.C. 1997, c. 13

[Footnote b](#)

S.C. 1998, c. 38, s. 3

[Footnote c](#)

S.C. 1997, c. 13

NOTICE:

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

Date Modified: 2011-10-17