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Regulations Amending the Tobacco Products Information Regulations

Statutory authority

Tobacco Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations*.)

Executive summary

Issue: Firstly, the current labelling requirements for health warnings, health information messages and toxic emissions statements on packages of tobacco products are prescribed in the *Tobacco Products Information Regulations* (TPIR). In light of the introduction of the proposed new *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)* [TPLR-CLC], the labelling requirements for cigarettes and little cigars in the TPIR would become obsolete and have to be removed. Secondly, the Standing Joint Committee for the Scrutiny of Regulations has identified several technical errors in the TPIR, such as grammar, terminology, and accordance of the English and French versions of the Regulations. Thirdly, the numerical values for toxic emissions that currently appear on tobacco product packaging have been found to be confusing and not clearly understood by smokers.

Description: The *Regulations Amending the Tobacco Products Information Regulations* (the "Regulations") would serve three main purposes: to remove the application of the TPIR to cigarettes and little cigars, to respond to the problems identified by the Standing Joint Committee for the Scrutiny of Regulations and to remove the obligation to list numerical values for toxic emissions.

Cost-benefit statement: The main benefit of this regulatory proposal would be to the health of Canadians through the removal of the numerical values for toxic emissions, which, in turn, would enable smokers to receive better information about the chemicals in tobacco smoke and obtain a better understanding of the health risks associated with the use of tobacco products. The benefit to the health of Canadians outweighs the relatively minor economic costs to the tobacco industry.

Business and consumer impacts: If the additional packaging costs were to be passed on to consumers, the retail price of a package of a tobacco product would be expected to increase by less than 1%.

Domestic and international coordination and cooperation: Domestic and international manufacturers of tobacco products will be notified of the amendments and a 75-day comment period will be provided. The regulatory proposal is not expected to affect any international trade agreement or have any significant trade implications.

Issue

The *Tobacco Products Information Regulations* (TPIR) came into force in 2000. It is necessary to amend the TPIR as a result of three main factors: the proposed *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)* [TPLR-CLC], technical errors identified by the Standing Joint Committee for the Scrutiny of Regulations, and problems associated with the interpretation of numerical values for toxic emissions on packages of most smoked tobacco products.

Proposed TPLR-CLC

The proposed new TPLR-CLC would specify labelling requirements for health warnings, health information messages and toxic emissions statements for packages of cigarettes and little cigars. Labelling requirements for those two types of tobacco products are currently in the TPIR. The applicability of the TPIR to these tobacco products would become obsolete and would have to be removed concurrently with the coming into force of the TPLR-CLC.

Standing Joint Committee for the Scrutiny of Regulations

The Standing Joint Committee for the Scrutiny of Regulations has identified problems in the TPIR with respect to redundant language, clarity and consistency in both the English and French language versions, consistency between the English and French renderings and errors in grammar and terminology.

Numerical values for toxic emissions

The TPIR currently require that numerical values for the quantity of six toxic emissions (tar, nicotine, carbon monoxide, formaldehyde, hydrogen cyanide and benzene) be displayed on the sides of packages of most smoked tobacco products.

It was intended that this information would serve an educational purpose, supporting one of the main purposes of the *Tobacco Act*, to enhance public awareness of the health hazards of using tobacco products. However, research conducted for the Department of Health has indicated that the numerical values are not clearly understood by some smokers and that most have little idea what the range of numbers displayed for each chemical means.

Objectives

The first objective of the Regulations would be to remove the applicability of the TPIR to cigarettes and little cigars, in order to support the introduction of the proposed TPLR-CLC.

The second objective would be to correct the technical errors identified by the Standing Joint Committee for the Scrutiny of Regulations as well as minor deficiencies reported by departmental officials and the tobacco industry. Included are minor changes to 5 of the 16 health information messages found in the "source document."

The third objective would be to respond to the evidence that many smokers do not understand the numerical values for toxic emissions and may find it confusing, by removing the obligation to list these values on packages of four types of smoked tobacco products (cigarette tobacco, kreteks, leaf tobacco and tobacco sticks). However, the requirement to display the names of the six toxic emissions would continue.

Description

The TPIR came into force in 2000. The TPIR establish the requirements for information that must be displayed on tobacco products that are for retail sale in Canada and support the federal *Tobacco Act* in providing a legislative response to a national health problem of substantial and pressing concern.

The TPIR set out specific requirements for graphics, size, location and content of information to be displayed — all aimed at ensuring that tobacco products display health warning messages, health information messages and information about their toxic emissions or constituents in a way that is easily legible, in a similar manner in both official languages and, where specified, in colour.

The Regulations would amend the TPIR in three ways:

(1) Removal of the applicability of the TPIR to cigarettes and little cigars when the TPLR-CLC come into force

The TPLR-CLC are proposed new Regulations that would replace the TPIR with respect to labelling requirements for cigarettes and little cigars. As a result, several sections of the TPIR would be amended to remove the application of those Regulations to those products. However, the TPIR would continue to apply to other tobacco products, including bidis, cigars, cigarette tobacco, kreteks, leaf tobacco, pipe tobacco, smokeless tobacco and tobacco sticks.

For consistency between the TPLR-CLC and the TPIR, the definition of "cigarette" in the TPIR would be removed and replaced by reference to the definition found in the TPLR-CLC. In addition the definition of "cigar" would be modified to ensure that the definition excludes little cigars.

(2) Response to the review by the Standing Joint Committee for the Scrutiny of Regulations

The Standing Joint Committee for the Scrutiny of Regulations identified problems in the TPIR with respect to redundant language, clarity and consistency in both the English and French language versions, as well as to consistency between the English and French renditions and to errors in terminology.

Section 1

The Regulations would amend section 1 of the TPIR by clarifying the following definitions:

— "health information" — modify the definition to clarify that words appearing in Part 4 of the source document that attribute the information to its source are not part of the definition;

— "health warning" — modify the definition to include reference to provisions that set out health warnings but are not currently referenced in the definition, specifically health warnings for bidis (a thin cigarette of tobacco rolled in a dry leaf, usually made in South Asia), chewing tobacco and snuff, and to clarify that words appearing in Parts 1, 2 and 3 of the source document that attribute the information to its source are not part of the definition;

— "manufacturer" — modify the definition to exclude the words "includes an importer of tobacco products" — the words are redundant in that the concept of importing of tobacco products is already in the definition of "manufacture" found in the *Tobacco Act*;

— "slide" — modify the definition to reflect accurately its use in other sections of the Regulations — this clarifies that slide is part of a "slide and shell" package;

— "source document" — modify the definition in order to provide reference to an amended version of the document *Health Warnings and Information for Tobacco Products* — the source document has been amended to correct several minor errors and omissions, including minor changes to five of the sixteen health information messages; and

— "type of package" — modify the definition to add "slide and shell package with a lateral slide" — would maintain consistency among the various regulations under the *Tobacco Act*.

Section 1 would also be amended to add the following definition:

— "identical products" — this definition would support the new wording in subsection 8(2) to describe which tobacco products are exempted from the requirements for toxic constituent testing.

Section 4

The Regulations would amend subsection 4(1) by clarifying that manufacturers who wish to attribute health warnings or health information can find the information required by this section for such an attribution in the source document.

Section 5

The Regulations would amend section 5 by deleting the word "cigares" (subsection 5(1), French version only), by clarifying that the formats for display of health warnings, except in the case of bidis, chewing tobacco and snuff, be selected from the formats set out in the source document — not, as is currently stated, from formats provided by the Minister (paragraph 5(2)(*d*)) — and by clarifying that the requirement for equal display of health warnings applies to each type of package of each brand (subsection 5(7)).

Section 6

The Regulations would amend section 6 to change the word "label" to "warning" for clarity, paragraphs 6(1)(*a*) and (*b*) to change the word "surface" to "side" to provide consistency with the terminology used in the first paragraph of subsection 6(1), and subsection 6(2) to reorder the sentence to improve comprehension.

Section 7

The Regulations would amend subparagraph 7(1)(*a*)(i) by deleting the word "extérieur" (French version only) and by clarifying provisions for equal display of health information on leaflets (subsection 7(3)) in English by aligning the wording more accurately with the French version.

Section 8

The Regulations would amend section 8 by deleting the reference to section 5 (alternative methods) of the *Tobacco Reporting Regulations* (TRR) as applying to testing for toxic constituents required by the TPIR (subsection 8(1)) and by deleting the references to subsections 14(3) [emissions — sampling] and 14(4) [emissions — replicates] of the TRR (subsection 8(1)) as well as the reference to section 9 of the TPIR, as the methodology for determining quantities of toxic emissions would no longer be required with the removal of the requirement for this information to be displayed on packages (see the last paragraph of "Obligation to display numerical values in the toxic emissions information" following). The Regulations would also clarify the wording to describe which tobacco products are exempted from the requirements for toxic constituent testing (subsection 8(2)).

Section 11

The Regulations would amend section 11 by clarifying the requirements for the height of characters to be used in the printing of toxic emissions and toxic constituents information on packages (paragraph 11(*b*)), as the phrase "in a pitch of 10 points" was not correct terminology. The marginal note in the English version would be amended to provide a better description of the section.

Section 12

The Regulations would amend section 12 by removing the phrase "Subject to subsection

(3)" (subsection 12(1)) as this phrase is unnecessary and by clarifying that the requirement for equal display of health information applies to each brand (subsection 12(3)).

In addition to the above, the French rendition of the term for a "slide and shell package," "paquet à coulisse," would be made consistent throughout the Regulations. Also, in the French version, the term "information" would be replaced by the term "renseignements" where health warnings and health information are referred to jointly.

(3) Obligation to display numerical values in the toxic emissions information

The toxic emissions information displayed on packages of certain types of smoked tobacco products was originally intended to provide smokers with information on six compounds found in the smoke they inhale to help them gain a better understanding of the health risks associated with the use of tobacco products (there are more than 4 000 compounds found in tobacco smoke).

Currently, numerical values must be displayed on the side of packages of five types of smoked tobacco products, for six toxic substances found in the smoke of these products. The five types of tobacco products are cigarettes, cigarette tobacco, kreteks, leaf tobacco and tobacco sticks, whereas the six toxic substances are tar, nicotine, carbon monoxide, formaldehyde, hydrogen cyanide and benzene.

The toxic emissions values are expressed as a range, with the lower number determined according to smoking conditions set in a method from the International Organization for Standardization (ISO) and the higher number by the same method but with modified smoking conditions (e.g. larger puff volumes). As no two people smoke the same way, it was reasoned that providing a lower and upper value of the yields for various toxic emissions would provide a better indication of the potential amounts of toxic substances a person might inhale.

The Department of Health has had research conducted which indicates that the numerical values for toxic emissions that currently appear on tobacco product packaging are not clearly understood by some smokers. In a 2003 study, most participants stated that they "have no idea" or "don't really know" what the numbers mean. Participants were also confused about whether the numbers referred to dose per cigarette or per package of cigarettes and the presence of a range of numbers made many of them question the accuracy of the numbers. A second 2003 study found that most people had little idea what the range of numbers for each chemical meant. People also questioned the accuracy of the large range of measurements. As a result, many people concluded that the numbers did not really mean anything. Only 17% of participants understood that the toxic emissions values are related to the fact that some smokers may take in larger amounts of smoke while other smokers may take in less.

In addition, the Guidelines for Implementation of Article 11 of the *WHO Framework Convention on Tobacco Control* advise Parties to the treaty not to require quantitative or qualitative statements on tobacco product packaging and labelling about toxic emissions that might imply that one brand is less harmful than another, such as tar, nicotine and carbon monoxide figures. The WHO Scientific Advisory Committee on Tobacco Products Regulation had previously recommended that tar, nicotine, and carbon monoxide numerical ratings not be displayed.

Based on the above, the Regulations would remove the requirement to have the toxic emissions values displayed on the sides of packages of four types of smoked tobacco products, namely cigarette tobacco, kreteks, leaf tobacco and tobacco sticks. As a result, the list of six toxic substances emitted during smoking would still remain but without the numerical values. The requirement for information on the amount of toxic constituents to be displayed on packages of smokeless tobacco products would not be affected by these amendments.

Internationally, Canada would join Australia, Brazil and Venezuela, which have already removed the obligation to display toxic emissions values on tobacco product packaging. It should be noted that many countries, including the United States, do not require toxic emissions values to be displayed on tobacco product packaging.

The proposed Regulations would thus amend section 9, as well as clause 13(1)(*c*)(ii)(B), by eliminating the requirement for information on the amount of each toxic emission. Concurrently, the Regulations would also repeal Schedule 1, which describes the official methods for the collection of data on toxic emissions, and the definitions in section 1 for "equivalent unit," "mainstream smoke," "toxic emission" and "unit," which are no longer required.

Coming into force and transition period

The proposed Regulations would come into force upon registration. The coming into force date would be coordinated with the coming into force date for the TPLR-CLC.

The proposed amendments would provide for a transition period of 18 months during which time the current Regulations would continue to apply to packages of tobacco products, other than cigarettes and little cigars, and any accompanying leaflets that are in accordance with that version. For cigarettes and little cigars, transitional provisions in the TPLR-CLC would provide transition periods that would allow manufacturers and retailers to continue to sell packages of those products that display information, in accordance with the current Regulations for six months and nine months respectively after the TPLR-CLC come into force. These provisions would allow tobacco product packages and leaflets that have been printed before the proposed amendment comes into force to be sold through the system.

The Regulations would also provide a second transitional period to allow packages that display health information messages that have been reproduced from the electronic images obtained from the electronic files used to generate the former "source document" to continue to display those health information messages for three years after the Regulations come into force. This provision would allow manufacturers of the tobacco products still covered by the TPIR to coordinate routine packaging changes with the changes required to the health information messages.

Regulatory and non-regulatory options considered

Given the nature and purpose of the proposed amendments to remove the applicability of the TPIR to cigarettes and little cigars when the TPLR-CLC come into force and to correct technical errors identified by the Standing Joint Committee for the Scrutiny of Regulations, no alternatives were considered.

Regarding the numerical toxic emissions information, various requirements have been implemented since 1989. A consultation, held in 2004, proposed new approaches and sought public input on the type of information to be displayed. Further to this consultation, the Department of Health is introducing in the TPLR-CLC text-based statements with easy to understand information about harmful toxic emissions for cigarettes and little cigars. For the tobacco products that would continue to be regulated by the TPIR, the Department believes that the recommendation of the WHO should be followed and that the removal of the obligation to display the numerical toxic emissions values is the most appropriate public health measure to implement. The following alternatives were considered.

(1) Status quo

The toxic emissions information displayed on packages of certain types of smoked tobacco products was originally intended to provide facts to smokers to help them gain a better understanding of the health risks associated with the use of tobacco products. However, in light of the recommendations from the WHO and of research conducted for the Department of Health indicating that many people do not understand the toxic emissions values, it is a reasonable conclusion that those values should be removed while the list of six toxic emissions should remain.

(2) Public education campaign

A public education campaign to explain how to interpret the toxic emissions values was

examined as an alternative. However, this option was not retained given the challenge of explaining the complexity of the smoking process to the general public and considering that the toxic emissions values would still not be reliable as a source of information about individual exposure.

(3) Voluntary removal of toxic emissions values

The voluntary removal of the toxic emissions values by industry is not an option because the inclusion of both the six toxic substances and their corresponding numerical toxic emissions values is a current regulatory requirement.

Benefits and costs

Costs

The amendments to remove the applicability of the TPIR to cigarettes and little cigars when the TPLR-CLC come into force and in response to the Standing Joint Committee for the Scrutiny of Regulations are cost neutral.

While there would be no new costs to the federal government as a result of the proposed Regulations, the tobacco industry would incur costs because of changes required to the packaging of tobacco products, and it could be anticipated that these costs would be passed on to consumers.

Industry costs related to the removal of the obligation to display toxic emissions values

The costs to the tobacco industry associated with the removal of the values from the toxic emissions information have been interpolated from the response of one major cigarette manufacturer to a survey carried out on behalf of the Department of Health in 2006. Taking into account recent changes in tobacco manufacturing in Canada, it was estimated that the one-time costs of removing the toxic emissions values from most smoked tobacco product packaging would have been approximately $1,500,000. The estimate would be much less if limited to those tobacco products that would remain regulated under the TPIR, namely cigarette tobacco, kreteks, leaf tobacco and tobacco sticks. These products comprise a very small portion of the market for tobacco products in Canada.

In addition, inventory-related costs would be mitigated significantly through the provision of an 18-month transition period that would allow tobacco product packages that have been printed before the proposed amendment comes into force to be sold through the system.

Industry costs related to modifications of the health information messages

The amendment of the source document includes minor changes to 5 of the 16 health information messages, 3 affecting both the slide and shell and the leaflet versions, one affecting only the slide and shell version and one affecting only the leaflet version.

From estimates done in 2006, the one-time costs of applying the new requirements to cigarette packages, printed using a rotogravure process to engrave printing cylinders, would have been expected to be less than $500,000. The proposed amendments of the TPIR would remove cigarettes and little cigars from the application of the TPIR. Manufacturers of the remaining tobacco products that would require health information messages, namely cigarette tobacco, kreteks, leaf tobacco and tobacco sticks, use techniques such as lithography or laser printing for printing health information messages. The costs for these manufacturers to change the health information messages, on both packages and leaflets, would be much less than the costs of engraving cylinders.

Furthermore, costs would be further mitigated through the provision of a three-year transition period that would allow packages that display health information messages that have been reproduced from the electronic images obtained from the electronic files used to generate

the former "source document" to continue to display those health information messages. This provision would allow manufacturers of the tobacco products still covered by the TPIR to coordinate routine packaging changes with the changes required to the health information messages.

The maximum total one-time costs for the revisions to the health information messages are expected to be much less than $500,000.

If the additional packaging costs were to be passed on to consumers, the retail price of a package of a tobacco product would be expected to increase by less than 1%.

Benefits

The main health benefits of this proposal are expected to result from the removal of the obligation to display the toxic emissions values on the tobacco products still regulated by the TPIR (cigarette tobacco, kreteks, leaf tobacco and tobacco sticks). This would better align Canadian regulations with current international expert opinion on the provision of information on toxic emissions and remove information from tobacco packaging that may be confusing and not understood by smokers.

Although the health benefits of the proposal are very difficult to quantify and while the health benefits are not expected to be large, nevertheless they may result in reduced health care costs, reduced demand on the health-care system and increased productivity.

The benefits of the proposal are expected to outweigh the costs.

Cost-Benefit Statement		Base Year	Final Year	Total (PV)	Average Annual
A. Quantified impacts ($)					
Costs	Tobacco industry	Less than $2M			
C. Qualitative impacts					
• Remove information from tobacco packaging that may be confusing and is not understood by smokers; • Limit potential that smokers will misinterpret information that may affect their decision to quit smoking and improve their health; and • Better align Canadian regulations with current international expert opinion.					

Rationale

The removal of the obligation to display toxic emissions values would remove information from tobacco packaging that is not understood by smokers. This in turn would mean that smokers will have better information about the chemicals in tobacco smoke and a better understanding of the health risks associated with the use of tobacco products.

The maximum total one-time costs to the tobacco industry for the removal of the numeric values for the toxic emissions and the revisions to the health information messages are expected to be much less than $2,000,000, costs which can be easily recouped through a very small increase in the price of their products.

The benefit of this regulatory proposal to the health of Canadians outweighs the relatively minor economic costs to the tobacco industry.

Consultation

Many of the proposed amendments included in these Regulations were first prepublished in the *Canada Gazette*, Part I, on May 31, 2008. That notice outlined the Department of Health's response to the Standing Joint Committee for the Scrutiny of Regulations and included a

proposed amendment to remove the obligation to list numerical values for toxic emissions on tobacco packaging. However, the proposed TPLR-CLC, which would replace the TPIR with respect to cigarettes and little cigars, would result in significant changes to the scope of the TPIR and has necessitated a new prepublication of the proposed Regulations.

The tobacco industry has been advised that the TPIR would no longer be applicable to cigarettes and little cigars with the coming into force of the TPLR-CLC.

May 2008 prepublication

With respect to the first prepublication, interested persons were invited to provide comments within 75 days of the date of publication of the notice. The Department of Health received nine responses to the proposed Regulations from a variety of stakeholders, including non-governmental organizations (NGOs), the tobacco industry and individual Canadians.

The comments generally fit into six categories: the response to the Standing Joint Committee for the Scrutiny of Regulations, the proposal to remove the obligation to display numerical values in the toxic emissions information, the transition time, the alternatives considered, the benefits and costs and recommendations for future packaging requirements.

Response to the Standing Joint Committee for the Scrutiny of Regulations

Two respondents, one from an NGO and one from industry, commented specifically on the response to the Standing Joint Committee for the Scrutiny of Regulations, with both supporting the recommended changes. However, the industry respondent also expressed concern that the minor amendments proposed for the source document are premature in light of the Department of Health's intention to further amend packaging requirements.

Department of Health's response:

Development of new Health Information Messages is part of the separate TPLR-CLC initiative underway to renew the labelling requirements for cigarettes and little cigars and a new source document will be needed as a result. However, it is anticipated that the new requirements will not be in force before autumn 2011. In the meantime, minor changes to the source document are required to fully respond to the comments made by the Standing Joint Committee for the Scrutiny of Regulations with respect to the *Tobacco Products Information Regulations*. In addition, minor linguistic problems with some of the Health Information Messages had been identified since their introduction, including some identified by the tobacco industry. The Department wants to take the opportunity to fix those problems in concert with the changes needed in the source document to respond to the Standing Joint Committee for the Scrutiny of Regulations. The proposal is unchanged.

Removal of numerical values for toxic emissions from tobacco packaging

While five respondents supported the removal of numerical values for the toxic emissions from tobacco packaging, four (three industry respondents and one individual) opposed the proposal on several grounds. All four emphasized the importance of providing consumers with the ability to compare the levels of toxic emissions in various products. One argued that with the removal of the descriptors "light" and "mild," the presence of the toxic emissions values would be more important in helping smokers identify lower tar products. Two suggested that smokers may switch to higher tar products in the absence of numerical values with which to compare and one respondent expressed concern that the removal of the numerical values may affect the marketability of lower delivery products. Two of the industry respondents suggested that it is the presence of a range of values that creates confusion.

Department of Health's response:

The Department maintains that the removal of the obligation to display toxic emissions values would remove information from tobacco packaging that may be confusing and not understood by smokers and would better align Canadian regulations with international expert

opinion. The proposal is unchanged.

Proposed transition period

Five of the nine respondents commented on the transition period. Two NGOs disagreed with the proposed transition period and recommended a shorter transition. One argued that an 18-month transition does not align with the assertion that tobacco is a "substantial and pressing concern" and that tobacco manufacturers have demonstrated their ability to institute timely changes to packaging in the past, and recommended that the transition period be reduced to six months. The other NGO suggested that, based on past experience in Canada and in other countries, a transition period of 12 months would be more than sufficient. Industry respondents questioned the timing of the proposed amendments, citing knowledge of further planned changes to the TPIR that will affect packaging, and requested that all packaging changes be coordinated so as to require manufacturers to adapt their printing equipment only once. One respondent specifically asked that the TPIR amendments also be coordinated with any changes to the Canada Revenue Agency's excise stamping regime.

Department of Health's response:

The Regulations allow manufacturers to modify their packaging in accordance with the new requirements as soon as the regulations are registered but also provide ample time for tobacco product packages that have been printed before the proposed amendment comes into force to be sold through the system. This transition period is designed to minimize the cost of compliance to industry while allowing the objectives of the amendments to be met.

As previously noted, the addition of a three-year transition period for the display of health information messages would allow manufacturers of the tobacco products still covered by these regulations to coordinate the changes required with routine packaging changes and provisions in the TPLR-CLC for cigarettes and little cigars would provide transition periods to allow tobacco product packages and leaflets that have been printed before the proposed amendment comes into force to be sold through the system.

The Department continues to work with the Canada Revenue Agency to ensure that packaging changes are coordinated.

Alternatives considered

Two respondents expressed dissatisfaction with the alternatives considered. One NGO respondent argued that not only do Canadians not understand the numerical values, there is solid evidence that Canadians do not understand the term "toxic emissions," the health repercussions of the exposure to toxins, nor the fact that these toxins are consumed by inhaling tobacco smoke and suggested that a mass media campaign is needed to address these issues. Industry respondents commented that it is the range of values that confuses smokers and that the range should be eliminated in favour of returning to a single ISO standard value, thus allowing for the use of the information as a "navigational tool" for smokers to compare various products.

Department of Health's response:

As stated elsewhere in this RIAS and the RIAS that accompanied the first prepublication in the *Canada Gazette*, Part I, a public education campaign was not retained as a viable option because of the challenge of explaining the complexity of the smoking process to the general public and because international experts have recommended that no numerical ratings be displayed for toxic emissions. The proposal is unchanged.

Benefits and costs

Four respondents commented on the benefits and costs. The Department of Health had estimated that the costs related to modification of the health information messages would be less than $150,000 and that the costs related to the removal of the obligation to display toxic

emissions values would be approximately $9,300,000. One industry respondent provided specific estimates of the cost of the proposed regulations. It estimated the cost for that company to implement the amendments to the health information messages to be approximately $150,000 and the cost to remove the numeric toxic emissions values to be approximately $500,000.

Department of Health's response:

The Department had already determined that the original cost estimates in the Regulatory Impact Analysis Statement needed some revision. The costs related to modification of the health information messages had been underestimated while the costs to remove the numeric toxic emissions values had been overestimated. The Department agrees that the estimates provided by the industry respondent are more accurate and has taken into account that cigarettes and little cigars will no longer be regulated under the TPIR. The cost estimates have been modified accordingly.

Future packaging requirements

Several recommendations were made for future packaging requirements, mostly by NGOs. These recommendations included prohibiting the printing of all toxic emissions values on tobacco product packaging, replacing the list of six toxic emissions by hard-hitting text messages and plain packaging.

Department of Health's response:

The Department will consider these recommendations and all others in any future regulatory initiatives concerned with labelling or packaging.

August 2004 consultation document

A public consultation paper titled "Building on Success: A Proposal for New Health-related Information on Tobacco Product Labels" was released in August 2004 and widely disseminated through a mailing to the tobacco industry, non-governmental organizations, public interest groups, professional organizations and others, as well as through posting on the Health Canada Web site. This paper included a proposal to replace the current toxic emissions information with a series of statements that would present clear and concise information about the toxicity of each of eight substances found in tobacco smoke (six substances are mentioned presently), including its health effect and its range of toxic emissions values. It was suggested in the proposal that these statements could be equally distributed amongst tobacco product packaging.

Respondents from non-governmental and governmental organizations supported the proposal, with four recommending that the range of toxic emissions values be removed. Respondents from the tobacco industry generally neither supported nor opposed the proposal although they emphasized that the information should be objective and fairly presented.

Further to this consultation, the Department of Health has continued its comprehensive review of the requirements for information on toxic emissions; this proposed amendment is one step. Tobacco manufacturers were advised of the proposed amendments with respect to the toxic emissions information in face-to-face meetings in 2006 with Department of Health management and offered no written comments. Changes to the toxic emissions information requirements for packages of cigarettes and little cigars will appear in the proposed TPLR-CLC.

Implementation, enforcement and service standards

Compliance with these requirements would be monitored through inspections at the retail and manufacturing/importing levels that would be undertaken to ensure that all changes, including those affecting the toxic emissions values, have been made in accordance with these amendments, taking into account the transitional period.

Contact

Interested parties are invited to seek further information on this proposal, by writing to

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

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to sections 17 and 33 (see footnote a) of the *Tobacco Act* (see footnote b), proposes to make the annexed *Regulations Amending the Tobacco Products Information Regulations*.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to the Manager, Office of Regulations and Compliance, Controlled Substances and Tobacco Directorate, Healthy Environments and Consumer Safety Branch, Health Canada, MacDonald Building, Address Locator: 3507C1, 123 Slater Street, Ottawa, Ontario K1A 0K9 (fax: 613-941-1551; email: pregs@hc-sc.gc.ca).

Ottawa, February 3, 2011

JURICA ČAPKUN
Assistant Clerk of the Privy Council

REGULATIONS AMENDING THE TOBACCO PRODUCTS INFORMATION REGULATIONS

AMENDMENTS

1. (1) The definitions "cigarette", "equivalent unit", "mainstream smoke", "toxic emission" and "unit" in section 1 of the *Tobacco Products Information Regulations* (see footnote 1) are repealed.

(2) The definitions "cigar", "health information", "manufacturer", "slide" and "source document" in section 1 of the Regulations are replaced by the following:

"cigar"
« *cigare* »

"cigar" means a roll or tubular construction, other than a little cigar, intended for smoking, that contains a filler composed of natural or reconstituted tobacco and has a wrapper, or a wrapper and a binder, composed of natural or reconstituted tobacco.

"health information"
« *information de santé* »

"health information" means the information set out in Part 4 of the source document, but does not include the attribution of that information to its source as provided for in subsection 4(1).

"manufacturer"
« *fabricant* »

"manufacturer" does not include an individual or an 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 *Health Warnings and Information for Tobacco Products*, published by the Department of Health, dated May 12, 2000, as amended on March 30, 2007.

(3) Paragraph (*a*) of the definition "kit" in section 1 of the Regulations is repealed.

(4) Paragraph (*a*) of the definition "health warning" in section 1 of the Regulations is replaced by the following:

(*a*) in respect of cigarette tobacco, kreteks, leaf tobacco and tobacco sticks, the warnings that are set out in Part 1 of the source document;

(5) The definition "health warning" in section 1 of the Regulations is amended by striking out "and" at the end of paragraph (*b*), by adding "and" at the end of paragraph (*c*) and by adding the following after paragraph (*c*):

(*d*) in respect of bidis, chewing tobacco and snuff, the warnings that are set out in subsections 5(4) to (6).

This definition does not include the attribution of those warnings to their source as provided for in subsection 4(1).

(6) The portion of paragraph (*a*) of the definition "type of package" in section 1 of the Regulations before subparagraph (i) is replaced by the following:

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

(7) Paragraph (*a*) of the definition "type of package" in section 1 of the Regulations is amended by adding the following after subparagraph (i):

(i.1) slide and shell package with a lateral slide,

(8) Section 1 of the Regulations is amended by adding the following in alphabetical order:

"identical products"
« *produits identiques* »

"identical products" means tobacco products that

(*a*) contain identical ingredients;

(*b*) are manufactured in an identical manner;

(*c*) have identical dimensions; and

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

2. Section 2 of the Regulations is replaced by the following:

Retail sale

2. These Regulations apply to every package of tobacco products, other than cigarettes as defined in section 1 of the *Tobacco Products Labelling Regulations (Cigarettes and Little Cigars)* and little cigars, that is intended for retail sale.

3. Subsection 3(1) of the French version of the Regulations is amended by the following:

Lisibilité des renseignements écrits

3. (1) Les renseignements écrits à fournir en application du présent règlement sont, à la fois :

a) présentés dans les deux langues officielles, de la même façon;

b) lisibles et bien en évidence.

4. Section 4 of the Regulations is replaced by the following:

Attribution

4. (1) If a manufacturer attributes health warnings or health information that in accordance with these Regulations must be displayed, the manufacturer shall do so by displaying only the phrase "Health Canada" under the English health warning or health information and the phrase "Santé Canada" under the French health warning or health information. The attribution, which is contained in the electronic files referred to in paragraph 3(2)(*a*), shall be displayed in the same colour as the text of the health warning or health information and in Universal type in a pitch that is not greater than the smallest pitch used in the attributed health warning or health information.

Removal of attribution

(2) Every manufacturer that does not attribute a health warning or health information may remove the attribution contained in the electronic files referred to in paragraph 3(2)(*a*).

5. (1) Subsection 5(1) of the Regulations is replaced by the following:

Obligation to display

5. (1) Subject to subsections (4) to (6), every manufacturer of bidis, chewing tobacco, cigarette tobacco, kreteks, leaf tobacco, pipe tobacco — other than pipe tobacco described in section 6 —, snuff or tobacco sticks shall display the applicable health warnings for the tobacco product on every package of the tobacco product that it manufactures, in accordance with this section.

(2) Paragraph 5(2)(*d*) of the Regulations is replaced by the following:

(*d*) be selected, except in the case of bidis, chewing tobacco and snuff, from the formats that are set out in the source document for each health warning and based on the shape of the space as determined in accordance with paragraph (*b*).

(3) The portion of subsection 5(7) of the Regulations before paragraph (*b*) is replaced by the following:

Equal display

(7) Every manufacturer shall, in respect of each type of package of each brand of a tobacco product that the manufacturer packages in a year, display each applicable health warning

(*a*) in the case of cigarette tobacco, kreteks, leaf tobacco and tobacco sticks, on between 3.25% and 9.25% of those tobacco products; and

6. Section 6 of the Regulations is replaced by the following:

Pipe tobacco and cigars

6. (1) Every manufacturer of pipe tobacco contained in a pouch or cigars contained in a box shall display, on only one side of the pouch or box, one of the bilingual health warnings set out in Part 3 of the source document such that the warning is not severed when the pouch or box is opened, as follows:

(*a*) if the side on which the warning is displayed is less than or equal to 149 cm^2, using a warning of at least 20 cm^2 with the width of the warning measuring not less than 4 cm; and

(*b*) if the side on which the warning is displayed is greater than 149 cm^2, using a warning placed on any side of the package other than the bottom, of at least 40 cm^2 with the width of the warning measuring not less than 4 cm.

Cigars in bundles

(2) Every manufacturer of cigars contained in a bundle shall display anywhere on the bundle, other than the top and bottom surfaces, one of the bilingual health warnings set out in Part 3 of the source document such that the warning is at least 40 cm^2 with the width of the warning measuring not less than 4 cm.

7. (1) The portion of subsection 7(1) of the Regulations before paragraph (*a*) is replaced by the following:

Display

7. (1) Every manufacturer of cigarette tobacco — other than cigarette tobacco contained in a pouch —, kreteks, leaf tobacco or tobacco sticks shall display health information in the following manner:

(2) The portion of paragraph 7(1)(*a*) of the French version of the Regulations before subparagraph (ii) is replaced by the following:

a) dans le cas de tout emballage, à l'exception d'un paquet à coulisse ou d'un pot :

(i) soit en un endroit quelconque de l'emballage, à l'exception de la principale surface exposée et du dessous, de façon que les versions française et anglaise soient côte à côte, qu'elles soient centrées et qu'ensemble, elles occupent de 60 % à 70 % de la surface du côté utilisé,

(3) The portion of paragraph 7(1)(*b*) of the French version of the Regulations before subparagraph (i) is replaced by the following:

b) dans le cas d'un paquet à coulisse :

(4) Subsection 7(3) of the Regulations is replaced by the following:

Equal display

(3) Every manufacturer shall, in respect of each type of package of each brand of a tobacco product specified in subsection (1) that the manufacturer packages in a year, display each message on between 3.25% and 9.25% of those tobacco products.

8. Sections 8 and 9 of the Regulations are replaced by the following:

Test methods

8. (1) Section 4 and subsections 12(4), (5) and (6) of the *Tobacco Reporting Regulations* apply to the testing of a tobacco product for the purpose of obtaining information that is to be displayed in accordance with section 10 of these Regulations.

Exception

(2) A manufacturer is not required to perform the tests in respect of a particular brand of tobacco product if the manufacturer

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

(*b*) performs the tests in respect of another of those brands of identical products (in this subsection referred to as the "reference brand");

(*c*) displays, in accordance with section 10, on the packages of the reference brand the information obtained from the tests described in paragraph (*b*); and

(*d*) displays, in accordance with section 10, the same information on the packages of all of the other brands of identical products, including the particular brand.

Toxic emissions

9. Every manufacturer of cigarette tobacco, kreteks, leaf tobacco and tobacco sticks shall display on every package, other than a carton, kit or wrapper, of those tobacco products the texts "Some of the toxic emissions: Tar, Nicotine, Carbon monoxide, Formaldehyde, Hydrogen cyanide, Benzene" and "Quelques-unes des émissions toxiques : goudron, nicotine, monoxyde de carbone, formaldéhyde, acide cyanhydrique, benzène" such that those texts are one under the other.

9. (1) The marginal note to section 11 of the English version of the Regulations is replaced by "Placement, presentation and expression."

(2) Paragraph 11(*b*) of the Regulations is replaced by the following:

(*b*) in Helvetica bold type in black characters of 10 points on a white background, or, if it is impossible to display the information without occupying more than 70% of the area in which it is to be displayed, in a pitch that results in the information occupying not less than 60% of that area; and

10. The heading before section 12 of the French version of the Regulations is replaced by the following:

PAQUETS À COULISSE

11. (1) Subsection 12(1) of the Regulations is replaced by the following:

Texts to be displayed

12. (1) Every manufacturer of bidis, kreteks or tobacco sticks contained in slide and shell packages shall, in accordance with this section, display on the upper slide-flap, the health information that is set out for that purpose in Part 4 of the source document.

(2) Subsection 12(3) of the Regulations is replaced by the following:

Equal display

(3) Every manufacturer shall, in respect of each brand of a tobacco product specified in subsection (1) that the manufacturer packages in a year, display each message on between 3.25% and 9.25% of those tobacco products.

(3) Subsection 12(4) of the Regulations is replaced by the following:

Definition of "upper slide-flap"

(4) In this section, "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 product.

12. (1) The portion of subsection 13(1) of the French version of the Regulations before paragraph (*a*) is replaced by the following:

Renseignements

13. (1) Le fabricant d'un produit du tabac contenu dans une cartouche ou une trousse doit, en plus des renseignements qui doivent par ailleurs figurer sur chaque emballage, faire figurer sur la cartouche ou la trousse les renseignements suivants :

(2) Clause 13(1)(*c*)(ii)(B) of the Regulations is replaced by the following:

(B) in any other case except bidis, the texts "Some of the toxic emissions: Tar, Nicotine, Carbon monoxide, Formaldehyde, Hydrogen cyanide, Benzene" and "Quelques-unes des émissions toxiques : goudron, nicotine, monoxyde de carbone, formaldéhyde, acide cyanhydrique, benzène".

13. Schedule 1 to the Regulations is repealed.

TRANSITIONAL

14. (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) In this section, "former source document" means the document defined as "source document" in section 1 of the former Regulations.

(3) Despite these Regulations, if a package of a tobacco product, other than cigarettes or little cigars, or any accompanying leaflet displays information in accordance with the former Regulations, the former Regulations continue to apply to the package or the leaflet until the day that is 18 months after the day on which these Regulations come into force. However, if a package of a tobacco product displays one of the health information messages reproduced from the electronic images obtained from the electronic files used by the Minister to generate the former source document, the manufacturer may continue to display that message until the day that is three years after the day on which these Regulations come into force.

COMING INTO FORCE

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

[8-1-o]

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

Footnote b
S.C. 1997, c. 13

Footnote 1
SOR/2000-272

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).

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