TobReg

Best Practices in Tobacco Control

Regulation of Tobacco Products
Canada Report

WHO Study Group on
Tobacco Product Regulation
(TobReg)

World Health Organization

Tobacco Free Initiative

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Preface

Fundamental to disease control is the accurate communication of the nature of agents that cause disease, since such knowledge better empowers people to reduce their risk of exposure to those agents. Examples include information about the role of mosquitoes in malaria, the nature and transmission of HIV in AIDS, and the importance of the caloric content of food in avoiding obesity. Since the mid-twentieth century, diseases caused by tobacco have been understood to be related to the nature of the tobacco product and the risk of disease has been known to be directly related to the amount of tobacco product toxicants consumed. Yet, at the dawn of the twenty-first century, conclusive evidence has emerged that the two most widely promulgated systems for communicating the nature and amount of toxicants in tobacco products are misleading and do not provide useful guidance to minimize toxicant exposure for those who are unable to cease their tobacco use. These two systems are the nearly identical cigarette-testing protocols of the International Organization for Standardization (ISO) and the United States Federal Trade Commission (FTC).[1]

The World Health Organization (WHO) has begun the process of addressing this critical communications gap through the identification of best practices in tobacco product regulation that have been initiated in various countries. Canada, one of the first 40 Contracting Parties to the WHO Framework Convention on Tobacco Control, has been identified by the WHO Tobacco Free Initiative and the WHO Study Group on Tobacco Product Regulation as having one of the best regimes for tobacco product regulation.

The regulation of tobacco products is encompassed within a set of provisions contained in Articles 9, 10, and 11 of the Framework Convention that are targeted at the regulation of the manufacture and distribution of tobacco products. The scientific basis for the principles guiding the implementation of Articles 9 and 10 establishes the rationale for the principles guiding the implementation of Article 11. For this reason, and in order to achieve the synergistic effect of these provisions, all three articles should be treated as a single set of interrelated and mutually reinforcing regulations. As in the case of Canada, and as discussed in this report, the regulatory authority for tobacco products should be delegated to a specialized agency within a ministry or department of government to

[1] There are no widely used protocols for testing and communicating the toxicants of tobacco products other than cigarettes.

address such matters as issuing and enforcing the regulations that require manufacturers and distributors: (i) to test the contents and emissions of tobacco products on a periodic basis (Article 9); (ii) to disclose, on a periodic basis and according to a specified format, not only the results of the tests based on a per mg of tar or nicotine, but also all the other characteristics of the tobacco product, such as paper porosity and moisture content[2] (Article 10); and (iii) to label and package tobacco products with large, clear health warnings and informational messages, using rotating messages developed by national authorities, and without the use of misleading health claims (Article 11).

The Tobacco Free Initiative hopes that those Contracting Parties to the Framework Convention and other WHO Member States that are looking for lessons learnt and best practices in the area of tobacco product regulation will glean some invaluable insights from Canada's experience that could inspire them to formulate policies and then subsequently issue and stringently enforce meaningful and effective regulations on the manufacture and distribution of tobacco products. It should also be noted that, as countries craft the language of their tobacco product regulations, it is critical to bear in mind not only that the drafting has to be such that potential loopholes are pre-empted, but also that allowance has to be made for the regular revision of the regulations to take into account new knowledge about any tobacco product or its modified or re-engineered version.

[2] For a complete list of tobacco-product characteristics that should be disclosed, see WHO Study Group on Tobacco Product Regulation (TobReg) Recommendation 1: Guiding principles for the development of tobacco- product research and testing capacity and proposed protocols for the initiation of tobacco- product testing. Geneva, World Health Organization, 2004.

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Regulation of Tobacco Products
Canada Report

1. Introduction

Tobacco control in Canada is a major public health success story, but it remains an unfinished achievement. Smoking is still the number one preventable cause of premature death in Canada. In the next year, it will claim more than 45 000 lives. In 2004, according to the findings of the Canadian Tobacco Use Monitoring Survey, about one in five Canadians (20%), 15 years of age and older, were daily (15%) or occasional (5%) smokers; that is just over 5 million Canadians. This represents more than a 50% decline in smoking prevalence since the mid-1960s.

About 800 farmers now supply the majority of tobacco that goes into Canadian-made cigarettes, although the use of foreign tobacco is significant and increasing. Over 99% of cigarettes sold in Canada are made from flue-cured tobacco. The manufactured cigarette market is supplied by a dozen of manufacturers, with the three largest ones controlling more than 90%; Imperial Tobacco Canada (a British American Tobacco subsidiary) alone controls 60% of that market.

Canada has a very small pipe tobacco and cigar market, although the sale of flavoured little cigars has recently been increasing. Smokeless tobacco amounts to less than 1% of the total tobacco market.

Public education about the risks of smoking began in the early 1960s in Canada. Since 1986, Canada has adopted a more comprehensive approach, implementing a series of tobacco control strategies encompassing policy development, legislation and regulations, enforcement, mass media campaigns, community action, capacity-building and public education, supported by taxation policies. These strategies were implemented by the federal and provincial/territorial governments, in conjunction with non-governmental organizations (NGOs). The outcome of these tobacco control strategies is difficult to attribute to individual measures adopted within those strategies.

The *National Strategy on Tobacco Control* was adopted in 1999 by agreement between federal and provincial/territorial levels of government, in collaboration with NGOs. A number of jurisdictions have since renewed their strategies, including the federal government, which launched in 2001

the *Federal Tobacco Control Strategy*, its fifth initiative since the mid-1980s.
The *Federal Tobacco Control Strategy* establishes a framework for a comprehensive, fully integrated, and multi-faceted approach to tobacco control. It focuses on four mutually reinforcing components: protection, prevention, cessation and harm reduction.

The federal *Tobacco Act*, adopted in 1997, regulates the manufacture, sale, labelling and promotion of tobacco products in Canada. Under this act, two important sets of regulations were established in 2000: the *Tobacco Products Information Regulations* and the *Tobacco Reporting Regulations*. Provincial laws also regulate, to varying degrees, the sale and promotion of tobacco products.

Canadian tobacco laws and regulations are under continuous legal challenge from the tobacco industry, requiring extensive litigation support. In 2002, the federal *Tobacco Act* was upheld by lower courts; the matter was under appeal. The appeal was heard by the Quebec Court of Appeal in November 2004. On August 22, 2005, the Quebec Court of Appeal upheld the vast majority of the provisions of the *Tobacco Act*, as well as all the provisions of the Tobacco Reporting Regulations and the Tobacco Products Information Regulations. The main effect of this decision is to allow the use of corporate names, unless they refer to, or include, tobacco-related brand names, in tobacco sponsorship promotions, and on permanent facilities. Either side could now seek to appeal the decision to the Supreme Court of Canada.

Canada ratified the WHO Framework Convention on Tobacco Control on November 26, 2004, after having played an active role throughout its negotiation.

2. Protection from exposure to tobacco smoke

The federal *Non-Smoker's Health Act* (NSHA) is the relevant legislation governing smoking in federally regulated workplaces. Under this act, the federal government has banned smoking from federal public service workplaces and restricted it in all other workplaces under federal jurisdiction, as well as on inter-provincial transport. The NSHA includes limited provisions of designated smoking rooms (DSRs) in some special circumstances. Currently, there are no DSRs on any railways in Canada and the prison system is undertaking consultations to determine the feasibility of eliminating smoking from federal correctional institutions. Protection from

exposure to environmental tobacco smoke in most workplaces and enclosed public places is generally regulated by provincial laws or municipal by-laws.

All of Canada's ten provinces and three territories have implemented some level of protection from exposure to tobacco smoke in workplaces and enclosed public places, which protects varying percentages of their populations. Nine provinces have put in place specific legislation to restrict smoking, one province and two territories use Workers' Compensation Board regulations, and one territory relies on a government policy. While three provinces and two territories have extended their total ban on smoking to restaurants and bars, five provinces still permit either designated smoking rooms or designated smoking areas, and two provinces have exempt them. Of the five provinces that still permit either designated smoking rooms or designated smoking areas, the two largest ones (Ontario and Quebec) have announced plans for smoke-free legislation extending equally to restaurants and bars that would take effect in 2006.

3. Regulation of the contents of tobacco products

The *Tobacco Act* provides the federal government with authority to regulate the manufacture of tobacco products, including the establishment of standards for ingredients. Currently, the only requirement pertaining to this authority is an ignition propensity standard that will apply by October 1, 2005 to all cigarettes sold in Canada. There are no regulations regarding the contents of tobacco products.

Research and science activities are conducted to assess the tobacco products on the Canadian market in terms of their physical, chemical and toxicological properties. Developing this knowledge is expected to contribute to the *Federal Tobacco Control Strategy*'s harm-reduction component and the government's exploration of product modification issues.

4. Regulation of tobacco products disclosures

4.1 Description

The *Tobacco Reporting Regulations*, made pursuant to the *Tobacco Act*, require manufacturers and importers of tobacco products in Canada to submit to the Minister of Health a number of detailed reports on their

tobacco products, including information on product composition and their emissions.

Tobacco product manufacturers and importers must supply monthly, quarterly, semi-annual or annual reports containing the following information:

- For cigarettes, cigarette tobacco, leaf tobacco, pipe tobacco, cigars, tobacco sticks, kreteks, bidis and smokeless tobacco:

  - information on all aspects of the products, including the tobaccos and other constituents or ingredients used in the manufacturing process, and the papers, tubes and filters. In addition, manufacturers must report all information on the ingredients, constituents and performance specifications of these products;

  - information on more than 20 constituents[3] of whole/unburned tobacco;

  - information on sales;

  - information on product packaging; and

  - information on research projects undertaken by or on behalf of a manufacturer; applicable studies include those that examine the toxicity and health effects of tobacco products, their taste and flavour, the modification and development of tobacco products, and the ingredients in tobacco products.

- For cigarettes, cigarette tobacco, leaf tobacco, tobacco sticks, and kreteks only:

[3] Constituents (unburned tobacco): Nicotine, Nornicotine , Anabasine,, Anatabine, Ammonia, , Propylene glycol, Triethylene glycol, Nickel, Lead, , Chromium, Arsenic, Selenium, Mercury, Benzo[a]pyrene, Nitrate, N-nitrosonornicotine, 4-(N-nitrosomethylamino)-l-(3-pyridyl)-1-butanone, N-nitrosoanatabine, N-nitrosoanabasine, Triacetin, Sodium propionate, Sorbic acid, and Eugenol [2- Methoxy-4-(2-propenyl)-phenol].

- information on more than 40 toxic emissions in both mainstream4 and sidestream smoke,5 under two smoking regimens (ISO regular, and a modified ISO).

The regulations specify the method that applies for each analysis (either a Health Canada Official Method, an ISO standard or an ISO standard modified by Health Canada).

Health Canada does not maintain any government laboratories to perform the analyses required under these regulations. Independent private laboratories perform the analytical work at the request of manufacturers. However, the regulations stipulate that any laboratory that performs an analysis must be accredited under ISO standard 17025.

Health Canada's Tobacco Control Programme is staffed in part by scientists. They guide the development of test methods, as well as conduct the analysis of the test results received from industry. The Tobacco Control Programme also operates a compliance-monitoring program, with inspectors visiting importers' and manufacturers' plants.

Health Canada is, because of its regulatory function, in regular dialogue with the tobacco industry.

4.2 Steps of implementation

The *Tobacco Reporting Regulations* were preceded by the *Tobacco Products Control Regulations* in 1989. The latter required limited information on product composition and sales. Based on the experience gathered since 1989, a new set of requirements was developed and a consultation paper released in 1998. This paper sought public input on the development of more extensive regulations in order to gain a better

[4] Emissions from mainstream smoke: Ammonia, 1-aminonaphthalene, 2-aminonaphthalene, 3-amonobiphenyl, 4-aminobiphenyl, Benzo[a]pyrene, Formaldehyde, Acetaldehyde, Acetone, Acrolein, Propionaldehyde, Crotonaldehyde, Butyraldehyde, Eugenol [2- Methoxy-4-(2-propenyl)-phenol], Hydrogen cyanide, Mercury, Lead, Cadmium, NO, Nox, N-nitrosonornicotine, 4-(N-nitrosomethylamino)- 1-(3-pyridyl)-1-butanone, N-nitrosoanatabine, N - nitrosoanabasine, Pyridine, Quinoline, Styrene, Hydroquinone, Resorcinol, Cathecol, Phenol, m+p-Cresol, o-Cresol, Tar, Nicotine, Carbon Monoxide, 1,3 Butadiene, Isoprene, Acrylonitrile, Benzene, and Toluene.

[5] Emissions from sidestream smoke: Same as above, minus Eugenol.

knowledge of tobacco products, which in turn would better inform policy development. The *Tobacco Reporting Regulations* were adopted in June 2000.

4.3 Success of the intervention

These regulations are meeting for the most part their main objective of providing Health Canada with timely, relevant information on tobacco products.

4.4 Other impacts of the intervention

With the coming into force of the *Tobacco Reporting Regulations*, a small number of foreign cigarette manufacturers halted exports of their products to Canada, presumably to avoid disclosing to government authorities the ingredients and additives contained in their products.

5. Packaging and Labelling of tobacco products

5.1 Description

The *Tobacco Products Information Regulations*, made pursuant to the *Tobacco Act*, require that tobacco product packaging display health warnings, informative and smoking cessation messages, and statements about toxic emissions or constituents, in a way that is easily legible, in the same manner in both official languages and, where specified, in colour.

Health Warnings

Canada's health warning requirements have become the standard best practice globally and have inspired other countries to require similar types of highly salient warnings on all tobacco products. The regulations require that manufacturers and importers ensure that every package of cigarettes, tobacco sticks, cigarette tobacco, leaf tobacco, kreteks, and pipe tobacco, other than pipe tobacco sold in a pouch, display one of 16 prescribed colour health warnings, consisting of a picture, or graphic, and text. With the exception of cigars and pipe tobacco, this health warning must occupy 50 percent of the principal display surface of the package. Packages of pipe tobacco and cigars must display one of four colour health warnings, also consisting of a picture and text. In the case of smokeless tobacco and bidis, manufacturers and importers must display one of four text-only health

warnings. All health warnings must be displayed equally in respect of each brand.

Health information

Every manufacturer or importer of cigarettes, tobacco sticks, cigarette tobacco, leaf tobacco or kreteks must also display a smoking cessation message or a disease information message. For "slide and shell" packages (the majority of cigarette packs sold in Canada are of the "slide and shell" type), this message must be displayed on the back of the slide or on a leaflet. For all other packages (with the exception of soft packs), a leaflet displaying the message must be provided. These messages must be displayed equally in respect of each brand.

Toxic emissions and constituents

The amount of six emissions (tar, nicotine, carbon monoxide, benzene, hydrogen cyanide and formaldehyde) in the smoke of cigarettes, kreteks, tobacco sticks, cigarette tobacco and leaf tobacco must be displayed on a side of the package. These amounts must be shown as a range, as determined by calculations of the means from smoking machine measurements under regular ISO conditions and under modified ISO conditions,[6] next to the statement "Toxic emissions/unit" or "Toxic

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[6] In this modified ISO protocol, puff volume is increased from 35 ml to 55 ml; puff interval is decreased from 60 s to 30 s, and all ventilation holes must be blocked by placing over them a strip of Mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape. These modified ISO conditions is what the WHO Study Group on Tobacco Product Regulation (TobReg) adopted in its recommendation (see footnote 1) and refers to as the intense machine smoking regime/protocol. In order to obtain maximum smoke yields, by having ventilation holes fully blocked, Canada amended its regulation subsection 14(6), in Part 3 of their Tobacco Reporting Regulations (made pursuant to the Tobacco Act) to read:

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

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

b) the conditions referred to in paragraph (a), but modified in the following manner:
i) puff volume must be increased from 35 mL to 55 mL,
ii) puff interval must be decreased from 60 s to 30 s, and
iii) all ventilation holes must be blocked by placing over them a

emissions/gram." Consumers are thereby able to compare brands more realistically and see that any differences in yields from different brands are negligible.

Information about three toxic constituents (nicotine, lead, nitrosamines) in smokeless tobacco must be displayed on a side or the bottom of the package. Single values are shown for all three constituents next to "Toxic constituents/gram."

5.2 Steps of implementation

The progress made in the labelling of tobacco products in Canada is the fruit of experimentation and public opinion research since the mid-1970s. Before 1989, labelling of tobacco products was the result of a voluntary process based on informal discussions between the tobacco industry and the federal government. Some manufacturers did display a health warning message, though it was often barely visible, as well as information on the average tar and nicotine yields per cigarette.

The 1989 *Tobacco Products Control Act* gave the government authority to regulate labelling. Under the *Tobacco Products Control Regulations*, four warning messages were designed and used; they had to occupy 20% of the principal display surface of the package. There was also a requirement that information on tar, nicotine and carbon monoxide yields in smoke be displayed on the side panel of the package. These regulations were amended in September 1994 to include four additional warnings. The eight warnings then had to occupy 25% of the principal display surface of the package, in either black on white, or white on black, and had to be surrounded by a border.

The Supreme Court of Canada, on September 21, 1995, ruled that, although the government was justified in making it mandatory for tobacco companies to display messages on tobacco product packages, it must allow them to attribute those messages to the government. This decision made the relevant

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strip of Mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape, and the tape must be cut so that it covers the circumference and is tightly secured from the end of the filter to the tipping overwrap seam, or by another method of equivalent efficiency."

As a result, Canada now requires manufacturers to use two smoking regimes, but still using the same ISO method -- old ISO/FTC and the modified (intense regime) ISO. They simply had to specify the changes in their regulations

provisions inoperative, although most manufacturers continued to display the same eight warnings.

Development of new warnings was initiated in 1996 with considerable public opinion research. The design of new, pictorial health warnings started in 1999. The display of these new warnings was required under the *Tobacco Products Information Regulations*, which took gradually effect, beginning in December 2000.

5.3 Success of the intervention

These regulations are a key element in education on tobacco use. Research has shown that people who use tobacco products regard the package as an important source of information and that the display of important facts on the package directly assists users in their decision not to smoke.

Evaluation of the health warnings 18 months after their introduction shows that smokers use them as a source of information about the impact of smoking on health and as a tool to increase their desire to quit smoking. In fact:

- More than seven in ten adult smokers and almost nine in ten youth smokers say health warnings are effective at informing them about tobacco-related health effects
- More than half of adults and youth say the messages compel them to smoke less around other people
- More than four in ten adults say that the new health warnings have been effective in getting them to try to quit smoking.

Canadians have indicated widespread support for the health warnings on cigarette packages. Most of them see the warnings as an accurate and important source of information. Moreover, most youth and adult smokers say the messages make smoking less attractive. Almost all Canadians have seen the current health warnings even though less than one-half of smokers say they read them every day. Only eighteen per cent of adult smokers say they never look at or read the warnings, while only 7% of youth smokers aged 12 to 18 years say they never look at the messages.

6. Tobacco advertising, promotion and sponsorship

6.1 Description

Advertising

Under the *Tobacco Act*, tobacco product advertising is permitted if it is "information" or "brand-preference" advertising and is:

- in a publication that is provided by mail and addressed to an adult who is identified by name;
- in a publication that has an adult readership of not less than 85%; or
- on signs in a place where young persons are not permitted by law.

Advertising that could be construed on reasonable grounds to be appealing to young persons and "lifestyle" advertising[7] are not permitted. With some exceptions, foreign publications and broadcasts are exempt from these restrictions.

Promotion

The *Tobacco Act* limits tobacco-related promotional activities. The act prohibits promotion of a tobacco product by means of a testimonial or endorsement, however displayed or communicated, including by means of the packaging. Depiction of a person, character or animal, whether real or fictional, is considered to be a testimonial for, or an endorsement of, the product.

Information is permitted as long as it is not false, misleading or deceptive, or likely to create an erroneous impression about the product or its emissions.

Sales promotions are also restricted. For example, manufacturers and retailers are prohibited from furnishing a tobacco product for free or in consideration of the purchase of a product or service or the performance of a service. They are not allowed either to offer or provide any gift, bonus,

[7] "Lifestyle advertising" is advertising that associates a product with, or evokes a positive or negative emotion about or image of, a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring.

premium, cash rebate or right to participate in a game, lottery or contest, to a purchaser, for the purchase of a tobacco product.

Sponsorship promotion

Since October 1, 2003, no person may display a tobacco product-related brand element or the name of a tobacco manufacturer in a promotion that is used, directly or indirectly, in the sponsorship of a person, entity, event, activity or permanent facility.

6.2 Steps of implementation

In 1995, the Supreme Court of Canada concluded that a total ban on tobacco product advertising was a violation of the tobacco manufacturers' freedom of expression and was not justified in a free and democratic society.

The *Tobacco Act*, adopted in 1997, does not ban tobacco product promotion in Canada, but it does restrict it, following the advice provided by the Supreme Court of Canada in its 1995 ruling.

6.3 Success of the intervention

The stated purpose of promotion restrictions under the *Tobacco Act* is to protect young persons, and others, from inducements to use tobacco products. Currently, youth smoking prevalence is at the lowest level ever reported by national surveys (18%), but this success cannot be attributed to this intervention alone. Further, prevalence of young adult smoking remains high (28%) and is an ongoing source of policy concern.

6.4 Other impacts of the intervention

Since 1997, there has been very little advertising of tobacco products by the tobacco industry, although advertising is still permitted.

This issue continues to be at the core of litigation opposing the federal government and the tobacco industry since 1988.

7. Fees for tobacco brand registration

This is not in the Canadian tobacco regulations, although some countries, such as Brazil, charge tobacco manufacturers and distributors a per brand per year registration fee.

8. Conclusion

Tobacco product regulation is an integral part of comprehensive tobacco control strategies in Canada. The contribution of such regulation to the overall effectiveness of these strategies is expected to grow as policy- and decision-makers gain better knowledge of tobacco products.

To view the actual language of the Canadian regulations cited in this paper, visit www.hc-sc.gc.ca/hl-vs/tobac-tabac/legislation/reg/index_e.html.