Developing Legislation for Tobacco Control

Template and Guidelines



Celebrating 100 Years of Health

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May 2002

FOREWORD

In October 2000, PAHO Member States joined with other WHO Member States to begin negotiations on the Framework Convention on Tobacco Control (FCTC), a WHO-sponsored international treaty on tobacco control. If a strong FCTC is ratified by WHO Member States at the World Health Assembly in May 2003, as planned, the efforts by governments around the world to reduce the scourge of tobacco will have received a strong boost.

However, even independent of the FCTC process, the evidence accumulated over the past several decades makes a compelling case for the need for governments to regulate tobacco products. Tobacco products kill one-half of all long-term users, including more than one million people annually in the Americas. Half of those users will die before the age of 70. The vast majority of those addicted to tobacco became addicted as children or adolescents. And—as court cases, parliamentary and congressional investigations, and internal documents of the companies themselves show—the tobacco industry has engaged in a widespread, active campaign of consumer deception for over 50 years to ensure the longevity of its business at the expense of the longevity of its customers. It is difficult to imagine a more compelling case for consumer and health protection.

The most effective measures to reduce tobacco use are regulatory in nature. Ample evidence shows that policy measures—such as higher tobacco taxes, the elimination of tobacco promotion, strong health information on tobacco packages, and the mandatory implementation of smoke free environments in public places and workplaces—reduce youth smoking initiation and help smokers quit smoking.

While some countries may initially see these policies as being unachievable, it is important to consider the costs of inaction. A report released in April 2002 by the US Centers for Disease Control and Prevention shows that every pack of cigarettes sold in the US costs that country an estimated \$7.18 in medical care costs and lost productivity, not to mention the 440,000 annual deaths caused by tobacco. The costs of tobacco use in lives—as well as in financial resources that could be redirected to a host of other pressing, less preventable health problems—are ones that no country can afford. This should provide the strength and political will needed for governments to act.

Regardless of the pace and outcome of the FCTC negotiations, PAHO urges governments to move their domestic legislative tobacco control agendas forward. We trust that the evidence compiled here will support them in doing so.

George A.O. Alleyne Director The costs of tobacco
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INTRODUCTION

Numerous Pan American Health Organization/World Health Organization (PAHO/WHO) Member States have expressed an interest in guidance in developing legislation to address various aspects of tobacco control. In response to this demand, PAHO/WHO has developed this publication to provide a starting point for countries that are considering new legislation or improvements to existing legislation.

PAHO/WHO has chosen the approach of a "template" for tobacco control legislation, that is, a proposal for legislative language that will best advance public health goals, given the evidence of the measures we know to be most effective in reducing tobacco use.¹ As a public health institution that relies on scientific evidence as the basis for technical cooperation, PAHO/WHO's first responsibility is to present the most effective options justified by the evidence, while recognizing that Member States will determine how they wish to respond to the evidence.

Member States will want to evaluate the applicability of provisions contained in the template in the context of their legal, social and political environments, and obviously will wish to consider particular modifications in light of these. They also will have to consider their policy priorities in determining which, if not all, aspects of the template they wish to consider at any given time.

The examples provided draw heavily on existing laws in the common law tradition of very few countries. This is not meant to be exclusionary or to imply a preference for a common law approach. Rather, we tried to gather the best examples of legislative experience that we could find, with a preference for examples from the Americas where they exist. Unfortunately, the most progress in regulating tobacco has occurred in a handful of countries, most of them within the common law tradition. As tobacco control continues to progress, we hope to see good examples from other legal traditions.

Although we present a single template law covering a broad range of policy goals, as many countries have implemented, countries can obviously address separate policy goals with separate legislative instruments. An advantage of a step-by-step approach is that governments can move forward in one area while political support is built for progress in others. However, a multitude of laws and regulations passed here and there can result in a piecemeal approach to legislation without a comprehensive vision. A single piece of legislation, with various measures taking effect within a short time frame, has the advantage of these measures complementing and enhancing one another. Research shows that the implementation of a combination of measures has a greater impact than that of each of the measures implemented in isolation.

We note here that WHO, with the cooperation and input of countries from all WHO regions, is in the process of developing a more comprehensive "tool kit" to assist the development of tobacco control legislation. The tool kit will consider

Reducing tobacco use refers in this document to preventing initiation, encouraging cessation, and reducing the amount consumed by those who continue to use tobacco products.

issues more broadly than we present here, and will address in more detail the process of policy development leading up to legislation, the drafting of legislation itself, and subsequent implementation and enforcement issues. The current publication is not intended to replace the forthcoming tool kit, but rather to complement it.

Finally, we appeal to all who use this template to contact us if you encounter problems or have suggestions for improvement. No template can be perfect, as those who have watched tobacco companies manoeuver around "watertight" provisions know well. We will do our best to accommodate all constructive comments.

PAHO Washington, D.C. May 2002

BACKGROUND TO THE GUIDELINES

Components of the Guidelines

This publication consists of two major parts. The basic component is the presentation of *template legislative language*. The second component is an annotation of the provisions of the template that explains the *evidentiary and legislative background* for each provision and, where the provision is drawn from actual legislation passed by one or more countries, the source of the provision.

It is hoped that these annotations will assist Member States in evaluating the applicability of various provisions to their policy goals. In addition, we provide references to the actual laws from which provisions in the template are drawn, to examples of more detailed regulations, and sources for the evidence described.

A permissive legal framework provides maximum regulatory flexibility, allowing for the efficient modification of regulations in response to unanticipated loopholes, increased political will to act, changes in public opinion, and advances

in scientific evidence.

Structure of the Template: A Comprehensive, Permissive Legal Framework

The fundamental structure of the template is that of a comprehensive, permissive legal framework. It is *comprehensive* in that it addresses a wide range of (but not all) tobacco control issues in a single piece of legislation. It is *permissive* in that the legislation assumes that the manufacture, promotion, sale and use of tobacco *is not* allowed except as permitted by regulation. This type of framework provides maximum regulatory flexibility, allowing for the efficient modification of regulations in response to unanticipated loopholes, increased political will to act, changes in public opinion, and advances in scientific evidence.

A permissive legislative framework gives governments the option of specifying regulations under the law that address issues in more detail, and that can be improved or expanded. For example, the template specifies that "No person shall manufacture a tobacco product except in compliance with this Act and the regulations made under this Act." Regulations can specify the conditions under which tobacco products could be manufactured. These conditions could be standards for ingredient disclosure or the content of additives, or design features. For other provisions, it may not be necessary to make regulations. For example, many countries may wish to ban all forms of tobacco promotion, in which case no regulations would be required (unless unanticipated loopholes need to be closed).

Regulations may need to be quite detailed when describing technical requirements for product regulation, ingredient disclosure, and even labelling. The template provides as appendices examples of regulations specifying technical standards for measuring and reporting ingredients, ventilation requirements for clean air regulations, health and other information required on packages, and signage at point of sale. PAHO/WHO can provide further examples as well as offer specialized technical cooperation to countries regarding the development of regulations upon request.

Many of the provisions in the template are drawn or adapted from actual laws at the national or sub-national level. The source of these provisions is cited.

Issues Not Addressed in the Template

The range of tobacco control issues that can be addressed by legislation is very broad. In addition to restricting tobacco manufacture, packaging, promotion, distribution and use, legislation can be used to:

- create institutions, educational programs, and coordinating bodies that advance tobacco control;
- implement taxation and other fiscal policies that deter tobacco use;
- establish funding mechanisms to support tobacco control initiatives such as mass media, community tobacco control initiatives and smoking cessation programs; and
- address liability issues related to the manufacture and promotion of tobacco products and related litigation.

These issues are not addressed here, however their absence from the template should not be seen as diminishing their importance. Indeed, using fiscal policy to raise the price of tobacco products is the single most effective measure known to reduce tobacco use. Additionally, when tax revenue is used to support comprehensive evidence-based tobacco control programs, dramatic declines in tobacco use have occurred. If Member States are interested in these or other avenues to reduce tobacco use not covered by the template, PAHO/WHO is able to provide specific technical cooperation upon request. In addition, the following references are offered as examples.

Legislation Establishing Funding Mechanisms and Institutions for Tobacco Control

Tobacco Control Act 1990, Part 3-Western Australian Health Promotion Foundation, State of Western Australia (Australia)

http://www.slp.wa.gov.au/statutes/swans.nsf/Current+Legislation+Version2? SearchView

Tobacco Act 1987, State of Victoria (Australia), including establishment of the Victorian Health Promotion Foundation

http://www.dms.dpc.vic.gov.au/l2d/T/ACT01228/2 1.html

Section 104350-104495, Health and Safety Code, State of California (USA) (also known as "Proposition 99")

http://www.leginfo.ca.gov/cgibin/waisgate?WAISdocID= 47204815307+1+0+0&WAISaction=retrieve

Litigation-Enabling Legislation

Tobacco Damages and Health Care Costs Recovery Act, Province of British Columbia (Canada)

http://www.legis.gov.bc.ca/2000/3rd_read/gov15-3.htm

Medicaid Third-Party Liability Act, State of Florida (USA) http://stic.neu.edu/Fl/2florida.htm

General Laws of Massachusetts, Part I, Title XVII, Chapter 118E: Division of Medical Assistance, State of Massachusetts (USA) http://www.state.ma.us/legis/laws/mgl/118E-22.htm

Legislation as an Evolving Process

The flexible regulatory structure of the template speaks to the need to view the development of tobacco legislation as an evolving process. For those countries that are unable to implement all of the proposals simultaneously, a flexible legislative structure allows for incremental, progressive regulation. However, even those jurisdictions that implement the "best practices" in all areas of regulation may find that in one, or two, or five years, there are even "better practices" that could be implemented. Governments will want to update legislation for a number of reasons, including:

- a need to close unintended loopholes;
- evaluation of the impact of legislation indicating the need for improvements;
- · new scientific evidence about effective measures; and
- progress in public opinion and or political will that enable implementation of stronger measures.

Responding to these factors requires at least a basic monitoring system that enables evaluation of all major elements of the legislation. This monitoring should include a research and surveillance system to track tobacco use (including initiation and quitting), exposure to second-hand tobacco smoke, and public knowledge and attitudes. It should also include monitoring of enforcement to ensure that the law is being implemented consistent with the intentions of legislators. This monitoring will help countries to continually evaluate their legislation with a view to expanding or strengthening it on a regular basis as needed.

The Legislative Process

Good legislative language is necessary but is not sufficient to ensure the satisfactory implementation of a law. The process of developing successful legislation consists of three basic phases: development, implementation, and enforcement.

Development

The development of the content of the law will be guided by various factors, the most important of which is the broader goals of a country's tobacco use reduction strategy. What does the country (or other jurisdiction) wish to achieve, and what role does legislation/regulation play in achieving these goals? (For example, a target might be set to reduce tobacco use by a specific percentage within a specific time period.) This context will inform the initial development of a legislative proposal.

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Another important guiding factor in the development of legislation is scientific evidence. Any tobacco control strategy should be guided by the evidence of what is most effective in reducing tobacco use. Clearly legislative effort, which is time-consuming, should be justified by scientific evidence. However it is also necessary to ensure that the law is defensible in court. It is likely that the tobacco industry will threaten to or actually challenge any law that it believes has the potential to reduce the sale of tobacco products. Many jurisdictions in the world that have passed effective legislation—Australia, Canada, Thailand, the state of Massachusetts in the US—have confronted legal challenges from the tobacco industry on constitutional or other grounds. Countries must be prepared to fight these challenges, and the best preparation is to have an evidence-based law.

Many provisions may be considered important from a human rights or consumer rights perspective. These include the right of the consumer to be informed about the ingredients in tobacco products and about the harm caused by tobacco products and their ingredients, the right of nonsmokers to be protected from second-hand smoke, and the right of children to grow up free from promotion of tobacco products. All of these examples also are justifiable by evidence of their impact on public health.

Expert Consultations—National and International

The drafting of legislative text itself should be informed by legal and tobacco control experts from within and outside of the country. Consultations with domestic experts will ensure compatibility with constitutional and other relevant national laws. Consultations with experts from outside the country will ensure that the wide range of international experience in successes and failures of tobacco control legislation is taken advantage of. While the template aims to draw the best language from existing legislation with as few loopholes as possible, specialized consultations with experts regarding specific areas of regulation will greatly increase the chances of the law achieving its intended purpose. PAHO/WHO can assist in identifying experts, depending on the particular interests of a jurisdiction.

Public Consultations

The process of public consultation is invaluable in building support for and awareness of a new law and in assisting implementation. Consultation may take the form of written proposals to which the public can respond, or it can include oral hearings in which the public or interested parties can express their views. Both of these types of consultation allow support as well as opposition to be expressed in a transparent manner.

Anticipating and responding to industry opposition

Hearing opposition to proposals during public consultations should not automatically dissuade governments from pursuing their intended course. Arguments need to be independently evaluated for their validity. Opposition will always come from the tobacco industry if proposals are anticipated to be effective in reducing tobacco use. By the tobacco industry we refer primarily to tobacco manufacturers, although arguments similar to those of the manufacturers may be heard from groups as diverse as tobacco farmers and arts or sports organizations that receive tobacco sponsorships. Governments need to be aware that the tobacco industry routinely

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funds "front groups" with more credibility than themselves to make their arguments. These arguments should not necessarily be dismissed out of hand, but experience shows that many, if not most, industry arguments rest on false assumptions or misrepresent experiences in other countries. The duplicity commonly found in many of these arguments is described in great detail internal tobacco industry documents.² Industry opposition to proposals generally falls into the following broad themes:

The proposals won't work.

If legislative proposals are based on solid scientific evidence, governments should be able to respond easily to this argument. The industry and its allies will almost certainly bring in experts and written expert opinions that claim to refute government evidence. However, past experience shows that the industry relies on paid consultants that are not independent experts, and the research presented is usually isolated from the consensus of the larger scientific community and not published in peer-reviewed journals. These attempts by the industry to position "independent" experts to make their arguments are described in detail in the internal tobacco industry documents.

The proposals will harm the economy. or The proposals will harm my business. The tobacco industry consistently argues that tobacco control will cost jobs and decrease government revenue from tobacco taxes. However, evidence demonstrates an economic benefit to almost all countries from tobacco control.3 Tobacco use costs the economy far more than tobacco taxes contribute. In any case, even if tobacco taxes paid for the harm caused by tobacco products this would hardly justify lack of government action to reduce its use. The payment of taxes does not buy the right of individuals or businesses to cause harm equal in value to the taxes paid.

The economic argument is also frequently applied to individual components of the economy. For example: "billboard companies will lose money if tobacco ads are banned;" "small retailers will lose money if they can't display tobacco products;" and "arts and sports events will cease to exist if the tobacco industry is no longer allowed to sponsor them." These arguments may seem more compelling than direct arguments from the industry, but they usually have little more validity.

Few jobs outside of the tobacco manufacturing and growing sectors themselves rely principally, or even in large part, on tobacco sales. When consumers stop buying tobacco products, they spend their money on other goods and services.3 Experience has shown that tobacco ads are replaced by ads for other products and services. If retailers make less money on tobacco, they will stock their shelves with other products that cause less harm to consumers.

Pan American Health Organization

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For example, see: Glantz et al, The Cigarette Papers, University of California Press, June 1996 http://www.library.ucsf.edu/tobacco/cigpapers/, UK House of Commons Health Committee, Second Report, June 2000

http://www.publications.parliament.uk/pa/cm199900/cmselect/cmhealth/27/2702.htm, Hammond R & Rowell A. Trust Us: We're the Tobacco Industry. Campaign for Tobacco-Free Kids (USA), Action on Smoking and Health (UK), May 2001. http://www.ash.org.uk/html/conduct/html/trustus.html

World Bank. Curbing the Epidemic: Governments and the Economics of Tobacco Control. Washington: World Bank, 1999. http://www1.worldbank.org/tobacco/reports.htm

Pharmacies in the province of Ontario, Canada, many of whom were owned by tobacco companies, argued that business would decline and stores would close when they were required to stop selling tobacco products. Yet the annual report of the pharmacy chain owned by tobacco interests indicated an expansion of stores following the ban on sale of tobacco products in pharmacies, and acknowledged that "our Ontario associates successfully filled the tobacco sales gap through creative merchandising programs...." Similarly, during the debate on banning tobacco advertising in Canada, an organization representing billboard companies argued that they would lose business. After the ban was implemented, the same organization indicated that the tobacco ad ban "... was arguably one of the best things to happen to our industry. It drove our members to develop other advertising categories that, today, packaged-goods clients, not tobacco, are our largest spending group and the loss of tobacco revenues has been completely recouped—and then some."

Probably the most compelling economic arguments have come from arts and sports events who receive sponsorships from tobacco companies and who claim that their events will close if tobacco money disappears. Although, as with bill-board companies, other sponsors have generally stepped in to replace tobacco sponsorships, the emotive arguments of arts groups are difficult to rebut successfully. To resolve this political obstacle to eliminating tobacco promotion including sponsorships, some jurisdictions, including the states of Western Australia and Victoria in Australia have, through legislation, created replacement funds to help compensate for any losses of tobacco sponsorships.^{6,7} The Province of Quebec in Canada has also made funding available to events formerly sponsored by tobacco companies that have given up tobacco sponsorship.⁸

We can't possibly implement the proposals in the time frame proposed.

Tobacco companies typically argue that they cannot adhere to the time frame proposed for the implementation of various measures. These arguments are often used to delay promotional restrictions, health labelling on tobacco packages, and regulation of tobacco product ingredients. Like almost all other tobacco industry arguments, this one has repeatedly been proven false. As an illustration Canada has improved health messages on packages several times over the past several years. In 1993, companies attempted to obtain a court injunction to delay the implementation of the improved messages, ostensibly because the companies would not be able to implement the new messages in the proposed time frame. However, when the court injunction was not granted, the tobacco companies implemented the new messages within a few months.⁹

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⁴ Non-Smokers' Rights Association. *Chicken Little* brochure. Ottawa: NSRA, 1996.

⁵ Ibid

State of Western Australia (Australia). Tobacco Control Act 1990, Part 3-Western Australian Health Promotion Foundation.

http://www.slp.wa.gov.au/statutes/swans.nsf/Current+Legislation+Version2?SearchView

State of Victoria (Australia), Tobacco Act 1987. http://www.dms.dpc.vic.gov.au/l2d/T/ACT01228/2 1.html

⁸ Grandes manifestations: fini la dépendance au tabac! Tourisme Québec news item. http://www.tourisme.gouv.qc.ca/mto/publications/tqvi/v4n2/echos/echos.html#manifestations

⁹ Mahood G. Canadian tobacco package warning system. *Tobacco Control* 1995; 4: 10-14.

Governments can be creative in preempting industry arguments. The next time Canada attempted to improve package health messages, in 1999, the industry again argued that it could not produce the new messages in the time required. In response the Canadian government commissioned a study by experts that showed that the new messages could be produced within three months, ¹⁰ and contracted a packaging company to produce several examples of the new packages. The new packages were produced without delay, again proving the industry's arguments to be false.

Communications Strategy

One of the most direct ways in which countries can build support for and assist the implementation of new legislation is through public education. Many countries have used communications campaigns to build support for legislation, to inform stakeholders about the changes to the law, and to independently educate the public about tobacco as a complementary strategy to change behavior. A communications strategy is critical to ensure that the government's aims are understood, and that communications by opponents of the law do not overwhelm the debate.

Communications campaigns can be expensive if paid media are used. However, cost alone should not deter use of paid media as this may save costs during the implementation and enforcement phases. In any case, communications can also occur though less costly channels. Public health personnel, the education sector, nongovernmental organizations and municipalities can be mobilized to disseminate messages that support the law. In addition, news conferences and opinion pieces in the print media provide an avenue for free media coverage. Providing complete and timely information to the media is central to any communications strategy. A proactive strategy helps ensures that the debate takes place on government terms rather than on terms that provide an advantage to opponents.

The U.S. Centers for Disease Control and Prevention maintains a library of print, television, and radio ads that have aired in the US (primarily in English although some materials are available in multiple languages). These materials are distributed without cost on request for viewing purposes, although permission must be obtained to use them. Details on how to order are found at: $\frac{http://www.cdc.gov/tobacco/mcrc/index.htm}{http://www.cdc.gov/tobacco/mcrc/index.htm}$

The use of positive language and an emphasis on the positive aspects of the proposals is very important in a communications strategy. For example, if the legislation proposes to eliminate smoking in indoor public places such as restaurants, the focus could be on the advantages of smoke-free dining, such as the improved taste, smell and freshness of food, the support for the majority of the population for smoke-free dining, and the decreased maintenance costs to proprietors of smoke-free establishments.

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Graphic Arts Technical Foundation. An Investigation of Health Warning Labels for Tobacco Packaging: A GATF Report to Health Canada. Undated.

http://www.hc-sc.gc.ca/hppb/tobacco/bureau/current_research/investigation.html

For example, see the Smoke-Free Ottawa web site developed by a nongovernmental coalition in support of smoke-free public and work places: http://www.smokefreeottawa.com/english/default.asp

It is important to remember that the public generally supports tobacco regulation aimed at protecting public health. Polling of the public and the release of results to the media is an extremely cost-effective way to build support for your initiatives.

Implementation

Implementation of legislation primarily involves decisions about when and how the law is implemented. For a provision such as the elimination of tobacco promotion, implementation may simply be a question of setting a date in the legislation for the elimination of promotion. However, the implementation of smoke-free environments will require not only the designation of smoke-free establishments, but also the posting of required signs. Implementation will be aided if the government actually provides the signs required by the law to proprietors of establishments. While this increases costs, it aids enforcement by eliminating arguments by proprietors that they did not know what was required or that they were not provided with sufficient guidance. It will require advance preparations to ensure that all establishments receive the needed number of signs in advance of coming into force of the law and are given ample time to post them.

All stakeholders—such as tobacco manufacturers and retailers and proprietors of workplaces and public places—need to be informed of the law and of their obligations under it. Individualized letters, meetings, or public fora can be used for this purpose. Explanatory materials and guidelines can be developed and disseminated. This education is critical to create a sense of fair process and to encourage compliance. As mentioned above, it will also eliminate the argument that stakeholders were not properly apprised of their obligations.

Enforcement

Legislation should primarily be self-enforcing, particularly if the development and implementation phases have been successfully carried out. However, it is important for the government to demonstrate its commitment to enforcing the law. Often, first violations by individuals or businesses receive only a warning in order to allow time for implementation, and to avoid the appearance of being draconian. However, after the first few months of coming into force of the law, the government will have to prosecute offences if it wishes to encourage compliance. This does not necessarily require a massive enforcement operation, however it should involve random checks sufficient in number to encourage deterrence, as well as investigations and appropriate action in response to complaints. In addition, prosecutions should be high-profile and communicated to the media to ensure that the public knows that the law is being enforced.

Monitoring efforts can be as diverse as:

- reviewing tobacco advertising and promotion (for conformity with the law if any promotion is allowed, and for the existence of any promotional efforts if promotion is banned);
- testing tobacco products for conformity with standards for manufacture;
- checking for the presence and display of health messages on tobacco packages at point of sale; and

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 randomly conducting compliance checks of retailers for sales of tobacco to minors.

Enforcement officers can be chosen from a variety of sources, including police forces and public health inspectors. Different jurisdictions will have to judge the relative advantages of different categories of enforcement officers. Regardless of who enforces the law, inspectors need to be adequately trained not only in the content of the law, but also in appropriate methods for handling complaints and interacting with offenders.

Countries should also enlist the assistance of the public in enforcing the law. Particularly with regard to sales of tobacco to minors or the enforcement of smoke-free environments, citizens who support the law can be valuable to enforcement efforts. Many jurisdictions, particularly at the municipal level, have established a toll-free number that the public can call to report violations of the law. This greatly reduces the burden of enforcement on inspectors and also empowers the public to take responsibility for enforcement of the law, in this case by asserting their right to breathe indoor air free of tobacco smoke.

Meaningful and varied penalties tailored to the offence are critical to providing a deterrent effect while not appearing draconian. A variety of enforcement mechanisms can increase the efficiency of enforcement. An alternative to judicial enforcement (court system) is administrative enforcement (provision for hearings of cases within the Ministry of Health or other designated agency). Administrative enforcement may enable the resolution of more cases, more quickly, provided this mechanism is allowed in the legal system of a country and the Ministry of Health has the capacity and political will to conduct such hearings and enforce appropriate penalties. Finally, a mechanism to recover the costs of enforcement from convicted violators can create a system that is largely self-financing, and provides a further deterrent to breaking the law.

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TOBACCO PRODUCTS CONTROL ACT (A TEMPLATE)

PART 1

Principles and Purpose

Most laws contain a general statement of the purpose and/or principles of the law. Although the wording may be general, the purpose of a law provides the framework within which the law will be implemented and interpreted. In the context of a legal challenge to a law or its regulations, this framework can play a critical role. Therefore, words should be carefully chosen and should clearly and accurately reflect the scope of issues that the government intends to regulate.

Legislative Text

WHEREAS the use of tobacco products constitutes one of the major public health problems in the world, causing more than one third of all deaths from cancer and heart disease and responsible for numerous other debilitating and fatal diseases;

WHEREAS smoke from tobacco products is a serious health threat to nonsmokers exposed to the smoke, causing serious diseases in adults, and particularly in children;

WHEREAS most smokers start smoking at a very young age, are not aware of the extent and nature of the harm caused by tobacco products, and because of the addictive properties of nicotine are often unable to quit even when they are highly motivated to do so;

WHEREAS the marketing of tobacco products though product design, promotion, packaging, pricing and distribution, is known to contribute to the demand for tobacco products,

Be enacted by ... as follows:-

An Act to regulate the manufacture, labeling, promotion, distribution, and use of tobacco products

- 1. The purpose of this law is to reduce tobacco use and its consequent harm by:
- a) protecting children and other nonsmokers from inducements to use tobacco;
- b) protecting nonsmokers from exposure to tobacco smoke;
- ensuring that the population is adequately informed about the risks of tobacco use and exposure to secondhand tobacco smoke and about the benefits of quitting smoking;
- d) ensuring that tobacco products are modified to reduce harm to the extent technologically and practically possible; and
- e) promoting a climate where nonsmoking and the absence of tobacco promotion is the norm.

PART 2

Preliminaries, including Definitions

Definitions are very important in the interpretation of any legal instrument. Definitions generally should be limited to those terms that have potential for ambiguous interpretation, or for which the generally accepted dictionary definition does not adequately reflect the meaning of the term for the purpose of the law. Clear and unambiguous definitions will greatly assist the efficient implementation of the law and reduce the likelihood of unanticipated loopholes.

Legislative Text

- 2. This Act may be cited as The Tobacco Control Act.
- 3. The definitions in this section apply to this Act:

appeal refers to the ability of a product to provide physical or psychological pleasure, satisfaction, or other positive quality to the consumer;

brand element includes the brand name, trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with those used for any brand of tobacco product;¹²

(Note: The proposed detailed definition of "brand element" derives from the need for a broad and clear definition of how indirect promotion of tobacco products and brand names might occur. Experience from numerous jurisdictions demonstrates the reasonable ease with which tobacco companies have been able to circumvent definitions that, on the face of it, appeared to be broad and "water-tight." For example, many tobacco advertisements in the US and elsewhere use partially obscured brand names or logos. However, these partial representations are still recognizable as belonging to the particular tobacco brand. Many commentators have suggested that tobacco companies are using these partial representations in anticipation of future restrictions on promotion of brand names. The definition above would guard against this particular loophole as well as many others.)

character refers to the distinctive qualities of a tobacco product;

composition refers to the content, arrangement or combination of substances included in the processing and manufacture of tobacco products;

(Note: Definitions for product regulation should support the regulatory scope of the law. The definition of the composition of a tobacco product simply as its ingredients could imply regulatory authority only to disclose the names of ingredients rather than their quantities, the way in which they interact, or the process by which they are added to the product. All of these can affect product safety and appeal. Access to such information could be critical in determining appropriate regulatory standards to reduce harm or appeal.)

¹² Adapted from Government of Canada, *Tobacco Act. Chapter T-11.5 (1997, c. 13)* http://www.cctc.ca/CCTCLAWweb.nsf/MainFrameSet?OpenFrameSet and from the United States Food and Drug Administration's *Draft Rule on Regulating Tobacco Products*, 1996.

distribute means to sell, offer to sell, expose for sale, give, supply exchange, convey, consign, deliver, furnish, or transfer possession for commercial purposes, or offer to do so, whether for a fee or other consideration or as a sample, gift, prize, or otherwise without charge;

emission means any substance or combination of substances that is produced as a result of a tobacco product being lighted;¹³

inspector/analyst means a person or class of persons designated as an inspector under clause xx;

manufacturer includes any entity that is associated with the manufacturer, including an entity that controls or is controlled by the manufacturer or that is controlled by the same entity that controls the manufacturer;¹⁴

(**Note:** A broad definition of the corporate relationships of the manufacturer is important to ensure that corporate affiliates are not able to engage in behaviour that would be illegal for the manufacturer itself to engage in.)

ministry means the Minister of Health or his or her designate;

package means the container, receptacle or wrapper in which a tobacco product is sold or displayed at retail, including a carton that contains smaller packages;¹⁵

(Note: If individual packages are required to carry health messages while other packaging, such as cartons containing multiple packages, is not, retailers and manufacturers will increasingly display containers without the message requirements. This would diminish the impact of health messages.)

promotion is the practice of fostering awareness of and positive attitudes toward a product, brand or manufacturer for the purpose of selling the product or encouraging tobacco use, through various means including direct advertisement, discounts, incentives, rebates, free distribution, promotion of brand elements through related events and products through a public medium of communication;¹⁶

(Note: The effective restriction or elimination of tobacco promotion is a challenge. Because the avenues of promotion have expanded over the years as a result of new technology, new marketing trends, and a need to creatively avoid legislative barriers to promotion, the word "promotion" has not always been defined sufficiently broadly in legislation to achieve the intended effect. Along with the definition of brand element, a broad definition of promotion will reduce the possibility of loopholes that enable tobacco promotion to continue.)

tobacco product means a product composed in whole or in part of tobacco, including tobacco leaves and any extract of tobacco leaves. It includes cigarette papers, tubes and filters;¹⁷

¹³ Adapted from Government of Canada, *Tobacco Act*, op cit.

¹⁴ Government of Canada, *Tobacco Act*, op cit.

¹⁵ Adapted from Government of Canada, *Tobacco Act*, op cit.

Adapted from New Zealand Smoke-free Environments Act 1990 108 http://www.govt.nz/nzgovt/leg.php3 and from United States Food and Drug Administration Draft Rule, op cit.

¹⁷ Adapted from Government of Canada, *Tobacco Act*, op cit.

(Note: A broad definition of tobacco products is advisable for several reasons. First, it ensures that all tobacco products are treated equally under the law, reducing the potential for a shift by consumers to products that are less regulated, and that are therefore more appealing and accessible than cigarettes, and preventing a shift by manufacturers to the promotion of products with less stringent regulations. Second, a broad definition eliminates the need to amend the law every time a new form of tobacco product comes on the market. Finally, the inclusion of products used in combination with tobacco products eliminates a loophole that has been exploited in the past, which is the promotion of these related products (for example cigarette papers) without regard to promotional restrictions or health messages.)

toxicity refers to the quality, relative degree or specific degree of being toxic or poisonous;

vending machine means any means of distribution of tobacco products that is not mediated by a human being;

youth means a person under 18 years old.

(**Note:** The age of 18 is used here as a marker; obviously countries will wish to set an age consistent with other national laws and taking into account national norms.)

PART 3

Product Regulation

This part of the act addresses regulation of the tobacco product itself, including the ability to require disclosure of ingredients to consumers and to set standards for the composition and design of tobacco products.

Rationale

Tobacco products, and particularly cigarettes, are highly engineered and sophisticated products. ¹⁸ Their ingredients and design features can be and are manipulated by manufacturers in ways that affect their safety, appeal, and addictiveness. For example, the pH level of smoke affects how easily nicotine is absorbed in the mouth or lungs. ¹⁹ Tobacco company researchers have also discussed the need for "low irritation" cigarettes in response to the "impediments to starting smoking tracing to a physical intolerance at early experiences." ²⁰ Of course, since most new smokers are children and adolescents, this really refers to the problem of kids getting sick from smoking their first cigarettes.

Just as manufacturers design tobacco products to sell them, legislative requirements can force manufacturers to make tobacco products in a way that reduces their appeal to children, decreases their addictive qualities, and decreases potential harm to users. In addition, consumers have a right to know the ingredients in

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World Health Organization. Monograph: Advancing Knowledge on Regulating Tobacco Products, 2001. http://tobacco.who.int/page.cfm?sid=67

⁹ United States Food and Drug Administration Draft Rule, op cit.

Project Viking, Volume III: Product Issues. The Creative Research Group Limited for Imperial Tobacco Limited, April 1987.

tobacco products and in tobacco smoke. This information can help them make more informed decisions about starting or quitting smoking.

For examples of regulations on ingredient disclosure, refer to:

Province of British Columbia's (Canada) *Tobacco Testing and Disclosure Regulation* http://www.cctc.ca/CCTCLAWweb.nsf/MainFrameSet? OpenFrameSet

Commonwealth of Massachusetts' (USA) *Testing and Reporting of Constituents of Cigarette Smoke* http://www.state.ma.us/dph/mtcp/report/smoktox.htm.

Legislative Text

- 4. No person shall manufacture, sell, or import a tobacco product except in compliance with this Act and any regulations made under this Act.²¹
- 5. Every manufacturer and importer of a tobacco product shall provide the Ministry/Government, in the prescribed manner and within the prescribed time, information about the product and its emissions as required by the Regulations.²²
- 6. No person shall sell, offer for sale, distribute, advertise or promote any brand of tobacco products that was not sold, distributed, advertised or promoted in the country at least one year before the effective date of this Act.²³

(**Note:** The introduction of new varieties of tobacco products into the market has been associated with increased uptake among specific population groups, such as women and children. This clause prevents the proliferation of new brands and varieties of tobacco products during discussion of and after passage of the legislation.)

- 7. The Minister/Government may make regulations:²⁴
 - a) establishing standards for the manufacture of tobacco products, including
 - i) prescribing the amount of substances that may be contained in the product or its emissions;
 - ii) prescribing substances that may not be added to tobacco products; and
 - iii) prescribing product design standards to reduce the harmful effects of tobacco products and to reduce their appeal to youth.
 - b) prescribing test methods, including methods to assess conformity with the standards;
 - c) prescribing information that manufacturers must provide to the Minister/Government and/or the public about tobacco products and their emission, including sales data and information on product composition, ingredients, hazardous properties, and brand elements;
 - d) generally as needed to carry out this part of the Act.

²¹ Adapted from Government of Canada, *Tobacco Act*, op cit.

²² Adapted from Government of Canada, *Tobacco Act*, op cit.

Adapted from United States Food and Drug Administration Draft Rule, op cit.

²⁴ Adapted from Government of Canada, *Tobacco Act*, op cit.

The tobacco package provides a potent vehicle for tobacco promotion

Conversely, if conspicuous health warnings are required on packages, their display becomes a valuable vehicle for health promotion messages.

PART 4

Packaging and Labeling

This part of the act addresses the labelling and packaging of tobacco products, including information that may be required on the package (such as health and ingredient information), as well as information that is prohibited on the package (such as misleading descriptors and brand names).

Rationale

The tobacco package provides a potent vehicle for tobacco promotion, and has increased in importance within the "marketing mix" as other forms of promotion are restricted.²⁵ Aside from the obvious visibility of packages to smokers every time they light a cigarette, in most countries, tobacco retailers are paid by tobacco companies to prominently display tobacco packages row-upon-row near the cash, providing an attractive promotional display just at the point when consumers are ready to purchase.²⁶

Conversely, if conspicuous health warnings are required on packages, their display becomes a valuable vehicle for health promotion messages. Seen by every smoker several times a day, packages are one of the most cost-effective communication tools available to governments to educate and inform consumers about the harmful effects of tobacco use.²⁷ Health information on or inside of packages that is effectively communicated in clear language, in a visible location and format and in a large size, has been found to motivate attempts to quit both by adults and youth.^{28, 29} Canada and Brazil use photos and other visual images to increase the impact of textual information (see web links below). In addition to general health information, quitting advice can be provided as a support and as a constant reminder to smokers who want to quit.³⁰ Information on the outside of the package can be supplemented by leaflets or inserts inside of the package.³¹

Youth are known to use packages and brands as symbols of the image that they would like to project to the outside world, whether that image is one of femininity, adventure, or sex appeal. Health information on packages detracts from the glamour and appeal of the colorful brand images with factual, graphic information about the not-so-glamourous consequences of tobacco use.

²⁵ Tobacco International March 1, 1991: 14.

²⁶ Feighery EC et al. Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California. *Tobacco Control 2001;10:*184-188.

Mahood G. Warnings that tell the truth: breaking new ground in Canada. Tobacco Control 1999:8:356-362.

Environics Research Group Limited. The Health Effects of Tobacco and Health Warning Messages on Cigarette Packages, February 2001. http://www.hc-sc.gc.ca/hppb/tobacco/bureau/current research/index.html

Environics Research Group Limited. Evaluation of New Warnings on Cigarette Packages, January 2002. http://www.ontario.cancer.ca/Siteboth/English/cigarette_package_warnings.asp

Australia, Brazil and Canada have printed toll-free numbers on tobacco packages for smokers to call for advice on quitting.

Canada requires more detailed messages on the inside slides of packages.

House of Commons. Towards Zero Consumption: Generic Packaging of Tobacco Products. Report of the Standing Committee on Health. Ottawa, June 1994.

In addition to requiring certain information on tobacco packages, legislation can prevent other information from appearing on tobacco packages. For many years in many countries, manufacturers have produced brands of cigarettes referred to as "light," "low-tar," or "mild." Numerous studies have found that smokers have perceived these brands to be safer or to pose less risk to health than "regular" brands, even though smokers of these cigarettes are at equal risk for tobacco-caused disease.³³ Brazil and the European Union have banned the use of such misleading terms, and other countries are considering doing so.^{34, 35}

Note that the definition of tobacco packaging provided in the definitions section would ensure that cartons or other containers displayed for sale would carry health warnings. Therefore, whatever container tobacco products are sold in, health messages would be visible to the consumer when tobacco products are displayed.





National Cancer Institute. Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine. Smoking and Tobacco Control Monograph No. 13. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 02-5074, October 2001. http://cancercontrol.cancer.gov/tcrb/monographs/13/ Not quite the macho image the tobacco companies had in mind: Brazil and Canada require graphic health messages on cigarette packages, including messages about smoking-caused impotence.

Government of Brazil, Resolução - RDC nº 46, de 28 de março de 2001 http://www.anvisa.gov.br/legis/resol/46_01rdc.htm

Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products - Commission statement. Official Journal L 194, 18/07/2001 P. 0026 - 0035 https://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEX numdoc&lg=EN&numdoc=32001L0037&model=guichett

Also note that warnings will need to be described in great detail through regulation in order to ensure that they appear the way the government intends.

For examples of the packaging regulations from Brazil and Canada and for visuals of the health messages please refer to:

Resolução - RDC nº 104, de 31 de maio de 2001 (labelling regulations, Brazil) http://www.anvisa.gov.br/legis/resol/104 01rdc.htm

Visual examples of the Brazilian health messages: http://www.anvisa.gov.br/divulga/noticias/040601 1.htm

Tobacco Products Information Regulations (Canada) http://www.cctc.ca/CCTCLAWweb.nsf/MainFrameSet?OpenFrameSet

Visual examples of the Canadian health messages: http://www.hc-sc.gc.ca/english/media/photos/tobacco labelling/.

Legislative Text

- 8. No person shall manufacture, sell, or import a tobacco product unless the package containing it displays, in the prescribed form and manner including through an enclosed leaflet if prescribed, the information required by the regulations about the product and its emissions, about the health hazards and health effects arising from the use of the product or from its emissions, other health-related messages such as *inter alia* advice on how to quit smoking, and markings designed to facilitate efforts to identify illegally manufactured or distributed tobacco products or products on which tax has not been paid.³⁶
- 9. No person shall package tobacco in a manner that allows a consumer or purchaser of tobacco products to be deceived or misled concerning its character, properties, toxicity, composition, merit or safety.³⁷

(**Note:** This clause would cover misleading terms such as "light," "low-tar" and "mild," however for greater clarity governments may wish to issue regulations specifying terms that are prohibited.)

10. Any requirements arising from the above-mentioned clauses, do not relieve a manufacturer or retailer of other obligations or liabilities arising from other applicable legal norms to warn consumers of the risks of using tobacco products.³⁸

(**Note:** In some jurisdictions requiring health warnings on tobacco packaging, tobacco manufacturers have used the presence of warnings as a defense in legal liability cases brought against them. This clause helps ensure that the law does not prejudice the success of such cases.)

Adapted from Government of Canada, Tobacco Act, op cit.

³⁷ Ibid.

³⁸ Ibid.

- 11. The Ministry/Government may make regulations:39
 - a) respecting the content and format of information described in section 8 of this Act that must appear on packages and in leaflets;
 - b) respecting information that may not appear on packages; and
 - c) generally as needed to carry out this part of the Act.

PART 5

Advertising and Promotion

This part of the act proposes a prohibition on all promotion of tobacco products through direct and indirect means, including advertising, sponsorships, give-aways, discounts, displays at point of sale, and promotion of tobacco brand names through non-tobacco items or through venues.

Rationale

The extent of promotion of tobacco products influences the level of tobacco use both in the general population and in particular target groups. ⁴⁰ In addition, promotion has been associated specifically with smoking initiation among youth. ^{41, 42} A study of more than 100 countries showed that countries with comprehensive restrictions or bans on tobacco promotion have lower levels of tobacco use than countries with weak or no restrictions on tobacco promotion. The same study found that in order for restrictions to have an impact, they need to be total or near-total, and that weak restrictions have little or no impact on tobacco use. ⁴³

The experience of many countries graphically illustrates why this is so. Partial restrictions are difficult to define and enforce, and have often resulted in unfore-seen loopholes. When tobacco promotion is restricted in one medium, such as billboards, companies simply increase the level of promotion in another. For example, in the United States, in 1998 the tobacco companies agreed under a legal settlement to eliminate outdoor advertising and advertising targeted at youth. 45

Partial restrictions
are difficult to define
and enforce, and have
often resulted in
unforeseen loopholes.

³⁹ Ibid.

⁴⁰ An excellent review of the evidence is found in Hammond R. *Tobacco Advertising and Promotion: The Need for a Coordinated Global Response.* Paper prepared for the WHO International Conference on Global Tobacco Control Law: Towards a WHO Framework Convention on Tobacco Control. 7-9 January 2000, New Delhi. https://tobacco.who.int/repository/tld94/ROSS2000X.doc

⁴¹ Pierce JP, Gilpin EA and Choi WS. Sharing the blame: smoking experimentation and future smoking-attributable mortality due to Joe Camel and Marlboro advertising and promotions. *Tobacco Control* 1999;8:37-44.

Pierce JP et al. Tobacco industry promotion of cigarettes and adolescent smoking. JAMA February 18, 1998;279(7),511-15.

⁴³ Curbing the Epidemic. Op cit.

⁴⁴ Cunningham R. R.J.R.-MacDonald Inc. v. Canada (A.G.): Reflections from the Perspective of Health. *McGill Law Journal 1995 40*, 229-267. http://journal.law.mcgill.ca/arts/401cunni.pdf

⁴⁵ Master Settlement Agreement with the Tobacco Industry. National Association of Attorneys General. http://www.naag.org/tobac/cigmsa.rtf

However, three years later the companies were spending even more money on promotion than they did before the settlement, with an increase in advertising in youth publications and a shift in advertising from outdoor to other media. 46, 47 Even when all direct advertising has been prohibited, companies have successfully used other promotional tactics, such as sponsorships, distribution of tobacco-branded non-tobacco items such as t-shirts and hats, the tobacco-brand naming of bars, restaurants and other establishments, and massive displays of cigarettes at retail outlets, to promote their products.

At a minimum, if partial bans are implemented, PAHO recommends the implementation of prominent (for example, at least 30% of ad space) health warnings on all tobacco promotional items and advertisements, similar to those recommended for tobacco packages. This will decrease the impact of promotion and afford the government a cost-effective opportunity to educate and inform the public.

PETER STUYVESAN

Cigarette ad? Look again. It's an ad for Stuyvesant "king size" matches, which look a lot like Stuyvesant cigarettes. Despite a ban on cigarette ads in France, this ad appeared legally courtesy of a loophole in the law.

Constitutional Considerations

Despite the difficulties involved with partial advertising restrictions, some countries believe that a total prohibition on tobacco promotion would violate their constitutions. It is likely that tobacco companies will threaten to or actually mount a constitutional challenge to any promotional restrictions that they perceive may reduce sales. This does not mean that the challenges are always valid or that they will succeed. However, countries will need to evaluate their constitutions carefully to determine whether or not they may be limited in implementing a ban on promotion. To be certain that they protect the public health as much as possible, they may wish to should test the limits of the constitution by implementing a total ban and defending it in court.

Because of the constitutional limitations that some countries believe they may face, we are providing two options for this section of the template. The first would achieve a ban on all tobacco promotion, while the second allows for limited promotional avenues. If countries do not have constitutional limitations, we highly recommend the first option to protect public health, as partial bans have been found to only marginally effective or ineffective.⁴⁸

⁴⁶ King C & Siegel M. The Master Settlement Agreement with the Tobacco Industry and Cigarette Advertising in Magazines. *The New England Journal of Medicine, August 16, 2001, 345*, 504-511. http://content.nejm.org/cgi/content/abstract/345/7/504

Wakefield M et al. Changes at the Point-of-Sale for Tobacco Following the 1999 Tobacco Billboard Ban. Research Paper Series, No. 4. ImpacTeen. July 2000. http://www.tobaccofreekids.org/reports/stores/

⁴⁸ Curbing the Epidemic, op cit.

Legislative Text

[Total ban clause:

- 12. No person shall promote or cause to promote by any other person, a tobacco product or a tobacco product-related brand element through direct or indirect means, including through sponsorship of an organization, service, physical establishment or vehicle of any kind, or event.⁴⁹
- 13. No person shall sell, promote, distribute or cause to be sold, promoted or distributed, any item other than a tobacco product which bears the brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product. [5] *I End total ban clause*

[Partial ban clause:

- 12. No person shall promote or cause to promote by any other person, a tobacco product or a tobacco product-related brand element, except as prescribed by this Act or its regulations.
- 13. Notwithstanding any regulation made under this Act, no person shall promote or cause to promote tobacco products or brand elements:
 - a) in a manner that allows a consumer or purchaser of tobacco products to be deceived or misled concerning its character, properties, toxicity, composition, merit or safety;⁵¹
 - b) that does not display, in the prescribed form and manner, the information required by the regulations about the product and its emissions, about the health hazards and health effects arising from the use of the product or from its emissions, and other health-related messages such as inter alia advice on how to quit smoking;
 - c) through means of promotion that can be viewed from outdoors;
 - d) utilizing any item other than a tobacco product, or a physical establishment or vehicle of any kind, which bears the brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product;⁵²
 - e) utilizing any athletic, musical, artistic or any other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction

⁴⁹ Adapted from United States Food and Drug Administration Draft Rule and from New Zealand Smoke-free Environments Act, op cit.

⁵⁰ Ibid.

Frovince of British Columbia (Canada) Tobacco Sales Act [RSBC1996] Chapter 451 http://www.cctc.ca/ncth/docs/legislation/ncthproj/docs/bc/451e.html

⁵² Adapted from United States Food and Drug Administration Draft Rule, op cit.

with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product;⁵³

f) nothing in clause 13 e) shall prevent a person from sponsoring or causing to be sponsored any athletic, musical, artistic or any other social or cultural event, or any entry or team in any event, in the name of a corporation which manufactures a tobacco product, provided that both the corporate name and the corporation were registered and in use in this country prior to (specify a date approximately 1 year prior to anticipated passage of the law) and that the corporate name does not include any brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product.⁵⁴ *] End partial ban clause*

(**Note:** This subclause is designed to allow continued support by tobacco companies for organizations and events, while guarding against the use of a corporate name, such as Rothmans, as a substitute for brand name advertising.)

- 14. Nothing in this subsection shall apply to the publication by a manufacturer of a tobacco product advertisement in a printed publication that is intended for distribution only to employees of the tobacco trade for trade purposes.⁵⁵
- 15. No person shall offer or provide any consideration, direct or indirect, for the purchase of a tobacco product, including a gift to a purchaser or a third party, bonus, premium, cash rebate or right to participate in a game, lottery or contest, or distribute a tobacco product without monetary consideration, or in consideration of the purchase of a product or service or the performance of a service.⁵⁶
- 16. The Ministry/Government may make regulations:

(**Note:** Subclauses a), b) and c) below are not necessary in the case of a total prohibition.)

- a) prescribing the form and manner of any health messages to be required on promotional material or representations by any means;
- b) prescribing the format, content and placement of any tobacco promotion;
- requiring tobacco manufacturers to report the amount of monetary expenditures on tobacco promotion by brand and by type of media and prescribing the format and frequency of reporting;
- d) prescribing schedules for the implementation of promotional restrictions;
- e) generally as needed to carry out this part of the Act.

⁵³ Adapted from United States Food and Drug Administration Draft Rule, op cit.

⁵⁴ Adapted from United States Food and Drug Administration Draft Rule, op cit.

⁵⁵ Adapted from New Zealand Smoke-free Environments Act, op cit.

⁵⁶ Adapted from Government of Canada, *Tobacco Act*, op cit.

PART 6

Distribution

This section addresses the minimum age of persons who can legally buy or sell tobacco products, the size of packages in which tobacco products can be distributed, the places where tobacco products can be sold, and the way in which products can be displayed at retail.

Rationale

Sales to young persons. This part covers a wide range of topics. The first, elimination of tobacco sales to and by young people, is a common provision of tobacco control laws. However, the evidence supporting the effectiveness of this measure in reducing tobacco use by youth is limited. It has been determined that, in order for this measure to even minimally impact tobacco use, compliance with the law needs to be nearly 100%. This speaks to a need for an effective enforcement strategy to support this provision. The provisions here are designed to maximize ease of enforcement by setting clear standards of defense and specifying the types of identification necessary to establish proof of age.

Limitations on package or unit size. The second type of measure proposed in this section is regulation of the quantity in which tobacco products can be sold. The main problem prompting this measure is the sale of single cigarettes and small packages (defined here as fewer than 20 cigarettes), which makes tobacco more affordable for youth. However, sales of cigarettes in larger quantities may also promote tobacco use. Many smokers smoke a pack a day. As standard pack sizes increase beyond 20 cigarettes, smokers may smoke more cigarettes per day in relation to pack size. In Australia, where tax advantages have led manufacturers to produce packs of as many as 50 cigarettes, researchers found that adults favouring packs of 40 or 50 cigarettes smoked almost twice as many cigarettes each day as smokers favouring packs of 20.58 Among children aged 12-17, the correlation between pack size preference and number of cigarettes smoked per day was even more marked.59

However, in countries where sales of single cigarettes are the norm, minimum packs of ten may be seen as an improvement. Therefore, the template proposes flexibility with regard to setting minimum and maximum quantities/sizes for sale of tobacco products.

It is important to note that, although the size of packages of cigarettes is discussed here as an example, the range of quantities allowed for retail sale will need to be determined for all tobacco products, including cigars, loose or "roll-your-own" tobacco, and smokeless (spit or chewing) tobacco.

⁵⁷ DiFranza J. Active enforcement of minors' access laws: a moral and ethical imperative. *Tobacco Control* 1995; 4:5.

Hill D White V and Scollo M. Smoking behaviours of Australian adults in 1995. Medical Journal of Australia 1992; 168.

⁵⁹ Hill D White V and Segan C. Prevalence of cigarette smoking among Australian secondary school students in 1993. Australian Journal of Public Health 1995;195:445 –449.

An emerging concern is the sale of tobacco products through mail and the Internet, as it is impossible to establish the age of the purchaser through these channels.

Location of sale. The third issue dealt with in this part is the locations where the sale of tobacco products is allowed. The rationale for this is twofold. First, certain types of institutions are seen as having the responsibility to promote a healthy environment, and from this perspective the sale of tobacco products in these institutions undermines their mandates and responsibilities. Second, from a very practical perspective, reducing the types of institutions that sell tobacco facilitates enforcement of various tobacco control measures. Some jurisdictions, for example the Province of Ontario in Canada, have successfully regulated place of sale. An emerging concern is the sale of tobacco products through mail and the Internet, as it is impossible to establish the age of the purchaser through these channels.

Some jurisdictions have discussed limiting sales of tobacco products to government-owned or regulated outlets, similar to the way in which alcohol is sold in some countries. While this would facilitate enforcement of tobacco control measures, and while can be logically argued that such a system could reduce tobacco use, no jurisdiction has implemented such a system. Therefore there is no evaluation of the impact of such a system on tobacco use. However, this is an option that countries may wish to consider.

Displays. Two issues related to the display of tobacco products are addressed here. First, self-service displays, including the use of vending machines to sell tobacco products, are prohibited in the template. These modes of sale may become a preferred method of obtaining cigarettes when restrictions against tobacco sales to minors are enforced. Youth worried about being asked for I.D. can obtain tobacco by stealing it from self-service displays. Fi Internally, tobacco companies acknowledge that stealing ("pilferage") from self-service displays is a problem, but they try to convince retailers to keep self-service displays by arguing that product placement fees more than compensate for losses from theft. They also acknowledge that a move from self-serve to non self-serve displays results in sales declines.

The visible public display of products for sale is also prohibited in the template, although retailers may post signs indicating that tobacco products are sold there, the brands available, and their prices. The display of tobacco products at point of sale is an important paid vehicle of promotion for tobacco manufacturers. Tobacco product displays become even more important and conspicuous when other promotional vehicles are eliminated, and provide a tempting display to encourage youth and smokers who are trying to quit to purchase tobacco products. The States of Victoria and Tasmania in Australia have restrictions on the display of tobacco products, ^{64, 65} and the Province of Saskatchewan in Canada has

Province of Ontario (Canada), Tobacco Control Act, 1994, Statutes of Ontario, 1994, Chapter 10. http://www.cctc.ca/ncth/docs/legislation/ncthproj/docs/on/tc94-10e.html

⁶¹ DiFranza J and Coleman M. Sources of tobacco for youths in communities with strong enforcement of youth access laws. *Tobacco Control* 2001;10:323-28.

RJReynolds. Pilferage Presentation. 1985. http://www.rjrtdocs.com/rjrtdocs/summarydisplay. wmt?z=1&tab=search&SEARCH=3&stab=summary

⁶³ Campaign for Tobacco-Free Kids. Tobacco Marketing that Reaches Kids: Point-of-Purchase Advertising and Promotion. Fact Sheet. 28 June 2001. http://www.tobaccofreekids.org/research/factsheets/pdf/0075.pdf

⁴ State of Victoria (Australia) *Tobacco Act 1987*, op cit.

⁶⁵ State of Tasmania (Australia) Public Health Act 1997 (No. 86 of 1997).

recently banned the display of tobacco products for sale in places where young persons are allowed to enter.⁶⁶

Signage. Finally, the law allows for the government to require the posting of signs at retail. Signs are an important component of law enforcement and retailer education, but they can also be used to educate the public. The most effective signs are those that not only clarify the law, but also inform the public about addiction and other health effects. For example, a sign that simply says, "It is against the law to sell tobacco to youth" may actually send a subtle message that tobacco use is an adult behavior, making it even more tempting for youth to try to purchase cigarettes. However, a strong visual combined with an educational message, such as "Tobacco products addict and kill. We want to prevent the next generation from making the mistakes we did. We don't sell to minors," sends a stronger and probably more effective message. For an example of innovative signage, refer to the requirements in the Province of New Brunswick in Canada, available at: http://www.cctc.ca/CCTCLAWweb.nsf/MainFrameSet?OpenFrameSet

Tobacco manufacturers have run numerous retail campaigns ostensibly aimed against preventing the sale of tobacco to minors. However, these campaigns do not promote the enforcement of laws, and have been evaluated to be ineffective. ⁶⁷ In addition, signs from these campaigns distract from more effective signs that a government jurisdiction would like to put in place. The template includes a clause banning the posting of signs regarding age of legal sale other than those approved by the government.

Legislative Text

- 17. No person shall sell or offer to sell tobacco to a person who is less than [insert age] years old.⁶⁸
- 18. It shall not be a defense to the above-mentioned clause that the person appeared to be [insert age] years old or older.
- 19. It shall be a defense to clause 17, that the purchaser presented a prescribed form of identification showing his or her age and that there was no apparent reason to doubt the authenticity of the document or that it was issued to the person producing it.⁶⁹
- 20. Nothing in this section prevents a person from giving tobacco or a tobaccorelated product to a young person if the gift is made solely for use in traditional Aboriginal spiritual or cultural practices or ceremonies.

(**Note:** Tobacco use is an integral component of the spiritual practices of peoples native to North America and may be a component of other traditions. This use of

Province of Saskatchewan (Canada), *The Tobacco Control Act*, Bill No. 56 of 2001 http://www.qp.gov.sk.ca/publications/index.cfm?fuseaction=details&c=117363&id=2 Tobacco product
displays become even
more important and
conspicuous when
other promotional
vehicles are
eliminated, and
provide a tempting
display to encourage
youth and smokers
who are trying to quit
to purchase tobacco
products.

⁶⁷ DiFranza JR Savageau JA and Aisquith BF. Youth access to tobacco: The effects of age, gender, vending machine locks and "It's the Law" programs. *American Journal of Public Health* 1996;86:221-4

⁶⁸ Adapted from Province of Ontario (Canada), Tobacco Control Act, op cit.

⁶⁹ Adapted from Province of Ontario (Canada), Tobacco Control Act, op cit.

tobacco is not typically in the form of manufactured cigarettes, and the practice does not condone the regular use of tobacco as smoked in manufactured form.)

21. No person shall sell or offer to sell tobacco products except in a package containing the quantities or number of units prescribed by regulation.⁷⁰

(Note: See rationale in section introduction above.)

22. No person shall sell or offer to sell tobacco products in a place other than those prescribed by regulation.⁷¹

(**Note:** Regulations specifying acceptable places to sell tobacco would have to be passed concomitant with coming into force of the law in order to avoid making the sale of tobacco products illegal.)

- 23. Notwithstanding any regulation made under this Act, no person shall sell or offer to sell tobacco products in the following places:
 - a) health institutions, including hospitals, pharmacies, and health clinics;
 - educational institutions, including primary, secondary, and postsecondary schools;
 - c) facilities with a significant (Note: the percentage perceived to be "significant" can be defined in the law or in regulations.) portion of youth clientele, including amusement parks, movie theatres and sports stadia; and
 - d) such other places as may be prescribed by regulation.
- 24. No person shall sell or offer to sell a tobacco product unless it is hidden from view of the general public at point of sale.⁷²
- 25. Notwithstanding Section 24, retailers may post signs indicating that tobacco products are available for sale, the specific products or brands available for sale, and their respective prices, provided that brand elements are not visibly displayed.
- 26. No person shall sell or offer to sell a tobacco product by means of a display that permits a person to handle the tobacco product before paying for it.⁷³
- 27. No person shall sell or offer to sell tobacco products through a vending machine.⁷⁴
- 28. No person shall sell or offer to sell tobacco products through the mails or through the Internet.
- 29. No person shall sell or offer to sell tobacco at retail unless signs bearing health warnings and other information are posted at the place in accordance with the regulations.⁷⁵

⁷⁰ Adapted from Government of Canada, *Tobacco Act*, op cit.

Adapted from Province of Ontario (Canada), Tobacco Control Act, op cit.

Adapted from Province of Saskatchewan (Canada), The Tobacco Control Act, op cit.

⁷³ Adapted from Government of Canada, *Tobacco Act*, op cit.

 $^{^{74}}$ Adapted from Province of Ontario (Canada), Tobacco Control Act, op cit.

⁷⁵ Adapted from Province of Ontario (Canada), *Tobacco Control Act*, op cit.

- 30. No person shall, at any place or premises in which tobacco or tobacco-related products are sold at retail, display any sign respecting the legal age to purchase tobacco or tobacco-related products unless the sign is supplied or approved by the Ministry of Health.⁷⁶
- 31. The Ministry of Health/Government may make regulations:
 - a) prescribing acceptable forms of identification under clause 19;
 - b) prescribing quantities of tobacco to be sold in a single package;
 - c) prescribing places where tobacco products may be sold;
 - d) prescribing required signage at point of sale;
 - e) generally as needed to carry out this part of the Act.

PART 7

Use

This section regulates the places where tobacco products can be smoked.

Rationale

The scientific community is united in its conclusion that exposure of nonsmokers to tobacco smoke causes serious harm and even death from a variety of causes.⁷⁷ It is also known that there is no known "threshold" or safe level of exposure to tobacco smoke, and that the mere separation of smokers and nonsmokers within the same airspace does not protect nonsmokers from harm regardless of the ventilation system used.^{78, 79} Therefore, strictly from a standpoint of health protection of nonsmokers, there is a strong case for implementing smoke free environments in every sector possible.

However, there is an additional benefit of smoke free environments: they are one of the most effective ways to reduce smoking. Smoke free environments encourage prevention of smoking initiation by striking at the heart of the social acceptability of tobacco, and they promote smoking cessation more effectively

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Adapted from Province of Saskatchewan (Canada), The Tobacco Control Act, op cit.

See, for example, National Cancer Institute. Health Effects of Exposure to Environmental Tobacco Smoke: The Report of the California Environmental Protection Agency. Smoking and Tobacco Control Monograph No. 10. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 99-4645, 1999 http://cissecure.nci.nih.gov/ncipubs/details.asp?pid=200; World Health Organization. International Consultation on Environmental Tobacco Smoke (ETS) and Child Health: Consultation Report, Geneva, 11-14 January 1999. (and related background papers) http://tobacco.who.int/page.cfm?sid=50

Repace JL and Lowrey AH. Issues and answers concerning passive smoking in the workplace: rebutting tobacco industry arguments. *Tobacco Control* 1992;1:208-219.

Americans for Nonsmokers' Rights. *Smoking and Ventilation Standards.* (fact sheet), October 15, 1998. http://www.no-smoke.org/vent.html

Smoke free environments encourage prevention of smoking initiation by striking at the heart of the social acceptability of tobacco, and they promote smoking cessation more effectively than efforts directed at smokers.

than efforts directed at smokers. Studies of the US and Australia, including internal tobacco industry studies, have attributed between 13 and 22% of the declines in tobacco consumption in those countries in recent years to the impact of smoke free environments.^{80, 81} The conclusion of a 1985 Tobacco Institute document was that, "At a dollar a pack, even the lightest of workplace smoking restrictions is costing this industry \$233 million dollars a year [in the US] in revenue."81

Smoke free environments also offer economic advantages: They lower the costs of health and fire insurance and of maintenance costs, create more productive workforces by offering a safer, healthier working environment, and in many cases may increase business (for example, in the hospitality sector).⁸²

To facilitate public education and smooth implementation and enforcement, the template allows for the designation of required signage to clearly mark smoke free areas as well as areas where smoking is allowed. Posting of signs at entrances, corridors and other places that clearly indicate that a building is smoke free helps with enforcement, and empowers nonsmokers to ask smokers to comply. Countries are urged to be creative in using signage as a public education tool. "No smoking" signs need not be the familiar, unattractive cigarette with a red line through it. Colorful and attractive visuals, accompanied by positive messages that tell the public why smoke free environments are necessary, will build public support for the law. For example, "Breathe easy. For your health, this building is smoke free," or "Tobacco smoke causes asthma in children and lung cancer in adult nonsmokers. For your health, this building is smoke free." Conversely, facilities that allow smoking could be required to post a warning. "Warning: Smoking is permitted in this building. Secondhand smoke kills nonsmokers."

Because of the lack of protection offered by shared smoking and nonsmoking areas, and because the impact of smoke free environments increases with the level of restrictions, the template proposes smoke free environments in all public places and workplaces. While such a proposal may seem unfeasible in some jurisdictions, it is far from impossible to achieve. Numerous jurisdictions around the world have successfully banned smoking in all public places and workplaces, with high compliance rates and few transitional difficulties.⁸⁴ Those jurisdictions where this achievement is currently not feasible should see 100% smoke free environments as their ultimate goal, with a step-by-step approach to ensure steady progress toward that goal.

⁸⁰ Chapman S et al. The Impact of Smoke-Free Workplaces on Declining Cigarette Consumption in Australia and the United States. American Journal of Public Health July 1999;89:1018-23.

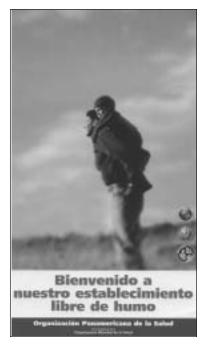
⁸¹ The Tobacco Institute. Public Smoking: The Problem. 1985. http://www.tobaccoinstitute.com/getallimg.asp?if=avtidx&DOCID=TIMN0014554/4565

Workplace Smoking: Trends, Issues and Strategies. Paper prepared for Health Canada, 1996. http://www.hc-sc.gc.ca/hecs-sesc/tobacco/facts/workplace/index.html

The Province of Ontario in Canada prepared posters to coincide with the implementation of provincial smoking restrictions that read, "Breathe Easy: This is a Smoke Free Building" with an attractive graphic backround. Costa Rica has a program that "certifies" smoke free establishments and provides attractive signs to post in smoke free buildings.

See, for example American Nonsmokers' Rights Foundation. 100% Smokefree Ordinances, March 29, 2002. (fact sheet) http://www.no-smoke.org/100ordlist.pdf and Canadian Cancer Society. Municipalities in Canada with Smoke-Free Laws For Restaurants and Bars, September 4, 2001. (fact sheet) http://www.ocat.org/ (go to "2nd hand smoke", then go to "by-laws")

Magzamen S Charlesworth A and Glantz S. Print media coverage of California's smokefree bar law. Tobacco Control 2001;10:154-60.







Many jurisdictions, usually as a compromise to ensure passage of legislation, have allowed some locations (most often bars or restaurants) to have enclosed, separately ventilated smoking areas. We have rejected this option in the template for several reasons. First, this option creates enforcement difficulties because adherence to technical standards needs to be monitored. Second, these smoking areas increase harm to smokers, and also put at risk workers who may be required to enter them. They may also not adequately protect nonsmokers because of drifting smoke as entrances are opened. Finally, in many countries separate ventilation systems are economically unfeasible and therefore impractical. In the end, countries may find as much support for totally smoke free environments as for separately-ventilated areas. In some jurisdictions, small businesses have supported the smoke free option, because separate ventilation systems are expensive and are advantageous to larger, wealthier businesses.

Examples of nonsmoking signs from the Pan American Health Organization, the Province of Ontario in Canada, and Costa Rica.

Legislative Text

- 32. No person shall smoke tobacco or hold lighted tobacco in enclosed, indoor areas of any private or public work place, or any public place.⁸⁶
- 33. For the purpose of this Act, private or public work places and public places include inter alia the following:
 - a) offices and office buildings including public areas, corridors, lounges, eating areas, reception areas, elevators, escalators, foyers, stairwells, restrooms amenity areas, laundry rooms and individual offices;
 - b) factories;

⁸⁶ Adapted from Province of Ontario (Canada), Tobacco Control Act, op cit.

- c) health institutions;
- d) educational institutions of all levels;
- e) any premises in which children are cared for for a fee;
- f) any means of transportation used for commercial, public or professional purposes and used by more than one person;
- g) public transportation terminals;
- h) retail establishments including shopping malls;
- i) cinemas;
- j) concert halls;
- k) sports stadia;
- bars and restaurants;
- m) pool and bingo halls;
- n) publicly owned facilities rented out for events;
- o) any other facilities accessible to the public; and
- p) any other facilities that employ paid personnel.
- 34. All private and public workplaces and public places shall post signs, in accordance with regulations, that clearly indicate that the establishment is smoke free.
- 35. The Minister/Government may make regulations:
 - a) prescribing the location, content and format of any signs required to identify smoke free establishments;
 - b) generally as needed to carry out this part of the Act.

PART 8

Measures to Combat Smuggling

This section covers provisions designed to reduce distribution and sales of contraband tobacco products.

Rationale

Approximately one-third of all exported tobacco products are imported illegally.⁸⁷ The distribution of contraband tobacco products is widely acknowledged to be a problem that diminishes government revenue from tobacco taxes, undermines the tobacco control aims of tobacco tax increases by ensuring widespread avail-

⁸⁷ Joossens L and Raw M. Smuggling and cross border shopping of tobacco in Europe. British Medical Journal 1995;310:1393-7.

ability of cheap tobacco products, and strains the law enforcement resources of all levels of government.

There is a misperception that smuggling is a result of high taxes on tobacco products. However a much better indicator of the level of smuggling is the level of corruption in a country as measured by the so-called "transparency index." There is also a misperception that smuggling is an inevitable consequence of the global tobacco trade. However, numerous jurisdictions have cited the value of coordinated enforcement efforts in reducing smuggling.

In recent years, primarily through the release of internal tobacco industry documents, a compelling story has emerged of the apparent involvement of multinational tobacco companies in facilitating smuggling through distribution networks deliberately established to supply the contraband market.⁸⁹ This story is sufficiently compelling that several countries, including Colombia, Ecuador and Canada in the Americas, have launched lawsuits against tobacco companies to recover lost tax revenue and enforcement costs, although most have been dismissed at lower court levels on technicalities.

The provisions in the template focus on two strategies:

- Eliminating the immediate tax advantage of exporting tobacco products by requiring exporters of tobacco products to post bonds until they prove that the tobacco products have reached their purported legal destination. If properly implemented, this would provide a positive incentive for manufacturers to ensure legal distribution of their products because they would assume a financial risk for products that end up as contraband.
- Implementing ways of tracking and tracing the chain of custody of tobacco
 products so that the point at which the distribution becomes illegal can be
 more easily identified and those responsible for selling to unauthorized
 distributors prosecuted. The specific means of tracing are left open to regulatory authority to allow flexibility to update requirements based on technological advances.

Legislative Text

36. Bond required for exported tobacco products.

- a) No tobacco product shall be exported from [specify country name] without the posting by the manufacturer or exporter of a bond for each shipment with the [specify Ministry or agency] in an amount [describe how the bond amount will be determined] and containing the following information and documents, as applicable:
 - I. the name, license number, address, telephone, and telefax numbers of the manufacturer, including the country of manufacture;

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by the so-called
"transparency index."

⁸⁸ Curbing the Epidemic, op cit.

Beelman M Ronderos MT and Schelzig EJ. Major tobacco multinational implicated in cigarette smuggling, tax evasion, documents show. The Public I: An Investigative Report of the Center for Public Integrity. March 23, 2000.

- II. the name, license number, address, telephone, and telefax numbers of the exporter, including the country of export;
- III. the name, license number, address, telephone, and telefax numbers of the importer/purchaser, and any person who receives the shipment on the importer/purchaser's behalf;
- IV. the name, address, telephone, and telefax numbers of the intended carrier(s) of the shipment and the means of transport;
- V. the names of the cities and countries through which the shipment will be transported;
- VI. identification of the country of final destination;
- VII. the name, license number, address, telephone, and telefax numbers of any distributors and other intermediaries handling the shipment;
- VIII. the date of the shipment, the period of time over which the shipment is to be in transit, the date of expected arrival in the country of final destination, and the itinerary correlated with dates of entry and exit for each point of entry and exit;
- IX. physical description of the products (e.g., cigarettes, cigars, bidis, smokeless tobacco, etc.) shipped, including lot, batch or serial numbers of all products contained in the shipment;
- X. number of individual packages, number of sticks in each package or gram amount, as applicable, number of bulk packages, number of individual packages contained in each bulk package, and the weight of each bulk package contained in the shipment;
- XI. copies of all purchase orders, invoices, shipping or transport, and transit documents related to the shipment;
- XII. a description of any tax stamps or special marking or design features on packages contained in the shipment;
- XIII. an affidavit of the exporter stating that:
 - he or she has exhausted all reasonable means to investigate the degree of demand for the products in the country of destination and determined that there is legitimate demand there for the number of products ordered and shipped;
 - ii. there is no substantial basis for believing that any person receiving or handling the shipment has been or is involved in illegal commercial activity or that the products will be sold illegally;
 - iii. he or she has complied with all labeling and other legal requirements; and
 - iv. information and documents supplied are true and correct to the best of his or her knowledge.

- b) The bond made pursuant to subsection (a) shall be forfeited unless the manufacturer or exporter, as applicable, provides [specify Ministry or agency] with the following information within [specify number] days of [specify triggering event (e.g., the date the goods are shipped)]:
 - I. evidence of the chain of custody and proof that all goods reached their final destination without any product being sold or distributed without the full payment of all applicable duties, including but not limited to:
 - copies of all bills of lading or other evidence of receipt by all importers and intermediaries;
 - ii. proof of payment of all applicable duties;
 - iii. copies of invoices received from any intermediaries handling the shipment;
 - iv. copies of delivery records;
 - v. copies of all payment records;
 - vi. [specify any other]
 - vii. and any other information required by the Minister in implementing regulations.
- 37. The Minister may make regulations under this Part to establish requirements that enable the tracking and tracing of tobacco products through the distribution chain from manufacture to the point where all relevant duties and taxes have been paid, for the purpose of assisting competent law enforcement authorities in detecting and investigating illicit manufacture and distribution of tobacco products and identifying those responsible for illegal activity. These requirements may include but are not limited to the use of:
 - a) overt or covert markings to uniquely identify each individual tobacco product and/or any of its packaging;
 - overt markings to clearly identify the legal intended end-market destination of tobacco products;
 - c) scanning of tobacco products and their packaging or other procedures that identify their origin and passage through the distribution chain; and
 - d) any other relevant technology that may emerge.

Enforcement, Inspection, Offences and Punishments

Rationale

The enforcement provisions of any law play a large part in determining the success of implementation of the law. If the provisions of the law are unenforced, or if they are understood to be unenforceable, they become nothing more than words on paper. Effective enforcement consists of four basic components:

- the designation of authority for enforcement to an agency able to fulfil this role;
- penalties for violation of provisions of the law that are sufficiently serious to deter violations;
- an enforcement process that allows for effective prosecution of violations, including adequate powers of inspection and reasonable burden of evidence; and
- financing of enforcement activities at a level sufficient to ensure a reasonable chance of violators being caught.

The first three of these are influenced primarily by the content of the law. Other enforcement and implementation issues are discussed in the introduction.

The template language provided generally proposes a two-tiered penalty system with a higher level of penalties for manufacturers and large institutions than for individuals and smaller institutions. This is because different levels of penalties are deterrent for individuals versus manufacturers, and because violations by manufacturers or other larger institutions have a greater impact on the effectiveness of the law than those by individuals.

Obviously, the template cannot suggest particular levels of fines appropriate for each country. However, countries should ensure that the penalties are sufficiently high to produce a deterrent effect, and should be at least as great as the benefit gained from the illegal activity. For example, if a retailer can make more money from selling tobacco to minors than he or she has to pay in penalties within the same time period, there is very little deterrent effect.

Legislative Text

38. For the purpose of this Act the Ministry/Government may appoint any person or designate any class of persons to perform the duties of inspector or analyst. The responsibilities of an inspector shall be specified in the act of appointment.⁹⁰

Pan American Health Organization

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they become nothing
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on paper.

⁹⁰ Adapted from Province of Quebec (Canada), Tobacco Act, Bill 444 (1998, chapter 33)

- 39. Every person authorized as an inspector or analyst under clause 38 may, at any reasonable time, to ascertain compliance with this Act and the regulation under it, enter and inspect any of the following places:
 - a) referred to in clause 33;
 - b) where tobacco is manufactured, tested, stored, packaged, labeled or sold;
 - c) where layouts and requirements stated in clause 25(a) are to be found;
 - d) where anything used in the manufacture, storage, packing, promotion, sale or testing of tobacco is to be found;
 - e) where information relating to the manufacture, storage, packaging, labeling, promotion, sale or testing of tobacco is to be found.⁹¹
- 40. Authorized inspectors and analysts shall have the following powers, which no person shall deny, obstruct, or hinder:
 - a) to examine, open, and test any equipment, tools, materials, packages or anything the authorized officer reasonably believes is used or capable of being used for the manufacture, packaging, labeling, storage, distribution, or advertising or promotion [if allowed] of tobacco products;
 - b) to examine any operation or process carried out on the premises;
 - to examine and make copies of or from any books, documents, notes, files, including electronic files, or other records the authorized officer reasonably believes might contain information relevant to determining compliance with regulatory requirements;
 - d) to interview or question any licensee or other person involved in manufacturing, importing, exporting, transporting, packaging, marketing [if allowed] or distributing tobacco products, any owner of the premises, or any person using the premises, and his or her employees, agents, contractors and workers, all of whom shall cooperate fully and truthfully with any inspection or investigation;
 - e) to take samples of tobacco products or components of products anywhere they are found and have them tested;
 - f) to stop, search, and detain any aircraft, ship, vehicle or other means of transport or storage in which the authorized officer reasonably believes tobacco products are contained or conveyed and examine, open, take samples of and have tested any tobacco products or product components found therein; and
 - g) to seize and detain, or order the storage without removal or alteration of any tobacco product the authorized officer reasonably believes does not comply with regulatory requirements, upon providing the licensee or owner of the tobacco products, or if he or she is unavailable, any other person on the premises where the tobacco products are located, written notice of the seizure and detention and the grounds for it. If any tobacco product so seized and detained is determined to meet regulatory require-

⁹¹ Ibid.

ments, it shall be returned immediately to the premises from which it was seized. If any tobacco product is determined not to meet regulatory requirements, it may be confiscated and destroyed or subject to other disposal, as ordered by the adjudicator of the case.

- 41. An inspector or analyst entering a place to inspect it under this chapter must, on request, provide the operator of the place with proof of identity and produce a certificate or appointment signed by the Minister, or by a person designated in accordance with the regulations.⁹²
- 42. An inspector may not enter a dwelling-place except with the consent of the occupant or under the authority of a warrant issued in accordance with section ... of the Criminal Code.⁹³
- 43. No person shall hinder in any way the performance of the duties of an inspector or analyst, mislead them by concealment or false statements, or refuse to provide them with any information or document to which they are entitled under this Act, or destroy any such information or document.⁹⁴
- 44. During an inspection under this Act, an inspector may seize any tobacco product or other thing by means of which or in relation to which the inspector believes on reasonable grounds that this Act has been contravened.⁹⁵
- 45. Any person found guilty of violating any provision under Part 3 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
 - b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 46. Any person found guilty of violating any provision under Part 4 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
 - b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 47. Any person found guilty of violating any provision under Part 5 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and

⁹² Ibid.

⁹³ Adapted from Government of Canada, Tobacco Act, op cit.

⁹⁴ Province of Quebec (Canada), Tobacco Act, op cit.

⁹⁵ Adapted from Government of Canada, Tobacco Act, op cit.

- b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 48. Any person found guilty of violating any provision under Part 6 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
 - b) in the case of the proprietor of a retail establishment, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
 - c) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 49. Any proprietor, owner, and/or manager of any premise listed under Part 7 of this Act found guilty of failing to enforce the smoke-free policy applicable to the facility under his or her responsibility, including the posting of prescribed signs and ensuring that any designated smoking areas meet the requirements of the Act and its regulations, shall be liable for a fine of not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 50. Any person found guilty of smoking in a place where smoking is prohibited under Part 7 of this Act shall be liable for a fine of not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 51. Any person found guilty of violating any provision under Part 8 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
 - b) in the case of a proprietor of a retail establishment, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
 - c) in the case of a wholesale distributor, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
 - d) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 52. In addition to any fines imposed, any person found guilty of violating any provision under Part 8 of this Act shall be liable for a penalty equivalent to the proceeds from the distribution of illegal tobacco products as well as taxes and duties owed on those products.

53. Nothing in this Act shall preclude the criminal enforcement of its provisions in a Court of competent jurisdiction.

(Note: This clause, as well as clause 52 above, are included to, among other things, provide a higher deterrent to smuggling, which can bring enormous profits to smugglers that may exceed "normal" penalties under the law. In addition, in acknowledgement of the criminal nature of illegal distribution of tobacco, wider prosecutory powers are granted that would allow penalties other than solely financial ones.)

- 54. Where a person is found guilty of an offence under any part of this Act other than Part 8, the judge may impose an additional fine in addition to any other penalty, following an application by the prosecuting party appended to the statement of offence, equal to the amount of monetary benefit gained by the person as a result of the offence, even if the maximum fine is imposed under another provision.
- 55. A person who commits or continues an offence under this Act on more than one day is liable to be convicted for a separate offence for each day on which the offence is committed or continued.
- 56. Any person found to have violated any requirement under this Act or implementing regulations may be ordered to pay the reasonable costs associated with any inspection, investigation, and enforcement action brought about by the noncompliance.
- 57. The Ministry of Health/Government shall make regulations:
 - a) respecting the powers and duties of inspectors and analyst;
 - b) respecting the taking of samples;
 - c) respecting the procedure to be followed by the inspector or analyst during an inspection;
 - d) respecting the procedure to be followed during an inspection for seizure, as well as the one to be applied and restoration of any tobacco product;
 - e) generally as needed to carry out this part of the Act.

PART 10

Final Clauses

Legislative Text

58. This Act shall come into force no later than one year [or specify other time period] following its passage into law.

ANNEX 1 Consolidated Template Without Notes

Tobacco Products Control Act (A Template)

PART 1

Principles and Purpose

WHEREAS the use of tobacco products constitutes one of the major public health problems in the world, causing more than one third of all deaths from cancer and heart disease and responsible for numerous other debilitating and fatal diseases;

WHEREAS smoke from tobacco products is a serious health threat to nonsmokers exposed to the smoke, causing serious diseases in adults, and particularly in children;

WHEREAS most smokers start smoking at a very young age, are not aware of the extent and nature of the harm caused by tobacco products, and because of the addictive properties of nicotine are often unable to quit even when they are highly motivated to do so:

WHEREAS the marketing of tobacco products though product design, promotion, packaging, pricing and distribution, is known to contribute to the demand for tobacco products,

Be enacted by... as follows:-

An Act to regulate the manufacture, labeling, promotion, distribution, and use of tobacco products

- 1. The purpose of this law is to reduce tobacco use and its consequent harm by:
 - a) protecting children and other nonsmokers from inducements to use tobacco;
 - b) protecting nonsmokers from exposure to tobacco smoke;
 - ensuring that the population is adequately informed about the risks of tobacco use and exposure to secondhand tobacco smoke and about the benefits of quitting smoking;
 - d) ensuring that tobacco products are modified to reduce harm to the extent technologically and practically possible; and
 - e) promoting a climate where nonsmoking and the absence of tobacco promotion is the norm.

PART 2

Preliminaries, including Definitions

- 2. This Act may be cited as *The Tobacco Control Act*.
- 3. The definitions in this section apply to this Act: *appeal* refers to the ability of a product to provide physical or psychological pleasure, satisfaction, or other positive quality to the consumer;
 - brand element includes the brand name, trade-mark, trade-name, distin-

guishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with those used for any brand of tobacco product;

character refers to the distinctive qualities of a tobacco product;

composition refers to the content, arrangement or combination of substances included in the processing and manufacture of tobacco products;

distribute means to sell, offer to sell, expose for sale, give, supply exchange, convey, consign, deliver, furnish, or transfer possession for commercial purposes, or offer to do so, whether for a fee or other consideration or as a sample, gift, prize, or otherwise without charge;

emission means any substance or combination of substances that is produced as a result of a tobacco product being lighted;

inspector/analyst means a person or class of persons designated as an inspector under clause xx;

manufacturer includes any entity that is associated with the manufacturer, including an entity that controls or is controlled by the manufacturer or that is controlled by the same entity that controls the manufacturer;

ministry means the Minister of Health or his or her designate;

package means the container, receptacle or wrapper in which a tobacco product is sold or displayed at retail, including a carton that contains smaller packages;

promotion is the practice of fostering awareness of and positive attitudes toward a product, brand or manufacturer for the purpose of selling the product or encouraging tobacco use, through various means including direct advertisement, discounts, incentives, rebates, free distribution, promotion of brand elements through related events and products through a public medium of communication:

tobacco product means a product composed in whole or in part of tobacco, including tobacco leaves and any extract of tobacco leaves. It includes cigarette papers, tubes and filters;

toxicity refers to the quality, relative degree or specific degree of being toxic or poisonous;

vending machine means any means of distribution of tobacco products that is not mediated by a human being;

youth means a person under 18 years old.

PART 3

Product Regulation

- 4. No person shall manufacture, sell, or import a tobacco product except in compliance with this Act and any regulations made under this Act.
- 5. Every manufacturer and importer of a tobacco product shall provide the Ministry/Government, in the prescribed manner and within the prescribed time, information about the product and its emissions as required by the Regulations.
- 6. No person shall sell, offer for sale, distribute, advertise or promote any brand of tobacco products that was not sold, distributed, advertised or promoted in

the country at least one year before the effective date of this Act.

- 7. The Minister/Government may make regulations:
 - a) establishing standards for the manufacture of tobacco products, including
 - prescribing the amount of substances that may be contained in the product or its emissions;
 - prescribing substances that may not be added to tobacco products;
 and
 - iii) prescribing product design standards to reduce the harmful effects of tobacco products and to reduce their appeal to youth.
 - b) prescribing test methods, including methods to assess conformity with the standards:
 - c) prescribing information that manufacturers must provide to the Minister/Government and/or the public about tobacco products and their emission, including sales data and information on product composition, ingredients, hazardous properties, and brand elements;
 - d) generally as needed to carry out this part of the Act.

PART 4

Packaging and Labeling

- 8. No person shall manufacture, sell, or import a tobacco product unless the package containing it displays, in the prescribed form and manner including through an enclosed leaflet if prescribed, the information required by the regulations about the product and its emissions, about the health hazards and health effects arising from the use of the product or from its emissions, other health-related messages such as inter alia advice on how to quit smoking, and markings designed to facilitate efforts to identify illegally manufactured or distributed tobacco products or products on which tax has not been paid.
- 9. No person shall package tobacco in a manner that allows a consumer or purchaser of tobacco products to be deceived or misled concerning its character, properties, toxicity, composition, merit or safety.
- 10. Any requirements arising from the above-mentioned clauses, do not relieve a manufacturer or retailer of other obligations or liabilities arising from other applicable legal norms to warn consumers of the risks of using tobacco products.
- 11. The Ministry/Government may make regulations:
 - a) respecting the content and format of information described in section 8 of this Act that must appear on packages and in leaflets;
 - b) respecting information that may not appear on packages; and
 - c) generally as needed to carry out this part of the Act.

Advertising and Promotion

[Total ban clause:

- 12. No person shall promote or cause to promote by any other person, a tobacco product or a tobacco product-related brand element through direct or indirect means, including through sponsorship of an organization, service, physical establishment or vehicle of any kind, or event.
- 13. No person shall sell, promote, distribute or cause to be sold, promoted or distributed, any item other than a tobacco product which bears the brand name (alone or in conjunction with any other word), trade-mark, tradename, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product.] End total ban clause

[Partial ban clause:

- 12. No person shall promote or cause to promote by any other person, a tobacco product or a tobacco product-related brand element, except as prescribed by this Act or its regulations.
- 13. Notwithstanding any regulation made under this Act, no person shall promote or cause to promote tobacco products or brand elements:
 - a) in a manner that allows a consumer or purchaser of tobacco products to be deceived or misled concerning its character, properties, toxicity, composition, merit or safety;
 - that does not display, in the prescribed form and manner, the information required by the regulations about the product and its emissions, about the health hazards and health effects arising from the use of the product or from its emissions, and other health-related messages such as inter alia advice on how to quit smoking;
 - c) through means of promotion that can be viewed from outdoors;
 - d) utilizing any item other than a tobacco product, or a physical establishment or vehicle of any kind, which bears the brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product;
 - e) utilizing any athletic, musical, artistic or any other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), trade-mark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product;
 - f) nothing in clause 13 e) shall prevent a person from sponsoring or causing to be sponsored any athletic, musical, artistic or any other social or

cultural event, or any entry or team in any event, in the name of a corporation which manufactures a tobacco product, provided that both the corporate name and the corporation were registered and in use in this country prior to (specify a date approximately 1 year prior to anticipated passage of the law) and that the corporate name does not include any brand name (alone or in conjunction with any other word), trademark, trade-name, distinguishing guise, logo, graphic arrangement, design, slogan, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of tobacco product.] End partial ban clause

- 14. Nothing in this subsection shall apply to the publication by a manufacturer of a tobacco product advertisement in a printed publication that is intended for distribution only to employees of the tobacco trade for trade purposes.
- 15. No person shall offer or provide any consideration, direct or indirect, for the purchase of a tobacco product, including a gift to a purchaser or a third party, bonus, premium, cash rebate or right to participate in a game, lottery or contest, or distribute a tobacco product without monetary consideration, or in consideration of the purchase of a product or service or the performance of a service.
- 16. The Ministry/Government may make regulations:

(Note: Subclauses a), b) and c) below are not necessary in the case of a total prohibition.)

- a) prescribing the form and manner of any health messages to be required on promotional material or representations by any means;
- b) prescribing the format, content and placement of any tobacco promotion;
- c) requiring tobacco manufacturers to report the amount of monetary expenditures on tobacco promotion by brand and by type of media and prescribing the format and frequency of reporting;
- d) prescribing schedules for the implementation of promotional restrictions;
- e) generally as needed to carry out this part of the Act.

PART 6

Distribution

- 17. No person shall sell or offer to sell tobacco to a person who is less than [insert age] years old.
- 18. It shall not be a defense to the above-mentioned clause that the person appeared to be [insert age] years old or older.
- 19. It shall be a defense to clause 17, that the purchaser presented a prescribed form of identification showing his or her age and that there was no apparent reason to doubt the authenticity of the document or that it was issued to the person producing it.
- 20. Nothing in this section prevents a person from giving tobacco or a tobaccorelated product to a young person if the gift is made solely for use in traditional Aboriginal spiritual or cultural practices or ceremonies.

- 21. No person shall sell or offer to sell tobacco products except in a package containing the quantities or number of units prescribed by regulation.
- 22. No person shall sell or offer to sell tobacco products in a place other than those prescribed by regulation.
- 23. Notwithstanding any regulation made under this Act, no person shall sell or offer to sell tobacco products in the following places:
 - a) health institutions, including hospitals, pharmacies, and health clinics;
 - b) educational institutions, including primary, secondary, and postsecondary schools;
 - c) facilities with a significant portion of youth clientele, including amusement parks, movie theatres and sports stadia; and
 - d) such other places as may be prescribed by regulation.
- 24. No person shall sell or offer to sell a tobacco product unless it is hidden from view of the general public at point of sale.
- 25. Notwithstanding Section 24, retailers may post signs indicating that tobacco products are available for sale, the specific products or brands available for sale, and their respective prices, provided that brand elements are not visibly displayed.
- 26. No person shall sell or offer to sell a tobacco product by means of a display that permits a person to handle the tobacco product before paying for it.
- 27. No person shall sell or offer to sell tobacco products through a vending machine.
- 28. No person shall sell or offer to sell tobacco products through the mails or through the Internet.
- 29. No person shall sell or offer to sell tobacco at retail unless signs bearing health warnings and other information are posted at the place in accordance with the regulations.
- 30. No person shall, at any place or premises in which tobacco or tobacco-related products are sold at retail, display any sign respecting the legal age to purchase tobacco or tobacco-related products unless the sign is supplied or approved by the Ministry of Health.
- 31. The Ministry of Health/Government may make regulations:
 - a) prescribing acceptable forms of identification under clause 19;
 - b) prescribing quantities of tobacco to be sold in a single package;
 - c) prescribing places where tobacco products may be sold;
 - d) prescribing required signage at point of sale;
 - e) generally as needed to carry out this part of the Act.



Use

- 32. No person shall smoke tobacco or hold lighted tobacco in enclosed, indoor areas of any private or public work place, or any public place.
- 33. For the purpose of this Act, private or public work places and public places

include inter alia the following:

- a) offices and office buildings including public areas, corridors, lounges, eating areas, reception areas, elevators, escalators, foyers, stairwells, restrooms amenity areas, laundry rooms and individual offices;
- b) factories:
- c) health institutions;
- d) educational institutions of all levels;
- e) any premises in which children are cared for for a fee;
- f) any means of transportation used for commercial, public or professional purposes and used by more than one person;
- g) public transportation terminals;
- h) retail establishments including shopping malls;
- i) cinemas:
- j) concert halls;
- k) sports stadia;
- l) bars and restaurants;
- m) pool and bingo halls;
- n) publicly owned facilities rented out for events;
- o) any other facilities accessible to the public; and
- p) any other facilities that employ paid personnel.
- 34. All private and public workplaces and public places shall post signs, in accordance with regulations, that clearly indicate that the establishment is smoke free.
- 35. The Minister/Government may make regulations:
 - a) prescribing the location, content and format of any signs required to identify smoke free establishments;
 - b) generally as needed to carry out this part of the Act.

PART 8

Measures to Combat Smuggling

36. Bond required for exported tobacco products.

- a) No tobacco product shall be exported from [specify country name] without the posting by the manufacturer or exporter of a bond for each shipment with the [specify Ministry or agency] in an amount [describe how the bond amount will be determined] and containing the following information and documents, as applicable:
 - I. the name, license number, address, telephone, and telefax numbers of the manufacturer, including the country of manufacture;
 - II. the name, license number, address, telephone, and telefax numbers of the exporter, including the country of export;

- III. the name, license number, address, telephone, and telefax numbers of the importer/purchaser, and any person who receives the shipment on the importer/purchaser's behalf;
- IV. the name, address, telephone, and telefax numbers of the intended carrier(s) of the shipment and the means of transport;
- V. the names of the cities and countries through which the shipment will be transported;
- VI. identification of the country of final destination;
- VII. the name, license number, address, telephone, and telefax numbers of any distributors and other intermediaries handling the shipment;
- VIII. the date of the shipment, the period of time over which the shipment is to be in transit, the date of expected arrival in the country of final destination, and the itinerary correlated with dates of entry and exit for each point of entry and exit;
- IX. physical description of the products (e.g., cigarettes, cigars, bidis, smokeless tobacco, etc.) shipped, including lot, batch or serial numbers of all products contained in the shipment;
- X. number of individual packages, number of sticks in each package or gram amount, as applicable, number of bulk packages, number of individual packages contained in each bulk package, and the weight of each bulk package contained in the shipment;
- XI. copies of all purchase orders, invoices, shipping or transport, and transit documents related to the shipment;
- XII. a description of any tax stamps or special marking or design features on packages contained in the shipment;
- XIII. an affidavit of the exporter stating that:
 - i. he or she has exhausted all reasonable means to investigate the degree of demand for the products in the country of destination and determined that there is legitimate demand there for the number of products ordered and shipped;
 - ii. there is no substantial basis for believing that any person receiving or handling the shipment has been or is involved in illegal commercial activity or that the products will be sold illegally;
 - iii. he or she has complied with all labeling and other legal requirements; and
 - iv. information and documents supplied are true and correct to the best of his or her knowledge.
- b) The bond made pursuant to subsection (a) shall be forfeited unless the manufacturer or exporter, as applicable, provides [specify Ministry or agency] with the following information within [specify number] days of [specify triggering event (e.g., the date the goods are shipped)]:
 - I. evidence of the chain of custody and proof that all goods reached their final destination without any product being sold or distributed without the full payment of all applicable duties, including but not limited to:
 - i. copies of all bills of lading or other evidence of receipt by all importers and intermediaries;

- ii. proof of payment of all applicable duties;
- iii. copies of invoices received from any intermediaries handling the shipment;
- iv. copies of delivery records;
- v. copies of all payment records;
- vi. [specify any other]
- vii. and any other information required by the Minister in implementing regulations.
- 37. The Minister may make regulations under this Part to establish requirements that enable the tracking and tracing of tobacco products through the distribution chain from manufacture to the point where all relevant duties and taxes have been paid, for the purpose of assisting competent law enforcement authorities in detecting and investigating illicit manufacture and distribution of tobacco products and identifying those responsible for illegal activity. These requirements may include but are not limited to the use of:
 - a) overt or covert markings to uniquely identify each individual tobacco product and/or any of its packaging;
 - b) overt markings to clearly identify the legal intended end-market destination of tobacco products;
 - c) scanning of tobacco products and their packaging or other procedures that identify their origin and passage through the distribution chain; and
 - d) any other relevant technology that may emerge.

Enforcement, Inspection, Offences and Punishments

- 38. For the purpose of this Act the Ministry/Government may appoint any person or designate any class of persons to perform the duties of inspector or analyst. The responsibilities of an inspector shall be specified in the act of appointment.
- 39. Every person authorized as an inspector or analyst under clause 38 may, at any reasonable time, to ascertain compliance with this Act and the regulation under it, enter and inspect any of the following places:
 - a) referred to in clause 33;
 - b) where tobacco is manufactured, tested, stored, packaged, labeled or sold;
 - c) where layouts and requirements stated in clause 25(a) are to be found;
 - d) where anything used in the manufacture, storage, packing, promotion, sale or testing of tobacco is to be found;
 - e) where information relating to the manufacture, storage, packaging, labeling, promotion, sale or testing of tobacco is to be found.
- 40. Authorized inspectors and analysts shall have the following powers, which no person shall deny, obstruct, or hinder:
 - a) to examine, open, and test any equipment, tools, materials, packages or anything the authorized officer reasonably believes is used or capable of being used for the manufacture, packaging, labeling, storage, distribution, or advertising or promotion [if allowed] of tobacco products;

- b) to examine any operation or process carried out on the premises;
- to examine and make copies of or from any books, documents, notes, files, including electronic files, or other records the authorized officer reasonably believes might contain information relevant to determining compliance with regulatory requirements;
- d) to interview or question any licensee or other person involved in manufacturing, importing, exporting, transporting, packaging, marketing [if allowed] or distributing tobacco products, any owner of the premises, or any person using the premises, and his or her employees, agents, contractors and workers, all of whom shall cooperate fully and truthfully with any inspection or investigation;
- e) to take samples of tobacco products or components of products anywhere they are found and have them tested;
- f) to stop, search, and detain any aircraft, ship, vehicle or other means of transport or storage in which the authorized officer reasonably believes tobacco products are contained or conveyed and examine, open, take samples of and have tested any tobacco products or product components found therein; and
- g) to seize and detain, or order the storage without removal or alteration of any tobacco product the authorized officer reasonably believes does not comply with regulatory requirements, upon providing the licensee or owner of the tobacco products, or if he or she is unavailable, any other person on the premises where the tobacco products are located, written notice of the seizure and detention and the grounds for it. If any tobacco product so seized and detained is determined to meet regulatory requirements, it shall be returned immediately to the premises from which it was seized. If any tobacco product is determined not to meet regulatory requirements, it may be confiscated and destroyed or subject to other disposal, as ordered by the adjudicator of the case.
- 41. An inspector or analyst entering a place to inspect it under this chapter must, on request, provide the operator of the place with proof of identity and produce a certificate or appointment signed by the Minister, or by a person designated in accordance with the regulations.
- 42. An inspector may not enter a dwelling-place except with the consent of the occupant or under the authority of a warrant issued in accordance with section ... of the Criminal Code.
- 43. No person shall hinder in any way the performance of the duties of an inspector or analyst, mislead them by concealment or false statements, or refuse to provide them with any information or document to which they are entitled under this Act, or destroy any such information or document.
- 44. During an inspection under this Act, an inspector may seize any tobacco product or other thing by means of which or in relation to which the inspector believes on reasonable grounds that this Act has been contravened.
- 45. Any person found guilty of violating any provision under Part 3 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
 - b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for

subsequent offences.

- 46. Any person found guilty of violating any provision under Part 4 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
 - b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 47. Any person found guilty of violating any provision under Part 5 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
 - b) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 48. Any person found guilty of violating any provision under Part 6 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
 - b) in the case of the proprietor of a retail establishment, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences; and
 - c) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 49. Any proprietor, owner, and/or manager of any premise listed under Part 7 of this Act found guilty of failing to enforce the smoke-free policy applicable to the facility under his or her responsibility, including the posting of prescribed signs and ensuring that any designated smoking areas meet the requirements of the Act and its regulations, shall be liable for a fine of not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 50. Any person found guilty of smoking in a place where smoking is prohibited under Part 7 of this Act shall be liable for a fine of not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 51. Any person found guilty of violating any provision under Part 8 of this Act shall be liable for a fine of
 - a) in the case of an individual, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
 - b) in the case of a proprietor of a retail establishment, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;

- c) in the case of a wholesale distributor, not less than \$xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences;
- d) in the case of a manufacturer, not less than xxx and not more than xxx for the first offence, and of not less than xxx and not more than xxx for subsequent offences.
- 52. In addition to any fines imposed, any person found guilty of violating any provision under Part 8 of this Act shall be liable for a penalty equivalent to the proceeds from the distribution of illegal tobacco products as well as taxes and duties owed on those products.
- 53. Nothing in this Act shall preclude the criminal enforcement of its provisions in a Court of competent jurisdiction.
- 54. Where a person is found guilty of an offence under any part of this Act other than Part 8, the judge may impose an additional fine in addition to any other penalty, following an application by the prosecuting party appended to the statement of offence, equal to the amount of monetary benefit gained by the person as a result of the offence, even if the maximum fine is imposed under another provision.
- 55. A person who commits or continues an offence under this Act on more than one day is liable to be convicted for a separate offence for each day on which the offence is committed or continued.
- 56. Any person found to have violated any requirement under this Act or implementing regulations may be ordered to pay the reasonable costs associated with any inspection, investigation, and enforcement action brought about by the noncompliance.
- 57. The Ministry of Health/Government shall make regulations:
 - a) respecting the powers and duties of inspectors and analyst;
 - b) respecting the taking of samples;
 - c) respecting the procedure to be followed by the inspector or analyst during an inspection;
 - d) respecting the procedure to be followed during an inspection for seizure, as well as the one to be applied and restoration of any tobacco product;
 - e) generally as needed to carry out this part of the Act

Final Clauses

58. This Act shall come into force no later than one year [or specify other time period] following its passage into law.

ANNEX 2

Consolidated List of Internet-Available Laws

Australia

Tobacco Act 1987, State of Victoria (Australia), including establishment of the Victorian Health Promotion Foundation

http://www.dms.dpc.vic.gov.au/l2d/T/ACT01228/2_1.html

Tobacco Control Act 1990, Part 3-Western Australian Health Promotion Foundation, State of Western Australia (Australia)

http://www.slp.wa.gov.au/statutes/swans.nsf/Current+Legislation+Version2? SearchView

Brazil

Resolução - RDC nº 104, de 31 de maio de 2001 (labelling regulations) http://www.anvisa.gov.br/legis/resol/104_01rdc.htm

Visual examples of the Brazilian health messages: http://www.anvisa.gov.br/divulga/noticias/040601_1.htm

Canada

The site below, maintained by the Canadian Council on Tobacco Control, links to of all of the Canadian laws cited in this document. http://www.cctc.ca/CCTCLAWweb.nsf/MainFrameSet?OpenFrameSet

Visual examples of the Canadian health messages: http://www.hc-sc.gc.ca/english/media/photos/tobacco_labelling/

European Union

Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products - Commission statement. Official Journal L 194, 18/07/2001 P. 0026 - 0035 http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32001L0037&model=guichett

New Zealand

Smoke-free Environments Act 1990 108 http://www.govt.nz/nzgovt/leg.php3

United States

Section 104350-104495, Health and Safety Code, State of California (USA) (also known as "Proposition 99") http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=47204815307+1+0+0&WAISaction=retrieve

Medicaid Third-Party Liability Act, State of Florida (USA) http://stic.neu.edu/Fl/2florida.htm

General Laws of Massachusetts, Part I, Title XVII, Chapter 118E: Division of Medical Assistance, State of Massachusetts (USA) http://www.state.ma.us/legis/laws/mgl/118E-22.htm

Commonwealth of Massachusetts' *Testing and Reporting of Constituents of Cigarette Smoke* http://www.state.ma.us/dph/mtcp/report/smoktox.htm



Pan American Health Organization

Regional Office of the

World Health Organization

Division of Health Promotion and Protection Program on Mental Health

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