

Model Legislation for Tobacco Control: A Policy Development and Legislative Drafting Manual

Rose Nathan, JD, MPH

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The IUHPE

The mission of the International Union for Health Promotion and Education (IUHPE) is to promote global health and to contribute to the achievement of equity in health between and within the countries of the world. The IUHPE fulfils its mission by building and operating an independent, global, professional network of people and institutions from more than 90 countries to encourage the free exchange of ideas, knowledge, know-how, experience, and the development of relevant collaborative projects, both at global and regional levels.

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Model Legislation for Tobacco Control: A Policy Development and Legislative Drafting Manual

Potential Uses and Constraints of the Manual

- This Manual is designed to assist policy makers by providing:
 1. information to enable a conceptualization and understanding of the elements of a comprehensive tobacco control law, and their importance;
 2. evidence in support of policies to enable strategic thinking about choices among legislative and regulatory measures; and
 3. options for actual language that can be used for drafting tobacco control legislation or regulations. This information is provided to help countries produce, on demand, legislation and regulations that reflect expertise in both legal drafting and the substantive areas of tobacco control.

The Manual was developed after studying tobacco control laws and regulations from countries in all regions of the world. It then went through a rigorous review process by a diverse group of tobacco control experts with legal, policy, scientific, and programming experience to ensure its broad applicability for countries ready for tobacco control legislation.

Because it cannot be universally applicable in all its provisions or fit all countries' needs, the Manual should be considered as a starting point. It will need to be adapted to suit the legal system, customs, and realities in any given country.

Adopting a Best Practices Approach to Tobacco Control Legislation

- The discipline of legal drafting and analysis generally is practiced by examining what has come before. Therefore, it is common when drafting legislation of any type to draw upon previous experiences and examples from other jurisdictions with a track record. Since there are many countries with solid, evidence-based tobacco control legislation, it only makes sense to examine what other countries have done, take what has been successful from around the world, and adapt it to meet national needs. Turning a time honoured practice on its head, the tobacco industry has



The WHO publication, *Tobacco Control Legislation: An Introductory Guide*

made the argument in some places that the legislative drafters merely cut and pasted their legislative provisions from other countries' laws, as though this is a bad practice. To the contrary, this practice is the best strategy for adopting a best practices approach to tobacco control legislation, so long as national needs have been considered and appropriate adaptations made.

Additional Resources

■ The World Health Organisation (WHO) has published an important tool to assist with preparing for the legislative process and developing legislation for tobacco control. The publication, *Tobacco Control Legislation: An Introductory Guide*,¹ explores in more depth some of the matters discussed briefly in the following introductory pages. It also provides background information that will be invaluable to anyone embarking on the legislative journey. It is suggested that the Manual be used in conjunction with the WHO Introductory Guide to gain a richer understanding of how the information in this Manual fits within the political and legislative frameworks around the world.



The PAHO publication, *Developing Legislation for Tobacco Control*

The Pan-American Health Organisation (PAHO) publication, *Developing Legislation for Tobacco Control*,² is another helpful and user-friendly resource containing provisions for comprehensive tobacco control legislation. The PAHO Guide covers much the same material as the Manual, but provides a somewhat different and simpler drafting style. It could be useful to consult both the Manual and the PAHO Guide and take those provisions from each that best suit the country's needs. Adaptation to fit the country's legal system, drafting style, and political and social context will be required using either of these resources.

Relationship to the Framework Convention for Tobacco Control (FCTC)

■ The Manual addresses the major regulatory topics covered by the FCTC. The FCTC calls upon national authorities to adopt and implement effective legislation, regulations, executive, administrative or other measures to carry out their regulatory obligations under the treaty. The Manual is a tool for carrying out the FCTC's regulatory mandates in the form of either legislation or regulations (discussed further, below). Following the Manual should ensure that national tobacco control legislation is FCTC compliant. Article 2 of the FCTC encourages Parties to implement measures beyond those required by the Convention and its protocols. The provisions in the Manual help accomplish that by providing a means for taking a comprehensive approach.

Legislative Drafting Style

■ Different countries' laws follow different styles of drafting. The nomenclature and ways of arranging the provisions in any given country may differ from the way these are presented in the Manual. The provisions contained in the Manual, therefore, will need to be adapted to follow the drafting style appropriate for any given country. Additionally, if there are existing laws/regulations that are being amended, there will be a need for introductory language specifying what in the old law or regulation is being deleted and replaced with new provisions and/or what is being added to existing provisions. Different countries have different ways of expressing an amendment or repeal of an existing law or regulation, and these, too, will need to be followed.

The Role of Regulations

■ Although the provisions in the Manual are presented as legislative provisions, many of them could be used for drafting administrative regulations to implement existing law that provides legal authority for tobacco measures. If there already exists enabling law that provides broad ministerial authority to address the topics covered in the Manual, many of the Manual's provisions — those that provide all the necessary detail to enable immediate implementation — could be used for drafting implementing regulations. To the extent that is the case, new legislation would not be necessary.

Enacting tobacco control measures administratively through regulations rather than legislatively, if adequate legal authority exists for doing so, can have strategic advantages: typically a quicker and less contentious process, and the possibility of avoiding the tremendous influence the tobacco industry may have in the legislature. Acting administratively will require a committed and strong Minister, as well as a legal system that vests the administrative branch of government with authority that the legislative and judicial branches cannot easily override.

In Brazil, for example, administrative orders by the Minister of Health make up most of Brazil's comprehensive and stringent tobacco control measures. Because of the Minister of Health's high level of commitment to tobacco control, the tobacco industry lacked the leverage to block the Ministry's administrative measures. On the other hand, in a country where the Minister is not committed, delay or weak regulations could be the result. Another consideration is the degree of turnover in Ministers — constant changes in the Ministry could result in changes in commitment and lack of consistent implementation.

If tobacco control is accomplished through the legislative route, there still will be a need to draft regulations to implement many of the laws' provisions, tailored to reflect the enacted version of the legislation. The Manual is designed to provide, in the legislation itself, much of the detail that otherwise might be left for the appropriate Ministry to address in implementing regulations. It is designed this way to avoid delay in implementation of the legislation while the regulations' drafting and enactment processes occur. The Manual, thus, seeks to strike a balance: providing sufficient detail to allow for immediate implementation of many of the legislation's provisions, once passed, while at the same time ensuring the Ministry has broad authority to provide further details through implementing regulations. Under the flexible regulatory authority set up in the Manual, implementing regulations may take the form of additional and/or more specific requirements and can be promulgated both after the law's passage and over time as the need arises.

National v. Sub-national Legislation

■ The Manual addresses legislation at the national level. In many countries, however, there has been a great deal of success in enacting strong tobacco control laws at the provincial/state and local levels. Considerations such as protection of the entire population, consistency of application of the law, and ease of enforcement weigh in favor of legislating at the national level. In societies or under legal systems where broad-based community support is necessary before legislation can be initiated or accepted, or in countries where the tobacco industry wields inordinate power at the national level compared to sub-national levels, legislating at provincial and local levels can be more effective. Sub-national legislation can even pave the way for legislative action at the national level.

Whether legislation is best drafted for and introduced at the national or sub-national level will depend on a number of factors. These may include the legal system, constitutional prescriptions on the power to legislate, custom, political and public support, infrastructure and capacity, and the power of the tobacco industry and of tobacco control advocates to influence the legislative process or the content of the legislation at the different levels of government.

Even where tobacco control legislation is enacted or already exists at the national level, sub-national jurisdictions often can, and do, enact legal requirements that are complementary to or more stringent than those found in the national law, where they have the legal authority to do so.

The Pre-emption Pitfall

■ In some jurisdictions, the tobacco industry has been successful in getting pre-emption language put into tobacco control legislation. Pre-emption language in legislation essentially provides that lower levels of government may not regulate in specified areas. For example, it has been a common tactic in some federal systems for the tobacco industry to insert pre-emption language in national legislation addressing advertising, tobacco product labelling, and smoking in public places. This is a particularly vexing problem in many U.S. localities that have tried to enact restrictions on smoking in public places, only to find they were foreclosed from doing so by pre-emption language in state laws.

These pre-emption provisions prohibit, or pre-empt, provincial/state and/or local governments from enacting legislation or regulations that address these topics. In such cases, lower levels of government may find themselves unable to do anything about weak legislative provisions sponsored by the tobacco industry at higher levels of government.

The Manual contains provisions that specifically authorize lower level jurisdictions to enact and implement their own legislation/regulations, so long as they are at least as stringent as those contained in the national legislation/ regulations and they do not conflict with the national provisions. In addition to this attempt to prevent pre-emption in the law itself, it will be necessary to be vigilant against the insertion of pre-emption language as any bill proposing legislation for tobacco control goes through the political and legislative processes.

Assessing the Legal Environment

■ Before embarking on the development of tobacco control legislation and/or regulations, it is important to assess the current legal framework in the country: constitutional authority and existing laws and regulations that may either support or undermine comprehensive tobacco control. In the latter case, laws will need to be amended before or contemporaneously with the introduction of new tobacco control provisions.

Constitutional analysis is important for understanding how far tobacco control legislation or regulations must or may go. For example, the constitution in some countries guarantees the right to health or the right to life. This has been interpreted by some courts to require stringent and comprehensive tobacco control measures and/or to prohibit certain tobacco industry tactics. For example, in Bangladesh, a court halted Imperial Tobacco Ltd.'s advertising and promotional campaigns that offered prizes, including a trip to London. The Law and Society Trust of Bangladesh successfully filed suit, arguing that since tobacco products are harmful to health, Imperial Tobacco's promotional campaign violated Bangladesh's Constitutional guarantees of fundamental rights.³

On the other hand, constitutional guarantees of free speech in Canada and the United States have been interpreted by their courts as elevating corporate interests over human rights, limiting how far the government can go with regulation of tobacco advertising.⁴⁵ This is not the case in the rest of the world. In most countries that have banned tobacco advertising, there have been no constitutional problems. Regardless, the tobacco industry has raised and can be expected to continue to raise the threat of legal challenges based upon supposed free commercial speech rights. Finally, where legislative provisions for tobacco control already exist in the country, these should be evaluated to determine how well they have been working. If weaknesses are found, amendments will need to be made. It may be easier to repeal and replace existing legislation that will need to be strengthened substantially than to make extensive amendments.

The Importance of Other Programming Components to Complement Tobacco Control Policy and Regulation

■ While comprehensive regulation, including enforcement of legal provisions, is central to tobacco control, it needs to be accompanied by complementary programs and activities. Ongoing surveillance is necessary to understand the extent of tobacco use and exposure, as well as the resulting morbidity and mortality and their costs. These data allow tobacco control professionals to make the case for necessary interventions and to tailor programs to populations' needs. Surveillance data also can provide measures by which tobacco control programs can be evaluated, among other things.

Surveillance data can and should be used to examine the effectiveness of regulatory measures, including whether any disparities in the level of protection afforded by programs and regulatory interventions exist among population groups. For example, in the absence of a complete ban on smoking in all public places, including workplaces, if any particular population groups (e.g., those of low socio-economic status) are found to be more exposed to tobacco smoke than others, as might be expected to be the case (See Part 6: Protection from Tobacco Smoke), it will be important to enact remedial measures.

Public awareness and education programs, and other communications activities, can be effective in reducing tobacco consumption and garnering support for tobacco control measures.⁶ As regulatory interventions encourage tobacco users to try to quit, tobacco use cessation programs become especially important. Public awareness, education, and cessation programs can be implemented in the absence of a legislative directive; however, a legislative mandate for these “can provide a powerful expression of governmental policy, assurance that implementation will occur with some consistency, and of course, financial resources needed to support these efforts.”⁷ For these reasons, provisions for public awareness and education and cessation programs, and their funding, are included in the Manual.

Legislative Evaluation and Improvement

■ The provisions in the Manual were written to be as air-tight as possible to prevent avenues for evasion. Where applicable, they are based on lessons learned from countries' experiences and from light shed about the tobacco industry's tactics in its own internal documents. Nonetheless, it should be understood that it is difficult to achieve a fail-proof law and it should be anticipated that the industry will continue to adapt its practices to find ways to evade even the most tightly designed provisions.

Additionally, as scientific and technological advances occur, as consumer and industry behavior changes, and as public and government readiness for policy advances increases, legal provisions that may be appropriate for today's environment may become outdated. For all of these reasons, any provisions enacted into legislation or regulations should be monitored periodically and evaluated over time to ensure they are, and remain, effective.

International Trade Issues: Tobacco Regulation and Free Trade Agreements

■ A wide variety of regulatory measures across just about all fields have the potential of being challenged under international or regional trade agreements as unnecessary restrictions on trade. To the extent any particular regulatory provision is viewed as an unnecessary restraint on trade in goods, services, or intellectual property under one or more of the World Trade Organization (WTO) agreements,ⁱ or under regional trade agreements, any member government enacting such measures may find itself subject to a legal trade challenge, or threats of such a challenge.ⁱⁱ Tobacco control regulation is no exception; however, guidance from cases brought before the WTO suggest that stringent tobacco control provisions for which there is sound scientific justification should pass WTO muster.

The provisions presented in the Manual are designed to be the most protective of public health (favoring public health over trade liberalization where the two conflict) and are supported by medical and social science-based evidence. Most, but not all, of the provisions of the Manual also are based on provisions found in a variety of countries' laws that have not been challenged to date under the WTO agreements.ⁱⁱⁱ

The Need for a Country-Specific Legal Review

■ Because the Manual cannot be wholly applicable to all legal systems or take into account all countries' legal requirements or specific needs, any draft legislation or regulations developed using this Manual must be reviewed by the Ministry of Justice or a lawyer familiar with the legal system and requirements of the country, as well as with international trade issues, to ensure that all applicable legal requirements are met. The Manual is not intended to give legal advice on the ultimate legality under national, regional, or international legal authority, of any given provision.

Structure of the Manual

■ The Manual is divided into Parts covering major topics important for comprehensive tobacco control laws and regulations: interpretation (definitions); administration; licensure; protection from tobacco smoke; advertising, sponsorships, and other forms of promotion; tobacco product labelling and packaging; product regulation; industry reporting; tobacco product sales; anti-smuggling measures; litigation enabling provisions; inspections and investigations; enforcement; and public awareness, education, and cessation programs.

It may be appropriate in some contexts for certain subjects covered in this Manual to be included as part of a law that addresses a topic or topics other than tobacco control specifically. For example, provisions for protection from exposure to tobacco smoke in the workplace might be covered in a labour or workplace safety law or regulations. Similarly, existing consumer, environmental, public health, or related laws may be vehicles for tobacco control provisions. Consolidating all of these subjects into a comprehensive tobacco control law may make administration easier, however. It also is more straight forward, when doing legal research, to find all governing tobacco control provisions when they are contained in a comprehensive tobacco control law rather than dispersed throughout a number of different laws.

The Manual covers some topics that are more appropriately found in non-tobacco specific laws. Provisions for taxation will need to be inserted into legislation addressing fiscal matters, rather than appearing in a comprehensive tobacco control law. Because they are critical for tobacco control, provisions for taxation are contained in the Manual nonetheless. They are provided, beginning on page 101, under the heading, Provisions for Tobacco Control Measures That Belong in Other Laws. Provisions for ending tobacco subsidies and for protecting the environment also are included, and similarly designated.

Each Part of the Manual starts with an explanation. The explanation addresses the importance of the regulatory topic covered in that Part, provides an evidence-based justification for the provisions applicable to the topic, and highlights the tobacco industry's strategies for defeating them. Finally, requirements of the Framework Convention on Tobacco Control (FCTC) relevant to each of the Manual's topics are highlighted in the explanation.

Explanatory notes appear at the beginning of each Part. Additional explanatory comments appear throughout the Manual text in [brackets]. The explanatory notes and comments are not intended to be included in the text of the legislation, but rather are for informational or instructional purposes for the reader. Underlined explanatory text in [brackets] represents blanks, such as dates, time periods, and similar information, to be filled in by the persons developing the legislation.

Options for legislative text follow the explanation. The most stringent and comprehensive provisions for achieving a best practices approach to tobacco control regulation appear first. In recognition of governments' constitutional, legal, political, or other constraints, the Manual then provides less restrictive and comprehensive, albeit less protective, alternative options for regulatory provisions. The alternative provisions appear in *blue italics*. The options presented in the Manual are based on and adapted from provisions found in a number of countries' laws.

The legislative text, with the explanatory provisions, begins in the next page.

[Legislative text:]

[Note: an index of the legislative parts and sections or clauses can be inserted here.]

BILL

An Act to: prevent tobacco use by young people; enhance public awareness of the hazards of tobacco use and ensure that consumers are provided with information to make more fully informed decisions about using tobacco; protect individuals from exposure to tobacco smoke; prohibit *[or restrict, if advertising still will be allowed]* promotional practices; prevent illegal conduct, including but not limited to smuggling; provide for regulation of tobacco products to mitigate against the harmful effects of tobacco; provide for sufficient regulatory flexibility to respond to new technological and scientific innovations and findings and to changes in consumer behaviors; provide for rules of evidence and procedures for addressing tobacco industry liability for damage caused by tobacco use and exposure to tobacco smoke; create a national coordinating institution for tobacco control; and provide for other related matters and purposes.

PREAMBLE AND PURPOSE

EXPLANATION

■ The Preamble, while not always a necessary component of legislation, lays out the government's objectives for the legislation and can establish the framework for interpreting its provisions. If the government has different or additional policy objectives for the legislation, these can be stated in lieu of, or in addition to the preamble provisions below. Alternatively, this part can be omitted altogether.

[Legislative text, continued:]
Part 1: Preamble and Purpose

UNDERSTANDING the devastating health, social, and economic effects of tobacco use and exposure to tobacco smoke on individuals and families, and the costs to the government, to society, to the environment, and to the socio-economic development potential of the nation;

ACKNOWLEDGING the existence of vast numbers of addicted tobacco users, making it impractical to make tobacco products illegal;

RECOGNIZING the right of consumers and the public to have meaningful information about the hazards from tobacco use and to be free from tobacco industry practices that undermine that information;

RECOGNIZING FURTHER that there is no such thing as a safe tobacco product;

REALIZING that people generally begin using tobacco products without recognizing the consequences of their highly addictive character;

REALIZING FURTHER that exposure to advertising and promotional practices encourages and glamorizes tobacco use, and that current widespread promotion of tobacco leads to youth initiation;

RECOGNIZING that scientific evidence has established unequivocally that exposure to tobacco smoke in non-smokers causes death, disease and disability, and, thus, cognizant of the need and responsibility to protect individuals from the hazards of tobacco smoke;

ASSERTING the government's legitimate public health function and its duty to protect its population from exposure to tobacco products and their toxic smoke, regulate the manufacture, promotion, and sale of tobacco products, and to do so within a regulatory framework that provides flexibility to address advances in knowledge, technology, and science as they occur, and to provide an efficient legal framework for addressing the harm caused by tobacco; and

RESOLVING to align national laws with the WHO Framework Convention on Tobacco Control,

The government undertakes the following measures to protect the health, rights, and well being of all of the people, taking into account specifically the needs of, and effects of these measures on, priority populations.

PRELIMINARY

Assent, short title, commencement, repeals, and amendments

EXPLANATION

■ The preliminary sections of a piece of legislation provide the common name for the law, the date the head of state assents to the legislation, and the date the law becomes effective. These sections also address repeals and amendments of earlier laws, if such exist. In some cases, it might be desirable to phase in certain provisions to give those affected by the law time to adjust to new requirements and to bring to a close any pre-existing obligations. The law generally can become effective on a certain date while providing for later effective dates for specified provisions to accomplish this.

There will be a need for a section on repeals only if an earlier law or specific provisions of it are being rescinded and replaced by the new legislation or by substituted provisions. In cases where there is no existing legislation, or where only relatively minor amendments are being made to an existing law, there may be no need to repeal the whole earlier Act or portions of it. Where existing provisions will be changed, it will be necessary to provide language stating what provisions are being amended and show how the new text will appear. It also may be necessary to signify that amended provisions are the new governing provisions, “as amended.”

[Legislative text, cont'd:]
Part 2: Preliminary

1. Assent, citation, and commencement.

a. **Date of assent:** The [\[specify the head of state\]](#) assents to the enactment of this Act on [\[specify day, month, and year of assent\]](#).

b. **Citation and commencement.** This Act may be cited as the [\[specify the name of the Act\]](#) and shall come into operation on [\[specify the triggering event under the country's legal system \(e.g., upon approval by Parliament, as the Minister may appoint, or upon publication in the Gazette\)\]](#); provided, however, that different commencement dates may be appointed for the commencement of different provisions of this Act.

2. Repeals and amendments [If applicable].

a. **Repeals.** This Act repeals the [\[specify the name of existing Act that is being replaced\]](#) in its entirety, effective with the date this Act comes into operation.

b. **Amendments.** This Act amends the [\[specify name of existing Act being amended\]](#) effective with the date this Act comes into operation, unless otherwise provided for in any specific provisions.

INTERPRETATION

EXPLANATION

■ The interpretation, or definitions, part of the law is critically important. In this Part, key terms used in the legislation are defined to ensure there is no ambiguity or need for subjective interpretation. Well-defined terms can prevent significant loopholes in coverage or application of the law's provisions. Terms may be defined differently than suggested below, depending on the interpretation the government would like the terms to have.

[Legislative text, cont'd:]

Part 3: Interpretation

3. Definitions. For the purposes of this Act, the terms below shall be given the meanings prescribed to them. Any words or terms not defined shall be given their plain and customary meanings, unless the context requires otherwise, and shall be interpreted in a manner consistent with the purposes and spirit of this Act. Terms in the singular or plural apply equally to the plural or singular, respectively. Terms defined as nouns or verbs shall have the corresponding meaning as verbs or nouns, respectively.

- a. *“Additive”* means any substance, chemical, compound, or component, other than tobacco or water, that is introduced into a tobacco product during processing, manufacturing, or packaging, including, as applicable, those contained in the paper, filter, portion pouch, or similar part of the tobacco product, its package, or accessories. The term “additive” also shall include any residues of pesticides, fungicides, and other chemicals used during tobacco growing, harvesting, curing, storing, or other stages of preparing tobacco products for consumption.
- b. *“Advertisement”* means any commercial communication through any media or means, that is intended to have, or is likely to have, the direct, indirect, or incidental effect of:
 - i. creating an awareness of a tobacco product, brand, manufacturer, or seller, or
 - ii. promoting the purchase or use of a tobacco product or brand.

A tobacco advertisement includes, but is not limited to, words, names, messages, mottos, slogans, letters, numbers, pictures, images, colors and other graphics, sounds, and any other auditory, visual, or sensory matter, in whole or part, that is or are:

- i. commonly identified or associated with a tobacco product, brand, manufacturer, or seller, or
 - ii. otherwise an indicia of product, brand, manufacturer, or seller identification.
- c. *“Constituents”*, in relation to smoked tobacco products, means the chemicals, including the particles, vapors, and gasses found in the smoke. In relation to smokeless tobacco products, constituents means the chemicals found in the product itself.
 - d. *“Disparate effect”* or *“disparity”* means an unacceptable gap, as determined by the Minister of Health [or other governing authority] in the level of protection provided by tobacco control measures to a priority population group in relation to the level of protection provided to other population groups.
 - e. *“Distributor”* or *“wholesaler”* means any person who buys tobacco products and re-sells them to another seller.

- f. “*Exporter*” means any person who sends tobacco products outside this country for sale or supply in another country.
- g. “*Factual information*” means, and is limited to, the brand name, manufacturer’s name, type of product (e.g., cigarettes, smokeless tobacco, etc.), prescribed messages, constituent and additives disclosures, price information, and any other information required or permitted in implementing regulations.
- h. “*Generic*”, with respect to packaging and labelling and otherwise in connection with this Act, means: the use of black and white text only; the presentation of only factual information; and no other auditory, visual, sensory, or other matter, unless authorized in implementing regulations.
- [Note: if advertising will not be banned, the definition of “generic” also should be specified as applying to advertising as well.]
- i. “*Graphic*” means any symbol, sign, logo, mark, trademark, pattern, emblem, design, crèche, recognizable colors or patterns of colors, or any other indicia of tobacco product, manufacturer, or seller identification.
- j. “*Health care services*”, in relation to any person who has suffered or is at risk of suffering any tobacco-related illness, means inpatient or outpatient examination, diagnosis, treatment, procedures, health status monitoring, counselling, pharmaceuticals, therapies, and other health-related goods or services.
- k. “*Health care services costs*” means the sum of the present value of the total expenditures by the government or other third party payer for health care services provided to persons resulting from, or to prevent or monitor any actual or potential, tobacco-related illness, including illness from tobacco smoke exposure, and the present value of the estimated total expenditures for health care services that could reasonably be expected to be provided to persons as a result of, or to prevent or monitor any actual or potential, tobacco-related illness.
- l. “*Importer*” means any person who receives or arranges for the receipt of tobacco products from another country for sale in this country.
- m. “*Manufacturer*” means the corporation or other person that manufactures, fabricates, produces, processes, packages and/or labels tobacco products, and includes any entity that is associated with a manufacturer, any entity that controls or is controlled by the manufacturer, or that is controlled by the same entity that controls the manufacturer.
- n. “*Media*” means broadcast, print, electronic, and any other avenues of communicating to the public.

- o. “*Message*” or “*health message*” means a warning or other information about the health effects of tobacco use or exposure to tobacco smoke, the benefits of and/or suggestions for quitting, and any other appropriate tobacco control message, as prescribed by the Minister [or other governing authority] in regulations.
- p. “*Minister*” means Minister of Health or his or her designate.
- q. “*Package*” means any covering, wrapper, container, or other enclosure that contains a tobacco product, or multiple packages of tobacco products (i.e., cartons), and includes any label and other written or graphic information on or in it.
- r. “*Person*” includes any individual, proprietor, firm, partnership, corporation, franchise, organization, agency, association, institution, or other entity possessing a legal personality.
- s. “*Place of collective use*” means any place open to the public, whether it is enclosed, partially enclosed, or an outdoor public space, where:
 1. persons congregate in close proximity to one another;
 2. smoking might pose a fire hazard; or
 3. other criteria established in implementing regulations are met.

Examples of places of collective use include, but are not limited to: stadiums, railway platforms, and similar places.
- t. “*Priority population*” means any population group that is, or traditionally has been, excluded from tobacco control planning, decision-making, or the benefits of tobacco control programs or interventions; has disproportionate rates, in relation to its population numbers, of tobacco use or tobacco-related morbidity or mortality; or experiences a disproportionate rate of exposure to tobacco smoke or to tobacco industry promotional practices.
- u. “*Promote*” or “*promotion*”, includes advertising but is a broader term that includes any commercial act or practice that is intended to or is likely to encourage, directly or indirectly, the purchase or use of any tobacco product or brand or create an awareness of or association with a tobacco product, brand, manufacturer or seller.
- v. “*Public conveyance*” means any form or mode of transportation that carries passengers for hire or reward, whether locally, between places within the country, or internationally.
- w. “*Public place*” means any place, fixed or mobile, including any work place, to which members of the general public or segments of the general public ordinarily have access by express or implied invitation. An enclosed public place is a partially or fully completed building or structure, including a mine or tunnel, that is separated from the outdoors.

- x. *“Retailer”* means a person who sells tobacco products to consumers.
- y. *“Seller”* means any person who supplies any tobacco product for a fee or other consideration, and includes any manufacturer, distributor, wholesaler, importer, exporter, and retailer.
- z. *“Separately ventilated smoking room”* means a room in an enclosed public place, including workplace, that:
 - i. is enclosed with four walls, or floor to ceiling partitions, and a door;
 - ii. has an air flow system that is exhausted directly to the outside; and
 - iii. has negative air pressure in comparison with the remainder of the building.
- aa. *“Supply”* means to sell, give, exchange, convey, consign, deliver, furnish, or transfer possession of or title to any tobacco product for the purpose of obtaining financial or business gain, or arrange or offer to do so, whether for a fee or other consideration or without charge.
- bb. *“Tobacco smoke”, “second-hand smoke”, or “environmental tobacco smoke”* means the smoke or other emissions released from a tobacco product or the smoke exhaled by a person smoking a tobacco product.
- cc. *“Smoking”* means inhaling, exhaling, or handling an ignited or heated tobacco product or a tobacco product producing emissions by any means.
- dd. *“Tobacco product”* means any product containing tobacco in any form that is intended for human use. A tobacco product includes all parts and materials, such as papers, filters and filter wrappers, over-wrappers, rods, portion pouches, and similar matter, as applicable, even if sold separately. Raw tobacco that has not been processed or prepared for human use shall not be considered a tobacco product under this Act.
- ee. *“Tobacco-related illness”* means any illness, disease, or condition resulting in whole or in part from tobacco use or exposure to tobacco smoke, and includes any illness, disease, or condition exacerbated by tobacco use or exposure to tobacco smoke.
- ff. *“Tobacco sponsorship”* means the direct or indirect public attribution, acknowledgment, association, identification, or display of a tobacco manufacturer, seller, brand, or product, or of any indicia of a tobacco manufacturer, seller, brand, or product with, on, or in connection with:
 - i. an entertainment, sporting, recreational, educational, cultural, fashion, or other event, show, activity, or work;
 - ii. any person or team participating in such an event, show, activity, or work, including their equipment, clothing, and accessories;
 - iii. activities in bars, nightclubs, restaurants, entertainment venues, and other similar venues;
 - iv. a service provided or contribution made by a tobacco manufacturer or seller; or
 - v. a building, institution, stadium, or other public place, other than one exclusively used to manufacture or sell tobacco products.

gg. “*Workplace*” means any place in which persons perform duties of employment or work and includes private offices, common areas, and any other area which generally is used during the course of employment or work. Workplaces shall not include private residences except to the extent that they are used for commercial purposes.

[Note: this provision may be modified to protect domestic workers.]

An enclosed workplace is a partially or fully completed building or structure, including a mine or tunnel, that is separated from the outdoors.

ADMINISTRATION

EXPLANATION

■ This Section grants the authority for administering the Act. Some countries' laws vest sole authority for administration in a specified Ministry or specialized regulatory body; others require the guidance of a multi-sectoral board or body to ensure that non-tobacco industry stakeholder interests are represented; others, still, vest the administrative decision-making in a board or body, itself. In some countries, different bodies or mechanisms play a role in coordinating different aspects of tobacco control. The FCTC speaks in terms of establishing a "coordinating mechanism or focal points for tobacco control."

If a board or coordinating mechanism is given final authority for decision-making, there is a need to carefully craft the provisions addressing the entity's composition and its decision-making methods in such a way that deadlock, obstruction, and delay are avoided. In order to avoid any conflict of interest, it should be specified that no one working for or on behalf of the tobacco industry may be allowed to be a member of any board or mechanism established.

Since the composition, operations, and authority of a board or coordinating mechanism will vary based on country-specific factors, the provisions below merely provide general legal authority for establishing and funding a coordinating body, leaving it to the drafter to specify the details of the body's composition, precise functions, decision-making authority, operations, degree of authority, and other necessary matters.

An example from Botswana of proposed legislative provisions establishing a National Tobacco Control Board can be found in Appendix 1.

FCTC OBLIGATIONS

The FCTC's **Second General Obligation, Article 5(2)(a)**, calls upon Parties, within their capabilities, to "establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control."

[Legislative text, cont'd:] Part 4: Administration

4. Ministry of Health [or other governing authority] responsible for overall administration. The Minister of Health [or other governing authority] shall be responsible for the overall administration of this Act. The Minister [or other governing authority] is authorized to prescribe in implementing regulations any requirements necessary or appropriate for the law's effective and efficient administration [If the national coordinating mechanism will have decision-making authority, add: subject to any authority granted to the [specify name of the national coordinating body], established below.

- a. **National Coordinating Body.** The Minister [or President or other governing authority] shall establish a national coordinating body, to be known as the [specify name], to be composed of persons with expertise in tobacco control, public health, or related fields, including persons competent to represent the interests of priority populations, to carry out the following functions: [prescribe the body's functions].
- b. **Qualifications, operation, governance, etc. of the [specify name of national coordinating body].** [Specify the qualifications for membership and staffing, details of operation, governance, remuneration (if any) for membership, and other matters necessary or appropriate for the effective and efficient administration of the coordinating body];
- c. **Conflicts of interest.** No person employed by or representing the interests of any tobacco product manufacturer, importer, exporter, wholesaler, or retailer, or any other tobacco-related business, shall be qualified to serve as a member of the coordinating body, and no such person shall be appointed or otherwise be allowed to serve as a member.
- d. **Funding for [specify name of national coordinating body].** Funding for the [specify name of the national coordinating body] shall be paid out of [specify the funding source(s), such as moneys appropriated by Parliament, moneys from tobacco excise taxes collected, licensing fees, and/or other funds]. Nothing in this Act shall prevent the [specify the name of the coordinating body] from receiving gifts or donations, other than from the tobacco industry or any other source for which a conflict of interest would arise or from any other source deemed unacceptable by [specify who has authority to make this determination].

5. Appointment of authorized officers. The Minister may appoint any person or class of persons as officers authorized to carry out inspections and investigations as necessary or appropriate under the Act, to take enforcement actions against persons found to have violated any provision of the Act, and [specify other powers of the officers, if any].

LICENSURE

EXPLANATION

■ Licensing tobacco businesses allows the government to track companies that manufacture, import, export, or sell tobacco products. This, in turn, allows the government to gauge the magnitude of the tobacco business and its affiliations in the country. Licensure is, therefore, important for administering the Act, especially with respect to anti-smuggling controls.⁸ Licensure sanction also can provide a powerful mechanism to compel compliance with legal requirements. Finally, licensing fees might be used to cover costs associated with administering the Act, to fund tobacco control efforts, and/or to cover health care costs incurred by the government in treating tobacco-related illnesses. Some countries, such as Canada, license tobacco businesses as part of tobacco taxation legislation.

Licensing retailers can be costly to administer, and difficult to establish if the country's infrastructure is not well developed. Where there is a large informal sector, retail licensing probably will not be feasible. Nonetheless, all of the benefits discussed above will be more likely to be achieved if retailers are included in the licensing scheme. Even if it cannot be done at the present time, licensing retailers should be an objective in the process of working toward achieving a best practices approach to tobacco control.

FCTC OBLIGATIONS

Article 15, Section 7, obliges the Parties to endeavor to adopt and implement "...licensing, where appropriate, to control or regulate the production and distribution of tobacco products in order to prevent illicit trade."

[Legislative text, cont'd:]

Part 5: Licensure

6. Licensing of sellers of tobacco products.

- a. **License required.** No person shall manufacture, import, export, or sell tobacco products at wholesale without first having a license; provided, however, that persons engaged in the business of manufacturing, importing, exporting or selling tobacco products on or before [specify date to give those currently operating time to apply for a license] shall have a period of up to [specify number] days from the date this Act comes into operation to apply for a license. A license, once granted, shall be valid for a period of [specify number of years] and shall be subject to renewal thereafter. If the application for an initial license or renewal is denied, the applicant shall cease manufacturing, importing, exporting, or selling tobacco products, as the case may be, immediately upon notification of the application denial, subject to any right to appeal [if appeal rights are applicable under the country's laws].

[Note: If it will be feasible to license retailers, “and retail” should be added after “wholesale” in the first sentence of (a). If retailers will be licensed but it will be infeasible to license very small retailers, the following text can be provided:]

- b. **Exemption for small retailers.** *Notwithstanding the requirement for licensure in subsection (a), retailers selling tobacco products shall be exempt from licensure if their tobacco product sales account for no more than [specify a monetary amount in the aggregate, or specify a monetary amount as a percentage of total sales of all goods sold by the retailer].*
- c. **Prohibition against selling to unlicensed sellers.** No person shall sell any tobacco product to any manufacturer, importer, exporter, wholesaler, retailer [if retailers will be subject to licensure] that does not certify that it holds a valid license or that it is exempt from licensure, [if an exemption will be made for small retailers], or that the person knows or has reason to know does not hold a valid license and is not exempt from licensure.
- d. **Prohibition against purchasing from unlicensed sellers.** No person shall purchase or take possession of any tobacco product from any manufacturer, importer, exporter, or wholesaler that does not certify that it holds a valid license, or that the person knows or has reason to know does not hold a valid license.

- e. Licensure procedure.** The Minister [or coordinating body or other appropriate entity which already may have licensing authority] shall serve as the licensing authority and shall have the authority to prescribe the requirements for the grant and renewal of a license, including attaching to the grant or renewal of any license such conditions as are reasonable or necessary for the effective and efficient administration of this Act. The Minister [or coordinating body or other appropriate entity] also shall have the authority to prescribe the procedure and forms for the licensure application. An application for an initial license and any renewal shall be made to the Minister [or national coordinating body or other appropriate entity] in accordance with any requirements prescribed in implementing regulations.
- f. Licensure fees.** The Minister [or licensing authority] additionally shall have the authority to set license fees, which shall be based on [specify amount or description of how amount is calculated [e.g., % of tobacco sales revenues, or specify a flat fee], which the Minister [or licensing entity] may raise from time to time as he or she [or it] deems appropriate.
- g. Denial of license.** Any person who fails to meet the requirements for a license on initial application or on renewal may be denied a license by the Minister [or licensing authority].
- h. Licensure sanction.** Any licensee found to have violated any provision of this Act or implementing regulations may be subject to licensure sanction, which may include limitation, suspension, or revocation, at the discretion of the Minister [or licensing entity], consistent with the purposes of this Act. In the event of suspension, the Minister [or licensing authority] may attach such conditions for reinstatement as he or she [or it] deems appropriate for the efficient and effective administration of this Act.

[If the right to appeal is applicable in the country, the following should be included:]

- i. Right to appeal.** Any applicant who is denied a license at initial application or renewal, and any licensee whose license is the subject of a sanction action, shall have a right to appeal in accordance with the provisions of Part 14.

PROTECTION FROM TOBACCO SMOKE

EXPLANATION

Health Hazards Resulting From Exposure to Tobacco Smoke

■ The scientific evidence unequivocally establishes that tobacco smoke causes disease, disability, and death to those exposed, both smokers and non-smokers. Tobacco smoke contains more than 60 known or suspected cancer causing compounds, as well as other toxins. For many of these compounds, there is no safe level of exposure.^{9, 10, 11} Definitive reports by the International Agency for Research on Cancer, the U.K. Scientific Committee on Tobacco and Health, and the U.S. Environmental Protection Agency, among others, have concluded that tobacco smoke is a human carcinogen.^{12, 13, 14} This classification is used only when there is sufficient evidence from epidemiological and other studies to support a causal association between exposure to a particular agent and cancer.

Exposure to tobacco smoke has been found to increase the risk for lung cancer in nonsmokers by 20-30%, and for heart disease by about the same amount.^{15, 16, 17} Tobacco smoke has harmful, even fatal, effects on children's health, such as asthma induction and exacerbation, bronchitis, pneumonia, middle ear infection, chronic respiratory problems, low birth weight, and Sudden Infant Death Syndrome, among others.^{18, 19, 20, 21, 22} A review of 14 studies on the effects of tobacco smoke in the workplace concluded that workplace exposure to tobacco smoke increased the risk of lung cancer by 39% among persons who never smoked.²³

Prohibiting Smoking in Public Places: Protecting Non-Smokers, Influencing Smoking Consumption, and Changing Social Norms

■ In addition to protecting individuals from involuntary exposure to hazardous tobacco smoke, prohibitions on smoking in public places, including workplaces, have been shown to be associated with a decrease in the amount individuals smoke and an increase in quit rates.²⁴ According to an internal document from Philip Morris, "Total prohibition of smoking in the workplace strongly affects industry volume. Smokers facing these

restrictions consume 11% - 15% less than average and quit at a rate that is 84% higher than average.”²⁵ Smoking bans also can challenge the social norm of smoking acceptability that still prevails in many places by reinforcing the message that smoking is unhealthy and socially unacceptable.²⁶

Protection Measures

■ Historically, laws providing protection from tobacco smoke in many jurisdictions began as bans on smoking in some priority public places (such as government buildings, health care facilities, and similar places) while simply restricting smoking to separately designated areas in other public places. A growing number of jurisdictions have begun banning smoking altogether, or allowing smoking only in separately ventilated rooms, in most or all public places, including workplaces. Progress continues as outright bans on smoking in restaurants and bars, which often have been excluded from smoking prohibitions, are becoming more prevalent in more jurisdictions.

From an equity perspective, the trend toward expanded protection is critical, especially for vulnerable workers. Studies in a number of countries have shown that persons with lower socio-economic status have greater exposure to tobacco smoke in the workplace.^{27, 28, 29} In Hong Kong, for example, lower paid workers were significantly more exposed to tobacco smoke in the workplace. Approximately 22% of females and 42% of males working in administrative, managerial, or professional positions were exposed to tobacco smoke, compared to 42% of females and 60% of males working as clerks, services workers or sales persons, and 41% of females and 61% of males working in the manufacturing sector. According to a national survey in the United States, the majority of employees working in environments that allow smoking disproportionately tend to be those in service occupations, restaurant workers, bar workers, laborers, and the young.³⁰

Designated Smoking Rooms and Separate Ventilation

■ The mere separation of smoking areas from non-smoking areas does not offer protection in the non-smoking areas.³¹ A 1998 study of hospitality venues by ventilation engineering experts in the U.S. showed that current technology using dilution, displacement, or air cleaning ventilation systems does not reduce the health risks from exposure to tobacco smoke, even under moderate smoking conditions, to *de minimus*, or “acceptable risk” levels for either workers or patrons.³² An independent scientific working group commissioned by the Health and Safety Authority and the Office on Tobacco Control in Ireland agreed with these findings.³³ One of the problems with designated smoking rooms is the difficulty of ensuring that ventilation maintenance and repairs are made as necessary.³⁴ Another significant problem is that employees, especially servers

and cleaners, may be required to enter the smoking rooms on a regular basis. It will take creative thinking about self-service options and other ways of protecting employees if smoking will continue to be allowed in separately ventilated rooms.

At a minimum, where smoking will be allowed in separately ventilated rooms, it is important that the rooms are required to be physically isolated (that is, rooms with four walls or floor to ceiling partitions and a door), negatively pressurized, and vented to the outside. Additionally, workers and members of the public should not be required to enter these rooms to do their jobs or to get to other parts of the premises.

While engineering principles suggest that rooms that meet these requirements will not result in the exposure of non-smokers to tobacco smoke, whether in practice rooms built to meet these requirements actually will do so, or will inadvertently produce leakage into non-smoking areas, has not been studied.

Places That Share Characteristics of Residences, Public Places, and/or Workplaces.

■ The Manual does not offer provisions that explicitly address whether smoking will be prohibited or allowed in places that share characteristics of residences, public places, and/or workplaces. (e.g., units in condominium and apartment buildings, rooms in residential care facilities, prisons, and similar places). There may be ambiguity in the Manual's provisions in relation to smoking in private residences within buildings containing condominiums and apartment. These types of places may be more properly construed as residences than as public places.

There also is ambiguity with respect to residential care facilities, which clearly combine the features of both residences and workplaces. A strong argument could be made that the workplace aspect outweighs the residence aspect of such places, but ambiguity nonetheless exists. These ambiguities can be removed by clearly specifying in this Part whether or not smoking will be permitted in each of these types of places that have components of a public place, workplace, and a residence.

FCTC OBLIGATIONS

Article 8, Section 2, obliges Parties to “adopt and implement in areas of existing national jurisdiction as determined by national law and actively promote at other jurisdictional levels, the adoption and implementation of effective legislative, executive, administrative, and/or other measures, providing for protection from exposure to tobacco smoke in indoor workplaces, public transport, indoor public places and, as appropriate, other public places.” The Convention's first Guiding Principle, Article 4, Section 1, calls on governments to contemplate measures to protect *all* persons from exposure to tobacco smoke.

THE TOBACCO INDUSTRY'S STRATEGIES

Defeating Smoke Free Environments Regulation

Disputing the Evidence

■ The tobacco industry's response to the evidence on the hazards of tobacco smoke traditionally has been to deny the adverse health effects and to pay researchers to dispute the findings of the hazards. While Brown & Williamson (B&W) and its parent British American Tobacco (BAT) publicly disputed the health effects findings early on, its own research already had shown that tobacco smoke contained several genotoxic and carcinogenic chemicals, including tobacco-specific nitrosamines found in laboratory tests to be biologically active, or carcinogenic.³⁵

A recent example of the industry's tactics is an article published in the British Medical Journal (BMJ).³⁶ This tobacco industry-funded study concluded that results did not support a causal relationship between exposure to tobacco smoke and tobacco-related mortality, although it did not rule out a small effect. The article's appearance in the well-respected BMJ resulted in a firestorm of criticism by the tobacco control and public health communities, who have responded that the study used insufficient data and was based on a flawed study design. The study used data from the American Cancer Society's (ACS) Cancer Prevention Study I (CPS-I), but only a small subset of it. According to the ACS, the study also suffers from "a critical design flaw: the inability to distinguish people who were exposed to second-hand smoke from those who were not."^{37,38}

The results of a WHO/International Agency for Research on Cancer (IARC) European study also have been misrepresented. This study found an increased risk of lung cancer due to tobacco smoke exposure among non-smoking spouses of smokers and in the workplace, but it was not statistically significant because of the small sample size of the study.³⁹ While the research has been mischaracterized as showing no effect, the study results, in fact, are consistent with the results of over 50 scientific reviews on the effects of tobacco smoke showing an increased risk.

Predictions of Economic Losses

■ The tobacco industry asserts that hospitality businesses will be hurt by smoking bans and restrictions. It has published papers claiming that smoking bans create economic losses in hospitality venues. Fueled by "dire predictions" by the tobacco industry of financial loss to the hospitality industry where smoking is the subject of ban or restriction regulation, the hospitality industry has mounted vigorous opposition to such regulation in many places.

Strong and credible studies on the financial impact of smoke-free policies in the hospitality industry provide evidence that counters the tobacco industry's economic claims. Scollo and Lal examined more than 100 studies from Canada, the U.K., the U.S., Australia, New Zealand, South Africa, Spain, and Hong Kong, comparing the quality and funding sources of the studies with their outcomes. They found no negative impact or a positive effect in studies based on objective and reliable measures, such as taxable sales receipts, data several years before and after the introduction of smoke-free policies, where controls for changes in economic conditions were employed, and where statistical tests were used to control for underlying trends and data fluctuations. The authors found a few objective studies with negative economic effects, but the evidence overwhelmingly supports that smoking bans benefit public health with no negative economic impact.⁴⁰

On the other hand, the studies funded predominantly by the tobacco industry, or industries allied with it, were based predominantly on predictions or on subjective impressions or estimates, rather than on objective, verified data. Practically none of these studies were published in a peer-reviewed journal. These studies typically found a negative economic impact from smoke-free regulation.⁴¹ The following quote from a Philip Morris memorandum in relation to no-smoking regulation in some U.S. locations lays bare the tobacco industry's economic scare tactics:

“...the economic arguments often used by the industry to scare off smoking ban activity were no longer working, if indeed they ever did. These arguments simply had no credibility with the public, which isn't surprising when you consider that our dire predictions in the past rarely came true.”⁴²

Philip Morris
memorandum

Nonetheless, the tobacco industry has been very adept at convincing the hospitality industry that economic harm will result from any serious attempt to regulate smoking in public places. Therefore, it will be important to be prepared to counter these arguments with the data from the wealth of solid studies that refute the industry's claims.

Promotion of “Accommodation” and “Courtesy of Choice” Programs

■ The tobacco industry also has undertaken campaigns with the hospitality industry to promote physical separation of smokers and non-smokers or ventilation as a way of “accommodating” both smokers and non-smokers, and as a strategy for defeating proposals for smoking ban legislation.⁴³ These campaigns attempt to elevate smoking as a right equal to that of being free from involuntary exposure to the hazards of tobacco smoke.

[Legislative text, cont'd:]**Part 6: Protection from Tobacco Smoke**

7. Freedom from exposure to tobacco smoke. All persons shall have the right to be free from involuntary exposure to tobacco smoke in all enclosed public places, including workplaces, places of collective use, and on public conveyances.

- a. Prohibition on smoking in enclosed public places, including workplaces.** No person shall smoke in any enclosed public place, including any workplace, or in any part of an enclosed public place or workplace, including private rooms and offices. In addition, no person shall smoke anywhere on the outside premises of any public place that provides services primarily to children or youth under the age of [specify age], or at any outdoor public places where children congregate, such as playgrounds.

[If it is not possible to prohibit smoking altogether, the following provisions may be used:]

- b. Designated smoking rooms.** *Notwithstanding the prohibition against smoking in enclosed public places, including workplaces, the owner or operator of a public place, or employer, as applicable, may designate separately ventilated smoking rooms where people may smoke, other than in places where health care services are provided, places where children or youth under the age of [specify age] represent [specify percent] or more of the population typically served there, educational facilities, and [specify other, if any], so long as the following conditions are met:*
- i. the room is fully enclosed with four walls, or partitions that join the ceiling and floor and a functional door that meets the ceiling and floor without any gap of more than [specify size] cm;*
 - ii. the room is separately ventilated directly to the outside, with negative air pressure in comparison to the remainder of the building;*
 - iii. non-smoking members of the public and workers are not required to enter the designated smoking room while any person is smoking or within [specify time] thereafter, to gain access to other areas of the premises generally open to them or to which they require access to perform their duties, respectively;*
 - iv. all designated smoking rooms together comprise no more than an aggregate of [specify percentage] % of the total floor space of the enclosed premises to which the public and workers generally have access; and*
 - v. the room otherwise meets any requirements imposed in implementing regulations.*
- c. Smoking on public conveyances.** No person shall smoke on any public conveyance carrying passengers or employees.

d. **Smoking in places of collective use.** No person shall smoke in any public place of collective use.

e. **No smoking signs.** The owner or occupier of any enclosed public place and place of collective use, or employer, as applicable, and the owner or operator of any public conveyance, shall post signs prominently on the premises or in the conveyance stating that smoking is not permitted *[or in the case of enclosed public places or workplaces, is permitted only in designated separately ventilated rooms, if allowed by the owner/occupier or employer]*. Signs shall meet the requirements in Annex A and shall comply with any requirements in implementing regulations.

f. **Obligations to ensure compliance.**

- i. It shall be the duty of the owner or occupier of any enclosed public place and any place for collective use, employer, and the owner or operator of any public conveyance, as applicable, to take all reasonable steps to ensure that no person smokes in violation of the provisions of this Part. Taking reasonable steps includes, but is not limited to: asking an offending person to stop smoking; demanding that the offending person who continues to smoke leave the premises or the conveyance when this can be done safely; refusing further service; in the case of an employee, disciplining, including dismissing the offending person from employment; and seeking the assistance of law enforcement personnel in cases where the offending person refuses to stop smoking or leave the premises or conveyance.
- ii. No owner or operator of any enclosed public place, any place of collective use, or public conveyance, and no employer, as applicable, shall permit the placement of ashtrays in any place under their control *[other than in a designated smoking room in an enclosed public place or workplace, if applicable]*.
- iii. No owner or operator of any public place, public place for collective use, or public conveyance, and no employer, as applicable, or any of their agents, shall retaliate against any person or employee who asserts his or her right to a smoke-free environment or who reports any violation under this Part.

g. **Establishment of a smoke-free environment.** Nothing in this part shall require an owner, occupier or employer to designate separately ventilated rooms for smoking.

8. The rights of non-smokers prevail. In interpreting the provisions of this Part, the rights of non-smoking members of the public and workers shall prevail and any question that may arise as to whether smoking is permitted in any given situation shall be resolved in favor of protecting non-smokers.

9. Evaluation for disparate effects. The Minister [or other governing authority] shall determine whether the provisions of the Act and any implementing regulations affording protection against exposure to tobacco smoke result in equal levels of protection across all population groups. In the event disparities in the level of afforded protection are found, the Minister [or other governing authority] shall report such findings to the [specify, e.g., name of legislative body] and remedial regulatory action shall be taken as appropriate.

10. Ministerial discretion to address requirements of this Part.

The Minister [or other governing authority] shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

11. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations to protect persons from exposure to tobacco smoke, so long as such laws or regulations are at least as stringent as, and do not conflict with, the provisions of this Part.

ADVERTISING, SPONSORSHIP AND OTHER FORMS OF PROMOTION

EXPLANATION

Advertising

■ Research shows that advertising increases tobacco consumption,^{44, 45, 46} and youth and young adults may be especially vulnerable to tobacco advertising.^{47, 48} Ubiquitous tobacco advertising also can create a conflicting environment that makes it difficult for consumers to fully absorb messages about the hazards of tobacco use and exposure to tobacco smoke, and to benefit fully from that information. Measures to eliminate tobacco advertising and other forms of promotion, thus, will support governments' health education campaigns and other tobacco control interventions by removing the tobacco industry's messages that glamorize tobacco use and counter the government's messages about the health and other consequences of tobacco use and exposure to tobacco smoke.⁴⁹ There is also evidence that media that rely on tobacco advertising are less likely to report on tobacco and health related matters.^{50, 51} Such measures also will promote consumers' rights by prohibiting misleading and deceptive advertising.

Research also shows that comprehensive tobacco advertising and promotion bans can decrease consumption. Partial bans, however, have been found to be ineffective, since substitution to other non-banned media occurs.^{52, 53} A study of 22 Organization of Economic Cooperation and Development (OECD) countries with weak, limited, and comprehensive provisions showed a significant decrease in consumption in countries with comprehensive bans. On the other hand, those with weak or limited restrictions showed no or relatively small decreases. Countries with comprehensive bans were shown to have the lowest consumption and greatest decline in consumption over time during the time period 1970-1992. If it had been the case that all of the countries had comprehensive advertising bans, the study predicts that a 5.4% reduction in tobacco use and an approximately 7.4% reduction in cigarette use would have occurred.⁵⁴

Other Forms of Promotion

■ Indirect forms of advertising, such as tobacco company sponsorship of sporting, cultural, and other events and “brand stretching” (tobacco names or logos on non-tobacco products), are important forms of promotion for the tobacco industry. These indirect forms are especially important when direct advertising has been banned or substantially restricted. A magazine article on sponsorships quotes an RJ Reynolds Company official as saying,

RJ Reynolds
Internal document

“We use sports as an avenue for advertising our products... We can go into an area where we’re marketing an event, measure the sales during the event and measure sales after the event, and see an increase in sales.”⁵⁵

According to a British American Tobacco internal document from 1979 related to “brand stretching,” it was felt that

British American Tobacco
Internal document

“Opportunities should be explored by all companies so as to find non-tobacco products and other services which can be used to communicate the brand or house name, together with their essential visual identities. This is likely to be a long-term and costly operation, but the principle is nevertheless to ensure that cigarette lines can be effectively publicised when all direct forms of communication are denied.”⁵⁶

From the studies cited above and the tobacco industry’s ability to get around direct advertising bans or restrictions, it is clear that the law must address not only direct forms of advertising but also indirect forms of advertising and promotion, such as sponsorships and brand stretching.

Other forms of promotion that require regulation include the distribution of free tobacco products or samples, gifts, bonuses, rebates, and the right to participate in lotteries or contests. Indirect advertising also can take the form of tobacco product packaging and public displays of tobacco products. Product packaging and displays are addressed in other parts of the Manual.

FCTC OBLIGATIONS

Article 13 requires that each Party, “in accordance with its constitution or constitutional principles, undertake a comprehensive ban on all forms of advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, a comprehensive ban on cross-border advertising, promotion, and sponsorship originating from its territory.” The ban must occur within 5 years after entry into force of the Convention.

In cases where constitutional requirements or principles prevent a Party from undertaking a comprehensive ban, Article 13 requires Parties to “apply restrictions on all tobacco advertising, promotion, and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, restrictions or a comprehensive ban on advertising, promotion and sponsorship originating from its territory with cross-border effects.”

Article 13 further provides:

As a minimum, consistent with constitutional requirements or principles, advertising, promotion, and sponsorship restrictions must:

- a. prohibit all forms of advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;
- b. require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;
- c. restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public;
- d. require, if it does not have a comprehensive ban, the disclosure to relevant government authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited . . .;
- e. undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion, and sponsorship on radio, television, print media, and, as appropriate other media, such as the internet, within a period of five years; and
- f. prohibit, or in the case of a Party that is not in a position to prohibit due to its constitution or constitutional principles restrict, tobacco sponsorship of international events, activities, and/or participants therein.

Parties are encouraged to implement measures beyond the minimal obligations set out above.

Scientific studies clearly show that complete bans on advertising, sponsorships, and other forms of promotion work while partial bans do not. The tobacco industry has proven time and again that it will find ways to get around any measures short of a stringent and comprehensive ban on all forms of advertising, sponsorship, and promotion. The FCTC negotiating process created a strong momentum for a complete ban; therefore, the Manual offers provisions only for a complete ban on all advertising, sponsorship, and other forms of promotion.

THE TOBACCO INDUSTRY'S STRATEGIES

Defeating Regulation of Advertising, Sponsorships, and other Forms of Promotion

Argument that Advertising does not Influence Consumption

■ The tobacco industry spent more than 11 billion dollars in 2001 on advertising and promotion in the U.S. alone.⁵⁷ That is over \$30 million per day in advertising and promotion expenditures. Yet, the industry

“I think advertising has certainly helped to introduce new smokers, be they women or be they in the Third World.”

British Advertising Executive

denies that advertising affects consumption, arguing instead that its only purpose is to motivate people to switch brands or to remain brand loyal. The response to this from the Chairman of a British advertising agency: “I think arguments like shifting brands are just insulting in their shallowness. There is no other category where you can spend between 70 million pounds and 100 million pounds

and not have an effect in protecting or increasing the market. I think advertising has certainly helped to introduce new smokers, be they women or be they in the Third World. The other thing about cigarettes advertising, I do think it makes it more difficult for health education in that it makes the Government’s attitude more ambivalent.”⁵⁸

In the words of another executive of an advertising agency that handled over \$20 million in tobacco accounts,

“the cigarette industry has been artfully maintaining that cigarette advertising has nothing to do with total sales. This is complete and utter nonsense. The industry knows it is nonsense. I am always amused by the suggestion that advertising, a function that has been shown to increase consumption of virtually every other product, somehow miraculously fails to work for tobacco products.”⁵⁹

Argument of Economic Harm

■ The tobacco industry also argues that advertising bans will have serious negative economic effects on the advertising industry, the media, and the economy as a whole. However, based on the experiences of a number of European Union (E.U.) countries imposing bans or significant advertising restrictions, expenditures on tobacco advertising, sponsorship and promotion were replaced by publicity from other sectors without revenue or net job losses.⁶⁰

A Push for “Voluntary Codes”

■ Tobacco manufacturers often argue that regulation of advertising and promotion is not necessary and that “voluntary codes” of conduct or voluntary agreements — self-regulation agreed to by the industry — are sufficient. In countries where voluntary codes are used in place of enforceable regulation, however, the provisions often contain significant loopholes and the industry fails to comply with them.⁶¹ By their very nature, voluntary codes generally cannot be enforced with legal sanctions and thus are neither effective nor sustainable. Further, voluntary codes do not apply to retailer advertising, or to any manufacturers that choose not to be bound by them.

Characterizing Advertising as a Rights Issue

■ Another major argument of the tobacco industry is the right to free speech, including the right to advertise a legal product. Tobacco is a legal product only because governments were unaware of the hazards and addictive nature of tobacco when they allowed its free trade and promotion. Now, too many people are addicted for it to be practical to make tobacco products illegal.⁶²

Many governments ban or restrict advertising of a variety of legal products. In the E.U., for example, there are bans or restrictions on advertising in existence both at the E.U. and Member State level for such products as firearms, medicines, and other items. These restrictions are adopted for public policy, public security, public morality and public health purposes.⁶³ Only a few governments around the world appear to have actual constitutional limits on imposing tobacco advertising bans.

Furthermore, tobacco sales to youth are illegal in many countries. It is very difficult, however, to ensure that tobacco advertising is only aimed at and only reaches adult audiences. For example, under the terms of the 1998 Master Settlement Agreement in the U.S. between the tobacco companies and the states, tobacco companies were prohibited from using advertising that “targets” youth. Researchers have found, however, that the settlement appears to have had little effect on cigarette advertising in magazines and that tobacco companies continued to allocate a higher percentage of their expenditures for youth cigarette brands in youth-oriented magazines than for adult brands. They further found that even though advertising in youth-oriented magazines declined in the second year after the settlement agreement, the overall level of exposure to cigarette advertising remained high among youth.⁶⁴

[Legislative text, cont'd:]
**Part 7: Advertising, Sponsorship
 and other Forms of Promotion**

12. Freedom from tobacco advertising and promotion. All persons shall have the right to be free from all forms of tobacco advertising, sponsorship, and other forms of tobacco-related promotion, whether such forms are direct, indirect, overt, covert, or incidental.

Advertising

13. Advertising prohibition. No person shall advertise, arrange for, or participate in the advertising of any tobacco product, brand, manufacturer or seller, directly or indirectly. This prohibition shall apply to advertising in, as well as to advertising transmitted into or out of [\[specify name of country\]](#).

a. Allowed activities. The following shall be allowed:

- i. incidental exposure of a tobacco product or tobacco product package from the time of manufacture until it reaches its point of retail sale; provided, however, that tobacco products and tobacco product packages shall not be displayed in view of customers or patrons at retail locations and other locations where tobacco products are sold to consumers;

[Note: if a ban on the free supply of tobacco products is not imposed (See Section 13), it will be necessary to add "or supplied" after "sold".]

- ii. a price list on paper no larger than [\[specify size\]](#) available at the counter at the point of sale for consultation by customers containing, in black and white text only, the brand name, price, and prescribed messages in accordance with implementing regulations, and no other text, colors or other graphics, or other information;
- iii. communications by persons in the tobacco growing, manufacturing, importing, exporting, distributing, selling or trading business directed solely at other persons in the tobacco growing, manufacturing, importing, exporting, distributing, selling or trading business;
- iv. an Internet web site for any particular tobacco company, so long as it presents business and or health information only and it is not intended to, and is not likely to encourage, directly or indirectly, the purchase or use of any tobacco product or brand;
- v. trade publications prepared for and distributed only to employees, shareholders, or investors that are not intended to, and are not likely to encourage, directly or indirectly, the purchase or use of any tobacco product or brand; provided, however, that the Minister [\[or other governing authority\]](#) may prescribe a list of allowed trade publications based upon those currently in existence prior to [\[specify date\]](#); and
- vi. the display of the company name on places of tobacco manufacturing, subject to conditions imposed by the Ministry.

- b. Private communications.** Private communications among individuals about tobacco products, brands, manufacturers, or sellers shall not be construed to be tobacco-related advertising, so long as these communications are not made at the behest of or for the benefit of any tobacco manufacturer or seller or any person working on the behalf or for the benefit of a tobacco manufacturer or seller.

Sponsorships

14. Prohibition of tobacco sponsorships. Tobacco sponsorships, and advertising and other promotion of tobacco sponsorships, are prohibited. This prohibition applies to sponsorships and advertising of sponsorships in, as well as sponsorships and advertising of sponsorships originating elsewhere but transmitted into or otherwise appearing in, [\[specify name of country\]](#).

Other Forms of Promotion

15. Prohibition against brand stretching. No person shall sell, display for sale, supply, or advertise any non-tobacco product or service that contains, either on the product, or in any advertisement of the product, any writing, picture, image, graphic, message, or other matter, in whole or part, that is commonly identified or associated with, or is likely or intended to be identified or associated with a tobacco product, brand, or manufacturer. For the purposes of this section, a non-tobacco product shall include a building, facility, premises, or business that is not a building, facility or business that manufactures tobacco products exclusively.

16. Prohibition against reverse brand stretching. No person shall use the brand name, trademark or other sign, symbol, logo, or similar matter, in whole or in part, commonly associated with a non-tobacco product or service on a tobacco product, except for tobacco products for which a trade or brand name of a non-tobacco product or service was in use on [\[specify a date on or before the Bill was introduced in Parliament\]](#).

17. Prohibition against incentive promotions and the free supply of tobacco products. Incentive promotions and the free supply of tobacco products shall be prohibited.

- a. Prohibition on tobacco products as bonuses, premiums, rebates, etc.** No person shall offer or provide any direct or indirect consideration for the purchase or use of a tobacco product, including a bonus, premium, cash rebate or right to participate in a game, lottery or contest; provided, however, that nothing in this section shall prohibit the giving of any normal trade discount or normal trade rebate, or providing compensation for monitoring compliance with this Act.

b. Prohibition on tobacco product samples and gifts. No person shall supply or offer to supply a tobacco product to any other person free of charge as a sample, gift, or otherwise. This subsection shall not be construed as prohibiting individuals from giving tobacco products to other individuals, so long as this is not done at the behest of, or for the benefit of, a tobacco manufacturer or seller or any person working on the behalf of or in the interest of a tobacco manufacturer or seller, or for financial gain for the individual offering the tobacco product.

18. Unintended consequences. The Minister [or other governing authority] shall have the authority, through implementing regulations, to make necessary limited exceptions to the provisions of this Part for the purpose of mitigating against or preventing any unintended consequences.

[If an outright ban on all advertising, sponsorship, and other forms of promotion is not undertaken, the following provision should be included to ensure assessment and remedial action in response to any disparities in the level of protection that may result from restrictions short of a ban.]

19. Evaluation for disparate effects. *The Minister [or other governing authority] shall determine whether the provisions of the Act and any implementing regulations affording protection against exposure to tobacco advertising, sponsorship, and other forms of promotion result in equal levels of protection across all population groups. In the event disparities in the level of afforded protection are found, the Minister [or other governing authority] shall report such findings to the [specify, e.g., name of legislative body] and remedial regulatory action shall be taken as appropriate.*

20. Ministerial discretion to address requirements of this Part.

The Minister [or other governing authority] shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

21. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing tobacco advertising, sponsorships, and other forms of promotion, so long as the provisions of such law or regulations are at least as stringent as, and do not conflict with, the provisions of this Part.

TOBACCO PRODUCT LABELLING AND PACKAGING

EXPLANATION

The Right to Be Informed of the Risks of Tobacco Use

■ Under many legal systems, a product manufacturer generally has a legal duty to warn consumers of any foreseeable hazards associated with its product so that consumers may exercise “informed consent” in deciding to use the product. While many tobacco users across the globe generally know that tobacco use is harmful, studies show that most smokers are unaware of the true risks, even in countries in which there has been a great deal of publicity about the health hazards of tobacco.⁶⁵ Smokers tend to be even less aware of the risks of tobacco smoke on others.⁶⁶

The Effectiveness of Health Messages on Tobacco Product Packages

■ Prominent health warnings and messages on tobacco product packages have been found to lead to an increased awareness of risks and an increased desire to quit.⁶⁷ Rotation of messages helps keep this information from becoming stale and worn out. Studies from a number of countries show the continued effectiveness of health messages even as the population has become more informed about the dangers of tobacco use over time, provided the messages are sufficiently prominent and contain hard hitting factual information.^{68,69} In Brazil, after tobacco product packages began to circulate with prominent picture-based health warnings and a Hot Line number to call for cessation assistance, Hot Line calls increased almost 300%.⁷⁰

Canada's Tobacco Products Information Regulations require that health messages comprise at least 50% of the package's front and back panels and provide graphic pictorial depictions showing the health effects of tobacco use.



Brazil's 2001 ANVISA Resolution requires that 100% of one principal display panel must consist of a pictorial health warning.

The law in Canada requires that health messages comprise at least 50% of the package's front and back panels and provide graphic pictorial depictions showing the health effects of tobacco use.⁷¹ In Brazil, 100% of one principal display panel must consist of a pictorial health warning.⁷² At the time of publication of this Manual, Belgium requires the world's largest warnings, at roughly 55%, on average, of the package front and back.⁷³ General guidance for labelling requirements is offered by the International Union Against Cancer.⁷⁴

Because of the industry's adeptness at evading labelling requirements, discussed in several contexts within this section, it might be advisable in some circumstances to require prescribed messages on individual sticks of smoked products and individual portion pouches of smokeless products.

Toxic Substance Disclosures

■ Tobacco smoke contains more than 4 000 constituents, over 60 of which are known or suspected carcinogens. Research shows that many smokers, understandably, are confused about the constituents of tobacco smoke.⁷⁵ As a result, an important component of informed consent, in addition to mandatory health and other messages, is to require that tobacco product packages provide tobacco users with prescribed factual information on the toxic substances contained in the products and their smoke.

In setting requirements for toxic substance disclosures, however, it is important to recognize the problem with tar, nicotine, and carbon monoxide (CO) measurements and disclosures of these based on current testing methods (discussed in more detail in Part 10: Product Requirements).

The WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACTob) recommends that “tar, nicotine, and CO numerical ratings based upon current International Standards Organization/Federal Trade Commission (ISO/FTC) methods and presented on cigarette packages and in advertising as single numerical values are misleading and should not be displayed.”⁷⁶ Nonetheless, consumers still should be informed of the *existence*, if not the levels, of these and other hazardous constituents, such as tobacco specific nitrosamines, polycyclic aromatic hydrocarbons, and a host of others, and of the dangers they pose.

Generic Packages

■ Cigarette packaging can act as an advertisement.⁷⁷ According to an internal document from Liggett and Myers cited by Wakefield *et al.*, the primary job of the package is to create a desire to purchase and try the product.⁷⁸ The package as a marketing tool can become especially important when advertising is banned or strictly regulated. In the face of increasingly stringent regulation of advertisements in Europe, it was urged at a Philip Morris International marketing meeting that the company's new product development program focus on “areas of opportunity which do not rely on conventional media,” such as “new types and forms of packaging that can act as a means of communication” as well as “using famous trademarks from other fields on tobacco products and sponsorships.”⁷⁹ (See the discussion about reverse brand stretching in Part 7: Advertising, Sponsorship, and Promotion).

The memo of the meeting also described the testing of a new pack designed to project a young, masculine appearance. According to the test results, the pack was found to have “tremendous appeal among young smokers.”⁸⁰ In Uganda, recent promotional packages of Benson and Hedges featured an advertisement that previously appeared on billboards before the company agreed to take it down.⁸¹

Tobacco companies also have used pack coloring to convey images of so called “low tar”, or reduced strength products, by lightening the colors and increasing the white spaces on the package. As discussed in Part 10: Product Requirements, so called “low tar”, “light”, and “mild” cigarettes have been used to mislead smokers into believing these products are less harmful than full strength brands when they are not.⁸²

These and other examples make a compelling case for generic packaging as an important tobacco control measure.⁸³ Generic packaging for tobacco products is plain (but for government prescribed information, such as messages and substance disclosures, and brand/company name), standardized packaging stripped of its marketing appeal. By making packaging unappealing to consumers, the objective of generic packaging is to “denormalize” tobacco product use and prevent the tobacco package from being an alluring advertisement that undermines health messages, confuses consumers about the risks of tobacco use generally and of “low

tar” brands in particular, and that otherwise detracts from governments’ attempts to ensure that consumers are aware of the hazards of tobacco use.⁸⁴ Packages should be required to be generic both inside and outside.

Studies from Canada, the U.S., Australia, and New Zealand found that a substantial proportion of adolescents surveyed believed that plain packaging would reduce experimentation and ongoing smoking.⁸⁵ A significant majority of adults refused to buy Marlboro cigarettes at half-price when they were packaged in generic brown boxes, despite the fact that they were assured of the freshness, authenticity, and identical nature to traditionally-packaged Marlboros.⁸⁶ Additionally, health messages on plain packages were found to be more noticeable and their presence more easily recalled than on traditional tobacco packages.⁸⁷ A resolution of the Ninth World Conference on Tobacco and Health (1994) urged countries to adopt generic packaging.

Labelling to Deter Smuggling

■ Tracking and tracing labelling requirements for such things as manufacturer identification, countries of origin and destination, tax stamp markings, and similar information play an important role in efforts to prevent smuggling. Tracking is the systematic monitoring of the movement of tobacco products from the place of manufacture where all relevant duties and taxes have been paid for the purpose of assisting the competent authorities in detecting, investigating, and analyzing illicit manufacturing and illicit trafficking. Tracing means the ability of competent authorities to recreate the route taken by a tobacco product from the place of manufacturing through the distribution chain to the point where all relevant duties and taxes have been paid.⁸⁸

Although some anti-smuggling measures are addressed separately in Part 12: Anti-Smuggling Measures, the labelling aspects of anti-smuggling provisions are provided in this section for the sake of continuity.

Minimum Package Size

■ Many countries’ laws prohibit the sale of single or unpackage tobacco products, or packages below a minimum size that tend to be more affordable and accessible to youth, who are especially price sensitive.⁸⁹ Additionally, requiring tobacco products to be sold in packages ensures consumers are provided with prescribed messages, toxic substance disclosures, and other important labelling information required by the government to be on the package. Where sales of single cigarettes are prevalent because of a large informal sector, it may be advisable to require manufacturers to place prescribed messages on individual sticks of smoked products as well as on packages.

FCTC OBLIGATIONS

Article 11 obliges Parties to adopt and implement effective measures, within 3 years after entry into force of the Convention for that party, to ensure that:

- a. tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as “low tar”, “light”, “ultra light”, or “mild”;
- b. each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages.
These warnings and messages:
 - i. shall be approved by the competent national authority,
 - ii. shall be rotating,
 - iii. shall be large, clear, visible and legible,
 - iv. should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas, may be in the form of or include pictures or pictograms.

Article 11 also requires each unit package and any outside packaging and labels to contain “information on relevant constituents and emissions of tobacco products as defined by national authorities.” Yield numbers are not required.

Article 15 requires Parties to adopt effective measures to “ensure that all unit packets and packages of tobacco products and any outside packaging of such products are marked to assist Parties in determining the origin of tobacco products, and in accordance with national law and relevant bilateral or multilateral agreements, assist Parties in determining the point of diversion and monitor, document and control the movement of tobacco products and their legal status.”

In addition, parties shall:

- a. require that unit packets and packages of tobacco products for retail and wholesale use that are sold on its domestic market carry the statement: ‘Sales only allowed in (*insert name of the country, subnational, regional or federal unit*)’ or carry any other effective marking indicating the final destination or which would assist authorities in determining whether the product is legally for sale on the domestic market; and
- b. consider, as appropriate, developing a practical tracking and tracing regime that would further secure the distribution system and assist in the investigation of illicit trade.

The packaging information or marking “shall be presented in legible form and/or appear in its principal language or languages.”

Article 16, Section 3, obliges the Parties to “endeavor to prohibit the sale of cigarettes individually or in small packets which increase the affordability of such products to minors.”

THE TOBACCO INDUSTRY'S STRATEGIES

Defeating Labeling Regulation

Technical, Economic and Legal Arguments

■ When Brazil enacted its law requiring graphic pictures on tobacco product packages to accompany its health warnings, the industry tried to delay implementation. It argued that it did not have the technical capacity to comply with new requirements for pictures. The industry tried to negotiate the use of only 2 colors for the warning pictures along with a 2 year period before the new requirements would be enforced, arguing it needed this time to upgrade its graphics structure. Ultimately it took 9 months

for the packages to comply with legal requirements.⁹⁰ The ability of the industry to produce “fun packs” with pictures in Uganda, South Africa, France, and elsewhere demonstrates the industry’s graphic capability.

The industry also makes its typical arguments of economic and job losses (in the packaging and printing industries), and increased smuggling as a result of passing on the costs of new labelling requirements to consumers. It additionally has argued that generic packaging requirements would violate patent law and international agreements on intellectual property.⁹¹

The economic arguments make no more sense with respect to packaging than with restrictions on smoking in public places or advertising, discussed above. Smuggling is a serious problem that needs to be addressed through enhanced enforcement measures, not through weakened legislative measures. Furthermore, the tobacco industry, itself, has been indicted for actively participating in smuggling (See Part 12: Anti-Smuggling Measures).

With respect to the legal arguments about intellectual property rights, an opinion submitted to the Canadian Standing Committee on Health suggests that limits on package design that are strongly based on public health data could withstand a challenge.⁹²

In response to the Brazilian government’s ban of the use of misleading descriptors, tobacco companies use colors associated with their “light” and “mild” brands



Exploiting Vague Legal Provisions

■ Poland’s experience illustrates the need for governments to specify all particulars of labelling requirements in great detail. Government prescribed health warnings in Poland are required to be in “contrasting colours”. What resulted in Poland is tobacco packages with warnings in gold or silver on white.⁹³ In Brazil, the government banned the use of the misleading descriptors “light” and “mild”. Between the time of the enactment of the law and the date nine months later when it came into operation, tobacco companies responded by using the colors associated with their “light” and “mild” brands, thus keeping the association of the product with the misleading terms without actually using the words. Some of the brand packs even circulated during the interim period with a pamphlet explaining that in the future the consumer would see these new brand colors, defined as new product “clothes”, as a way to identify the light versions of their products.⁹⁴

A template for prescribing labelling details that can be incorporated in implementing regulations is provided in Appendix 2. This appendix is provided to help ensure all necessary details are covered.

[Legislative text, cont'd:]**Part 8: Tobacco Product Labelling and Packaging**

22. Right to be informed of the risks of tobacco use. All consumers shall have the right to be informed fully of the health and other effects of tobacco use and the risks to others from exposure to tobacco smoke. The right to be fully informed includes the right to receive this information without interference from distracting or misleading tobacco product labelling or packaging practices.

23. Conformity with packaging and labelling requirements. All tobacco product labelling and packaging shall comply with the provisions of this Part.

a. Prohibition on sales of noncompliant tobacco product packages.

No person shall sell, offer for sale, supply, display, import, or export any tobacco product that is not labelled and packaged in a manner that complies with all requirements of this Part and with implementing regulations.

b. Prohibition on commercial purchase of noncompliant tobacco product packages.

No seller shall acquire tobacco products that are not packaged and labelled in a manner that complies with all requirements of this Part and with implementing regulations.

Labelling

24. Prescribed messages on tobacco products and packages.

All tobacco products shall contain, permanently affixed on their packages [and on individual sticks of smoked products], or individual wrappers in the case of cigars, messages as prescribed in implementing regulations.

a. Requirement for unattributed messages. Prescribed messages shall be unattributed.

b. Prohibition on obscuring messages. No person may sell or supply any product, device, or other thing that is intended to be used, or that can be used, to cover, obscure, mask, alter, or otherwise detract from the prescribed messages on tobacco product packages. This prohibition includes design of the product package in such a way that parts of the package, itself, or accessories can cover or obscure the messages.

25. Constituent and additives disclosures on tobacco product packages.

All tobacco products shall contain, permanently affixed on their packages, or wrapper in the case of cigars, a list of the constituents and additives specified, and in the manner prescribed, in implementing regulations. Constituent yield numbers shall not be displayed on tobacco product packages unless specifically authorized in implementing regulations.

26. Prohibition on deceptive or misleading information. No tobacco product package or label shall contain any information that is false, misleading, or deceptive, or that is likely or intended to create an erroneous impression about the characteristics, health effects, or health or other hazards of the tobacco product or its emissions. This prohibition includes, but is not limited to, the use of: words or descriptors, whether or not part of the brand name, such as “light”, “ultra light”, “mild”, “low tar”, “slim” or similar words or descriptors; any graphics associated with, or likely or intended to be associated with, such words or descriptors; and any product package design characteristics, associated with, or likely or intended to be associated with, such descriptors.

27. Continuing duty to warn. Compliance with this Part in no way shall be construed as relieving any tobacco manufacturer or seller of any duty prescribed by law, custom, convention, or otherwise, to fully inform consumers of all dangers associated with tobacco use and exposure to tobacco smoke.

28. Multiple packaging. If any tobacco product is placed in multiple layers of packaging, all health messages and constituents and additives disclosures shall be permanently affixed to the package in which the tobacco product ultimately is intended for consumer use, as well as to any external packaging, including cartons.

29. Requirements for name, license number, etc. on package.

Tobacco product manufacturers, exporters, and importers, as applicable, shall ensure their product packages contain the tracking and tracing and tax stamp status labelling information required by this Section.

- a. **Tracking and tracing information.** The following information shall be presented in an invisible manner, in languages required by the Minister [\[or other governing authority\]](#), and shall be permanently affixed under the cellophane or other wrapping on each tobacco product package, including each carton, at the time of manufacture; provided, however, that those denoted below as visible shall be presented in both a visible and an invisible manner:
 - I. name (visible) and license number of the manufacturer, and as applicable, wholesaler, importer, and exporter;
 - II. unique manufacturer serial number date of manufacture (visible), and location;
 - III. name of the country in which it was manufactured (visible); and
 - IV. name of the country in which the product is intended for legal sale (visible).

- b. **Tax paid status information.** The following information shall be clearly visible on all tobacco product packages:
 - I. tax paid stamp or marking, as prescribed in [\[cite to law/regulation addressing tax markings or stamps\]](#); and
 - II. [\[Specify other requirements, if any.\]](#)

30. Requirements for tamper-proof packaging and labelling. Tobacco product manufacturers shall design their product packaging and labelling in such a way as to make them tamper-proof, using the best available technology. Manufacturers, importers, exporters, wholesalers, and retailers shall exercise all reasonable and necessary precautions to prevent tampering with such information while the products are under their control or supervision.

31. Language of labelling information. All labelling information shall appear in the principal languages of the country in which the products will be sold.

32. Evaluation for disparate effects. The Minister [or other governing authority] shall determine whether the messages required under this Act and any implementing regulations are providing information in an appropriate and effective manner to the general population and to priority populations. To the extent the mix of messages is not found to be effective in reaching the general population or priority populations, the Minister [or other governing authority] shall report such findings to the [specify, e.g., name of legislative body] and remedial regulatory action shall be taken as appropriate.

33. Labelling requirements for exported products. Notwithstanding the provisions contained in this Part, tobacco products that will be exported from [specify country name] shall not be required to meet labelling requirements under this Part, other than the requirements of Section 24; provided, however, that they shall be required to meet the labelling requirements of the importing country. In the absence of labelling requirements in the importing country, the labelling requirements under this Part shall apply fully to exported tobacco products and any required messages, constituent and additives disclosures, and other required labelling information shall appear in the official languages of the country of destination.

Packaging

34. Requirement for generic packaging. Tobacco products shall not be contained in anything other than a package that is generic on the inside and the outside, and that complies with labelling requirements under this Act and implementing regulations. Cartons containing individual packages also shall be generic on the inside and outside.

- a. Prohibition on sale of noncompliant tobacco product packages.
No seller shall sell, offer to sell, supply, display, import, or export, subject to the provisions of Section 32, tobacco products in packaging other than generic packaging.
- b. Prohibition on commercial purchase of noncompliant tobacco product packages. No seller shall purchase tobacco products in packaging other than generic packaging.

35. Minimum package size for smoked tobacco products. Smoked tobacco products, with the exception of cigars which may be sold as individual units so long as they are individually labelled as required, shall be contained in a package of at least [specify number] units. No person shall sell single cigarettes or other smoked tobacco products, or sell any smoked tobacco product other than as part of a complete and intact package that meets minimum quantity requirements.

36. Minimum package size for smokeless products. Smokeless tobacco products shall be contained in a package of at least [specify number] mg. No person shall sell any portion of a smokeless tobacco product package, or sell any smokeless tobacco product other than as part of a complete and intact package that meets the minimum weight requirement.

37. Packaging requirements for exported tobacco products. Notwithstanding the provisions of this Part, tobacco products that will be exported from [specify country name] shall not be required to meet the packaging requirements of this Part; provided, however, that in the absence of packaging requirements in the importing country, the packaging requirements under this Part shall apply fully to exported tobacco products.

38. Ministerial discretion to address requirements of this Part. The Minister [or other governing authority] shall have the authority to prescribe, in implementing regulations, additional and/or more stringent standards and requirements for labelling and packaging than those prescribed in this Part. Ministerial authority shall include prescribing testing methods applicable to making the required constituents and additives disclosures.

39. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing tobacco product labelling and packaging, so long as such laws or regulations are at least as stringent as, and do not conflict with, the provisions of this Part; provided, however, no other level of government may prescribe messages other than those prescribed in implementing regulations.

TOBACCO PRODUCT SALES

EXPLANATION

■ Most individuals begin using tobacco products during youth or adolescence when they may have limited capacity to use information on the health and other adverse effects of tobacco use wisely. Young persons have been shown to underestimate the addictive nature of tobacco products, and they may know less about the health effects of tobacco use than adults.⁹⁵ As a result, many jurisdictions prohibit sales of tobacco products to minors and place other restrictions on youth access to tobacco products.

These provisions vary around the world, with the main difference being upon whom the sanction for non-compliance with youth access restrictions falls. The emphasis has been placed either on the retailer not to sell to minors, or on the young person not to buy, possess, or use tobacco products. Variations also exist on the severity of penalties imposed, ranging from confiscation of tobacco products to community services sentences, in the case of violations by minors. In the case of retailers, penalties range from fines to loss of license to sell.

While an important element of a comprehensive tobacco control programme, the benefits of measures to reduce youth access to tobacco products recently have been called into question for a number of reasons. First, the tobacco industry has tried to position itself as a proponent of youth smoking prevention by strongly supporting youth access type measures as part of a vast public relations exercise, including so called youth prevention campaigns, and close links with educators and parents (discussed in greater detail in Part 16). These industry tactics are designed to shift the public debate on tobacco away from being a societal problem, to confine it solely as a youth issue, to position the industry as a responsible commercial enterprise, and most importantly, to avoid and delay the adoption and enforcement of more stringent and effective evidence based tobacco control regulatory measures.^{96,97}

Second, placing responsibility on youth to resist tobacco in the face of aggressive tobacco industry promotional practices that glamorize tobacco use creates a paradox, especially when penalties are imposed against youth purchasers/users. Finally, the evidence on the effectiveness of youth access restrictions is mixed, both with respect to achieving high levels of retailer compliance with restrictions and achieving reduced youth consumption even when retail access is significantly restricted in practice.

Some studies have produced results calling into question the ability of youth access laws to effect reductions in youth consumption, even in communities with high retailer compliance.^{98, 99, 100} These studies have found that as tobacco products become less accessible at retail locations, youth tend to get their tobacco from friends, parents, strangers outside of stores, vending machines, and other sources.^{101, 102}

Other studies, on the other hand, have suggested that youth access laws can reduce illegal sales to minors and lead to reduced smoking rates among youth.^{103, 104, 105} Strict and active enforcement of these laws, a resource intensive and costly endeavour, is critical, however,^{106, 107} as are efforts to educate retailers and make them aware of penalties.¹⁰⁸

Di Franza reviewed over 250 papers on youth access strategies from the scientific literature and found that 18 studies using a variety of study designs provided evidence that reduced youth access was associated with reduced youth use. In every study in which there was a documented reduction in the availability of tobacco to youth, there also was a substantial reduction in youth tobacco use, the effect of which did not diminish over time. The effects were observed in both ethnically and culturally diverse settings.¹⁰⁹

Chaloupka and Pacula conducted a study employing a nationally representative sample of U.S. youth, controlling for state approaches to monitoring compliance and looking at state and local tobacco control policies and cigarette prices. They conclude that limiting access to cigarettes can be effective in reducing youth smoking, but alone will not result in a decline as high as 50%, the level called for by most proposed legislation at the national level in the U.S.¹¹⁰

The conflict in the evidence notwithstanding, Jha and Chaloupka recommend that even low —and middle— income countries include comprehensive youth access policies as an integral component of a comprehensive tobacco control strategy. Comprehensive youth access policies include mandating minimum age requirements, banning vending machine sales, banning single cigarette sales (addressed in Part 8: Packaging and Labelling), limiting self-service displays, licensing vendors, and imposing graduated fines for retailer violations.

It is important to keep in mind, however, that taxation and other demand measures, especially advertising and promotion bans, are proven and indispensable interventions to reduce youth tobacco use. As discussed in the Manual section addressing taxation, imposing sufficiently high taxes on tobacco products is the most successful and important tobacco control intervention for preventing youth access to and consumption of tobacco products. Restrictions on sales to minors in no way should be seen as an alternative to, but rather should be viewed as a complement to, taxation and other proven effective strategies.

FCTC OBLIGATIONS

Article 16 obliges the Parties to adopt and implement effective measures “to prohibit the sales of tobacco products to persons under the age set by national law or 18.”

These may include:

1. a. requiring that all sellers of tobacco products place a clear and prominent indicator inside their point of sale about the prohibition of tobacco sales to minors and, in the case of doubt, request that each tobacco purchaser provide appropriate evidence of having reached full legal age;
- b. banning the sale of tobacco products in any manner by which they are directly accessible, such as on store shelves;
- c. prohibiting the manufacture and sale of sweets, snacks, toys or any other objects in the form of tobacco products which appeal to minors;
- d. ensuring vending machines under its jurisdiction are not accessible to minors and do not promote the sale of tobacco products to minors.
2. Each party shall prohibit or promote the prohibition of the distribution of free tobacco products to the public and especially minors. Each Party should, as appropriate, adopt...measures... to prohibit the sales of tobacco products by person under the age set by domestic law, national law or 18.

The provisions below are based on the types of youth access restrictions found in many countries' laws. Because of a concern that calling attention to youth access restrictions might reinforce the notion that tobacco is an adult product attractive to youth, requirements for signs emphasizing the ban on sales to minors are not included.

THE TOBACCO INDUSTRY'S STRATEGIES

To pre-empt effective legislation in this area, the tobacco industry has launched its own youth access measures in many places. Sometimes this takes the form of the “We Card” system, as in the U.S., or the Retail Access Programmes in Uganda. Both measures purportedly require retailers to verify the consumer's age. These measures are ineffective, however, and only serve to position tobacco products as adult products, which are attractive to youth aspiring to be adult-like. They do not contain any enforcing mechanism by which suppliers no longer sell to retailers who do not comply.

As already discussed above, the tobacco industry's support for youth access provisions, and its youth access programs are undertaken for public relations purposes. According to a Philip Morris memo, “If we don't do something fast to project the sense of industry responsibility regarding the youth access issue, we are going to be looking at severe marketing restrictions in a very short time. Those restrictions will pave the way for equally severe legislation or regulation on where adults are allowed to smoke.”¹¹¹

[Legislative text, cont'd:] Part 9: Tobacco Product Sales

40. Prohibition on sales to minors. No person shall sell any tobacco product to any person under the age of 18 years [or specify at least the legal age of majority in the country]. Prior to selling a tobacco product to any person who appears not to be at least 10 [or specify other age] years older than [specify minimum age, as above], it shall be necessary to take all reasonable steps to verify the age of that person, by requiring, at a minimum, [specify reliable means of verification].

41. Prohibition on sales by minors. No person who sells tobacco products shall hire or use any person under [specify age, as above] years of age to sell any tobacco product or to handle any tobacco product.

42. Prohibition on self-service displays. No person shall sell any tobacco product in such a way that a consumer may handle the product without the assistance of a sales clerk or other employee or agent of the seller prior to purchase.

43. Prohibition on public displays. No person shall display tobacco products in such a way that they are visible to the public; provided, however, that the provisions of this section prohibiting public displays of tobacco products shall not apply to individuals incidentally displaying tobacco products during carrying or use.

[If it will not be politically possible to ban the public display of tobacco products by sellers, the following provision may be adopted as an alternative, though absent an outright ban on public displays, the tobacco industry likely will find a way around restrictions:]

43. Prohibition on tobacco product displays as advertisements. No person shall display tobacco product packages in such a way that the packages convey a selling message or otherwise constitute an advertisement. Additionally, any display of any tobacco product packages shall be accompanied by a sign carrying prescribed messages, as prescribed in implementing regulations.

44. Prohibition on vending machines, Internet, and certain other sales of tobacco products. No person shall sell any tobacco product through any self-service means, including through automatic vending machines, through the mail or the Internet. The Minister [or other governing authority] may prohibit any other means of sale where the age of the purchaser of the tobacco product cannot be verified reliably.

45. Prohibition on sales of tobacco products in certain places. No person shall sell tobacco products in any of the following places: facilities where health care services are provided; sports, athletic, or recreational facilities; government buildings; educational facilities; and any other place prescribed by the Minister [or other governing authority] in implementing regulations.

46. Prohibition on toy or candy cigarettes. No person shall manufacture, sell, display for sale, or supply any sweets, snacks, toys, or other non-tobacco items or objects in the form of tobacco products, or which imitate tobacco products.

47. Ministerial discretion to address requirements of this Part.

The Minister [or other governing authority] shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

48. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing the sale or supply of tobacco and related products, so long as such laws or regulations are at least as stringent as, and they do not conflict with, the provisions of this Part.

TOBACCO PRODUCT REQUIREMENTS

EXPLANATION

Composition of Tobacco Products

■ Manufactured tobacco products and their smoke contain thousands of chemical compounds, including the more than sixty known or suspected human carcinogens in tobacco smoke previously mentioned.¹¹² Many toxic or otherwise harmful substances are contained in the tobacco leaf itself or are created upon combustion. Other chemicals are introduced during the growing, curing, storage, and manufacturing processes.¹¹³ These include pesticides, anti-fungal agents, and other preservatives.

Hoffmann *et al.* have classified the major and minor contributing agents for cigarette smoke-related disorders. Carbon monoxide, nitrogen oxides, hydrogen cyanide, cadmium, zinc, and tar are contributing agents for cardiovascular disease. Hydrogen cyanide, volatile aldehydes, nitrogen oxides, carbon monoxide, and tar are contributing agents for chronic obstructive lung disease. Polycyclic aromatic hydrocarbons (PAHs), tobacco specific nitrosamines, 210 polonium, formaldehyde, acetaldehyde, butadiene, and metals are contributing agents for lung and larynx cancer. Tobacco-specific nitrosamines also contribute to oral cavity cancer (along with PAHs), esophageal cancer, and pancreatic cancer. Aromatic amines contribute to urinary bladder cancer. Nicotine, secondary Nicotiana alkaloids, and flavor components contribute to tobacco dependence.¹¹⁴ Some of the hundreds of chemicals in tar residue are classified as hazardous waste. Some chemicals in tobacco smoke, such as 2-aminonaphthalene, and 4-aminobiphenyl, are banned or restricted for other uses in some countries because there is no safe level of exposure.^{115, 116, 117, 118}

The huge variety of additives in tobacco products purposely introduced during the manufacturing process serve different functions to make the products more acceptable to consumers. For example, some are flavorants that can improve taste¹¹⁹ which can make youth initiation easier. Others can make smoke seem milder and easier to inhale, while some additives prolong burning.¹²⁰ Ammonia alters the pH of nicotine, converting it from a bound form to a freebase form, increasing its absorption and making the product potentially more addictive.^{121, 122}

Regulatory Approach

■ The main reason dependent individuals use tobacco is to get nicotine. Manufactured tobacco products are more toxic, carcinogenic, and hazardous to health and the environment than they need to be to deliver nicotine. Nonetheless, to date, no country has adopted extensive product regulation requirements. Flawed testing methods currently in use for measuring tar, nicotine, and carbon monoxide complicate the ability to regulate tobacco products.

For these reasons, this Part follows the approach of merely providing broad legal authority to the Ministry (or regulatory body) to develop requirements and standards for constituents, emissions, product design, and testing methods, once there is clear guidance for doing so. WHO's Scientific Advisory Committee on Tobacco Product Regulation (SACTob) has been commissioned to develop product and testing guidelines, work that is underway. The government of Canada is well along the way to establishing a regulatory regime for tobacco products. Some jurisdictions are moving to require design features that lower ignition propensity as a means of preventing cigarettes from continuing to be such a large cause of preventable fires. The FCTC's Conference of the Parties also is charged with developing guidelines for product regulation and testing. Therefore, such guidance should be forthcoming.

Some of the issues making it a challenge presently to regulate the content and design of tobacco products are highlighted below.

Regulatory and Research Questions

Tar and Nicotine

■ When levels of tar are purported by the tobacco industry to be lowered, as with so called “low tar”, “light”, and “mild” cigarettes, smokers tend to adapt their smoking behavior to get the same level of nicotine they are used to getting with higher tar yield products. As a result, tar exposure also is maintained,¹²³ and no benefits accrue to the smoker.¹²⁴ In fact, there is evidence that these products increase the risk of adenocarcinoma, a fatal form of cancer, as a result of the smoker inhaling more deeply as a compensatory measure.¹²⁵

Additionally, because of limitations of the FTC and ISO testing methods, the levels reported by tobacco companies do not accurately portray true absorbed doses.¹²⁶ Tobacco companies have exploited the inaccuracies of the testing methods, using what they know to be inaccurate tar levels as a marketing strategy to promote “light” and “mild” cigarettes.¹²⁷ Studies show that some consumers motivated to quit may delay quitting or reducing consumption because they perceive these products to be a safer alternative to full-strength cigarettes.¹²⁸ As a result of compensatory smoking behaviors, flawed testing methods, and the potential unintended consequence of smokers delaying quitting behavior if they perceive that mandated reduced tar levels provide benefits, caution is required in regulating tar and nicotine.

Tobacco Specific Nitrosamines, Polycyclic Aromatic Hydrocarbons, and Additives

■ Different brands of tobacco products on the market today contain significantly different levels of the potent carcinogens, tobacco specific nitrosamines (TSNAs) and polycyclic aromatic hydrocarbons (PAHs). This demonstrates that these compounds can be reduced to a level at least as low as that found in the brand containing the lowest level on the market. There also is the possibility of prohibiting the use of additives that make tobacco products more appealing and easier for youth to initiate tobacco use behaviors, such as additives that impart sweet, menthol, or other flavors, that alter the harshness, or that mask tobacco smoke's true odors. Prohibition of the use of toxic or otherwise harmful constituents and additives also is a potential regulatory measure.

“New tobacco” or “Reduced harm” Products and Health Claims

■ Tobacco companies have released a new generation of tobacco products that heat rather than burn. The companies claim these products to be less dangerous and to emit smoke that is less hazardous. There have not yet been sufficient epidemiologic studies to substantiate these claims, however, and public health authorities are not convinced at this time of an overall benefit of these products.¹²⁹ Whether to allow health claims for so-called “reduced harm” products of these or any other varieties must be considered very carefully in light of the lessons learned from the marketing of “light” and “mild” products.

The Manual follows the approach of prohibiting health claims since there has not been sufficient evidence of the health effects of any of the so-called “reduced harm” products currently on the market to support any claims of health benefits that might be made or implied. Provisions in the Manual leave the door open to the Minister (or other governing authority), through the rule-making process, to allow health claims at a future time if there becomes sufficient evidence to support such claims for existing or newly developed products. Evidence should include epidemiological and other studies over an adequate length of time demonstrating that the product will significantly reduce harm to the individual tobacco user. Evidence also should take into account the increased or decreased likelihood that current tobacco users would quit or that non-users might initiate tobacco use.

FCTC OBLIGATIONS

Article 9 obliges Parties, where approved by national authorities, to adopt and implement effective measures for regulating contents and emissions of tobacco products and for their testing and measuring, based on guidelines developed and proposed by the Conference of the Parties.

TOBACCO INDUSTRY STRATEGY

The tobacco industry argues that additives introduced during the manufacturing process are generally regarded as safe pursuant to regulatory requirements for food under U.S. standards. Most, if not all, additives, while generally regarded as safe for use in food, have not been assessed for safety when combusted.¹³⁰ Also, some compounds while safe when used in isolation, are not necessarily safe when they interact with other compounds. Thus, there remains a compelling case for regulating additives along with other components of tobacco products and tobacco smoke, once there is capacity to do so. This will help to ensure they contain the lowest possible levels of toxicity, carcinogenicity, fire propensity, and other hazards, and that additives are not used solely for the purposes of making tobacco products more palatable, socially acceptable, or more addictive.

[Legislative text, cont'd:] Part 10: Tobacco Product Requirements

49. Regulation of tobacco products. The Minister [or other governing authority] shall have the authority to prescribe, in implementing regulations, requirements and standards for tobacco product constituents, including emissions of smoked products, additives, and product design, and to specify methods for testing and measuring compliance with the performance standards and requirements prescribed.

50. Compliance with standards. No person shall manufacture, import, export, supply, or sell any tobacco product unless it conforms to requirements and standards prescribed in this Act and implementing regulations.

51. Filter demarcation on smoked tobacco products. The area of any filter containing ventilation holes shall be marked and shall be clearly visible to the smoker, as follows:

- a. there shall be bands of color on each side of the area containing the ventilation holes;
- b. the color of the bands shall clearly contrast with the area of the filter or rod containing the ventilation holes;
- c. the ventilation holes shall be in the form of, or be surrounded by, raised dots that can be felt by the lips and fingers of the smoker; and
- d. filter demarcation shall comply with any additional requirements prescribed by the Minister [or other governing authority] in implementing regulations.

52. Tobacco product research. All tobacco product research conducted by any tobacco manufacturer, or by any person conducting research paid for in whole or in part by a tobacco manufacturer, shall be made available to and/or reported to the Minister [or other governing authority], as required by the Minister [or other governing authority].

53. Prohibition on health claims. No tobacco product package [or advertisement, if advertising still will be permitted] may make any claim stating, suggesting, or implying that its use or exposure to its smoke is not hazardous or is less hazardous than other tobacco products or brands, unless authorized by the Minister [or other governing authority] after he or she is satisfied that the claim is accurate upon a showing of scientifically competent and reliable evidence, including:

- a. evidence demonstrating that the product will significantly reduce harm to the individual tobacco user;
- b. evidence that the product will benefit the health of the population as a whole, taking into account the increased or decreased likelihood that current tobacco users would delay or avoid quitting or that non-tobacco users might initiate tobacco use; and
- c. any other considerations deemed appropriate by the Minister [or other governing authority].

54. Product standards for exported products. Notwithstanding the provisions of this Part, tobacco products that will be exported from [\[specify name of country\]](#) shall be required to meet the product and testing standards of the country of final destination; in the event, however, that such standards in the country of destination do not exist, the provisions in this Part and in implementing regulations shall apply fully. To the extent standards in the country of destination exist but are less protective of human health, the more protective standards of this Part shall apply.

55. Evaluation for disparate effects. The Minister [\[or other governing authority\]](#) shall determine whether the provisions of the Act and any implementing regulations regulating tobacco product composition and design result in equal levels of protection across all population groups. In the event disparities in the level of afforded protection are found, the Minister [\[or other governing authority\]](#) shall report such findings to the [\[specify, e.g., name of legislative body\]](#) and remedial regulatory action shall be taken as appropriate.

56. Ministerial discretion to address requirements of this Part. The Minister [\[or other governing authority\]](#) shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

57. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing tobacco product requirements and their testing, so long as such laws or regulations are at least as stringent as, and do not conflict with, the provisions of this Part.

REPORTING

EXPLANATION

■ Some jurisdictions require tobacco companies to report information periodically to the government on the constituents and additives in the tobacco products they manufacture or import. These reports help resource-strapped governments keep up, to some degree, with what is contained in tobacco products and, thus, enhance their ability to determine how best to regulate tobacco products, what research to pursue, and the like. Some jurisdictions also require that certain business information be reported. The reporting regulations from Canada¹³¹ and from the Canadian province of British Columbia¹³² (B.C.) are extremely useful examples for developing implementing regulations. A copy of Canada's regulations is provided in Appendix 3.

FCTC OBLIGATIONS

Article 10 obliges Parties, in accordance with their national law, to adopt and implement effective measures “requiring manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products. Each Party shall further adopt and implement effective measures for public disclosure of information about toxic constituents of the tobacco products and the emissions they may produce.” Article 13 obliges Parties who have not adopted a comprehensive ban on advertising, sponsorship, and promotion to require “disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of the Parties...”

[Legislative text, cont'd:] Part 11: Reporting

58. Reports of constituents, additives, and certain business information.

Every manufacturer and importer of tobacco products shall submit to the Minister [or other governing authority] on at least a [specify frequency] basis, beginning [specify beginning date], unless otherwise prescribed in implementing regulations to be more frequent, reports containing the information required by this Part, as well as any other information the Minister [or other governing authority] may prescribe in implementing regulations. Such reports shall be submitted in the form and manner prescribed.

59. Information required in reports. Reports shall identify and list, by brand, for every brand of smoked and smokeless tobacco product of the manufacturer and importer that is manufactured, imported into, sold, or offered for sale in [specify name of country], or exported from [specify name of country] during the preceding reporting period, the following:

[Note: This section contemplates that the provisions in Part 7 prohibiting the free supply of tobacco products, such as samples and gifts, will be included in the legislation being developed. If they will not be, it will be necessary to speak in terms of “sold, offered for sale, or supplied” in the preceding sentence.]

- a. measures of tar, nicotine, and proportion of unbound nicotine in smoke;
- b. pH of whole smoke and puff-by-puff pH profile;
- c. filter efficiency and percentage ventilation of filters;
- d. and all other individual constituents, additives, and yields of constituents and additives in smoke, unless otherwise specified in implementing regulations, expressed in their individual concentrations and as a ratio to nicotine, or as otherwise required in implementing regulations.

60. Product preparation and testing. Reports shall be made on the basis of products prepared and tested in accordance with the method(s) prescribed in implementing regulations.

61. Reports for new products. No tobacco product or brand that has not previously been offered for sale or sold in [specify name of country] prior to the date this Act comes into operation shall be sold or offered for sale until all required reports for that brand have been submitted.

[Note: This section contemplates that the provisions in Part 7 prohibiting the free supply of tobacco products, such as samples and gifts, will be included in the legislation being developed. If they will not be, it will be necessary to speak in terms of “sold, offered for sale, or supplied” in the preceding sentence.]

62. Additional information required. In addition to the other reporting requirements of this Part, every manufacturer, importer, and exporter of tobacco products shall submit to the Minister [or other governing authority] in a prescribed manner on at least a [specify frequency], basis beginning [specify date], unless otherwise prescribed in implementing regulations to be more frequent, reports containing the following information, as well as any other information the Minister [or other governing authority] may prescribe in implementing regulations:

- a. the number of packages and the number of sticks, or as applicable the number of grams of smokeless product, of each brand of each tobacco product manufactured, imported, exported, and sold, as applicable, during the reporting period; provided that sales data shall be reported with respect to aggregate sales to the entire population, by brand, and with respect to sales, by brand, to distinct population groups;
- b. for exported products:
 - i. export volumes for each brand, by country of destination and by wholesaler;
 - ii. a list of the countries of final destination and a list of the countries through which the products are transported, correlated with serial numbers;
 - iii. the number of packages and sticks or grams, as applicable, in each shipment for export; and
 - iv. the dates on which the products, by serial number, were shipped;
- c. for imported products:
 - i. import volumes for each brand, by country of origin and by wholesaler;
 - ii. a list of the countries through which the products are transported, correlated with serial numbers;
 - iii. the number of packages and sticks or grams, as applicable, in each shipment imported; and
 - iv. the dates on which the products, by serial number, were received;
- d. prices charged for the tobacco products, by brand, along with the dates and amounts of any price increases during the reporting period;
- e. disclosure, by date, of the amount of all contributions, loans, or other payments, and the value of all gifts made to any elected or appointed government official or government entity, and to any political party during the reporting period;
- f. copies of audited financial statements made during the reporting period;
- g. copies of all tobacco product packaging and labelling, including any required package inserts;
- h. a description of all marketing activities and, as applicable, copies of all marketing materials, correlated with expenditures by brand of tobacco product, and correlated with each distinct population group for which such activities, materials, and expenditures are intended;

- i. [\[specify any other\]](#); and
- j. any other information required by the Minister [\[or other governing authority\]](#) in implementing regulations.

63. Disclosure of reports. Reports required under this Part and in implementing regulations shall be public information. Reports shall be published by the government in the Gazette [\[or specify other official publication\]](#).

64. Form and manner of reports. Reports required by this Part shall be submitted in the form and manner prescribed, and shall include all information required by this Part and in implementing regulations.

65. Ministerial discretion to address requirements of this Part. The Minister [\[or other governing authority\]](#) shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

66. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing tobacco product or business reporting.

ANTI-SMUGGLING MEASURES

EXPLANATION

■ Tobacco product smuggling deprives the government of significant tax revenues. Total revenue lost to governments on account of smuggling is estimated to be \$25-30,000 million annually.¹³³ Smuggling also brings tobacco products into markets more cheaply, making them more affordable. Access to more affordable tobacco products, in turn, increases consumption.¹³⁴

“Total revenue lost to governments on account of smuggling is estimated to be \$25-30,000 million annually.”

Luk Joossens

Large scale, organized smuggling commonly is executed by buying tax free cigarettes under an “in transit” regime that allows the temporary suspension of customs duties,

excise, and value added taxes payable on goods originating from or destined for a third country while under transport across a defined customs area. In “round tripping”, smuggled tobacco products are exported to countries where there is no market and then secretly transported back into the country of export. There, they are sold illegally at one-half to one-third the legal price.¹³⁵

Legislative efforts to prevent smuggling must be matched by enhanced enforcement. Transport of tobacco products will need to be monitored vigorously, and coordination will need to be assured among customs, tax, and other relevant authorities. Among other things, if it has not already done so, the government (most likely the customs authority) will need to develop a tax stamp or other marking to show that all required tax and duties have been paid prior to the final sale to consumers.

The stamps or markings should meet minimum criteria for visibility, tamper-resistance, and anti-counterfeiting. For example, laser-stamping technology and encrypted information, such as the identity of the company that purchased the cigarettes from the distributor and the supplier of the cigarettes to the distributor that affixed the tax stamps, and the tax stamp date and value, can be employed. Tax stamps can be read by a bar code-type scanning device that reveals the encrypted information.

Anti-smuggling provisions are contained in five parts of the Manual. Labelling measures to help control smuggling already have been included in the provisions under Part 8: Tobacco Product Packaging and Labelling. Licensing is addressed in Part 5: Licensure. Some provisions for requiring information relevant to assessing smuggling activity is covered in Part 11: Reporting. Provisions eliminating and prohibiting duty free sales are contained in the section on taxation. The provisions in the legislative text below concentrate on other elements of anti-smuggling measures: payment of taxes and duties at the place of manufacture or import; bonding requirements; product quantity limits for non-licensed entities; and record-keeping and additional reporting requirements.

The information above is a summary from a paper written by Luk Joossens, UICC Consultant and WHO Expert on European Tobacco Control Activities. The entire paper can be found in Appendix 4.

FCTC OBLIGATIONS

Article 15 obliges Parties to “monitor and collect data on cross-border trade in tobacco products, including illicit trade, and exchange information among customs, tax and other authorities, as appropriate, and in accordance with national law and relevant applicable bilateral or multilateral agreements.” Additionally, Parties are required to implement measures to monitor, document and control the storage and distribution of tobacco products held or moving under suspension of taxes or duties within its jurisdiction. . . .” Additional Article 15 obligations on smuggling are related to labelling and to enforcement. These are discussed in Part 8 and Part 14 of the Manual.

THE TOBACCO INDUSTRY’S STRATEGIES

The tobacco industry advances the argument that smuggling will be the inevitable result of tobacco product tax increases. According to Joossens (see Appendix 4), smuggling is a problem worldwide, even in countries where taxes are low. Further, according to Joossens and a number of jurisdictions that have sued the tobacco companies for alleged smuggling activity, the tobacco companies themselves are complicit in smuggling.

“For years, the tobacco industry has used the spectre of cigarette smuggling to frighten governments into not raising tobacco taxes. . . rather than being a result of price differentials, tobacco smuggling is largely the result of actions taken by the tobacco industry itself, which appears to be complicit in the global smuggling trade.”

Illegal Pathways to Illegal Profits-The Big Cigarette Companies and International Smuggling Campaign for Tobacco-Free Kids.
Available at
<http://tobaccofreekids.org/campaign/global/framework/docs/Smuggling.pdf>

[Legislative text, cont'd:]
Part 12: Anti-Smuggling Measures

67. Collection of taxes at manufacture and import. No tobacco products manufactured in [specify name of country] and produced for domestic consumption shall be removed from their place of manufacture prior to the payment of all applicable taxes and duties. No imported tobacco products shall be removed from their place of import without proof that all applicable taxes and duties have been paid.

68. Bond requirements for exported tobacco products.

- a. No tobacco products manufactured in [specify name of country] and produced for export shall be removed from their place of manufacture or exported without payment of an export bond; provided, however, that tobacco products for export may be transferred from the place of manufacture to a bonded facility, under payment of a transfer bond, prior to export. The bond shall be payable to the [specify Ministry or agency] in an amount [describe how the bond amount will be determined] and shall be accompanied with the following information and, as specified, documents:
- 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 from which the products were exported;
 - III. the name, license number, address, telephone, and telefax numbers of all importers/purchasers, and of any persons who receive the shipment on the importers'/purchasers' behalf;
 - IV. the name, address, telephone, and telefax numbers of all intended carriers of the shipment, and the means of transport;
 - V. the names of all cities and countries through which the shipment will be transported;
 - VI. identification of the country of final destination;
 - VII. information on the approximate number of users in the country of destination of each of the brands being shipped and a complete description of the sources of this information;
 - VIII. the name, license number, address, telephone, and telefax numbers of any distributors and other intermediaries handling the shipment;
 - IX. 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;
 - X. physical description of the products (e.g., cigarettes, cigars, bidis, smokeless tobacco, etc.) shipped, including brands and serial numbers of all products contained in the shipment;
 - XI. number of individual packages; number of sticks in each package or gram amount, as applicable; number of cartons and number of packages in each carton; number of bulk packages; number of individual packages or cartons contained in each bulk package; and the weight of each bulk package contained in the shipment;

- xii. copies of all purchase orders, invoices, shipping or transport, and transit documents related to the shipment;
 - xiii. copies of tax stamps and a description of special markings and design features on packages contained in the shipment;
 - xiv. an affidavit of the manufacturer and 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, along with a description of the means used to investigate the demand in the country of destination, in addition to obtaining the information required in subsection (vii);
 - 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 labelling and other legal requirements;
 - 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 and taxes, 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 and taxes;
 - 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 [\[or other governing authority\]](#) in implementing regulations.

69. Ministerial discretion to address requirements of this Part.

The Minister [\[or other governing authority\]](#) shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

70. Protection for employees. No person shall retaliate or attempt to retaliate in any way against any employee who notifies government authorities or who testifies in court regarding any activity on the part of his or her employer that violates or allegedly violates any provision of this Part, Part 8, Part 11, or of any applicable law imposing taxes or duties.

INSPECTIONS AND INVESTIGATIONS

EXPLANATION

■ It is important to establish inspection and investigation powers that enable the government to determine if violations of the Act or implementing regulations have occurred. It also is important to collect evidence that supports charges of noncompliance that will follow from an inspection or investigation that reveals any violation(s). Evidence will need to be collected, handled, and preserved in such a way that is reliable and that documents the chain of custody.

FCTC OBLIGATIONS

Article 19 obliges Parties to address criminal and civil liability, as discussed in the next Part, but does not address inspection powers explicitly. In order to accomplish holding violators civilly or criminally liable, however, it first will be necessary to ensure adequate legal authority for inspections and investigations.

[Legislative text, cont'd:]
Part 13: Inspections and Investigations

71. Identification of authorized officers. While carrying out official duties, authorized officers shall present proof of identity and/or of their appointment if requested by the person being inspected or investigated.

72. Inspection and investigative powers. Authorized officers shall have the following powers, which no person shall deny, obstruct, or hinder, and which no authorized officer shall abuse or use for his or her own financial or personal gain:

- a. to enter the premises of any place where tobacco is manufactured, sold, transported, received, distributed, supplied, or otherwise found or is likely to be found, or to have been present during the previous [specify time] period. For the purposes of enforcing Part 6 of this Act, authorized officers shall have the right to enter any public place, including workplace, and any place of collective use, to conduct inspections or investigations at any time during business or operating hours or at any other reasonable or necessary time;
- b. 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, including packaging and labelling, storage, distribution, or advertising or promotion of tobacco products, manufacturers or sellers;
- c. to examine any manufacturing operation or process carried out on the premises;
- d. 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 the provisions of this Act and implementing regulations and any other applicable law, including laws and regulations imposing duties or taxes;
- e. to interview any person the officer believes may have information relevant to making a compliance determination;
- f. to take samples of tobacco products or components of products, and their packaging, anywhere they are found, and have them tested;
- g. 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 or were contained or conveyed, and examine, open, and take samples of them;

- h. to seize and detain, or order the storage without removal or alteration of, any tobacco product or other thing the authorized officer reasonably believes does not comply with the provisions of this Act or implementing regulations and any other applicable law, including laws and regulations imposing duties or taxes; provided, however, that the officer shall first provide the licensee or owner of the tobacco products or other things, or if he or she is unavailable, any other person on the premises where the tobacco products or other things are located, with written notice of the seizure and detention and the grounds for it. If any tobacco product or other thing so seized and detained is determined to meet legal requirements, it shall be returned to the premises from which it was seized within [\[specify number\]](#) business days from the date it is determined to meet legal requirements, unless it is needed as evidence in a legal proceeding. If any tobacco product or other thing is determined not to meet legal requirements, it may be confiscated and destroyed or subject to other disposal, as ordered by the adjudicator of the case, subject to any appeal rights that may be applicable; and
- i. to take any other action reasonable or necessary for the effective and efficient administration of this Act.

73. Inspection and investigation reports. Inspection and investigation reports, and documents collected pursuant to inspections and investigations, shall be public information once the inspection or investigation has concluded; provided, however, that the person that is the subject of the inspection or investigation may apply to [\[specify who would hear the petition, e.g., the Minister \[or other governing authority\] or a court of competent jurisdiction\]](#) for an order to protect the confidentiality of any trade secrets or the privacy or confidentiality of any personal information that it demonstrates are contained in the records.

74. Subpoena power. The Minister [\[or other governing authority\]](#) shall have the power to require by subpoena the attendance and testimony of witnesses and the production of any documentary or other evidence related to any matter under investigation.

ENFORCEMENT

EXPLANATION

■ This part deals both with the penalties that may be imposed for a violation of the law, as well as with the legal mechanism for imposing penalties. A broad array of penalties will provide the government with sufficient flexibility to tailor meaningful penalties to specific violations. Enforcement issues can arise where penalties exclusively or primarily take the form of small fines or jail. It often is more cost efficient for violators to pay a small fine and continue doing business as usual than to comply with the law. On the other hand, enforcers may be reluctant to impose a jail sentence in the absence of an egregious violation. Therefore, having available a range of graduated penalties provides an enabling framework for enforcing legal requirements.

[Note: Since enforcement might involve the Ministry of Health, the customs authority, Ministry of Finance, and law enforcement officials, the national coordinating body may have an important role here.]

If it is permissible under the legal system of the country, the appropriate Ministry can be vested with authority to bring an administrative action for noncompliance and hold a hearing on the matter, subject to the right to appeal in court. This can be more efficient and less costly than having to initiate an action in court. The provisions below assume that the Ministry may initiate an enforcement action administratively, without having to do so in Court.

FCTC OBLIGATIONS

Article 19 obliges Parties to deal with criminal and civil liability. Other articles of the Convention contain specific requirements for penalties for certain violations. For example, Article 15 (4)(c) obliges Parties to take appropriate steps to ensure that confiscated manufacturing equipment and counterfeit and contraband tobacco products are destroyed, using environmentally friendly methods where feasible, and to confiscate the proceeds derived from illicit trade. Article 16 obliges Parties to include penalties against sellers and distributors who violate sales to minors provisions.

[Legislative text, cont'd:] Part 14: Enforcement

75. Sanctions for non-compliance. The Minister [or other governing authority] shall ensure the diligent enforcement of this Act.

- a. Civil penalties.** In any civil action for non-compliance with any provision of this or any applicable law and regulations, including any law or regulation imposing duties or taxes [if this does not fall within the exclusive jurisdiction of the customs authority or Ministry of Finance], the following penalties may be imposed, singly or in combination, as determined by the Minister [or other governing authority] in his or her [or its] discretion, unless otherwise specified:
- I. licensure suspension, revocation, or limitation;
 - II. fines in accordance with Schedule 1; provided, however, that the imposition of spot fines or tickets shall be authorized; provided further, that the imposition of spot fines or tickets shall not prejudice the right to appeal;
 - III. adverse publicity; provided that the form and content of the publicity and media vehicle used shall be determined by the Minister [or other governing authority], and the cost of the publicity shall be borne by the person found to be in violation;
 - IV. removal by an authorized officer of an offending person from the premises or public conveyance, and confiscation and forfeiture of any tobacco products, for smoking in violation of the provisions of Part 6 (Protection from Tobacco Smoke); and
 - V. confiscation and forfeiture, including, where appropriate, destruction, using environmentally-friendly methods where feasible, of:
 - i. any item that contains a tobacco advertisement and any promotional item prohibited under Part 7: Advertising, Sponsorship, and Other Forms of Promotion, regardless of the knowledge or intent of the person who owns or possesses such products;
 - ii. any tobacco product packaged or labelled in a manner that does not conform to the requirements of Part 8: Tobacco Product Packaging and Labelling or Part 12: Anti-Smuggling Measures, wherever they may be located and regardless of the knowledge or intent of the person who owns or possesses such products, and any equipment, machinery, materials, and related items used to evade the requirements of those Parts;
 - iii. any and all tobacco products owned by or under the control of the person found to have committed a violation of Part 9: Sales and Distribution;
 - iv. equipment, machinery, raw materials, components, packaging and labelling materials, and any other items used to manufacture tobacco products in violation of Part 10: Product Requirements or Part 12: Anti-Smuggling Measures;

- v. any and all tobacco products or components that fail to conform to the requirements of Part 10: Product Requirements, including forfeiture of any tobacco product located anywhere in the country that does not comply, regardless of the owner's intent or knowledge of its noncompliant status;
 - vi. any and all tobacco products for which all applicable taxes and duties have not been paid or that otherwise have not legally entered the country of destination; and
 - vii. removal from office, in addition to any other applicable penalty, and referral for criminal prosecution, of any authorized officer or other government official who uses his or her office or authority to undermine the effective and efficient administration of this Act with the purpose of obtaining financial or personal gain.
- b. Continuing violations.** For any continuing violation, each day the violation continues shall constitute a separate offence.
- c. Repeat violations.**
Escalating penalties shall be imposed for repeat violations.
- d. Forfeiture of ill-gotten gains.** Where any person derived any monetary or financial benefit directly or indirectly from any act or omission that constitutes a violation under this Act or implementing regulations or other applicable law, including any law imposing duties or taxes, all proceeds so gained shall be forfeited in addition to any other penalty imposed.
- e. Liability of corporate officers.** Where the person committing any violation is a corporate director or officer who authorized or acquiesced in the act, or who knew or, using due diligence, should have known of the commission or omission of the act constituting the violation, he or she shall be held liable. In addition, a corporation may be held liable as a corporate person.
- f. Strict liability for illicit trade.** Any person who domestically manufactures or supplies tobacco products shall be held strictly liable for any of its exported products that do not legally enter the designated country of destination or that later are found to have escaped payment of all applicable taxes and duties or to otherwise be contraband goods.

76. Statute of limitations. The applicable statute of limitations for any violation of this Act or implementing regulations shall be [\[specify period\]](#) years from the date of the act or omission constituting the violation, or from the discovery of the act or omission constituting a violation. [\[It may be necessary to have different statute of limitation periods for violations of different Parts, or even for different provisions within a Part. For more serious violations, it may be advisable to provide that there is no limitation period for the commencement of an enforcement action.\]](#)

77. Civil enforcement proceedings. Any person charged with violating this Act or implementing regulations shall be entitled to a hearing before the Ministry [\[or court of competent jurisdiction\]](#).

- a. **Right to notice.** Prior to imposing any penalty, the Ministry [\[or prosecutor, if a proceeding must be initiated in court rather than administratively\]](#) first shall provide the person accused of violating any provision of the Act or implementing regulation, or any other applicable act, including a law or regulations imposing excise duties or taxes [\[if this does not fall within the exclusive jurisdiction of the customs authority or Ministry of Finance\]](#), with written notice of all alleged violations, the sanctions to be imposed, the dates sanctions will become effective, and the right to contest the charges in an administrative hearing [\[or in a court of competent jurisdiction, if required\]](#).
- b. **Waiver.** If no such hearing is requested by the accused in writing within the time period specified in the notice for doing so, the accused shall be deemed to have waived his or her right to a hearing, and any right to appeal, and the proposed sanction may be executed within [\[specify period\]](#).
- c. **Governing rules.** If a hearing is requested, it shall be held in accordance with all applicable requirements of [\[specify any governing legal authority, e.g. Rules of Court, or, if none exists, it will be necessary to prescribe requirements in implementing regulations\]](#), and the standard of proof shall be by [\[specify the applicable standard of proof, preponderance of the evidence, if that is an appropriate standard\]](#). In any hearing under this section, the following shall apply:
- I. an affidavit or certification under oath by a laboratory analyst who tested any tobacco product or component which is the subject of the proceedings shall be admissible on its mere production as *prima facie* proof of the violations shown by the examination or analysis of the tobacco product or component; provided, however, that the accused shall be notified in writing in advance of the intent to produce such an affidavit or certification and shall have the right to compel the analyst's presence at the hearing or to cross-examine him or her in advance of the hearing and offer this testimony into evidence at the hearing;
 - II. copies from any record, book, or document certified by the Ministry as true and correct copies shall be deemed admissible into evidence as authentic;
 - III. where any tobacco product or component is found in or on any premises used for the manufacture, import, export, distribution, supply, or sale of such products, such product or component shall be presumed to be intended for manufacture, import, export, packaging, distribution, or sale, respectively;
 - IV. any tobacco product from the same lot or batch shall be presumed to possess the same characteristics as those products from the same lot or batch found on the premises or at another location under the control of the owner or operator of the premises; provided, however that if there is no lot or batch number on the products, as required under the Act, any tobacco product found on the premises shall be presumed to possess the same characteristics as other tobacco products found on the premises or at another location under the control of the owner or operator of the premises.

- v. the person identified on the label or packaging of any tobacco product as the manufacturer, importer, exporter, distributor, or seller shall be presumed to have manufactured, imported, distributed or sold the tobacco product, respectively.

78. Right to appeal. Any person found in a hearing before the Ministry to have violated any provision of this Act or implementing regulations, or any other applicable law, including laws and regulations imposing excise duties or taxes [if this does not fall within the exclusive jurisdiction of the customs authority or Ministry of Finance], shall have a right to appeal the findings before [specify the appropriate judicial body], provided a notice of appeal is filed as required. [Note: if there is a law governing appeals, it should be referenced in this section.]

79. Enforcement cost recovery. Any person found to have violated any requirement under this Act or implementing regulations, or any other applicable law, including laws and regulations imposing duties or taxes [if this does not fall within the exclusive jurisdiction of the customs authority or Ministry of Finance], may be ordered to pay all reasonable costs associated with any investigation and enforcement action brought about by the non-compliance.

80. Criminal enforcement. Nothing provided in this Act shall preclude the criminal enforcement of any of its provisions in a Court of competent jurisdiction. [If appropriate, provide for applicable criminal penalties; otherwise, it may be necessary to amend the criminal law to cover non-compliance with the tobacco control law.]

81. General right of action for violation of provisions of the Act.

Any person may commence a civil action before the appropriate Court against any person, including any governmental official or agency or other body, who or which is alleged to have violated any of the provisions of this Act. It shall not be necessary for the plaintiff to show that he or she has been harmed by the alleged violation or has any special interest in the suit, save for the enforcement of this Act.

- a. **Exemption from filing fees.** Any action instituted under the provisions of this section shall be exempt from any Court filing fees.
- b. **Cost recovery.** Where it is established that the action brought under this section asserts one or more colorable claims and is designed to effectuate strong public policies and benefit to the public, the plaintiff shall be entitled to recover the costs of the action, including reasonable attorneys' fees.
- c. **Statutory damages.** In cases where the plaintiff is successful, statutory damages in a amount up to [specify amount] may be awarded; provided, however, that statutory damages shall not be available against a government official performing a discretionary function in good faith.

RECOVERY OF DAMAGES

EXPLANATION

■ Some jurisdictions have enacted legal provisions that establish applicable evidentiary standards, including allowing the use of statistical evidence and aggregate data, in lawsuits against tobacco companies for recovery of health care costs incurred on account of tobacco-related illnesses. Other provisions are needed to clarify the process of proof in individual cases. The provisions below are modelled largely after the law from the province of British Columbia, Canada.¹³⁶

FCTC OBLIGATIONS

The FCTC's **5th Guiding Principle** reminds the parties that issues relating to liability are an important part of comprehensive tobacco control. Article 19 obliges Parties to “consider taking legislative action or promoting their existing laws, where necessary to deal with criminal and civil liability, including compensation where appropriate.”

[Legislative text, cont'd:]
Part 15: Recovery of damages

82. Direct cause of action accruing to the government. The government of [\[specify name of country\]](#) shall have a direct cause of action against a manufacturer of any tobacco product sold in [\[specify name of country\]](#) to recover the costs of health care services provided or funded by the government in whole or part to any person on account of any tobacco-related illness or at the risk of suffering from any tobacco related illness.

- a. **Government right to recover.** Such action may be brought by the government in its own right and not on the basis of a subrogated claim, and any recovery by the government shall not be affected by the recovery of damages by any other persons who have suffered damage caused or contributed to by a tobacco-related illness.
- b. **Recovery on an aggregate basis.** The government shall be entitled to recover the cost of health care services provided to particular individuals on an aggregate basis for a population of persons on account of any tobacco-related illnesses or at the risk of suffering from any tobacco related illness.
- c. **Proof required.** To recover the costs of health care services on an aggregate basis, the government shall prove by a preponderance of the evidence [\[or specify other legal standard\]](#) that:
 - i. the defendant breached a common law, equitable, statutory or other duty or obligation owed to persons in [\[specify name of country\]](#) who have used tobacco or have been exposed to tobacco smoke, or who might use any particular tobacco product or become exposed to its smoke;
 - ii. such use or exposure can cause or contribute to illness or disease; and
 - iii. during all or part of the period of breach of duty, the type of tobacco product manufactured by the defendant was offered for sale in [\[specify name of country\]](#).
- d. **Presumptions.** In an action to recover the costs of health care services on an aggregate basis, there shall be a rebuttable presumption that use of tobacco or exposure to its smoke by any person in the population would not have occurred but for the defendant's breach of duty and that the use or exposure caused or contributed to illness or disease or the risk of illness or disease in a portion of the population.
- e. **Individualized proof.** For the government to seek recovery of the cost of health care services on an aggregate basis, it shall not be necessary to:
 - i. identify particular individuals who received health care services on account of a tobacco-related illness or because of the risk of suffering from a tobacco-related illness;
 - ii. prove the cause of the tobacco-related illness in any particular individual; and
 - iii. prove the cost or value of health care services provided to any particular individual on account of a tobacco-related illness.

- f. Individualized records.** In an action by the government on an aggregate basis, the health care records, treatment records, records showing the costs of health care services provided, and related documents pertaining to particular individuals shall not be compellable, unless such documents are relied upon by an expert witness for the government; provided, however, that a court may order discovery of a statistically meaningful sample of documents upon application by a defendant; provided, further, that such order shall provide direction on the nature, level of detail, and type of information to be disclosed while also providing that any information that identifies or potentially identifies particular individuals shall first be deleted if determined appropriate by the Court.
- g. Individual testimony.** In an action by the government on an aggregate basis, no person shall be compelled to answer questions with respect to the health of, or provision of health care services to, any particular individual provided health care services on account of a tobacco-related illness or because of the risk of suffering from a tobacco-related illness; provided, however, that a court may order discovery of a statistically meaningful sample of documents upon application by a defendant, and such order shall provide direction on the nature, level of detail, and type of information to be disclosed, while further providing that any information that identifies or potentially identifies particular individuals shall first be deleted if determined appropriate by the Court.
- h. Statistical and related information.** Statistical information and information derived from epidemiological, sociological, and other relevant scientific studies, including information derived from sampling, is admissible as evidence for the purposes of establishing causation and quantifying damages or the costs of health care services in relation to any action brought by the government, or by an individual on his or her own behalf or as member of a class of plaintiffs suffering from a tobacco-related illness, or at risk of suffering from a tobacco-related illness.
- i. Defendants' portion of liability.**
- I. In the case of more than one defendant, there shall be a rebuttable presumption that each defendant's portion of liability in relation to the aggregate amount of damages is equal to its average market share in the type of tobacco product that is the subject of the litigation; provided, however, that each defendant shall remain jointly and severally liable for any damages recovered.
 - II. In the event there has been a change of ownership in any tobacco company during the time period in which damages were alleged to have accrued, and the previous owner was the government, the new owner shall have a right to offset any damages that accrued and that can be attributed to the government during the period of government ownership.

83. Private Right of Action by individuals and classes of individuals.

Any person harmed by tobacco use or exposure to tobacco smoke, or who is at risk of suffering from a tobacco-related illness, shall have a cause of action against the manufacturer of the product that caused or contributed to the harm or the risk of harm. Any such action may be brought by the individual on his or her own behalf, or on behalf of an affected class of individuals. In any such action, the following shall apply:

- a. **Capacity of young tobacco users.** There shall be an irrebuttable presumption that a plaintiff who began using a tobacco product before attaining the age of [specify age of majority or other age] years lacked the capacity to understand, consent to, or assume any risk associated with using the product, even if he or she was provided by any person with information about the risks of using tobacco. Any proffered evidence or legal argument by any defendant that the plaintiff assumed the risk, was contributorily negligent, or should be not be entitled to recovery under any similar theory, shall be inadmissible if the Plaintiff proves, by a preponderance of the evidence, that:
 - i. he or she started using tobacco before he or she reached the age of [specify age of majority or other age] years; and
 - ii. he or she made a reasonable effort, as determined by the trier of fact, to quit at some time during his or her period of use. In considering the question of whether a reasonable effort to quit was made, the highly addictive nature of tobacco products shall be taken into account.
- b. **Effect of advertising and promotion.** If any plaintiff proves by a preponderance of the evidence that he or she was exposed to and was aware of any tobacco-related advertising or other forms of promotion during his or her time of tobacco use, there shall be a rebuttable presumption that his or her ability to understand and incorporate fully the true risks of using tobacco was undermined by the tobacco-related advertising and promotion. For any plaintiff for which a presumption under this subsection is not successfully rebutted, a claim of assumption of the risk, contributory negligence, or other similar legal argument denying entitlement to recover damages shall not defeat a claim for damages.
- c. **“Low tar” tobacco products.** There shall be an irrebuttable presumption that any person who used a tobacco product described or implied by its label, design, or otherwise, or in advertising, to be “low tar”, “light”, “mild”, or of a similar nature, was deceived or misled into thinking that use of that product was safer or less harmful than using a full strength tobacco product.
- d. **Admissibility of statistical information.** Statistical information and information derived from epidemiological, sociological, and other relevant studies, including information derived from sampling, shall be admissible as evidence for the purposes of establishing causation and quantifying damages, and for supporting any evidence submitted by the plaintiff under subsections (a) through (c).

e. Defendants' portion of liability. In the case of more than one defendant, there shall be a rebuttable presumption that each defendant's portion of liability in relation to the aggregate amount of damages is equal to the proportion of its tobacco products used by the plaintiff; provided, however, that each defendant shall be jointly and severally liable for any damages recovered, as long as more than a *deminimis* quantity of the defendant's tobacco products were used by the plaintiff.

84. Ministerial discretion to address requirements of this Part.

The Minister [or other governing authority] shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

85. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing recovery of damages for tobacco-related harm, so long as they do not conflict with the provisions of this Part.

PUBLIC EDUCATION, AWARENESS, AND CESSATION PROGRAMMES

Public Education and Awareness

■ Public education and awareness campaigns have been shown to be effective in informing the public about the health hazards of tobacco use and in reducing consumption. “Information shocks”, such as the report of the Royal College of Physicians in 1962 in the U.K., the 1964 U.S. Surgeon General’s Report about Smoking, a systematic anti-smoking campaign in Greece in 1979, and smoking campaigns and health warnings on packages in Turkey in the 1980s, were shown to reduce tobacco consumption.¹³⁷ These data, along with data from cross-sectional studies in a number of countries showing that more knowledgeable consumers smoke less, suggest that providing health information is an effective tobacco control strategy.¹³⁸ Ongoing mass media campaigns, which can be considered to include counter-advertising and warning labels, also have been successful in providing consumers with tobacco-related information,¹³⁹ and constitute important elements of tobacco control programming.

Cessation assistance may take the form of education, counselling, diagnosis, and treatment programs, but also may take the form of efforts to make nicotine replacement pharmaceuticals more accessible to the tobacco-using population. In some countries, this may require a re-examination and amendment of drug laws to reduce barriers to access to these products.

FCTC OBLIGATIONS

Article 12 obliges Parties to “promote and strengthen public awareness of tobacco control issues, using all available communication tools, as appropriate. Toward that end, each Party shall adopt and implement effective legislative, executive, administrative or other measures to promote:

- a. broad access to effective and comprehensive educational and public awareness programmes on the health risks and addictive characteristics of tobacco consumption and exposure to tobacco smoke;
- b. public awareness about the health risks of tobacco consumption and exposure to tobacco smoke, about the benefits of cessation of tobacco use and tobacco free lifestyles . . . ;
- c. public access, in accordance with national law, to a wide range of information on the tobacco industry as relevant to the objective to this Convention;
- d. effective and appropriate training or sensitization and awareness programmes on tobacco control addressed to persons such as health workers, community workers, social workers, media professionals, educators, decision-makers, administrators and other concerned persons;
- e. awareness and participation of public and private agencies and nongovernmental organizations not affiliated with the tobacco industry in developing and implementing inter-sectorial programmes and strategies for tobacco control; and
- f. public awareness of and access to information regarding adverse, health, economic, and environmental consequences of tobacco production and consumption.

TOBACCO INDUSTRY STRATEGIES

■ In response to growing criticism from governments and civil society, some tobacco companies have initiated “youth prevention programs”, ostensibly aimed at reducing youth smoking. Published studies suggest that certain measures and messages favored by tobacco companies may be counter-productive and actually can enhance the appeal of smoking to teenagers by strengthening the definition of tobacco use as an ‘adult’ activity.^{140, 141}

An analysis of the tobacco industry’s evaluation of its programs and proposed school curricula found no evidence that the effects on youth smoking were measured but instead its public relations impact was measured.¹⁴² As already discussed in Part 9, the tobacco industry has used these youth prevention programs and curricula, as well as youth organization partnerships, to avoid governmental regulation, and to maintain access to youth.¹⁴³ The International Union Against Cancer, the World Heart Federation, the World Medical Association and the International Union Against Tuberculosis and Lung Disease have advised governments not to accept funding from or form partnerships with tobacco companies for youth smoking prevention programs.¹⁴⁴

[Legislative text, cont'd:]
**Part 16: Public Education, Awareness
and Cessation programmes**

86. Public awareness, education, and cessation programs. The Minister [and/or national coordinating body or other governing authority] shall establish and carry out evidence-based programs to inform the public of: the dangers and addictiveness of tobacco use and of exposure to tobacco smoke; the benefits of and strategies for quitting; information on the tobacco industry and on the health, economic, and environmental effects of tobacco production and manufacturing; and such other information as he or she determines to be effective in mitigating against the health effects, social, and environmental costs of tobacco, and for increasing public and consumer awareness of pertinent tobacco-related issues. The Minister [or other governing authority] shall make public awareness, educational, and cessation materials available to provincial and local governments, health care workers and facilities, schools, the media, and such other entities the Minister [or other governing authority] deems appropriate.

- a. Requirement for evidence-based, populations-based educational programs.** In carrying out such programs, the Minister [or other governing authority] shall develop evidence-based educational programs and materials appropriate to the population at large and to priority populations.
- b. Requirement for evidence-based, populations-based cessation programs.** The Minister [or other governing authority] shall establish and carry out evidence-based tobacco use cessation programs, including diagnosis, counselling, and treatment services, and, as appropriate, access to nicotine replacement therapies.

87. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing public education, awareness, or cessation programmes.

CONCLUDING CLAUSES

[Legislative text, cont'd:] Part 17: Concluding Clauses

88. Severability. In the event any provision of this Act is found by a Court of competent jurisdiction to be unconstitutional, illegal, or otherwise invalid, the remaining provisions shall remain in full force and effect.

PROVISIONS FOR TOBACCO CONTROL MEASURES THAT BELONG IN OTHER LAWS

Taxation

EXPLANATION

■ As highlighted in the introduction to the Manual, tobacco tax provisions will not be found in a tobacco control law; rather they will need to be inserted into the appropriate fiscal legal instrument.

Price increases through taxation on tobacco products are among the most effective interventions in reducing demand, especially among youth and persons with low incomes. According to the World Bank, sustaining a high tax rate on tobacco products over the long term reduces teen use, with a lasting impact on consumption. At the same time, tobacco taxes are very efficient at raising government revenues.¹⁴⁶ The World Bank advises that the tax component of a retail pack of cigarettes in countries with comprehensive tobacco control policies is between 2/3 and 4/5 of the total retail cost.¹⁴⁷ The World Health Organization advises governments to raise the real price (over and above inflation) of tobacco products regularly.¹⁴⁸ France has used tax rate increases to raise real cigarette prices by at least 5% each year over the past decade.¹⁴⁹

Tobacco taxes typically consist of an excise tax, a sales tax, and, if imported, an import tax.¹⁵⁰ Excise taxes are taxes on selected goods for sale. Thus, excise taxes are the subject of the discussion in this Manual. The two main types of tobacco excise taxes are:

1. specific (a fixed tax amount per quantity or weight of the goods) or,
2. *ad valorem* (a percentage of the value of the manufacturer's price or sales price).¹⁵¹ A combination of factors usually goes into choosing whether the excise tax will be a specific tax or an *ad valorem* tax, or some combination of the two. These include the rate of inflation, the objectives of the taxation, and the differences in price and quality between imports and domestic products, among others.¹⁵²

A disadvantage of the *ad valorem* tax for tobacco products is that tobacco product manufacturers may lower their prices in response to an *ad valorem* tax increase in order to keep the sales price at a level consumers will continue to pay. Such a pricing strategy not only negates the health benefits that otherwise accrue with a tax increase; it also can result in reduced tax revenues to the government since, as a percentage of price, the *ad valorem* tax amount goes down if the price goes down. An *ad valorem* tax also is more difficult to administer since it is more difficult to measure the products' value than their quantity.¹⁵³

If a specific excise tax is imposed, it is important to provide for automatic adjustment of the tax according to changes in the consumer price index (CPI) or increases in earnings. It also is advisable to remove tobacco from the basket of products used to measure the CPI.¹⁵⁴ In the case of imported/exported tobacco products, the World Bank states that the best international practice is to impose taxes at the point of destination so that countries tax imports rather than exports.¹⁵⁵

Some countries, such as Thailand, Finland and Poland, earmark tobacco excise taxes to designate use of some or all of the revenue for tobacco control or other health measures. This can help provide critical funding for such things as public awareness and education, cessation services and devices, events that no longer are sponsored by tobacco companies, and administration of the law.

There probably already exists in every country a tax law and/or regulations that impose taxes on a variety of goods. Often, the taxable goods are listed in a Schedule. In order to increase the excise taxes on tobacco products, it may just be a matter of amending the schedule, with some introductory language in the text to the effect that excise taxes on tobacco products are being increased. Taxes should be imposed on all forms of smoked and smokeless tobacco products. For example, taxes on roll-your-own tobacco can be set at a rate equivalent to the taxes on cigarettes, bidis, kreteks, or other forms of smoked products. This may mean that the tax on one gram of roll-your-own tobacco would be equal to the tax for one cigarette or other form of smoked product. If expanded tobacco is used, the tax for 0.5 grams might be set at the same rate as on one cigarette or other form of smoked product. Failure to set the tax rate on roll-your-own or other popular forms of tobacco can create a loophole that can result in increased consumption of the products and reduced tax revenues.

Another option for taxation is to have a surtax on the profits of tobacco businesses in addition to excise taxes on tobacco products. This has been done in Canada since 1994, where tobacco manufacturers pay higher corporate income taxes than other industries.

FCTC OBLIGATIONS

Article 6 obliges Parties to determine and establish their taxation policies taking into account their national health objectives concerning tobacco control and adopt measures which may include “implementing tax policies and, where appropriate, price policies . . . aimed at reducing tobacco consumption.” Measures also may include prohibiting or restricting sales to and/or importations by international travellers of tax and duty-free tobacco products.”

TOBACCO INDUSTRY STRATEGIES

Defeating Tax Increases

■ Tobacco companies argue that tax increases will result in revenue losses to the government and increases in smuggling. According to the World Bank, tax increases, to the contrary, result in increased tax revenues to governments, at least in the short and medium terms (with less certain results in the very long term).¹⁵⁶ Better tracking and tracing systems, such as those suggested in the Manual, along with a commitment to vigorous enforcement, are the best responses to smuggling concerns. Avoiding tax increases, the most effect deterrent against tobacco use initiation and consumption, is not an appropriate response.

Another argument is that tobacco excise taxes fall disproportionately on the poor.¹⁵⁷ Jha and Chaloupka respond that given tobacco use is more prevalent among lower income individuals, tax *increases* might be progressive. Since increased taxes would reduce tobacco use more in lower income groups than in higher income groups, the relative tax burden of tobacco taxes on the poor would be reduced. Furthermore, earmarking new revenues from tax increases for programmes targeting the poor could offset the regressive nature of tobacco taxes.¹⁵⁸

[Legislative text, cont'd:] Taxation

Schedule

Goods and products

[Specify each type
of tobacco product]

Specific [or ad valorem] excise tax rate

[specify amount (or %) and currency]
per [specify unit or weight (or value)]
for each type of tobacco product

1. Automatic adjustment to keep pace with inflation and increased earnings. Excise tax amounts shall be adjusted automatically to account for inflation, as measured by the consumer price index, and for increases in earnings. The Minister of Finance [or other appropriate governing authority] shall have authority to remove tobacco products from the consumer price index.

2. Dedication of tobacco product excise taxes to tobacco prevention and control. [Specify %] of excise tax revenues collected on tobacco products shall be marked as dedicated funds for use by the Ministry of Health [or other authority] for tobacco prevention and control, which may include the administration of tobacco control laws.

3. Prohibition on duty-free sales. Full duties and taxes shall be collected on all tobacco products and duty-free and duty-reduced sales of any tobacco product shall be prohibited.

Tabacco Subsidies

EXPLANATION

■ Subsidies to tobacco farmers make tobacco farming more profitable than it otherwise would be. As a result, any form of subsidy may encourage farmers to keep producing tobacco rather than switching to viable alternatives. Thus, the practice of subsidizing tobacco farmers flies in the face of Article 17 of the FCTC, which obliges the Parties to “promote, as appropriate economically viable alternatives for tobacco workers, growers, and, as the case may be, individual sellers.”

[Legislative text, cont'd:]
Tabacco subsidies

1. Elimination and prohibition of tobacco subsidies. Any subsidies to tobacco farmers or manufacturers shall be eliminated effective [\[specify date, possibly allowing reductions in subsidy amounts over time in order to allow for a transition period\]](#), and tobacco subsidies after that date shall be prohibited.

[Note: It also will be necessary to repeal any law providing financial support for the growing, importation or exportation of tobacco.]

Protection of the Environment

EXPLANATION

■ Tobacco growing is responsible for 1.7% of global deforestation. This figure rises dramatically to 4.6% for developing countries and to 12% for countries in Southern Africa. In the wake of deforestation comes loss of bio-diversity, soil erosion, consequent loss of soil fertility and adverse changes to the ecology of rural areas.¹⁵⁹

The unregulated use of huge amounts of pesticides by family farm workers with little or no training and little or no protective clothing also is an important issue with respect to tobacco farming.¹⁶⁰ Pesticides and fertilizers used for tobacco growing deplete nutrients from the soil.¹⁶¹

Other environmental concerns include the fire hazard posed by smoked tobacco products. Litter from cigarette butts and cellophane from wrappers of tobacco products also are of increasing concern. Pollution from leaf threshing plants and noises from cigarette making plants additionally are environmental concerns.

FCTC REQUIREMENTS

Article 18 obliges Parties, in carrying out their obligations under the Convention to “have due regard to the protection of the environment and the health of persons in relation to the environment in respect of tobacco cultivation and manufacture within their respective territories.”

[Legislative text, cont'd:]

Protection of the Environment¹⁶²

1. Ameliorating the adverse effects of the use of chemicals in tobacco farming. The Minister [or other governing authority] shall take steps to ameliorate the adverse effects of chemical use in tobacco farming, including the following:

- a. **Training for farm workers.** The [specify appropriate governing authority] shall take measures to ensure that tobacco companies and other persons providing assistance to tobacco growers provide training to tobacco farm workers on the application of chemicals, including application methods and the use of protective clothing and equipment.
- b. **Investment in alternatives to chemical use.** The [specify appropriate governing authority] shall take measures to ensure that tobacco companies and other persons providing assistance to tobacco growers invest in alternatives to chemical use and to prohibit the use of chemicals that may be harmful to humans or the environment.
- c. **Monitoring the use of chemicals.** The [specify appropriate governing authority] shall monitor the use of chemicals in the tobacco growing process and may, for this purpose, require tobacco companies and other persons providing assistance to tobacco growers to give periodic reports on the use of chemicals in their growing processes.

2. Protection of forests. The [specify appropriate governing authority] shall take measures to require tobacco leaf buying companies to invest in alternative technologies for tobacco curing that are not based on wood fuel. Each such company shall be required to carry out reforestation projects using indigenous species.

3. Environmental impact audits. The [specify appropriate governing authority] shall require tobacco companies and other persons engaged in providing assistance to tobacco growers to undertake annual periodic environmental impact audits of the process of growing, curing and manufacturing of tobacco products, and to provide copies of the same to the Minister. The Minister shall make these audits available as public information.

Content, Design, and Placement of NO SMOKING Signs

NO SMOKING Signs

- 1. Sign size, content and design.** Pursuant to Part 6, owners or occupiers of enclosed public places, places of collective use, employers, as applicable, and operators of public conveyances shall ensure that No Smoking signs are posted and comply substantially with the following:
 - a. Size.** The signs shall be at least [specify size] cm. by [specify size] cm. in dimension.
 - b. Language.** The information displayed on the signs shall be printed in [specify language(s) required].
 - c. Text of message.** The text of the signs shall read as follows: [specify text and/or symbols, pictures, etc. and provide a telephone number or other contact information to report violations]
 - d. Font size.** Font shall be [specify size] point type for the text specified in Section 1(c).
 - e. Message placement.** The text required in Section 1(c) shall be placed at the [specify top, bottom, or middle] of the sign and shall cover [specify proportion] % of the sign. No other text or visual information shall appear on the signs, unless otherwise required or authorized in implementing regulations.
 - f. Placement of signs.** Signs shall be posted [specify where throughout the premises or conveyance].
- 2. Other requirements.** [Specify other requirements, if any].
- 3. Ministerial authority.** The Minister [or other governing authority] shall have the authority to enhance any requirement related to signage.

Schedule 1: Applicable Fines

Violation	Fine amount (per day for continuing violations)		
	1 st violation	2 nd violation	≥ 3 rd violation
Part 6: Protection from Second Hand Smoke			
Against:			
Owner/occupier/employer/ conveyance operator	[specify range]	[specify range]	[specify range]
Smoker	[specify range]	[specify range]	[specify range]
Part 7: Advertising, Sponsorship, and Promotion			
Against:			
Tobacco product manufacturer/seller	[specify range]	[specify range]	[specify range]
Any person participating in ad., sponsorship, or promotion	[specify range]	[specify range]	[specify range]
Part 8: Tobacco Product Labelling and Packaging			
Against:			
Tobacco product manufacturer	[specify range]	[specify range]	[specify range]
Commercial seller/purchaser	[specify range]	[specify range]	[specify range]
Part 9: Tobacco Product Sales			
Against:			
Commercial seller/distributor	[specify range]	[specify range]	[specify range]
Part 10: Product Requirements			
Against:			
Tobacco product manufacturer	[specify range]	[specify range]	[specify range]
Part 11: Reporting			
Against:			
Tobacco product manufacturer/importer	[specify range]	[specify range]	[specify range]

Violation	Fine amount (per day for continuing violations)		
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Part 12: Anti-Smuggling Measures, including provisions of Part 8 related to labelling for tracking tobacco products

Against:

Tobacco product manufacturer*	[specify range]	[specify range]	[specify range]
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*The fine shall be in the amount specified above or an amount equal to the amount [specify for e.g., 10 x the amount] the retail price including all taxes for the tobacco products, whichever is greater.

Any other person participating in the smuggling activity **

[specify range]	[specify range]	[specify range]	[specify range]
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** The fine shall be in the amount specified above or an amount equal to the amount [specify for e.g., 10 x the amount] the retail price including all taxes for the tobacco products, whichever is greater.

Part 13: Inspections and Investigations

Against:

Any person hindering or obstructing, supplying false information, etc.

[specify range]	[specify range]	[specify range]	[specify range]
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An authorized officer or other government official for abusing his or her authority

[specify range]	[specify range]	[specify range]	[specify range]
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Draft Provisions for the Establishment of a Tobacco Control Board in Botswana

(Excerpt from the Draft Tobacco Control Bill, Section 4 (2003))

ESTABLISHMENT OF THE TOBACCO CONTROL BOARD

- 4.1** There is established a body to be known as the Tobacco Control Board.
- 4.2** The Board shall be a body corporate with perpetual succession and an official seal and may, for the discharge of its functions under this Act-
- a.** acquire, hold and dispose of moveable and immoveable property;
 - b.** sue and be sued in its corporate name; and
 - c.** do all acts and things which a body corporate may lawfully do.
- 5. Official Seal of the Board**
- 5.1** The official seal of the Board shall be in a form determined by the Board.
- 5.2** The official seal shall, when affixed to any document, be authenticated by the signatures of the Executive Director and one other member of the Board.
- 5.3** In the absence of the Executive Director, the person performing the functions of the Executive Director shall sign.
- 5.4** An instrument or contract which if executed or entered into by a person other than a body corporate would not require to be under seal may be executed or entered into on behalf of the Board by the Executive Director, or by any member of the Board or any other person if that member of the Board or other person has been duly authorised by resolution of the Board to execute the instrument or enter into the contract as the case may be.
- 5.5** Every document purporting to be an instrument or contract executed or issued by or on behalf of the Board in accordance with this section shall be deemed to be so executed or issued until the contrary is proved.

6. Composition of Board

- 6.1** The Tobacco Control Board shall comprise five members, including a Chairperson and four other persons and shall be appointed by the President with the approval of Parliament.
- 6.2** The members of the Board shall be persons of eminent standing and good repute in society and with experience or qualifications in public health, law or social sciences.
- 6.3** The members of the Board shall hold office on a part-time basis for a term of three years and are eligible for re-appointment for one further term.
- 6.4** The members of the Board shall hold office on terms and conditions specified in their instruments of appointment.

7. Disqualification from appointment as member

A person shall not be appointed to the Board who-

- a.** is engaged in the tobacco industry as an owner, shareholder, partner, grower, importer, distributor, retailer or otherwise, whether directly or indirectly;
- b.** has a financial or proprietary interest in an organisation engaged in the manufacture, importation or distribution of tobacco products anywhere; or
- c.** is an undischarged bankrupt or has made any assignment or arrangement with his or her creditors.

8. Vacancies

- 8.1** A member of the Board may be removed from office at any time if he or she-
- a.** is continuously and persistently unable to discharge the functions of his or her office;
 - b.** engages in misbehaviour or abuse of office;
 - c.** is subsequently disqualified from membership in accordance with section 7; or
 - d.** fails to disclose to the Board any interest in a contract or proposed contract or any other matter before the Board.
- 8.2** The Minister shall, on the recommendation of the Board, determine that a vacancy exists under subsection (1).
- 8.3** A member of the Board may, at any time, resign office upon written notification to the Minister.
- 8.4** Upon the resignation, falling vacant of office, or removal of a member of the Board, the President shall, with the approval of Parliament appoint another person qualified in terms of section 4, to fill the vacancy and to hold office until expiry of the term of the person so replaced.

9. Functions of the Board

The functions of the Board are-

- a.** to determine, in writing, the procedures governing its operations;
- b.** to implement the provisions of this Act and exercise the powers conferred upon it by this Act;
- c.** to monitor health trends resulting from tobacco consumption and exposure;
- d.** to monitor and review the effectiveness of the requirements contained in this Act and regulations, and recommend amendments as it deems appropriate;
- e.** to develop and implement a national programme for tobacco control, including public awareness campaigns and cessation activities;
- f.** to co-ordinate activities on tobacco control of various government departments and voluntary agencies;
- g.** to make recommendations to the Minister responsible for finance with respect to the taxation of tobacco products in order to keep the prices of tobacco products ahead of the rate of inflation and increases in earnings; and
- h.** any other function conferred on it by the Minister

10. Meetings of the Board

The Second Schedule has effect with respect to meetings of the Board and other matters provided in it.

11. Independence of the Board

Except as provided under this Act or any other law, the Board shall exercise its functions independent of any person or body.

SECRETARIAT AND STAFF OF THE BOARD

12. Secretariat and staff of the Board

The Board shall have a Secretariat consisting of an Executive Secretary and other staff.

13. Executive Secretary

- 13.1** There shall be a full time Executive Secretary who shall be appointed by the Board on terms and conditions specified in his or her instrument of appointment.
- 13.2** The Executive Secretary shall be a person with considerable knowledge and experience in public health, law or administration.
- 13.3** The Executive Secretary shall hold office for a period of five years and is eligible for re-appointment for one more term.
- 13.4** The Executive Secretary shall cease to hold office if-
- a.** he or she resigns;
 - b.** he or she is removed from office by the Board for-
 - i.** gross misconduct;
 - ii.** physical or mental inability to discharge the functions of his or her office;
 - iii.** mismanagement of the affairs of the Board; or
 - iv.** incompetence.

14. Functions of the Executive Secretary

- 14.1** The Executive Secretary is responsible for the day-to-day operations and administration of the Board.
- 14.2** Subject to this Act and to the general supervision and control of the Board, the Executive Secretary shall-
- a.** be the Chief Executive of the Board;
 - b.** implement the policies and programs of the Board;
 - c.** manage the funds and property of the Board;
 - d.** organise, supervise and generally control the staff of the Secretariat;
 - i.** keep the Board informed on the activities of the Secretariat;
 - ii.** keep a record of all the transactions of the Board; and
 - iii.** perform any other duty that may be assigned by the Board.
- 14.3** The Executive Secretary shall, in the performance of his or her duties, be answerable to the Board.

15. Other officers and staff of the Board

- 15.1** The Board may appoint other officers and employees as may be necessary for the effective performance of its functions.
- 15.2** The employees appointed under this section shall hold office on such terms and conditions as may be specified in their instruments of appointment.
- 15.3** The Board may establish pension or superannuation schemes and such other financial schemes as it may determine for the benefit of its officers and employees.

16. Protection of members and employees

A member of the Board or an employee of the Board, or a person acting on the directions of such a person is not personally liable for any act or omission done or omitted to be done, in good faith, in the exercise of the functions of the Board.

FINANCIAL AND RELATED PROVISIONS

17. Funds of the Board

The funds of the Board shall consist of-

- a. money appropriated by Parliament from time to time, for enabling the Board to perform its functions;
- b. licence fees from importers, distributors, retailers and manufacturers charged under section 24;
- c. money borrowed by the Board; and
- d. grants, gifts or donations from Government and other sources, acceptable to the Minister and the Minister responsible for finance.

18. Application of funds

The funds of the Board may be applied-

- a. in the payment or discharge of its expenses and obligations, including international obligations, or liabilities incurred in connection with the performance of its functions or exercise of its powers under this Act; and
- b. in the payment of any remuneration or allowances payable under this Act.

19. Power to open and operate bank accounts

19.1 The Board shall open and maintain such bank accounts as are necessary for the performance of its functions.

19.2 The Board shall ensure that all money received by or on behalf of the Board is banked as soon as practicable after being received.

19.3 The Board shall ensure that no money is withdrawn from, or paid out of any of its bank accounts without the authority of the Board.

20. Investment of surplus funds

Any funds of the Board not immediately required for any purpose under this Act may be invested in a manner, which the Board may, after consultation with the Minister and the Minister responsible for finance, determine.

21. Estimates

21.1 The Executive Secretary shall, within three months before the commencement of each financial year, cause to be prepared and submitted to the Board for its approval, estimates of the expenditure of the Board for the next financial year.

21.2 The Board shall, within three months, after the submission of the estimates by the Executive Secretary, cause to be submitted to the Minister for his or her approval, the estimates of income and expenditure as approved by the Board under subsection (1).

22. Financial year of the Board

The financial year of the Board is the period of twelve months ending on the 31st March.

23. Accounts

23.1 The Executive Secretary shall cause to be kept, proper books of accounts and records of the transactions of the Board.

23.2 Subject to any direction given by the Minister, the Board shall cause to be prepared and submitted to the Minister responsible for finance in respect of each financial year, and not later than three months after the end of the financial year, a statement of accounts, which shall include-

- a.** a balance sheet, a statement of income and expenditure and a statement of surplus or deficit; and
- b.** any other information in respect of the financial affairs of the Board as the Minister responsible for finance may, in writing, require.

24. Audit

24.1 The Auditor-General or an auditor authorised by the Auditor-General in that behalf shall, in each financial year, audit the accounts of the Board.

24.2 The Board shall ensure that within four months after the end of each financial year, a statement of accounts described in section 23(2) is submitted to the Auditor-General or an auditor authorised by the Auditor-General for auditing.

24.3 The Auditor-General and any auditor authorised by the Auditor-General shall have access to all books, records, reports and other documents relating to the accounts of the Board, and is entitled to any information and explanation required in relation to those documents.

24.4 The Auditor-General and any auditor authorised by the Auditor-General shall, within four months after receipt of the statement of accounts under subsection (2), deliver to the Board a copy of the audited accounts together with a report on the accounts.

Template for Content, Design, and Placement of Messages and Constituents and Additives Disclosures on/in Tobacco Product Packages

1. Messages on tobacco product packages. The health messages prescribed in subsection (b) shall appear on all individual tobacco product packages and on all cartons containing individual packages.

[Note: the following can be added: Additionally messages shall appear on individual sticks of smoked products.]

a. Simultaneous display of messages. Every manufacturer and importer shall, for each brand of a tobacco product that the manufacturer packages in a year, display each health message with the accompanying picture specified in subsection (b) randomly in each 12-month period in as equal a number of times as possible on each brand of the product. Each message also shall be randomly distributed in all parts of [\[specify name of country\]](#) in which the product is sold. The phrase “equal number of times as possible” means deviations of [\[specify percent\]](#) or less in a 12-month period. “Random distribution” means that there is nothing in the production or distribution process of a tobacco product that would prevent the health messages on packages from being distributed evenly in all parts of the country where they are sold.

b. Content of messages. The messages shall be as follows:

I. for cigarettes:

a.i [\[specify content of message\]](#).

a.ii [\[show accompanying picture\]](#).

b.i [\[specify content of message\]](#).

b.ii [\[show accompanying picture\]](#).

c.i [\[specify content of message\]](#).

c.ii [\[show accompanying picture\]](#).

d.i [\[specify content of message\]](#).

d.ii [\[show accompanying picture\]](#).

[etc.]

- II. for [specify other forms of tobacco products commonly sold]:
- a.i [specify content of message].
 - a.ii [show accompanying picture].

 - b.i [specify content of message].
 - b.ii [show accompanying picture].

 - c.i [specify content of message].
 - c.ii [show accompanying picture].

 - d.i [specify content of message].
 - d.ii [show accompanying picture].
- [etc.]
- c. **Language of messages.** The messages shall appear in [specify required language(s)]: in [specify language] on one of the required package and carton panels as described in subsection (e) and in [specify language] on the other package and carton panel as described in subsection (e) [if more than one principal language is spoken]. The health messages on any exported tobacco product shall be in the official languages of the country of final destination, unless otherwise specified by law in the country of final destination.
- d. **Font type, size and color for messages.** The font used for the messages shall be as follows:
- I. font shall be: [specify type].
 - II. font size shall be: [specify size] point type for packages greater than [specify size] in height or width, whichever is larger, and [specify size] point type for packages less than [specify size] height or width. Font size shall be [specify size] point type for cartons greater than [specify size] in height or width, whichever is larger, and [specify size] point type for cartons less than [specify size] in height or width.
 - III. font color shall be black.
 - IV. the text of the message shall appear against a white background.
 - V. [if desired, specify how message should be placed within a border or other instructions for ensuring the text of the message is distinct from other text on the package].

- e. Placement of message.** The text and picture of the message shall be placed on the 2 largest package and carton panels visible under normal or customary conditions of sale or use and shall cover [specify proportion, (preferably 50% or more, but at least 30%, to be in compliance with FCTC)]% of each panel, including the sides of any lid or cover, as applicable; shall be positioned parallel to the top edge of the package and carton, towards the top part of the package/carton as much as possible without being severed when the package/carton is opened; and shall be positioned in the same direction as other text on the package/carton. Provided, however, that where packages are of a design such that they do not have 2 panels of equal size, the health message shall be placed [specify placement (e.g., on the entire surface of the largest panel)].
- f. Placement of pictures.** Pictures shall occupy at least [x]% of the total message area. [Specify where pictures must be placed].

2. Constituent and additives disclosures on packages. Each tobacco product package and carton shall disclose simultaneously, as prescribed in Section 1 for messages, the following constituents/their emissions and additives, as applicable, as prescribed below:

a. Content of constituent and additives disclosures.

- I.** Unless otherwise specified in implementing regulations, the constituents/emissions and additives listed below shall be disclosed using the full name of the constituent and additive and not its chemical formula or any other abbreviated name.
- II.** The disclosed substances shall appear under the heading, “Some of the Carcinogenic/Toxic Chemicals Contained in This Product Include:” [or specify other heading] immediately above or preceding the list of constituents, which shall be disclosed in groups, as specified below, simultaneously on packages, as described with respect to messages in Section 1.
- III.** The disclosed substances shall appear without reference to the levels of the constituents/emissions and additives contained in the product, unless otherwise specified in implementing regulations; and
- IV.** The disclosed substances shall be followed by the statement, [specify text, e.g., something to the effect that there are no safe levels of consumption of, or exposure to, these substances].
- V.** For cigarettes, the disclosures shall be:
 - a.** group 1: [Specify several constituents/emissions and additives of concern];
 - b.** group 2: [Specify several constituents/emissions and additives of concern];
 - c.** group 3: [Specify several constituents/emissions and additives of concern];
[etc.]

- VI. for [specify other smoked products]:
 - a. group 1: [Specify several constituents/emissions and additives of concern];
 - b. group 2: [Specify several constituents/emissions and additives of concern];
 - c. group 3: [Specify several constituents/emissions and additives of concern];
[etc.]
- VII. for [specify smokeless tobacco products]:
 - a. group 1: [Specify several constituents/emissions and additives of concern];
 - b. group 2: [Specify several constituents/emissions and additives of concern];
 - c. group 3: [Specify several constituents/emissions and additives of concern];
[etc.]

b. Language of constituent and additives disclosures.

The information required by subsection (a) shall be displayed in [specify languages]. For exported tobacco products, the information shall be displayed in the official languages of the country of destination unless otherwise specified by law in the country of destination.

- c. Placement of constituents and additives information on packages and cartons.** The information required by subsection (a) shall be placed on any side of the package, other than a side displaying a prescribed message and other than on a bottom side, and shall be placed on all sides of a carton. Placement shall be in such a manner that it occupies no less than [specify]% of the entire side, including the sides of any lid or cover, as applicable.

d. Font style, size, and colors for constituent and additives disclosures. The font used for the constituents and additives disclosures shall be as follows:

- I. for the heading prescribed by Section 2(a)(ii) and list of constituents and additives prescribed by Section 2(a)(v) and (vi):
 - a. font shall be: [specify type].
 - b. font size shall be: [specify size] point type for packages greater than [specify size] cm. in height or width, whichever is larger, and [specify size] point type for packages less than [specify] cm. in height or width. Font size shall be [specify size] point type for cartons greater than [specify] cm. in height or width, whichever is larger, and [specify size] cm. for cartons less than [specify] cm. in height or width.
 - c. font color shall be black.

- II. for the statement required by Section 2(a)(iv):
- a. font shall be: [specify type].
 - b. font size shall be: [specify size] point type for package sides greater than [specify size] cm. in height or width, whichever is larger, and [specify size] point type for packages sides less than [specify size] cm. in height or width. Font size shall be [specify size] point type for carton sides greater than [specify size] cm. in height or width, whichever is larger, and [specify size] point type for carton sides less than [specify size] cm. in height or width.
 - c. font color shall be black.
 - d. Requirement for contrasting background. The text of the heading, list of constituents and additives, and statement required by Section 2(a)(iv) shall appear against a white [or specify color in detail or precise degree of contrast other color in relation to the text] background.
 - e. [if desired, specify how message should be placed within a border or other instructions for ensuring the text of the constituents disclosures is distinct from other text on the package].

3. Records demonstrating compliance. Tobacco product manufacturers and importers shall keep records demonstrating their compliance with the requirements for prescribed messages and constituent and additives disclosures on product packages.

[Note: Canada requires that tobacco product packages contain inserts providing information that enhances package health messages. Inserts may be a promising way to provide consumers with additional information, but their effectiveness has not been fully evaluated].

Canada's Tobacco Reporting Regulations

Available at Canada's Department of Justice website:
<http://laws.justice.gc.ca/en/T-11.5/SOR-2000-273/182944.html>

Users are advised that this is not an official version of the regulations and that provision of these regulations have not been made in affiliation with or with the endorsement of the Department of Justice.

Tobacco Reporting Regulations

SOR/2000-273
Registration 26 June, 2000

TOBACCO ACT Tobacco Reporting Regulations

P.C. 2000-1040 21 June, 2000

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

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

^a S.C. 1997, c. 13

TOBACCO REPORTING REGULATIONS

INTERPRETATION

Definitions

1. The definitions in this section apply in these Regulations

“accredited representative” “représentant accrédité”

“accredited representative” means a person who is entitled to the tax exemptions specified in Article 34 of the Convention set out in Schedule 1 to the *Foreign Missions and International Organizations Act* or Article 49 of the Convention set out in Schedule II to that Act. (*représentant accrédité*)

“Act” « *Loi* »

“Act” means the Tobacco Act. (*Loi*)

“brand” « *marque* »

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

“cigar” « *cigare* »

“cigar” includes

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

“cigarette” « *cigarette* »

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

“constituent” « *constituant* »

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

“consumer tobacco product” « *produit du tabac pour consommation* »

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

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

“designated tobacco product” « *produit du tabac désigné* »

“designated tobacco product” means any of the following types of consumer tobacco product:

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

“duty free shop” « *boutique hors taxes* »

“duty free shop” has the same meaning as in subsection (2.1) of the *Customs Act*. (*boutique hors taxes*)

“emission” « *émission* »

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

“equivalent unit” « *unité équivalente* »

“equivalent unit” means

- a. in respect of cigarette tobacco, a cigarette prepared in accordance with the method set out in the Canadian General Standards Board standard CAN/CGSB-176.1-92, entitled *Preparation of Cigarettes from Cigarette Tobacco for Testing*, dated December 1992; and
- b. in respect of leaf tobacco, a cigarette prepared in accordance with Official Method T-401, entitled *Preparation of Cigarettes from Leaf Tobacco for Testing*, made by the Department of Health, dated December 31, 1999. (*unité équivalente*)

“identical products” « *produits identiques* »

“identical products” means tobacco products that

- a. contain identical ingredients;
 - b. are manufactured in an identical manner; and
 - c. perform in an identical manner under the same conditions.
- (*produits identiques*)

“ingredient” « *ingrédient* »

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

“kit” « *trousse* »

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

“mainstream smoke” « *fumée principale* »

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

“manufacturer” « *fabricant* »

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

“sidestream smoke” « *fumée latérale* »

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

“smokeless tobacco” « *tabac sans fumée* »

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

“type of package” « *type d’emballage* »

“type of package” includes each size of the following types of packages:

- a. in respect of bidis, cigarettes, kreteks and tobacco sticks,
 - i. a slide and shell package,
 - ii. a flip-top package, and
 - iii. a soft package;
- b. in respect of cigarette tobacco and pipe tobacco,
 - i. a pouch,
 - ii. a can, and
 - iii. a tub;
- c. in respect of cigars,
 - i. a tube,
 - ii. a flip-top box,
 - iii. a soft package, and
 - iv. a bundle; and
- d. in respect of smokeless tobacco, a plastic or metal container.
(*type d’emballage*)

“type of tobacco” « *type de tabac* »

“type of tobacco” includes the following types of tobacco commonly known as

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

“unit” « *unité* »

“unit” means

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

REPORTS

Content and form

- 2.1** Every report made under these Regulations must be submitted to the Minister in writing or in an electronic format and must set out, in addition to the information required by these Regulations, the following information:
- a. the name, street address and telephone number of
 - i. the manufacturer on whose behalf the report is made, and
 - ii. the person who makes the report;
 - b. the street address of the manufacturer's principal place of business in Canada;
 - c. the street address of the place of business where the tobacco product that is the subject of the report was manufactured;
 - d. the date of the report;
 - e. the period covered by the report;
 - f. in respect of any tobacco product that is to be reported, its type and brand; and
 - g. the section of these Regulations under which the report is made.

Information gathering and analysis

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

ATTESTATION

By person reporting

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

LABORATORIES

Accreditation

- 4.1** Any laboratory that performs an analysis for the purposes of these Regulations must be accredited under the International Organization for Standardization standard ISO/IEC Guide 25: 1990, entitled *General requirements for the competence of calibration and testing laboratories*.

Exception

- 2** During the four-year period following the coming into force of these Regulations, any laboratory may perform an analysis for the purposes of these Regulations.

ALTERNATIVE METHODS

Conditions of use

- 5.** Despite sections 12 and 14, a laboratory may use a method that is not provided for in these Regulations (in this section referred to as an “alternative method”) to collect information if
- a. the use of the alternative method results in information that is at least as accurate and precise as the information that would be produced if the method provided were used; and
 - b. the laboratory submits a description of the alternative method to the Minister together with data that demonstrate that the requirements of paragraph (a) have been met.

PART 1
GENERAL INFORMATION

Special Requests

Urgent Requests

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

Requests for additional information

- 7.** Where additional information is required for any of the purposes set out in section 4 of the Act, the Minister may, in writing and with reasons, request that a manufacturer provide any additional information that is related to information provided in a report made under these Regulations, including
- a. any report made by a laboratory that is the basis for a report made under these Regulations; and
 - b. any information relating to a research activity reported under Part 4, including a copy of any document for which a cover page was included.

Time to provide additional information

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

Permanent Reports

Content

- 9.1** Every manufacturer shall report the following information:
- a. their name, street address and telephone number;
 - b. the street address of each establishment where they manufacture a tobacco product;
 - c. a list of every consumer tobacco product that they manufacture, by brand and by each type of package and carton of the brand, and, in the case of a kit, a list of every tobacco product contained in it; and
 - d. a list of consumer tobacco products that they manufacture that are identical products sold under different brands, including an indication of which of the products are identical.

Samples of packages, cartons, and kits

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

Initial report

3. Every manufacturer of a consumer tobacco product shall, within 90 days after the coming into force of these Regulations, provide the following to the Minister:
 - a. the information described in subsection (1); and
 - b. the samples or facsimiles described in subsection (2).

Notice of changes

4. If the information reported under subsection (1), or anything provided under subsection (2), is changed by the manufacturer, the manufacturer shall, within 30 days after the change is made,
 - a. advise the Minister of the change in the information; and
 - b. provide the Minister with a copy of the changed package, carton or kit.

Manufacturing Procedures

Requirement to provide

- 10.1 Every manufacturer shall provide to the Minister, by brand, their manufacturing procedures for each of their consumer tobacco products.

Time to provide procedures

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

Change in information

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

PART 2 REPORTS

Ingredients

Quarterly report

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

Inventory

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

Content of report

- 3.** The report shall set out the following information:
- a. in the case of a bidi, cigarette, cigar, tobacco stick, or kretek, its weight in milligrams per unit;
 - b. in respect of each ingredient in a consumer tobacco product, a paper, a tube or a filter,
 - i. its common, chemical and commercial names,
 - ii. if applicable, its biological origin, in standard Latin nomenclature,
 - iii. if applicable, the registry number assigned to it in accordance with the Chemical Abstracts Service of the American Chemical Society,
 - iv. the mean, standard deviation and 95% confidence limit of the amount of it in milligrams
 - a. per gram of the consumer tobacco product, paper, tube or filter, and
 - b. in the case of a bidi, cigarette, cigar, tobacco stick or kretek, per unit of the product,
 - v. the name and street address of its supplier,
 - vi. its country of origin,
 - vii. in the case of tobacco, its type,
 - viii. in the case of a paper, its type and specifications, and
 - ix. in the case of a filter, a description of it, its specifications and pressure drop and, with respect to nicotine for those brands analyzed pursuant to subsection 14(13), its efficiency, determined in accordance with Official Method T-106, entitled *Determination of Filter Efficiency in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999; and

- c. in respect of each component of an ingredient in a consumer tobacco product, a paper, a tube or a filter
 - i. its commercial, common and chemical names,
 - ii. if applicable, its biological origin, in standard Latin nomenclature,
 - iii. if applicable, the registry number assigned to it in accordance with the Chemical Abstracts Service of the American Chemical Society,
 - iv. the mean, standard deviation and 95% confidence limit of the amount of it in milligrams
 - a. per gram of the ingredient and of the consumer tobacco product, paper, tube or filter, and
 - b. in the case of a bidi, cigarette, cigar, tobacco stick or kretek, per unit of the tobacco product,
 - v. the name and street address of its supplier, and
 - vi. its country of origin.

When report to be submitted

- 4.** The report shall be submitted
 - a. for the period beginning on January 1 and ending on March 31 of a year, on or before April 30 of that year;
 - b. for the period beginning on April 1 and ending on June 30 of a year, on or before July 31 of that year;
 - c. for the period beginning on July 1 and ending on September 30 of a year, on or before October 31 of that year; and
 - d. for the period beginning on October 1 and ending on December 31 of a year, on or before January 31 of the following year.

Exception - identical products

- 5.** The report is not required for a consumer tobacco product if
 - a. the product is one of identical products of the manufacturer sold under different brands; and
 - b. a report under this section is submitted in respect of another of those identical products.

Constituents

Annual report

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

Initial report

- 2.** The initial report, relating to the portion of the year remaining of the year in which these Regulations come into force, shall be submitted within the later of
- a. January 31 of the year following the year these Regulations come into force, or
 - b. 180 days after these Regulations come into force.

Method of collecting information

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

Sampling

- 4.** A sample used for the purpose of determining the amount of a constituent must be
- a. selected in accordance with the procedures described in items A and B of Table 1 of the International Organization for Standardization standard ISO 8243, second edition, dated 1991-10-15 and entitled *Cigarettes - Sampling*; and
 - b. prepared in accordance with Official Method T-402, entitled *Preparation of Cigarettes, Cigarette Tobacco, Cigars, Kreteks, Bidis, Packaged Leaf Tobacco, Pipe Tobacco and Smokeless Tobacco for Testing*, made by the Department of Health, dated December 31, 1999.

Replicates

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

Adjustment for moisture

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

Content of report

- 7.** The report shall set out the following information:
- a. in the case of bidis, cigarettes, cigars, tobacco sticks and kreteks, the weight in milligrams per unit;
 - b. the name of each constituent in the consumer tobacco product;
 - c. the mean, standard deviation and 95% confidence limit of the amount of each constituent in milligrams, micrograms, or nanograms
 - i. per gram of the consumer tobacco product, and
 - ii. in the case of bidis, cigarettes, cigars, tobacco sticks and kreteks, per unit; and
 - d. the pH of the consumer tobacco product, determined in accordance with Official Method T-310, entitled *Determination of Whole Tobacco pH*, made by the Department of Health, dated December 31, 1999.

Exception - identical products

- 8.** The report is not required for a consumer tobacco product if
- a. the product is one of identical products of the manufacturer sold under different brands; and
 - b. a report under this section is submitted in respect of another of those identical products.

Exception - sales volume

- 9.** The report is not required for the following tobacco products where the total sales of the manufacturer for the year preceding to the year covered by the report are less than
- a. in the case of cigars, 1,000,000 units per brand; and
 - b. in the case of pipe tobacco, 8000 kg per brand.

Exception - short report

- 10.** A manufacturer may, instead of submitting the report described in subsection (1) or (2) for a consumer tobacco product, submit a report on the amount of nicotine, nitrosamines, nickel, lead, cadmium, chromium, arsenic, selenium and mercury in the product if
- a. in respect of cigarettes, cigarette tobacco and tobacco sticks, including any cigarettes, cigarette tobacco or tobacco sticks sold in kits, the manufacturer's total sales for that product in the year preceding the period covered by the report is less than 1% of the total sales of that product in that year in Canada; and
 - b. in respect of leaf tobacco, bidis and kreteks, the manufacturer's total sales for that product in the year preceding the period covered by the report is less than 5% of the total sales of that product in that year in Canada.

Exception - eugenol

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

Sales

Report

- 13.1** Every manufacturer of a consumer tobacco product shall report the information described in subsection (3) in respect of the following categories, by brand and by each type of package of the brand:
- a. in Canada;
 - b. in each province;
 - c. in each duty free trade customer and operator;
 - d. as ships' stores in accordance with the Ships' Stores Regulations;
 - e. to accredited representatives; and
 - f. for export, by country of destination.

Duty free shop importers

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

Manner of reporting

- 3.** The information in respect of the sales of a consumer tobacco product for each category described in subsection (1) and (2) shall be reported as follows:
- a. in respect of bidis, cigarettes, cigars, tobacco sticks and kreteks,
 - i. by unit, and
 - ii. by number of packages sold, specifying the type of package, the number of units in a package, and the dollar value of the total sales of each type of package;
 - b. in respect of kits
 - i. by number sold,
 - ii. by weight, in kilograms, of tobacco contained in each kit,
 - iii. if applicable, by the number of papers, tubes or filters included in each kit, and
 - iv. by the number of units intended to be made;
 - c. in respect of cigarette tobacco, by weight in kilograms of tobacco in each specified type of package; and
 - d. in respect of any other consumer tobacco product
 - i. by weight in kilograms of the consumer tobacco product, and
 - ii. by number of packages sold, specifying the type of package, the weight of the tobacco product in the package and the dollar value of the total sales of each type of package.

Time to report

4. The report shall be submitted
 - a. for cigarettes, cigarette tobacco or tobacco sticks, on or before the 15th day of each month, for the previous month; and
 - b. for every other consumer tobacco product,
 - i. for the period beginning on January 1 and ending on March 31 of a year, on or before April 30 of that year,
 - ii. for the period beginning on April 1 and ending on June 30 of a year, on or before July 31 of that year,
 - iii. for the period beginning on July 1 and ending on September 30 of a year, on or before October 31 of that year, and
 - iv. for the period beginning on October 1 and ending on December 31 of a year, on or before January 31 of the following year.

PART 3 EMISSIONS FROM DESIGNATED TOBACCO PRODUCTS

Report

- 14.1** Every manufacturer of a designated tobacco product shall report the information described in subsections (2) and (7), by brand and type of designated tobacco product, in respect of
- a. the emissions contained in the mainstream smoke produced from the combustion of the designated tobacco product; and
 - b. the emissions contained in the sidestream smoke produced from the combustion of the designated tobacco product.

Content of report

2. The report shall, in respect of the emissions contained in the mainstream and sidestream smoke produced from a cigarette, tobacco stick, kretek or equivalent unit of a designated tobacco product that is placed in a smoking machine and combusted, identify the emission and set out the mean, standard deviation and 95% confidence limit
 - a. of the number of puffs;
 - b. of each emission, expressed in milligrams, micrograms or nanograms per unit or equivalent unit; and
 - c. of the weight of tobacco contained in the designated tobacco product expressed in milligrams per unit or equivalent unit.

Sampling

3. A sample to be used for the purpose of determining the amount of an emission must be
 - a. selected in accordance with the procedures described in items A and B of Table 1 of the International Organization for Standardization standard ISO 8243, second edition, dated 1991-10-15 and entitled *Cigarettes – Sampling*; and
 - b. conditioned and smoked in an environment as described in the International Organization for Standardization standard ISO 3402, third edition, dated 1991-07-01 and entitled *Tobacco and Tobacco Products – Atmosphere for Conditioning and Testing*.

Replicates

4. The mean, standard deviation and 95% confidence limit of the amount of each emission must be based
 - a. in the case of tar, nicotine and carbon monoxide, on 20 replicates of a sample; and
 - b. in every other case, on 7 replicates of a sample.

Method of collecting data

5. Every manufacturer shall use the following methods to collect data for an emission:
 - a. in the case of mainstream smoke, the applicable official method set out in column 2 of Schedule 2; and
 - b. in the case of sidestream smoke, the applicable official method set out in column 2 of Schedule 3.

Conditions for the collection of data

6. For the purpose of subsection (2), both of the following conditions are to be used to determine the amount of an emission:
 - a. the conditions set out in the International Organization for Standardization standard ISO 3308, Third Edition 1991-10-15, entitled *Routine analytical cigarette-smoking machine – Definitions and standard conditions*, 1991 (E); and
 - b. the conditions referred to in paragraph (a), but modified in the following manner:
 - i. puff volume must be increased from 35 mL to 55 mL,
 - ii. puff interval must be decreased from 60 s to 30 s, and
 - iii. all ventilation holes must be blocked by placing over them a strip of Mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape, and the tape must be cut so that it covers the circumference and is tightly secured from the end of the filter to the tipping overwrap seam, or by another method of equivalent efficiency.

pH levels

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

When report to be submitted

- 8.** The report shall be submitted
- a. in the case of a report in respect of the emissions of tar, nicotine and carbon monoxide in the mainstream and sidestream smoke produced from the combustion of a cigarette or an equivalent unit of cigarette tobacco
 - i. in relation to the conditions set out in paragraph (6)(b), for the period beginning on January 1 and ending on June 30 of a year, on or before July 31 of that year, and
 - ii. in relation to the conditions set out in paragraph (6)(a), for the period beginning on July 1 and ending on December 31 of a year, on or before January 31 of the following year; and
 - b. in the case of the report in respect of all other emissions in the mainstream and sidestream smoke or the short report referred to in subsection (9), annually on or before January 31 of the year following the year covered by the report.

Exception - short report

- 9.** A manufacturer may, instead of submitting the report described in subsection (1) for a designated tobacco product, submit, every two years, a report on the amount of tar, nicotine, carbon monoxide, benzene, hydrogen cyanide and formaldehyde emissions contained in the smoke produced from the designated tobacco product if
- a. in respect of cigarettes, cigarette tobacco and tobacco sticks, including any cigarettes, cigarette tobacco or tobacco sticks sold in kits, the manufacturer's total sales for that product in the year preceding the period covered by the report is less than 1% of the total sales of that product in that year in Canada; and
 - b. in respect of leaf tobacco and kreteks, the manufacturer's total sales of that product in the year preceding the period covered by the report is less than 5% of the total sales of that product in that year in Canada.

Exception

- 10.** The report, other than a report in respect of the emissions of tar, nicotine and carbon monoxide, is not required for a designated tobacco product if
- a. the product is one of identical products of the manufacturer sold under different brands; and
 - b. a report under this section is submitted in respect of another of those identical products.

Exemption - functional relationship of certain emissions

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

$$y=mx+b$$
 where
 y is the amount of the other emission,
 m is the slope,
 x is the mean amount of tar as determined by 7 replicates, and
 b is the intercept,
 - ii. by applying a regression analysis to the results obtained under subparagraph (i), and
 - iii. by applying an F-test to the results obtained under that subparagraph; and
 - b. between nicotine and the other emissions produced from the combustion of the designated tobacco product, by making the calculation and applying the analysis and test described in paragraph (a), except that the references to “tar” in subparagraph (i), other than in the description of “y”, shall be read as references to “nicotine”.

Conditions

- 12.** The conditions under which the statistical analysis to be provided in subsection (11) are as follows:
- a. in the case of mainstream smoke, under the conditions set out in paragraphs (6)(a) and (b); and
 - b. in the case of sidestream smoke, under the conditions set out in paragraph (6)(a).

Sample size

- 13.** To qualify for an exemption under subsection (11), the manufacturer must submit to the Minister
- a. a sample that must be composed of at least 28 different brands and 2 standard samples of a type of the designated tobacco product that represent the range of tar and nicotine deliveries for that type of designated tobacco product as determined
 - i. in the case of mainstream smoke, in accordance with Official Method T-115, entitled *Determination of “Tar”, Nicotine and Carbon Monoxide in Mainstream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999, and

- ii. in the case of sidestream smoke, in accordance with Official Method T-212 entitled *Determination of "Tar" and Nicotine in Sidestream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999;
- b. a list of the brands of the designated tobacco product for which the application for exemption is made; and
- c. a list of the properties of the designated tobacco product, such as the type of tobacco, type of filter and characteristics of a cigarette paper, which demonstrate the functional linear relationship between
 - i. the brands of the designated tobacco product that form the sample, and
 - ii. one or more of the brands of the designated tobacco product for which the application for exemption is made.

Joint Sample

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

Decision of the Minister

- 15.** The Minister shall, without delay, decide to accept or reject
- a. an application made under subsection (11), based on the
 - ii. methodology used, and
 - ii. the demonstration of a satisfactory functional linear relationship based on
 - a. the mean and standard deviations of the amount of each of the emissions, other than tar and nicotine,
 - b. the estimates and 95% confidence limits for the slope "m" and the intercept "b" referred to in subparagraph (11)(a)(i),
 - c. regression statistics, including the degree of freedom for error, degree of freedom for regression, mean square regression, mean square error and the F statistic, and
 - d. the fact that the data must fall under a 95% prediction interval; and
 - b. a sample made in accordance with subsection (13) or (14), based on the methodology used and the representativeness of the sample.

Satisfactory functional relationship

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

PART 4
RESEARCH ACTIVITIES

Annual Report

- 15.1** Every manufacturer of a consumer tobacco product shall report annually on each research activity that was undertaken, continued or completed during a year by or on behalf of the manufacturer in respect of that consumer tobacco product, including, but not limited to, research regarding
- a. its toxicity;
 - b. its health effects;
 - c. its ingredients;
 - d. its taste and flavour;
 - e. its modification;
 - f. its marketing; and
 - g. the manner in which it is used by consumers.

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

Content of report

- 2.** The report shall set out the following information in respect of each research activity:
- a. the cover page of any relevant document;
 - b. any progress report, synopsis or outline made in respect of the activity; and
 - c. the expected duration of the activity, the date it began and the expected date of completion.

New consumer tobacco products

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

PART 5
PROMOTIONAL ACTIVITIES

Semi-annual Reports

Promotional activities

- 16.1** Every manufacturer of a consumer tobacco product shall report
- a. subject to subsection 18(2), quarterly and at the following times, the dates of release of any promotional activity in respect of that consumer tobacco product and the applicable descriptive information set out in sections 17 to 24:
 - i. for the period beginning on January 1 and ending on March 31 of a year, on or before April 30 of that year;
 - ii. for the period beginning on April 1 and ending on June 30 of a year, on or before July 31 of that year;
 - iii. for the period beginning on July 1 and ending on September 30 of a year, on or before October 31 of that year;
 - iv. for the period beginning on October 1 and ending on December 31 of a year, on or before January 31 of the following year.
 - b. semi-annually, the information described in subsection (2) in respect of each promotional activity undertaken by the manufacturer or for the manufacturer for consideration in respect of that consumer tobacco product
 - i. for the period beginning on January 1 and ending on June 30 of a year, on or before July 31 of that year, and
 - ii. for the period beginning on July 1 and ending on December 31 of a year, on or before January 31 of the following year.

Content of report

- 2.** In addition to the information to be reported under sections 17 to 24, the semi-annual report mentioned in paragraph (1)(b) shall set out, for each province and specifying national totals,
- a. by brand family and, where applicable, by brand
 - i. the total semi-annual costs of each of the promotional activities described in sections 17 to 24, and
 - ii. by type of consumer tobacco product, the total semi-annual costs of all promotional activities; and
 - b. in respect of all of the manufacturer's promotional activities for all of their consumer tobacco products, the total semi-annual costs of those promotional activities.

Advertisements in Publications

Information about advertisements

- 17.1** If a consumer tobacco product is advertised in a publication, the manufacturer of that product shall report the following information:
- a. every province in which the publication was distributed;
 - b. the dates the advertisement was published; and
 - c. the total cost of the advertisement.

Copy of advertisement

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

Sponsorship

Information to be provided

- 18.1** If a consumer tobacco product-related brand element is displayed, before October 1, 2003, in a promotion that is used in the sponsorship of a person, entity, event, activity or permanent facility, the manufacturer of the consumer tobacco product shall report the following information:
- a. if the sponsorship is in respect of
 - i. a person or an entity, the name of the person or entity and a description of any items bearing the consumer tobacco product-related brand element of the manufacturer,
 - ii. an event or activity, a description of the event or activity and its date, or
 - iii. a permanent facility, the name of the facility, a description of it and its street address;
 - b. whether the consumer tobacco product-related brand element was displayed between January 25, 1996 and April 25, 1997 in promotional material that was used in the sponsorship of an event or activity that took place in Canada and, if so, the date of the event or activity;
 - c. a copy or reasonable facsimile with a detailed description of any promotional material containing a brand element of the manufacturer, including, with respect to the promotional material,
 - i. the colours used in it,
 - ii. its size, and
 - iii. a copy of any text appearing in it;
 - d. the expected duration of the display of any promotional material used in the sponsorship;
 - e. if promotional material used in the sponsorship appears in a publication, the information required by section 17; and
 - f. the total cost of the sponsorship.

When required

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

Permanent facilities

- 19.** If a consumer tobacco product-related brand element, or the name of a manufacturer, is displayed, on or after October 1, 2003, on a permanent facility where the brand element or name is not thereby associated with a sport or cultural event or activity, the manufacturer of the consumer tobacco product shall report the following information:
- a. the name, the street address and a description of the facility;
 - b. a description of the brand element or name displayed, including
 - i. the colours used in it, and
 - ii. its size;
 - c. the expected duration of the display; and
 - d. the total cost of the display.

Packaging

Information to be provided

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

Services

Information to be provided

- 21.** If a service uses a consumer tobacco product-related brand element of a manufacturer for consideration by the manufacturer, the manufacturer shall report the following information:
- a. a detailed description of the service;
 - b. in respect of the service, the expected duration of the use of the consumer tobacco product-related brand element;
 - c. the province in which the consumer tobacco product-related brand element is used by the service; and
 - d. the consideration given by the manufacturer for the promotion of the consumer tobacco product.

Display at Retail

Report

- 22.** Every manufacturer of a consumer tobacco product that uses a sign to promote the product, specifies the manner of displaying the product at retail or pays a fee for the display of the product shall report the following information in respect of the display at retail of the product:
- a. if a sign or display is used,
 - i. a detailed description of the sign or display,
 - ii. a photo or reasonable facsimile of the sign or display, and
 - iii. the cost of providing the display or using the sign, including the cost of their production and distribution;
 - b. the total amount paid to retailers to display the product or sign, by province;
 - c. the number of retailers, by province and by each of the following categories, that have received a fee to display the product or sign:
 - i. a convenience store, including
 - a. an independently owned convenience store, and
 - b. any other convenience store,
 - ii. a grocery store,
 - iii. a pharmacy,
 - iv. a restaurant,
 - v. a tavern, bar or beverage room, and
 - vi. any other establishment not described in subparagraphs (i) to (v); and
 - d. in the case of a sign,
 - i. the number of establishments, including their names and addresses, that do not permit entry to young persons and that displayed the sign; and
 - ii. the period during which the sign was specified to be displayed.

Accessories

Information to be provided

- 23.** If an accessory that displays a consumer tobacco product-related brand element is promoted, the manufacturer of that consumer tobacco product shall report the following information about the accessory:
- a. photograph or reasonable facsimile of it;
 - b. a detailed description of it;
 - c. the number sold, by province; and
 - d. its cost
 - i. of development,
 - ii. of manufacture,
 - iii. of distribution, and
 - iv. of promotion.

Other Products

Information to be provided

- 23.** If a non-tobacco product, other than an accessory that displays a consumer tobacco product-related brand element, displays a consumer tobacco product-related brand element of a manufacturer, the manufacturer shall report the following information in respect of the non-tobacco product:
- a. a photograph or reasonable facsimile of it;
 - b. a detailed description of it;
 - c. the number sold, by province; and
 - d. its cost
 - i. of development,
 - ii. of manufacture,
 - iii. of distribution, and
 - iv. of promotion.

PART 6
REPEAL AND COMING INTO FORCE

Repeal

- 25.** *The Tobacco Products Control Regulations¹ are repealed.*

¹ SOR/89-21

Coming into Force

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

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

OFFICIAL METHODS FOR THE COLLECTION OF DATA
ON CONSTITUENTS

Column 1 Item - Constituent	Column 2 Official Method
1. (a) Nicotine (b) Nornicotine (c) Anabasine (d) Myosmine (e) Anatabine	Official Method T-301, <i>Determination of Alkaloids in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
2. Ammonia	Official Method T-302, <i>Determination of Ammonia in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
3. (a) Glycerol (b) Propylene glycol (c) Triethylene glycol	Official Method T-304, <i>Determination of Humectants in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
4. (a) Nickel (b) Lead (c) Cadmium (d) Chromium (e) Arsenic (f) Selenium (g) Mercury	Official Method T-306, <i>Determination of Ni, Pb, Cd, Cr, As, Se and Hg in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
5. Benzo[a]pyrene	Official Method T-307, <i>Determination of Benzo[a]pyrene in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
6. Nitrate	Official Method T-308, <i>Determination of Nitrate from Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999
7. (a) N-nitrosornicotine (b) 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone (c) N-nitrosoanatabine (d) N-nitrosoanabasine	Official Method T-309, <i>Determination of Nitrosamines in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999

- | | |
|---------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| 8. Triacetin | Official Method T-311, <i>Determination of Triacetin in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999 |
| 9. Sodium propionate | Official Method T-312, <i>Determination of Sodium Propionate in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999 |
| 10. Sorbic acid | Official Method T-313, <i>Determination of Sorbic Acid in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999 |
| 11. Eugenol
[2- Methoxy-4-(2-propenyl)-phenol] | Official Method T-314, <i>Determination of Eugenol in Whole Tobacco</i> , made by the Department of Health, dated December 31, 1999 |

SCHEDULE 2

(Section 1 and subsection 14(5))

OFFICIAL METHODS FOR THE COLLECTION OF EMISSION DATA ON MAINSTREAM SMOKE

- | Column 1
Item - Emission | Column 2
Official Method |
|-----------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Ammonia | Official Method T-101, <i>Determination of Ammonia in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 2. (a) 1- aminonaphthalene
(b) 2- aminonaphthalene
(c) 3- amonobiphenyl and
(d) 4- aminobiphenyl | Official Method T-102, <i>Determination of 1- and 2- Aminonaphthalene and 3- and 4- Aminobiphenyl in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 3. Benzo[a]pyrene | Official Method T-103, <i>Determination of Benzo[a]pyrene in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |

- | | | |
|-----|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4. | (a) Formaldehyde
(b) Acetaldehyde
(c) Acetone
(d) Acrolein
(e) Propionaldehyde
(f) Crotonaldehyde
(g) Butyraldehyde | Official Method T-104, <i>Determination of Selected Carbonyls in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 5. | Eugenol
[2- Methoxy-4-(2-propenyl)-phenol] | Official Method T-105, <i>Determination of Eugenol in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 6. | Hydrogen cyanide | Official Method T-107, <i>Determination of Hydrogen Cyanide in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 7. | Mercury | Official Method T-108, <i>Determination of Mercury in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 8. | (a) Lead
(b) Cadmium | Official Method T-109, <i>Determination of Ni, Pb, Cd, Cr, As and Se in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 9. | (a) NO
(b) NO _x | Official Method T-110, <i>Determination of Oxides of Nitrogen in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 10. | (a) N-nitrosornicotine
(b) 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone
(c) N-nitrosoanatabine
(d) N-nitrosoanabasine | Official Method T-111, <i>Determination of Nitrosamines in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 11. | (a) Pyridine
(b) Quinoline
(c) Styrene | Official Method T-112, <i>Determination of Pyridine, Quinoline and Styrene in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |

- | | | |
|-----|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 12. | (a) Hydroquinone
(b) Resorcinol
(c) Cathecol
(d) Phenol
(e) m+p-Cresol
(f) o-Cresol | Official Method T-114, <i>Determination of Phenolic Compounds in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 13. | (a) Tar
(b) Nicotine
(c) Carbon Monoxide | Official Method T-115, <i>Determination of "Tar", Nicotine and Carbon Monoxide in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 14. | (a) 1,3 Butadiene
(b) Isoprene
(c) Acrylonitrile
(d) Benzene
(e) Toluene | Official Method T-116, <i>Determination of 1,3-Butadiene, Isoprene, Acrylonitrile, Benzene and Toluene in Mainstream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |

SCHEDULE 3

(Section 1 and subsection 14(5))

OFFICIAL METHODS FOR THE COLLECTION OF EMISSION DATA ON SIDESTREAM SMOKE

Column 1 Item - Emission	Column 2 Official Method
1. Ammonia	Official Method T-201, <i>Determination of Ammonia in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
2. (a) 1- aminonaphthalene (b) 2- aminonaphthalene (c) 3- aminobiphenyl and (d) 4- aminobiphenyl	Official Method T-202, <i>Determination of Aminonaphthalene in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999
3. Benzo[a]pyrene	Official Method T-203, <i>Determination of Benzo[a]pyrene in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999

- | | | |
|-----|---------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4. | (a) Formaldehyde
(b) Acetaldehyde
(c) Acetone
(d) Acrolein
(e) Propionaldehyde
(f) Crotonaldehyde
(g) Butyraldehyde | Official Method T-204, <i>Determination of Carbonyls in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 5. | Hydrogen cyanide | Official Method T-205, <i>Determination of Hydrogen Cyanide in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 6. | Mercury | Official Method T-206, <i>Determination of Mercury in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 7. | (a) Lead
(b) Cadmium | Official Method T-207, <i>Determination of Ni, Pb, Cd, Cr, As, and Se in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 8. | (a) NO
(b) NO _x | Official Method T-208, <i>Determination of Oxides of Nitrogen in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 9. | (a) N-nitrosornicotine
(b) 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone
(c) N-nitrosoanatabine
(d) N-nitrosoanabasine | Official Method T-209, <i>Determination of Nitrosamines in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 10. | (a) Pyridine
(b) Quinoline | Official Method T-210, <i>Determination of Selected Basic Semi-Volatiles (Pyridine and Quinoline) in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |
| 11. | (a) Hydroquinone
(b) Resorcinol
(c) Cathecol
(d) Phenol
(e) m+p-Cresol
(f) o-Cresol | Official Method T-211, <i>Determination of Phenolic Compounds in Sidestream Tobacco Smoke</i> , made by the Department of Health, dated December 31, 1999 |

12. (a) Tar
(b) Nicotine
- Official Method T-212, *Determination of "Tar" and nicotine in Sidestream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
13. (a) 1,3 Butadiene
(b) Isoprene
(c) Acrylonitrile
(d) Benzene
(e) Toluene
(f) Styrene
- Official Method T-213, *Determination of Selected Volatiles (1,3 Butadiene, Isoprene, Acrylonitrile, Benzene, Toluene and Styrene) in Sidestream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999
14. Carbon Monoxide
- Official Method T-214, *Determination of Carbon Monoxide (Co) in Sidestream Tobacco Smoke*, made by the Department of Health, dated December 31, 1999

Smuggling Paper

by Luk Joossens, UICC Consultant and WHO Expert
on European Tobacco Control Activities

■ Tobacco smuggling has become a critical public health issue. Smuggling affects public health because it brings tobacco products into markets cheaply, making cigarettes more affordable. More affordable tobacco products stimulate consumption, consequently increasing the burden of disease caused by their use. Additionally, substantial revenue losses to governments result from smuggling. Total lost revenue by governments due to cigarette smuggling is estimated at \$25-30 000 million annually.⁷

Cigarette smuggling occurs in all parts of the world, even in regions where taxes are low. One internal document of the tobacco company British American Tobacco Co.⁸ estimated that 324 billion, or nearly 6% of world cigarette sales of 5,400 billion, were duty not paid (DNP) cigarettes, an industry term for contraband. Eastern Europe and the Asia-Pacific region accounted for the majority of this amount, at about 85 billion each. Western Europe also was significantly hit by smuggling, at about 50 billion. In relation to total market sales, DNP volumes are largest in Eastern Europe (about 13%), Africa, and the Middle East (ca 12%). Smuggled volumes in Latin America were ca 9% and in Western Europe, about 7%.

Western Europe has the highest cigarette prices in the world, four to five times higher than in Africa, the Middle East or Eastern Europe in 1996. Despite these high prices, smuggling is on average lower than in other regions. This illustrates that cigarette smuggling is not caused principally by “market forces”. It is supply driven, caused mainly by fraud through the illegal evasion of taxes.⁹ While difference in price between countries or states will increase the incentive for smuggling, the key smuggling concern remains large scale smuggling or container smuggling.

Large-scale organized smuggling (or container smuggling) involves the illegal transportation, distribution, and sale of large consignments of cigarettes and other tobacco products, generally avoiding all taxes. This type of smuggling usually involves millions of cigarettes that are smuggled over long distances. Large-scale smuggling is encouraged by the presence of criminal organisations and is a relatively sophisticated system for distributing smuggled cigarettes at the local level. It is hugely aided by the lack of control of the international movement of tax-free cigarettes. Significant sums of money are involved with organized smuggling. Large-scale smugglers transport containers of 10 million cigarettes.

A container of 10 million cigarettes can be bought without taxes in 'transit' for US\$200,000, but has a current fiscal value (import taxes, excise duties and VAT) which is three to ten times higher. Large-scale smugglers operate in all parts of the world, as the container transport costs are small compared to the market value of their goods.

The most common way to buy tax-free cigarettes, is to buy cigarettes under the 'in transit' regime. Transit is a concession system aimed at facilitating trade. Its essence is to allow the temporary suspension of customs duties, excise and VAT payable on goods originating from and/or destined for a third country while under transport across a defined customs area. However, many containers disappear during their international transport and never arrive at their final destination.

The key points about container fraud are that it is highly organized and that the cigarettes are supplied to the illegal market, by the tobacco manufacturers, through (legal) exports to countries where they have no market. They are transported from these countries (often by circuitous and complex routes) back into the country from which they were exported to be sold illegally, at half to one third of the legal price.

Smuggling is mainly caused by cigarettes which are duty suspended under the transit regime and which disappear during their international transport. Most of these cigarettes are classified in world trade statistics as missing. It has been estimated that a third of internationally exported cigarettes are lost to smuggling.

According to the World Bank, economic theory suggests that the industry itself will benefit from the existence of smuggling.^{viii} Studies of the impact of smuggling show that when smuggled cigarettes account for a high percentage of the total sold, the average price for all cigarettes, taxed and untaxed, will fall, increasing sales of cigarettes overall.

Despite its professed opposition to criminal activity, the tobacco industry benefits from smuggling in several ways:

- smuggling stimulates consumption both directly (through the street sale of cheap cigarettes) and indirectly (through pressure to lower or keep down taxes);
- the threat of smuggling has also been used to avoid trade barriers or to force open new markets.

The cigarette companies often blame organized crime for the massive amount of cigarette smuggling world-wide, but much of the organized criminal smuggling that accounts for the vast majority of all cigarette smuggling worldwide has occurred with the knowledge of the major cigarette companies themselves, and would not occur without the cigarette companies' compliance. These facts have been established largely through previously secret, internal cigarette company documents, which have become available through various lawsuits against the companies.

The documents describe extensive knowledge, oversight, and support of smuggling by the transnational cigarette companies in numerous countries. At the same time, only a small portion of the smuggling-related documents uncovered to date have appeared in the press or elsewhere.⁸⁸

To address smuggling, governments must create a liability regime in which manufacturers are made responsible for the safe transport of cigarettes to their end market: it would be their responsibility to prove that their cigarettes reached intended, legitimate end markets.⁸⁹ Currently, tobacco manufacturers and wholesalers have no incentives to guard against smuggling and strong incentives to facilitate smuggling for commercial and political gain. The Framework Convention Alliance (FCA) which comprises over 200 groups from more than 87 countries, therefore suggested a two-pronged approach:

1. **Reverse the perverse incentives to smuggle:** develop a liability regime, introduce export taxes or bonds, license wholesalers (but not retailers) and launch investigations and legal action aimed at those orchestrating smuggling. The aim must be to make it in the interests of otherwise legitimate traders to prevent smuggling, not to benefit from it.
2. **Secure the distribution system:** develop a proper system of supervised import-export control; mark the packs with the final destination; introduce systems for tracking and tracing; ban duty free and improve co-operation and mutual assistance.⁹⁰

Tracking: shall mean the systematic monitoring of the movement of tobacco products from the place of manufacture to the place where all relevant duties and taxes have been paid for the purpose of assisting the competent authorities in detecting, investigating and analyzing illicit manufacturing and illicit trafficking.

Tracing: means the ability of competent authorities to recreate the route taken by a tobacco product from the manufacturing place through the distribution chain to the point where all relevant duties and taxes have been paid.

Each Party shall undertake the following legal, administrative and other measures in order to prevent and combat the illicit trade in tobacco products:

- carry covert chain-of-custody marks on all packages of tobacco products under the cellophane wrapping which allow the competent authorities the systematic tracking of tobacco products from manufacturer to wholesaler and/or retailer for the purpose to detect, investigate or analyse illicit manufacturing and illicit trafficking.
- ensure the maintenance, for not less than ten years, of information in relation to tobacco trade (such place and date of manufacturing, export, transit, import and sales data) that is necessary to trace and identify tobacco products which are illicitly manufactured or trafficked and to prevent and detect such activities.
- ensure that any manufacturer or exporter of tobacco products sell and ship tobacco products such that the only quantity of tobacco products that are sold to any destination are those which can be demonstrated to be actually consumed or sold legitimately in the intended end market.

Smuggling Paper Notes

- I. The agreements most applicable to regulation of tobacco include the General Agreement on Tariffs and Trade (GATT) and its subsidiary agreements, the Agreement on Technical Barriers to Trade (TBT), and the Trade-Related Aspects of Intellectual Property (TRIPS). The Agreement on the Application of Import Licensing Procedures, the Agreement on Sanitary and Phytosanitary Measures (SPS), and the General Agreement on Trade in Services (GATS), and others, also could come into play.

- II. The international agreements generally acknowledge the right of governments to undertake policy and regulatory measures, even if they have the effect of restricting trade, if they are necessary to protect, among other things, health or the environment. The agreements specifically provide exceptions to the trade restriction prohibition, so long as, depending on the specific agreement(s) applicable in any given case, the measures are necessary, science-based, there are no alternative measures that reasonably could be applied which are not inconsistent with the applicable trade agreement, and the measures are not disguised restrictions on trade.

A tobacco case involving a U.S. government challenge to Thailand's 1990 Tobacco Control Act, brought before the predecessor to the WTO under an earlier version of GATT, may provide some guidance. The dispute involved Thailand's attempt to ban the import of cigarettes and impose differential excise and business tax rates on domestic and imported cigarettes through its tobacco control law. The law also imposed, among other things, an advertising ban and labelling restrictions on tobacco products. The Thai government argued that because chemical and other additives contained in cigarettes manufactured in the United States might make them more harmful than the Thai cigarettes available in the market through the Thai tobacco monopoly, the restrictions were necessary to protect human health. The GATT decision-making panel noted that the health exception under GATT clearly allowed contracting parties to give priority to human health over trade liberalization; however, it found the import prohibition to be an unnecessary restriction on trade because reasonable alternatives (e.g., non-discriminatory labelling, ingredient disclosure requirements, an advertising ban (even though it found that an advertising ban might create unequal competitive opportunities between the existing Thai cigarette supplier and new foreign suppliers), and a ban on unhealthy substances in cigarettes) were available options. The panel also noted that Thailand already had implemented some of these and other non-discriminatory controls on cigarette demand. Significantly, the panel found the import ban to constitute a discriminatory trade practice since domestic cigarettes still would be available for sale. At the same time, it acknowledged the legitimacy of many of the controls that are addressed in the Manual. Since the date of this decision, GATT has been amended (though the relevant provisions are largely the same) and the other complementary trade agreements (e.g., TRIPS) have been enacted.

- III. The Manual's provisions requiring generic packaging, some of the requirements found under the anti-smuggling provisions, and some of the evidentiary provisions found under the recovery of damages section are not found in or based upon countries' laws, however.

- IV.** Belgium imposes this amount.
- V.** Joossens L, How to combat tobacco smuggling through the WHO Framework Convention on Tobacco Control, Presentation at the Second World Conference on Modern Criminal Investigation, Organized Crime and Human Rights, Durban, 7 December 2001.
- VI.** BATco Global Five Year Plan 1994-1998, bates number 50018206-10.
- VII.** Jha P, Chaloupka FJ. Curbing the epidemic: governments and the economics of tobacco control. Washington, DC: World Bank; 1999.
- VIII.** Joossens L, Raw M, Turning of the tap: the real solution to cigarette smuggling. *International Journal of Tuberculosis and Lung Disease*, 2003, 7(3):212-222.
- IX.** Framework Convention Alliance, Briefing on the Chair's text for INB 5, August 2002.

Extracted Legislative text

The legislative text without explanations is presented on the following pages for ease of use in drafting

[Legislative text:]

[Note: an index of the legislative parts and sections or clauses can be inserted here.]

BILL

An Act to: prevent tobacco use by young people; enhance public awareness of the hazards of tobacco use and ensure that consumers are provided with information to make more fully informed decisions about using tobacco; protect individuals from exposure to tobacco smoke; prohibit *[or restrict, if advertising still will be allowed]* promotional practices; prevent illegal conduct, including but not limited to smuggling; provide for regulation of tobacco products to mitigate against the harmful effects of tobacco; provide for sufficient regulatory flexibility to respond to new technological and scientific innovations and findings and to changes in consumer behaviors; provide for rules of evidence and procedures for addressing tobacco industry liability for damage caused by tobacco use and exposure to tobacco smoke; create a national coordinating institution for tobacco control; and provide for other related matters and purposes.

Part 1: Preamble and Purpose

UNDERSTANDING the devastating health, social, and economic effects of tobacco use and exposure to tobacco smoke on individuals and families, and the costs to the government, to society, to the environment, and to the socio-economic development potential of the nation;

ACKNOWLEDGING the existence of vast numbers of addicted tobacco users, making it impractical to make tobacco products illegal;

RECOGNIZING the right of consumers and the public to have meaningful information about the hazards from tobacco use and to be free from tobacco industry practices that undermine that information;

RECOGNIZING FURTHER that there is no such thing as a safe tobacco product;

REALIZING that people generally begin using tobacco products without recognizing the consequences of their highly addictive character;

REALIZING FURTHER that exposure to advertising and promotional practices encourages and glamorizes tobacco use, and that current widespread promotion of tobacco leads to youth initiation;

RECOGNIZING that scientific evidence has established unequivocally that exposure to tobacco smoke in non-smokers causes death, disease and disability, and, thus, cognizant of the need and responsibility to protect individuals from the hazards of tobacco smoke;

ASSERTING the government's legitimate public health function and its duty to protect its population from exposure to tobacco products and their toxic smoke, regulate the manufacture, promotion, and sale of tobacco products, and to do so within a regulatory framework that provides flexibility to address advances in knowledge, technology, and science as they occur, and to provide an efficient legal framework for addressing the harm caused by tobacco; and

RESOLVING to align national laws with the WHO Framework Convention on Tobacco Control,

The government undertakes the following measures to protect the health, rights, and well being of all of the people, taking into account specifically the needs of, and effects of these measures on, priority populations.

Part 2: Preliminary

1. Assent, citation, and commencement.

a. **Date of assent:** The [\[specify the head of state\]](#) assents to the enactment of this Act on [\[specify day, month, and year of assent\]](#).

b. **Citation and commencement.** This Act may be cited as the [\[specify the name of the Act\]](#) and shall come into operation on [\[specify the triggering event under the country's legal system \(e.g., upon approval by Parliament, as the Minister may appoint, or upon publication in the Gazette\)\]](#); provided, however, that different commencement dates may be appointed for the commencement of different provisions of this Act.

2. Repeals and amendments [If applicable].

a. **Repeals.** This Act repeals the [\[specify the name of existing Act that is being replaced\]](#) in its entirety, effective with the date this Act comes into operation.

b. **Amendments.** This Act amends the [\[specify name of existing Act being amended\]](#) effective with the date this Act comes into operation, unless otherwise provided for in any specific provisions.

Part 3: Interpretation

3. Definitions. For the purposes of this Act, the terms below shall be given the meanings prescribed to them. Any words or terms not defined shall be given their plain and customary meanings, unless the context requires otherwise, and shall be interpreted in a manner consistent with the purposes and spirit of this Act. Terms in the singular or plural apply equally to the plural or singular, respectively. Terms defined as nouns or verbs shall have the corresponding meaning as verbs or nouns, respectively.

- 1 a. *“Additive”* means any substance, chemical, compound, or component,
2 other than tobacco or water, that is introduced into a tobacco product
3 during processing, manufacturing, or packaging, including, as applicable,
4 those contained in the paper, filter, portion pouch, or similar part of the
5 tobacco product, its package, or accessories. The term “additive” also
6 shall include any residues of pesticides, fungicides, and other chemicals
7 used during tobacco growing, harvesting, curing, storing, or other stages
8 of preparing tobacco products for consumption.
9
- 10 b. *“Advertisement”* means any commercial communication through any media
11 or means, that is intended to have, or is likely to have, the direct, indirect,
12 or incidental effect of:
13 I. creating an awareness of a tobacco product, brand, manufacturer,
14 or seller, or
15 II. promoting the purchase or use of a tobacco product or brand.
16
- 17 A tobacco advertisement includes, but is not limited to, words, names,
18 messages, mottos, slogans, letters, numbers, pictures, images, colors
19 and other graphics, sounds, and any other auditory, visual, or sensory
20 matter, in whole or part, that is or are:
21 I. commonly identified or associated with a tobacco product, brand,
22 manufacturer, or seller, or
23 II. otherwise an indicia of product, brand, manufacturer, or seller identification.
24
- 25 c. *“Constituents”*, in relation to smoked tobacco products, means the
26 chemicals, including the particles, vapors, and gasses found in the smoke.
27 In relation to smokeless tobacco products, constituents means the
28 chemicals found in the product itself.
29
- 30 d. *“Disparate effect”* or *“disparity”* means an unacceptable gap,
31 as determined by the Minister of Health [or other governing authority]
32 in the level of protection provided by tobacco control measures to a priority
33 population group in relation to the level of protection provided to other
34 population groups.
35
- 36 e. *“Distributor”* or *“wholesaler”* means any person who buys tobacco
37 products and re-sells them to another seller.
38
- 39 f. *“Exporter”* means any person who sends tobacco products outside
40 this country for sale or supply in another country.
41
- 42 g. *“Factual information”* means, and is limited to, the brand name,
43 manufacturer’s name, type of product (e.g., cigarettes, smokeless tobacco,
44 etc.), prescribed messages, constituent and additives disclosures, price
45 information, and any other information required or permitted in
46 implementing regulations.
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- h. “*Generic*”, with respect to packaging and labelling and otherwise in connection with this Act, means: the use of black and white text only; the presentation of only factual information; and no other auditory, visual, sensory, or other matter, unless authorized in implementing regulations.

[Note: if advertising will not be banned, the definition of “generic” also should be specified as applying to advertising as well.]

- i. “*Graphic*” means any symbol, sign, logo, mark, trademark, pattern, emblem, design, crèche, recognizable colors or patterns of colors, or any other indicia of tobacco product, manufacturer, or seller identification.
- j. “*Health care services*”, in relation to any person who has suffered or is at risk of suffering any tobacco-related illness, means inpatient or outpatient examination, diagnosis, treatment, procedures, health status monitoring, counselling, pharmaceuticals, therapies, and other health-related goods or services.
- k. “*Health care services costs*” means the sum of the present value of the total expenditures by the government or other third party payer for health care services provided to persons resulting from, or to prevent or monitor any actual or potential, tobacco-related illness, including illness from tobacco smoke exposure, and the present value of the estimated total expenditures for health care services that could reasonably be expected to be provided to persons as a result of, or to prevent or monitor any actual or potential, tobacco-related illness.
- l. “*Importer*” means any person who receives or arranges for the receipt of tobacco products from another country for sale in this country.
- m. “*Manufacturer*” means the corporation or other person that manufactures, fabricates, produces, processes, packages and/or labels tobacco products, and includes any entity that is associated with a manufacturer, any entity that controls or is controlled by the manufacturer, or that is controlled by the same entity that controls the manufacturer.
- n. “*Media*” means broadcast, print, electronic, and any other avenues of communicating to the public.
- o. “*Message*” or “*health message*” means a warning or other information about the health effects of tobacco use or exposure to tobacco smoke, the benefits of and/or suggestions for quitting, and any other appropriate tobacco control message, as prescribed by the Minister [or other governing authority] in regulations.
- p. “*Minister*” means Minister of Health or his or her designate.

- 1 q. “*Package*” means any covering, wrapper, container, or other enclosure
2 that contains a tobacco product, or multiple packages of tobacco products
3 (i.e., cartons), and includes any label and other written or graphic
4 information on or in it.
5
- 6 r. “*Person*” includes any individual, proprietor, firm, partnership, corporation,
7 franchise, organization, agency, association, institution, or other entity
8 possessing a legal personality.
9
- 10 s. “*Place of collective use*” means any place open to the public, whether
11 it is enclosed, partially enclosed, or an outdoor public space, where:
12
13 1. persons congregate in close proximity to one another;
14 2. smoking might pose a fire hazard; or
15 3. other criteria established in implementing regulations are met.
16
- 17 Examples of places of collective use include, but are not limited to:
18 stadiums, railway platforms, and similar places.
19
- 20 t. “*Priority population*” means any population group that is, or traditionally
21 has been, excluded from tobacco control planning, decision-making,
22 or the benefits of tobacco control programs or interventions;
23 has disproportionate rates, in relation to its population numbers,
24 of tobacco use or tobacco-related morbidity or mortality; or experiences
25 a disproportionate rate of exposure to tobacco smoke or to tobacco
26 industry promotional practices.
27
- 28 u. “*Promote*” or “*promotion*”, includes advertising but is a broader term
29 that includes any commercial act or practice that is intended to or is likely
30 to encourage, directly or indirectly, the purchase or use of any tobacco
31 product or brand or create an awareness of or association with a tobacco
32 product, brand, manufacturer or seller.
33
- 34 v. “*Public conveyance*” means any form or mode of transportation
35 that carries passengers for hire or reward, whether locally, between places
36 within the country, or internationally.
37
- 38 w. “*Public place*” means any place, fixed or mobile, including any work place,
39 to which members of the general public or segments of the general public
40 ordinarily have access by express or implied invitation. An enclosed public
41 place is a partially or fully completed building or structure, including a mine
42 or tunnel, that is separated from the outdoors.
43
- 44 x. “*Retailer*” means a person who sells tobacco products to consumers.
45
- 46 y. “*Seller*” means any person who supplies any tobacco product for a fee or
47 other consideration, and includes any manufacturer, distributor, wholesaler,
48 importer, exporter, and retailer.
49
50

- z. *“Separately ventilated smoking room”* means a room in an enclosed public place, including workplace, that:
- I. is enclosed with four walls, or floor to ceiling partitions, and a door;
 - II. has an air flow system that is exhausted directly to the outside; and
 - III. has negative air pressure in comparison with the remainder of the building.
- aa. *“Supply”* means to sell, give, exchange, convey, consign, deliver, furnish, or transfer possession of or title to any tobacco product for the purpose of obtaining financial or business gain, or arrange or offer to do so, whether for a fee or other consideration or without charge.
- bb. *“Tobacco smoke”, “second-hand smoke”, or “environmental tobacco smoke”* means the smoke or other emissions released from a tobacco product or the smoke exhaled by a person smoking a tobacco product.
- cc. *“Smoking”* means inhaling, exhaling, or handling an ignited or heated tobacco product or a tobacco product producing emissions by any means.
- dd. *“Tobacco product”* means any product containing tobacco in any form that is intended for human use. A tobacco product includes all parts and materials, such as papers, filters and filter wrappers, over-wrappers, rods, portion pouches, and similar matter, as applicable, even if sold separately. Raw tobacco that has not been processed or prepared for human use shall not be considered a tobacco product under this Act.
- ee. *“Tobacco-related illness”* means any illness, disease, or condition resulting in whole or in part from tobacco use or exposure to tobacco smoke, and includes any illness, disease, or condition exacerbated by tobacco use or exposure to tobacco smoke.
- ff. *“Tobacco sponsorship”* means the direct or indirect public attribution, acknowledgment, association, identification, or display of a tobacco manufacturer, seller, brand, or product, or of any indicia of a tobacco manufacturer, seller, brand, or product with, on, or in connection with:
- I. an entertainment, sporting, recreational, educational, cultural, fashion, or other event, show, activity, or work;
 - II. any person or team participating in such an event, show, activity, or work, including their equipment, clothing, and accessories;
 - III. activities in bars, nightclubs, restaurants, entertainment venues, and other similar venues;
 - IV. a service provided or contribution made by a tobacco manufacturer or seller; or
 - V. a building, institution, stadium, or other public place, other than one exclusively used to manufacture or sell tobacco products.

1 gg. “*Workplace*” means any place in which persons perform duties of
 2 employment or work and includes private offices, common areas,
 3 and any other area which generally is used during the course of
 4 employment or work. Workplaces shall not include private residences
 5 except to the extent that they are used for commercial purposes.
 6 [Note: this provision may be modified to protect domestic workers.]
 7 An enclosed workplace is a partially or fully completed building
 8 or structure, including a mine or tunnel, that is separated from
 9 the outdoors.

12 Part 4: Administration

13
 14 **4. Ministry of Health [or other governing authority] responsible for**
 15 **overall administration.** The Minister of Health [or other governing authority]
 16 shall be responsible for the overall administration of this Act. The Minister
 17 [or other governing authority] is authorized to prescribe in implementing
 18 regulations any requirements necessary or appropriate for the law’s effective
 19 and efficient administration [If the national coordinating mechanism will have
 20 decision-making authority, add: subject to any authority granted to the [specify
 21 name of the national coordinating body], established below.

- 22
 23 **a. National Coordinating Body.** The Minister [or President or other
 24 governing authority] shall establish a national coordinating body, to be
 25 known as the [specify name], to be composed of persons with expertise
 26 in tobacco control, public health, or related fields, including persons
 27 competent to represent the interests of priority populations, to carry out
 28 the following functions: [prescribe the body’s functions].
 29
- 30 **b. Qualifications, operation, governance, etc. of the [specify name of**
 31 **national coordinating body].** [Specify the qualifications for membership
 32 and staffing, details of operation, governance, remuneration (if any) for
 33 membership, and other matters necessary or appropriate for the effective
 34 and efficient administration of the coordinating body];
 35
- 36 **c. Conflicts of interest.** No person employed by or representing the interests
 37 of any tobacco product manufacturer, importer, exporter, wholesaler,
 38 or retailer, or any other tobacco-related business, shall be qualified to serve
 39 as a member of the coordinating body, and no such person shall be
 40 appointed or otherwise be allowed to serve as a member.
 41
- 42 **d. Funding for [specify name of national coordinating body].** Funding for
 43 the [specify name of the national coordinating body] shall be paid out of
 44 [specify the funding source(s), such as moneys appropriated by Parliament,
 45 moneys from tobacco excise taxes collected, licensing fees, and/or other
 46 funds]. Nothing in this Act shall prevent the [specify the name of the
 47 coordinating body] from receiving gifts or donations, other than from
 48 the tobacco industry or any other source for which a conflict of interest
 49 would arise or from any other source deemed unacceptable by [specify
 50 who has authority to make this determination].

5. Appointment of authorized officers. The Minister may appoint any person or class of persons as officers authorized to carry out inspections and investigations as necessary or appropriate under the Act, to take enforcement actions against persons found to have violated any provision of the Act, and [specify other powers of the officers, if any].

Part 5: Licensure

6. Licensure of sellers of tobacco products.

- a. License required.** No person shall manufacture, import, export, or sell tobacco products at wholesale without first having a license; provided, however, that persons engaged in the business of manufacturing, importing, exporting or selling tobacco products on or before [specify date to give those currently operating time to apply for a license] shall have a period of up to [specify number] days from the date this Act comes into operation to apply for a license. A license, once granted, shall be valid for a period of [specify number of years] and shall be subject to renewal thereafter. If the application for an initial license or renewal is denied, the applicant shall cease manufacturing, importing, exporting, or selling tobacco products, as the case may be, immediately upon notification of the application denial, subject to any right to appeal [if appeal rights are applicable under the country's laws].

[Note: If it will be feasible to license retailers, “and retail” should be added after “wholesale” in the first sentence of (a). If retailers will be licensed but it will be infeasible to license very small retailers, the following text can be provided:]

- b. Exemption for small retailers.** *Notwithstanding the requirement for licensure in subsection (a), retailers selling tobacco products shall be exempt from licensure if their tobacco product sales account for no more than [specify a monetary amount in the aggregate, or specify a monetary amount as a percentage of total sales of all goods sold by the retailer].*

- c. Prohibition against selling to unlicensed sellers.** No person shall sell any tobacco product to any manufacturer, importer, exporter, wholesaler, retailer [if retailers will be subject to licensure] that does not certify that it holds a valid license or that it is exempt from licensure, [if an exemption will be made for small retailers], or that the person knows or has reason to know does not hold a valid license and is not exempt from licensure.
- d. Prohibition against purchasing from unlicensed sellers.** No person shall purchase or take possession of any tobacco product from any manufacturer, importer, exporter, or wholesaler that does not certify that it holds a valid license, or that the person knows or has reason to know does not hold a valid license.

- 1 e. **Licensure procedure.** The Minister [or coordinating body or other
2 appropriate entity which already may have licensing authority] shall serve
3 as the licensing authority and shall have the authority to prescribe the
4 requirements for the grant and renewal of a license, including attaching to
5 the grant or renewal of any license such conditions as are reasonable or
6 necessary for the effective and efficient administration of this Act. The
7 Minister [or coordinating body or other appropriate entity] also shall have
8 the authority to prescribe the procedure and forms for the licensure
9 application. An application for an initial license and any renewal shall be
10 made to the Minister [or national coordinating body or other appropriate
11 entity] in accordance with any requirements prescribed in implementing
12 regulations.
- 13
- 14 f. **Licensure fees.** The Minister [or licensing authority] additionally shall have
15 the authority to set license fees, which shall be based on [specify amount
16 or description of how amount is calculated [e.g., % of tobacco sales
17 revenues, or specify a flat fee], which the Minister [or licensing entity]
18 may raise from time to time as he or she [or it] deems appropriate.
- 19
- 20 g. **Denial of license.** Any person who fails to meet the requirements for
21 a license on initial application or on renewal may be denied a license
22 by the Minister [or licensing authority].
- 23
- 24 h. **Licensure sanction.** Any licensee found to have violated any provision of
25 this Act or implementing regulations may be subject to licensure sanction,
26 which may include limitation, suspension, or revocation, at the discretion of
27 the Minister [or licensing authority], consistent with the purposes of this Act.
28 In the event of suspension, the Minister [or licensing authority] may attach
29 such conditions for reinstatement as he or she [or it] deems appropriate for
30 the efficient and effective administration of this Act.

31
32 [If the right to appeal is applicable in the country, the following should be included:]

- 33
- 34 i. **Right to appeal.** Any applicant who is denied a license at initial application
35 or renewal, and any licensee whose license is the subject of a sanction action,
36 shall have a right to appeal in accordance with the provisions of Part 14.
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Part 6: Protection from Tobacco Smoke

7. Freedom from exposure to tobacco smoke. All persons shall have the right to be free from involuntary exposure to tobacco smoke in all enclosed public places, including workplaces, places of collective use, and on public conveyances.

- a. Prohibition on smoking in enclosed public places, including workplaces.** No person shall smoke in any enclosed public place, including any workplace, or in any part of an enclosed public place or workplace, including private rooms and offices. In addition, no person shall smoke anywhere on the outside premises of any public place that provides services primarily to children or youth under the age of [specify age], or at any outdoor public places where children congregate, such as playgrounds.

[If it is not possible to prohibit smoking altogether, the following provisions may be used:]

- b. Designated smoking rooms.** *Notwithstanding the prohibition against smoking in enclosed public places, including workplaces, the owner or operator of a public place, or employer, as applicable, may designate separately ventilated smoking rooms where people may smoke, other than in places where health care services are provided, places where children or youth under the age of [specify age] represent [specify percent] or more of the population typically served there, educational facilities, and [specify other, if any], so long as the following conditions are met:*
- i. the room is fully enclosed with four walls, or partitions that join the ceiling and floor and a functional door that meets the ceiling and floor without any gap of more than [specify size] cm;*
 - ii. the room is separately ventilated directly to the outside, with negative air pressure in comparison to the remainder of the building;*
 - iii. non-smoking members of the public and workers are not required to enter the designated smoking room while any person is smoking or within [specify time] thereafter, to gain access to other areas of the premises generally open to them or to which they require access to perform their duties, respectively;*
 - iv. all designated smoking rooms together comprise no more than an aggregate of [specify percentage] % of the total floor space of the enclosed premises to which the public and workers generally have access; and*
 - v. the room otherwise meets any requirements imposed in implementing regulations.*

- c. Smoking on public conveyances.** No person shall smoke on any public conveyance carrying passengers or employees.

1 **d. Smoking in places of collective use.** No person shall smoke in any public
2 place of collective use.

3
4 **e. No smoking signs.** The owner or occupier of any enclosed public place
5 and place of collective use, or employer, as applicable, and the owner
6 or operator of any public conveyance, shall post signs prominently on
7 the premises or in the conveyance stating that smoking is not permitted
8 *[or in the case of enclosed public places or workplaces, is permitted*
9 *only in designated separately ventilated rooms, if allowed by*
10 *the owner/occupier or employer].* Signs shall meet the requirements in
11 Annex A and shall comply with any requirements in implementing regulations.

12
13 **f. Obligations to ensure compliance.**

- 14 i. It shall be the duty of the owner or occupier of any enclosed public
15 place and any place for collective use, employer, and the owner
16 or operator of any public conveyance, as applicable, to take all
17 reasonable steps to ensure that no person smokes in violation of
18 the provisions of this Part. Taking reasonable steps includes,
19 but is not limited to: asking an offending person to stop smoking;
20 demanding that the offending person who continues to smoke leave
21 the premises or the conveyance when this can be done safely; refusing
22 further service; in the case of an employee, disciplining, including
23 dismissing the offending person from employment; and seeking
24 the assistance of law enforcement personnel in cases where
25 the offending person refuses to stop smoking or leave the premises
26 or conveyance.
- 27 ii. No owner or operator of any enclosed public place, any place of
28 collective use, or public conveyance, and no employer, as applicable,
29 shall permit the placement of ashtrays in any place under their control
30 *[other than in a designated smoking room in an enclosed public*
31 *place or workplace, if applicable].*
- 32 iii. No owner or operator of any public place, public place for collective
33 use, or public conveyance, and no employer, as applicable, or any
34 of their agents, shall retaliate against any person or employee who
35 asserts his or her right to a smoke-free environment or who reports
36 any violation under this Part.

37
38 **g. Establishment of a smoke-free environment.** Nothing in this part shall
39 require an owner, occupier or employer to designate separately ventilated
40 rooms for smoking.

41
42 **8. The rights of non-smokers prevail.** In interpreting the provisions of this Part,
43 the rights of non-smoking members of the public and workers shall prevail
44 and any question that may arise as to whether smoking is permitted in any given
45 situation shall be resolved in favor of protecting non-smokers.

9. Evaluation for disparate effects. The Minister [or other governing authority] shall determine whether the provisions of the Act and any implementing regulations affording protection against exposure to tobacco smoke result in equal levels of protection across all population groups. In the event disparities in the level of afforded protection are found, the Minister [or other governing authority] shall report such findings to the [specify, e.g., name of legislative body] and remedial regulatory action shall be taken as appropriate.

10. Ministerial discretion to address requirements of this Part.

The Minister [or other governing authority] shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

11. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations to protect persons from exposure to tobacco smoke, so long as such laws or regulations are at least as stringent as, and do not conflict with, the provisions of this Part.

Part 7: Advertising, Sponsorship and other Forms of Promotion

12. Freedom from tobacco advertising and promotion. All persons shall have the right to be free from all forms of tobacco advertising, sponsorship, and other forms of tobacco-related promotion, whether such forms are direct, indirect, overt, covert, or incidental.

Advertising

13. Advertising prohibition. No person shall advertise, arrange for, or participate in the advertising of any tobacco product, brand, manufacturer or seller, directly or indirectly. This prohibition shall apply to advertising in, as well as to advertising transmitted into or out of [specify name of country].

a. Allowed activities. The following shall be allowed:

- i. incidental exposure of a tobacco product or tobacco product package from the time of manufacture until it reaches its point of retail sale; provided, however, that tobacco products and tobacco product packages shall not be displayed in view of customers or patrons at retail locations and other locations where tobacco products are sold to consumers;

[Note: if a ban on the free supply of tobacco products is not imposed (See Section 13), it will be necessary to add “or supplied” after “sold”.]

- ii. a price list on paper no larger than [specify size] available at the counter at the point of sale for consultation by customers containing, in black and white text only, the brand name, price, and prescribed messages in accordance with implementing regulations, and no other text, colors or other graphics, or other information;

- 1 iii. communications by persons in the tobacco growing, manufacturing,
2 importing, exporting, distributing, selling or trading business directed
3 solely at other persons in the tobacco growing, manufacturing,
4 importing, exporting, distributing, selling or trading business;
5 iv. an Internet web site for any particular tobacco company, so long as it
6 presents business and or health information only and it is not intended
7 to, and is not likely to encourage, directly or indirectly, the purchase
8 or use of any tobacco product or brand;
9 v. trade publications prepared for and distributed only to employees,
10 shareholders, or investors that are not intended to, and are not likely
11 to encourage, directly or indirectly, the purchase or use of any tobacco
12 product or brand; provided, however, that the Minister [or other
13 governing authority] may prescribe a list of allowed trade publications
14 based upon those currently in existence prior to [specify date]; and
15 vi. the display of the company name on places of tobacco manufacturing,
16 subject to conditions imposed by the Ministry.

17
18 **b. Private communications.** Private communications among individuals
19 about tobacco products, brands, manufacturers, or sellers shall not be
20 construed to be tobacco-related advertising, so long as these
21 communications are not made at the behest of or for the benefit of
22 any tobacco manufacturer or seller or any person working on the behalf
23 or for the benefit of a tobacco manufacturer or seller.

24 25 **Sponsorships**

26 **14. Prohibition of tobacco sponsorships.** Tobacco sponsorships,
27 and advertising and other promotion of tobacco sponsorships, are prohibited.
28 This prohibition applies to sponsorships and advertising of sponsorships in,
29 as well as sponsorships and advertising of sponsorships originating elsewhere
30 but transmitted into or otherwise appearing in, [specify name of country].
31

32 **Other Forms of Promotion**

33 **15. Prohibition against brand stretching.** No person shall sell, display
34 for sale, supply, or advertise any non-tobacco product or service that contains,
35 either on the product, or in any advertisement of the product, any writing, picture,
36 image, graphic, message, or other matter, in whole or part, that is commonly
37 identified or associated with, or is likely or intended to be identified or associated
38 with a tobacco product, brand, or manufacturer. For the purposes of this section,
39 a non-tobacco product shall include a building, facility, premises, or business
40 that is not a building, facility or business that manufactures tobacco products
41 exclusively.
42

43 **16. Prohibition against reverse brand stretching.** No person shall use
44 the brand name, trademark or other sign, symbol, logo, or similar matter, in whole
45 or in part, commonly associated with a non-tobacco product or service on
46 a tobacco product, except for tobacco products for which a trade or brand name
47 of a non-tobacco product or service was in use on [specify a date on or before
48 the Bill was introduced in Parliament].
49
50

17. Prohibition against incentive promotions and the free supply of tobacco products. Incentive promotions and the free supply of tobacco products shall be prohibited.

a. Prohibition on tobacco products as bonuses, premiums, rebates, etc.

No person shall offer or provide any direct or indirect consideration for the purchase or use of a tobacco product, including a bonus, premium, cash rebate or right to participate in a game, lottery or contest; provided, however, that nothing in this section shall prohibit the giving of any normal trade discount or normal trade rebate, or providing compensation for monitoring compliance with this Act.

b. Prohibition on tobacco product samples and gifts. No person shall supply or offer to supply a tobacco product to any other person free of charge as a sample, gift, or otherwise. This subsection shall not be construed as prohibiting individuals from giving tobacco products to other individuals, so long as this is not done at the behest of, or for the benefit of, a tobacco manufacturer or seller or any person working on the behalf of or in the interest of a tobacco manufacturer or seller, or for financial gain for the individual offering the tobacco product.

18. Unintended consequences. The Minister [or other governing authority] shall have the authority, through implementing regulations, to make necessary limited exceptions to the provisions of this Part for the purpose of mitigating against or preventing any unintended consequences.

[If an outright ban on all advertising, sponsorship, and other forms of promotion is not undertaken, the following provision should be included to ensure assessment and remedial action in response to any disparities in the level of protection that may result from restrictions short of a ban.]

19. Evaluation for disparate effects. *The Minister [or other governing authority] shall determine whether the provisions of the Act and any implementing regulations affording protection against exposure to tobacco advertising, sponsorship, and other forms of promotion result in equal levels of protection across all population groups. In the event disparities in the level of afforded protection are found, the Minister [or other governing authority] shall report such findings to the [specify, e.g., name of legislative body] and remedial regulatory action shall be taken as appropriate.*

20. Ministerial discretion to address requirements of this Part.

The Minister [or other governing authority] shall have the authority to prescribe in implementing regulations additional and/or more stringent requirements than any of those prescribed in this Part.

21. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing tobacco advertising, sponsorships, and other forms of promotion, so long as the provisions of such law or regulations are at least as stringent as, and do not conflict with, the provisions of this Part.

Part 8: Tobacco Product Labelling and Packaging

22. Right to be informed of the risks of tobacco use. All consumers shall have the right to be informed fully of the health and other effects of tobacco use and the risks to others from exposure to tobacco smoke. The right to be fully informed includes the right to receive this information without interference from distracting or misleading tobacco product labelling or packaging practices.

23. Conformity with packaging and labelling requirements. All tobacco product labelling and packaging shall comply with the provisions of this Part.

a. Prohibition on sales of noncompliant tobacco product packages.

No person shall sell, offer for sale, supply, display, import, or export any tobacco product that is not labelled and packaged in a manner that complies with all requirements of this Part and with implementing regulations.

b. Prohibition on commercial purchase of noncompliant tobacco product packages.

No seller shall acquire tobacco products that are not packaged and labelled in a manner that complies with all requirements of this Part and with implementing regulations.

Labelling

24. Prescribed messages on tobacco products and packages.

All tobacco products shall contain, permanently affixed on their packages [and on individual sticks of smoked products], or individual wrappers in the case of cigars, messages as prescribed in implementing regulations.

a. Requirement for unattributed messages. Prescribed messages shall be unattributed.

b. Prohibition on obscuring messages. No person may sell or supply any product, device, or other thing that is intended to be used, or that can be used, to cover, obscure, mask, alter, or otherwise detract from the prescribed messages on tobacco product packages. This prohibition includes design of the product package in such a way that parts of the package, itself, or accessories can cover or obscure the messages.

25. Constituent and additives disclosures on tobacco product packages.

All tobacco products shall contain, permanently affixed on their packages, or wrapper in the case of cigars, a list of the constituents and additives specified, and in the manner prescribed, in implementing regulations. Constituent yield numbers shall not be displayed on tobacco product packages unless specifically authorized in implementing regulations.

26. Prohibition on deceptive or misleading information. No tobacco product package or label shall contain any information that is false, misleading, or deceptive, or that is likely or intended to create an erroneous impression about the characteristics, health effects, or health or other hazards of the tobacco product or its emissions. This prohibition includes, but is not limited to, the use of: words or descriptors, whether or not part of the brand name, such as “light”, “ultra light”, “mild”, “low tar”, “slim” or similar words or descriptors; any graphics associated with, or likely or intended to be associated with, such words or descriptors; and any product package design characteristics, associated with, or likely or intended to be associated with, such descriptors.

27. Continuing duty to warn. Compliance with this Part in no way shall be construed as relieving any tobacco manufacturer or seller of any duty prescribed by law, custom, convention, or otherwise, to fully inform consumers of all dangers associated with tobacco use and exposure to tobacco smoke.

28. Multiple packaging. If any tobacco product is placed in multiple layers of packaging, all health messages and constituents and additives disclosures shall be permanently affixed to the package in which the tobacco product ultimately is intended for consumer use, as well as to any external packaging, including cartons.

29. Requirements for name, license number, etc. on package.

Tobacco product manufacturers, exporters, and importers, as applicable, shall ensure their product packages contain the tracking and tracing and tax stamp status labelling information required by this Section.

a. Tracking and tracing information. The following information shall be presented in an invisible manner, in languages required by the Minister [\[or other governing authority\]](#), and shall be permanently affixed under the cellophane or other wrapping on each tobacco product package, including each carton, at the time of manufacture; provided, however, that those denoted below as visible shall be presented in both a visible and an invisible manner:

- I. name (visible) and license number of the manufacturer, and as applicable, wholesaler, importer, and exporter;
- II. unique manufacturer serial number date of manufacture (visible), and location;
- III. name of the country in which it was manufactured (visible); and
- IV. name of the country in which the product is intended for legal sale (visible).

b. Tax paid status information. The following information shall be clearly visible on all tobacco product packages:

- I. tax paid stamp or marking, as prescribed in [\[cite to law/regulation addressing tax markings or stamps\]](#); and
- II. [\[Specify other requirements, if any.\]](#)

1 **30. Requirements for tamper-proof packaging and labelling.** Tobacco
2 product manufacturers shall design their product packaging and labelling in such
3 a way as to make them tamper-proof, using the best available technology.
4 Manufacturers, importers, exporters, wholesalers, and retailers shall exercise
5 all reasonable and necessary precautions to prevent tampering with such
6 information while the products are under their control or supervision.
7

8 **31. Language of labelling information.** All labelling information shall appear
9 in the principal languages of the country in which the products will be sold.
10

11 **32. Evaluation for disparate effects.** The Minister [or other governing
12 authority] shall determine whether the messages required under this Act and
13 any implementing regulations are providing information in an appropriate
14 and effective manner to the general population and to priority populations.
15 To the extent the mix of messages is not found to be effective in reaching
16 the general population or priority populations, the Minister [or other governing
17 authority] shall report such findings to the [specify, e.g., name of legislative body]
18 and remedial regulatory action shall be taken as appropriate.
19

20 **33. Labelling requirements for exported products.** Notwithstanding
21 the provisions contained in this Part, tobacco products that will be exported from
22 [specify country name] shall not be required to meet labelling requirements
23 under this Part, other than the requirements of Section 24; provided, however,
24 that they shall be required to meet the labelling requirements of the importing
25 country. In the absence of labelling requirements in the importing country,
26 the labelling requirements under this Part shall apply fully to exported tobacco
27 products and any required messages, constituent and additives disclosures,
28 and other required labelling information shall appear in the official languages of
29 the country of destination.
30

31 Packaging

32 **34. Requirement for generic packaging.** Tobacco products shall not be
33 contained in anything other than a package that is generic on the inside
34 and the outside, and that complies with labelling requirements under this Act
35 and implementing regulations. Cartons containing individual packages also
36 shall be generic on the inside and outside.
37

- 38 a. Prohibition on sale of noncompliant tobacco product packages.
39 No seller shall sell, offer to sell, supply, display, import, or export, subject to
40 the provisions of Section 32, tobacco products in packaging other
41 than generic packaging.
42
- 43 b. Prohibition on commercial purchase of noncompliant tobacco product
44 packages. No seller shall purchase tobacco products in packaging other
45 than generic packaging.
46
47
48
49
50

35. Minimum package size for smoked tobacco products. Smoked tobacco products, with the exception of cigars which may be sold as individual units so long as they are individually labelled as required, shall be contained in a package of at least [specify number] units. No person shall sell single cigarettes or other smoked tobacco products, or sell any smoked tobacco product other than as part of a complete and intact package that meets minimum quantity requirements.

36. Minimum package size for smokeless products. Smokeless tobacco products shall be contained in a package of at least [specify number] mg. No person shall sell any portion of a smokeless tobacco product package, or sell any smokeless tobacco product other than as part of a complete and intact package that meets the minimum weight requirement.

37. Packaging requirements for exported tobacco products. Notwithstanding the provisions of this Part, tobacco products that will be exported from [specify country name] shall not be required to meet the packaging requirements of this Part; provided, however, that in the absence of packaging requirements in the importing country, the packaging requirements under this Part shall apply fully to exported tobacco products.

38. Ministerial discretion to address requirements of this Part. The Minister [or other governing authority] shall have the authority to prescribe, in implementing regulations, additional and/or more stringent standards and requirements for labelling and packaging than those prescribed in this Part. Ministerial authority shall include prescribing testing methods applicable to making the required constituents and additives disclosures.

39. Effect on other laws. Nothing in this Act shall affect the ability of any other level of government to enact laws or regulations addressing tobacco product labelling and packaging, so long as such laws or regulations are at least as stringent as, and do not conflict with, the provisions of this Part; provided, however, no other level of government may prescribe messages other than those prescribed in implementing regulations.

Part 9: Tobacco Product Sales

40. Prohibition on sales to minors. No person shall sell any tobacco product to any person under the age of 18 years [or specify at least the legal age of majority in the country]. Prior to selling a tobacco product to any person who appears not to be at least 10 [or specify other age] years older than [specify minimum age, as above], it shall be necessary to take all reasonable steps to verify the age of that person, by requiring, at a minimum, [specify reliable means of verification].

41. Prohibition on sales by minors. No person who sells tobacco products shall hire or use any person under [specify age, as above] years of age to sell any tobacco product or to handle any tobacco product.

1 **42. Prohibition on self-service displays.** No person shall sell any tobacco
2 product in such a way that a consumer may handle the product without
3 the assistance of a sales clerk or other employee or agent of the seller prior
4 to purchase.

5
6 **43. Prohibition on public displays.** No person shall display tobacco products
7 in such a way that they are visible to the public; provided, however, that
8 the provisions of this section prohibiting public displays of tobacco products
9 shall not apply to individuals incidentally displaying tobacco products during
10 carrying or use.

11
12 [If it will not be politically possible to ban the public display of tobacco products
13 by sellers, the following provision may be adopted as an alternative, though
14 absent an outright ban on public displays, the tobacco industry likely will find a
15 way around restrictions:]

16
17 *43. Prohibition on tobacco product displays as advertisements. No person*
18 *shall display tobacco product packages in such a way that the packages*
19 *convey a selling message or otherwise constitute an advertisement.*
20 *Additionally, any display of any tobacco product packages shall be*
21 *accompanied by a sign carrying prescribed messages, as prescribed in*
22 *implementing regulations.*

23
24 **44. Prohibition on vending machines, Internet, and certain other sales**
25 **of tobacco products.** No person shall sell any tobacco product through any
26 self-service means, including through automatic vending machines, through
27 the mail or the Internet. The Minister [or other governing authority] may prohibit
28 any other means of sale where the age of the purchaser of the tobacco product
29 cannot be verified reliably.

30
31 **45. Prohibition on sales of tobacco products in certain places.** No person
32 shall sell tobacco products in any of the following places: facilities where health
33 care services are provided; sports, athletic, or recreational facilities; government
34 buildings; educational facilities; and any other place prescribed by the Minister
35 [or other governing authority] in implementing regulations.

36
37 **46. Prohibition on toy or candy cigarettes.** No person shall manufacture, sell,
38 display for sale, or supply any sweets, snacks, toys, or other non-tobacco items
39 or objects in the form of tobacco products, or which imitate tobacco products.

40
41 **47. Ministerial discretion to address requirements of this Part.**

42 The Minister [or other governing authority] shall have the authority to prescribe
43 in implementing regulations additional and/or more stringent requirements
44 than any of those prescribed in this Part.

45
46 **48. Effect on other laws.** Nothing in this Act shall affect the ability of any other
47 level of government to enact laws or regulations addressing the sale or supply of
48 tobacco and related products, so long as such laws or regulations are at least
49 as stringent as, and they do not conflict with, the provisions of this Part.

50

Part 10: Tobacco Product Requirements

49. Regulation of tobacco products. The Minister [or other governing authority] shall have the authority to prescribe, in implementing regulations, requirements and standards for tobacco product constituents, including emissions of smoked products, additives, and product design, and to specify methods for testing and measuring compliance with the performance standards and requirements prescribed.

50. Compliance with standards. No person shall manufacture, import, export, supply, or sell any tobacco product unless it conforms to requirements and standards prescribed in this Act and implementing regulations.

51. Filter demarcation on smoked tobacco products. The area of any filter containing ventilation holes shall be marked and shall be clearly visible to the smoker, as follows:

- a. there shall be bands of color on each side of the area containing the ventilation holes;
- b. the color of the bands shall clearly contrast with the area of the filter or rod containing the ventilation holes;
- c. the ventilation holes shall be in the form of, or be surrounded by, raised dots that can be felt by the lips and fingers of the smoker; and
- d. filter demarcation shall comply with any additional requirements prescribed by the Minister [or other governing authority] in implementing regulations.

52. Tobacco product research. All tobacco product research conducted by any tobacco manufacturer, or by any person conducting research paid for in whole or in part by a tobacco manufacturer, shall be made available to and/or reported to the Minister [or other governing authority], as required by the Minister [or other governing authority].

53. Prohibition on health claims. No tobacco product package [or advertisement, if advertising still will be permitted] may make any claim stating, suggesting, or implying that its use or exposure to its smoke is not hazardous or is less hazardous than other tobacco products or brands, unless authorized by the Minister [or other governing authority] after he or she is satisfied that the claim is accurate upon a showing of scientifically competent and reliable evidence, including:

- a. evidence demonstrating that the product will significantly reduce harm to the individual tobacco user;
- b. evidence that the product will benefit the health of the population as a whole, taking into account the increased or decreased likelihood that current tobacco users would delay or avoid quitting or that non-tobacco users might initiate tobacco use; and
- c. any other considerations deemed appropriate by the Minister [or other governing authority].

1 **54. Product standards for exported products.** Notwithstanding
2 the provisions of this Part, tobacco products that will be exported from [\[specify](#)
3 [name of country\]](#) shall be required to meet the product and testing standards of
4 the country of final destination; in the event, however, that such standards
5 in the country of destination do not exist, the provisions in this Part
6 and in implementing regulations shall apply fully. To the extent standards
7 in the country of destination exist but are less protective of human health,
8 the more protective standards of this Part shall apply.

9
10 **55. Evaluation for disparate effects.** The Minister [\[or other governing](#)
11 [authority\]](#) shall determine whether the provisions of the Act and any
12 implementing regulations regulating tobacco product composition and design
13 result in equal levels of protection across all population groups. In the event
14 disparities in the level of afforded protection are found, the Minister [\[or other](#)
15 [governing authority\]](#) shall report such findings to the [\[specify, e.g., name of](#)
16 [legislative body\]](#) and remedial regulatory action shall be taken as appropriate.

17
18 **56. Ministerial discretion to address requirements of this Part.**

19 The Minister [\[or other governing authority\]](#) shall have the authority to prescribe
20 in implementing regulations additional and/or more stringent requirements
21 than any of those prescribed in this Part.

22
23 **57. Effect on other laws.** Nothing in this Act shall affect the ability of any other
24 level of government to enact laws or regulations addressing tobacco product
25 requirements and their testing, so long as such laws or regulations are at least
26 as stringent as, and do not conflict with, the provisions of this Part.

27
28 **Part 11: Reporting**
29

30
31 **58. Reports of constituents, additives, and certain business information.**

32 Every manufacturer and importer of tobacco products shall submit to the Minister
33 [\[or other governing authority\]](#) on at least a [\[specify frequency\]](#) basis, beginning
34 [\[specify beginning date\]](#), unless otherwise prescribed in implementing
35 regulations to be more frequent, reports containing the information required by
36 this Part, as well as any other information the Minister [\[or other governing](#)
37 [authority\]](#) may prescribe in implementing regulations. Such reports shall be
38 submitted in the form and manner prescribed.

39
40 **59. Information required in reports.** Reports shall identify and list, by brand,
41 for every brand of smoked and smokeless tobacco product of the manufacturer
42 and importer that is manufactured, imported into, sold, or offered for sale in
43 [\[specify name of country\]](#), or exported from [\[specify name of country\]](#) during the
44 preceding reporting period, the following:

45
46 [Note: This section contemplates that the provisions in Part 7 prohibiting the free
47 supply of tobacco products, such as samples and gifts, will be included in
48 the legislation being developed. If they will not be, it will be necessary to speak
49 in terms of "sold, offered for sale, or supplied" in the preceding sentence.]
50

- a. measures of tar, nicotine, and proportion of unbound nicotine in smoke;
- b. pH of whole smoke and puff-by-puff pH profile;
- c. filter efficiency and percentage ventilation of filters;
- d. and all other individual constituents, additives, and yields of constituents and additives in smoke, unless otherwise specified in implementing regulations, expressed in their individual concentrations and as a ratio to nicotine, or as otherwise required in implementing regulations.

60. Product preparation and testing. Reports shall be made on the basis of products prepared and tested in accordance with the method(s) prescribed in implementing regulations.

61. Reports for new products. No tobacco product or brand that has not previously been offered for sale or sold in [specify name of country] prior to the date this Act comes into operation shall be sold or offered for sale until all required reports for that brand have been submitted.

[Note: This section contemplates that the provisions in Part 7 prohibiting the free supply of tobacco products, such as samples and gifts, will be included in the legislation being developed. If they will not be, it will be necessary to speak in terms of “sold, offered for sale, or supplied” in the preceding sentence.]

62. Additional information required. In addition to the other reporting requirements of this Part, every manufacturer, importer, and exporter of tobacco products shall submit to the Minister [or other governing authority] in a prescribed manner on at least a [specify frequency], basis beginning [specify date], unless otherwise prescribed in implementing regulations to be more frequent, reports containing the following information, as well as any other information the Minister [or other governing authority] may prescribe in implementing regulations:

- a. the number of packages and the number of sticks, or as applicable the number of grams of smokeless product, of each brand of each tobacco product manufactured, imported, exported, and sold, as applicable, during the reporting period; provided that sales data shall be reported with respect to aggregate sales to the entire population, by brand, and with respect to sales, by brand, to distinct population groups;
- b. for exported products:
 - i. export volumes for each brand, by country of destination and by wholesaler;
 - ii. a list of the countries of final destination and a list of the countries through which the products are transported, correlated with serial numbers;
 - iii. the number of packages and sticks or grams, as applicable, in each shipment for export; and
 - iv. the dates on which the products, by serial number, were shipped;

- 1 c. for imported products:
- 2 I. import volumes for each brand, by country of origin and by wholesaler;
- 3 II. a list of the countries through which the products are transported,
- 4 correlated with serial numbers;
- 5 III. the number of packages and sticks or grams, as applicable, in each
- 6 shipment imported; and
- 7 IV. the dates on which the products, by serial number, were received;
- 8
- 9 d. prices charged for the tobacco products, by brand, along with the dates
- 10 and amounts of any price increases during the reporting period;
- 11
- 12 e. disclosure, by date, of the amount of all contributions, loans,
- 13 or other payments, and the value of all gifts made to any elected
- 14 or appointed government official or government entity, and to any political
- 15 party during the reporting period;
- 16
- 17 f. copies of audited financial statements made during the reporting period;
- 18
- 19 g. copies of all tobacco product packaging and labelling, including any
- 20 required package inserts;
- 21
- 22 h. a description of all marketing activities and, as applicable, copies of
- 23 all marketing materials, correlated with expenditures by brand of tobacco
- 24 product, and correlated with each distinct population group for which
- 25 such activities, materials, and expenditures are intended;
- 26 i. [\[specify any other\]](#); and
- 27
- 28 j. any other information required by the Minister [\[or other governing authority\]](#)
- 29 in implementing regulations.
- 30

31 **63. Disclosure of reports.** Reports required under this Part and

32 in implementing regulations shall be public information. Reports shall be published

33 by the government in the Gazette [\[or specify other official publication\]](#).

34

35 **64. Form and manner of reports.** Reports required by this Part shall be

36 submitted in the form and manner prescribed, and shall include all information

37 required by this Part and in implementing regulations.

38

39 **65. Ministerial discretion to address requirements of this Part.**

40 The Minister [\[or other governing authority\]](#) shall have the authority to prescribe

41 in implementing regulations additional and/or more stringent requirements

42 than any of those prescribed in this Part.

43

44 **66. Effect on other laws.** Nothing in this Act shall affect the ability of

45 any other level of government to enact laws or regulations addressing tobacco

46 product or business reporting.

47

48

49

50

Part 12: Anti-Smuggling Measures

67. Collection of taxes at manufacture and import. No tobacco products manufactured in [specify name of country] and produced for domestic consumption shall be removed from their place of manufacture prior to the payment of all applicable taxes and duties. No imported tobacco products shall be removed from their place of import without proof that all applicable taxes and duties have been paid.

68. Bond requirements for exported tobacco products.

- a. No tobacco products manufactured in [specify name of country] and produced for export shall be removed from their place of manufacture or exported without payment of an export bond; provided, however, that tobacco products for export may be transferred from the place of manufacture to a bonded facility, under payment of a transfer bond, prior to export. The bond shall be payable to the [specify Ministry or agency] in an amount [describe how the bond amount will be determined] and shall be accompanied with the following information and, as specified, documents:
- 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 from which the products were exported;
 - III. the name, license number, address, telephone, and telefax numbers of all importers/purchasers, and of any persons who receive the shipment on the importers'/purchasers' behalf;
 - IV. the name, address, telephone, and telefax numbers of all intended carriers of the shipment, and the means of transport;
 - V. the names of all cities and countries through which the shipment will be transported;
 - VI. identification of the country of final destination;
 - VII. information on the approximate number of users in the country of destination of each of the brands being shipped and a complete description of the sources of this information;
 - VIII. the name, license number, address, telephone, and telefax numbers of any distributors and other intermediaries handling the shipment;
 - IX. 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;
 - X. physical description of the products (e.g., cigarettes, cigars, bidis, smokeless tobacco, etc.) shipped, including brands and serial numbers of all products contained in the shipment;
 - XI. number of individual packages; number of sticks in each package or gram amount, as applicable; number of cartons and number of packages in each carton; number of bulk packages; number of individual packages or cartons contained in each bulk package; and the weight of each bulk package contained in the shipment;

- 1 XII. copies of all purchase orders, invoices, shipping or transport,
2 and transit documents related to the shipment;
- 3 XIII. copies of tax stamps and a description of special markings and design
4 features on packages contained in the shipment;
- 5 XIV. an affidavit of the manufacturer and exporter stating that:
- 6 i. he or she has exhausted all reasonable means to investigate
7 the degree of demand for the products in the country of destination
8 and determined that there is legitimate demand there for
9 the number of products ordered and shipped, along with
10 a description of the means used to investigate the demand in
11 the country of destination, in addition to obtaining the information
12 required in subsection (vii);
- 13 ii. there is no substantial basis for believing that any person receiving
14 or handling the shipment has been or is involved in illegal
15 commercial activity or that the products will be sold illegally;
- 16 iii. he or she has complied with all labelling and other legal
17 requirements;
- 18 iv. information and documents supplied are true and correct to
19 the best of his or her knowledge;
- 20
- 21 b. The bond made pursuant to subsection (a) shall be forfeited unless
22 the manufacturer or exporter, as applicable, provides [\[specify Ministry
23 or agency\]](#) with the following information within [\[specify number\]](#) days of
24 [\[specify triggering event \(e.g., the date the goods are shipped\)\]](#):
- 25 i. evidence of the chain of custody and proof that all goods reached
26 their final destination without any product being sold or distributed
27 without the full payment of all applicable duties and taxes, including
28 but not limited to:
- 29 i. copies of all bills of lading or other evidence of receipt by
30 all importers and intermediaries;
- 31 ii. proof of payment of all applicable duties and taxes;
- 32 iii. copies of invoices received from any intermediaries handling
33 the shipment;
- 34 iv. copies of delivery records;
- 35 v. copies of all payment records;
- 36 vi. [\[specify any other\]](#);
- 37 vii. and any other information required by the Minister [\[or other
38 governing authority\]](#) in implementing regulations.

69. Ministerial discretion to address requirements of this Part.

41 The Minister [\[or other governing authority\]](#) shall have the authority to prescribe
42 in implementing regulations additional and/or more stringent requirements than
43 any of those prescribed in this Part.

45 **70. Protection for employees.** No person shall retaliate or attempt to retaliate
46 in any way against any employee who notifies government authorities
47 or who testifies in court regarding any activity on the part of his or her employer
48 that violates or allegedly violates any provision of this Part, Part 8, Part 11,
49 or of any applicable law imposing taxes or duties.

50

Part 13: Inspections and Investigations

71. Identification of authorized officers. While carrying out official duties, authorized officers shall present proof of identity and/or of their appointment if requested by the person being inspected or investigated.

72. Inspection and investigative Powers. Authorized officers shall have the following powers, which no person shall deny, obstruct, or hinder, and which no authorized officer shall abuse or use for his or her own financial or personal gain:

- a. to enter the premises of any place where tobacco is manufactured, sold, transported, received, distributed, supplied, or otherwise found or is likely to be found, or to have been present during the previous [specify time] period. For the purposes of enforcing Part 6 of this Act, authorized officers shall have the right to enter any public place, including workplace, and any place of collective use, to conduct inspections or investigations at any time during business or operating hours or at any other reasonable or necessary time;
- b. 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, including packaging and labelling, storage, distribution, or advertising or promotion of tobacco products, manufacturers or sellers;
- c. to examine any manufacturing operation or process carried out on the premises;
- d. 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 the provisions of this Act and implementing regulations and any other applicable law, including laws and regulations imposing duties or taxes;
- e. to interview any person the officer believes may have information relevant to making a compliance determination;
- f. to take samples of tobacco products or components of products, and their packaging, anywhere they are found, and have them tested;
- g. 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 or were contained or conveyed, and examine, open, and take samples of them;

- 1 h. to seize and detain, or order the storage without removal or alteration of,
2 any tobacco product or other thing the authorized officer reasonably
3 believes does not comply with the provisions of this Act or implementing
4 regulations and any other applicable law, including laws and regulations
5 imposing duties or taxes; provided, however, that the officer shall first
6 provide the licensee or owner of the tobacco products or other things,
7 or if he or she is unavailable, any other person on the premises where
8 the tobacco products or other things are located, with written notice of
9 the seizure and detention and the grounds for it. If any tobacco product
10 or other thing so seized and detained is determined to meet legal
11 requirements, it shall be returned to the premises from which it was seized
12 within [specify number] business days from the date it is determined to
13 meet legal requirements, unless it is needed as evidence in a legal
14 proceeding. If any tobacco product or other thing is determined not to
15 meet legal requirements, it may be confiscated and destroyed or subject to
16 other disposal, as ordered by the adjudicator of the case, subject to
17 any appeal rights that may be applicable; and
- 18
- 19 i. to take any other action reasonable or necessary for the effective
20 and efficient administration of this Act.
- 21

22 **73. Inspection and investigation reports.** Inspection and investigation
23 reports, and documents collected pursuant to inspections and investigations,
24 shall be public information once the inspection or investigation has concluded;
25 provided, however, that the person that is the subject of the inspection
26 or investigation may apply to [specify who would hear the petition, e.g.,
27 the Minister [or other governing authority] or a court of competent jurisdiction]
28 for an order to protect the confidentiality of any trade secrets or the privacy
29 or confidentiality of any personal information that it demonstrates are contained
30 in the records.

31

32 **74. Subpoena power.** The Minister [or other governing authority] shall have
33 the power to require by subpoena the attendance and testimony of witnesses
34 and the production of any documentary or other evidence related to any matter
35 under investigation.

36

37 **Part 14: Enforcement**

38

39

40 **75. Sanctions for non-compliance.** The Minister [or other governing authority]
41 shall ensure the diligent enforcement of this Act.

42

- 43 a. **Civil penalties.** In any civil action for non-compliance with any provision of
44 this or any applicable law and regulations, including any law or regulation
45 imposing duties or taxes [if this does not fall within the exclusive
46 jurisdiction of the customs authority or Ministry of Finance], the following
47 penalties may be imposed, singly or in combination, as determined by
48 the Minister [or other governing authority] in his or her [or its] discretion,
49 unless otherwise specified:
- 50

- I. licensure suspension, revocation, or limitation; 1
- II. fines in accordance with Schedule 1; provided, however, 2
that the imposition of spot fines or tickets shall be authorized; 3
provided further, that the imposition of spot fines or tickets shall not 4
prejudice the right to appeal; 5
- III. adverse publicity; provided that the form and content of the publicity 6
and media vehicle used shall be determined by the Minister [or other 7
governing authority], and the cost of the publicity shall be borne 8
by the person found to be in violation; 9
- IV. removal by an authorized officer of an offending person from 10
the premises or public conveyance, and confiscation and forfeiture of 11
any tobacco products, for smoking in violation of the provisions of 12
Part 6 (Protection from Tobacco Smoke); and 13
- V. confiscation and forfeiture, including, where appropriate, destruction, 14
using environmentally-friendly methods where feasible, of: 15
 - i. any item that contains a tobacco advertisement and any 16
promotional item prohibited under Part 7: Advertising, Sponsorship, 17
and Other Forms of Promotion, regardless of the knowledge 18
or intent of the person who owns or possesses such products; 19
 - ii. any tobacco product packaged or labelled in a manner that does 20
not conform to the requirements of Part 8: Tobacco Product 21
Packaging and Labelling or Part 12: Anti-Smuggling Measures, 22
wherever they may be located and regardless of the knowledge 23
or intent of the person who owns or possesses such products, 24
and any equipment, machinery, materials, and related items used to 25
evade the requirements of those Parts; 26
 - iii. any and all tobacco products owned by or under the control of 27
the person found to have committed a violation of Part 9: Sales 28
and Distribution; 29
 - iv. equipment, machinery, raw materials, components, packaging 30
and labelling materials, and any other items used to manufacture 31
tobacco products in violation of Part 10: Product Requirements 32
or Part 12: Anti-Smuggling Measures; 33
 - v. any and all tobacco products or components that fail to conform to 34
the requirements of Part 10: Product Requirements, including 35
forfeiture of any tobacco product located anywhere in the country 36
that does not comply, regardless of the owner's intent 37
or knowledge of its noncompliant status; 38
 - vi. any and all tobacco products for which all applicable taxes and 39
duties have not been paid or that otherwise have not legally entered 40
the country of destination; and 41
 - vii. removal from office, in addition to any other applicable penalty, and 42
referral for criminal prosecution, of any authorized officer or other 43
government official who uses his or her office or authority to 44
undermine the effective and efficient administration of this Act with 45
the purpose of obtaining financial or personal gain. 46

1 **b. Continuing violations.** For any continuing violation, each day the violation
2 continues shall constitute a separate offence.

3
4 **c. Repeat violations.**
5 Escalating penalties shall be imposed for repeat violations.
6

7 **d. Forfeiture of ill-gotten gains.** Where any person derived any monetary
8 or financial benefit directly or indirectly from any act or omission that
9 constitutes a violation under this Act or implementing regulations or other
10 applicable law, including any law imposing duties or taxes, all proceeds
11 so gained shall be forfeited in addition to any other penalty imposed.
12

13 **e. Liability of corporate officers.** Where the person committing
14 any violation is a corporate director or officer who authorized or
15 acquiesced in the act, or who knew or, using due diligence,
16 should have known of the commission or omission of the act constituting
17 the violation, he or she shall be held liable. In addition, a corporation
18 may be held liable as a corporate person.
19

20 **f. Strict liability for illicit trade.** Any person who domestically manufactures
21 or supplies tobacco products shall be held strictly liable for any of its
22 exported products that do not legally enter the designated country of
23 destination or that later are found to have escaped payment of all
24 applicable taxes and duties or to otherwise be contraband goods.
25

26 **76. Statute of limitations.** The applicable statute of limitations for any violation
27 of this Act or implementing regulations shall be [specify period] years from
28 the date of the act or omission constituting the violation, or from the discovery of
29 the act or omission constituting a violation. [It may be necessary to have different
30 statute of limitation periods for violations of different Parts, or even for different
31 provisions within a Part. For more serious violations, it may be advisable to provide
32 that there is no limitation period for the commencement of an enforcement action.]
33

34 **77. Civil enforcement proceedings.** Any person charged with violating
35 this Act or implementing regulations shall be entitled to a hearing before
36 the Ministry [or court of competent jurisdiction].

37 **a. Right to notice.** Prior to imposing any penalty, the Ministry [or prosecutor,
38 if a proceeding must be initiated in court rather than administratively]
39 first shall provide the person accused of violating any provision of the Act
40 or implementing regulation, or any other applicable act, including a law
41 or regulations imposing excise duties or taxes [if this does not fall within
42 the exclusive jurisdiction of the customs authority or Ministry of Finance],
43 with written notice of all alleged violations, the sanctions to be imposed,
44 the dates sanctions will become effective, and the right to contest
45 the charges in an administrative hearing [or in a court of competent
46 jurisdiction, if required].
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- b. **Waiver.** If no such hearing is requested by the accused in writing within the time period specified in the notice for doing so, the accused shall be deemed to have waived his or her right to a hearing, and any right to appeal, and the proposed sanction may be executed within [specify period].
- c. **Governing rules.** If a hearing is requested, it shall be held in accordance with all applicable requirements of [specify any governing legal authority, e.g. Rules of Court, or, if none exists, it will be necessary to prescribe requirements in implementing regulations], and the standard of proof shall be by [specify the applicable standard of proof, preponderance of the evidence, if that is an appropriate standard]. In any hearing under this section, the following shall apply:
- I. an affidavit or certification under oath by a laboratory analyst who tested any tobacco product or component which is the subject of the proceedings shall be admissible on its mere production as *prima facie* proof of the violations shown by the examination or analysis of the tobacco product or component; provided, however, that the accused shall be notified in writing in advance of the intent to produce such an affidavit or certification and shall have the right to compel the analyst's presence at the hearing or to cross-examine him or her in advance of the hearing and offer this testimony into evidence at the hearing;
 - II. copies from any record, book, or document certified by the Ministry as true and correct copies shall be deemed admissible into evidence as authentic;
 - III. where any tobacco product or component is found in or on any premises used for the manufacture, import, export, distribution, supply, or sale of such products, such product or component shall be presumed to be intended for manufacture, import, export, packaging, distribution, or sale, respectively;
 - IV. any tobacco product from the same lot or batch shall be presumed to possess the same characteristics as those products from the same lot or batch found on the premises or at another location under the control of the owner or operator of the premises; provided, however that if there is no lot or batch number on the products, as required under the Act, any tobacco product found on the premises shall be presumed to possess the same characteristics as other tobacco products found on the premises or at another location under the control of the owner or operator of the premises.
 - v. the person identified on the label or packaging of any tobacco product as the manufacturer, importer, exporter, distributor, or seller shall be presumed to have manufactured, imported, distributed or sold the tobacco product, respectively.

1 **78. Right to appeal.** Any person found in a hearing before the Ministry to have
2 violated any provision of this Act or implementing regulations, or any other
3 applicable law, including laws and regulations imposing excise duties or taxes
4 [if this does not fall within the exclusive jurisdiction of the customs authority
5 or Ministry of Finance], shall have a right to appeal the findings before [specify
6 the appropriate judicial body], provided a notice of appeal is filed as required.
7 [Note: if there is a law governing appeals, it should be referenced in this section.]
8

9 **79. Enforcement cost recovery.** Any person found to have violated
10 any requirement under this Act or implementing regulations, or any other
11 applicable law, including laws and regulations imposing duties or taxes
12 [if this does not fall within the exclusive jurisdiction of the customs authority
13 or Ministry of Finance], may be ordered to pay all reasonable costs
14 associated with any investigation and enforcement action brought about
15 by the non-compliance.
16

17 **80. Criminal enforcement.** Nothing provided in this Act shall preclude
18 the criminal enforcement of any of its provisions in a Court of competent
19 jurisdiction. [If appropriate, provide for applicable criminal penalties; otherwise,
20 it may be necessary to amend the criminal law to cover non-compliance
21 with the tobacco control law.]
22

23 **81. General right of action for violation of provisions of the Act.**

24 Any person may commence a civil action before the appropriate Court against
25 any person, including any governmental official or agency or other body, who
26 or which is alleged to have violated any of the provisions of this Act.
27 It shall not be necessary for the plaintiff to show that he or she has been harmed
28 by the alleged violation or has any special interest in the suit, save for
29 the enforcement of this Act.
30

- 31 **a. Exemption from filing fees.** Any action instituted under the provisions of
32 this section shall be exempt from any Court filing fees.
33
- 34 **b. Cost recovery.** Where it is established that the action brought under
35 this section asserts one or more colorable claims and is designed to
36 effectuate strong public policies and benefit to the public, the plaintiff
37 shall be entitled to recover the costs of the action, including reasonable
38 attorneys' fees.
39
- 40 **c. Statutory damages.** In cases where the plaintiff is successful, statutory
41 damages in a amount up to [specify amount] may be awarded; provided,
42 however, that statutory damages shall not be available against
43 a government official performing a discretionary function in good faith.
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Part 15: Recovery of damages

82. Direct cause of action accruing to the government. The government of [specify name of country] shall have a direct cause of action against a manufacturer of any tobacco product sold in [specify name of country] to recover the costs of health care services provided or funded by the government in whole or part to any person on account of any tobacco-related illness or at the risk of suffering from any tobacco related illness.

- a. **Government right to recover.** Such action may be brought by the government in its own right and not on the basis of a subrogated claim, and any recovery by the government shall not be affected by the recovery of damages by any other persons who have suffered damage caused or contributed to by a tobacco-related illness.
- b. **Recovery on an aggregate basis.** The government shall be entitled to recover the cost of health care services provided to particular individuals on an aggregate basis for a population of persons on account of any tobacco-related illnesses or at the risk of suffering from any tobacco related illness.
- c. **Proof required.** To recover the costs of health care services on an aggregate basis, the government shall prove by a preponderance of the evidence [or specify other legal standard] that:
 - i. the defendant breached a common law, equitable, statutory or other duty or obligation owed to persons in [specify name of country] who have used tobacco or have been exposed to tobacco smoke, or who might use any particular tobacco product or become exposed to its smoke;
 - ii. such use or exposure can cause or contribute to illness or disease; and
 - iii. during all or part of the period of breach of duty, the type of tobacco product manufactured by the defendant was offered for sale in [specify name of country].
- d. **Presumptions.** In an action to recover the costs of health care services on an aggregate basis, there shall be a rebuttable presumption that use of tobacco or exposure to its smoke by any person in the population would not have occurred but for the defendant's breach of duty and that the use or exposure caused or contributed to illness or disease or the risk of illness or disease in a portion of the population.
- e. **Individualized proof.** For the government to seek recovery of the cost of health care services on an aggregate basis, it shall not be necessary to:
 - i. identify particular individuals who received health care services on account of a tobacco-related illness or because of the risk of suffering from a tobacco-related illness;
 - ii. prove the cause of the tobacco-related illness in any particular individual; and
 - iii. prove the cost or value of health care services provided to any particular individual on account of a tobacco-related illness.

1 **f. Individualized records.** In an action by the government on an aggregate
2 basis, the health care records, treatment records, records showing
3 the costs of health care services provided, and related documents
4 pertaining to particular individuals shall not be compellable, unless such
5 documents are relied upon by an expert witness for the government;
6 provided, however, that a court may order discovery of a statistically
7 meaningful sample of documents upon application by a defendant;
8 provided, further, that such order shall provide direction on the nature,
9 level of detail, and type of information to be disclosed while also providing
10 that any information that identifies or potentially identifies particular
11 individuals shall first be deleted if determined appropriate by the Court.

12
13 **g. Individual testimony.** In an action by the government on an aggregate
14 basis, no person shall be compelled to answer questions with respect to
15 the health of, or provision of health care services to, any particular
16 individual provided health care services on account of a tobacco-related
17 illness or because of the risk of suffering from a tobacco-related illness;
18 provided, however, that a court may order discovery of a statistically
19 meaningful sample of documents upon application by a defendant,
20 and such order shall provide direction on the nature, level of detail,
21 and type of information to be disclosed, while further providing that any
22 information that identifies or potentially identifies particular individuals
23 shall first be deleted if determined appropriate by the Court.

24
25 **h. Statistical and related information.** Statistical information and
26 information derived from epidemiological, sociological, and other relevant
27 scientific studies, including information derived from sampling, is
28 admissible as evidence for the purposes of establishing causation and
29 quantifying damages or the costs of health care services in relation to any
30 action brought by the government, or by an individual on his or her own
31 behalf or as member of a class of plaintiffs suffering from a tobacco-related
32 illness, or at risk of suffering from a tobacco-related illness.

33
34 **i. Defendants' portion of liability.**

- 35 I. In the case of more than one defendant, there shall be a rebuttable
36 presumption that each defendant's portion of liability in relation to
37 the aggregate amount of damages is equal to its average market
38 share in the type of tobacco product that is the subject of the litigation;
39 provided, however, that each defendant shall remain jointly
40 and severally liable for any damages recovered.
- 41 II. In the event there has been a change of ownership in any tobacco
42 company during the time period in which damages were alleged to
43 have accrued, and the previous owner was the government,
44 the new owner shall have a right to offset any damages that accrued
45 and that can be attributed to the government during the period of
46 government ownership.
- 47
48
49
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83. Private Right of Action by individuals and classes of individuals.

Any person harmed by tobacco use or exposure to tobacco smoke, or who is at risk of suffering from a tobacco-related illness, shall have a cause of action against the manufacturer of the product that caused or contributed to the harm or the risk of harm. Any such action may be brought by the individual on his or her own behalf, or on behalf of an affected class of individuals. In any such action, the following shall apply:

- a. **Capacity of young tobacco users.** There shall be an irrebuttable presumption that a plaintiff who began using a tobacco product before attaining the age of [specify age of majority or other age] years lacked the capacity to understand, consent to, or assume any risk associated with using the product, even if he or she was provided by any person with information about the risks of using tobacco. Any proffered evidence or legal argument by any defendant that the plaintiff assumed the risk, was contributorily negligent, or should be not be entitled to recovery under any similar theory, shall be inadmissible if the Plaintiff proves, by a preponderance of the evidence, that:
 - i. he or she started using tobacco before he or she reached the age of [specify age of majority or other age] years; and
 - ii. he or she made a reasonable effort, as determined by the trier of fact, to quit at some time during his or her period of use. In considering the question of whether a reasonable effort to quit was made, the highly addictive nature of tobacco products shall be taken into account.
- b. **Effect of advertising and promotion.** If any plaintiff proves by a preponderance of the evidence that he or she was exposed to and was aware of any tobacco-related advertising or other forms of promotion during his or her time of tobacco use, there shall be a rebuttable presumption that his or her ability to understand and incorporate fully the true risks of using tobacco was undermined by the tobacco-related advertising and promotion. For any plaintiff for which a presumption under this subsection is not successfully rebutted, a claim of assumption of the risk, contributory negligence, or other similar legal argument denying entitlement to recover damages shall not defeat a claim for damages.
- c. **“Low tar” tobacco products.** There shall be an irrebuttable presumption that any person who used a tobacco product described or implied by its label, design, or otherwise, or in advertising, to be “low tar”, “light”, “mild”, or of a similar nature, was deceived or misled into thinking that use of that product was safer or less harmful than using a full strength tobacco product.
- d. **Admissibility of statistical information.** Statistical information and information derived from epidemiological, sociological, and other relevant studies, including information derived from sampling, shall be admissible as evidence for the purposes of establishing causation and quantifying damages, and for supporting any evidence submitted by the plaintiff under subsections (a) through (c).

1 e. **Defendants' portion of liability.** In the case of more than one defendant,
2 there shall be a rebuttable presumption that each defendant's portion of
3 liability in relation to the aggregate amount of damages is equal to
4 the proportion of its tobacco products used by the plaintiff; provided,
5 however, that each defendant shall be jointly and severally liable for any
6 damages recovered, as long as more than a *deminimis* quantity of
7 the defendant's tobacco products were used by the plaintiff.
8

9 **84. Ministerial discretion to address requirements of this Part.**

10 The Minister [or other governing authority] shall have the authority to prescribe in
11 implementing regulations additional and/or more stringent requirements
12 than any of those prescribed in this Part.
13

14 **85. Effect on other laws.** Nothing in this Act shall affect the ability of any
15 other level of government to enact laws or regulations addressing recovery of
16 damages for tobacco-related harm, so long as they do not conflict with
17 the provisions of this Part.
18

19
20 **Part 16: Public Education, Awareness**
21 **and Cessation programmes**
22

23 **86. Public awareness, education, and cessation programs.** The Minister
24 [and/or national coordinating body or other governing authority] shall establish
25 and carry out evidence-based programs to inform the public of: the dangers
26 and addictiveness of tobacco use and of exposure to tobacco smoke;
27 the benefits of and strategies for quitting; information on the tobacco industry
28 and on the health, economic, and environmental effects of tobacco production
29 and manufacturing; and such other information as he or she determines to be
30 effective in mitigating against the health effects, social, and environmental costs
31 of tobacco, and for increasing public and consumer awareness of pertinent
32 tobacco-related issues. The Minister [or other governing authority] shall make
33 public awareness, educational, and cessation materials available to provincial
34 and local governments, health care workers and facilities, schools,
35 the media, and such other entities the Minister [or other governing authority]
36 deems appropriate.

- 37 a. **Requirement for evidence-based, populations-based educational**
38 **programs.** In carrying out such programs, the Minister [or other governing
39 authority] shall develop evidence-based educational programs and
40 materials appropriate to the population at large and to priority populations.
41 b. **Requirement for evidence-based, populations-based cessation**
42 **programs.** The Minister [or other governing authority] shall establish
43 and carry out evidence-based tobacco use cessation programs, including
44 diagnosis, counselling, and treatment services, and, as appropriate, access
45 to nicotine replacement therapies.
46

47 **87. Effect on other laws.** Nothing in this Act shall affect the ability of any
48 other level of government to enact laws or regulations addressing public education,
49 awareness, or cessation programmes.
50

Part 17: Concluding Clauses

88. Severability. In the event any provision of this Act is found by a Court of competent jurisdiction to be unconstitutional, illegal, or otherwise invalid, the remaining provisions shall remain in full force and effect.

Taxation

Schedule

Goods and products [Specify each type of tobacco product]	Specific [or ad valorem] excise tax rate [specify amount (or %) and currency] per [specify unit or weight (or value)] for each type of tobacco product
-----------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------

1. Automatic adjustment to keep pace with inflation and increased earnings. Excise tax amounts shall be adjusted automatically to account for inflation, as measured by the consumer price index, and for increases in earnings. The Minister of Finance [or other appropriate governing authority] shall have authority to remove tobacco products from the consumer price index.

2. Dedication of tobacco product excise taxes to tobacco prevention and control. [Specify %] of excise tax revenues collected on tobacco products shall be marked as dedicated funds for use by the Ministry of Health [or other authority] for tobacco prevention and control, which may include the administration of tobacco control laws.

3. Prohibition on duty-free sales. Full duties and taxes shall be collected on all tobacco products and duty-free and duty-reduced sales of any tobacco product shall be prohibited.

Tabacco subsidies

1. Elimination and prohibition of tobacco subsidies. Any subsidies to tobacco farmers or manufacturers shall be eliminated effective [specify date, possibly allowing reductions in subsidy amounts over time in order to allow for a transition period], and tobacco subsidies after that date shall be prohibited.

[Note: It also will be necessary to repeal any law providing financial support for the growing, importation or exportation of tobacco.]

Protection of the Environment

Protection of the Environment¹⁶²

1. Ameliorating the adverse effects of the use of chemicals in tobacco farming. The Minister [or other governing authority] shall take steps to ameliorate the adverse effects of chemical use in tobacco farming, including the following:

- a. **Training for farm workers.** The [specify appropriate governing authority] shall take measures to ensure that tobacco companies and other persons providing assistance to tobacco growers provide training to tobacco farm workers on the application of chemicals, including application methods and the use of protective clothing and equipment.
 - b. **Investment in alternatives to chemical use.** The [specify appropriate governing authority] shall take measures to ensure that tobacco companies and other persons providing assistance to tobacco growers invest in alternatives to chemical use and to prohibit the use of chemicals that may be harmful to humans or the environment.
 - c. **Monitoring the use of chemicals.** The [specify appropriate governing authority] shall monitor the use of chemicals in the tobacco growing process and may, for this purpose, require tobacco companies and other persons providing assistance to tobacco growers to give periodic reports on the use of chemicals in their growing processes.
- 2. Protection of forests.** The [specify appropriate governing authority] shall take measures to require tobacco leaf buying companies to invest in alternative technologies for tobacco curing that are not based on wood fuel. Each such company shall be required to carry out reforestation projects using indigenous species.
- 3. Environmental impact audits.** The [specify appropriate governing authority] shall require tobacco companies and other persons engaged in providing assistance to tobacco growers to undertake annual periodic environmental impact audits of the process of growing, curing and manufacturing of tobacco products, and to provide copies of the same to the Minister. The Minister shall make these audits available as public information.

Annex A

NO SMOKING Signs

1. Sign size, content and design. Pursuant to Part 6, owners or occupiers of enclosed public places, places of collective use, employers, as applicable, and operators of public conveyances shall ensure that No Smoking signs are posted and comply substantially with the following:

- a. **Size.** The signs shall be at least [specify size] cm. by [specify size] cm. in dimension.
- b. **Language.** The information displayed on the signs shall be printed in [specify language(s) required].
- c. **Text of message.** The text of the signs shall read as follows: [specify text and/or symbols, pictures, etc. and provide a telephone number or other contact information to report violations]
- d. **Font size.** Font shall be [specify size] point type for the text specified in Section 1(c).
- e. **Message placement.** The text required in Section 1(c) shall be placed at the [specify top, bottom, or middle] of the sign and shall cover [specify proportion] % of the sign. No other text or visual information shall appear on the signs, unless otherwise required or authorized in implementing regulations.
- f. **Placement of signs.** Signs shall be posted [specify where throughout the premises or conveyance].

2. Other requirements. [Specify other requirements, if any].

3. Ministerial authority. The Minister [or other governing authority] shall have the authority to enhance any requirement related to signage.

Schedule 1: Applicable Fines

Violation	Fine amount (per day for continuing violations)		
Part 6: Protection from Second Hand Smoke	1 st violation	2 nd violation	≥ 3 rd violation
Against:			
Owner/occupier/employer/ conveyance operator	[specify range]	[specify range]	[specify range]
Smoker	[specify range]	[specify range]	[specify range]
Part 7: Advertising, Sponsorship, and Promotion			
Against:			
Tobacco product manufacturer/seller	[specify range]	[specify range]	[specify range]
Any person participating in ad., sponsorship, or promotion	[specify range]	[specify range]	[specify range]

Part 8: Tobacco Product Labelling and Packaging

Against:

Tobacco product manufacturer	[specify range]	[specify range]	[specify range]
Commercial seller/purchaser	[specify range]	[specify range]	[specify range]

Part 9: Tobacco Product Sales

Against:

Commercial seller/distributor	[specify range]	[specify range]	[specify range]
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Part 10: Product Requirements

Against:

Tobacco product manufacturer	[specify range]	[specify range]	[specify range]
------------------------------	-----------------	-----------------	-----------------

Part 11: Reporting

Against:

Tobacco product manufacturer/importer	[specify range]	[specify range]	[specify range]
---------------------------------------	-----------------	-----------------	-----------------

Violation **Fine amount (per day for continuing violations)**

Part 12: Anti-Smuggling Measures, including provisions of Part 8 related to labelling for tracking tobacco products

Against:

Tobacco product manufacturer*	[specify range]	[specify range]	[specify range]
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*The fine shall be in the amount specified above or an amount equal to the amount [specify for e.g., 10 x the amount] the retail price including all taxes for the tobacco products, whichever is greater.

Any other person participating in the smuggling activity **	[specify range]	[specify range]	[specify range]
-------------------------------------------------------------	-----------------	-----------------	-----------------

** The fine shall be in the amount specified above or an amount equal to the amount [specify for e.g., 10 x the amount] the retail price including all taxes for the tobacco products, whichever is greater.

Part 13: Inspections and Investigations

Against:

Any person hindering or obstructing, supplying false information, etc.	[specify range]	[specify range]	[specify range]
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An authorized officer or other government official for abusing his or her authority	[specify range]	[specify range]	[specify range]
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Appendix 1

ESTABLISHMENT OF THE TOBACCO CONTROL BOARD

- 4.1 There is established a body to be known as the Tobacco Control Board.
- 4.2 The Board shall be a body corporate with perpetual succession and an official seal and may, for the discharge of its functions under this Act-
- a. acquire, hold and dispose of moveable and immovable property;
 - b. sue and be sued in its corporate name; and
 - c. do all acts and things which a body corporate may lawfully do.

5. Official Seal of the Board

- 5.1 The official seal of the Board shall be in a form determined by the Board.
- 5.2 The official seal shall, when affixed to any document, be authenticated by the signatures of the Executive Director and one other member of the Board.
- 5.3 In the absence of the Executive Director, the person performing the functions of the Executive Director shall sign.
- 5.4 An instrument or contract which if executed or entered into by a person other than a body corporate would not require to be under seal may be executed or entered into on behalf of the Board by the Executive Director, or by any member of the Board or any other person if that member of the Board or other person has been duly authorised by resolution of the Board to execute the instrument or enter into the contract as the case may be.
- 5.5 Every document purporting to be an instrument or contract executed or issued by or on behalf of the Board in accordance with this section shall be deemed to be so executed or issued until the contrary is proved.

6. Composition of Board

- 6.1 The Tobacco Control Board shall comprise five members, including a Chairperson and four other persons and shall be appointed by the President with the approval of Parliament.
- 6.2 The members of the Board shall be persons of eminent standing and good repute in society and with experience or qualifications in public health, law or social sciences.
- 6.3 The members of the Board shall hold office on a part-time basis for a term of three years and are eligible for re-appointment for one further term.

1 **6.4** The members of the Board shall hold office on terms and conditions
2 specified in their instruments of appointment.
3
4

5 **7. Disqualification from appointment as member**

6 A person shall not be appointed to the Board who-

- 7 **a.** is engaged in the tobacco industry as an owner, shareholder,
8 partner, grower, importer, distributor, retailer or otherwise,
9 whether directly or indirectly;
- 10 **b.** has a financial or proprietary interest in an organisation engaged
11 in the manufacture, importation or distribution of tobacco
12 products anywhere; or
- 13 **c.** is an undischarged bankrupt or has made any assignment
14 or arrangement with his or her creditors.

15 **8. Vacancies**

16
17
18 **8.1** A member of the Board may be removed from office at any time
19 if he or she-

- 20 **a.** is continuously and persistently unable to discharge the functions
21 of his or her office;
- 22 **b.** engages in misbehaviour or abuse of office;
- 23 **c.** is subsequently disqualified from membership in accordance
24 with section 7; or
- 25 **d.** fails to disclose to the Board any interest in a contract
26 or proposed contract or any other matter before the Board.

27
28 **8.2** The Minister shall, on the recommendation of the Board,
29 determine that a vacancy exists under subsection (1).
30

31 **8.3** A member of the Board may, at any time, resign office upon
32 written notification to the Minister.
33

34 **8.4** Upon the resignation, falling vacant of office, or removal of a member
35 of the Board, the President shall, with the approval of Parliament
36 appoint another person qualified in terms of section 4, to fill
37 the vacancy and to hold office until expiry of the term of the person
38 so replaced.
39
40

41 **9. Functions of the Board**

42 The functions of the Board are-

- 43 **a.** to determine, in writing, the procedures governing its operations;
- 44 **b.** to implement the provisions of this Act and exercise the powers
45 conferred upon it by this Act;
- 46 **c.** to monitor health trends resulting from tobacco consumption
47 and exposure;
- 48 **d.** to monitor and review the effectiveness of the requirements
49 contained in this Act and regulations, and recommend
50 amendments as it deems appropriate;

- e. to develop and implement a national programme for tobacco control, including public awareness campaigns and cessation activities;
- f. to co-ordinate activities on tobacco control of various government departments and voluntary agencies;
- g. to make recommendations to the Minister responsible for finance with respect to the taxation of tobacco products in order to keep the prices of tobacco products ahead of the rate of inflation and increases in earnings; and
- h. any other function conferred on it by the Minister

10. Meetings of the Board

The Second Schedule has effect with respect to meetings of the Board and other matters provided in it.

11. Independence of the Board

Except as provided under this Act or any other law, the Board shall exercise its functions independent of any person or body.

SECRETARIAT AND STAFF OF THE BOARD

12. Secretariat and staff of the Board

The Board shall have a Secretariat consisting of an Executive Secretary and other staff.

13. Executive Secretary

13.1 There shall be a full time Executive Secretary who shall be appointed by the Board on terms and conditions specified in his or her instrument of appointment.

13.2 The Executive Secretary shall be a person with considerable knowledge and experience in public health, law or administration.

13.3 The Executive Secretary shall hold office for a period of five years and is eligible for re-appointment for one more term.

13.4 The Executive Secretary shall cease to hold office if-

- a. he or she resigns;
- b. he or she is removed from office by the Board for-
 - i. gross misconduct;
 - ii. physical or mental inability to discharge the functions of his or her office;
 - iii. mismanagement of the affairs of the Board; or
 - iv. incompetence.

14. Functions of the Executive Secretary

14.1 The Executive Secretary is responsible for the day-to-day operations and administration of the Board.

14.2 Subject to this Act and to the general supervision and control of the Board, the Executive Secretary shall-

- a. be the Chief Executive of the Board;
- b. implement the policies and programs of the Board;
- c. manage the funds and property of the Board;
- d. organise, supervise and generally control the staff of the Secretariat;
 - i. keep the Board informed on the activities of the Secretariat;
 - ii. keep a record of all the transactions of the Board; and
 - iii. perform any other duty that may be assigned by the Board.

14.3 The Executive Secretary shall, in the performance of his or her duties, be answerable to the Board.

15. Other officers and staff of the Board

15.1 The Board may appoint other officers and employees as may be necessary for the effective performance of its functions.

15.2 The employees appointed under this section shall hold office on such terms and conditions as may be specified in their instruments of appointment.

15.3 The Board may establish pension or superannuation schemes and such other financial schemes as it may determine for the benefit of its officers and employees.

16. Protection of members and employees

A member of the Board or an employee of the Board, or a person acting on the directions of such a person is not personally liable for any act or omission done or omitted to be done, in good faith, in the exercise of the functions of the Board.

FINANCIAL AND RELATED PROVISIONS

17. Funds of the Board

The funds of the Board shall consist of-

- a. money appropriated by Parliament from time to time, for enabling the Board to perform its functions;
- b. licence fees from importers, distributors, retailers and manufacturers charged under section 24;
- c. money borrowed by the Board; and
- d. grants, gifts or donations from Government and other sources, acceptable to the Minister and the Minister responsible for finance.

18. Application of funds

The funds of the Board may be applied-

- a. in the payment or discharge of its expenses and obligations, including international obligations, or liabilities incurred in connection with the performance of its functions or exercise of its powers under this Act; and
- b. in the payment of any remuneration or allowances payable under this Act.

19. Power to open and operate bank accounts

19.1 The Board shall open and maintain such bank accounts as are necessary for the performance of its functions.

19.2 The Board shall ensure that all money received by or on behalf of the Board is banked as soon as practicable after being received.

19.3 The Board shall ensure that no money is withdrawn from, or paid out of any of its bank accounts without the authority of the Board.

20. Investment of surplus funds

Any funds of the Board not immediately required for any purpose under this Act may be invested in a manner, which the Board may, after consultation with the Minister and the Minister responsible for finance, determine.

21. Estimates

21.1 The Executive Secretary shall, within three months before the commencement of each financial year, cause to be prepared and submitted to the Board for its approval, estimates of the expenditure of the Board for the next financial year.

21.2 The Board shall, within three months, after the submission of the estimates by the Executive Secretary, cause to be submitted to the Minister for his or her approval, the estimates of income and expenditure as approved by the Board under subsection (1).

22. Financial year of the Board

The financial year of the Board is the period of twelve months ending on the 31st March.

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23. Accounts

23.1 The Executive Secretary shall cause to be kept, proper books of accounts and records of the transactions of the Board.

23.2 Subject to any direction given by the Minister, the Board shall cause to be prepared and submitted to the Minister responsible for finance in respect of each financial year, and not later than three months after the end of the financial year, a statement of accounts, which shall include-

- a. a balance sheet, a statement of income and expenditure and a statement of surplus or deficit; and
- b. any other information in respect of the financial affairs of the Board as the Minister responsible for finance may, in writing, require.

24. Audit

24.1 The Auditor-General or an auditor authorised by the Auditor-General in that behalf shall, in each financial year, audit the accounts of the Board.

24.2 The Board shall ensure that within four months after the end of each financial year, a statement of accounts described in section 23(2) is submitted to the Auditor-General or an auditor authorised by the Auditor-General for auditing.

24.3 The Auditor-General and any auditor authorised by the Auditor-General shall have access to all books, records, reports and other documents relating to the accounts of the Board, and is entitled to any information and explanation required in relation to those documents.

24.4 The Auditor-General and any auditor authorised by the Auditor-General shall, within four months after receipt of the statement of accounts under subsection (2), deliver to the Board a copy of the audited accounts together with a report on the accounts.

Appendix 2: Content, Design and Placement of No Smoking Signs

1. **Messages on tobacco product packages.** The health messages prescribed in subsection (b) shall appear on all individual tobacco product packages and on all cartons containing individual packages.

[Note: the following can be added: Additionally messages shall appear on individual sticks of smoked products.]

a. Simultaneous display of messages. Every manufacturer and importer shall, for each brand of a tobacco product that the manufacturer packages in a year, display each health message with the accompanying picture specified in subsection (b) randomly in each 12-month period in as equal a number of times as possible on each brand of the product. Each message also shall be randomly distributed in all parts of [specify name of country] in which the product is sold. The phrase “equal number of times as possible” means deviations of [specify percent] or less in a 12-month period. “Random distribution” means that there is nothing in the production or distribution process of a tobacco product that would prevent the health messages on packages from being distributed evenly in all parts of the country where they are sold.

b. Content of messages. The messages shall be as follows:

I. for cigarettes:

- a.i** [specify content of message].
- a.ii** [show accompanying picture].

- b.i** [specify content of message].
- b.ii** [show accompanying picture].

- c.i** [specify content of message].
- c.ii** [show accompanying picture].

- d.i** [specify content of message].
- d.ii** [show accompanying picture].

[etc.]

II. for [specify other forms of tobacco products commonly sold]:

- a.i** [specify content of message].
- a.ii** [show accompanying picture].

- b.i** [specify content of message].
- b.ii** [show accompanying picture].

- c.i** [specify content of message].
- c.ii** [show accompanying picture].

- d.i** [specify content of message].
- d.ii** [show accompanying picture].

[etc.]

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- c. Language of messages.** The messages shall appear in [specify required language(s)]: in [specify language] on one of the required package and carton panels as described in subsection (e) and in [specify language] on the other package and carton panel as described in subsection (e) [if more than one principal language is spoken]. The health messages on any exported tobacco product shall be in the official languages of the country of final destination, unless otherwise specified by law in the country of final destination.
- d. Font type, size and color for messages.** The font used for the messages shall be as follows:
- I.** font shall be: [specify type].
 - II.** font size shall be: [specify size] point type for packages greater than [specify size] in height or width, whichever is larger, and [specify size] point type for packages less than [specify size] height or width. Font size shall be [specify size] point type for cartons greater than [specify size] in height or width, whichever is larger, and [specify size] point type for cartons less than [specify size] in height or width.
 - III.** font color shall be black.
 - IV.** the text of the message shall appear against a white background.
 - V.** [if desired, specify how message should be placed within a border or other instructions for ensuring the text of the message is distinct from other text on the package].
- e. Placement of message.** The text and picture of the message shall be placed on the 2 largest package and carton panels visible under normal or customary conditions of sale or use and shall cover [specify proportion, (preferably 50% or more, but at least 30%, to be in compliance with FCTC)]% of each panel, including the sides of any lid or cover, as applicable; shall be positioned parallel to the top edge of the package and carton, towards the top part of the package/carton as much as possible without being severed when the package/carton is opened; and shall be positioned in the same direction as other text on the package/carton. Provided, however, that where packages are of a design such that they do not have 2 panels of equal size, the health message shall be placed [specify placement (e.g., on the entire surface of the largest panel)].
- f. Placement of pictures.** Pictures shall occupy at least [x]% of the total message area. [Specify where pictures must be placed].

2. Constituent and additives disclosures on packages. Each tobacco product package and carton shall disclose simultaneously, as prescribed in Section 1 for messages, the following constituents/their emissions and additives, as applicable, as prescribed below:

a. Content of constituent and additives disclosures.

- I.** Unless otherwise specified in implementing regulations, the constituents/emissions and additives listed below shall be disclosed using the full name of the constituent and additive and not its chemical formula or any other abbreviated name.
- II.** The disclosed substances shall appear under the heading, “Some of the Carcinogenic/Toxic Chemicals Contained in This Product Include:” [or specify other heading] immediately above or preceding the list of constituents, which shall be disclosed in groups, as specified below, simultaneously on packages, as described with respect to messages in Section 1.
- III.** The disclosed substances shall appear without reference to the levels of the constituents/emissions and additives contained in the product, unless otherwise specified in implementing regulations; and
- IV.** The disclosed substances shall be followed by the statement, [specify text, e.g., something to the effect that there are no safe levels of consumption of, or exposure to, these substances].
- V.** For cigarettes, the disclosures shall be:
 - a.** group 1: [Specify several constituents/emissions and additives of concern];
 - b.** group 2: [Specify several constituents/emissions and additives of concern];
 - c.** group 3: [Specify several constituents/emissions and additives of concern];
[etc.]
- VI.** for [specify other smoked products]:
 - a.** group 1: [Specify several constituents/emissions and additives of concern];
 - b.** group 2: [Specify several constituents/emissions and additives of concern];
 - c.** group 3: [Specify several constituents/emissions and additives of concern];
[etc.]
- VII.** for [specify smokeless tobacco products]:
 - a.** group 1: [Specify several constituents/emissions and additives of concern];
 - b.** group 2: [Specify several constituents/emissions and additives of concern];
 - c.** group 3: [Specify several constituents/emissions and additives of concern];
[etc.]

1 **b. Language of constituent and additives disclosures.**

2 The information required by subsection (a) shall be displayed
3 in [specify languages]. For exported tobacco products,
4 the information shall be displayed in the official languages of
5 the country of destination unless otherwise specified by law
6 in the country of destination.
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8 **c. Placement of constituents and additives information on
9 packages and cartons.**

10 The information required by subsection (a)
11 shall be placed on any side of the package, other than a side
12 displaying a prescribed message and other than on a bottom side,
13 and shall be placed on all sides of a carton. Placement shall be
14 in such a manner that it occupies no less than [specify]% of
15 the entire side, including the sides of any lid or cover, as applicable.

16 **d. Font style, size, and colors for constituent and additives
17 disclosures.**

18 The font used for the constituents and additives
19 disclosures shall be as follows:

- 20 **I.** for the heading prescribed by Section 2(a)(ii) and list of
21 constituents and additives prescribed by Section 2(a)(v) and (vi):
- 22 **a.** font shall be: [specify type].
 - 23 **b.** font size shall be: [specify size] point type for packages
24 greater than [specify size] cm. in height or width,
25 whichever is larger, and [specify size] point type for
26 packages less than [specify] cm. in height or width.
27 Font size shall be [specify size] point type for cartons
28 greater than [specify] cm. in height or width, whichever
29 is larger, and [specify size] cm. for cartons less than
30 [specify] cm. in height or width.
 - 31 **c.** font color shall be black.
- 32 **II.** for the statement required by Section 2(a)(iv):
- 33 **a.** font shall be: [specify type].
 - 34 **b.** font size shall be: [specify size] point type for package
35 sides greater than [specify size] cm. in height or width,
36 whichever is larger, and [specify size] point type
37 for packages sides less than [specify size] cm. in height
38 or width. Font size shall be [specify size] point type
39 for carton sides greater than [specify size] cm. in height
40 or width, whichever is larger, and [specify size] point type
41 for carton sides less than less than [specify size] cm.
42 in height or width.
 - 43 **c.** font color shall be black.
 - 44 **d.** Requirement for contrasting background. The text of
45 the heading, list of constituents and additives,
46 and statement required by Section 2(a)(iv) shall appear
47 against a white [or specify color in detail or precise degree
48 of contrast other color in relation to the text] background.
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- e. if desired, specify how message should be placed within a border or other instructions for ensuring the text of the constituents disclosures is distinct from other text on the package.

3. Records demonstrating compliance. Tobacco product manufacturers and importers shall keep records demonstrating their compliance with the requirements for prescribed messages and constituent and additives disclosures on product packages.

[Note: Canada requires that tobacco product packages contain inserts providing information that enhances package health messages. Inserts may be a promising way to provide consumers with additional information, but their effectiveness has not been fully evaluated].

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