



Manual for Developing Tobacco Control Legislation in the Region of the Americas

Manual for Developing Tobacco Control Legislation in the Region of the Americas



Sustainable Development and Environmental Health Area

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Contents

Preface	ix
Foreword	xi
Acknowledgments	xiii
Abbreviations	xv
Executive Summary	xvii
Chapter 1. Introduction	1
1.1 Overview of the tobacco epidemic in the world and the Region	2
1.1.1 Mortality attributable to tobacco	2
1.1.2 Prevalence of tobacco consumption	2
1.1.3 Cost-effectiveness of tobacco control	3
1.2 Overview of the international legal framework	4
1.2.1 The World Health Organization Framework Convention on Tobacco Control	4
1.2.2 Guidelines for implementation of the WHO FCTC	5
1.2.3 Why legally binding and enforceable measures?	6
1.3 Tobacco control and international human rights law obligations	7
1.3.1 The link between tobacco control policies and human rights instruments	8
1.3.2 Progressive realization of protection of the right to health	10
1.4 Legislation and litigation	11
1.4.1 Article 19 of the WHO FCTC	11
1.4.2 Litigation and the development of legislative frameworks for tobacco control	11
1.5 Tobacco and trade	12
1.5.1 The World Trade Organization	12
1.5.2 International Investment Agreements	14
1.6 Other considerations	14
1.6.1 Youth interventions versus adult interventions: A false dichotomy	14
1.6.2 Electronic nicotine delivery systems	15
References	18
Annex 1. Treaties and conventions	21

Annex 2. Countries in the Region of the Americas that are Parties to inter-American and United Nations treaties	22
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Chapter 2. Developing Tobacco Control Laws 23

2.1 Different routes to effective implementation of the WHO FCTC	24
2.1.1 Legislative or executive measures	24
2.1.2 Measures at the national or subnational level	26
2.1.3 A single comprehensive law or separate laws, for one or several tobacco control topics	29
2.1.4 Content of laws and regulations	30
2.2 Key components of tobacco control legislation and cross-cutting topics	31
2.2.1 Provide clear legislative objectives	31
2.2.2 Define key terms	31
2.2.3 Ensure comprehensive application of requirements and prohibitions	31
2.2.4 Impose legal duties of compliance	31
2.2.5 Provide effective enforcement mechanisms	32
2.2.6 Provide a range of deterrents and proportionate penalties	32
2.2.7 Provide a role for civil society	32
2.2.8 Require evaluation and public dissemination of results	33
2.2.9 Grant broad regulatory power to the appropriate authority to address implementation details	33
2.3 Role of civil society in implementing the WHO FCTC	33
References	35

Chapter 3. Protection from Exposure to Tobacco Smoke 37

3.1 Background	38
3.1.1 Rationale and evidence	38
3.1.2 Regional situation	41
3.2 Responding to opposition to comprehensive smoke-free measures	42
3.2.1 Countering tobacco industry arguments	42
3.2.2 Regional experiences with legal challenges to comprehensive smoke-free laws	45
3.3 Implementing WHO FCTC Article 8 at the domestic level: Drafting effective smoke-free measures	47
3.3.1 Provide clear legislative objectives	47
3.3.2 Define key terms	49
3.3.3 Ensure comprehensive application of the smoking ban	50
3.3.4 Impose legal duties of compliance	55
3.3.5 Provide effective enforcement mechanisms	57
3.3.6 Provide a range of deterrents and proportionate penalties	57
3.3.7 Provide a role for civil society	58
3.3.8 Require evaluation and public dissemination of results	58
3.3.9 Grant broad regulatory power to the appropriate authority to address implementation details	58

References	59
Additional resources	65
Chapter 4. Packaging and Labeling of Tobacco Products	67
4.1 Background	68
4.1.1 Rationale and evidence	68
4.1.2 Regional situation	70
4.2 Tobacco industry strategies against effective packaging and labeling of tobacco products	70
4.2.1 Industry uses of tobacco packaging	71
4.2.2 Countering tobacco industry arguments against effective measures	72
4.2.3 Regional experience with legal challenges to packaging and labeling laws	73
4.3 Implementing WHO FCTC Article 11 at the domestic level: Drafting effective packaging and labeling measures...	75
4.3.1 Provide clear legislative objectives	75
4.3.2 Define key terms	76
4.3.3 Ensure comprehensive application of packaging and labeling measures	78
4.3.4 Impose legal duties of compliance	86
4.3.5 Provide effective enforcement mechanisms	88
4.3.6 Provide a range of deterrents and proportionate penalties	88
4.3.7 Provide a role for civil society	88
4.3.8 Require evaluation and public dissemination of results	88
4.3.9 Grant broad regulatory power to the appropriate authority to address implementation details	88
References	89
Additional resources	94
Chapter 5. Tobacco Advertising, Promotion, and Sponsorship	95
5.1 Background	96
5.1.1 Rationale and evidence	96
5.1.2 Regional situation	101
5.2 Responding to tobacco industry opposition to strong and comprehensive TAPS bans	101
5.2.1 Tobacco industry arguments against strong and comprehensive bans on tobacco advertising, promotion, and sponsorship	101
5.2.2 Legal challenges advanced by the tobacco industry against TAPS bans: The Colombian case	103
5.3 Implementing WHO FCTC Article 13 at the domestic level: Drafting effective measures on tobacco advertising, promotion, and sponsorship	105
5.3.1 Provide clear legislative objectives	105
5.3.2 Define key terms	106
5.3.3 Ensure a comprehensive ban on all TAPS	107
5.3.4 Impose legal duties of compliance	111
5.3.5 Provide a range of deterrents and proportionate penalties	112
5.3.6 Grant broad regulatory power to the appropriate authority to address implementation details	114

References	115
Additional resources	121
Chapter 6. Protecting Tobacco Control Policies from the Commercial and Other Vested Interests of the Tobacco Industry	123
6.1 Background	124
6.1.1 Rationale and evidence	124
6.1.2 Regional situation	125
6.2 Implementing WHO FCTC Article 5.3 at the domestic level: Drafting effective measures to prevent tobacco industry interference	126
6.2.1 Provide clear legislative objectives	128
6.2.2 Define key terms	129
6.2.3 Ensure comprehensive application of FCTC Article 5.3 implementing measures	129
6.2.4 Impose legal duties of compliance	140
6.2.5 Provide effective enforcement mechanisms	140
6.2.6 Provide a range of deterrents and proportionate penalties	141
6.2.7 Provide a role for civil society	141
6.2.8 Grant broad regulatory power to the appropriate authority to address implementation details	142
References	143
Additional resources	145
Chapter 7. Regulation of the Contents of Tobacco Products and of the Reporting of Constituents and Emissions	147
7.1 Background	148
7.1.1 Evidence and rationale	148
7.1.2 Regional situation	149
7.2 Strategies against effective regulation of tobacco products	149
7.2.1 Countering tobacco industry arguments	149
7.2.2 Experiences with legal challenges to product regulation	150
7.3 Implementing WHO FCTC Articles 9 and 10 at the domestic level: Drafting effective measures on tobacco product regulation	151
References	157
Additional resources	158

Chapter 8. WHO FCTC Articles 12 and 14 as Components of an Integrated, Multisectoral Tobacco Control Strategy	159
8.1 Background	160
8.1.1 Rationale and evidence	160
8.1.2 Regional situation	163
8.2 Tobacco industry strategies to weaken implementation of WHO FCTC Articles 12 and 14	163
8.3 Implementing WHO FCTC Articles 12 and 14 at the domestic level: Drafting effective demand reduction measure	164
8.3.1 Implementing WHO FCTC Article 12	164
8.3.2 Implementing WHO FCTC Article 14	165
References	167
Additional resources	169

Chapter 9. Template for a Tobacco Control Act	171
Chapter I -- Preliminary	172
Chapter II -- Defined terms	172
Chapter III -- Administration	174
Chapter IV -- Smoke-free environments	175
Chapter V -- Prohibition on tobacco advertising, promotion, and sponsorship	177
Chapter VI -- Tobacco product packaging and labelling	179
Chapter VII -- Tobacco product sales	183
Chapter VIII -- Regulation of tobacco products; tobacco product contents and emissions disclosures	185
Chapter IX -- Protection of tobacco control policies from the commercial and other vested interests of the tobacco industry	186
Chapter X -- Miscellaneous	194

Preface

Tobacco consumption and exposure to secondhand smoke are a leading cause of morbidity and mortality worldwide. Globally, they are responsible for almost 6 million deaths per year, including 1 million in the Region of the Americas. In addition, a much larger number of people suffer from noncommunicable diseases, for which tobacco is an important risk factor. This is a staggering health problem, but the damaging effects go beyond health. The epidemic also has a huge socioeconomic impact, not only on individuals and families, but also on health systems and on the socioeconomic development of the countries of the Region.

The World Health Organization Framework Convention on Tobacco Control (WHO FCTC) is an evidence-based treaty that lays out the most effective measures to curb the tobacco epidemic. Since its entry into force in 2005, great progress has been achieved in tobacco control in the Americas. The experiences of the countries in our Region which have implemented the treaty demonstrate consistently that its mandates can be implemented and enforced at minimal cost to governments. Evaluation of the effectiveness of the measures in those countries shows decreases in tobacco consumption, in some cases of quite dramatic proportions.

However, there is still a long road ahead. Some countries of the Region are not yet Parties to the WHO FCTC, while others are Parties but have not implemented any of the treaty's mandates. A specific matter of concern is that in some countries, tobacco consumption in the population aged 13–15 years shows a trend toward feminization, with rising consumption among girls. Moreover, throughout the Region, the tobacco industry persists in its efforts to undermine public health policies. Its increasingly aggressive approach includes challenging governments in court, at both the domestic and international levels.

In publishing this manual, the Pan American Health Organization reaffirms its commitment to support all Member States in their efforts to overcome this deadly epidemic and prevent private interests from jeopardizing the health and well-being of the Region's population.

Dr. Carissa F. Etienne
Director

Foreword

The Pan American Health Organization (PAHO) has developed this manual to provide technical support to Member States in drafting domestic legislation to comply with the mandates of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC). In addition to assisting Parties to the treaty in meeting their obligations, the manual will also be useful to those few countries that are not yet Parties but still want to protect their populations from the risks of tobacco use and secondhand smoke exposure.

The manual is intended as a tool for those who are in charge of developing tobacco control legislation, working either with national tobacco control programs or at the parliamentary level. It should also prove useful for tobacco control advocates in organized civil society groups, which have played an important role in creating a propitious climate for such legislation in the Region. The English version is specifically tailored for the Caribbean region, both from the point of view of the examples provided as in the structure of the law template provided at the last chapter of the manual.

Since the adoption of the WHO FCTC by the 56th World Health Assembly in May 2003, PAHO has been providing technical assistance, first to facilitate countries becoming Parties to the treaty and then to support the implementation and enforcement of national tobacco control legislation in line with the mandates of the FCTC and the recommendations of its guidelines for implementation.

Ministers of Health of the Region, meeting in the Directing Council of PAHO, adopted resolutions on tobacco control in 2008 and 2010. These resolutions urged Member States to ratify the WHO FCTC (if they had not already done so) and to implement its provisions and the recommendations of its implementation guidelines. The 2010 resolution also urged Member States to be aware of tobacco industry interference aimed at undermining tobacco control efforts. Both resolutions request PAHO to continuing supporting Member States in these activities; the production of this manual responds to this mandate.

The technical advice provided here has been enriched with the experiences of countries in the Region of the Americas and other parts of the world that have advanced in certain areas of tobacco control. It also reflects lessons learned from the attempts of the tobacco industry to influence or stop the development of legislation, whether during parliamentary deliberation or through judicial challenges.

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From the PAHO Tobacco Control team, Adriana Blanco Marquizo was the project director; she conceived the idea for the manual, contributed to the chapters, and oversaw the entire project. Rosa Carolina Sandoval was the project coordinator and helped ensure consistency between the Spanish and English versions. Roberta Caixeta reviewed the epidemiological data, and Carmen Audera-López assisted with the editing of the Spanish text.

Abbreviations

ANVISA	National Health Surveillance Agency (Brazil)
BAT	British American Tobacco
CARICOM	Caribbean Community
CEDAW	Convention on the Elimination of All Forms of Discrimination against Women
CESCR	Committee on Economic, Social and Cultural Rights
CONICQ	National Commission for Implementation of the WHO FCTC (Brazil)
COP	Conference of the Parties to the WHO FCTC
CRC	Convention on the Rights of the Child
CSR	corporate social responsibility
ENDS	electronic nicotine delivery systems
FCTC	Framework Convention on Tobacco Control
FDA	US Food and Drug Administration
GATS	Global Adult Tobacco Survey
GATT	General Agreement on Tariffs and Trade
GYTS	Global Youth Tobacco Survey
ICAC	Independent Commission Against Corruption (Hong Kong)
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICSID	International Centre for Settlement of Investment Disputes
IIA	International Investment Agreement
ILO	International Labour Organization
NCD	chronic noncommunicable disease
NGO	nongovernmental organization
PAHO	Pan American Health Organization
PMI	Philip Morris International
POS	point of sale
RBH	Rothmans Benson & Hedges
RIP	reduced ignition propensity
RJR	R. J. Reynolds
SHS	secondhand smoke
TAPS	tobacco advertising, promotion, and sponsorship
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNCAC	United Nations Convention Against Corruption
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary

This manual provides technical assistance to the countries of the Region of the Americas for the development of tobacco control legislation consistent with the mandates of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) and the recommendations of its guidelines for implementation.

Chapter 1 briefly describes the global and regional dimensions of the tobacco epidemic and reviews the basic provisions of the WHO FCTC and its guidelines. Since the objective of the treaty is to protect present and future generations from the devastating consequences of tobacco consumption and exposure to tobacco smoke, there is an obvious relationship between the WHO FCTC and human rights instruments at the global and regional levels. The incorporation of a human rights perspective strengthens tobacco control legislation, making it less vulnerable to challenges from the tobacco industry. In addition, the relationship between public health and trade is an emerging issue. Some commercial practices need to be regulated in order to curb the tobacco epidemic and the growing burden of chronic, noncommunicable diseases associated with tobacco use. Finally, the chapter discusses specific issues such as the false dichotomy between youth and adult tobacco prevention and the challenges of new products such as e-cigarettes.

Chapter 2 addresses the process of developing tobacco control policies, considering the different approaches that countries have used to meet their goals. The chapter also analyses the important role that civil society can play, and has played, in helping governments in the Region develop tobacco control legislation.

Chapters 3, 4, and 5 focus respectively on smoke-free legislation (WHO FCTC Article 8); packaging and labeling of tobacco products (WHO FCTC Article 11); and tobacco advertising, promotion, and sponsorship (WHO FCTC Article 13). These are the articles on which there has been the most progress globally and in the Region. Each chapter briefly summarizes the scientific evidence on the policy, reviews the mandates of the WHO FCTC and the recommendations in its guidelines, examines and refutes the most common tobacco industry arguments against the policies, looks at the regional situation with respect to implementation of the policies, and makes specific recommendations for the development of domestic legislation. In-Practice boxes provide examples of current legislation in different countries that illustrate good practice and lessons learned.

Chapter 6 addresses the protection of tobacco control policies from the interference of the tobacco industry, based on WHO FCTC Article 5.3. Legislative experience in the Region is very limited in this regard. Therefore, the chapter concentrates on the recommendations in the Article 5.3 Guidelines and how they can be implemented domestically.

Chapter 7 discusses regulation of the contents of tobacco products and the reporting of constituents and emissions (WHO FCTC Articles 9 and 10). **Chapter 8** looks at education, communication, training, and public awareness (WHO FCTC Article 12) and measures concerning tobacco dependence and cessation (WHO FCTC Article 14). As with Article 5.3, there exists very little legislative experience with regard to these articles. In the case of Articles 9 and 10, the directives for their implementation are still in partial form, and a study group is working on proposals to be approved by future Conferences

of the Parties. These chapters therefore do not go into as much depth as the preceding chapters. Recommendations have been prepared based not so much on experience as on the interpretation of the relevant articles and their guidelines for implementation.

Chapter 9 provides a template for a comprehensive tobacco control law covering all the aspects discussed in the manual. The template can be used in its entirety, with appropriate adaptation for the country context, as the basis for a comprehensive law. Alternatively, specific chapters can be used to guide legislation that addresses selected topics.

All the organizations involved in the development of this manual will be available to provide technical support for the process, including by reviewing legislative drafts. Users of the manual are invited to contact the author team for assistance as they embark upon the legislative drafting process.

Each chapter contains a list of references cited in the text and a set of suggestions for obtaining additional information and educational resources.

Chapter 1

Introduction

THREE WAYS TO SAVE LIVES.



F C T C

WHO FRAMEWORK CONVENTION
ON TOBACCO CONTROL

This treaty is the world's answer to the tobacco epidemic, which kills nearly 6 million people each year. Already legally binding in more than 170 countries, it's our most powerful tobacco-control tool. **Let's use it!**



31 MAY: WORLD NO TOBACCO DAY
www.paho.org/tobacco



1. Introduction

1.1 Overview of the tobacco epidemic in the world and the Region

1.1.1 Mortality attributable to tobacco

Chronic noncommunicable diseases (NCDs) are now responsible for almost two-thirds of deaths worldwide. The principal NCDs are cardiovascular diseases, cancers, diabetes, and respiratory diseases, and tobacco is a major risk factor common to all (WHO 2010a). In the Region of the Americas, NCDs account for 77% of all deaths. Of these, tobacco is responsible for 15% of the deaths from cardiovascular diseases, 26% of the cancer deaths, and 51% of the deaths from respiratory diseases (PAHO 2011; WHO 2012).

For this reason, in September 2011 the high-level meeting of the General Assembly of the United Nations focused on NCDs. This is only the second time in history that the United Nations has focused its attention on a health issue, and tobacco control was part of the discussions on health and development.

According to the World Health Organization (WHO), consumption of tobacco and exposure to tobacco smoke remains one of the major individual causes of death, preventable disease, and disability worldwide and is responsible for 12% of all deaths of adults over 30 years of age. The regions with the highest proportion of deaths attributable to tobacco are the Americas and Europe, both at 16% (WHO 2012).¹

If we consider both active and passive exposure, tobacco smoke currently kills nearly 6 million people around the world each year. If current trends continue, by 2030 tobacco will have killed more than 8 million people per year. Eighty percent of these premature deaths will occur in low- and middle-income countries, with huge implications for the health systems and economies of these countries (Mathers and Loncar 2006; Öberg et al. 2010).

With respect to the gender distribution of mortality attributable to tobacco, the proportion of tobacco-related deaths that occur among women is highest in Region of the Americas (15%), followed by the European region (7%) (WHO 2012).

1.1.2 Prevalence of tobacco consumption

Globally, the prevalence of tobacco smoking is 24%. The regions of Europe and Western Pacific have the highest prevalence of smoking, with 32% and 31% respectively, well above the world average.

Around the world, tobacco consumption is higher among men (40%) than among women (9%). However, there is wide variation in the gender distribution of smoking from one region to another. The Americas and Europe have the highest rates of smoking among women, 17% and 22% respectively. However, if we analyze the difference between the smoking rates of adult men and women, the gap is bigger in Southeast Asia and Western Pacific, where the prevalence of smoking

¹ WHO is composed of 194 Member States that are divided into six regions: Africa, the Americas, Eastern Mediterranean, Europe, Southeast Asia, and Western Pacific. See "WHO: Its People and Offices," at <http://www.who.int/about/structure/en/index.html>.

among men is 37% and 57%, respectively, while the prevalence among women is about 4% to 5% (WHO 2010b). As will be seen below, the Region of the Americas has the smallest gap between male and female consumption, showing an increasing feminization of smoking.

The Region of the Americas has 145 million smokers, accounting for 12% of the more than one billion smokers in the world. The prevalence of smoking among all adults is 22% in the Americas, which ranks fourth among the six WHO regions. Within the Americas, the age-standardized prevalence of tobacco smoking varies widely, from more than 25% in Argentina, Bolivia, Chile, the United States, and Uruguay to less than 8% in Barbados, Dominica, and St. Kitts and Nevis (WHO 2011a). Data from the WHO's Global Youth Tobacco Survey are not encouraging: the prevalence of consumption of any tobacco product in adolescents 13 to 15 years of age ranges from 35.1% in Santiago de Chile to 7.8% in the US Virgin Islands and 8.4% in Panama. Moreover, 23.4% of this age group surveyed in the Americas reported they would probably initiate tobacco use within the next year (PAHO 2012).

A particularly disturbing feature of smoking in the Americas is rising consumption rates among women, a pattern not seen to the same extent in other regions of the world. This aspect is even more pronounced in the cigarette consumption in the population aged 13 to 15 years (12.3% prevalence in boys, 11.3% prevalence in girls). Indeed, in some countries of South America, there is even a reversal of the male: female ratio in this age range, with girls consuming more tobacco than boys (WHO 2011a; PAHO 2012). The increasing feminization of consumption is driven by, among other things, the aggressive effort by the tobacco industry to promote their products, especially to women and youth.

So far, attention has focused mainly on smoked tobacco products, but it is important to note that consumption of smokeless tobacco products is high in some countries of the world—for example, in Bangladesh (27.9% in females, 26.4 % in males) and India (18.4% in females, 32.9% in males) (WHO 2009–2010). In the Americas, data on the consumption of smokeless tobacco products by adults are not available for many countries, but in those countries with available data, consumption is low, as for example in Brazil (0.4%) and Mexico (0.3%). However, data from the Global Youth Tobacco Survey in the Americas indicate that this is still an issue in the Region. There is a non-negligible prevalence of consumption of smokeless products among youth, particularly in the subregion of the non-Latin Caribbean² (7.3%, almost twice the regional average of 3.9%) (PAHO 2012).

1.1.3 Cost-effectiveness of tobacco control

Tobacco use cuts across socioeconomic boundaries, and it is very costly for society. The tobacco epidemic, as well as the NCDs it contributes to, causes even more damage in low-income countries than in wealthier ones, and it has the greatest impact on the poorest population sectors within those countries (WHO 2010c). The accumulated evidence is unequivocal. Over the next 20 years, chronic diseases will cost more than US\$ 30 billion globally, representing 48% of the global gross domestic product in 2010 and dragging millions of people below the poverty line. The evidence also shows, however, that millions of deaths can be prevented and economic losses can be reduced by billions of dollars if increased efforts are made to prevent NCDs (Bloom et al. 2011). Stepped-up efforts to address tobacco use must be an integral part of any strategy to prevent NCDs.

Several recent studies by WHO (2010a), as well as others published in the *Lancet* (Beaglehole et al. 2011) and by the World Economic Forum (WEF 2011), have identified tobacco control as a cost-effective prevention strategy. In preparation for

² In this publication, the non-Latin Caribbean includes Antigua and Barbuda, the Bahamas, Barbados, Dominica, Grenada, Guyana, Jamaica, Montserrat, St. Kitts and Nevis, St. Vincent and the Grenadines, St. Lucia, Suriname, Trinidad and Tobago, the US Virgin Islands, and the British Virgin Islands.

the United Nations high-level meeting on NCDs in September 2011, economists from WHO developed a costing tool that can assist governments in their national health planning (WHO 2011b). One affordable, cost-effective strategy for the prevention of NCDs is investing in implementation of the WHO Framework Convention on Tobacco Control (WHO 2003; hereafter, WHO FCTC). Several of its measures have been listed as “best buys” for the prevention of these diseases (WHO 2010a; WEF 2011). The political declaration issued at the United Nations high-level meeting urges Member States to accelerate their implementation of the treaty.

In considering tobacco control strategies, it is critical to bear in mind the counter-efforts of the tobacco industry to subvert and undermine these strategies. In the Americas, the industry is increasingly directing its marketing and promotion efforts to low-income populations, women, and youth, and it is carrying out an aggressive strategy of interference in the development and implementation of legislation for tobacco control. Despite the progress made in several countries in the Region, the tobacco epidemic in the Americas will continue to grow unless governments significantly accelerate the adoption and implementation of national laws in line with the mandates of the WHO FCTC and its Guidelines, paying special attention to FCTC Article 5.3, in order to keep one step ahead of the industry’s attempts to undermine these advances.

1.2 Overview of the international legal framework

1.2.1 The World Health Organization Framework Convention on Tobacco Control

The WHO FCTC (WHO 2003) is the world’s first public health treaty negotiated under the auspices of the World Health Organization, and it is the first coordinated global effort to reduce tobacco use and protect against health, social, financial, and environmental harms caused by tobacco. Its overarching objective, as stated in Article 3, is to “protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke . . .” Toward this end, the treaty covers a broad range of measures aimed at reducing both the demand for and the supply of tobacco products, along with other related measures.

The WHO FCTC was unanimously adopted at the 56th World Health Assembly in May 2003 and entered into force 90 days after the 40th ratification, in February 2005. As of October 2012, the treaty has 176 Parties, 29 of them from the Region of the Americas. Within the Region, only Argentina, Cuba, the Dominican Republic, El Salvador, Haiti, and the United States of America have not ratified it. The WHO FCTC is one of the most widely embraced treaties in the history of the United Nations³

The core demand-reduction measures covered by the treaty are contained in Articles 6 through 14. Article 6 sets forth price and tax measures to reduce the demand for tobacco. This is followed by nonprice measures to reduce demand, including:

- Protection from exposure to tobacco smoke (Article 8);
- Regulation of tobacco product contents and emissions and disclosures of information on constituents and emissions (Articles 9 and 10);
- Packaging and labeling of tobacco products (Article 11);
- Education, communication, training, and public awareness (Article 12);
- Tobacco advertising, promotion, and sponsorship (Article 13); and

³ The WHO FCTC homepage is at <http://www.who.int/fctc/en/>.

- Demand-reduction measures concerning tobacco dependence and cessation (Article 14).

Supply-reduction measures include:

- Prevention and elimination of illicit trade in tobacco products (Article 15);
- Prevention of youth access to tobacco products (Article 16);
- Promotion of economically viable alternatives for tobacco workers, growers, and, as appropriate, sellers (Article 17), with due regard for protection of the environment and the health of persons involved in tobacco cultivation and manufacture (Article 18).

In developing and implementing these measures, the treaty requires Parties to protect public health policies for tobacco control from the commercial and other vested interests of the tobacco industry (Article 5.3); to make provisions for criminal and civil liability, including compensation where appropriate (Article 19); and to initiate and cooperate in research and surveillance programs and exchange scientific, technical, and legal information (Articles 20–22).

It is important to keep in mind that none of the articles of the WHO FCTC, alone, will be enough to end the tobacco epidemic. This will be achieved only by the full implementation of the whole package of measures included in the Convention, since they act synergistically. This does not mean that all measures need to be implemented at the same time, but that the final goal must be the complete implementation of the Convention.

The governing body of the WHO FCTC is the Conference of the Parties (COP), made up of all Parties to the Convention. It continuously monitors the implementation of the Convention, since each Party is required to report periodically on its national situation regarding tobacco consumption and tobacco control.⁴ The COP also makes the decisions necessary to promote effective implementation of the WHO FCTC, and it can adopt protocols, guidelines, annexes, and amendments to the Convention. Observers may also participate in the work of the COP. Regular sessions of the COP are held at two-year intervals; the fifth regular session of the COP was held in Seoul, Republic of Korea, in November 2012.⁵

The COP may establish such subsidiary bodies as are necessary to achieve the objective of the Convention. One example is the Intergovernmental Negotiating Body on a Protocol on Illicit Trade in Tobacco Products. This panel met five times and presented a draft protocol to the fifth COP, which adopted the measure. The COP has also established several working groups with the mandate to develop guidelines and recommendations for the implementation of different treaty provisions.

Parties' general obligation under the treaty is to enact and implement *effective* measures to fulfill the different treaty articles. This manual provides in-depth guidance for drafting legal measures (legislation, regulations, or other legal enactments) that meet the WHO FCTC's effectiveness requirement and that incorporate best practices.

1.2.2 Guidelines for implementation of the WHO FCTC

The WHO FCTC establishes principles and general obligations for international governance with respect to tobacco control. It provides only a limited degree of detail about what Parties must do to fulfill their treaty obligations, which they must do "in good faith," according to Article 26 of the Vienna Convention on the Law of Treaties.

⁴ Party reports can be found at <http://www.who.int/fctc/reporting/en/index.html>.

⁵ As of this writing, the official resolutions of the fifth COP have not yet been published..

Article 7 of the WHO FCTC requires the COP to propose guidelines for implementation of the Convention. Developed through a wide, consultative, intergovernmental process established by the COP, the Guidelines cover a wide range of provisions of the Convention. They are intended to assist Parties in meeting their obligations under the treaty and are acknowledged by the Parties as a valuable tool. They are to be taken into account in interpreting the scope and content of Parties' obligations, in accordance with Article 31 of the Vienna Convention.

The Guidelines set forth principles, definitions, and key legislative elements that the Parties agree are necessary to fulfill their obligations under the relevant FCTC articles. In some cases the Guidelines provide legislative elements that will enhance the effectiveness of the Convention's measures, going beyond what is minimally required to fulfill its obligations. This is supported by Article 2.1 of the WHO FCTC, which states that in order to better protect human health, Parties are encouraged to implement measures beyond those required by the Convention and its protocols. Parties should, therefore, enact the most effective and protective measures possible, consistent with their constitutional and other international legal obligations.

The Guidelines are based on the strongest and most widely accepted scientific, health, and engineering evidence and on Parties' experiences. They were approved by the COP by consensus. Incorporating the Guidelines into domestic legislation will provide the effective protection required by the different WHO FCTC articles, minimize loopholes, and facilitate proper implementation of legal requirements.

This manual focuses on the articles for which Guidelines have been approved. The contents of many of the Guidelines have already been incorporated into domestic legislation in many countries, so the recommendations in this manual are enriched by the experiences and decisions of these Parties.

1.2.3 Why legally binding and enforceable measures?

Article 5.2 of the WHO FCTC requires Parties to adopt and implement effective legislative, executive, administrative, and/or other measures and to cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction, and exposure to tobacco smoke. This is reiterated in Article 7 in relation to nonprice measures to reduce the demand for tobacco. Article 7 also calls on the COP to develop guidelines for the implementation of Articles 8 to 13, covering these measures.

In order to be effective, measures must be legally binding and enforceable. Voluntary codes of conduct and agreements with the tobacco industry meet neither of these criteria. In fact, voluntary codes or agreements, which are usually initiated by the tobacco industry, have time and again proven to be *ineffective* because they offer only weak promises of protection. Furthermore, even these weak protections are often violated by the tobacco industry, as was made clear in the 2006 case of *U.S. v. Philip Morris et al.* In the words of the appellate court judge:

[T]he industry adopted a voluntary advertising code, and publically promised [that] they would not market to young people. After establishing the voluntary advertising code as a collective umbrella to diffuse public concern about their marketing activities, Defendants continued unabated their efforts to capture as much of the youth market as possible, effectively ignoring the code's provisions and eliminating its enforcement mechanisms entirely within a few years of the code's adoption.⁶

⁶ U.S. v. Philip Morris USA, Inc., et al., No. 99-CV-02496GK (US Dist. Court, DC), Final Opinion, 17 August 2006, Executive Summary, p. 28.

Internal tobacco industry documents, made public as a result of litigation against the tobacco industry in the United States, reveal that voluntary codes are a strategy the tobacco industry uses to divert policy makers from enacting effective, evidence-based legislative, executive, or administrative measures and to portray itself as a responsible corporate citizen in the eyes of policy makers and the public. For example, a Philip Morris memorandum following a meeting with British American Tobacco (BAT) and Rothmans representatives laid out a plan that included the following strategy: “An industry code will be written . . . so that it can be used as both a lobbying lever and an argument against not [*sic*] introducing formal legislation” (Philip Morris Asia 1994). In another industry document, a BAT representative in Southeast Asia noted that “in the absence of industry self-regulation the industry runs the risk of losing communications facilities very quickly as has happened in Laos. There is a need to consider industry cooperation on voluntary advertising restrictions which would negate the need for implementation of existing bans” (BAT 1994).

For this reason, the WHO FCTC Article 5.3 Guidelines, in Recommendation 3.1, provide that Parties should not accept, support, or endorse nonbinding or nonenforceable agreements, or any voluntary arrangement with the tobacco industry, in the place of legally binding and enforceable measures.

1.3 Tobacco control and international human rights law obligations

The connection between the WHO FCTC and human rights is made clear from the beginning of the Convention text (Cabrera and Gostin 2011). The Preamble of the FCTC expressly links the tobacco control treaty to three human rights treaties:

- International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 12
- Convention on the Rights of the Child (CRC)
- Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)

In order to fulfill its goal of protecting present and future generations from the wide-ranging harms caused by tobacco use and exposure to tobacco smoke, the treaty establishes comprehensive measures aimed at reducing the prevalence of tobacco consumption and exposure to tobacco smoke.

The human rights protected by the WHO FCTC include, then, the rights to life, to health, to work, and to live in a healthy environment, and the right of boys and girls to live and grow in such an environment, among others. As will be explained further on, all of these human rights, recognized at the international, regional, and constitutional levels, generate concrete legal obligations for the States Parties to the human rights treaties.

Tobacco control policies usually run into strong opposition from the tobacco industry and its allies. This opposition reveals conflicts of interests and of rights that are often raised by the tobacco industry and its allies, both during legislative discussion and at the time of implementation. In legislatures, those who oppose the approval of effective tobacco control policies typically attempt to delay the process of legislative approval and weaken the legislative text under discussion. Later, after approval of the tobacco control law, judicial challenges to the constitutionality of the measure have been presented in some countries.

Those who draft tobacco control laws or who defend them before jurisdictional bodies have found it advisable to expand the initial legal foundations of the WHO FCTC through human rights instruments (treaties, conventions, protocols, and standards), which can play a key role in supporting and strengthening tobacco control policies. The link between tobacco

control policies and human rights instruments gains even greater importance in Latin America, where human rights are accorded great weight from a legal, political, and even social standpoint.

The majority of the countries of the Region have ratified the key human rights treaties, including the ICESCR, CEDAW, and CRC, as well as the International Covenant on Civil and Political Rights (ICCPR) (see Annexes 1 and 2). Even countries such as Argentina and El Salvador that have not yet ratified the WHO FCTC have moved forward with other legal instruments that would make it possible to require strict tobacco control policies, such as the ICESCR, CEDAW, or CRC.

All these treaties generate the obligation to respect, protect, and fulfill the rights that are recognized in them. With regard to health, the Committee on Economic, Social and Cultural Rights (CESCR), the official monitoring body of the ICESCR, explicitly indicates the implications of each of those obligations contained in that Covenant:

The obligation to *respect* requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 guarantees. Finally, the obligation to *fulfill* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health. (CESCR 2000, emphasis in original)

As established in Article 27 of the Vienna Convention on the Law of Treaties, “A party may not invoke the provisions of its internal law as justification for its failure to perform a treaty.”

It is understood, then, that the obligations arising from international treaties acquire a special rank that gives them preeminence over domestic legislation. It is important to emphasize that Member States of the Region have given high rank to human right treaties. Some countries give them constitutional rank, while several even grant them preeminence over the constitution.

1.3.1 The link between tobacco control policies and human rights instruments

Given the connection between tobacco control policies and human rights, it is particularly important to consider the scope of the protection of the right to health provided by Article 12 of the ICESCR. The standard of interpretation in this regard is General Comment No. 14 by the CESCR (2000).

According to General Comment No. 14, States Parties to the ICESCR have the obligation to respect, protect, and fulfill the right to the highest attainable standard of health. This obligation implies different duties in different areas, such as access to medicines, child nutrition, and control of epidemics, among many others. With respect to control of the tobacco epidemic, States Parties have the obligation to adopt measures to protect and promote the right to health. For the purpose of determining which measures States Parties should take, official human rights bodies have used the WHO FCTC as a standard. The CESCR has already analyzed the connection between tobacco control and States’ obligation to protect the health of their populations. For example, during the periodic examination of Brazil’s implementation of the ICESCR in 2009, the committee began by welcoming that country’s ratification of the WHO FCTC in 2005. It further recommended that Brazil, as a Party to the ICESCR, adopt measures to reduce the impact of tobacco on the population:

The Committee notes with concern that it is still permissible to promote the use of tobacco through advertising in the State party and that, while the use of tobacco-derived products is banned in publicly accessible areas, smoking is permitted in areas specially designed for the purpose. [. . .] The Committee recommends that the State party

take measures to ban the promotion of tobacco products and enact legislation to ensure that all enclosed public environments are completely free of tobacco. (CESCR 2009)

This recommendation was made partly in response to a shadow report presented jointly by the Aliança de Controle do Tabagismo (a Brazilian tobacco control coalition) and the O’Neill Institute for National and Global Health Law at Georgetown University.⁷

From General Comment No. 14 and from the corresponding recommendation provided to Brazil, it is clear that the CESCR uses the WHO FCTC as a standard for evaluating fulfillment of the obligations that are derived from the right to health as recognized in the ICESCR. This approach was deepened when the committee evaluated Argentina’s ICESCR implementation report in 2011. The CESCR, concerned about the high levels of tobacco consumption in Argentina, and responding to a shadow report presented jointly by the InterAmerican Heart Foundation–Argentina and the O’Neill Institute for National and Global Health Law,⁸ recommended that Argentina “ratify and implement the WHO Framework Convention on Tobacco Control and develop effective public awareness and tax and pricing policies to reduce tobacco consumption, in particular targeting women and youth” (CESCR 2011). This shows that the linkage between the right to health and the WHO FCTC can be made even in a country that has not yet ratified the Convention.

In addition to the CESCR, the United Nations Committee on the Elimination of Discrimination against Women, the monitoring body of CEDAW, also issues reports in which it analyzes the types of measures a Party should implement in order to wholly fulfill its obligations arising from that Convention. After reviewing Argentina’s sixth country report, the CEDAW Committee explicitly indicated its concern about the levels of tobacco consumption among Argentine women and about tobacco industry marketing campaigns specifically targeted to women. It urged “the State party to ratify and implement the World Health Organization Framework Convention on Tobacco Control and put in place legislation aimed at banning smoking in public spaces and restricting tobacco advertising” (CEDAW 2010). This illustrates, again, how an official human rights monitoring body uses the WHO FCTC as a standard in order to interpret the obligation to protect health, in this case of women.

The connection between tobacco control and human rights has also been expressed at the domestic level in countries of the Region. One example is a 2011 decision by the Constitutional Tribunal of Peru, which even stated that the WHO FCTC is actually a human rights treaty. According to the tribunal:

[T]he WHO Framework Convention on Tobacco Control is a human rights treaty, since it seeks to clearly, expressly and directly protect the basic right to health protection recognized in Article 7 of the Constitution. Indeed, the Convention’s introduction points out that it represents a “groundbreaking step in advancing national, regional and international action and global cooperation to protect human health against the devastating impact of tobacco consumption and exposure to tobacco smoke.”⁹

These precedents at the international and domestic levels support an important conclusion: at a minimum, the WHO FCTC has been established as a legal standard that gives concrete content to the general obligation to respect, protect, and fulfill

⁷ The full report is available on the CESCR website at http://www2.ohchr.org/english/bodies/cescr/docs/info-ngos/ONeillInstitute_CTFK_ACT_Brazil42.pdf.

⁸ The full report is available on the CESCR website at http://www2.ohchr.org/english/bodies/cescr/docs/ngos/ONeill_FIC_Fundeps_Argentina47_en.pdf.

⁹ 5000 Citizens v. Article 3 of Law No. 28705 – General Law for the Prevention and Control of Tobacco Use Risks. Judgment from the Full Jurisdictional Bench of the Constitutional Court of Peru, July 19, 2011, unconstitutionality proceedings, para. 67. Unofficial translation by authors.

the right to health with regard to the tobacco epidemic (Cabrera and Madrazo 2010: 288–297). As seen in the monitoring bodies' recommendations, the WHO FCTC has been applied as a valid legal standard for the interpretation of human rights obligations even for states that have not ratified the Convention, as in the case of Argentina, because the right to health requires certain actions by states.

This approach is also shared by the Secretariat of the Pan American Health Organization (PAHO). Referring to smoke-free policies, PAHO has stated that “national governments have the authority to regulate smoking in public places and both public and private workplaces and should implement laws, policies, plans and practices, *guided by their human rights obligations*, that require all of these settings to be 100% smoke-free indoors” (PAHO 2006: 22, emphasis added). It is clear, then, that the human rights protected under the WHO FCTC and the ranking of the human rights treaties ratified by States in the Americas expand the technical resources available to support the promotion and implementation of effective tobacco control measures.

1.3.2 Progressive realization of protection of the right to health

From the human rights perspective, key principles to consider with respect to effective implementation of the WHO FCTC and the sustainability of tobacco control policies are the principles of progressive realization and non-retrogression (CESCR 2009). “Progressive realization” refers to the commitment of a State Party to take steps to achieve progressively, through all appropriate means, in particular the adoption of legislative measures, the full effectiveness of the protected human rights. In the context of the ICESCR, Parties commit to progressive realization of economic, social, and cultural rights, including the basic right to health (ICESCR Article 2.1). In accordance with the CESCR, this principle should be understood as obliging the States Parties to advance expeditiously and effectively toward the full realization of Article 12, which sets forth the right to health. The same obligation is also established in Article 26 of the American Convention on Human Rights with regard to “the rights implicit in the economic, social, educational, scientific, and cultural standards set forth in the Charter of the Organization of American States.” However, certain human rights protected by the American Convention on Human Rights and intrinsically related to tobacco control, such as the right to life and the right to personal integrity, are not subject to progressive realization and shall be protected by governments “immediately” and not “progressively.”

The principle of progressive realization in turn gives rise to a prohibition against adoption of regressive measures (known as the principle of non-retrogression). As explained by the CESCR (1990), “any deliberately retrogressive measures [. . .] would require the most careful consideration and would need to be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources.” This principle tries to provide States Parties with flexibility, taking into account the fact that limited resources usually make it impossible to immediately guarantee the fulfillment of social, cultural, and economic rights. At the same time, it sets forth concrete legal obligations to ensure the steps taken toward an effective protection of these human rights. Thus, it is understood that “the obligation of non-retrogression constitutes a limit that the relevant human rights treaties and, ultimately, the Constitution impose on the executive and legislative branches regarding the possibilities of restriction of economic, social, and cultural rights” (Abramovich and Curtis 2002: 95).

This principle is of essential importance for legislative discussions of tobacco control. Once a state has achieved a certain level of protection against tobacco, it cannot adopt measures that weaken that protection. This principle was highlighted by the Constitutional Tribunal of Peru in its ruling on the abovementioned 2011 case, which challenged the constitutionality of smoke-free environments:

Taking into consideration [. . .] that the State has the duty to protect the right to health at the maximum level possible, that smoking is an epidemic, that rights must be protected through progressive steps, which means that except in highly exceptional circumstances, the legal steps taken to protect health mark a point of no return and that, according to Article 3 of the WHO Framework Convention on Tobacco Control, the aim of reducing use and exposure to tobacco smoke must be achieved “continually,” it is found constitutionally prohibited that in the future, legislative or any other steps be taken that protect to a lesser degree the fundamental right to health in face of the smoking epidemic, in comparison to the protection afforded by current legislation.¹⁰

It should be clear that the principle of progressive realization does not mean that a State Party may adopt WHO FCTC measures gradually. On the contrary, the State has the duty to advance as expeditiously and effectively as possible toward full realization of the right to health. The principle of progressive realization operates as a stimulus for a State to move forward. The protection of health is continually improved, yet it will always be possible to further strengthen the protection of the right to the highest attainable standard of health. The principle of progressive realization and non-retrogression is thus another tool of vital importance in crafting a legislative framework for tobacco control.¹¹

1.4 Legislation and litigation

1.4.1 Article 19 of the WHO FCTC

WHO FCTC Article 19, under the heading “Liability,” specifically addresses the matter of litigation linked to tobacco regulation: “For the purpose of tobacco control, the Parties shall consider taking legislative action or promoting their existing laws, where necessary, to deal with criminal and civil liability, including compensation where appropriate.” In the same article, the WHO FCTC requires Parties to cooperate with each other in exchanging information on the health effects of tobacco and on pertinent legislation and jurisprudence.

During the fourth COP, held in Punta del Este, Uruguay, in 2010, an initial report was submitted on progress by the Parties in the implementation of Article 19. Of those states that had delivered their implementation reports by that time, 34% reported having adopted some measure dealing with civil or criminal liability for the purpose of tobacco control. Legislation in some of Canada’s provinces specifically addresses compensation for health harms caused by the tobacco industry.¹² A technical paper on the implementation of Article 19 was presented to the fifth COP, which decided to establish an expert group to review the matter and report to the sixth COP.

1.4.2 Litigation and the development of legislative frameworks for tobacco control

The tobacco industry and its allies pursue two interrelated strategies to defeat effective tobacco control (O’Neill Institute 2012). First, they allocate a large quantity of resources to efforts to influence lawmakers and dissuade them from approving effective laws for tobacco control. Second, if they fail in their efforts to defeat or weaken tobacco control bills during the legislative process, they resort to litigation to attack strong tobacco control legislation in the courts. For example, the industry and its allies allege that some tobacco control measures are unconstitutional based on the supposed “right” to advertise

¹⁰ Ibid, para. 148.

¹¹ It should be noted that many tobacco control measures require very few resources on the part of the government. Unlike protection of rights such as access to housing, for example, protection of health against the tobacco epidemic does not require large expenditures by the State. As a result, the obligations of protection and immediate realization become even more important. The very minimal cost to governments for implementing smoke-free measures is discussed in Chapter 3.

¹² For example, British Columbia’s legislation, the Tobacco Damages and Health Care Costs Recovery Act, Chapter 30, SBC 2000, is available at http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_00030_01.

and market their products, the “rights” of citizens to consume those products in public or in the workplace, and the “rights” of owners and employers to permit such consumption. This double strategy of the tobacco industry requires that legislative drafters and advocates not only be prepared to address tobacco industry arguments during the legislative development and approval process, but also draft the legislation in a way that minimizes the risk of a successful legal challenge.

Linking legislative frameworks with human rights instruments that protect the rights to health and life and related rights can be an effective legislative drafting strategy in anticipation of the tobacco industry’s more commercially oriented rights-based legal challenges. This might mean, for example, stating explicitly in the tobacco control law’s objectives that a primary purpose of the law is to protect the right to health and related human rights (such as the rights to life, to personal integrity, and to equal protection under the law) as enshrined in human rights treaties such as the ICESCR, ICCPR, and the American Convention, among others, to which the State is a Party. This can strengthen the case for judicial interpretations that protect health.

Many judicial rulings in the Region establish or indirectly acknowledge the link between human rights and tobacco control policies. For example, in Mexico, claimants challenged the national tobacco control law on the grounds that it provides only weak protection of the rights to health, to information, and to life guaranteed by the Constitution of Mexico, and that it fails to meet WHO FCTC requirements. Although the court dismissed the case on procedural grounds without considering the substantive merits, the case is important because in acknowledging the petitioner’s standing (legal right to bring the case), the court confirmed the existence of positive State obligations arising from economic, social, and cultural rights.¹³ In several tobacco industry–initiated legal challenges described in different chapters of this manual, courts have emphasized the right to health in their rulings upholding the challenged tobacco control laws.

1.5 Tobacco and trade

International trade and investment agreements are designed to facilitate open trade and investment, respectively. While health measures, including those for tobacco control, are designed with a different, and possibly competing, purpose, tobacco control measures and trade and investment agreements can be in harmony with one another. Recent legal challenges to tobacco control measures in the World Trade Organization (WTO) and in relation to investment treaties, however, suggest that policy makers should take into account their international trade and investment commitments as they design and implement tobacco control measures.

1.5.1 The World Trade Organization

The WTO, established in 1995, oversees a number of “covered agreements” that oblige WTO Members to liberalize trade. For example, the General Agreement on Tariffs and Trade (GATT 1994) obliges each WTO Member to refrain from imposing customs duties (tariffs) on importation of goods above the bound rates set out in each Member’s schedule of concessions. This commitment is complemented by a number of other commitments designed to limit the ability of Members to create nontariff barriers to trade, such as regulatory measures.

Although there have been few claims related to tobacco control regulatory measures under WTO law to date, this body of law has been invoked recently as a basis for challenges to tobacco product regulations implemented by the United States and tobacco packaging and labeling measures (plain packaging) to be implemented by Australia. These challenges suggest that WHO FCTC Parties and non-Parties should be mindful of how their commitments under trade agreements have the potential to affect tobacco control regulation.

¹³ Mexican Supreme Court of Justice, Jorge Francisco Balderas Woolrich, revised amparo 315/2010 against 1791/2008, decided 28/03/2011, rapporteur José Ramón Cossío Díaz, p. 8.

At the same time, it is important not to overstate the limitations embodied in international trade agreements. With respect to WTO law, the director general of the WHO has confirmed that there is no inherent incompatibility between the WHO FCTC and WTO rules.¹⁴ Nonetheless, the specific manner in which a WTO Member implements a tobacco control measure could lead to violation of WTO law. In considering how to implement tobacco control measures, there are two important WTO law principles to be considered. These are that measures should be nondiscriminatory and that regulations must be necessary to protect human health.

The principle of nondiscrimination, first of all, means that tobacco control measures must not treat imported products less favorably than “like products” produced domestically. It prohibits measures that discriminate in their form, such as measures that only apply to imported tobacco products. But the principle of nondiscrimination also applies to measures that have a discriminatory effect, even if the measures are not discriminatory on their face. This is particularly relevant where WTO Members draw regulatory distinctions between different categories of tobacco products. For example, in *United States—Measures Affecting the Production and Sale of Clove Cigarettes*,¹⁵ a US law that prohibits flavored cigarettes other than cigarettes with a tobacco or menthol flavor was found to violate the principle of nondiscrimination in Article 2.1 of the WTO Agreement on Technical Barriers to Trade. Indonesia argued successfully that the effect of the law was to treat clove cigarettes produced predominately in Indonesia less favorably than like menthol-flavored cigarettes produced predominately in the United States, amounting to discrimination. In situations such as this, where the effect of a measure falls primarily on imported products rather than domestic products, one question will be whether the products treated differently are in fact “like products.” This is judged by reference to the extent of competition between the products, and WTO case law suggests that most tobacco products will be considered like products.

Another key question is whether the detrimental effects on imported products stem exclusively from a legitimate regulatory distinction. For example, in *United States—Clove Cigarettes*, the WTO Appellate Body rejected the argument that the United States treated clove and menthol cigarettes differently on the basis of a legitimate regulatory distinction between the two products. Rather, both clove and menthol were found to mask the harshness of tobacco and to appeal to youth. Accordingly, the prohibition on clove cigarettes was found to be discriminatory. The detrimental effect of the ban on competition between imported products (clove cigarettes) and domestic products (menthol cigarettes) was found not to be based on a legitimate regulatory distinction.

The second central principle of WTO law to be considered here is that measures to protect health should be “necessary” for that purpose. This principle of necessity plays a role in all of the WTO covered agreements relevant to tobacco control. Article XX of the GATT¹⁶ creates an exception for measures necessary to protect human life or health. In the Agreement on Technical Barriers to Trade,¹⁷ Article 2.2 creates an obligation to ensure that technical regulations, such as product regulations and packaging and labeling measures, are not more trade-restrictive than necessary to achieve a legitimate objective, such as protection of human health. Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)¹⁸ there are “flexibilities” that permit WTO Members to implement their obligations in accordance with their own legal systems and practices. As the Doha Declaration¹⁹ on the TRIPS Agreement and Public Health emphasized, these flexibilities should be interpreted in a manner supportive of the rights of Members to protect public health.

¹⁴ See “WTO Rules and the Implementation of the WHO FCTC Are Not Incompatible” on the FCTC website, http://www.who.int/fctc/wto_fctc/en/index.html.

¹⁵ <http://www.worldtradelaw.net/reports/wtoab/us-clovecigarettes%28ab%29.pdf>.

¹⁶ http://www.wto.org/english/docs_e/legal_e/legal_e.htm#GATT94.

¹⁷ http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf.

¹⁸ http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

¹⁹ http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html.

Although the necessity concept may be applied slightly differently under different WTO covered agreements, a few basic concepts are common to all the agreements. First, WTO Members have a right to determine the level of health protection they wish to pursue. Second, in determining whether a measure is necessary, a WTO panel may weigh the potential contribution of a measure to its objective against the extent to which that measure will restrict trade. Third, WTO panels may examine whether there exist less trade-restrictive alternative measures. Such measures must be capable of achieving the Member's objective, must be reasonably available, and must be true alternatives and not complementary measures. Finally, measures cannot be *applied* in a manner that would constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade.

1.5.2 International Investment Agreements

International Investment Agreements (IIAs), which are most often bilateral agreements between two states, permit foreign investors (often corporations) to bring claims directly against a state concerning protection of investments. Claims under IIAs are heard by a panel of arbitrators, and the IIA in question is the law applied by the arbitration panel, along with any other commitments incorporated by reference.

In general, IIAs provide foreign investors with protection against expropriation of their property rights and protection against treatment that is unfair or inequitable. In recent years, Philip Morris has used IIAs to challenge packaging and labeling measures in Uruguay and Australia. In Uruguay, Philip Morris filed a legal challenge to a requirement for graphic health warnings that cover 80% of the surface of the pack, as well as restrictions on misleading branding that impose limits of a single presentation per brand. For example, Philip Morris may only sell one variant of the Marlboro brand in Uruguay. In Australia, the company filed a legal challenge to new laws that require plain packaging of tobacco products. At this writing, both legal challenges are ongoing.

Because IIAs are mostly bilateral in character, it is difficult to generalize about their requirements in the same way as may be done with respect to WTO law. Nonetheless, there are a few basic principles that should be followed. First, in implementing tobacco control measures, States should ensure that those measures only interfere with property rights to the extent that is necessary to achieve a particular health objective: that is, the measures should be proportional to the objective. Second, States should not create for foreign investors any legitimate expectation that they will not be subject to the type of regulation in question. This includes representations made by public or private statements as well as agreements with tobacco companies. Third, within the bounds of Article 5.3 of the WHO FCTC, States should ensure that principles of due process and natural justice are followed. Finally, States should ensure that measures are nondiscriminatory. Following these basic principles will minimize the risk of liability under an IIA.

1.6 Other considerations

There are two issues generally connected with tobacco control regulation that arise repeatedly when governments begin to discuss their tobacco control plans. The first is prevention of youth smoking, a subject about which there are many misconceptions, some promoted by the tobacco industry itself. The second is the issue of electronic nicotine delivery systems, more commonly known as electronic cigarettes, which pose a challenge to tobacco control policies.

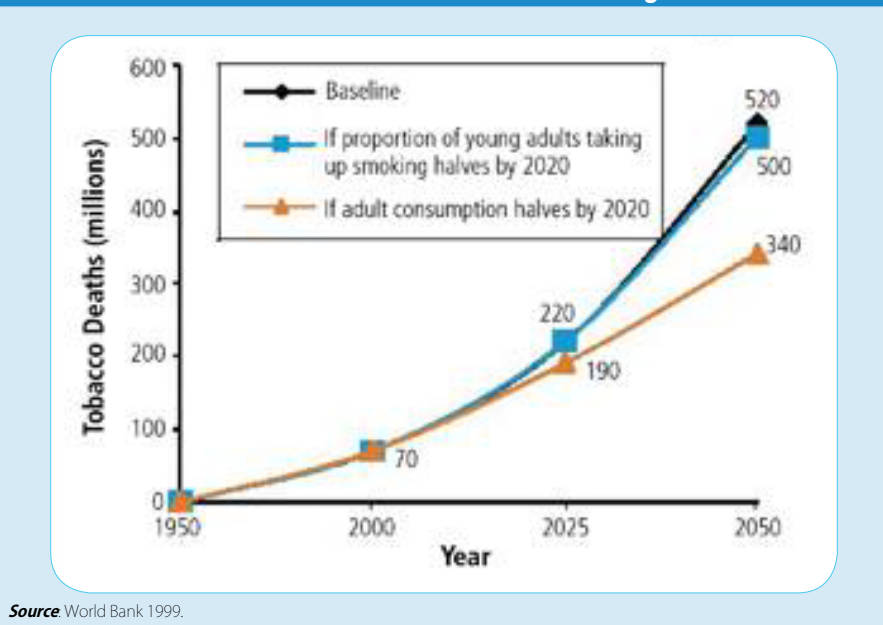
1.6.1 Youth interventions versus adult interventions: A false dichotomy

It is well established that most tobacco users begin using tobacco as youth (World Bank 1999). When discussing the implementation of tobacco control measures at the national level, policy makers often say that they want to focus on

youth, the rationale being that ending the tobacco epidemic depends ultimately on preventing tobacco initiation. The tobacco industry, for its own reasons, has also favored strategies that limit preventive efforts to youth.

There is no doubt that preventing young people from taking up tobacco use is one of the components of a comprehensive, long-term strategy to end the tobacco epidemic. It is important to recognize, however, that in the short term—in the first half of the current century—the burden of tobacco-related disease and mortality will fall most heavily on the people who are already smoking today, as shown in Figure 1.1. This means that focusing prevention efforts only on youth, while ignoring adult smokers, is no more than a partial solution to the global tobacco epidemic.

Figure 1.1 Estimated cumulative tobacco deaths, 1950–2050, with different intervention strategies



Moreover, strategies for preventing youth initiation usually focus only on the supply reduction measures described in Article 16 of the WHO FCTC and on educational interventions in schools. A broader approach is needed. Even though Article 16 of the WHO FCTC restricts youth access to tobacco products, it is not the only article in the Convention that affects tobacco use by youth. The full implementation of the WHO FCTC will curtail both youth initiation and ongoing tobacco consumption by youth and adults. The main conclusions of the most recent report of the US Surgeon General (HHS 2012) support this approach.

1.6.2 Electronic nicotine delivery systems

Electronic nicotine delivery systems (ENDS) are a category of consumer products, marketed as cigarette alternatives, that are designed to deliver nicotine into the lungs through inhalation. They are known by many names, including electronic cigarettes, e-cigarettes, e-ciggy, e-cig, MiniCiggy, e-pipe, e-cigar, etc.

ENDs contain an electronic vaporization system, a battery, electronic controls, and replaceable cartridges that contain nicotine and other chemicals. Some brands claim to deliver a range of nicotine concentrations or no nicotine at all, and some claim to provide sensory experiences similar to those obtained with major cigarette brands. The chemicals used to produce the odors and flavors that simulate those of cigarettes have not all been identified, although some products claim to include “menthol” (WHO 2010e).

At present, there is no certainty about the exact content of these devices or the safety of their use in humans (WHO 2010e). Moreover, a study by the US Food and Drug Administration (FDA) analyzed the chemicals contained in 18 varieties of ENDS cartridges from two different brands and found a significant variation in content and levels of substances released. The FDA analysis also revealed that nicotine levels did not necessarily correspond to the information appearing on the labels of the cartridges, and it detected the presence of nicotine in some cartridges that were advertised as being nicotine-free. In addition, several products contained detectable levels of nitrosamines, tobacco compounds that are known carcinogens (FDA 2009).

Advertising for ENDS frequently claims its therapeutic qualities as a smoking cessation aid. But the effectiveness of ENDS as a pharmacological means of quitting smoking has not been proven, as the World Health Organization has clearly stated: "WHO has no scientific evidence to confirm the product's safety and efficacy. Its marketers should immediately remove from their web sites and other informational materials any suggestion that WHO considers it to be a safe and effective smoking cessation aid" (WHO 2008). In order to be considered as cessation aids, ENDS would have to undergo all the tests that health authorities require to ensure the safety and effectiveness of any drug approved for medical treatment.

Not surprisingly, ENDS have become more popular and are more heavily advertised as countries have implemented Article 8 of the WHO FCTC, calling for protection from exposure to tobacco smoke. There is significant concern that the sale, dissemination, and use of ENDS may undermine one of the key objectives of the WHO FCTC, a decrease in the prevalence of tobacco consumption, since ENDS may "facilitate and perpetuate nicotine addiction" (WHO 2010e).

The WHO study group on product regulation discussed the issue of ENDS regulation. It recommended regulating ENDS as combination drugs and medical devices, not as tobacco products (WHO 2010e).

During the fourth session of the COP, the Convention Secretariat issued a report on the subject of ENDS. The report summarized the recommendations that emerged from the WHO Regulatory Consultation on the Safety of Electronic Nicotine Delivery Systems held in May 2010. Delegates of WHO Member States, invited experts in the field of tobacco product regulation, members of the WHO Study Group on Tobacco Product Regulation, members of the Convention Secretariat, and WHO staff participated in that meeting (WHO 2010d). The recommendations were as follows:

- Nicotine is a highly toxic and addictive substance that poses a serious risk to health. Nicotine and nicotine products for human use should be regulated.
- There is an emerging group of products called Electronic Nicotine Delivery Systems that may or may not deliver nicotine. These products, commonly including e-cigarettes, may be used to deliver other potentially toxic chemicals and drug ingredients. These products are often accompanied by inaccurate information. Regulators are concerned that the quality and safety of these products has not been established.
- Regulators of medical and tobacco products should collaborate in assessing the regulatory framework within their own countries to determine the most effective means of regulating (or possibly banning) Electronic Nicotine Delivery Systems to protect public health.
- Where health and/or therapeutic claims are being made or implied, quality, safety and efficacy data substantiating those claims should be presented to the regulator.

- National regulators are encouraged to inform the public and other interested parties about concerns related to these products, including their safety and misleading marketing, and to share information among themselves about these products, including research findings and related policies.
- National regulators encourage WHO to facilitate information exchange between tobacco control and medical products regulators.

In the absence of elements that can ensure their safety, and given the fact that these devices deliver an addictive drug, several governments have preferred to use the precautionary principle (e.g., Brazil) and prohibit their sale in the country. ENDS are banned in Argentina, Brazil (ANVISA 2009), Panama, and Uruguay, among other places. In Canada, ENDS are regulated under the Food and Drugs Act and require market authorization. Companies wishing to market an electronic cigarette with nicotine as a smoking cessation product in Canada must submit evidence demonstrating that the product is safe, effective, and of high quality under its recommended conditions of use prior to its approval for importation, advertising, and sale. No ENDS products have received such approval, either in Canada (as of October 2012) or in any other country (Health Canada 2009a, 2009b).

The fifth COP mandated the Convention Secretariat to invite WHO to undertake further research on ENDS and report its findings to the sixth COP.

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Annex 1. Treaties and conventions

This section provides links to the treaties and conventions mentioned in Chapter 1 and throughout the manual.

- **Agreement on Technical Barriers to Trade.** Entry into force: 1995.
http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm.
- **Agreement on Trade-Related Aspects of Intellectual Property Rights.** Entry into force: 1995.
http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.
- **American Convention on Human Rights (“Pact of San José, Costa Rica”).** Entry into force: 1978.
<http://www.oas.org/juridico/english/treaties/b-32.html>.
- **International Covenant on Economic, Social and Cultural Rights.** Entry into force: 1976.
<http://www2.ohchr.org/english/law/cescr.htm>.
- **Convention on the Rights of the Child.** Entry into force: 1990.
<http://www2.ohchr.org/english/law/crc.htm>.
- **Convention on the Elimination of All Forms of Discrimination against Women.** Entry into force: 1981.
<http://www2.ohchr.org/english/law/cedaw.htm>.
- **General Agreement on Tariffs and Trade 1994.** Entry into force: 1995.
http://www.wto.org/english/docs_e/legal_e/06-gatt.pdf.
- **International Covenant on Civil and Political Rights.** Entry into force: 1976.
<http://www2.ohchr.org/english/law/ccpr.htm>.
- **Vienna Convention on the Law of Treaties.** Entry into force: 1980.
<http://www.ilsa.org/jessup/jessup11/basicmats/VCLT.pdf>

Annex 2. Countries in the Region of the Americas that are Parties to inter-American and United Nations treaties

Parties to Inter-American treaties

American Declaration of the Rights and Duties of Man: Not subject to ratification.

American Convention on Human Rights (Pact of San José): Argentina, Barbados, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, Trinidad and Tobago, Uruguay, Venezuela.

Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador): Argentina, Brazil, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Mexico, Panama, Paraguay, Peru, Suriname, Uruguay.

Inter-American Convention on the Prevention, Punishment and Eradication of Violence against Women (Convention of Belém do Pará): Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, Venezuela.

Parties from the Americas to United Nations treaties

Universal Declaration of Human Rights: Not subject to ratification.

International Covenant on Civil and Political Rights: Argentina, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago, United States of America, Uruguay, Venezuela.

International Covenant on Economic, Social and Cultural Rights: Argentina, Barbados, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, Venezuela.

Convention on the Elimination of All Forms of Discrimination against Women: Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, Venezuela.

Convention on the Rights of the Child: Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago, Uruguay, Venezuela.

Chapter 2

Developing Tobacco Control Laws



Source: Shutterstock.

2. Developing Tobacco Control Laws

2.1 Different routes to effective implementation of the WHO FCTC

There are multiple routes to achieving the objectives of the World Health Organization Framework Convention on Tobacco Control (WHO 2003; hereafter, WHO FCTC), and multiple ways to effectively implement measures required by the treaty. It is critical that each Party craft a comprehensive tobacco control policy and/or law that fits its legal landscape and that will most efficiently and effectively achieve the objectives of the WHO FCTC.

The text of the treaty itself recognizes the various routes for implementation. For example, Articles 5.2 and 7 state that “each Party shall adopt and implement effective *legislative, executive, administrative or other measures*” necessary to meet its obligations under the treaty. Similar language is also invoked in other articles. In this chapter, when identifying possible routes for effective WHO FCTC implementation, we will discuss the considerations that come into play when choosing between:

- Legislative or executive measures;
- Measures at the national or subnational level;
- A single comprehensive law or separate laws, for one or several tobacco control topics.

Finally, we note several considerations concerning the content of laws and regulations before moving on to a discussion of key components of tobacco control legislation. The 2004 WHO publication, *Tobacco Control Legislation: An Introductory Guide*, provides useful guidance for developing such legislation and discusses in depth many of the topics addressed in this and the preceding chapter.

2.1.1 Legislative or executive measures

Legal measures include both acts emanating from the legislative branch and administrative orders, decrees, and implementing regulations issued by the executive branch. Executive measures, also commonly referred to as administrative measures, are issued in the performance of the executive’s regulatory power or administrative duties. Legislative acts are most commonly used to implement the WHO FCTC and are often accompanied by regulations or other administrative measures that provide implementation details. Below we will analyze executive measures, since they may be less familiar as sources of binding legal requirements.

2.1.1.1 Pros and cons of legislative versus executive action

Laws enacted by the legislative body are, after a State’s constitution, at the highest level in the legal hierarchy, generally speaking. Thus they are usually the preferred means of WHO FCTC implementation where politically feasible. There are two main reasons for this: (a) they are more stable forms of law than regulations, requiring subsequent acts of the legislature to

undo or weaken them, and (b) the legislative process promotes general public debate on topics of public interest, allowing opportunities for broad societal participation in shaping or contributing to the policy under development. The executive process does not confer these benefits, and executive measures can be more easily dismantled by a new minister or other executive who may have a different political agenda. Additionally, executive measures may be voided by subsequent legislative action, especially where the public has not “bought into” the measures.

There are examples of strong and comprehensive tobacco control measures taking the form of regulations, either in place of tobacco control legislation or as a precursor to such legislation, in the Region. For example, in the Caribbean, Barbados enacted comprehensive smoke-free regulations in 2010 that banned smoking in all enclosed public places and workplaces under the authority of the pre-existing Health Services Act.¹ Examples from Latin America demonstrate the use of executive action as a precursor to legislative action. Uruguay and Colombia opted for executive action, which could be done relatively quickly, and then followed with legislative action, resulting in the enactment of strong and comprehensive national tobacco control laws.

In Uruguay, the government in 2005 first issued Decree 268, an executive order banning smoking in all indoor public places and workplaces, including all means of public transport.² In doing so, Uruguay became the first country in the Americas to fully implement Article 8 of the WHO FCTC, and its public places have been smoke-free since Decree 268/005 went into effect on 1 March 2006. At the same time, the government pursued comprehensive tobacco legislation (Law 18.256)³ which was passed by the Uruguay Parliament on 29 February 2008. This legislation currently governs smoke-free places and other tobacco control policies. With the executive decree in 2005, the citizens of Uruguay began benefitting from the favorable health impacts of the smoking ban while the legislation was still being drafted and debated, a process that took over two years. During the period between the enactment and carefully planned implementation of the decree and the time the legislature enacted the comprehensive legislation, the executive measure gained more and more public support, reflected in opinion polls that PAHO (2006) conducted during that period. This evidence was used to successfully advocate for the legislation.

Colombia's government first enacted a ban on smoking in “indoor or enclosed areas in workplaces and/or public places” through a resolution issued by the Ministry of Social Welfare.⁴ The Congress then passed a comprehensive tobacco control law, including an indoor public and workplace smoking ban, approximately a year later, on 21 July 2009. As in the case of Uruguay, the Colombian public broadly supported the executive measure and benefited from the protection the resolution provided for approximately one year before the comprehensive legislation was enacted (YanHaas Advanced Market Research 2009).

The cases of Uruguay and Colombia illustrate the potential of using an executive measure as a step in the policy development process. Ultimately, however, the extent of political will—and the susceptibility to political pressure exerted by the tobacco industry and its allies in both the legislature and the executive—must be evaluated before making a decision about which route to follow.

¹ Health Services (Prohibition of Tobacco Smoking in Public Places) Regulations, 2010, <http://tobaccocontrolaws.saforian.com/files/live/Barbados/Barbados%20-%20SF%20Regs%20-%20national.pdf>.

² A decree is an authoritative order generally issued by the head of state. Because it is issued by the executive branch, it is not subject to the usual parliamentary procedures, but immediately acquires the force of law when it enters into force.

³ Unofficial English translation available at <http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Law%20No.%2018.256.pdf>. Official version available at <http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18256&Anchor>.

⁴ A resolution is another form of executive measure applicable in some countries.

In addition, if the decision is made to use executive action with the intention of later pursuing legislation, it is critical that the administrative measures be planned and implemented very carefully to ensure their success, and their success should be widely publicized to help pave the way for legislation. Otherwise, any failures in implementation of the administrative measures likely will be used to argue against legislative attempts.

2.1.1.2 Legal bases for executive action

The legal bases for action by the executive or administrative branch to enact legal measures usually derive from existing enabling legislation. This may be, for example, a public health, environmental, or workplace safety law, if not a tobacco control law, that grants the relevant ministry or ministries the authority to enact implementing regulations to give effect to the provisions of the enabling legislation. In countries where international treaties have the force of law without the need to first enact implementing legislation to give effect to the treaty, a treaty may provide direct legal grounds for the executive to enact implementing regulations. Likewise, in countries where the constitution guarantees the right to life, health, the enjoyment of healthy environments, or other relevant rights, the constitution itself may provide the direct legal grounds for the executive to enact implementing regulations.

A careful review of any relevant legal authority that may enable executive measures for tobacco control must be made before undertaking executive action. It is necessary to determine not only whether the executive branch has legal authority to enact legal measures on tobacco control, but also whether any existing legislative acts would prevent the executive from enacting stronger tobacco control measures that conflict with the existing law. For example, if a preexisting act of the legislature requires the establishment of smoking areas in workplaces, the executive could not enact regulations prohibiting such smoking areas, since only a subsequent act of the legislature can amend or change a prior legislative act.

2.1.2 Measures at the national or subnational level

In federal political systems, where law-making authority rests both with subnational jurisdictions and with the national government, subnational jurisdictions generally enjoy a higher degree of law-making autonomy than they do in centralized political systems, where the law-making power rests primarily with the national government. Thus, in federal systems particularly, there are legislative and executive branches at the subnational level that might have the specific competency, or power, to regulate health or related matters relevant to tobacco control (such as consumer protection or environmental matters), either exclusively or concurrently with the national level of government. Where legally and politically possible, tobacco control laws are generally better developed at the national level, since the protections will apply and be enforceable countrywide. However, given the trend toward decentralization in some countries, subnational jurisdictions may have been granted some autonomy to enact laws, including tobacco control laws, at the level of the territorial units—states, provinces, municipalities, or other subnational units. These subnational jurisdictions may be the more appropriate arena for tobacco law making, depending on the legal system in the country. In determining whether to go the national or subnational route, the degree of autonomy of territorial units on health and related policies under which particular tobacco control measures may fall, and whether there is concurrent competency at the national level, must be understood as a threshold matter. The enquiry does not end there, however.

Box 2.1 The case of Mexico City

México DF, Mexico's federal district and capital, has a population of 8.8 million. The population of the greater metropolitan area is almost 20 million, making Mexico City the third-largest metropolis in the world.

On 26 February 2008, the Mexico City Legislative Assembly approved amendments to the 2004 Law for the Protection of the Health of Non-Smokers in the Federal District and the corresponding Law for the Functioning of Commercial Establishments. The amendments required all enclosed public places and workplaces, including public transport, restaurants, and bars, to be 100% smoke-free. Designated smoking rooms were not allowed, making Mexico City the largest jurisdiction in Latin America at the time to introduce a comprehensive smoke-free law. The law came into effect on 3 April 2008. On the same day, the Senate approved a new national law. The General Law on Tobacco Control restricts smoking in indoor workplaces and enclosed public places, but allows them to have separate smoking rooms (which must comply with strict specifications) or outdoor smoking areas. The federal law came into force on 28 August 2008, and regulations were issued on 31 May 2009. In Mexico City, the stronger municipal law takes precedence over the less restrictive federal law.

Source: Adapted from *Smoke Free City: Mexico DF* (International Union Against Tuberculosis and Lung Disease, 2009), http://www.tobaccofreeunion.org/assets/Technical%20Resources/Case%20Studies/Mexico_DF_Case_Study_Summary_EN.pdf.



Source: The Union.

Box 2.2 The case of São Paulo state, Brazil

The Brazilian state of São Paulo has 645 municipalities and a population of over 40 million. The law that became effective on 7 August 2009 banned smoking in public places and workplaces in the state. Enactment of this law in São Paulo helped advance a movement toward smoke-free laws at the subnational level in Brazil. This led to a situation in which some individual states and cities had stronger smoke-free protections, consistent with the Guidelines for implementation of WHO FCTC Article 8, than the rest of the country.

The São Paulo law prohibits consumption of tobacco products in “environments of collective use,” whether public or private, and totally or partially enclosed. It covers places of work, study, culture, religious observance, leisure, sport, and entertainment, including, among other places, the common areas of condominiums, theaters, cinemas, bars, discotheques, food courts, hotels, banks, supermarkets, warehouses, bakeries, pharmacies, public institutions, health institutions, schools, museums, and libraries. Public or private vehicles used for collective transportation, official vehicles, and taxis are also covered.

Enactment of the stringent state law was consistent with Article 24 of the federal constitution, which allows subnational units to legislate concurrently in specific areas. In 2012, Brazilian federal law on tobacco control was amended to make all enclosed public places and workplaces in the country 100% smoke-free (regulations are pending as of late 2012).

Estudo de caso: São Paulo respira melhor: adoção de ambientes fechados livres do tabaco no maior estado brasileiro (Organização Pan-Americana da Saúde -- Representação Brasil, 2010), http://actbr.org.br/uploads/conteudo/422_ESTUDO_DE_CASO_SP.pdf.



Source: ACT Brazil.

Where there is legal authority for subnational jurisdictions to regulate with respect to tobacco control, the next step would be to determine whether any of the WHO FCTC articles might be more feasible to implement, both legally and politically, through legal measures at the subnational level, and if so, which ones. For example, with respect to packaging and labeling

measures pursuant to WHO FCTC Article 11, national regulation probably would make more sense than subnational regulation since tobacco products are traded across subnational territories. It would not be feasible as a practical matter, or politically, for different territorial units to have different legal requirements for packaging and labeling. On the other hand, it is perfectly feasible to enact smoke-free measures at the subnational level. Some tobacco advertising, promotion, and sponsorship matters can also be appropriate for regulation at the subnational level, such as point of sale (POS) advertising and promotion, including POS product displays, or other practices that are more territorially based (e.g., outdoor advertising and some publications and broadcasts).

Political considerations then come into play, including the degree of political will and the relative ease or difficulty with which the tobacco industry can exert its influence at the national versus subnational levels. The primary drawback with subnational regulation is that the protection provided will be limited to the particular jurisdiction enacting the law. As has been observed in many countries in Latin America, however, subnational action may spur action among other subnational jurisdictions and produce a “domino effect” that creates momentum for national legislation.

Where there is a national tobacco control law or other governing law applicable to tobacco control that contains gaps or weaknesses, a subnational jurisdiction may wish to enact stronger, more protective legal measures. In this case it must also be determined whether the subnational jurisdiction has the legal authority to implement laws that are more stringent (protective) than governing national law. While subnational laws generally cannot conflict with national laws, they often can be more stringent as long as no conflict with the national law is created.⁵ This is particularly true in countries where the constitution includes a right to health and the subnational entity is responsible for health policy concurrently with or in addition to the national government.

In many cases, subnational statutes will need to meet a minimum standard of protection set by the national law. For instance, in Mexico, two conditions are required to consider local legislation constitutional. First, the local law must adhere to the principles established in the constitution and the applicable legal framework. Second, local legislation may add to or increase the rights regulated, but it may not provide less protection of those rights (Madrado 2008).

2.1.3 A single comprehensive law or separate laws, for one or several tobacco control topics

As explained in Chapter 1, the WHO FCTC pulls together all the strategies supported by scientific evidence in order to curb the tobacco epidemic. To achieve the objective of the WHO FCTC, full implementation of its measures is necessary. This means that the more topics addressed in legal measures, the better; but it does not necessarily mean that all of the WHO FCTC topics must be included in a single law. In considering whether to implement the WHO FCTC through successive laws in a stepwise approach or through a comprehensive single law, policy makers should review the possibilities, feasibilities, urgent necessities, and opportunities that may exist.

A comprehensive bill can offer the most efficient means of providing the widest protection all at once. At the same time, passage of a comprehensive bill requires the negotiation of multiple policy areas and involves the interests of multiple stakeholders who likely will submit comments, lobby, and otherwise attempt to influence the legislative process.⁶ This

⁵ For example, the national legislation may allow (but not require) businesses to establish separate smoking rooms, while subnational jurisdictions may want to enact stronger smoke-free protections that do not allow separate smoking rooms.

⁶ For example, in the case of Peru, when Law 29517 (2010) was being considered by the legislature, the draft bill contained provisions for 100% smoke-free indoor public places, workplaces, and public transport, for stronger health warning provisions, and for banning tobacco advertising, promotion, and sponsorship (TAPS), among other things. Because there was no political agreement on the tobacco TAPS provisions, it was decided to remove those from the bill and consider only the implementation of Articles 8 and 11 of the WHO FCTC. The 100% smoke-free measures were approved, as was the requirement to extend health warnings to both sides of the pack, with the promise to consider additional legislation covering WHO FCTC Article 13 (on TAPS) in the near future.

can result in delay, weakened protections, and/or failure of the government to meet international obligations and secure health protections for the public. Single-topic bills, or bills that address more than one but not all of the WHO FCTC topics, may be easier to enact because they involve fewer parties and competing interests. However, they must be supplemented by additional bills that cover the remaining requirements of the WHO FCTC. In determining whether a comprehensive or stepwise legislative approach should be taken, the degree of political will and public support or opposition, the timing, and other readiness issues must all be taken into account. Additionally, some topics may by their very nature and by legal custom lend themselves better to separate enactments, such as tax measures.

Examples of both approaches can be found in the region. For example, the government of Guatemala successfully pursued a smoke-free law and was able to achieve a very strong law within a relatively short period of time. Separate initiatives to enact packaging and labeling restrictions and taxes were put before the Congress and were pending as of late 2012. Other governments in the Region (e.g., Colombia, Costa Rica, Ecuador, Honduras, Panama, Trinidad and Tobago, and Uruguay, among others) have enacted comprehensive, multitopic laws, some relatively quickly. In the case of Costa Rica's law, which covers many topics, including tobacco taxes, the process took around three years. Many of the comprehensive laws enacted in the Region contain very strong provisions on all of the topics covered in the law, while others are strong only on certain topics. In any case, if we compare countries that have legislated on single topics with countries that have enacted comprehensive laws, the single-topic approach seems to be less efficient and more resource-intensive. Consequently, the trend in recent years has been toward drafting and advocating for comprehensive legislation.

When considering tobacco control regulation through topic-specific measures rather than comprehensive, multitopic legislation, the principle of progressive development in protecting the right to health must be kept in mind. This requires treating each statute as one more stage in a dynamic process that moves forward as quickly as possible, without delay.⁷ It also needs to be kept in mind that enacted legislation, even if comprehensive, is not the end of the road. Laws need to be continually evaluated, updated, and improved as necessary—to strengthen weak areas in the law, keep up with new scientific evidence and technologies, and counter the latest tobacco industry tactics and strategies for evading and undermining effective tobacco control measures.

2.1.4 Content of laws and regulations

It is not appropriate (and probably not even possible) to make a rigid distinction between topics and details that should be included in the legislation itself and those that should be left for the implementing regulations. Deciding what to include in legislation versus regulations is a balancing act that requires attention to the following considerations, at a minimum:

- The need for security and relative permanence of certain provisions, as provided by legislation (since legislation can only be changed by subsequent legislative acts), compared to the need for flexibility of certain provisions over time (e.g., the content of pack warnings, which needs to change periodically, and rotational requirements for pack warnings, which need to be quite detailed);

⁷ As explained in Chapter 1, the human rights principle of “progressive realization” recognizes that resource-limited governments may not be able to immediately and fully implement measures necessary to protect guaranteed economic, social, and cultural rights if vast resources are required (for example, to provide safe water and sanitation or health care infrastructure). Most tobacco control measures, however, do not require large government expenditures and can be implemented without significant delay. Also, while lack of resources may justify progressive realization over an extended period of time, lack of political will alone does not provide an adequate excuse. As a result, while it is strategic to consider progressive development of tobacco control measures where there is insufficient political will to achieve them all at once, this cannot justify undue delay.

- The political will of the legislature to include the strongest best-practice measures in legislation compared to the political will and capacity of the implementing ministry or ministries to formulate strong measures;
- The ability of the tobacco industry to influence and weaken legal provisions in the legislature compared to its ability to do so in the implementing ministry or ministries.

If any law enacted has gaps or weaknesses due to lack of clarity, then regulations, by providing clarifications, may be able to help to strengthen the provisions of the law. Therefore, it is important that legislation provide the appropriate ministry or other authority with broad rule-making powers.

2.2 Key components of tobacco control legislation and cross-cutting topics

There are at least nine key legislative components that apply across all tobacco control policy areas. These key components can provide a framework for drafting tobacco control legislation. Relying on the WHO FCTC articles and incorporating the various WHO FCTC Guidelines to fill out the key components framework will help ensure the development and implementation of effective tobacco control measures, as required by the WHO FCTC.

2.2.1 Provide clear legislative objectives

Clear articulation of legislative objectives can play an important role in justifying the legitimacy of the law's provisions, especially in the face of any legal challenge that may be brought by the tobacco industry or other interests. This should become evident when one reviews the sections of the manual addressing legal challenges that have been brought against different tobacco control measures. Clear objectives can also be important in interpreting any ambiguities that may be found in the law.

2.2.2 Define key terms

It is important to define all key terms, based on the definitions already provided by WHO FCTC (Articles 1 and 11.4) and its Guidelines. Incorporating these definitions into domestic legislation will help ensure the proper interpretation and application of FCTC requirements.

However, defining terms that are not actually used in the legislation and terms that have plain meanings should be avoided in order to prevent confusion and avoid inadvertently limiting the meaning of the terms. Defining a term (e.g., "tobacco advertising and promotion") but then using a synonymous term (e.g., tobacco "marketing" or "publicity") instead of the defined term should also be avoided in order to prevent misinterpretation.

2.2.3 Ensure comprehensive application of requirements and prohibitions

Effective implementation of the WHO FCTC requires comprehensive application of all its articles. The WHO FCTC Guidelines are particularly instrumental in helping Parties ensure comprehensive application of legal requirements in order to meet their treaty obligations for each FCTC article, as discussed in the applicable manual chapter.

2.2.4 Impose legal duties of compliance

Clarifying duties of compliance is critical to ensuring enforceability of the provisions of the law. Different duties of compliance may apply to different persons and entities, according to the WHO FCTC article being addressed.

2.2.5 Provide effective enforcement mechanisms

Provisions for enforcement should specify:

- Which authority or authorities have inspection powers and duties, and the places and/or matters falling within each authority's purview when more than one has inspection responsibilities;
- The mechanisms for coordination if more than one authority or level of government is involved in inspecting and enforcing; and
- Inspection powers, including the right to enter premises subject to the law and to obtain relevant evidence.

When specifying which authority or authorities are charged with inspections, it is advisable to consider what inspection systems already exist and whether inspections for tobacco control measures should be added to them rather than creating a separate tobacco control inspection infrastructure. It is important, however, to consider how well those existing inspection systems are functioning, how well-resourced the inspection agencies are, and how strong the political will is within the agencies to carry out inspection and enforcement duties related to tobacco control.

2.2.6 Provide a range of deterrents and proportionate penalties

Legislation should provide a range of penalties that are sufficiently large to deter noncompliance. As provided in the different WHO FCTC Guidelines, the penalties should be proportionate to the seriousness of the violation within the context of customary penalties in the country, and they should be commensurate with the degree of responsibility for the violation. Penalties should increase for repeat violations. Penalties may include, but are not limited to:

- Fines;
- Business or operating licensure suspension or revocation, especially for flagrant or repeated violations;⁸
- Criminal penalties, if appropriate in the jurisdiction; and
- Actions to remedy the violation(s), for example, confiscation and, at the expense of the violator(s), destruction of illicitly traded tobacco products, using environmentally friendly means (WHO FCTC Article 15.4(c)), removal of tobacco advertising, promotion, and sponsorship, and public notification of violations, such as by publication of court decisions, as determined by the court (FCTC Article 13 Guidelines).

2.2.7 Provide a role for civil society

WHO FCTC Article 4.7 underscores the essential role of civil society in achieving the objective of the FCTC and its protocols. In addition, Section 2.3 of this chapter highlights the vital contributions civil society has made toward advancing tobacco control policy in the region. Tobacco control legislation should, therefore, empower and enable members of the public and civil society organizations to play a significant role in tobacco control, establishing mechanisms that, among other things:

⁸ For example, Puerto Rico's Smoking Regulations in Public and Private Areas Act, Sec. 899, provides that the Regulations and Permits Administration may not issue or renew any use permit to facilities that violate the provisions of the act. See Laws of Puerto Rico Unannotated, Title 24, Health and Sanitation, Chapter 62. Available at <http://www.lexisnexis.com/hottopics/lawsofpuertorico/>. Click on "I agree," which takes you to the index page. Once there, click on + for Title 24, Health and Sanitation, then on + for Part III, Food, Drugs, and Cosmetics, then on + for Chapter 62, Tobacco Act, then on applicable section number.

- Include, as participants in tobacco control commissions or bodies, members of civil society with appropriate knowledge or experience who are not affiliated with the tobacco industry;
- Establish channels for filing and following up complaints of noncompliance, as provided in the Guidelines to WHO FCTC Articles 8, 11, and 13;
- As also provided in the Articles 8 and 13 Guidelines, facilitate ways for civil society to demand compliance with tobacco control policies, such as by authorizing members of the public and civil society organizations to take legal action against persons and entities violating the law where this is possible under the legal system. In jurisdictions where civil society is granted authority to initiate legal action to compel compliance, providing for waiver of court fees and recovery of litigation costs can make it feasible for civil society organizations to fulfill this role.

2.2.8 Require evaluation and public dissemination of results

WHO FCTC Article 20.4, addressing research, surveillance, and exchange of information, calls on Parties to “progressively establish and maintain an updated database of laws and regulations on tobacco control and, as appropriate, information about their enforcement . . .” Many of the Guidelines highlight the importance of monitoring and evaluating tobacco control measures. Together, these can be seen as creating an obligation on the part of the government to monitor and evaluate enforcement of legal measures and legal provisions. This evaluation should include an analysis of the law’s effectiveness in relation to specific groups, disaggregating the information by sex, age groups, socioeconomic groups, etc.

Although a government does not need a legal mandate in order to undertake monitoring and evaluation, imposing a duty on the responsible authority or authorities to track compliance rates and evaluate the overall effectiveness of the inspection and enforcement program and of the legislative provisions will help ensure that these activities are undertaken and sustained. Evaluation data can then be used to identify any barriers to compliance and/or enforcement as well as any areas where the law and the inspection/enforcement system may need strengthening. Evaluation information should be made readily available to the public.

2.2.9 Grant broad regulatory power to the appropriate authority to address implementation details

The appropriate authority—the one with responsibility for ensuring the highest degree of protection for consumers, workers, or members of the public—should be given broad regulatory powers to address implementation details and any other matters necessary or appropriate for effectual implementation of the legislation. Care should be taken to avoid implying limitations on regulatory power, such as by explicitly granting only some powers and presenting them in an exhaustive manner.

2.3 Role of civil society in implementing the WHO FCTC

Between 1999 and 2003, civil society organizations and coalitions around the world dedicated to tobacco control embraced the idea of an international tobacco control treaty. To promote the treaty, they came together as the Framework Convention Alliance (FCA)⁹ which became an important nonstate actor within the international system of tobacco control (Mamudu and Glantz 2009).

⁹ See the Framework Convention Alliance homepage at http://www.fctc.org/index.php?option=com_content&view=article&id=2&Itemid=9.

The vitality of tobacco control groups in the Region of the Americas predates the WHO FCTC and exemplifies the role that civil society can play in tobacco control efforts. In addition to carrying out activities in their respective countries, nongovernmental organizations (NGOs) concerned with tobacco control developed strong regional networks and collaborate closely with international organizations.¹⁰ Civil society organizations in Latin America have played multiple roles in tobacco control as media and policy advocates, legal advisors, coalition builders, researchers, and watchdogs (Marcet Champagne, Sebríe, and Schoj 2010). As nongovernmental entities, they often have greater flexibility than governments to quickly mobilize technical and financial resources and launch direct legislative and media advocacy in support of tobacco control legislation. Civil society groups in the Region have provided the following types of support, among others:

- Capacity building for civil society groups at the country level;
- Providing assistance with drafting and/or legal analysis of tobacco control legislation, in accordance with WHO FCTC mandates, Guidelines, and national legal systems;
- Developing fact sheets to support legislation using regional and international evidence to provide to legislators and the media;
- Coordinating media briefings;
- Assisting with direct legislative and media activities;
- Coordinating visits of regional experts to advise government officials, conduct media interviews, and interact with key stakeholders (such as the business/hospitality sector) on the benefits of effective tobacco control legislation and successful regional examples;
- Coordinating letters from international organizations to national authorities to promote implementation of tobacco control policies;
- Providing technical assistance for public opinion surveys to measure the level of support for tobacco control policies;
- Conducting research or providing research findings on a variety of tobacco control topics; and
- Monitoring tobacco industry activity and denouncing interference by the industry in the development and/or implementation of tobacco control policies.

¹⁰ International NGOs working in the Region include, among others: the Campaign for Tobacco-Free Kids, <http://www.tobaccofreekids.org/index.php>; Corporate Accountability International, <http://www.stopcorporateabuse.org/>; InterAmerican Heart Foundation, <http://www.interamericanheart.org/?lang=eng>; and International Union against Tuberculosis and Lung Disease, <http://www.theunion.org/>.

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Chapter 3

Protection from Exposure to Tobacco Smoke

100% SMOKE-FREE ENVIRONMENTS
AMBIENTES LIBRES DE FUMO
100% LIBRES DE HUMO

**World 31 May
No Tobacco Day**

**Dia 31 de maio
Mundial sem Tabaco**

**Día 31 de mayo
Mundial Sin Tabaco**



Source: PAHO.

3. Protection from Exposure to Tobacco Smoke

3.1 Background

3.1.1 Rationale and evidence

Scientific evidence has unequivocally established that exposure to tobacco smoke causes death, disease, and disability, a fact recognized by the Parties to the World Health Organization Framework Convention on Tobacco Control (WHO 2003; hereafter, WHO FCTC), in Article 8. Based on this evidence, there is a need for strong and comprehensive laws requiring all indoor public places, indoor workplaces, and public transport to be completely smoke-free. These laws have been widely shown to provide the only means of effective protection against the hazards of exposure to tobacco smoke. Additionally, comprehensive smoke-free laws have been shown to reduce tobacco consumption. More and more national and subnational jurisdictions around the world, especially in the Americas, are protecting their populations by legislating bans on smoking in indoor public places and workplaces, and in some outdoor public places and workplaces.

There is no safe level of exposure to the thousands of chemicals and compounds in tobacco smoke, approximately 70 of which are known or probable human carcinogens, and hundreds of which are otherwise toxic (HHS 2006, 2011; WHO 2007; Cal/EPA 2005). Even brief exposure to low levels of tobacco smoke is harmful (Pell et al. 2008; Bonetti et al. 2011). Worldwide, 40% of children, 33% of male nonsmokers, and 35% of female nonsmokers were exposed to tobacco smoke in 2004 (Öberg et al. 2010).

Since 2002, many researchers in the Region have conducted studies to assess the concentration of tobacco smoke in public places (Barnoya, Mendoza-Montano, and Navas-Acien 2007; Navas-Acien et al. 2004). An assessment in seven Latin American capital cities detected nicotine in 94% of the locations surveyed in 2002 and 2003 (Navas-Acien et al. 2004). The highest concentrations were found in bars and restaurants, but nicotine was also found in hospitals, schools, and governmental buildings.

Youth exposure to tobacco smoke in public places is high in Latin America and the Caribbean, according to the latest data collected by the Global Youth Tobacco Survey (GYTS) between 2000 and 2010 (PAHO 2012). Among respondents 13 to 15 years old, exposure to tobacco smoke outside their homes¹ was, on average, 53%. Youth exposure was higher than the regional average in many Caribbean countries. For example, 64% of youth surveyed in Trinidad and Tobago were exposed to tobacco smoke in public places, according to 2007 GYTS data. In Guyana, 55.5% of youth surveyed were exposed in public places in 2009. Youth exposure was 66.8% in Jamaica (in 2010); 64% in St. Lucia (in 2007); and 59% in St. Vincent and the Grenadines (in 2007).

Given the lethality of tobacco smoke and the widespread exposure to it, it is no surprise that it is an important cause of cancer, heart disease, respiratory diseases, and other illnesses, resulting in many deaths globally and in the region. An

¹ Places outside the home may include indoor and outdoor places.

assessment of 2004 data from 192 countries examining the worldwide burden of disease from exposure to secondhand smoke (SHS) estimated that 600,000 of the six million tobacco-caused premature deaths were the result of exposure to SHS (Öberg et al. 2010). Of these deaths caused by SHS exposure, 47% were in women and 28% in children.

Workplace exposure to SHS is a significant risk factor for cancer and heart disease. A meta-analysis of data from 22 studies showed that tobacco smoke exposure in the workplace increases lung cancer risk by 24% (Stayner et al. 2007). The results of case-control and cohort studies carried out in multiple populations consistently show that SHS exposure poses about a 25% to 30% increase in the risk of coronary heart disease (IOM 2010).

Additionally, for persons with asthma or heart disease, exposure to SHS in public places or workplaces can be immediately life-threatening. Children exposed to SHS are at increased risk of acute respiratory infections, ear problems, asthma induction and severe asthma exacerbation, and sudden infant death syndrome (HHS 2006). Pregnant women who are exposed to SHS are estimated to be 23% more likely to experience stillbirth and 13% more likely to give birth to a child with a congenital malformation (Leonardi-Bee, Britton, and Venn 2011).

Fortunately, exposure to tobacco smoke in indoor workplaces and public places is entirely preventable. We know which smoke-free protection measures are effective, both from the scientific evidence and from experiences in a variety of national and subnational jurisdictions.

There is a clear consensus in the scientific and engineering communities that 100% smoke-free indoor workplaces, indoor public places, and public transport provide the only effective means of protection for workers and members of the public. Numerous studies have compared 100% indoor smoke-free places with places that allow smoking in separate areas or rooms. Taken together, they demonstrate that places with complete indoor smoking bans have drastically better air quality than places with smoking rooms (Barnoya et al. 2011; Blanco-Marquizo et al. 2010; Issa et al. 2010), notably in terms of a reduction in small-particle pollution containing cancer-causing agents (Ireland Office of Tobacco Control 2005). Smoking bans have been shown to result in reduced overall exposure to SHS in nonsmoking adults. For example, in Scotland, overall concentrations of cotinine, a marker for exposure to tobacco smoke, in adult nonsmokers fell by 39% after the country's comprehensive smoke-free legislation took effect. In the same study, geometric mean cotinine concentrations fell by 49% in nonsmokers from nonsmoking households (Haw and Gruer 2007).

Studies also demonstrate the corollary, that is, high levels of tobacco smoke pollution and adverse health effects in workers in places where smoking is allowed in separate smoking areas or rooms (Fernández et al. 2009; Cains et al. 2004; Bates et al. 2002). Places with separate smoking areas have been shown to experience reduced but still high levels of indoor pollution, or—depending on the air flow, the distance between smokers and nonsmokers, and other factors—no reductions at all (Erazo et al. 2010; Fernández et al. 2009; Nebot et al. 2005; Fong et al. 2006). An Australian study carried out in casinos showed that the reduction in pollutants achieved when a separate room was designated “no smoking” was only marginally better than the reduction achieved when a “no smoking” area was contiguous with a smoking area (Cains et al. 2004). An engineering study by the Hong Kong government helps explain why separate smoking areas or rooms do not provide effective protection against exposure to SHS. This study demonstrated that tobacco smoke invariably leaks out of smoking rooms, even those conforming to the most rigorous ventilation standards and state-of-the-art room design (Legislative Council Panel 2009). Similarly, studies conducted in trains that contain both smoking and nonsmoking coaches found tobacco smoke pollution in nonsmoking coaches adjacent to, and even in some cases not adjacent to, smoking coaches. This was the case even though all coaches were equipped with automatic sliding doors and separate heat, ventilation, and air conditioning systems (Invernizzi et al. 2004).

Smoke-free environments provide many benefits, such as immediate health improvements for individuals and populations, reductions in tobacco consumption, and economic benefits. Some of the most compelling evidence of dramatic health improvements brought about by comprehensive smoking bans comes from studies that looked at hospital admissions before and after smoking bans entered into force in a number of jurisdictions, including Scotland (Pell et al. 2008), Italy (Cesaroni et al. 2008), Uruguay (Sebrié et al. 2011), Argentina (Ferrante et al. 2011), Canada, and the United States (Sargent, Shepard, and Glantz 2004). Significant reductions in hospital admissions due to acute myocardial infarction (heart attack) were shown to be associated with implementation of the comprehensive smoking bans in those places. Heart attack admissions decreased 22% in Uruguay, for example (Sebrié et al. 2011). In Scotland, in addition to the reduction in heart attack admissions, a significant reduction in children's hospital admissions for acute asthma and a dramatic decrease in babies with low birthweight were associated with the smoking ban (Mackay et al. 2010, 2012). Other reports show significant improvement in workers' health in places covered by 100% smoke-free legislation (Schoj et al. 2010; Menzies et al. 2006; Goodman et al. 2007; New York City Department of Finance 2004).

In addition to direct effects on health, comprehensive bans on smoking in indoor workplaces and public places have been associated with reduced social acceptability of smoking and have been shown to reduce consumption (Thrasher 2009). According to a World Bank (1999) analysis, smoking bans can decrease tobacco consumption by 4% to 10%. Reviews of studies in Australia, Canada, Germany, and the United States found that smoke-free workplaces result in an average 29% reduction in consumption by smokers (Fichtenberg and Glantz 2002; Evans, Farrelly, and Montgomery 1999). Among smokers in Ireland who quit after smoke-free legislation was implemented, 80% reported that the law helped them quit, and 88% reported that the law helped them remain free of tobacco use (Fong et al. 2006).

Implementation of indoor workplace and public place smoking bans has also been shown to result in reductions in exposure to tobacco smoke in the home. In a four-country European study (Ireland, France, Germany, and the Netherlands), the number of smokers with voluntary restrictions on smoking in their homes increased dramatically after the legislation, and the number of cigarettes smoked per day at home by smokers with no household smoking restriction either decreased significantly or remained stable (Mons et al. 2012). Similarly, studies from Scotland found an increase in voluntary smoking restrictions in the home following implementation of the smoke-free law, reducing both household and overall exposure of children to tobacco smoke (Akhtar et al. 2007, 2009). After implementation of a smoking ban in England in 2007, the number of children with smoking parents who lived in smoke-free homes increased significantly in 2008 compared to 2006 or the six months of 2007 immediately prior to implementation of the ban (Jarvis et al. 2011).

Strong and comprehensive smoke-free laws generally enjoy high levels of public support, even among smokers, and have high rates of compliance when properly implemented (Crosbie, Sebrié, and Glantz 2011; Ireland Office of Tobacco Control 2005; Thrasher et al. 2009; Barnoya et al. 2011). In addition, despite economic concerns advanced by the tobacco industry, reliable studies from around the world demonstrate revenue neutrality for businesses following the implementation of laws banning smoking in all indoor workplaces and public places (Ramos and Curti 2006; González-Rozada, Molinari, and Virgolini 2008; Scollo et al. 2003; Guerrero-López et al. 2011).

It is widely acknowledged that, in addition to causing direct damage to health, smoking in workplaces and public places leads to other massive societal costs, including economic costs. A 2005 study in the United States estimates that tobacco smoke exposure results in over US\$ 5 billion in direct medical costs and another US\$ 5 billion in indirect medical costs, such as disability and lost wages (Behan, Eriksen, and Yijia 2005). The International Labour Organization (ILO) has recognized that smoking in the workplace creates a drain on productivity because of work days lost to illness and the financial burden

of health-related costs (Rudnick 1998). The ILO further recognizes that smoking has an either additive or multiplicative interaction with environmental hazards found in certain workplaces. This, in turn, significantly increases the risk of many occupational diseases.

Finally, improved health and reduced tobacco consumption as a consequence of comprehensive smoke-free measures lead to increased productivity (Halpern et al. 2011), reduced health care expenditures, and other benefits that relieve resource-strapped governments and families of the financial burdens caused by tobacco use and exposure to tobacco smoke (Tsai et al. 2005). After enactment of the smoking ban in 2006, the English government estimated net benefits of up to £2.1 billion a year based on the large number of lives saved, reduced government expenditures on health care, increased productivity at work, and fewer fires and cleaning costs (Medical Research Council 2007).

The significant health, financial, social, and environmental benefits that follow from enacting and implementing smoke-free laws come at little cost to governments or businesses. According to a study published by WHO (2011), the annual per capita cost for implementing smoke-free policies in low- and middle-income countries, including program management and media support, is US\$ 0.016—less than two cents per person per year. Moreover, the share of the cost borne by governments is only 14% of this amount. Enactment and implementation of these laws, therefore, should be within the immediate reach of all governments. The savings that can be gained from decreased health costs and increased productivity may be directed to other strategic areas. Therefore, these measures are especially important for developing countries looking to optimize the use of their limited resources.

3.1.2 Regional situation

As of October 2012, 14 of the 35 Member States of the Pan American Health Organization (PAHO) have enacted comprehensive smoke-free laws, either at the national level or at the subnational level covering at least 90% of the population (Table 3.1).² However, not all of them have implemented the legislation. Some countries have also banned smoking in certain outdoor areas (e.g., within a specified distance of health and/or educational facilities, sports venues, etc.). Progress toward smoke-free environments has not been homogeneous within the Region, however. For example, only two of the PAHO Member States belonging to the English-speaking Caribbean have enacted such legislation (PAHO 2011).

² El Salvador passed legislation in 2011 but it was later amended. Regulations (which had not been approved as of October 2012) are needed in order to determine the comprehensiveness of the law.

Table 3.1 PAHO Member States with comprehensive smoke-free legislation as of October 2012

Country	Date of legislation	Country	Date of legislation
Uruguay	2006/2008 ^a	Peru	2010
Panama	2008	Venezuela	2011
Guatemala	2008	Ecuador	2011
Colombia	2008/2009 ^a	Argentina	2011 ^b
Trinidad and Tobago	2009	Brazil	2011 ^b
Barbados	2010	Costa Rica	2012
Honduras	2010	Canada	n.a. ^c

Note: Comprehensive smoke-free legislation is defined as that which covers, at a minimum, health care facilities, educational facilities including universities, government facilities, indoor offices, restaurants, pubs, bars, and public transportation.

a. Decree followed by national law.

b. Pending regulation and implementation

c. Not applicable: different subnational jurisdictions passed legislation in different years.

Important advances have been made at the subnational level in some countries, including Argentina, Brazil, Canada, Mexico, and the United States. In some cases this was a first step toward comprehensive national legislation.

In general, workers in restaurants and bars have the least protection from the hazards of tobacco smoke exposure in the workplace. But it is also worth noting that there are still many countries in the Region where health care and educational facilities are not covered by smoke-free laws.

3.2 Responding to opposition to comprehensive smoke-free measures

3.2.1 Countering tobacco industry arguments

The tobacco industry has advanced a number of arguments against strong and comprehensive smoke-free laws. This section examines the most common arguments and suggests responses.

3.2.1.1 Argument: Both smokers and nonsmokers should be accommodated in public places; separate ventilation provides a solution

The tobacco industry asserts that smokers and nonsmokers alike should be accommodated in public places by having separate smoking and nonsmoking areas, a strategy known as “Courtesy of Choice” (Sebrié and Glantz 2007). In order to advance this accommodation strategy, the industry developed a sophisticated plan to use ventilation experts as consultants to promote separate ventilation as a solution to governments and businesses, especially businesses in the hospitality industry. The aim of the strategy was to eliminate the need for smoking bans in public places. Tobacco companies even covered the costs of installing ventilation systems for some businesses (Drope, Bialous, and Glantz 2004).

Separate smoking areas and engineering approaches using ventilation and air-cleaning technologies have repeatedly been shown to be ineffective in providing protection against the hazards of SHS exposure. This is explicitly recognized by the Parties to the WHO FCTC in the Guidelines for Implementation of Article 8 (WHO 2008; hereafter, Article 8 Guidelines). Legislation allowing for separately ventilated areas or rooms fails to provide the effective protection required by WHO FCTC Article 8, as discussed in Section 3.1.1. It also makes it much more difficult politically to enact a complete indoor smoking ban, the only effective protection measure, in the future. Businesses that have installed ventilation systems and/or made other structural changes to their buildings pursuant to an exemption in the law are likely to object strenuously to any change that removes that exemption, even if the remodeling was paid for by the tobacco industry.

3.2.1.2 Argument: Smoke-free laws harm the economy, especially the hospitality and tourism industries

The tobacco industry has been successful in a number of jurisdictions in convincing governments and businesses that economic harm will result from any serious attempt to regulate smoking in public places. Wherever smoke-free legislation is under consideration, the industry warns that hospitality and tourism businesses in particular will be hurt by a smoking ban. A vast body of credible studies on the financial impact of smoke-free policies in the hospitality industry directly discredits these claims. Studies using objective and reliable measures³ overwhelmingly demonstrate that smoking bans confer enormous public health and other benefits with no negative economic impact on businesses in any sector (Scollo et al. 2003; Selin 2005). A Philip Morris USA internal document from 1994 shows that the tobacco industry itself has recognized that such claims lack credibility (Box 3.1).

Box 3.1 **Tobacco company acknowledges economic argument is weak**

David Laufer, a Philip Morris official, told an internal company meeting on 8 July 1994:

“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.”

Source: Philip Morris, “CAC Presentation #4,” 8 July 1994, Bates No. 2041183751/3790, http://www.pmdocs.com/pdf/2041183751_3790_88_201292092910.pdf.

3.2.1.3 Argument: Smoke-free laws will result in more smokers smoking in their homes, causing more children to be exposed to secondhand smoke

As noted in Section 3.1.1, there is evidence that comprehensive smoke-free laws applied to public places do *not*, in fact, increase smoking in the home (Fong et al. 2006). To the contrary, they have been shown to reduce secondhand smoke exposure of children at home.⁴ The same study found that comprehensive smoke-free laws did not increase the levels of smoking in private cars (Fong et al. 2006).

3.2.1.4 Argument: Smoke-free laws violate an individual’s right to smoke

There is no so-called “right to smoke.” Legal rights generally are conferred by constitutions and laws at the domestic level, and by treaties at the international and regional levels, and none enshrines a right to smoke. On the other hand, many treaties and constitutions provide explicit guarantees of the rights to health, life, personal integrity, and workplace and environmental safety, and obligate the State to protect that right, as discussed in Chapter 1.⁵ The right to health is also

³ Reliable measures include examining taxable sales receipts, covering several years before and after a smoking ban, and controlling for changes in economic conditions and underlying data trends and fluctuations.

⁴ One exception is recorded in the literature, but it is thought to be due to a unique situation. In Hong Kong, reported exposure to secondhand smoke in the home among primary school children increased following the implementation of Hong Kong’s smoke-free law. However, in densely populated Hong Kong many people live in high-rise apartments, and the authors report that many of the outdoor spaces surrounding the apartment buildings became subject to restrictions when the legislation on smoke-free public places took effect. This may have displaced smoking into the homes of children, a situation that has not been found elsewhere (Ho et al. 2010).

⁵ Examples include the International Covenant on Civil and Political Rights; the Covenant on Economic, Social and Cultural Rights; and the American Convention on Human Rights.

articulated in the preamble to the WHO FCTC. Even governments with no treaty or constitutional obligations requiring them to protect these rights generally are authorized to impose legal measures to protect the public health pursuant to their inherent police powers.

Although the tobacco industry has argued that a legal right to smoke is derived from the right to individual freedom, this argument has not been successful in court cases in the Region. This is because smoking infringes on the right to health held by others, as noted in the next section on legal challenges.⁶ Smoke-free measures restrict where people can smoke; they do not prohibit people from smoking where the activity does not cause harm to others in public and workplace settings.

A related tobacco industry argument is that smoke-free measures are unjustified actions by a paternalistic state (“nanny state”), undertaken with the aim of requiring certain “moral” behaviors.⁷ This argument ignores the health justifications for smoking bans and the functions and obligations of governments to protect the population under their jurisdiction.

3.2.1.5 Argument: Smoking bans violate the right to work

Laws prohibiting smoking in the workplace only regulate workplace conditions and conduct; they do not prevent employment of persons who are smokers. Smoking bans are necessary to protect the lives and health of other workers and to fulfill any obligations the State may have to ensure safe and healthy workplaces.

3.2.1.6 Argument: Smoke-free measures discriminate against smokers

According to the tobacco industry, workplace and public place smoking bans discriminate against smokers. As in the response to the previous argument, it is important to differentiate the smoker from the act of smoking. It is the act that is prohibited in public places and workplaces; smoke-free laws do not exclude smokers from any such place. They simply prevent people from smoking where it is prohibited.

3.2.1.7 Argument: Smoking bans violate the right to property

Although the right to property is enshrined in many countries’ constitutions and in Article 21 of the American Convention on Human Rights, it is not an absolute right. The State is empowered to regulate activities that cause harm to others, including those that take place on private property. Private businesses are subject to a host of regulations, among them hygiene, work safety, and fire safety requirements. The Inter-American Commission on Human Rights recognizes numerous exceptions to the right to property, including limitations on property rights when necessary to guarantee other rights in the interest of society. Smoking bans do not affect the essence of the right to property, are reasonable to achieve State aims of protecting the rights to life and health, and are, in fact, obligations of the State under the WHO FCTC and other treaties.

3.2.1.8 Argument: Smoking bans violate the right to freedom of commerce

The tobacco industry’s argument that smoking bans violate the right to free commerce is similar to its right-to-property argument. This argument is addressed in a recent judgment by the Constitutional Court of Guatemala in a case brought by the Guatemalan Chamber of Commerce, discussed in the next section.

⁶ Courts have upheld smoke-free laws on the grounds that these laws are a reasonable exercise of governmental authority to protect health. Two such cases are highlighted in the next section of this chapter.

⁷ This argument was made in cases before the Constitutional Tribunal of Peru and the Constitutional Court of Colombia.

3.2.2 Regional experiences with legal challenges to comprehensive smoke-free laws

The tobacco industry and its allies have used litigation advancing many of the arguments discussed in the previous section to challenge effective smoke-free measures in the Region. The industry has also challenged technical aspects of the laws.

In the two cases discussed below, the courts rejected these arguments, finding that smoking bans contested on the grounds that they interfere with private property rights, commercial freedom, or individual liberty are in fact legitimate, proportionate, and justified by the need to protect the right to health. In addition, the courts found that smoking bans do not *prohibit* conduct in absolute terms, but merely restrict conduct insofar as it affects the other people's right to health.

These cases are instructive on two levels. First, the decisions show that well-articulated justifications for legislation based on treaty-enshrined human rights can play an important role in resolving interpretation issues and in defending against legal challenges. Second, even where technical drafting issues were raised by the tobacco industry, the cases were resolved in favor of upholding the law, though careful attention to the technical drafting issues raised can help drafters avoid such pitfalls in the future.

Table 3.2 Legal challenges to smoke-free laws

Tobacco industry argument	Judicial decision
Violation of trade freedom	Limitations on trade rights and economic freedoms are legitimate if they are proportional to the good protected, in this case health. Furthermore, there is no damage to the essential minimum content of this right.
Violation of private property	Restrictions on tobacco consumption are another regulation attempting to ensure health and safety in public places (similar to the requirements for emergency exits, for example).
Violation of individual freedoms	Smoking in itself is not prohibited, but its consumption is restricted where it affects the right to health of other people (other members of the public or workers).

3.2.2.1 Legal challenge to Guatemala's smoke-free law

The Guatemalan Chamber of Commerce filed a legal challenge in the Constitutional Court of Guatemala against the 2009 law banning smoking in enclosed public environments, in workplaces, and in any type of publicly used group or community transportation, with a sole exemption allowing hotels to designate certain guest rooms as smoking rooms.⁸ The Chamber argued, among other things, that (a) the law violated the right to commerce; (b) the term "enclosed public environments" was vague and overly broad; (c) the exemption for designated guest rooms denied the right to equal protection; and (d) the sanctions regime was excessive and deprived violators of their property.

In February 2010, the Constitutional Court upheld the law. It found that imposing limitations on the places where people can smoke does not limit the freedom of businesses to engage in commerce because the purpose of the law is not to regulate commerce of the entities manufacturing, producing, distributing, and marketing tobacco products, but rather to regulate the consumption of tobacco products to protect the right to health of both smokers and nonsmokers. In its ruling, the court noted the significance of Guatemala's signature and ratification of the WHO FCTC, as mandated by the right to health enshrined in Guatemala's constitution, and the role of the FCTC in establishing an international norm to protect against exposure to tobacco smoke.

⁸ Chamber of Commerce v. Guatemala, Docket 2158-2009. Excerpts from court rulings in this section are unofficial translations by the authors.

In response to the charge of vagueness, the court found that the meaning of “enclosed public environments” is supplied by its context. It linked this analysis with the stated purpose of the law: “to protect nonsmokers from forced exposure to tobacco smoke in an enclosed structure that retains the smoke.” Furthermore, the court found that regulations can define the term “enclosed public environments” with greater precision. With respect to the claim of excessive sanctions, the court found that the purpose of the law is not, as alleged, to take money from tobacco users. Rather, the law’s purpose is to persuade smokers not to consume tobacco products in certain places, as this is detrimental to their own health and that of nonsmokers. Furthermore, the court found that the decision to fine the violator is subject to review by the competent authorities.

This case demonstrates the priority given by the court to the right to health. It also illustrates the role that clearly established legal objectives and principles of interpretation can play in justifying the law’s provisions and overcoming potential uncertainty.

3.2.2.2 Legal challenge to Peru’s smoke-free law

In 2011, the Constitutional Tribunal of Peru considered a challenge to Peru’s smoke-free law, which prohibits smoking in all indoor public places and workplaces, in the case of *5000 Citizens v. Article 3 of Law No. 28705*.⁹ The challenge asserted that (a) the measures in the law violate the right to free private initiative and private enterprise by establishing an absolute prohibition on having establishments exclusively for smokers, and (b) the measures violate the right to free personal development. The court upheld the law, finding that although the law does affect rights to commerce and economic freedom and to personal development, the limitations on these rights are legitimate because the impact on these freedoms is minimal in comparison to the protection of the fundamental right to health afforded by the law.

In its decision, the court took the opportunity to analyze the extension of the smoking ban to open spaces associated with health care, sports, and educational facilities and the prohibition against allowing spaces exclusively for smokers, including in the workplace. The court accepted that a prohibition on spaces exclusively for smokers and on smoking in open areas at educational institutions seeks to reduce tobacco consumption and has an ultimate purpose of reducing the high smoking-related health care costs incurred by the State. Such funds, it noted, could be better used to carry out the State’s fundamental duty to “guarantee the full enforcement of human rights.”¹⁰

After citing a report by the World Health Organization and several academic and institutional studies, the court concluded that the public policy measures under challenge are clearly appropriate for the purpose of substantially reducing tobacco consumption, protecting health, and reducing health care costs. It soundly rejected the option of allowing areas exclusively for smokers, because such areas are not as effective in reducing consumption; because they are unconstitutional, in that they necessarily infringe the right to health of nonsmokers who share the same spaces; and because they would promote smoking and the damage it causes, contrary to the State’s obligations as a Party to the WHO FCTC. This case demonstrates, among other things, the importance of having strong and credible evidence that supports the objectives of a smoke-free law, as well and the potential role well-articulated objectives can play in justifying the law’s provisions.

⁹ Constitutional Tribunal of Peru, *5000 Citizens v. Article 3 of Law No. 28705 – General Law for the Prevention and Control of Tobacco Use Risks*. Judgment from the Full Jurisdictional Bench of the Constitutional Court of Peru, July 19, 2011, unconstitutionality proceedings.

¹⁰ *Ibid.*, 39.

3.3 Implementing WHO FCTC Article 8 at the domestic level: Drafting effective smoke-free measures

Article 8 of the WHO FCTC requires Parties to adopt and implement *effective* measures to protect people from exposure to tobacco smoke in indoor workplaces, indoor public places, public transport, and other appropriate public places. The treaty, being a framework document, does not say explicitly what Parties must do to fulfill this requirement. However, the Article 8 Guidelines provide such guidance to Parties on the scope and content of their Article 8 obligations. Among other things, the Guidelines clarify:

- What constitutes “effective measures” for protection against the hazards of tobacco smoke;
- The meaning of the terms “public place,” “workplace,” “public transport,” “enclosed,” “indoor,” and other key terms used, but not defined, in Article 8; and
- How to effectively implement the Article 8 requirements.

Together, WHO FCTC Article 8 and its Guidelines establish the international standard for smoke-free measures that Parties must meet, at a minimum, to fulfill their Article 8 obligations: measures must require all indoor workplaces, indoor public places, and public transport, along with some outdoor or quasi-outdoor public places as appropriate, to be 100% smoke-free, without exception. The WHO FCTC’s provisions are the floor, setting the minimum requirements Parties must fulfill to meet their treaty obligations. As stated in Article 2 of the WHO FCTC, Parties are encouraged to go beyond the treaty, its protocols, and implementing guidelines to provide the most effective measures. In addition, as discussed in Chapter 2 of this manual, in countries with federal systems, care should be taken to ensure that language used in national legislation does not inadvertently restrict the ability of subnational jurisdictions to enact and implement more protective smoke-free measures, as some have done.

Chapter 2 of this manual lists nine key components that can provide the framework for effective tobacco control legislation in any of the policy areas covered by the WHO FCTC. The discussion of the key components in this chapter focuses on those components that must be tailored specifically for implementation of WHO FCTC Article 8.

The accompanying “In Practice” boxes present examples of good-practice legislation from different countries. Legislative development and legislative drafting are both a science and an art, and they occur within a political context. Achieving best-practice legislation often takes time; the examples highlighted in the boxes either achieve or approach this standard. The best means of ensuring best-practice legislation is to fully incorporate WHO FCTC Article 8 and its Guidelines into domestic smoke-free provisions (see Chapter IV of the legislative template for a tobacco control act, included as Chapter 9 of this manual).

3.3.1 Provide clear legislative objectives

As illustrated by the court decisions from Guatemala and Peru, it is important to provide clear objectives for legislation. For smoke-free measures, these might include:

- Implementing effective evidence-based measures to protect against exposure to the hazards of tobacco smoke in order to promote and protect the population’s rights to health, life, physical integrity, safe and healthy workplaces, and any other human rights adversely impacted by tobacco smoke exposure;

- Denormalizing smoking and reducing consumption by discouraging smoking initiation and encouraging smokers to quit;
- Providing protection to all workers and members of the public in all indoor workplaces and public places, on all public transport, and in outdoor public spaces where smoking would create a hazard or would otherwise undercut the objectives of the legislation;
- Providing equal protection for all workers, regardless of where they work, and for all population groups; and
- Reducing the economic costs attributable to smoking and exposure to tobacco smoke.

One or more rules of interpretation that flow from the objectives could be articulated in the legislation, as illustrated by Uruguay's law (Box 3.2).

Box 3.2 In practice: Examples of legislative objectives and interpretation

New Zealand

New Zealand's Smoke-free Environments Act 1990 includes the following objective:

Section 3A(1)(a)

"[T]o reduce the exposure of people who do not themselves smoke to any detrimental effect on their health caused by smoking by others. . . ."

The Smoke-free Environments Act 1990 is available at

<http://www.legislation.govt.nz/act/public/1990/0108/latest/DLM223191.html>.

Kenya

Kenya's Tobacco Control Act 2007 states the following objective, among others:

Section 3

"The object and purpose of this Act is to provide a legal framework for the control of the production, manufacture, sale, labeling, advertising, promotion, sponsorship and use of tobacco products, including exposure to tobacco smoke, in order to—

- protect the health of the individual in light of conclusive scientific evidence implicating tobacco production, use and exposure to tobacco smoke and tobacco products, in the incidence of debilitating illness, disease, disability and death; . . .
- protect and promote the right of non-smokers to live in a smoke-free environment. . . ."

The Tobacco Control Act 2007 is available at

http://www.kenyalaw.org/kenyalaw/klr_home/index.php.

Argentina

Argentina's Law 26,687 includes several objectives that are relevant to smoke-free measures.

Article 2

"The purposes of this law are:

- Reduce the consumption of products prepared with tobacco;
- Reduce to a minimum people's exposure to the harmful effects of the smoke from products prepared with tobacco;
- Reduce the health, social and environmental damages caused by smoking;
- Prevent the onset of smoking, especially in children and in the teenage population;
- Raise the awareness of present and future generations of the consequences caused by the consumption of products made with tobacco and from the exposure to the smoke from products made with tobacco."

(continued)

Box 3.2 (continued)

Excerpt above is from an unofficial English translation of Law 26,687 available at <http://www.tobaccocontrolaws.org/files/live/Argentina/Argentina%20-%20Law%2026687.pdf>.

Uruguay

Uruguay's Law 18.256 includes an interpretative clause that favors collective health protection in order to ensure equal protection.

Article 23. Interpretation

"When interpreting the provisions of this law, in order to protect equally all population groups from tobacco smoke exposure, the right to group health protection shall prevail."

Excerpt above is from an unofficial English translation of Law 18.256 at

<http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Law%20No.%2018.256.pdf>. The law is available in the original Spanish at

<http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18256&Anchor>.

3.3.2 Define key terms

Definitions of terms in the WHO FCTC and the Article 8 Guidelines are comprehensive, were extensively discussed and accepted by the Parties, and will help ensure the proper interpretation and implementation of the smoking ban. It is critical, therefore, to incorporate these definitions into domestic smoke-free legislation.

Key definitions for implementing WHO FCTC Article 8, or elements of the definitions, as set forth in the Article 8 Guidelines, include:

- *"Smoking"*: being in possession or control of a lit tobacco product regardless of whether the smoke is being actively inhaled or exhaled
- *"Public place"*: any place accessible to the general public and any place for collective use, regardless of ownership or right to access
- *"Indoor" or "enclosed"*: any space covered by a roof or enclosed by one or more walls or sides, regardless of the type of material used for the roof, wall, or sides, and regardless of whether the structure is permanent or temporary
- *"Workplace"*: any place used by people during their paid or voluntary employment or work, including all attached or associated areas commonly used in or incidental to the course of their employment, as well as work vehicles
- *"Public transport"*: any vehicle used for carriage of members of the public, usually for reward or commercial gain, including taxis

The definition of "tobacco products" is also relevant to smoke-free provisions. This is defined in Article 1(f) of the WHO FCTC and referenced in Chapter 2 of this manual and in the legislative template in Chapter 9.

Definitions should provide a conceptual framework or criteria for determining whether or not a particular place falls within the definitions of "public place" or "workplace," or whether a particular mode of transportation falls within the definition of "public transport." Reliance on lists of places or vehicles to "define" the terms, without providing the criteria for determining what is meant, should be avoided. This is because it is very difficult to provide lists that include all public places and

workplaces and all means of public transport without some inadvertent omission. A list can be used to supplement a definition providing a conceptual framework, however, as long as it is made clear that the list is not meant to be exhaustive or limiting (this can be done, for example, by introducing a list with the phrase “including but in no way limited to…”).

Box 3.3 **In Practice: Examples of comprehensive definitions**

Colombia

Colombia’s Law 1335 (2009) largely incorporates definitions of key terms from the Guidelines. Its definition of “workplace” is especially comprehensive because it protects domestic and other workers who are employed in other people’s homes. Its definition of “enclosed” is less comprehensive than that in the Guidelines, however, since it requires both a roof and some number of walls, thereby covering fewer structures.

Article 21

“Secondhand tobacco smoke or environmental tobacco smoke: Smoke that is given off from the burning end of a cigarette or other tobacco product, generally in combination with the smoke exhaled by the smoker.

Workplace: Any place used by people during their employment or job, including all connected or annexed places, and vehicles which workers use in the performance of their work. This definition covers those places that are a residence for some people and a place of work for others.

Public place: Any place accessible by the general public or place of group use, regardless of who the owner is or who has the right of access.

Public transport: Any vehicle used to transport the public, generally for commercial purposes or to obtain remuneration, including taxis.

Enclosed area: Any space covered by a roof and confined by walls, regardless of the material used for the roof, walls or partitions and whether the structure is permanent or temporary.”

Excerpt above is from an unofficial English translation of Law 1335 (2009) available at <http://www.tobaccocontrolaws.org/files/live/Colombia/Colombia%20-%20Law%20No.%201335.pdf>. The law is available in the original Spanish at http://www.secretariasenado.gov.co/senado/basedoc/ley/2009/ley_1335_2009.html.

3.3.3 Ensure comprehensive application of the smoking ban

In order to ensure effective protection from the hazards of tobacco smoke exposure, it is necessary to enact and implement measures that apply a complete smoking ban to all indoor public places, all indoor workplaces, all means of public transport, and, as appropriate, other specified outdoor or quasi-outdoor public places and workplaces. The Article 8 Guidelines make clear that no exemptions to a smoking ban can be justified on the basis of health or legal arguments.

There is also no economic justification for granting exemptions, as discussed in the background section of this chapter, since evidence has consistently demonstrated the revenue neutrality of smoke-free measures for businesses, including bars, restaurants, hotels, and other hospitality venues. Because workers in these places tend to be at greatest risk of heavy exposure to SHS and resulting disease, they are among those most in need of effective protection (Tulunay et al. 2005;

Siegel 1993). Exemptions for these places, therefore, must be consistently rejected in order to ensure effective and equal protection for these high-risk workers and for patrons frequenting these venues. Legislative proposals should always be the strongest possible, since the tobacco industry and its allies will undoubtedly exert pressure to weaken any measures drafted.

Exemptions also create compliance and enforcement problems. It is much simpler for enforcement officers to inspect for and identify violations if smoking is prohibited in *all* indoor public places and workplaces and on all means of public transport, since inspectors will be looking for the same things in all places. If different requirements apply to certain categories of establishments, inspection will be more complex and time consuming, and potentially confusing. If designated indoor smoking areas or rooms are permitted, an additional layer of enforcement that may require additional enforcement resources is needed to assess compliance. For example, if designated smoking areas are subject to size limitations or are based on the proportion of smoke-free areas to smoking areas, mathematical calculations may be necessary to determine compliance, and ambiguities and questions of interpretation are likely to arise. With ventilation requirements, engineers and other specialized personnel may need to be employed to inspect the operation of smoking rooms and/or to review maintenance records, since inspectors are unlikely to have this expertise.

The Article 8 Guidelines recommend that each Party to the WHO FCTC strive for universal protection within five years of the Convention's entry into force for that Party. If, despite a strong and comprehensive draft of smoke-free legislation, exemptions are introduced during the legislative process, it is important that the legislation phase out any exemptions by a specified date, and that any exemptions be very limited and strictly controlled in the meantime (Article 8 Guidelines). Some jurisdictions deal with incomplete bans by listing the places covered by the ban and giving authority to the Ministry of Health to add places to the list through regulations. This approach should be avoided, however, because it allows an incomplete ban to continue indefinitely if the ministry lacks sufficient political will and/or legal capacity to promulgate such regulations. Article 8 obligations would not be fulfilled unless the Ministry of Health acts quickly to extend the ban to all indoor public places and workplaces and all means of public transport—and no subsequent minister reverses this expansion through regulations.

With respect to the technical details of best drafting practices, it is best to state clearly that no person may smoke in any part of any indoor workplace or public place, on any means of public transport, or in any specified outdoor public place or workplace. If the legislation uses the comprehensive definitions of "public place" and "workplace" set forth in the Article 8 Guidelines, it is not necessary to list the places or means of public transport subject to the smoking ban. If, however, it is necessary or customary in any given jurisdiction to provide lists of examples in legislation, the legislative provisions should first clearly articulate the smoking ban, as above, and then provide the examples. It should be explicitly stated that any examples provided are for illustrative purposes only and are in no way meant to be exhaustive or limiting.¹¹

On the other hand, outdoor public places and workplaces where smoking is banned should be listed, since only some outdoor sites will be covered by a smoking ban. The Article 8 Guidelines state that in identifying outdoor and quasi-outdoor places where it would be appropriate to prohibit smoking, evidence as to the possible health hazards in various settings should be considered. Where the evidence shows that a hazard exists, the most effective protection against exposure should be adopted. Although not explicitly stated in the Guidelines, it should be considered reasonable to prohibit smoking in any outdoor public place where allowing smoking would undercut any of the objectives of the legislation. For example, some jurisdictions prohibit smoking on the outdoor premises of educational facilities and health facilities, because of the

¹¹ Even with language making clear that any lists or examples are illustrative only, ambiguity could still be created by listing some places and not others.

role these institutions play in modeling good practices and in establishing social norms, as well as on playgrounds and other outdoor places catering to youth.¹²

Among laws that ban smoking in some outdoor settings, many prohibit smoking within a specified distance of doorways, operable windows, and air intake mechanisms in order to prevent smoke pollution from drifting inside and to protect persons entering or exiting the enclosed place from having to pass through heavy concentrations of tobacco smoke. These laws vary in terms of the distance from the doorway, window, or intake mechanism within which smoking is prohibited.¹³ Determining the appropriate distance should take into account scientific, environmental, and practical factors. The list of further reading provided at the end of this chapter includes articles that discuss outdoor smoke exposure in different settings and the factors that affect exposure.

¹² The Stanford Outdoor Tobacco Smoke Study investigated exposure to secondhand smoke in certain outdoor settings. A summary is available at <http://tobaccosmoke.exposurescience.org/outdoor-tobacco-smoke>.

¹³ For example, some Canadian provinces impose distance limitations of three to five meters (summary available at <http://www.no-smoke.org/learnmore.php?dp=d14%7Cd35%7Cp213>). In San Francisco, California, in the United States, smoking is allowed only at the curb, or if there is no curb, at least 15 feet from exits, entrances, operable windows, and vents (San Francisco Health Code, Article 19F, Section 1009.22(19)(e), available at [http://www.amlegal.com/nxt/gateway.dll/California/health/article19fprohibitingsmokinginenclosedar?f=templates\\$fn=default.htm\\$3.0\\$vid=amlegal:sanfrancisco_ca](http://www.amlegal.com/nxt/gateway.dll/California/health/article19fprohibitingsmokinginenclosedar?f=templates$fn=default.htm$3.0$vid=amlegal:sanfrancisco_ca)). Smoking is banned within four meters of doorways of nonresidential buildings in Queensland, Australia (Tobacco and other Smoking Products Act, 1998, as amended, available at <http://www.legislation.qld.gov.au/LEGISLTN/CURRENT/T/TobacoPrPrSuA98.pdf>).

Box 3.4 In Practice: Good practices in application of the smoking ban

Trinidad and Tobago

Trinidad and Tobago's Tobacco Control Act, 2009 applies the smoking ban to all indoor public places and workplaces and all means of public transport, without exemption. The law includes a clear statement prohibiting smoking in any enclosed public place or workplace or any public conveyance. Examples of places where smoking is prohibited are provided in a schedule to the act. The law makes clear that the places listed in the schedule are not meant to be exhaustive by using the phrase "including but not limited to."

Section 12

"(1) No person shall smoke or hold a lighted tobacco product in any enclosed public place, enclosed workplace, or public conveyance including but not limited to any place listed in the Second Schedule."

Second Schedule

"NO SMOKING AREAS

- a. public transportation terminals
- b. workplaces
- c. retail establishments including bars, restaurants and shopping malls
- d. clubs
- e. cinemas
- f. concert halls
- g. sports facilities
- h. pool and bingo halls
- i. publicly owned facilities rented out for events
- j. any other facilities that are accessible to the public."

The Tobacco Control Act, 2009 is available at

<http://www.tobaccocontrollaws.org/files/live/Trinidad%20and%20Tobago/Trinidad%20and%20Tobago%20-%20Tobacco%20Control%20Act%202009%20-%20national.pdf>.

Puerto Rico

Puerto Rico's Act to Regulate Smoking in Certain Public Places, as amended in 2006, bans smoking in all indoor workspaces and in an exhaustive list of places that meet the criteria of the Article 8 Guidelines definition of "public place." Although providing a list of places where the ban applies is potentially limiting in coverage and is not generally recommended as a drafting practice, this law defines "workspaces" very broadly, so that essentially all public places would fall within the definition. That, combined with the list of specific public places to which the ban applies, provides comprehensive coverage in line with WHO FCTC Article 8 and the Article 8 Guidelines.

Exemptions are provided, however, for places that exclusively sell tobacco products; for theater or film productions and presentations in which actors smoke as part of the performance; and for hotel rooms, subject to rules established by the Tourism Company. Although these exemptions are limited, the hotel exemption in particular allows for continued exposure to significant numbers of people.

§ 892 Prohibition (as amended)

(continued)

Box 3.4 *(continued)*

"Smoking is prohibited at all times in the following places:

- a. Public buildings, departments, agencies, public instrumentalities and public corporations of the Commonwealth of Puerto Rico.
- b. Classrooms, meeting halls, libraries, halls, school lunchrooms, cafeterias, and rest rooms in schools, and public and private institutions at all learning levels.
- c. Elevators for public use for the transportation of passengers and cargo in public and private buildings.
- d. Theaters and movie houses.
- e. Public and private hospitals and health centers.
- f. Public transportation vehicles, official vehicles and public or private ambulances.
- g. Restaurants, cafeterias, coffee shops, bakeries, establishments devoted to the sale of food and fast food establishments.
- h. Museums.
- i. Funeral parlors.
- j. Courts.
- k. Areas that contain flammable fluids, gases or materials.
 - l. Gasoline retail sales service stations.
- m. Public or private child care centers.
- n. Public or private recreational installations.
- o. Elderly care centers.
- p. Bars, pubs, discotheques, and liquor stores.
- q. Casinos.
- r. Business establishments and convention centers.
- s. Shopping centers.
- t. Any work setting in where there are one (1) or more employees. This prohibition shall not prevent employees or other persons from being able to smoke outdoors and outside the work space.
- u. Private transportation vehicles when there is a minor in a car seat present or when there is a child under the age of thirteen (13)."

§ 894. Designation of smoking areas

"The prohibitions established herein shall not apply to those business establishments exclusively engaged in the sale of tobacco and its by-products, nor to theater or film productions and presentations in which actors smoke as part of their character. Likewise, the prohibitions established in this chapter shall not apply in people's homes, places in which each person shall be free to use tobacco or its by-products without being subject to this chapter, except for the provisions of § 891(r) of this title; in the case of hotel rooms, the Tourism Company shall establish regulations to determine which rules shall apply to rooms set aside for smokers."

§ 895. Penal institutions and others

"The authorities in control of any penal institution or addiction treatment center shall adopt an institutional policy to regulate smoking in its facilities, in order for the health of nonsmoking inmates not to be affected."

The Act to Regulate Smoking is available at <http://www.lexisnexis.com/hottopics/lawsofpuertorico/>. (Click on "I agree," which takes you to the index of Laws of Puerto Rico Unannotated. Click on + for Title 24, Health and Sanitation, then on + for Part III, Food, Drugs, and Cosmetics, then on + for Chapter 62, Tobacco Act, then on applicable section number.) The 2006 amendments to the law are available at <http://www.oslpr.org/download/en/2006/A-0066-2006.pdf>.

(continued)

Box 3.4 (continued)

New York City, USA

New York City's Smoke Free Air Act (2002, as amended) prohibits smoking in almost all indoor public places and workplaces, including work vehicles, and an extensive number of outdoor public places. Limited exemptions apply largely to public places with a residential character and to tobacco-related businesses. These include some residential health care and day treatment program facilities, which may have separately ventilated smoking rooms; tobacco bars; hotel rooms; nonprofit membership associations with no employees; and enclosed rooms in specified entertainment facilities used exclusively for sampling tobacco products, no more than five times per year. An application for exemption is required. Although these exemptions are limited and strictly controlled, the hotel exemption in particular allows for continued exposure to a potentially significant number of people.

Smoking is prohibited in outdoor public places that include restaurant dining areas with no roof (smoking is allowed in a limited outdoor space that is three feet from the nonsmoking area); service lines; ticketed seating or viewing areas of performance venues and sports arenas; recreational areas; premises of children's institutions; playgrounds; premises of day care centers and schools through secondary level; and all parks, beaches, marinas, boardwalks, and pedestrian plazas. Smoking is also banned within 15 feet of entrances, exits, and grounds of New York City hospitals, diagnostic and treatment centers, and residential health care facilities.

Clear statements in the law prohibit smoking in enclosed areas within public places, subject to exemptions provided, and indoor areas of places of employment to which the public does not generally have access. Examples of places where smoking is prohibited are provided, with language making clear that the list is not exhaustive ("places include but are not limited to the following").

Because applicable provisions in the 2002 law and the 2009 and 2011 amendments are lengthy, they are not excerpted here. The NYC smoke-free law and amendments are available at <http://www.nycsmokefree.org/existing-legislation>. The consolidated (but unofficial) implementing rules are available at <http://www.nyc.gov/html/doh/downloads/pdf/smoke/tc6-unofficial.pdf>.

3.3.4 Impose legal duties of compliance

Enforceable smoke-free legislation places responsibility for compliance on the owner, manager, or other person in charge of the premises or means of public transport (Article 8 Guidelines). Persons in charge of public places and workplaces generally have a legal responsibility to keep the premises safe and sanitary, and to fulfill other legal requirements. Holding them responsible for smoke-free compliance naturally follows.

Smoke-free legislation should specify the mandatory requirements such persons must undertake to fulfill their responsibility, including ongoing duties to:

- Post "no smoking" signs in accordance with requirements specified in regulations (as to content, size, placement, etc.);
- Remove ashtrays from all indoor areas and from any outdoor areas where smoking is prohibited;
- Supervise observance of legal requirements; and
- Take reasonable steps to discourage and stop smoking where it is prohibited, including asking any person who is smoking to stop; discontinuing service and asking the person to leave if s/he refuses; and, if necessary, contacting law enforcement authorities for assistance.

It would also be possible to establish fines for smokers, where appropriate (Article 8 Guidelines). Global experience shows that the vast majority of people support smoke-free measures. As the no-smoking norm takes hold, self-enforcement becomes the normal practice.

Box 3.5 In Practice: Examples of legal duties

Colombia

Colombia's Law 1335 imposes a duty on persons in charge of premises to oversee compliance with the smoking ban, to post visible "no smoking" signs, and to adopt specified, reasonable measures to dissuade people from smoking in the place, such as asking the person not to smoke, interrupting service, asking him or her to leave the premises, or contacting the competent authority. Although removal of ashtrays is not specifically mentioned, it can be inferred as a reasonable duty necessary for overseeing compliance. To prevent any question, however, it would be better to include the prohibition on ashtrays inside the premises and in any outside areas where smoking is banned among the specified duties.

Article 20. Obligations

"Property owners, employers, and administrators of the places to which Article 19 refers have the following obligations:

- a. To oversee compliance with the bans established in this law in order to protect people from exposure to environmental tobacco smoke;
- b. To put up notices in a place visible to the public containing messages alluding to smoke-free environments, pursuant to the regulation issued by the Ministry of Social Welfare;
- c. To adopt specific, reasonable measures to dissuade people from smoking in the place, such as asking the person not to smoke, interrupting service, asking him to leave the premises, or contacting the competent authority."

Excerpt above is from an unofficial English translation of Law 1335 at <http://www.tobaccocontrolaws.org/files/live/Colombia/Colombia%20-%20Law%20No.%201335.pdf>. The law is available in the original Spanish at: http://www.secretariasenado.gov.co/senado/basedoc/ley/2009/ley_1335_2009.html.

New York City, USA

New York City's Smoke Free Air Act requires employers to post "no smoking" signs in specified places to ensure their visibility, to remove ashtrays from smoke-free areas, and to inform persons smoking where it is prohibited that they are in violation of the law. The additional duties outlined in the WHO FCTC Article 8 Guidelines (refusing service, asking the person to leave, and calling upon law enforcement when necessary with respect to any person who refuses to stop smoking) would strengthen the law. Employers must also adopt a no-smoking policy and must refrain from taking retaliatory action against any applicant or employee who asserts his or her rights to a smoke-free environment. "Rules of the City of New York, Title 24, Chapter 10: Smoking Under the New York City Smoke-Free Air Act" requires that signs be posted in lobbies and other appropriate locations and specifies the content of the signs and other details.

Sections 17-504 and 17-507 are the relevant provisions of the law. The implementing rules at § 10-12 specify the signage requirements. The New York City law and rules are available at www.nyc.gov/html/doh/html/smoke/tc1.shtml.

Trinidad and Tobago

Under Trinidad and Tobago's Tobacco Control Act, 2009, persons responsible for premises who authorize or acquiesce in the act of smoking are held personally liable for the offense and are subject to penalty. While the threat of personal liability should encourage diligent monitoring and action to stop persons from smoking, specifying the duties to remove ashtrays, post signs, and take other mandatory actions would be more likely to enhance enforceability.

(continued)

Box 3.5 *(continued)*

Section 12

“(1) No person shall smoke or hold a lighted tobacco product in any enclosed public place,

enclosed workplace, or public conveyance including but not limited to any place listed in the Second Schedule.

(2) Where a person contravenes subsection (1), the manager, owner or lessee of the place where the contravention occurred who authorized or acquiesced in the act, that manager, owner or lessee is deemed to have committed the offence and shall also be held personally liable.”

The Tobacco Control Act, 2009 is available at <http://www.tobaccocontrollaws.org/files/live/Trinidad%20and%20Tobago/Trinidad%20and%20Tobago%20-%20Tobacco%20Control%20Act%202009%20-%20national.pdf>.

3.3.5 Provide effective enforcement mechanisms

As part of its protection function, the State is obligated to enforce smoke-free laws. When specifying which authority or authorities are charged with smoke-free inspections, it is advisable to consider what inspection systems already exist and whether smoke-free inspections should be added to the existing systems. These might include inspection systems for hygiene and sanitation, occupational health and safety, fire safety, business licensing, and any other relevant systems (Article 8 Guidelines). In making this assessment, it is important to consider how well those existing inspection systems function, how well resourced the inspection agencies are, and the extent of political will within the agencies to carry out inspection duties. Discussion and agreement by the relevant authorities is an important step before assigning inspection and enforcement duties in the legislation.¹⁴ Once the appropriate enforcement mechanisms are determined, the legislation should provide the specified agencies not only the authority to inspect and enforce, but also the legal duty to do so.

3.3.6 Provide a range of deterrents and proportionate penalties

Since the primary duty of compliance should rest with the person responsible for the premises or means of public transport, fines should be larger for these persons than for smokers who violate the law, if smokers are penalized under the law. Business licensing sanctions for repeated violations should be an available option.

Trinidad and Tobago’s law provides for a fine of TT\$ 10,000 and imprisonment of six months. In Puerto Rico, violators face a penalty of US\$ 250 for a first offense and up to US\$ 2,000 for repeat violations. In both places, the law could be strengthened by establishing different penalties for individual smokers and for business owners or other persons responsible for the premises or means of public transport, concomitant with their respective resources and legal responsibilities, as suggested in the Article 8 Guidelines.

If the legal system of the country allows it, it would also be a good option to enable the funds derived from such fines to be used to support tobacco control activities.

¹⁴ It is also important to provide training to the enforcing agents.

3.3.7 Provide a role for civil society

Social norms have a very important role in enforcing smoke-free legislation, since enforcement agencies cannot be everywhere at all times. If there are open channels for communication with the competent authority, civil society may be able to act as an informal enforcement network, albeit one with no official power, that can provide important information and assist with enforcement. As recommended by the WHO FCTC Article 8 Guidelines, many jurisdictions have established a toll-free line and/or an e-mail address for this purpose, recognizing the vital role civil society can play in monitoring compliance and reporting violations.

3.3.8 Require evaluation and public dissemination of results

Analyzing inspection data on the most common areas of noncompliance can help the government determine whether there are weaknesses, gaps, or ambiguities in the law that need to be addressed and whether additional public information campaigns are needed. Compliance information gathered through the inspection process and analyzed periodically by the government can be especially important in helping the inspection authority or authorities determine how to best target inspection resources.

One way to do this is to compile the results of each inspection performed. This will allow data to be disaggregated by geographic area, type of business, etc. If particular businesses, workplaces, or sectors are found to have higher incidences of noncompliance in comparison to other sectors, the government can focus its resources on the problem areas. Analyzing success or failure rates of enforcement actions undertaken can also help the government determine whether the law may need to be clarified or strengthened and whether more training and/or resource materials may be needed for inspectors and other enforcement staff. Ultimately, monitoring and evaluation data can be useful in advocating for legislative changes, additional resources, or whatever other measures may be seen as needed in light of the evaluation findings.

3.3.9 Grant broad regulatory power to the appropriate authority to address implementation details

The appropriate authority should be granted power to address a broad range of matters in regulations, including, but not limited to:

- Adding additional outdoor public places and workplaces to the list of those where smoking is banned;
- If the legislation lists examples of indoor public places and workplaces or forms of public transport where smoking is banned, adding examples to any such lists, for illustrative purposes;
- Specifying all aspects of signage requirements and elaborating any other duties imposed on persons responsible for premises and for means of public transport; and
- Addressing any other matter necessary or appropriate for implementing the law.
- Care should be taken to avoid implying limitations on regulatory power, such as by explicitly granting only some powers and presenting them in a way that makes these powers appear to be exhaustive.

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Chapter 4

Packaging and Labeling of Tobacco Products



4. Packaging and Labeling of Tobacco Products

4.1 Background

There are compelling reasons to enact strong and comprehensive measures to regulate the packaging and labeling of tobacco products. First, most tobacco users are unaware of the true risks of tobacco use and exposure to tobacco smoke (WHO 2011), and there is abundant evidence showing that health warnings on packages are effective in making users aware of those risks (Hammond et al. 2003, 2004, 2006; Miller et al. 2009; INCA 2008). Second, tobacco companies use tobacco product packaging, and the products within, as promotional tools, contrary to Article 13 of the World Health Organization Framework Convention on Tobacco Control (WHO 2003; hereafter, WHO FCTC). Packaging and labeling are used to recruit new tobacco users and target youth, women, and other groups. Tobacco companies also use packaging and labeling to mislead consumers about the harm caused by smoking, for example, by promoting so-called “low-tar” products (Wakefield et al. 2002). Taken together, these reasons provide a compelling case for implementing the obligations established in WHO FCTC Article 11 and the recommendations set out in the Guidelines for Implementation of Article 11 (WHO 2009; hereafter, Article 11 Guidelines).

4.1.1 Rationale and evidence

Worldwide, people are largely unaware of specific diseases caused by tobacco use and the magnitude of the risks, generally underestimating their seriousness (Yang et al. 2010; Hammond et al. 2006; Weinstein, Marcus, and Moser 2005; World Bank 1999). There is even less awareness of the risks of exposure to secondhand tobacco smoke (Gallup News Service 2006; Scollo and Winstanley 2008). Large pictorial warnings on tobacco product packaging and labeling have been shown to increase knowledge about specific tobacco-related harms and to motivate tobacco users to quit (Hammond et al. 2007; Datafolha 2002; Health Promotion Board Singapore 2004; Li and Grigg 2009; Borland, Yong, et al. 2009, Shanahan and Elliott 2009). These warnings may also have a deterrent effect on tobacco use initiation among youth (Vardavas et al. 2009). Tobacco product packaging and labeling is a good vehicle for communicating the risks and harms of tobacco use at the times of both purchase and use. An added advantage is that the tobacco industry bears the cost of warning consumers.

Most governments now require tobacco product packaging and labeling to carry some form of health warning. Laws have progressed from requiring small text-only health warnings to requiring larger text warnings to the present trend of requiring large, if not very large, graphic health warnings on the principal display areas of packs. For example, in Uruguay, warnings must cover 80% of the principal surfaces of the pack; in Canada, 75% of the two principal display surfaces; and in Mauritius, 60% of the front and 70% of the back. In Australia, warnings must cover 75% of the front and 90% of the back.¹ In addition, many other countries around the world and in the Americas require graphic warnings to cover at least 50% of the pack’s principal display areas (WHO 2011).

¹ In 2011 Australia approved a new law requiring plain packaging. Nothing, other than the required graphic warnings and other required markings such as tax stamps, can adorn a cigarette package: no company logos, stylized fonts, colors, designs, images, or additional descriptive language are allowed. The law will enter into force in December 2012. Section 4.1.1.1, on the rationale for plain packaging, presents a more detailed description of what this entails. The new Australian law and the legal challenge presented by the tobacco industry are discussed later in this chapter.

The global experience with packaging and labeling has generated a large body of evidence that demonstrates which components of tobacco product packaging and labeling regulation are most effective in educating consumers and, ultimately, reducing tobacco consumption. It is clear that large, graphic health warnings are more effective than text-only warnings in communicating the risks of tobacco use and exposure to tobacco smoke (Hammond et al. 2007; Borland, Wilson, et al. 2009). The larger the pictorial warning, the more effective it is (WHO/the Union 2011; Borland, Wilson, et al. 2009). After Canada began requiring graphic health warnings in 2000, evidence showed that smokers who had read, thought about, and discussed the warnings were more likely to have quit, attempted to quit, or reduced their tobacco consumption (Canadian Cancer Society 2001; Hammond et al. 2007). In Australia, after the introduction of graphic health warnings in 2006, more than half of smokers reported believing that they had an increased risk of dying from a smoking-related illness, with 38% feeling motivated to quit (Miller et al. 2009). In Uruguay, the Global Adult Tobacco Survey (GATS) in 2009 showed that health warnings were more effective in youth than in adults (54.3% of respondents 15 to 24 years of age thought about quitting because of the warnings, compared to only 42% of those between the ages of 25 and 64). It also showed that warnings were more effective in the population with less education (50% of those with only primary education thought about quitting because of the health warnings, but only 33.3% of those with tertiary education did)² (MSP/PAHO 2011).

Brazil was one of the first countries in the world, and the second in the Americas, to implement large graphic health warnings. The GATS showed that 96.1% of Brazilian adults believe that smoking causes serious illnesses, and 65% of smokers said that warnings on tobacco packages encouraged them to quit smoking (INCA/PAHO 2010). An earlier public opinion poll found that 67% of smokers in Brazil said the images made them want to stop smoking (Datafolha 2002).

Evidence showing the effectiveness of graphic health warnings comes from different areas of the world, including Canada (Hammond et al. 2003, 2004), Australia (Miller et al. 2009), Singapore (Health Promotion Board 2004), Thailand (International Tobacco Control Policy Evaluation Project 2010), Brazil (WHO 2011: 24), Uruguay (Thrasher et al. 2010), and Mexico (Thrasher et al. 2010). A study conducted by the Ministry of Health of Uruguay³ showed that the stronger the images, the greater the impact; the study both compared different rounds of warnings implemented in Uruguay and compared Uruguayan warnings against those in Brazil. Another study compared warnings consisting of text only (Mexico), abstract images (Uruguay),⁴ and figurative images⁵ (Brazil). It confirmed that warnings with images are more effective than text-only warnings and that figurative images are more effective than abstract ones (Thrasher et al. 2010).

Just as the package is an effective tool for communicating the risks and harms of tobacco use, it is also a tool used by the tobacco industry to achieve its competing objectives of promoting its products. Packaging can communicate brand image and brand presence, and brand image is very important to young smokers in distinguishing between brands of cigarettes and ultimately selecting which brand to smoke (Wakefield et al. 2002). Innovative packaging is available to the tobacco industry for providing and hiding promotional messages and for disrupting and obscuring mandated health warnings, and many of those designs have been used (WHO/the Union 2011: 3). The tobacco industry's ever-evolving tactics to undermine packaging and labeling requirements underscore the importance of fully incorporating the Article 11 Guidelines, including its best-practice recommendations, into domestic packaging and labeling measures.

² GATS data collection began on 19 October 2009 and ended on 4 December 2009. The size of the health warnings was increased by Decree 287/09 of 15 June 2009, but the decree established a 180-day phase-in period for implementation, so 80% of the larger warnings were introduced after completion of the survey.

³ Findings of the unpublished study by the Ministry of Health are reported in an internal document, "Pre Test de Campaña Antitabaco," 2008.

⁴ At the time the study was conducted, Uruguay was implementing round two of its health warnings, which used abstract images (e.g., a bomb, a poison container) rather than images of specific tobacco-related diseases.

⁵ Figurative images depict human suffering and gruesome diseased organs.

4.1.2 Regional situation

In the seven years since the WHO FCTC entered into force in 2005, 19 countries in the Region of the Americas have passed national legislation on packaging and labeling. In many cases, the new legislation is consistent with most of the provisions included in WHO FCTC Article 11 and the Article 11 Guidelines. In fact, 16 countries have approved laws specifying that warnings must cover between 50% and 80% of the main display areas of the pack and must include images.⁶ Colombia mandates a warning that includes images, but it only requires the warning to cover 30% of the main display areas, the minimum established in WHO FCTC Article 11. Cuba and Jamaica fulfill the minimum 30% size requirement but do not require warnings to include images (PAHO 2011).

All 19 countries that have passed packaging and labeling legislation have banned the use of misleading terms. In addition, Uruguay's law requires only one presentation per brand (sub-brands are not allowed) as a means of preempting the tobacco industry from evading the ban on misleading packaging and labeling.⁷ As with implementation of other WHO FCTC mandates, progress on packaging and labeling policies is uneven in the Region, with the Caribbean countries lagging significantly behind countries in Latin America.⁸

In the Caribbean, a regional approach to health warnings was initiated in 2006 with the intent of advancing packaging and labeling legislation in many countries at the same time. The Jamaica Bureau of Standards was selected as the regional agency responsible for revising the existing cigarette labeling standards. In 2010 the bureau developed a revised standard that included graphic warnings and submitted it to the Caribbean Community (CARICOM) Regional Organization for Standards and Quality (CROSQ). In order for the regional standard to move forward, each of the CARICOM Member States had to approve the standard. As September 2012, despite majority support for the standard, it has not been approved yet but the government of Jamaica is now taking steps to implement the revised standard on a national level, and other Caribbean countries have expressed intentions to do the same.

4.2 Tobacco industry strategies against effective packaging and labeling of tobacco products

As already mentioned, the tobacco industry and its allies have consistently attempted to obstruct, delay, or weaken the implementation of national laws and regulations consistent with WHO FCTC Article 11. This section discusses how the tobacco industry uses the packaging and labeling of tobacco products to promote sales, reviews the principal arguments that the industry has made in opposition to packaging and labeling restrictions, and describes two prominent legal cases brought recently by the tobacco industry on this topic.

⁶ The 16 countries are Argentina, Bolivia, Brazil, Canada, Chile, Costa Rica, Ecuador, El Salvador, Honduras, Mexico, Nicaragua, Panama, Peru, the United States, Uruguay, and Venezuela. As of October 2012, however, six of those countries (Argentina, Costa Rica, Ecuador, El Salvador, Nicaragua, and the United States) have yet to regulate and/or implement their respective laws. In the case of Mexico, although the law requires warnings to cover more than 50% of the total surface of the pack, an image-based warning is required to cover only 30% of the front of the pack, while the text related to the image must cover 100% of the back side of the pack, with an accompanying text warning covering 100% of a lateral side of the pack.

⁷ "One presentation" means that each brand manufacturer can have only one product on the market. For example, Marlboro can sell either Marlboro Red or Marlboro Gold, but not both.

⁸ The only Caribbean country to pass legislation on this matter was Trinidad and Tobago, in 2009. However, the act does not specify implementation details, and implementing regulations have not been promulgated as of October 2012.

4.2.1 Industry uses of tobacco packaging

4.2.1.1 Packaging designed to promote tobacco consumption

The pack is designed to be a powerful promotional tool. It is becoming even more important now that other advertising avenues for the tobacco industry are being curtailed as more governments enact stronger bans on tobacco advertising, promotion, and sponsorship. An internal Philip Morris document (Hulit 1994) states:

Our final communication vehicle with our smokers is the pack itself. In the absence of any other marketing messages, our packaging . . . is the sole communicator of our brand essence. Put another way: When you don't have anything else, our packaging is our marketing.

Packaging is also carefully designed to target tobacco industry priority groups such as women and youth (Doxey and Hammond 2011; Hammond et al. 2011). For example, long slim packs are used to appeal to women (Wakefield et al. 2002). Special-edition packs, such as those with novel eye-catching designs available for a limited time period, are used to attract youth (Gallopel-Morvan et al. 2011). Chapter 5 discusses this topic in more detail.



Source: David Hammond
www.tobaccolabels.ca.

4.2.1.2 Packaging designed to mislead consumers

Tobacco companies use packaging and labeling to present descriptors such as “low-tar,” “light,” or “mild.” Studies show that smokers believe tobacco products described in these terms are less harmful than others, although in fact they are just as harmful (Seema et al. 2011). Once governments caught on to the low-tar deception, many enacted legislation banning the use of such misleading descriptors. In response, tobacco companies have successfully used colors, numbers, and shapes—on the pack, on the product, or in the brand name—as substitutes for the restricted descriptors to suggest a less harmful product. For example, silver, white, gold, and slim packaging/products are perceived as being less harmful, whereas products in red and black packages are perceived as more harmful (Seema et al. 2011). WHO FCTC Article 11.1(a) seeks to close the descriptor loophole by making it clear that laws need to prohibit the promotion of a tobacco product “by *any* means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health



Source: Cristianne Viana.

effects, hazards or emissions” (emphasis added). This includes, but is not limited to, the use of 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.”



Source: Cristianne Viana.

4.2.1.3 Packaging designed to undermine health warnings

The tobacco industry has devised a number of tactics to undermine health warning requirements. These include, among others, using colors and text that make the warnings less visible against the pack background (INCA 2008); placing the warning in an obscure position on the pack; and adjusting the size of the warning to distort warning images, among many others (Tan and Foong 2011). Innovative pack designs, such as accordion packs, sliding packs, and hinge packs, allow for manipulation of the pack to hide or obscure the



Source: PAHO.

warnings (Dahiya and Arora 2009). Stickers and sleeves (“onserts”) accompanying the products can also be used to cover the warnings (INCA 2008).

4.2.2 Countering tobacco industry arguments against effective measures

This section summarizes the principal arguments used by the tobacco industry and its allies against effective packaging and labeling measures. Some of the arguments are of a legal nature, while others are technical, questioning the effectiveness or necessity of the measures. In each case, clear counterarguments can be made.

4.2.2.1 Argument: Graphic health warnings restrict tobacco manufacturers’ freedom of expression

Countries with various legal systems have rejected industry claims that graphic health warnings violate tobacco companies’ freedom of expression or freedom of commercial expression, and they have enacted laws requiring large pictorial warnings. When the industry has filed legal challenges to these laws, courts generally have ruled against the tobacco companies and in favor of public health.⁹

4.2.2.2 Argument: Graphic health warnings violate international treaties on trade and intellectual property and are tantamount to the expropriation of brands

The tobacco industry frequently uses international agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (WTO 1994) and the Paris Convention for the Protection of Industrial Property (1883) to argue that large graphic health warnings and significant packaging and labeling restrictions, such as those enacted in Uruguay and Australia, violate international trade law. According to the industry, packaging and labeling requirements “unjustifiably encumber” (TRIPS 1994, Article 20) tobacco companies in the use of their trademarks in the course of trade (Freeman, Chapman, and Rimmer 2007). However, the fact that a measure affects the use of a trademark does not in itself constitute a violation of these agreements. TRIPS and the Paris Convention do not oblige States to permit trademark owners to use their marks in any manner they choose. Rather, under these agreements, trademark rights are rights to exclude others from unauthorized use of the mark in certain circumstances.¹⁰

Tobacco companies also use International Investment Agreements, which are often bilateral agreements between two States designed to protect the investments of foreign investors, among other things. In recent years, Philip Morris has used such agreements to challenge tobacco packaging measures in Uruguay and Australia, arguing that those measures were in fact expropriation of their investments, including trademarks. These cases are discussed in section 4.2.3.2.

4.2.2.3 Argument: Large graphic health warnings and plain packaging will increase illicit trade

The tobacco industry baldly makes this claim without any specificity or supporting evidence, other than to say that prominent trademarks will make counterfeiting more difficult. Until the tobacco industry reveals some basis for making this claim, governments should not let this assertion deter them from moving forward with large graphic health warnings

⁹ In the Region of the Americas, the Supreme Court of Justice of Paraguay repealed the decree on packaging and labeling, but this was on procedural rather than substantive grounds. On the case, *Tabacalera del Este S.A. y Otros con Poder Ejecutivo s/Amparo Constitucional*, see Corte Suprema de Justicia (2010). In the United States, some federal district courts and a higher circuit court have ruled against the requirement for graphic health warnings as violating the companies’ free speech rights, while other district courts and a circuit court have upheld the requirement. It will be up to the US Supreme Court to resolve the conflicts among the courts. On the United Kingdom, see High Court of Justice of England and Wales, Queen’s Bench Division (Administrative Court), *The Queen v. Secretary of State for Health, ex parte British American Tobacco (Investments) Ltd. and Imperial Tobacco Ltd.*, reference for a preliminary ruling, 2002, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62001J0491:EN:HTML>. On Canada, see Supreme Court of Canada, *Canada (Attorney General) v. JTI-Macdonald Corp.*, 2 S.C.R. 610, 2007 SCC 30, <http://scc.lexum.org/en/2007/2007scc30/2007scc30.html>. On New Zealand, see Hoek et al. (2010).

¹⁰ For more details on trade and tobacco, see Chapter 1. For more information on the Uruguay and Australia cases, see the next subsection in this chapter.

and/or plain packaging. In addition, it is important to point out that trademarked products have long been subject to counterfeiting.¹¹

4.2.2.4 Argument: Tobacco companies need more time to implement pictorial warnings than is allowed by law

In a stalling maneuver, tobacco manufacturers invariably argue that they will need more time to switch to the new warnings. When governments refuse to back down from the time prescribed by law, however, the industry typically complies with the legally imposed deadline, as has happened in numerous jurisdictions (Health Canada 2000; Cavalcante 2003). In countries such as Panama, Uruguay, Chile, and Venezuela, tobacco manufacturers were able to print warnings on packages as established by the health authority in nine months or less after the new specifications were approved.

4.2.3 Regional experience with legal challenges to packaging and labeling laws

4.2.3.1 Uruguay cases

In February 2010, three affiliate companies of Philip Morris International (PMI) filed an arbitration request at the International Centre for Settlement of Investment Disputes (ICSID) against the government of Uruguay under the 1991 Switzerland-Uruguay Bilateral Agreement on the Promotion and Protection of Foreign Investments.¹² PMI claims that Uruguay's restrictions on tobacco product packaging violate the bilateral investment treaty. Specifically, PMI objects to three provisions of the Uruguayan tobacco control legislation:

- The requirement that 80% of the front and back of tobacco packs must be covered with graphic health warnings;
- The specific content of the graphic images chosen for printing on tobacco packaging;
- The restriction of brand usage to a single presentation.

PMI argues that these measures result in an indirect expropriation of their property rights, particularly their trademarks and goodwill; that they result in unfair and inequitable treatment; and that they are arbitrary and unreasonable. PMI's request for arbitration is being heard by an ICSID tribunal composed of three arbitrators: one appointed by PMI, one appointed by the government of Uruguay, and one appointed by ICSID, who serves as president of the tribunal. The arbitration process started in May 2011 and is expected to last at least three to four years. Uruguay has challenged the jurisdiction of the tribunal to hear the claim, arguing that health measures fall outside the scope of the bilateral investment treaty.

The international community has taken a public stand in support of the government of Uruguay. In September 2010, during the 50th Directing Council meeting of the Pan American Health Organization (PAHO 2010), ministers of health from PAHO's Member States unanimously approved a resolution in support of the policies adopted by the Uruguayan government and critical of the tobacco industry's efforts to undermine tobacco control in Uruguay and throughout the region. In November 2010, the fourth session of the Conference of the Parties to the WHO FCTC voted unanimously in favor of the Punta del Este Declaration (WHO 2010), which affirms the Parties' "firm commitment to prioritize the implementation of health measures designed to control tobacco consumption in their respective jurisdictions" and their "concern regarding actions taken by the tobacco industry that seek to subvert and undermine government policies on tobacco control." The declaration further affirms that "Parties have the right to define and implement national public health policies pursuant to compliance with conventions and commitments under WHO, particularly with the WHO FCTC." This was a clear statement that Uruguay and other countries have a sovereign right to take strong actions to protect their citizens from tobacco without interference from the tobacco industry.

Abal Hermanos SA, a tobacco company that joined PMI in the arbitration case, challenged the law in the Uruguayan domestic court system, claiming that it granted unlimited authority to the executive branch to require tobacco product

¹¹ Furthermore illicit trade is addressed in Article 15 of the WHO FCTC. A protocol on illicit trade in tobacco products was approved by COP 5 and will be open for signature from January 2013.

¹² The three companies are Philip Morris Products SA (PMI's Swiss affiliate), Abal Hermanos SA (an Uruguayan tobacco company), and FTR Holdings SA (a Swiss conglomerate that owns both co-plaintiffs).

manufacturers to affix warnings occupying at least 50% of the principal display areas of the pack.¹³ According to the company, this unlimited grant of authority violated several rights, including property, intellectual property, and trademark rights, freedom of industry and trade, and freedom of speech, that only the legislative branch had the authority to limit. The Supreme Court dismissed the action, finding that the law did not grant unlimited powers to the executive to restrict individual rights in breach of provisions of a higher order. The Supreme Court also recognized the competency of the Ministry of Public Health to issue these measures pursuant to its authority to adopt all measures it deems necessary to maintain public health.

4.2.3.2 Australia cases

Philip Morris (Asia) brought a claim under the 1993 Agreement between the Government of Australia and the Government of Hong Kong for the Promotion and Protection of Investments. The claim relates to the Australian government's Tobacco Plain Packaging Act 2011 (Cth), described below. The act requires that tobacco products be sold in plain packaging beginning in December 2012. The company argues that plain packaging results in indirect expropriation of Philip Morris trademarks and the goodwill associated with those trademarks and that such treatment is unfair, inequitable, arbitrary, and unreasonable. These arguments are similar to the arguments made with respect to the Uruguayan measures. The claim remains pending as of this writing.

Phillip Morris, along with British American Tobacco, Imperial Tobacco, and Japan Tobacco, also challenged the constitutional validity of Australia's plain packaging legislation, claiming its provisions were invalid because they were an acquisition of plaintiffs' property otherwise than on just terms (the government has the authority to acquire property on just terms).¹⁴ The court found the legislation to be constitutionally valid, but as of late 2012 had not provided a full decision with its reasons.

¹³ Abal Hermanos SA v. Legislative Branch et al., action for unconstitutionality of Articles 9 and 24 of Law 18,256, File No. 1-65/2009.

¹⁴ British American Tobacco Australasia Limited & Ors v. Commonwealth of Australia, HCA 30 (2012).

4.3 Implementing WHO FCTC Article 11 at the domestic level: Drafting effective packaging and labeling measures

Domestic legislation that fully incorporates WHO FCTC Article 11 and its Guidelines for Implementation will help ensure that required health warnings appropriately inform consumers about tobacco-caused harms; that companies are not able to use packaging and labeling, or the product itself, to mislead consumers or promote the product; and that opportunities for tobacco companies to evade packaging and labeling measures are limited.

Chapter 2 lists nine key components that can provide the framework for effective packaging and labeling measures.¹⁵ This chapter focuses on those that must be tailored for implementation of WHO FCTC Article 11. The accompanying “In Practice” boxes present examples of good-practice legislation from different countries. Legislative development and legislative drafting are both a science and an art, and they occur within a political context. Achieving best-practice legislation often takes time; the examples highlighted in the boxes either achieve or approach this standard. The best means of ensuring best-practice legislation is to fully incorporate WHO FCTC Article 11 and its Guidelines into domestic packaging and labeling provisions (see Chapter VI of the legislative template for a tobacco control act, included as Chapter 9 of this manual).

4.3.1 Provide clear legislative objectives

The objectives of legislation on packaging and labeling could include at least the following:

- Remediating consumers’ lack of knowledge about the true risks and specific harms of tobacco use and exposure to tobacco smoke, and encouraging smokers to avoid smoking around others, especially in the home;
- Increasing the effectiveness of pack warnings;
- Reducing the appeal of tobacco products and discouraging tobacco use, encouraging users to quit, and helping those who have quit avoid relapse; and
- Preventing tobacco product packaging and labeling and the product itself from being used to mislead consumers, promote the product, and undermine health warning requirements.

One or more rules of interpretation may flow from these objectives. For example, because the tobacco industry is adept at continuing to mislead consumers about tobacco products’ characteristics, health effects, hazards, and emissions through its packaging and labeling methods, rules of interpretation could provide that legislative provisions should be interpreted as prohibiting any means or methods whatsoever that are likely to create an erroneous impression about the product, whether used in or on the packaging, the labeling, or the product itself, and whether those means and methods are currently in use or may arise in the future through technological innovations.

¹⁵ The tenth key component, providing subnational authorities with the power to enact more protective measures, may not apply in the case of packaging and labeling.

Box 4.1 In Practice: Examples of legislative objectives

Australia

Australia's Tobacco Plain Packaging Act 2011 lays out legislative objectives that apply to plain packaging. These objectives also apply to more general packaging and labeling measures, and, in fact, are reflected in the suggested objectives above.

Part 1, section 3. Objects of this Act

- (1)** The objects of this Act are:
- a.** to improve public health by:
 - i.** discouraging people from taking up smoking, or using tobacco products; and
 - ii.** encouraging people to give up smoking, and to stop using tobacco products; and
 - iii.** discouraging people who have given up smoking, or who have stopped using tobacco products, from relapsing; and
 - iv.** reducing people's exposure to smoke from tobacco products; and
 - b.** to give effect to certain obligations that Australia has as a party to the Convention on Tobacco Control.
- (2)** It is the intention of the Parliament to contribute to achieving the objects in subsection (1) by regulating the retail packaging and appearance of tobacco products in order to:
- a.** reduce the appeal of tobacco products to consumers; and
 - b.** increase the effectiveness of health warnings on the retail packaging of tobacco products; and
 - c.** reduce the ability of the retail packaging of tobacco products to mislead consumers about the harmful effects of smoking or using tobacco products."

The Tobacco Plain Packaging Act 2011 is available at <http://www.comlaw.gov.au/Details/C2011A00148>.

4.3.2 Define key terms

WHO FCTC Articles 1 and 11 define key terms for packaging and labeling legislation as follows:

- *"Tobacco products"*: products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing (Article 1(f))
- *"Tobacco industry"*: tobacco manufacturers, wholesale distributors, and importers of tobacco products (Article 1(e))
- *"Outside packaging and labeling"* in relation to tobacco products applies to any packaging and labeling used in the retail sale of the product (Article 11.4)

Using these definitions will help ensure proper interpretation and application of tobacco product packaging and labeling requirements in accordance with WHO FCTC requirements.

Box 4.2

In Practice: Examples of comprehensive definitions

Ireland

European Communities (Manufacture, Sale, and Presentation of Tobacco Products) (Amendment) Regulations 2003 (SI 425 of 2003) was passed by the Irish Parliament in 2003 (and amended by SI 255 of 2008) to give effect to Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001.¹⁶ The European Communities Directive defines key terms in accordance with the WHO FCTC and Article 11 Guidelines. These definitions have been adopted in domestic legislation in Ireland and other European Union countries. The definitions excerpted below are from the regulations issued by Irish government. The regulations use the term “packet” to include both unit packaging and what FCTC Article 11.4 terms “outside packaging and labeling.” This comprehensive definition encompasses all packaging used for retail sale.

SI 425. Regulation 2(1)

“Tobacco products means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not.”

SI 255. Regulation 3(1)(a)

“Packet, in relation to a tobacco product, means any box, package, container, wrapping or other receptacle which contains the product and in which the product is, or is intended to be, presented for retail supply, excluding any additional transparent outer wrapping which may be discarded on opening and excluding any wrapping of individual cigars or cigarillos and where any such receptacle is or is to be contained in another receptacle (excluding such outer wrapping), includes each such receptacle.”

The principal 2003 regulations are available at <http://www.irishstatutebook.ie/2003/en/si/0425.html>. The 2008 amendments, which include the definitions above, are available at <http://www.irishstatutebook.ie/2008/en/si/0255.html>.

Uruguay

Although Uruguay’s Law 18.256 does not technically define the term “tobacco product,” its regulation, Ministry of Public Health Decree 284/008, defines the scope of the regulations in such a way as to ensure they are applicable to the types of tobacco products covered by the WHO FCTC. The definition of “outside packaging and labeling” in Decree 248/008 follows the definition for that term provided in WHO FCTC Article 11.4.

Article 1

“Included in this regulation are cigarettes, cigars, tobaccos and other products of similar use, prepared totally or in part by using tobacco leaves as raw material and designed to be smoked, inhaled, sucked, chewed or used as snuff.”

Article 12

“Outside packaging and labeling applies to any packaging and labeling used in the retail sale of tobacco products including cigarette cartons.”

Excerpt above is from an unofficial English translation of Decree 284/008 at http://www.tobaccocontrallaws.org/files/live/Uruguay/Uruguay%20-%20Decree%20No.%20284_008.pdf. The decree is available in the original Spanish at http://archivo.presidencia.gub.uy/_web/decretos/2008/06/CM496__00001.PDF.

¹⁶ The Directive is available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:194:0026:0034:EN:PDF>.

4.3.3 Ensure comprehensive application of packaging and labeling measures

First, it is crucial that the measures established in the law and subsequent regulations apply to all smoked and smokeless tobacco products, whether domestically manufactured or imported, and regardless of whether the products are intended for duty-free sale, as provided in the Article 11 Guidelines.

WHO FCTC Article 11 requires Parties to adopt and implement effective measures to accomplish the prohibition of deceptive packaging and labeling; the determination of the content, size, display, and other details of health warnings and other messages; and the determination of the content, size, display and other details of required constituent and emissions information.

4.3.3.1 Prohibition on false, misleading, or deceptive packaging and labeling

WHO FCTC Article 11.1(a) requires effective measures to ensure that tobacco product packaging and labeling do not promote a tobacco product by any means that are false, misleading, deceptive, or likely to create an erroneous impression about the product's characteristics, health effects, hazards, or emissions. This includes a prohibition on the use of any term, descriptor, trademark, figurative or other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than others. This may include—but is not limited to—terms such as “low tar,” “light,” “ultra-light,” or “mild,” and, as provided in the Article 11 Guidelines, “extra,” “ultra,” and similar terms “in any language that might mislead consumers.”

Because most people believe that lower yield figures (for example, for tar, nicotine, or carbon monoxide) mean less harm (Gallopel-Morvan et al. 2010), the Article 11 Guidelines provide that their display anywhere on or in the package, including when used as part of a brand name or trademark (e.g., “Kent 4” or “Kent 7”), should be prohibited.

In drafting legislation aimed at prohibiting false, misleading, or deceptive packaging and labeling, it is important to use broad language and extensive examples; prohibit misleading packaging and labeling; guard against packaging innovations that undermine legislation; and consider establishing plain packaging.

Use broad language and extensive examples. In drafting provisions to prohibit misleading packaging and labeling, it is important to use the language in FCTC Article 11.1(a) as a starting point. Taking into account the tobacco industry's determination to evade governments' efforts to prohibit misleading packaging and labeling, the language of Article 11.1(a) is carefully crafted to prohibit not only misleading terms and descriptors (e.g., “low tar,” “light,” “mild”) but also any “trademark, figurative *or other sign* that directly or indirectly creates the false impression that a particular tobacco product is less harmful than others” (emphasis added). It may also be a good idea to provide even more extensive examples of the types of misleading practices prohibited. Experience shows that even when a law broadly prohibits misleading packaging and labeling, if it specifically mentions only some prohibited signs and terms but not others—for example, mentioning “trademarks, figurative and other signs” but not “colors,” or mentioning “mild” but not “smooth”—the tobacco industry continues to market the products by using the misleading signs and terms not specifically mentioned in the law. Even with extensive examples provided in the legislation or regulations, it is still important for the law to make clear that any examples provided are not meant to be exclusive; this can be done through the inclusion of a phrase like “including but not limited to.”

Prohibit misleading packaging and labeling both inside and out. To avoid loopholes, the prohibitions on misleading packaging and labeling should apply to the entire package, inside and out, and to the product itself. This will help prevent such practices as color- or number-coding on the inside of the pack, on the foil wrapping inside the pack, or on the product

itself. Uruguay's law (Box 4.3) has gone even further, limiting each commercial brand of tobacco products to a single package design and prohibiting the use of terms, descriptive elements, manufacturer or business brand names, colors, or combinations of colors that may have the effect of creating the false impression that a particular tobacco product is less harmful than others.

Box 4.3

In Practice: Examples of comprehensive provisions prohibiting false, misleading, or deceptive packaging and labeling

Uruguay

Uruguay's Law 18.256, together with Ordinance 514 (2008), provides broad language prohibiting any kind of misleading packaging and labeling. Of special note is its use of the phrase "or anything else."

Law 18.256, Article 8. Packaging and labeling

"It is forbidden for tobacco product packages and labels to promote themselves in a false, erroneous or deceptive manner or that might lead to error regarding their characteristics, health effects, risks or emissions. It is also forbidden to use terms, descriptive elements, trademarks or business names, figurative symbols, or anything else that may have the direct or indirect effect of creating the false impression that a specific tobacco product is less harmful than others."

Ordinance 514 takes Law 18.256 further by limiting each brand of tobacco products to just one form of packaging presentation.

Ordinance 514, Section 3

"Every commercial brand of tobacco products must have one single package design, such that it is forbidden to employ terms, descriptive elements, manufacturer or business brand names, figurative symbols or those of another type, such as colors, combinations of colors, numbers or letters, that may have the direct or indirect effect of creating the false impression that a particular tobacco product is less harmful than another, varying only the graphic illustrations and the inscription according to Number 1 of this Ordinance."

First excerpt above is from an unofficial English translation of Law 18.256 at

<http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Law%20No.%2018.256.pdf>.

The law is available in the original Spanish at

<http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18256&Anchor>.

Second excerpt above is from an unofficial English translation of Ordinance 514 at

<http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Ordinance%20No.%20514.pdf>.

The ordinance is available in the original Spanish at

<http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Ordinance%20No.%20514%20-%20national.pdf>.

Guard against packaging innovations that undermine legislation. Drafters of legislation should be aware of the different packaging innovations available to the tobacco industry and of how the industry uses these innovations to evade and undermine packaging and labeling requirements.¹⁷ In addition to the innovative pack designs mentioned in sections 4.1.1 and 4.2.1, the industry uses the tear tape on the pack both for branding and as a communication device: unique codes on the tape can provide access to interactive Web-based or SMS text message promotions and competitions. Other features may be designed to change the packaging after sale of the product, for example, by using inks designed to appear over time. It is only with an understanding of the innovations and the ways the tobacco industry is using and can use them that legislation can effectively prevent the industry from continuing to evade legal requirements.

Consider establishing plain packaging. The Article 11 Guidelines provide that Parties should consider adopting “plain packaging” measures that restrict or prohibit the use of logos, stylized fonts, colors, brand images, or other promotional information on or in packaging, other than brand and product names displayed in a standard color and font style on a plain background.¹⁸ In other words, plain packaging means that, aside from the health warnings and messages required by national regulations, only the minimum necessary information can appear on the pack. Australia is the first country in the world to adopt a law requiring plain packaging (Box 4.4). The British government is reported to be moving in the direction of plain packaging (UK Department of Health 2012), and the New Zealand government is reported to be seriously considering a plain packaging initiative (Library of Congress of New Zealand 2012).

As noted by WHO (2011: 22), plain packaging can prevent the tobacco industry from using misleading packaging and labeling to create the erroneous impression that some tobacco products are less harmful than others. Additionally, plain packaging should make it more difficult for the industry to use promotional features that both detract from the warnings and other required information and that effectively promote the product. The plainer the package and the fewer branding elements included, the less favorably smokers may perceive the packs and the greater may be the impact of graphic warnings (Wakefield, Germain, and Durkin 2008). Moreover, the maximum reduction in the marketing effect of tobacco product packaging is likely to be achieved by plain packaging in combination with large pictorial health warnings (Quit Victoria 2011).



Source: PAHO.

While plain packaging measures regulate the text, images, colors, and other one-dimensional features used by the industry to make the pack attractive and/or misleading, regulation of package design affects the shape and dimensions of the pack, mechanisms for pack openings, and other such features (for example, those mentioned in section 4.1.1). Such regulation can prevent the tobacco industry from using new packaging technologies to continue to suggest that some tobacco products are less harmful than others or to target certain populations, obscure or disrupt required pack information, or create hidden spaces in the package to be used for brand and other promotional elements.

¹⁷ Different types of pack design can be used to disrupt or conceal warnings and provide hidden spaces for promotional messages. See, for example, the website of the packaging manufacturer Amcor at <http://www.amcor.com/productSearch/?2931=143066#searchtop>.

¹⁸ Product/brand names would still be prohibited from including any misleading descriptor or element, such as “Kent 4,” “Mild Seven,” or “Marlboro Lights.” It should be noted that applying similar prohibitions to the product itself will prevent the tobacco industry from doing with the product what it no longer can do with the packaging and labeling.

Box 4.4

In Practice: Australia's law on plain packaging

Australia's Tobacco Plain Packaging Act will go into effect in December 2012. The packages must be "drab dark brown," made of cardboard, rectangular in shape, with no trademarks or other marks anywhere on the outer or inner surfaces of the package other than those permitted by regulations. Other than health warnings, tobacco packages may contain only the brand, business, or company name; relevant legislative requirements; and any other mark or trademark permitted by regulations issued under the Tobacco Plain Packaging Act. Packages may not have inserts or onserts, make a noise or produce a scent, or include any features designed to change after retail sale.

The Tobacco Plain Packaging Act is available at
<http://www.comlaw.gov.au/Details/C2011A00148>.

4.3.3.2 Required content and other details for health warnings and messages

WHO FCTC Article 11.1(b) and Article 11.3 require the display of large, clear, visible, and legible health warnings in the country's principal language(s) on unit and outside packaging and labeling of *all* tobacco products. The Article 11 Guidelines describe how to most effectively address placement/location, size, composition and content, rotation, and color of the warnings and messages prescribed.¹⁹ Some of these characteristics will probably not be explicitly prescribed in the law. As a general rule, the law should set out the framework and minimum requirements for packaging and labeling while providing for implementation details to be prescribed in regulations.²⁰ This allows for greater flexibility and can help protect against tobacco industry interference during the legislative process with respect to the specific content of required warnings and messages. If, however, it is not clear whether the health authority will have the capacity or political will to act quickly to promulgate the implementation details for the warnings and messages, it might be advisable to include in the legislation an initial set of warnings and messages and sufficient implementing detail for their display, while also granting the Ministry of Health clear authority to develop additional or future warnings and messages and to strengthen the legal requirements for their display through regulations.

Following is a summary of the various provisions regarding health warnings in the WHO FCTC and the Article 11 Guidelines.

Placement/location. According to the Article 11 Guidelines, warnings and messages should be required to appear:

- On all display areas of the unit and outside packaging and labeling. The Guidelines indicate that Parties should consider requiring health warnings and messages on the principal sides of a package, on package inserts and onserts, on the filter overwrap portion of cigarettes, and/or on other related materials and instruments. ("Related materials" might include packages of cigarette tubes, filters, and papers, and "related instruments" might include those used for water pipe smoking.) Warnings on all the principal display areas are more difficult for smokers to ignore, because they are visible whether the package is lying on its front or back. In addition, in jurisdictions that have not yet prohibited the display of packages at the point of sale, having the warning on all main faces makes it harder for the manufacturer or retailer to hide the warning and highlight the brand name in the display. Panama

¹⁹ FCTC Article 11 requires that health warnings be "approved" by the national authority, but the Article 11 Guidelines make clear that it is the government that determines, not merely approves, the warnings.

²⁰ Ideally, the authority in charge of developing the regulations for health warnings and messages will have a health orientation and the necessary health expertise. This will usually be the Ministry of Health rather than, for example, a ministry or authority with a commerce/trade orientation, although jurisdictional issues may dictate otherwise in a given country.

and Brazil, which initially required warnings to appear on 100% of only one side, with no warning on the other side of the pack, changed their regulations to require warnings on 50% of both the front and the back, in the case of Panama, and 100% of the back and 30% of the front, in the case of Brazil.²¹

- At the top of each principal display area rather than at the bottom. According to the Guidelines, Parties should require that health warnings and messages be positioned at the top to increase visibility. Canada and Mexico, for example, require warnings to be placed at the top of the principal display areas.²²

It is essential to ensure that neither the warnings nor other required pack information are damaged or concealed by normal opening of the package or by other required markings such as tax stamps.²³ This “normal opening” reference in the Article 11 Guidelines is meant to take account of packaging such as flip-top packs, common in many jurisdictions, which temporarily disrupt the warning when the pack is opened. Labels, stickers, cases, covers, sleeves, wrappings, or other materials provided by the tobacco manufacturers on or in the package can also be used to conceal the warnings. See the previous two sections, dealing with the prohibition on false, misleading, or deceptive packaging and labeling and with plain packaging, for a discussion about addressing other kinds of packages designed to disrupt, conceal, or otherwise undermine warnings and messages.

In drafting legislation on placement and location, it should be made clear that the warnings and other messages must be placed, at a minimum, on each principal display area. FCTC Article 11.1(iv) refers to “the principal display areas” (in the plural). Not all tobacco products come in the form of rectangular packs with a front and back, so it is not advisable to draft legislation that applies to only one such presentation. In addition, it is important to ensure that the legislation is drafted broadly enough to address future forms of package presentation that companies may seek to introduce that might be used to obstruct or evade packaging and labeling requirements, whether deliberately or not. This can be accomplished by providing the national health authority with power to issue further regulatory measures.²⁴

Size. WHO FCTC Article 11 establishes that warnings should be required to occupy at least 50% or more, but not less than 30%, of each principal display area, not counting space taken up by any border around them. Since the larger the warnings and messages the more effective they are, the Article 11 Guidelines provide that warnings and messages should cover as much of each principal display area as possible. In drafting legislation, it is advisable to specify the size of the warnings on each principal display area in terms of a mandated minimum, so that regulations can require larger warnings in order to increase their effectiveness.

Pictorial warnings and messages. FCTC Article 11.1(b)(iv) specifies that health warnings and messages on tobacco product packaging and labeling may be in the form of or include pictures or pictograms with accompanying text in the principal language(s) of the country. The Article 11 Guidelines cite evidence that warnings containing both pictures and text are far more effective than those that are text-only. In addition, in countries with high illiteracy rates or multiple languages, pictorial health warnings are the only *effective* means of ensuring that the entire population is reached by the warnings. Under these circumstances, it can be argued that pictorial warnings and messages are helpful in order to meet Article 11 obligations.

²¹ This requirement will come into force in 2016.

²² In Mexico, the image must cover 30% of the front side on the upper part, with a text-only warning covering 100% of the back side.

²³ This will require coordination in developing the requirements for markings pursuant to WHO FCTC Article 15.

²⁴ Alternatively, the legislation may also create a registry of tobacco product packaging, requiring every new presentation to be submitted to the national health authority before it enters the market.

Online databases containing health warnings currently in use in the world can be a useful resource when determining what health warnings to require. One online database is from the WHO FCTC Convention Secretariat. Mercosur, the Common Market of the South, also has an online database of health warnings. Both databases allow any government to request permission to use the images from other countries, whenever copyright restrictions allow.²⁵

In many cases a country's tobacco control program does not end up owning the copyright to the warnings it has commissioned. If a government decides to create its own images and text, it should that they are available for free use by other countries that request authorization to use them.

Messages. The Ministry of Health or competent national health authority should develop or approve multiple health warnings and messages. Seeing a variety of messages attracts the consumer's attention more than seeing the same message every time. Using a variety of warnings and messages also increases the likelihood of impact, as different warnings and messages will resonate with different sectors of the population.²⁶ Many countries have also required the inclusion of a toll-free "quit line" number or a URL for a website that helps tobacco users quit. As pointed out in the Article 11 Guidelines, including information designed to increase users' motivation and confidence in their ability to quit can be important in helping them change their behavior.

Rotation/concurrent display of warnings. WHO FCTC Article 11.1(b)(ii) requires rotation of warnings and messages. In order to follow the most effective rotation scheme, as described in the Article 11 Guidelines:

- The various warnings and messages should be grouped in sets, with each set consisting of several warnings/messages to be displayed concurrently. The minimum number of warnings included in each set should be specified. Concurrent display of the different warnings/messages in a set should be mandated so that each appears on an equal number of retail packages for each brand within each brand family for each package size and type. The objective is to have all warnings/messages in a set appear with the same frequency, with no single message favored over any other.
- The maximum period of time that each set can be displayed before a change of sets should be specified. This is because the communication impact of an image or message goes down with repeated viewings over time. Hence, the period should be related to the number of warnings in a set. If the set contains only two or three warnings, the period should be much shorter (e.g., 6 to 12 months) than if it contains 10 or 12 warnings (e.g., 12 to 36 months). Legislation and regulations from different countries in the Region mandate different numbers of health warnings at a time. For example, Canada mandates 16, Peru mandates 11, and Venezuela, Argentina, and Brazil mandate 10.
- The method for changing the warnings/messages set at the end of a period should include a deadline by which the new set of warnings must be in place and the old set removed from the market. This is particularly relevant when warnings/messages are implemented for the first time, as discussed below in section 4.3.4.1 addressing supply deadlines. There might be a short phase-in period between sets during which both sets may be used, but this might be unnecessary if the plan is fully defined sufficiently in advance in the legislation.

Color. To ensure realistic images and easy-to-read text, full-color printing for pictures and contrasting text and background colors should be specified.

²⁵ The WHO FCTC Health Warnings database is available at <http://www.who.int/tobacco/healthwarningsdatabase/en/index.html>. The Mercosur Intergovernmental Commission for Tobacco Control database is available at <http://www.cictmercosur.org/esp/>.

²⁶ The Article 11 Guidelines suggest the different issues that warnings/messages should cover.

Authority to the competent national health authority. It is important that the law make clear that the competent authority, usually the Ministry of Health or another appropriate authority with expertise in health and tobacco control, has the authority to prescribe the warnings/messages. As provided in the Guidelines, Parties should consider empowering the Ministry of Health or other appropriate authority to provide a source document containing high-quality visual samples of how all health warnings and messages and other information are to appear on packaging. The tobacco industry should have no role in determining the content and specifications of the warnings. Additionally, it should be clear that the cost of pack warnings and messages is borne by the tobacco industry, as established in the Article 11 Guidelines.

Box 4.5

In Practice: Provisions for strong warnings and messages

Canada

Canada's Tobacco Act provides for issuing regulations that prescribe how to display health-related information on tobacco packages. The 2011 regulations require three types of messages on packaging and labeling of smoked tobacco products: health warnings, health information messages, and qualitative statements about toxic emissions. Electronic samples of the required messages are provided by the government on DVDs upon request by manufacturers.

Section 15

(1) No manufacturer or retailer shall sell a tobacco product unless the package containing it displays, in the prescribed form and manner, the information required by the regulations about the product and its emissions, and about the health hazards and health effects arising from the use of the product or from its emissions.

(2) If required by the regulations, every manufacturer or retailer shall provide, in the prescribed form and manner, a leaflet that displays the information required by the regulations about a tobacco product and its emissions and about the health hazards and health effects arising from the use of the product and from its emissions."

Section 16

"This Part does not affect any obligation of a manufacturer or retailer at law or under an Act of Parliament or of a provincial legislature to warn consumers of the health hazards and health effects arising from the use of tobacco products or from their emissions."

The Tobacco Act is available at <http://laws-lois.justice.gc.ca/PDF/T-11.5.pdf>.

The Tobacco Products Labelling Regulations (Cigarettes and Little Cigars), issued in 2011, set out details for the packaging and labeling requirements for cigarettes and little cigars. The regulations stipulate that the warnings must cover 75% of the front and 75% of the back principal display areas of unit and outside packaging. The warnings must be in English on the front, and in French on the back. Sixteen different health warnings are required to be displayed concurrently over the course of a year. Pictorial health information messages as well as qualitative statements on toxic emissions are also required.

The Tobacco Products Labelling Regulations (Cigarettes and Little Cigars) are available at <http://laws-lois.justice.gc.ca/PDF/SOR-2011-177.pdf>.

For other types of tobacco products (e.g., cigarette tobacco, kreteks, bidis, pipe tobacco, smokeless tobacco), the labeling regulations adopted in 2000 (and most recently amended in 2011) continue to require pictorial or text-only health warnings covering 50% of the front and 50% of the back principal display areas, with different requirements based on product type. Health information messages and descriptive statements on toxic emissions are also required.

(continued)

Box 4.5 (continued)

The Tobacco Products Information Regulations (as amended in 2011) are available at <http://laws-lois.justice.gc.ca/PDF/SOR-2000-272.pdf>.

Uruguay

Together, Law 18.256 and Decree 287/009 establish the requirements for health warnings. The authorized pictures and text warnings set forth in the decree are to be displayed on 80% of the two principal display areas (front and back) of each tobacco product unit and outside packaging and labeling. Each of the pictures and warnings must appear on an equal number of packs. The law specifies that the warnings must be periodically modified pursuant to regulatory provisions. Regulations specify that the warnings should change every 12 months.

Law 18.256, Article 9. Health warnings

"All tobacco product packages and wrappers and all their outside packaging and labeling must show health warnings and images or pictograms that describe the harmful effects of tobacco consumption or other appropriate messages. Such warnings and messages must be approved by the Ministry of Public Health; be clear, visible and legible; and fill at least 50% (fifty percent) of the total exposed principal surfaces [amended by Decree 287/009 to 80%]. These warnings must be periodically modified pursuant to regulatory provisions."

Excerpt above is from an unofficial English translation of Law 18.256 at

<http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Law%20No.%2018.256.pdf>.

The law is available in the original Spanish at

<http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18256&Anchor>.

An unofficial English translation of Decree 287/009 is available at

http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Decree%20No.%20287_009.pdf.

The decree is available in the original Spanish at

http://archivo.presidencia.gub.uy/_web/decretos/2009/06/CM751%20.pdf.

Source document. As mentioned, the Article 11 Guidelines recommend that Parties consider providing a source document containing high-quality visual samples of health warnings/messages and other required information, showing how they are supposed to appear on packaging. This can be accomplished by authorizing the Ministry of Health or other appropriate authority to provide electronic samples of the warnings and messages, constituent and emissions disclosures, and other required information in an electronic file, and requiring that these be reproduced and displayed on packaging and labeling as closely as technologically possible. This has been done effectively in many Latin American countries, including Ecuador, for example.²⁷

4.3.3.3 Required content and other details for constituents and emissions information

WHO FCTC Article 11.2 requires the display of information on relevant constituents and emissions of tobacco products, as defined by national authorities, on unit and outside packaging and labeling. This should be done by requiring specific *descriptive only* statements (containing no references to numerical values) about constituents and emissions in the country's principal language(s).²⁸ As provided in the Article 11 Guidelines, display of figures for emissions yields (e.g., tar, nicotine, carbon monoxide), even when part of the trademark or brand name, should be prohibited. The prohibition should be applied as well to proxies for emission yield figures (for example, nonnumerical signs such as colors). Machine-

²⁷ The source document for the health warnings required under Ecuador's law is available in Spanish at http://www.cilaecuador.gob.ec/index.php?option=com_content&view=article&id=154:advertencias-sanitarias-en-cajetillas-de-cigarrillos-y-otros-empaques-de-productos-de-tabaco&catid=42:noticias&Itemid=67.

²⁸ A descriptive constituents and emissions statement might list some of the chemicals, along with their effects on the body. It would not show the corresponding yield numbers. An example of such a descriptive statement from Australia is "Smoking exposes you to more than 40 harmful chemicals. These chemicals damage blood vessels, body cells and the immune system. . . ." In contrast, a numerical statement would show yield figures measured by a testing machine. An example of a numerical statement from the European Union is "10 mg tar, 0.9 mg nicotine, 10 mg carbon monoxide." WHO FCTC Guidelines, Article 11.

measured yields do not provide valid estimates of human exposure, and the marketing of cigarettes with lower machine-measured tar and nicotine yields has resulted in the mistaken belief that these cigarettes with lower stated yields are less harmful than cigarettes with higher yields.

Finally, as provided in the Guidelines, care should be taken to avoid any required descriptive statements about constituents or emissions from implying that one brand is less harmful than another. Governments working on fulfilling the mandate for pack constituents and emissions information should also pay attention to the Partial Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC.

Box 4.6

In Practice: Effective provisions for disclosure of constituents and emissions

Kenya

Kenya's Tobacco Control Act, 2007 requires tobacco products to display a descriptive-only statement regarding tar, nicotine, and other constituents on the side of the package.

Section 21(c)(5)

"Every package containing a tobacco product shall bear such statement as to the tar, nicotine and other constituents as may be prescribed and such statement shall be placed directly on the right hand side of the package, underneath the cellophane or other clear wrapping in a conspicuous and prominent format and shall be limited to the disclosure of the contents and not their quantities."

The Tobacco Control Act, 2007 is available at

<http://www.tobaccocontrollaws.org/files/live/Kenya/Kenya%20-%20Tobacco%20Control%20Act%20-%20national.pdf>.

4.3.4 Impose legal duties of compliance

Legislation should impose legal duties of compliance with packaging and labeling requirements on all tobacco product manufacturers, importers, wholesalers, and retailers, with no exemption for small-volume businesses. Legislation should also explicitly state that the requirement to display health warnings and messages and other required information on tobacco product packaging and labeling does not remove or diminish any other industry obligations, including but not limited to obligations to warn consumers about the health hazards from tobacco use and exposure to tobacco smoke (Article 11 Guidelines).²⁹ This would be consistent with WHO FCTC Article 19(1), which provides that Parties must consider taking legislative action or promote existing laws to deal with criminal and civil liability where appropriate.

²⁹ The ability to do this may depend on the legal system in the country.

Box 4.7

In Practice: Imposing duties of compliance

Kenya

Kenya's Tobacco Control Act, 2007 imposes a duty of compliance with packaging and labeling requirements on all manufacturers, sellers, importers, and distributors.

Section 21

"No person shall manufacture, sell, distribute, or import a tobacco, product unless the package containing the product displays, in the prescribed form and manner, such information as may be prescribed with respect to the product and its emissions and the health hazards or effects arising from the use of the product or from its emissions."

The Tobacco Control Act, 2007 is available at <http://www.tobaccocontrollaws.org/files/live/Kenya/Kenya%20-%20Tobacco%20Control%20Act%20-%20national.pdf>.

Canada

Canada's Tobacco Act (1997), as amended, imposes a duty of compliance with packaging and labeling requirements on all manufacturers and retailers. See Box 4.5 in this manual for the provision prohibiting manufacturers and retailers from selling products in noncompliant packaging.

The Tobacco Act (1997) is available at <http://laws-lois.justice.gc.ca/PDF/T-11.5.pdf>.

4.3.4.1 Single supply deadline

It is important that a single supply deadline be provided, specifying the date after which manufacturers, importers, wholesalers, and retailers may only supply products that comply with the new requirements (Article 11 Guidelines).³⁰ Experience has shown that a single supply deadline is important for preventing manufacturers from intentionally increasing production of products in the old packs prior to the date the new requirements take effect. If legislation only provides a date by which tobacco manufacturers and importers must supply the new packaging and labeling, without also prohibiting the supply or sale of products in old packaging after that date, a potential loophole is created.

Mexico's experience is a case in point. The Mexican regulations specify the date by which tobacco product packages must include the new warnings. When that date came up, the tobacco industry argued that this was the date for *initiating* the production of packages with the new warnings on them, not the date by which packages with the new warnings had to be at retail shops and/or packages with the old warnings could no longer be sold (El Universal 2011). Tobacco industry interests argued that they needed extra time to use up their stocks with the old warnings, and the regulatory authority could not do anything, as the regulations are ambiguous on this point. This resulted in a considerable period of time in which packs with old warnings and those with new warnings were both available on the market.

³⁰ A reasonable deadline might be 12 months from the enactment date of the relevant legal measure that prescribes the content and details of the warnings, other required pack information, and other necessary implementation details.

Packaging and labeling provisions should explicitly state that after the supply deadline, noncompliant products, packaging, and labeling in the possession or under the control of any business in the tobacco industry and any retailers are not allowed and will be subject to confiscation and destruction, in addition to the application of appropriate penalties.

4.3.5 Provide effective enforcement mechanisms

Responsibility for inspection and enforcement of tobacco product packaging and labeling should be specified in the legislation. Usually this duty will fall primarily to the national health authority, but it is likely that other governmental agencies (for example, customs agencies dealing with imported products) may be well positioned to also have a role in inspecting and enforcing packaging and labeling requirements.

4.3.6 Provide a range of deterrents and proportionate penalties

Tobacco industry manufacturers and importers have the most control over packaging and labeling of tobacco products and, thus, the greatest responsibility for complying with the relevant requirements. As a result, they should generally be subject to higher penalties than others in the marketing chain. The Article 11 Guidelines establish that Parties should specify a range of fines and other penalties commensurate with the severity of the violation and its recurrence. Parties should also consider the application of suspension, limitation, or cancellation of business and import licenses among the penalties provided by law.

4.3.7 Provide a role for civil society

Civil society can definitely contribute to effective enforcement, and it is therefore important to assign a role to it. For instance, the law or regulations can authorize civil society to submit complaints or denounce noncompliance with the law. Mechanisms for channeling such input could be delineated in the law.

4.3.8 Require evaluation and public dissemination of results

It is particularly important to monitor and evaluate the implementation of measures on packaging and labeling, as in the case of other measures contained in the WHO FCTC. Monitoring and evaluation allow countries to assess the impact of the measures and identify areas for improvement. They also contribute to the body of evidence that can assist other countries.

4.3.9 Grant broad regulatory power to the appropriate authority to address implementation details

The appropriate governmental authority should be granted power to address a broad range of matters in regulations, including but not limited to:

- The content, size, number, and placement of warnings and messages and constituents and emissions statements, as well as the manner in which they are to appear, including their rotation, and any other matter related to warnings and messages and constituent and emissions statements;
- Restrictions and/or prohibitions on tobacco product packaging and labeling and on tobacco products to prevent any misleading or promotional features;
- Providing a source document with samples of warnings and messages, constituent and emissions statements, and any other required information; and
- Any other necessary or appropriate matter.

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Additional resources

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Chapter 5

Tobacco Advertising, Promotion, and Sponsorship



Source: Shutterstock.

5. Tobacco Advertising, Promotion, and Sponsorship

5.1 Background

5.1.1 Rationale and evidence

There is extensive evidence to support a total ban on tobacco advertising, promotion, and sponsorship (TAPS), as called for by Article 13 of the World Health Organization Framework Convention on Tobacco Control (WHO 2003; hereafter, WHO FCTC) and the Guidelines for Implementation of Article 13 (WHO 2009; hereafter, Article 13 Guidelines). The rationale for implementing a comprehensive ban on TAPS is well described in the National Cancer Institute's tobacco control monograph (NCI 2008). Key reasons include the health consequences of tobacco use and its addictive nature; the deceptive or misleading nature of many tobacco promotion campaigns; the unavoidable exposure of youth to these campaigns; the role of TAPS in increasing tobacco use in the population, especially among youth, women, and ethnic and racial minorities; the failure of self-regulation by the tobacco industry; and the limited effect of partial advertising bans.

TAPS are particularly effective in attracting new customers, especially youth (Capella, Webster, and Kinard 2011; Pierce, Gilpin, and Choi 1999). Research conducted after the launch of a promotional campaign for a brand targeted to youth shows an increase in the prevalence of use of that brand, as well as in general smoking prevalence (Fielding et al. 2004; Pierce et al. 2002; Evans et al. 1995; Pollay et al. 1996; CDC 1994). A 2003 review of nine longitudinal studies including more than 12,000 youth concluded that tobacco advertising and promotion increase the likelihood of adolescent smoking initiation (Lovato et al. 2003). Another study done between 1999 and 2004 in the United Kingdom determined that for each type of tobacco marketing that youth recognized, the probability of initiation of tobacco consumption increased by 7% (Moodie et al. 2008). Adolescent smokers frequently take up the most advertised brands (CDC 1994; Cummings et al. 1997), and the cigarette brands most popular among youth are also those most heavily advertised in magazines with high youth readership (King et al. 1998; King and Siegel 2001). Marketing has been shown to have a stronger influence on adolescents' uptake of smoking than peer pressure (Evans et al. 1995). Indirect advertising, such as depictions of smoking in the movies, has also been shown to cause young people to begin smoking (HHS 2012).

Tobacco industry documents cite the importance of using advertising to promote the social acceptability of smoking to attract new consumers (frequently adolescents) while also pushing "healthier" low-tar cigarette brands in an effort to keep health-concerned consumers smoking (Pollay 2000). These two segments of consumers are often the focus of advertising campaigns. More generally, studies demonstrate that TAPS has a significant effect on consumers' decisions to continue smoking and undermines their attempts to quit (Capella, Webster, and Kinard 2011; Pierce, Gilpin, and Choi 1999).

The tobacco industry's long-standing practice of evading TAPS bans makes clear that any legal measures that do not require a complete ban serve only to motivate the industry to exploit loopholes in creative ways that can seldom be predicted when legislation is drafted. According to an internal document from British American Tobacco (BAT), prohibitions and limitations on advertising:

should not be allowed to discourage the cigarette advertiser, but rather exhilarate him. To be able to meet the new confining conditions . . . more effectively than one's competitors is a challenge to creativity and ingenuity. (BAT 1972)

As a result, only a complete ban can halt the trend of rising consumption in the Region of the Americas and globally and lead to decreases in consumption. The World Health Organization (WHO) estimates that a comprehensive ban on all tobacco advertising and promotion reduces tobacco consumption by about 7%, with a decrease in consumption of up to 16% in some countries (WHO 2011a). Several of the studies cited above support these estimates.

Anything short of a comprehensive ban—for example, a ban on only some forms of TAPS or restrictions on content, target audience, location, or similar factors—has little or no effect in reducing tobacco consumption. In a study examining TAPS laws in 22 countries belonging to the Organisation for Economic Co-operation and Development (OECD), countries with a comprehensive ban saw significant decreases in consumption after the ban, whereas countries with limited or weak restrictions saw minimal or no decreases in consumption (Saffer and Chaloupka 2000). The study predicted that if governments in the countries with limited or weak restrictions were to institute comprehensive bans on TAPS, there would be an average decrease in the consumption of cigarettes of about 7.4% and an average decrease in the consumption of tobacco of about 5.4% in these countries. A second study covering developed and developing countries showed a 6.7% decrease in per capita consumption after imposition of a comprehensive ban (Blecher 2008). Remarkably, when only developing countries were considered, the study showed a consumption decline of 23.5% on average for a comprehensive TAPS ban.

5.1.1.1 A comprehensive ban versus a partial ban or restrictions on TAPS

Tobacco companies respond to measures short of a comprehensive ban by simply redirecting their vast expenditures to allowed forms, a practice that tobacco companies have used for decades (Marks 1982). For example, when the United Kingdom banned cigarette advertisements on television in the 1960s, there was a subsequent increase in overall promotional expenditures, specifically in coupon gift schemes, in addition to a shift toward sponsorship (Hastings 2000). Similar patterns were seen in Canada (Dewhirst 2004) and the United States (King and Siegel 2001). In the United States, after the tobacco companies agreed under a legal settlement to eliminate outdoor advertising and advertising targeted at youth (the Master Settlement Agreement of 1998),¹ marketing at the point of sale increased substantially (NCI 2008), and overall TAPS expenditures increased as well (King and Siegel 2001).



Source: PAHO.

5.1.1.2 Banning advertising and promotion, including product display, at the point of sale

The next several sections address specific forms of TAPS that deserve special attention. Some of these forms have often been overlooked and/or addressed less comprehensively than other forms of TAPS. The focus on these underrecognized practices is in no way meant to diminish the importance of prohibiting all forms, manner, and means of TAPS.

¹ In 1998, the attorneys general of 46 states signed a Master Settlement Agreement with the four largest tobacco companies in the United States. The text is available at <http://ag.ca.gov/tobacco/pdf/1msa.pdf>.

As tobacco companies have faced prohibitions on more and more forms of TAPS, they have increasingly turned to advertising and promotion at the point of sale (POS). Various types of POS advertising and promotion, including product displays, have become among the most prominent and resourced forms of TAPS, prompting governments to take more aggressive action to prevent advertising and promotion at POS. In 2000, for example, 81.2% of marketing dollars spent by cigarette companies in the United States went to retail stores for POS advertising, payments to retailers for prime display space, promotional price reductions, or gifts with purchase, among others (Feighery et al. 2003).

Tobacco industry documents reveal how highly the industry values POS advertising and promotion (Lavack and Toth 2006). For example, marketing plans from Brown & Williamson dating back to 1975 recognize the value of POS advertising and promotion and call for the company to give them priority: “As media advertising diminishes in impact due to increasing restrictions and cluttered environment, new in-store advertising items designed to create and reinforce brand awareness at the point-of-sale become increasingly important and should receive priority consideration.”

Tobacco companies continue to reach a large audience through POS advertising and promotion. Results from the Global Adult Tobacco Survey in Brazil and Uruguay, both of which exempted POS advertising and promotion from their otherwise comprehensive TAPS bans at the time, showed that 30.4% and 26.8% of adults respectively had seen tobacco advertisements at the POS (INCA/PAHO 2010; MSP/PAHO 2011).² Prevalence of POS tobacco advertising and promotion was also measured in two Latin American capital cities, Guatemala City, Guatemala, and Buenos Aires, Argentina. In Guatemala City, 60% of stores surveyed contained cigarette advertising; in Buenos Aires, 78% did (Barnoya et al. 2010). In the United States, 92% of surveyed stores had some form of POS marketing (Feighery et al. 2003).

Advertising and promotion at POS is especially problematic for tobacco control because it is particularly effective with youth. In the United States, cigarettes are marketed more heavily in stores where adolescents shop as compared to other stores in the same communities, suggesting that youth may be disproportionately exposed to this form of marketing (Henriksen et al. 2004). In the survey mentioned above of shops in Guatemala City and Buenos Aires, tobacco advertising was frequently found next to candy and sweets (Barnoya et al. 2010). POS advertising has also been shown to be particularly effective at encouraging youth to try smoking for the first time, as compared to other promotional practices that are more effective in pushing price-sensitive youth from experimenting with cigarettes to becoming regular consumers (Slater et al. 2007). Because younger adolescents are more influenced by advertising than older adolescents, POS advertising has a particularly significant impact on youth smoking uptake.



Source: PAHO.

Product displays at POS are also a form of advertising, so it is important that such displays be covered under TAPS bans. In TAPS-restricted environments, it is estimated that tobacco product displays may increase sales by 10% to 28%, much of this due to impulse purchases (Carter, Mills, and Donovan 2009). One-fifth of consumers who were interviewed immediately after they purchased tobacco products revealed that their purchases were unplanned, with product displays playing a significant role in influencing the purchases (Carter, Mills, and Donovan 2009). Moreover, placement of tobacco products (and TAPS) adjacent to candy and sweets likely enhances their visibility to youth. It has been suggested that such placement encourages youth to equate tobacco products with commonplace items such as candy and sweets that young people are already used to consuming (Barnoya et al. 2010; Pollay 2007).

² Advertising at POS was allowed in Brazil at the time of the survey, but was banned in 2011 by Law 12.546. Product displays at POS continue to be allowed if accompanied by a prescribed health warning.

Several countries that have enacted bans on advertising and promotion at POS but not on product displays have seen tobacco companies adapt their product displays into elaborate vehicles for advertising. For example, the Australian state of New South Wales banned most forms of advertising, including at POS. In response, tobacco companies provided retailers with large transparent cabinets to enable prominent display of their tobacco products (NCI 2008). Similar results were observed in New Zealand, where displays became “blatant,” “prolific,” “larger,” and “more prominent” as TAPS restrictions became more stringent (Fraser 1998). In addition, the displays began to feature colorful price lists, as price lists were exempted from the TAPS ban. This shift by tobacco companies to elaborate displays underscores the need for a comprehensive TAPS ban that clearly includes POS product displays. These examples also illustrate how tobacco companies exploit loopholes permitting any form of TAPS.

5.1.1.3 Banning sponsorships

Tobacco companies have increasingly used sponsorship of sporting events, cultural activities, and the arts as a way of promoting their tobacco products indirectly (Mbongwe, n.d.; Holman et al. 1997; HHS 1994). Frequently, tobacco-sponsored activities are targeted at youth, and young smokers are paying attention. In The Gambia, for example, tobacco companies not only sponsor but also organize sporting events during school holidays, where they hand out free samples of cigarettes (BBC News 2000). After an affiliate of British American Tobacco sponsored the 1996 Cricket World Cup, played mostly in India, smoking among Indian teenagers increased fivefold, according to one survey (WHO 2002). Industry documents confirm the effects of this strategy, refuting the claim by tobacco companies that they sponsor sports or the arts out of a sense of philanthropic duty (WHO 2002). For example, an internal R. J. Reynolds memo from 1989 states, “We’re in the cigarette business. We’re not in the sports business. We use sports as an avenue for advertising our products. We can go into an area where we’re marketing an event, measure sales during an event and measure sales after the event, and see an increase in sales” (quoted in Rabinoff 2006). A Philip Morris spokesperson described the company’s sponsorship of a superbike show in Taiwan as intended to “strengthen Marlboro’s brand image with excitement, vitality, and masculinity, especially among young viewers” (quoted in Rabinoff 2006).

Source: CTFK



The tobacco industry reaches a wide global public through sponsorship of sports events. Tobacco companies have historically been the main sponsors of Formula One, an auto-racing event that is the most viewed sports event after the Olympic Games and the FIFA World Cup (Chapman 2002). Formula One sponsorship provides the tobacco industry with the desired access to emergent markets in developing countries (Carlyle et al. 2004). The industry also sponsors concerts, including those featuring performers with a strong youth following, such as Alicia Keys, Kelly Clarkson, MIA, the Beastie Boys, and the Teenagers. Smaller, less publically visible events may be sponsored as well, such as parties and entertainment in bars and venues popular with young adults (Cruz, Shuster, and Andreeva-Cook 2008). Industry sponsorships are not limited to events, but also include such activities as “adventure tours” and other travel (Hammond 2000). Some forms of tobacco company sponsorship specifically target women, such as sponsorship of beauty contests and women’s sports events. Companies also make donations to women’s organizations (Ernster et al. 2000; O’Keefe and Pollay 1996).

5.1.1.4 Banning tobacco industry “corporate social responsibility”

“Corporate social responsibility” (CSR) refers to the practices that many corporations undertake to portray themselves as “good corporate citizens” that make a positive contribution to society, in some cases by redressing the adverse impacts their businesses may have on society and the environment (Hirschhorn 2004). Tobacco companies have adopted CSR as

a strategy to promote their corporate images and their products and to influence development and implementation of tobacco control policies.

Examples of CSR activities by the tobacco industry include donating to disaster relief assistance, schools, and scholarship programs, and undertaking a wide range of community initiatives. Companies may issue statements purporting to support policies against child labor while not making any meaningful changes to their own business practices in relation to child labor (*Otañez et al. 2006*). They also sponsor youth smoking prevention programs.³ It should be understood that the tobacco industry's CSR initiatives are a form of tobacco sponsorship that should be subject to a comprehensive tobacco sponsorship ban. The WHO FCTC Article 13 Guidelines (WHO 2009) make clear that CSR contributions are a form of tobacco sponsorship because the aim, effect, or likely effect of the contributions is to promote a tobacco product or tobacco use, either directly or indirectly. The Guidelines also make clear that tobacco contributions should be banned, whether or not they are publicized or acknowledged.

As also discussed in Chapter 6, tobacco companies have embraced CSR as a strategy to achieve public relations goals, gain legitimacy, and curry favor with politicians and policy makers in order to prevent or delay regulation (*MacKenzie and Collin 2008*). Internal industry documents reveal the industry's true motivations. For example, in an internal British American Tobacco memorandum in 1998, a BAT official described the company's new CSR program as "commercially driven" and as "respond[ing] to the increasing scrutiny . . . to be a better employer, a community resource and to be seen to be part of the solution rather than a societal problem." The document goes on to list the external benefits to be gained from the CSR program, which include "enhanc[ing] BAT's 'license to operate' with local communities and the media" and "extend[ing] access and influence with regulators and politicians" (Oliver 1998).

In light of the industry's CSR strategies, it is important to draft a comprehensive ban on TAPS that clearly covers CSR programs and activities. Failure to do so creates a loophole that can undermine the objectives of both WHO FCTC Article 13 and Article 5.3.

5.1.1.5 Banning TAPS of all tobacco products

It is critical not to overlook advertising, promotion, and sponsorship of other tobacco products, in addition to cigarettes, such as shisha (water pipe) and smokeless tobacco. These products are growing in popularity, and there is a push to develop new smokeless tobacco products as a way to get around smoke-free policies. The US Surgeon General's Report released in 2012 notes that companies selling smokeless tobacco products still rely heavily on the more traditional forms of advertising, largely print and POS advertising, where permitted (HHS 2012). In the United States alone, expenditures for marketing of smokeless tobacco products in 2008 were 277% higher than in 1998, compared to a 48% increase in cigarette marketing expenditures over the same time period (HHS 2012). Remarkably, more than half of advertising, promotion, and sponsorship expenditures for smokeless tobacco products in the United States are spent on providing price discounts to consumers, underscoring the importance of ensuring that the ban on TAPS applies to the marketing of all kinds of tobacco products.

5.1.1.6 Regulating the package, the ultimate form of advertising and promotion

Packaging, for any product, functions as a promotional tool and is an important part of the marketing mix; this is no less true for tobacco products (Moodie and Hastings 2010). In an environment of increasing restrictions on TAPS, the package takes on an even more prominent promotional role for the tobacco industry, as also discussed in Chapter 4. Comprehensive

³ See sections in Chapter 6 (on WHO FCTC Article 5.3) and Chapter 8 (on WHO FCTC Article 12) for further discussion of industry-sponsored youth prevention programs.

regulation of the industry's use of packaging thus takes on added importance. Tobacco control legislation can address the promotional aspects of packaging and labeling in either its tobacco TAPS or its packaging and labeling provisions.

5.1.2 Regional situation

As of October 2012, Panama and Colombia are the only countries in Latin America that impose a total ban on TAPS (PAHO 2011). Brazil recently amended its legislation to ban TAPS, with a sole exemption for POS product displays. Other countries, including Argentina, Costa Rica, Ecuador, El Salvador and Uruguay, also have strong bans. However, progress is much slower with TAPS than with smoke-free environments or packaging and labeling. There are 24 countries where the existing TAPS bans do not cover advertising via television, radio, and newspapers (PAHO 2011). Regionally, therefore, there is much room for progress in implementing comprehensive TAPS bans in compliance with WHO FCTC Article 13.

5.2 Responding to tobacco industry opposition to strong and comprehensive TAPS bans

5.2.1 Tobacco industry arguments against strong and comprehensive bans on tobacco advertising, promotion, and sponsorship

The tobacco industry and groups that promote its interests have made significant efforts to delay the effective implementation of Article 13, or, when that fails, to find loopholes or gaps in the legislation. The arguments used to support these efforts are legal, technical, and political. The following sections examine some of the principal arguments used by the tobacco industry.

5.2.1.1 Argument: Tobacco advertising, promotion, and sponsorship only target adult smokers

Tobacco companies place great value on recruiting young people, since capturing this market will yield significant long-term returns (Pollay 2000). Use initiation usually occurs during adolescence (WHO 2011b), and younger smokers have a propensity to change brands more often than adult consumers, who tend to remain brand-loyal once they have established a brand preference (Pollay 2000). Advertising expenditure figures and internal industry documents provide rich sources of information about the importance to the industry of younger smokers, who are expected to drive the growth of the cigarette market. These sources confirm that tobacco companies consciously and consistently market to youth (Pollay 2000; Di Franza et al. 1991; Pierce et al. 1991; Braun et al. 2008).

For example, a Rothmans Benson & Hedges (RBH) document outlining “critical success factors” confirms that the “15–19 age group is a must for RBH,” though it also notes that the company cannot ignore the older age groups that have higher smoking prevalence levels (Rothmans Benson & Hedges 1997). Documents from R. J. Reynolds (RJR), released in 1998, show that the company sought to reverse its declining sales by targeting 14- to 24-year-olds (RJR 1984). RJR memos described the success of the Joe Camel cartoon in France and stated that the campaign was “about as young as you can get” and aimed “right at the young adult smoker Camel needs to attract” (RJR 1974). Industry documents also show that tobacco companies carefully study the habits, tastes, and desires of their potential consumers, using this information to develop product and marketing campaigns addressed to them (Hafez and Ling 2005; Hastings and MacFadyen 2000).

5.2.1.2 Argument : Advertising and promotion only affect market share, not overall consumption

Tobacco companies argue that advertising does not persuade nonsmokers to begin smoking, but instead only affects market share by encouraging brand loyalty or by enticing current smokers to switch brands (Saffer and Chaloupka 2000). Tobacco companies have used this argument especially in connection with POS product displays (Carter, Mills, and Donovan 2009).

There is ample evidence, however, that TAPS has very little influence on what brand a consumer buys. For example, in a study examining the effect of POS product displays, smokers indicated that product displays rarely influence their decision about which brand to purchase (Wakefield and Germain 2006). On the other hand, a separate study showed that over one-fifth (22%) of purchasers had not planned to buy cigarettes before entering a store but were prompted by product displays to make the purchase (Carter, Mills, and Donovan 2009). In that study, only 5% of all purchasers (not just those who made impulse buys) bought a brand other than their usual brand. This evidence suggests that POS product displays have a more significant effect on impulse purchases than on brand preference. The number of consumers who switch from one company's brand to another's is only 7% (Goldberg, Davis, and O'Keefe 2006). Remarkably, if the industry's argument held true, tobacco companies would lose hundreds of advertising dollars for every brand switcher they attracted (J. Gottheil Marketing 2005). TAPS, therefore, is about more than influencing market share.

As discussed in the previous section, TAPS frequently targets youth to attract new smokers. It targets females for the same reason (O'Keefe and Pollay 1996; Amos 1996). These are segments of the population that, in some countries, have relatively low smoking prevalence rates when compared to adults and men, respectively—and thus offer great potential for expanding the number of smokers. In targeting women, the tobacco industry associates tobacco consumption with images of slimness, glamour, and elegance (Amos and Haglund 2000). TAPS also targets so-called “concerned smokers” who are contemplating quitting because of concerns about health. Toward this end, the industry uses marketing terms like “light,” “low-tar,” and similar descriptions to reassure these consumers that there are alternatives to quitting (Pollay 2000).

5.2.1.3 Argument: Freedom of expression includes the “right” to advertise a legal product

Proponents of tobacco advertising and promotion argue that the only factor relevant to whether a product can be advertised is its legal status (Chapman 1996). However, there are several precedents for restricting and even prohibiting the advertising of dangerous or potentially dangerous products that are legal (e.g., alcohol, firearms, and pharmaceuticals) (Anderson 2005). TAPS glamorizes tobacco use by associating consumption of tobacco products with positive social and personal images that convey fitness, health, and carefree relaxation (Pollay 2000). Yet there is no use of tobacco that does not harm the user and others who may be exposed to tobacco smoke.

Finally, in countries where the constitution guarantees the right to freedom of expression, this right does not necessarily apply to commercial expression, which is often more closely connected to commercial freedoms. Commercial expression may not enjoy the same level of protection as other forms of expression. In any event, any right to freedom of expression, and especially commercial expression, usually is not absolute and must be balanced against competing rights, such as the right to health established in many countries' constitutions and/or in human rights treaties to which those countries may be parties. Several national courts have ruled in favor of TAPS bans on the grounds that restrictions and/or prohibitions are necessary to protect health. This is exemplified in the court decision in the legal challenge to TAPS provisions of Colombia's law, discussed in section 5.2.2.

5.2.1.4 Argument: A tobacco advertising ban will harm the advertising industry and the overall economy, and a sponsorship ban will negatively affect the arts, sports, and other cultural activities

Advertising and promotion of tobacco products represents only a small portion of the overall advertising industry. Evidence from implementation of comprehensive bans in several European countries shows no evidence of net job losses, but instead shows continuous growth in the advertising industry after the implementation of tobacco advertising and promotion bans (Bjartveit, n.d.).

Similarly, the industry argues that bans on sponsorship by tobacco companies will negatively affect and even endanger arts, sports, and other cultural activities. In countries that have implemented sponsorship bans, these negative effects have not materialized, as replacement sponsors have typically stepped up. For example, after legislation in Australia banning tobacco sponsorship of sports (with a few exceptions) went into effect in 1996, there was no decrease in revenue raising or in overall corporate sponsorship of sports (Woodward 2001).

5.2.2 Legal challenges advanced by the tobacco industry against TAPS bans: The Colombian case

In a regional context where the full implementation of Article 13 of the WHO FCTC is advancing slowly, the ruling by the Constitutional Court of Colombia on 20 October 2010 (C-830/10) is particularly notable. This case involved a challenge to the constitutionality of Articles 14, 15, 16, and 17 of Law 1335 of 2009.⁴ In particular, the challenge focused on the total ban on TAPS enacted in Colombia. The judgment confirming the constitutionality of the law is very comprehensive and provides clear bases on which a State, in view of its international human rights commitments and constitutional obligations, is justified in establishing a comprehensive prohibition on TAPS.

The judgment rested on three primary conclusions:

- Commercial speech should be understood as an aspect of commercial freedoms and not as covered by the guarantee of freedom of expression, which is subject to greater protection.
- Restrictions on advertising, promotion, and sponsorship do not substantively violate commercial freedoms.
- Even when regulating a legal product, the State has the authority to discourage its consumption, provided that there are compelling reasons to do so.

5.2.2.1 Commercial speech as part of commercial freedoms

This point responds to an argument that is often used by the tobacco industry: that advertising cannot be restricted because such restriction involves an attack on the guarantee of freedom of expression. Refuting this notion, the Constitutional Court of Colombia held that advertising is an aspect of freedom of commerce and is, therefore, subject to greater restrictions than those that may be imposed on freedom of expression.

The court noted the specific nature of commercial advertising, which warrants differential constitutional treatment because it is a “mode of exercising economic freedoms.” The court relied heavily on Judgment C-010/00, quoting the following from that decision:

[A] systematic and teleological interpretation . . . leads to another conclusion, namely that commercial advertising does not receive the same constitutional protection as other content protected by freedom of expression, so the law can intervene more heavily in advertising . . . The Constitution expressly provides that the law should regulate information to be provided to the public for the marketing of different goods and services (CP Art. 78).⁵

⁴ Law 1335 of 2009 is available in the original Spanish at http://www.secretariasenado.gov.co/senado/basedoc/ley/2009/ley_1335_2009.html. An unofficial English translation of the law is available at <http://www.tobaccocontrolaws.org/files/live/Colombia/Colombia%20-%20Law%20No.%201335.pdf>.

⁵ Unofficial translation by authors. Judgment C-010/00 is available in the original Spanish at <http://www.flip.org.co/resources/documents/66c464528f628f4eee70584d0640cad2.pdf>.

This means that the Constitution not only permits but mandates a regulation of this material, while in no way extending the authority to regulate to information in the political, religious, cultural, or other such domains. Again turning to Judgment C-010/00, the court notes that the mandate for the regulation of commercial information, which unquestionably includes advertising, derives from the close relationship of these messages with economic and market activity, insofar as such messages constitute incentives to engage in specific commercial transactions. Therefore, advertising activity is, in general, more an exercise of economic freedom than a component of freedom of expression, and for that reason commercial advertising is subject to regulation by the “Economic Constitution.”⁶ Thus, the court clearly stated that commercial speech does not enjoy the same level of protection as political, religious, or cultural speech.

5.2.2.2 The limited impact of the ban on free trade

The Constitutional Court of Colombia understands that the right to trade is not substantively affected by these bans on TAPS. The court affirmed that:

it is clear that the rules being challenged only prohibit activities aimed at the *promotion* of a certain group of goods (tobacco products and their derivatives) intended for consumption; the scope of the rules is not sufficient to affect the manufacture of such products, nor their availability to consumers. Therefore, we cannot conclude that the measure banning the advertising of tobacco and sponsorship of cultural and sporting events by tobacco companies in itself affects free enterprise.⁷

5.2.2.3 The State and its authority to discourage use of a legal product

In an interesting conceptual development that has already been reported in other cases in the region,⁸ the Constitutional Court of Colombia used the concept of the “passive market,” in which consumption of a legal product is subject to disincentives because of powerful reasons to discourage its consumption. According to the court:

The same jurisprudence has provided that restrictions on commercial advertising can become particularly intense when the State finds that a particular activity, although lawfully exercised, should be discouraged because of the damage inflicted on society or the verifiable danger of harm to others. As a result, it is not *prima facie* unconstitutional for the legislature to enact rules that seek the formation of a passive market, that is, a situation in which production and marketing of a particular good or service is permitted but policies are enacted to discourage its consumption . . . [To quote Judgment C-010/00,] “the activity is tolerated, making it legal, but it cannot be promoted, so that not only is advertising of the activity prohibited or severely restricted, but the authorities may even mount publicity campaigns against the activity. This type of strategy has been developed in some countries to control, for example, the abuse of legal psychoactive substances such as alcohol or tobacco. Therefore, it is not contradictory, nor a violation of the Constitution, for the law to prohibit commercial advertising of an activity that is legal, since it is reasonable for the authorities to establish various forms of a ‘passive market’ for those activities that are tolerated but that society deems it necessary to discourage.”⁹

⁶ Constitutional Court of Colombia, Expediente D-8096, Sentencia C-830/10, 2010, para. 13. http://www.tobaccocontrollaws.org/files/live/litigation/271/CO_Caceres%20Corrales%20v.%20Colombia_1.pdf. Unofficial translation by authors.

⁷ *Ibid.*, para. 28.

⁸ See the judgment by the Constitutional Tribunal of Peru in the case of *5000 Citizens*, discussed in Chapter 3 of this manual.

⁹ Constitutional Court of Colombia, Expediente D-8096, Sentencia C-830/10, 2010, para. 13 (quoting Judgment C-010/00).

5.3 Implementing WHO FCTC Article 13 at the domestic level: Drafting effective measures on tobacco advertising, promotion, and sponsorship

WHO FCTC Article 13.2 requires Parties to impose a comprehensive ban on all TAPS within five years of the treaty's entry into force for the Party. The treaty itself provides some details as to the scope and content of a comprehensive ban. However, it does not fully elaborate on what Parties must do to fulfill their Article 13 obligations. It is the Article 13 Guidelines, approved at the third session of the Conference of the Parties, that interpret and elaborate the scope and content of Parties' obligations.

The Guidelines make clear, for example, that:

- Only a comprehensive ban will be effective for meeting WHO FCTC Article 13 obligations. The effect of a partial ban on consumption is limited since the tobacco industry will inevitably shift to other TAPS strategies using creative, indirect ways to promote tobacco products and tobacco use, especially among young people;
- A comprehensive ban applies to all direct and indirect TAPS, without exemption; and
- Legal duties of compliance should apply to all persons and entities in the entire marketing chain.

WHO FCTC Article 13.2 and its Guidelines recognize that some Parties' constitutions or constitutional principles may not permit a full ban on TAPS. If a Party is constitutionally precluded from implementing a comprehensive ban, that Party is required to enact TAPS restrictions that are as stringent as is legally permitted.

The appendix to the Guidelines includes an illustrative, nonexhaustive list of forms of TAPS that fall within the terms of the WHO FCTC. The Guidelines also detail the importance of tracking permitted forms of TAPS, identifying responsible entities and imposing legal duties of compliance, imposing a range of deterrent penalties, and identifying the authority or authorities responsible for inspection and enforcement.

Chapter 2 of this manual lists nine key components that can provide the framework for effective tobacco control legislation in any of the policy areas covered by the WHO FCTC. While each of the nine components applies to TAPS legislation, this chapter focuses on those that must be tailored for implementation of WHO FCTC Article 13.

The accompanying "In Practice" boxes present examples of good-practice legislation from different countries. Legislative development and legislative drafting are both a science and an art, and they occur within a political context. Achieving best-practice legislation often takes time; the examples highlighted in the boxes either achieve or approach this standard. The best means of ensuring best-practice legislation is to fully incorporate WHO FCTC Article 13 and its Guidelines into domestic tobacco advertising, promotion, and sponsorship provisions (see Chapter V of the legislative template for a tobacco control act, included as Chapter 9 of this manual).

5.3.1 Provide clear legislative objectives

Example of clear legislative objectives for measures on TAPS may include:

- Preventing tobacco use initiation, which typically occurs during adolescence and young adulthood, by eliminating messages, images, and other inducements that encourage or are intended or are likely to encourage people to begin or continue using tobacco products, and
- Reducing the social acceptability of tobacco use.

One or more rules of interpretation may flow from the TAPS objectives. For example, in ensuring that all people are protected from inducements to begin or continue using tobacco products, any question that may arise as to whether any commercial communication, recommendation, or action constitutes a form or manner of tobacco advertising, promotion, or sponsorship prohibited under the act shall be resolved in favor of protecting public health.

5.3.2 Define key terms

Definitions of TAPS-relevant terms in the WHO FCTC are comprehensive, and their use in domestic legislation will help ensure the proper interpretation and implementation of the law. Key terms for TAPS include:

- *“Tobacco advertising and promotion”*: any form of commercial communication, recommendation or action with the aim, effect, or likely effect of promoting a tobacco product or tobacco use either directly or indirectly (WHO FCTC Article 1(c))
- *“Tobacco sponsorship”*: any form of contribution to any event, activity, or individual with the aim, effect, or likely effect of promoting a tobacco product or tobacco use either directly or indirectly (WHO FCTC Article 1(g))

The definitions of “tobacco products” and “tobacco industry” are also relevant to provisions regulating TAPS. These key terms are defined in the legislative template provided in Chapter 9.

WHO FCTC Article 1 defines “tobacco advertising and promotion” and “tobacco sponsorship” in broad and inclusive terms, providing a conceptual basis for determining whether any particular communication, recommendation, or action would be considered TAPS under the law. These broad definitions may have some overlap between them, but this overlap is desirable as it helps ensure that all forms of marketing are covered under the ban (Article 13 Guidelines). Both definitions also include two phrases that are key to their breadth: first, “directly or indirectly,” and second, “with the aim, effect, or likely effect.” By including these terms, a comprehensive ban will apply to communications, recommendations, and actions that may not be designed to promote tobacco products but that have promotional effects nonetheless.

It is critical that the definition of “tobacco advertising and promotion” include more than just commercial communications. Many marketing practices commonly used by the industry take the form of actions, such as sales and/or distribution arrangements with retailers (for example, retailer incentive programs in which a tobacco company pays retailers to prominently display its products) or with customers (for example, incentive programs or loyalty schemes where customers earn coupons when purchasing tobacco products) (Article 13 Guidelines). The definition of “tobacco sponsorship” places the emphasis on any form of contribution, irrespective of whether there is acknowledgement or publicity associated with the contribution. It is critical that these key features of these definitions be replicated in any tobacco control legislation with TAPS provisions.

Box 5.1

In Practice: Examples of comprehensive definitions

Trinidad and Tobago

The definitions used in Trinidad and Tobago's Act 15, Tobacco Control Act, 2009 incorporate the WHO FCTC Article 1 definitions for TAPS-relevant terms.

Section 4

"[T]obacco advertising and promotion' means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly.

'[T]obacco sponsorship' means any form of contribution to any event, activity, organization, or individual that has the aim, effect or likely effect of promoting a tobacco product or tobacco use directly or indirectly."

The Tobacco Control Act, 2009 is available at <http://www.health.gov.tt/downloads/DownloadItem.aspx?id=152>

Uruguay

Ministry of Public Health Decree 284/008 essentially replicates the WHO FCTC definitions. The definition of "sponsorship" includes a contribution to a "private institution," helping ensure that philanthropic contributions are covered under the definition.

Article 7

"Advertising and promotion: Any form of commercial action, communication, or recommendation in any medium with the goal, effect, or possible effect of directly or indirectly promoting a tobacco product or its use.

Sponsorship: Any form of contribution to any event, activity, individual, or public or private institution with the goal, effect, or possible effect of directly or indirectly promoting a tobacco product or the use of tobacco. Donations are included in this definition."

An unofficial English translation of Decree 284/008 is available at http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Decree%20No.%20284_008.pdf. The decree is available in the original Spanish at http://archivo.presidencia.gub.uy/_web/decretos/2008/06/CM496__00001.PDF. The excerpts above are unofficial translations by the authors.

5.3.3 Ensure a comprehensive ban on all TAPS

WHO FCTC Article 13.2 requires each Party to impose, in accordance with its constitution and constitutional principles, a comprehensive ban on all TAPS within five years of the treaty's entry into force in the country. The comprehensive ban should apply to all tobacco TAPS without exemption, as specified in the Guidelines, including both domestic and cross-border TAPS.¹⁰ Application to cross-border TAPS is particularly important in the many Caribbean countries that receive a significant amount of television programming from the United States (Ernster et al. 2000).

In the rare case that a Party may not be able to undertake a comprehensive TAPS ban on account of its constitution or constitutional principles, the Guidelines provide that restrictions should be made as comprehensive as legally possible.

¹⁰ As specified in WHO FCTC Article 13.2, a Party shall include in its ban all cross-border TAPS originating within its territory, "subject to the legal and technical means available to that Party." WHO FCTC Article 13.7 recognizes a Party's "sovereign right" to treat TAPS entering its territory in the same way that it treats domestic forms of TAPS.

The FCTC provision acknowledging constitutional considerations must be read very narrowly; Parties are obligated to implement a total ban unless their constitution truly will not allow it. Because the tobacco industry can be counted on to argue that a comprehensive ban will violate constitutional principles, it is critical that each Party rigorously assess its constitutional framework to determine whether constitutional considerations are in fact an issue, keeping in mind that many constitutions of Caribbean and Latin American countries specifically include protection of the rights to life and health.

A case in point is Brazil, where there was a discussion on whether the country's 1988 constitution prevented a total ban on TAPS. The constitution states that TAPS should be regulated, and this requirement led to the perception that if something should be regulated it is inherently permitted. Brazil's Aliança de Controle do Tabagismo commissioned a study by a prominent constitutional lawyer who concluded there was no constitutional restriction precluding a total ban (da Silva 2009).

5.3.3.1 Including an indicative list

The appendix to the Article 13 Guidelines provides an indicative, nonexhaustive list of TAPS falling within the scope of a comprehensive ban. It is advisable to include the examples from this list in the legislation or implementing regulations, with any adaptation appropriate for the country's context (Article 13 Guidelines). This is because many forms of TAPS are indirect, hidden, or not easily recognized as tobacco promotion. Examples of these less-obvious forms of TAPS may include toys and candy resembling tobacco products, brand sharing, brand stretching, product placement in films, so-called corporate social responsibility, and retailer incentive programs, among many others.

The appropriate place for an indicative list, whether in legislation or regulations, will vary by country and should be specified in the legal instrument where such information would customarily be found. If the list is provided in legislation, clear power should be given to the appropriate authority to expand the examples as it deems appropriate and useful. If it is included in legislation, the list of examples may be best located in a schedule (or other appropriate legal instrument) attached to the law, so as not to detract from the clear statement in the law imposing the comprehensive ban. Alternatively, the legislation could authorize the appropriate authority to provide, in implementing regulations, nonexhaustive examples of TAPS falling within the ban.

Whether the examples are provided in the legislation or in regulations, it is critical to state clearly that any examples given are only for illustrative purposes and are in no way meant to be, nor should they be interpreted as being, exhaustive. This can be accomplished by using language such as "including but not limited to" and/or "and any other form of tobacco advertising, promotion, or sponsorship" (Article 13 Guidelines).

Limited (incidental) forms of relevant commercial communications, recommendations, or actions expected to continue

There are some very limited forms of relevant commercial communications, recommendations, or actions that the Article 13 Guidelines recognize might continue to exist after implementation of a comprehensive ban. These limited forms are:

- Display of brand name, product name, and/or manufacturer's name on tobacco product packaging that meets prescribed standards, without any logo or other promotional features on or in the package;
- A very carefully prescribed text-only listing, without any promotional elements, of tobacco products and their prices at places where tobacco products are sold (including Internet sales);

- Dissemination or reporting of information on tobacco company business practices (e.g., good employee-employer relations) that do not involve contributions to other parties where, and only where, this information is required for necessary business administration (e.g., for recruitment purposes or communications with suppliers) or for mandated corporate reporting (e.g., annual reports);
- Legitimate journalistic, artistic, or academic expression of tobacco content and genuine social or political commentary (e.g., news images with coincidental background tobacco-related content, or views on regulation or policy) for which no payment or any other consideration is made by tobacco manufacturers, importers, or sellers or by any person acting on their behalf;¹¹
- Product information provided to entities within the tobacco trade, with access only to persons or entities needing the information for business decisions, and only to the extent that access is limited to those persons or entities; and
- Tobacco manufacturers' newsletters destined for and distributed only to the manufacturers' employees, contractors, suppliers, and other tobacco-related business partners, and only to the extent that their distribution is limited to such persons or entities.

Careful consideration should be given to whether these limited communications, recommendations, and actions should be explicitly acknowledged in the legislation. If not acknowledged, they might be interpreted as fitting within the definition of “tobacco advertising and promotion” or “tobacco sponsorship” and, consequently, within the scope of the ban. Acknowledging these as not covered by the ban can prevent the legislation from being considered overly broad. In addition, doing so should also make clear that all communications, recommendations, or actions not so acknowledged are prohibited. On the other hand, acknowledging them can create opportunities for exploitation by the tobacco industry and its allies. If the decision is made to acknowledge these limited forms, the text of the Guidelines should be closely consulted to ensure that the permitted forms are described in a way that eliminates any ambiguities or loopholes.

Box 5.2 **In Practice: Examples of strong and comprehensive TAPS bans**

Panama

Article 14 of Panama's Law 13 of 24 January 2008 imposes a comprehensive ban on TAPS and does so in a manner that is clear and concise.

Article 14

“Any kind of marketing, advertising, or sponsorship of tobacco and its products is totally prohibited, whether through indirect or subliminal means, whether aimed at minors or adults. Equally prohibited are all forms of cross-border advertising, promotion, and sponsorship of tobacco and its products that may penetrate the national territory.”

(continued)

¹¹ As provided in the Guidelines, these depictions could be made subject to a requirement for the inclusion of appropriate warnings or disclaimers prescribed by the government. When tobacco is depicted in entertainment media, the requirements in the Guidelines should be imposed (e.g., prohibit the depiction of identifiable brands, require anti-tobacco advertising, etc.).

Box 5.2 (continued)

An unofficial English translation of Law 13 is available at <http://www.tobaccocontrolaws.org/files/live/Panama/Panama%20-%20Law%2013%20of%202008.pdf>. The law is available in the original Spanish at http://www.asamblea.gob.pa/APPS/LEGISPAN/PDF_NORMAS/2000/2008/2008_557_1078.PDF. Excerpts above are unofficial translation by the authors.

Ireland

Section 43 of the Public Health (Tobacco) Act 2002 (as amended in 2004) provides a strong example of a prohibition on the display of tobacco products at POS. As part of the display ban, the law prohibits self-service. The law, however, does allow sale by vending machines, a form of self-service that is inherently a form of advertising and should be prohibited.

Section 43

- “(1) Subject to subsection (2), it shall be an offence for a person to sell a tobacco product by retail, or cause a tobacco product to be sold by retail, by means of self service.
- (2) It shall be lawful for tobacco products to be sold by retail, in accordance with regulations made by the Minister, by means of a vending machine on licensed premises or the premises of a registered club by such persons, or by persons belonging to such classes of persons, as are specified in the regulations (being persons who are registered under section 37 [requirements for registering as retailers of tobacco products] . . .
- (3) A person registered under section 37 . . . shall ensure that tobacco products sold by him or her are kept in a closed container or dispenser that is not visible or accessible to any person other than the first-mentioned person, or a person employed by him or her in connection with the business of selling goods by retail while so employed.”

The Public Health (Tobacco) Act 2002 is available at <http://www.irishstatutebook.ie/2002/en/act/pub/0006/print.html>.

5.3.3.2 Regulating forms of TAPS not banned

As provided in the Article 13 Guidelines, any form of TAPS that is not prohibited must meet the minimum requirements of WHO FCTC Article 13.4. These requirements would apply in the rare case where a TAPS ban cannot be comprehensive as a result of constitutional considerations, in cases where the legislation recognizes the incidental forms of TAPS that may remain permissible,¹² and where Parties may be in the process of establishing a comprehensive ban, leaving some forms of TAPS permitted for a limited time period. WHO FCTC Article 13.4 requires that Parties impose the following on TAPS not banned or not yet banned:

- A prohibition on the use of any term, descriptor, trademark, emblem, marketing image, logo, color, or figurative or any other sign that promotes a tobacco product or tobacco use directly or indirectly by any means that are false, misleading, deceptive, or likely to create an erroneous impression about the characteristics, health effects, hazards, or emissions of any tobacco product, or about the health effects or hazards of tobacco use, including, but not limited to, use of the terms or signs indicating the terms “low tar,” “light,” “ultra-light,” “mild,” “extra,” “ultra,” and other terms in any language that may be misleading or create an erroneous impression (WHO FCTC Article 13.4(a), and Article 13 Guidelines);
- A requirement that prescribed warnings/messages consistent with required pack warnings/messages under WHO FCTC Article 11 accompany all TAPS, being given prominence at least equal to that of the TAPS (WHO FCTC Article 13.4(b) and Article 13 Guidelines); and

¹² See discussion in section 5.3.3.2.

- A requirement that businesses in the tobacco industry report to the government periodically and upon request the information required by WHO FCTC Art. 13.4(d) and outlined in the Article 13 Guidelines with respect to any TAPS in which they engage. The government should make this information readily available to the public (Article 13 Guidelines).

With respect to the second point above, a warning requirement is critical in instances where POS product displays are not yet banned. With respect to the third point, the Article 13 Guidelines recommend that *all* legislation, even legislation establishing a comprehensive ban, include the requirement that tobacco companies must disclose to the government any TAPS expenditures. Requiring such disclosure could help the government identify any TAPS it thought was covered as well as any TAPS undertaken by the tobacco industry in contravention of the ban.

Box 5.3 In Practice: Actions required for forms of TAPS not yet legally banned by countries

Canada

Part 5 of Canada's Tobacco Reporting Regulations establishes reporting requirements for any advertisements published.

Section 17

"(1) If a consumer tobacco product is advertised in a publication, the manufacturer of that product shall report the following information:

- every province in which the publication was distributed;
- the dates the advertisement was published; and
- the total cost of the 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)."

Section 16 requires quarterly and semiannual reporting of promotional activities undertaken by manufacturers similar to the reporting required of advertisements in publications. Section 18 requires similar disclosures for sponsorship activities.

The Tobacco Reporting Regulations are available at <http://laws-lois.justice.gc.ca/PDF/SOR-2000-273.pdf>.

5.3.4 Impose legal duties of compliance

It is critical that legislation create a legal duty of compliance for *all* persons or entities responsible for TAPS. That means a legal duty of compliance should be imposed on the entire marketing chain, including media companies. The duties imposed will depend on the role played. The Article 13 Guidelines identify the following responsible persons or entities and their duties:

- Initiators, which should bear primary responsibility for compliance and should be prohibited from initiating any TAPS;¹³

¹³ Initiators may include, but are not limited to, tobacco manufacturers, wholesale distributors, importers, and retailers, and their agents and associates.

- Producers and publishers, which should be prohibited from including TAPS in the content they produce, publish, or make accessible;¹⁴
- Entities that disseminate communications content, which should have a duty to remove prohibited content or make reasonable efforts to disable access to it, when technically possible, when they are in a position to control the publication or dissemination of the content, and when they become aware of, or are in a position to become aware of, the prohibited content;¹⁵
- Persons or entities engaged in TAPS as media and event organizers, sportspeople, celebrities, film stars, and other artists, who should be prohibited from engaging in TAPS; and
- Persons or entities who make, receive, or facilitate any sponsorship contribution, who should be prohibited from making, receiving, or facilitating such contributions.

The Article 13 Guidelines include detailed information about each class of responsible persons/entities and should be consulted carefully when crafting legislation or regulations covering legal duties of compliance for TAPS measures.

5.3.5 Provide a range of deterrents and proportionate penalties

As stated in Chapter 2, section 2.2, penalties should be proportionate to the seriousness of the violation and should be commensurate with the degree of responsibility for the violation. Because TAPS are usually initiated by the tobacco manufacturers with vast resources, penalties should accordingly be set high.

Provisions for remedial action are particularly relevant for TAPS violations. These may include removal and/or confiscation of the items or materials containing TAPS content, a requirement that the violator pay for counter-advertising, invalidation of contracts in violation of TAPS provisions, forfeiture of contributions from tobacco companies, and similar actions.

¹⁴ Producers and publishers include, but are not limited to, tobacco companies (e.g., with respect to online content and any other content they produce or publish themselves); advertising agencies; designers; producers and publishers of printed materials; broadcasters and producers of films, television and radio programs, games, and live performances; and Internet, mobile phone, satellite, and game content producers.

¹⁵ This would apply, for example, to entities providing access to or distributing content through any communications technology (including, but not limited to, telecommunications (e.g., mobile telephone companies), direct broadcast satellite companies, and entities responsible for providing Internet service or that serve as Internet content hosts or navigators, including those who aggregate content and make it available on social networking websites or platforms).

Box 5.4 In Practice: Providing a range of deterrent penalties

Trinidad and Tobago

Articles 36 and 37 of Trinidad and Tobago's Tobacco Control Act, 2009 contain several good provisions for penalties and approach the standard set in the Article 13 Guidelines. The penalties are applicable to all violations under the act, but with some TAPS-specific provisions. In particular, the law provides for a range of penalties, from financial penalties to suspension or revocation of licenses to confiscation of TAPS in violation of the law. Penalties increase in cases of continuous violations, with each day constituting a separate offense. However, it is also recommended that penalties increase with repeat violations, whether they are continuous or not. (It should be noted that while the Article 13 Guidelines do not specifically mention increasing penalties for repeat violations, this is recommended in the Article 8 Guidelines and the Article 11 Guidelines, and is a best practice for TAPS penalties as well.)

Article 36

(1) In any action for non-compliance with this Act or Regulations, the following penalties may be imposed:

- a. suspension, revocation or limitation of licences;
- b. removal by an authorized officer of an offending person from the premises or public conveyance, and confiscation and forfeiture of any tobacco products in violation of the provisions of this Act; and
- c. confiscation and forfeiture of—
 - i. (any item that contains a tobacco advertising and promotion prohibited under this Act;
 - ii. any tobacco product packaged or labelled in a manner that does not conform with this Act; . . .
 - iii. all non-tobacco products that fail to conform with section 18 [prohibition on toy or candy cigarettes].

(2) For any continuing violation, each day the violation continues shall constitute a separate offence.

(3) Where any person derives any monetary or financial benefit directly or indirectly from any act or omission that constitutes a violation under this Act, Regulations or other applicable law, including any imposing duties and taxes, all proceeds so gained shall be forfeited in addition to any other penalty imposed.

(4) Where a corporate person contravenes this Act, the corporate director or other corporate officer who authorized or acquiesced in the act or who knew or, using due diligence, ought to have known that the commission or omission constituted a contravention, that director or other corporate officer as the case may be, is deemed to have committed the offence and shall be held personally liable."

Article 37

(2) A person who contravenes any provision of this Act for which there is no penalty prescribed, commits an offence and is liable—

- a. on summary conviction, to a fine of one hundred thousand dollars and to imprisonment for six months; or
- b. on conviction on indictment, to a fine of two hundred thousand dollars and to imprisonment for one year."

The Tobacco Control Act, 2009 is available at
<http://www.health.gov.tt/downloads/DownloadItem.aspx?id=152>.

5.3.6 Grant broad regulatory power to the appropriate authority to address implementation details

The appropriate authority should be given adequate powers to address a broad range of matters in regulations, including but not limited to:

- Expanding any indicative list of TAPS covered by the law that may be provided in the law, as it deems useful;
- Prescribing warning or message requirements, and the conditions for their use, for any TAPS not banned or not yet banned;
- Prescribing industry TAPS reporting requirements (content, frequency, format, and all other details);
- Requesting information from persons or entities responsible for TAPS; and
- Taking any other action necessary or appropriate for implementing the legislation.

Care should be taken to avoid inadvertently limiting the regulatory powers of the authority, such as by granting only some powers and/or expressing them in an exhaustive way.

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Chapter 6

Protecting Tobacco Control Policies from the Commercial and Other Vested Interests of the Tobacco Industry



Source: PAHO.

6. Protecting Tobacco Control Policies from the Commercial and Other Vested Interests of the Tobacco Industry

6.1 Background

6.1.1 Rationale and evidence

Tobacco products are inherently deadly to their users and to those exposed to secondhand smoke, causing death in up to one half of smokers (WHO 2012b; Peto et al. 1992). In addition to causing disease and death, the tobacco industry's core operations contribute to worldwide environmental destruction and a variety of social ills, including increased poverty (de Beyer, Lovelace, and Yürekli 2001). Accordingly, the business interests of the tobacco industry are in direct and irreconcilable conflict with the goals of public health and tobacco control.¹

According to World Health Assembly resolution WHA54.18 (WHO 2001), "the tobacco industry has operated for years with the express intention of subverting the role of governments and of [the World Health Organization] in implementing public health policies to combat the tobacco epidemic." This is not surprising, since the industry's stated approach, according to internal tobacco industry documents, is:

"to fight aggressively, with all available resources, against any attempt, from any quarter, to diminish our ability to manufacture our products efficiently, and market them effectively." (Parrish 1995)²

Strategies and tactics used by the industry (WHO 2008, 2012) in pursuit of this approach include, but are not limited to:

- Lobbying government office holder, often by undisclosed means, to prevent, delay, or weaken tobacco control policies;
- Offering its own drafts of laws and regulations and privately commenting on government drafts;
- Using front groups, such as tobacco growers, hospitality associations, and retailers to advance its arguments, often using "evidence" from studies the tobacco industry has openly or secretly funded or otherwise influenced;
- Making campaign contributions to political parties and candidates;
- Making contributions to government institutions and providing contributions, gifts, and perks to public office holders, including elected officials and civil servants;
- Funding conferences and other events for policy makers in the legislative and executive branches and members of the judiciary and paying for their travel and expenses;

¹ Tobacco industry" is defined in WHO FCTC Article 1(e) as "tobacco manufacturers, wholesale distributors and importers of tobacco products."

² This statement by Steve Parrish, a Philip Morris official, is included in internal documents of the tobacco industry that were made public as a result of *The State of Minnesota and Blue Cross and Blue Shield of Minnesota v. Philip Morris et al.* and other legal cases. Even though the document is from 1995, there is evidence that the industry continues to engage in aggressive marketing practices, despite its claims of change. For example, see Malone and Balbach (2000).

- Inserting its people—those working for or on behalf of the industry—in government positions and on bodies, commissions, and delegations that deal with tobacco control issues, including tobacco control boards and delegations to meetings of the Conference of the Parties;
- Offering weak voluntary codes of conduct in place of enforceable regulation, and funding and engaging in youth prevention programs and other so-called corporate social responsibility activities that in reality are undertaken for the purposes of gaining influence with policy makers and legitimacy with the public, avoiding adverse publicity, and preventing, delaying, or weakening regulation;
- Exaggerating the economic importance of the industry for the economy of the country and for jobs, and making dire predictions of economic losses that will result from effective tobacco control policies;
- Discrediting well-established scientific evidence; and
- Intimidating governments with litigation or the threat of it.

The tobacco industry argues that because its products are legal, it is a legitimate stakeholder and should be “at the table” when tobacco policies are being developed and implemented. However, Parties to the World Health Organization Framework Convention on Tobacco Control (WHO 2003; hereafter, WHO FCTC) are obligated to treat the tobacco industry differently than other industries producing and marketing legal products. No other industry is the subject of a treaty provision like WHO FCTC Article 5.3, which calls on the Parties to “protect these [tobacco control] policies from commercial and other vested interests of the tobacco industry in accordance with national law.”

The Guidelines for implementation of Article 5.3 (WHO 2009a; hereafter, Article 5.3 Guidelines) provide recommendations for protecting tobacco control policies from the tobacco industry’s conflicting interests and interference with tobacco control policy development and implementation. The measures recommended in the Guidelines aim to protect against interference by the tobacco industry itself (tobacco product manufacturers, importers, and wholesale distributors) as well as by any entities and individuals that work to further the interests of the tobacco industry. It should be noted that any person or entity engaged directly or indirectly in the supply chain for tobacco leaf and its products has a commercial interest in making profits from tobacco and is likely to resist effective tobacco control measures. This may include tobacco leaf growers and tobacco product retailers, for example (WHO 2012a). It is also important to note that tobacco industry interests are sometimes represented by front groups. These groups usually present themselves as independent, when actually they are serving the interests of the tobacco industry. For example, front groups may include industry-funded growers’ associations and allied third-party industries such as the hospitality industry (WHO 2012a).

6.1.2 Regional situation

The tobacco industry has been very active in the Region of the Americas (PAHO 2002). Since ratification of the WHO FCTC and the implementation of domestic legislation consistent with it, the tobacco industry and its allies have intensified use of the strategies listed above to resist, obstruct, weaken, and subvert effective tobacco control policies. In addition, the tobacco industry and its allies have been very aggressively using litigation to try to reverse the strong legal measures in place for tobacco control.

This was recognized by countries of the Region in Resolution CD50.R6 of the Pan American Health Organization 50th Directing Council in September 2010 (PAHO 2010). It was also discussed at the fourth session of the Conference of the Parties

(COP) to the WHO FCTC, held in Uruguay in November 2010. The fourth COP adopted the Punta del Este Declaration on the implementation of the WHO FCTC in response to a tobacco industry challenge to amendments enacted to strengthen packaging and labeling provisions in Uruguay's tobacco control law (WHO 2010). Among other things, the FCTC Parties declared their firm commitment to prioritize the implementation of health measures designed to control tobacco consumption in their jurisdictions and their concern about tobacco industry actions that seek to subvert and undermine governments' tobacco control policies. Subsequently, at the United Nations High-Level Meeting on Non-communicable Diseases in 2011, Member States noted that they "recognize the fundamental conflict of interest between the tobacco industry and public health" (United Nations 2011, para. 38).

Although little has been done to implement WHO FCTC Article 5.3 as of October 2012, a highlight in the region is Brazil's enactment of Administrative Rule 713 in April 2012. This rule makes public the ethical guidelines applicable to the members of CONICQ, the National Commission for FCTC Implementation (Ministério da Saúde de Brasil 2012).³ These guidelines feature many of the recommendations in the FCTC Article 5.3 Guidelines. Information on the Brazilian rule is available in subsequent sections of this chapter.

6.2 Implementing WHO FCTC Article 5.3 at the domestic level: Drafting effective measures to prevent tobacco industry interference

Recognizing that the conflict between the tobacco industry and tobacco control cannot be reconciled, Parties to the WHO FCTC have agreed to take action to protect the development and implementation of public health policies from the commercial and other vested interests of the tobacco industry. At their core, successful Article 5.3 implementing measures will (a) insulate tobacco control policy, and the persons and authorities responsible for developing and implementing such policy, from the influence and interference of the tobacco industry, and (b) ensure transparency in the operations and actions of both government and the tobacco industry, especially the interactions between them. It is critical that these measures apply across government, to all branches and at all levels of government.

Effective Article 5.3 implementing measures will fulfill the WHO FCTC requirements by fully incorporating and going beyond the Article 5.3 Guidelines. The Guidelines provide that while the recommended measures "should be applied . . . as broadly as necessary, in order best to achieve the objectives of Article 5.3 of the Convention, *Parties are strongly urged to implement measures beyond those recommended in these guidelines* when adapting them to their specific circumstances" (emphasis added).

Most measures incorporating the Guidelines' recommendations can take the form of either legal enactments or government policies and codes of conduct, or some combination of these. Several considerations will inform the decision about whether to implement specific recommendations as legal or policy measures, or both. Legal measures can apply civil and criminal penalties such as fines and imprisonment, among others, as sanctions for violations of legal duties. Legal measures may also have the advantage of being capable of binding all government institutions and bodies across all branches of government, whereas it may not be possible for one governmental body to bind all bodies in other ministries or branches through policy measures unless it is given specific legislative authority to do so. Legal enactments tend to be less subject to discretion and to provide less flexibility in implementation, which may be desirable for some measures but undesirable for others. Finally, a high degree of political will is likely to be necessary for the enactment of legal measures.

³ CONICQ is a governmental body created by a presidential decree. It is multisectoral, drawing from 18 different sectors of the federal government, with the minister of health as its president and INCA, the National Cancer Institute, as its executive secretariat.

Administrative policies, on the other hand, would likely be limited in their sanctioning power to employment disciplinary actions, which may not have the same deterrent effect as the threat of monetary penalties and/or imprisonment. Each branch of government and/or each ministry or body may have to enact its own policies if there is no legal authority in place granting one overarching body policy-making power over all of government. Policies are likely to allow more flexibility and discretion in implementation, which may be desirable when there could be grey areas, such as whether a particular relationship gives or could give rise to a conflict of interest. Adopting policies may not require as much political will as enacting laws, but a high degree of political will still would be necessary for effective implementation across the various governmental sectors and departments.

Even where requirements or prohibitions take the form of legal measures, there will be a need for accompanying policies and/or guidelines. Guidance will be needed, for example, to define:

- What constitutes an interaction;
- What constitutes a necessary interaction;
- Circumstances in which a public forum and advance notice are not possible;
- The records that need to be kept, required content, what is done with the records, how they are made accessible to the public, and within what time frame;
- What circumstances and relationships give or could give rise to a conflict of interest (e.g., just those involving the public office holder or also his or her close family members); and
- What constitutes appropriate disciplinary actions for violations by public office holders.⁴

A determination will need to be made about the best combination of legal enactments and policy measures. The objective is to implement the Article 5.3 Guidelines in a way that makes sense under the circumstances in a given jurisdiction and that takes into account any existing laws and policies relevant to implementing the article. Persons with in-depth knowledge of the local legal and political environments and a clear understanding of the practical considerations will be best able to strike an effective balance. The legislative template in Chapter 9 provides commentary on the legislative and policy options for the different provisions contained in the template. Chapter 2 of this manual lists nine key components that can provide the framework for effective tobacco control legislation in any of the policy areas covered by the WHO FCTC. This chapter focuses on those elements that must be tailored for implementation of WHO FCTC Article 5.3. The accompanying “In Practice” boxes present examples of good-practice legislation from different countries. Legislative development and legislative drafting are both a science and an art, and they occur within a political context. Achieving best-practice legislation often takes time; the examples highlighted in the boxes either achieve or approach this standard. The best means of ensuring best-practice legislation with respect to tobacco industry interference is to fully incorporate WHO FCTC Article 5.3 and its Guidelines (see Chapter IX of the legislative template for a tobacco control act, included as Chapter 9 of this manual).

⁴ See also Technical Resource for Country Implementation of WHO Framework Convention on Tobacco Control Article 5.3 (WHO 2012).

6.2.1 Provide clear legislative objectives

Taking into account, on one hand, the inherent and irreconcilable conflict of interests between the goals of tobacco control policies and the interests of the tobacco industry arising from the addictive and deadly nature of tobacco products, and on the other hand, the longstanding history of efforts by the tobacco industry to subvert the role of government and undermine the development and implementation of effective policies, the objectives of Article 5.3 implementing measures might include:

- Insulating government from tobacco industry influence and interference; and
- Ensuring transparency in the operations of government and of the tobacco industry in order to fulfill the State's obligations under the WHO FCTC.

One or more rules of interpretation may flow from these objectives. For example, if there is any question as to whether an interaction with the tobacco industry is necessary or not, whether transparency is required, or whether a conflict of interest exists, it must be resolved in a way that favors protection of tobacco control policies from tobacco industry influence and interference.

Box 6.1 In Practice: Examples of objectives

Brazil

Administrative Rule 713 (2012), which contains the ethical rules established for members of CONICQ, lays out principles of application that combine what the manual characterizes as objectives and rules of interpretation.

Chapter I. Principles and Their Application

"Art. 2º The relationships established among members of CONICQ and the tobacco industry are to be governed by the following principles:

- i. Principle of Transparency, whereby the relationships established among the members of CONICQ and the tobacco industry or those acting to promote its interests must be transparent and responsible;
- ii. Principle of the Primacy of the Interests of Public Health Policy, whereby the interests of the tobacco industry are irreconcilable with those of the policy of public health, which in all circumstances has priority;
- iii. Principle of the Sharing of Information, whereby information concerning the tobacco industry to which they have access in the exercise of their duties and the interference by the latter in public policies for tobacco control must be widely shared among the representatives of CONICQ; and
- iv. Principle of the Publicity of Interactive Practices, whereby interactive practices between CONICQ and its members and the tobacco industry must be characterized, preferably, by publicity."

Excerpts above are from an unofficial English translation of Administrative Rule 713 at <http://www.tobaccocontrolaws.org/files/live/Brazil/Brazil%20-%20Ord.%20No.%20713.pdf>.

The rule is available in the original Portuguese at http://bvsm.sau.gov.br/bvs/sau/legis/gm/2012/prt0713_17_04_2012.html.

6.2.2 Define key terms

WHO FCTC Articles 1(d) and 1(e) provide definitions of “tobacco control” and “tobacco industry,” respectively. Although the Article 5.3 Guidelines do not define other key terms, there are some terms it would be useful to define in legislation or policy. One such term is “conflict of interest.” The Organisation for Economic Co-operation and Development defines this as “a conflict between the public duty and private interests of a public official, in which the public official has private-capacity interests which could improperly influence the performance of their official duties and responsibilities” (OECD 2005). For the purpose of tobacco-related conflicts of interest, the term could be defined to mean an actual or perceived conflict between the public duties and private interests of any person working in or on behalf of government in any capacity where that person has tobacco-related interests or is defending/representing a tobacco-related interest which could improperly influence the performance of his or her official duties and responsibilities.

The Article 5.3 Guidelines apply to government officials, representatives, and employees of the different branches and levels of government. Implementing measures could designate a term for these people in order to have a more concise way of referring to the range of government figures covered under the measures—for example, “public office holder” or some other appropriate term. The term could then be defined to mean officials, representatives, and employees in all branches and at all levels of government, whether appointed, elected, or in career public service.

In addition to definitions, implementing measures should, in line with the Article 5.3 Guidelines, make clear that:

- Reference to government includes semi- or quasi-public institutions or bodies and any entities or persons working on their behalf or to further their interests;
- Reference to the “tobacco industry” includes entities and persons working on behalf of or to further the interests of any business in the tobacco industry;
- Reference to “public office holders” (or other term used to cover government officials, representatives, and employees) includes persons or entities working on their behalf or to further their interests;
- Reference to “tobacco control” includes tobacco control policies, laws, regulations, and programs, and those that are relevant or related to tobacco control (such as, but not limited to, tax, price, agriculture, and trade);
- The phrase “responsible for tobacco control” includes contributing to or being in a position to contribute to the formulation, implementation, administration, or enforcement of tobacco control policies, laws, regulations, or programs; and
- Reference to “occupational activity” includes occupational activities whether gainful or not.

6.2.3 Ensure comprehensive application of FCTC Article 5.3 implementing measures

The WHO FCTC itself provides no implementing details for giving effect to Article 5.3’s mandate that Parties must act to protect their tobacco control policies from the commercial and other vested interests of the tobacco industry. Rather, these details are provided in eight recommendations and multiple subrecommendations elaborated in the Article 5.3 Guidelines. This section highlights the provisions that should be included in legislation and/or policy to effectively implement Article 5.3. The highlighted provisions are based on the Guidelines’ recommendations and in some cases go beyond them, as strongly urged in Guidelines.

Box 6.1 In Practice: of comprehensive definitions

The Philippines

The Philippines Joint Memorandum Circular 2010-01 applies to “all government officials and employees, regardless of status, in the national or local government including government-owned and controlled corporations . . .” The definition of “tobacco industry” is a very broad definition that covers any person or entity working to further the interests of the industry.

2.0. Definition of Terms

“2.1. Tobacco Industry shall refer to organizations, entities, associations, and individuals that work for or in behalf of the tobacco industry, such as, but not limited to, tobacco manufacturers, wholesale distributors, importers of tobacco products, tobacco retailers, front groups and any other individuals or organizations, including, but not limited to lawyers, scientists, and lobbyists that work to further the interests of the tobacco industry.”

Joint Memorandum Circular 2010-01 is available at <http://www.smokefree.doh.gov.ph/uploads/attachments/199597c6480f1fbad91e61cfd8c1a3a41a5621de.pdf>.

6.2.3.1 Limiting interactions between government and the tobacco industry to only those strictly necessary for effective regulation

Interactions between the tobacco industry and government should take place only if they are strictly necessary for effective regulation of the tobacco industry or tobacco products (Article 5.3 Guidelines, Recommendation 2.1). Such interactions may take the form of meetings, communications, or other forms of engagement, whether attempted or fully carried out. Necessary tobacco industry–government interactions would include, for example, those having to do with:

- Licensure
- Compliance determinations
- Enforcement actions
- Proactive or defensive litigation
- Mandated tobacco industry reporting
- Identifying contraband tobacco products

In some jurisdictions the constitution may require government to allow all sectors of society to participate in the policy-making process. In such case, it would be important to determine whether the constitutional requirement is subordinate to the State’s treaty obligations before concluding that any policy-related interaction with the tobacco industry is required. As discussed in section 6.1.1 above, a strategy of the tobacco industry is to argue that it is a legitimate stakeholder entitled to consultation on the development of tobacco control policies. This is, however, a legal determination that must be made based on the country’s constitutional and FCTC obligations.

Where government–tobacco industry interactions are necessary for effective regulation or legally required, they should be subject to strict controls. Interactions should be carried out in a manner that ensures full transparency, discussed below, and

that avoids the creation of any perception of a partnership or collaboration. If any such perception may have been created by a necessary interaction, the government should act immediately to correct the perception.

Prohibited interactions or other forms of engagement include, for example:

- Working with the tobacco industry or requesting or accepting its assistance to draft or implement legislative, regulatory, or policy proposals, or otherwise engaging with the industry in its attempts to influence tobacco control policy (Recommendation 3.4);⁵
- Participation in or attendance at industry-initiated or industry-funded meetings, seminars, dialogues, and other forums or events;
- Allowing the tobacco industry to play any role in, including providing funding for, any activity that is properly a government function, such as any involvement in monitoring or enforcement or in any tobacco control or public health program, for example, youth education programs (Recommendations 3.2 and 6.2).

The tobacco industry pursues a wide range of interactions with government in an effort to influence and undermine effective tobacco control (WHO 2008). As a result, it is important for governments to define clear criteria for making determinations about whether an interaction is necessary and what is required for it to be properly conducted. If a national coordinating mechanism for tobacco control has been established pursuant to WHO FCTC Article 5.2(a) and is functional and effective, it may be able to play a role in guiding and overseeing these matters.

Box 6.2 **In Practice: Limiting government–tobacco industry interactions**

The Philippines

The Philippines Joint Memorandum Circular 2010-01 largely follows the Article 5.3 Guidelines language in limiting interactions to only those strictly necessary for effective regulation. An annex provides rules that are to be written into codes of conduct adopted by the various agencies, including rules applicable to meetings between government and the tobacco industry. But needs to be noted that other types of government–industry interactions that do not take the form of meetings are not addressed, and that the policy does not apply beyond the executive branch.

Section 3. Prohibitions

3.1. Unnecessary Interaction with the Tobacco Industry

“Public officials and employees shall interact with the tobacco industry only when strictly necessary for the latter’s effective regulation, supervision or control. Transparency in all interactions with the tobacco industry shall be observed. Any necessary interaction with the tobacco industry should be carried out in such a way as to avoid the creation of any perception of a real or potential partnership or cooperation resulting from or on account of such interaction. In the event the tobacco industry engages in any conduct that may create such a perception, public officials and employees shall act to prevent or correct this perception.”

Joint Memorandum Circular 2010-01 is available at <http://www.smokefree.doh.gov.ph/uploads/attachments/199597c6480f1fbad91e61cfd8c1a3a41a5621de.pdf>.

(continued)

⁵ This could be subject to any prevailing constitutional requirements that may exist.

Box 6.2 *(continued)*

Brazil

Sections II and IV of the ethical guidelines in Administrative Rule 713 establish rules of engagement with respect to interactions of CONICQ members with the tobacco industry. Section II focuses on transparency of government–tobacco industry interactions and is featured in Box 6.3 in this chapter. Section IV addresses participation in tobacco industry–sponsored events such as seminars. As with Section II, the focus of the guidelines is on transparency and disclosure, with strong transparency and disclosure requirements, rather than on limiting participation in such events.

An unofficial English translation of Administrative Rule 713 is available at <http://www.tobaccocontrolaws.org/files/live/Brazil/Brazil%20-%20Ord.%20No.%20713.pdf>. The rule is available in the original Portuguese at http://bvsm.sau.de.gov.br/bvs/sau.delegis/gm/2012/prt0713_17_04_2012.html.

6.2.3.2 Ensuring transparency in the operations of government and the tobacco industry, and in the interactions between them

Transparency of government–tobacco industry interactions, communications, and contacts. Where interactions between government and the tobacco industry are necessary, they should be required, whenever possible, to be conducted in public, such as through public hearings with advance notice, followed by public disclosure of records of the interactions (Article 5.3 Guidelines, Recommendation 2.2). Documentation and disclosure requirements should apply to all communications and contacts between government and the tobacco industry, not just meetings.⁶ Such a requirement could encourage more diligent attempts to make a correct determination about the necessity of interactions. At the very least, the documentation would provide some measure of transparency when unnecessary interactions do occur.

Many jurisdictions have “right to information” laws that could play some useful role in relation to Article 5.3. Such laws may provide the public with the right to obtain documentation of government–tobacco industry interactions. These laws typically do not require documentation to be created, however. Many jurisdictions also have lobbying laws that require all lobbyists to disclose their funding, contributions, and lobbying activities. These laws most likely would apply to lobbyists for the tobacco companies, but depending on how they are written, the laws might not require disclosure of all relevant communications, contacts, and financial and in-kind contribution. If right to information and lobbying laws exist in a given country, they should be consulted to determine their scope, whether they can be supplemented with transparency measures specific to Article 5.3 to fill any gaps, and/or whether they can provide guidance for the development of transparency measures specific to Article 5.3. In any event, these laws can be quite useful for obtaining any records that have been made until such time as Article 5.3 measures requiring both the creation and disclosure of records are enacted.

⁶ While not explicitly recommended in the Article 5.3 Guidelines, such a requirement can be inferred from the language in Recommendation 4.1, which provides that Parties should “mandate a policy on the disclosure and management of conflicts of interest” (emphasis added).

Box 6.3 In Practice: Lobbying transparency

Canada

Canada's Lobbying Act applies generally to all lobbying. It provides a good example that could be adapted and broadened to apply to government–tobacco industry interactions.

The law applies to any individual who for payment, on behalf of any person or organization, undertakes any communication or meeting arrangement with a public office holder or between a public office holder and any other person regarding:

- the development of any legislative proposal by the government or legislature;
- the introduction, passage, defeat, or amendment of any bill or resolution that is before the legislature;
- the making or amendment of any regulation;
- the development or amendment of any policy or program; or
- the awarding of any grant, contribution or other financial benefit by or on behalf of the government.
- In such cases the lobbyist must file a return within 10 days containing details that identify:
 - the subject matter of the communication undertaken or meeting sought and any other subject matter information prescribed;
 - any relevant legislative proposal, bill, resolution, regulation, policy, program, grant, contribution, financial benefit, or contract;
 - the public office holder/institution; and
 - any communication technique the individual uses or expects to use, including grass-roots communications of the undertaking.

The Commissioner of Lobbying may follow up with any key decision maker referenced in a return to verify the information provided. Monthly reports on the undertakings are also required. Records of all returns and other documents are then retained in a registry that is open to public inspection and is available online.

Lobbying Act (R.S.C., 1985, c. 44 (4th Supp.)), secs. 5, 7, 9. The text of the law is available at <http://laws-lois.justice.gc.ca/eng/acts/L-12.4/FullText.html>.

Brazil

Section II of Administrative Rule 713 imposes transparency and disclosure requirements on CONICQ members related to government–tobacco industry interactions. These include rules for written requests by the tobacco industry for a meeting with CONICQ members and a requirement for making a record of the meeting, including retroactively in the case of an unexpected meeting. The ethical guidelines do not impose a requirement for publicly held meetings with advance notice or public disclosure of the records created, as provided in the Article 5.3 Guidelines.

Section II. Interactive Practices with the Tobacco Industry

“Art. 6. CONICQ and its members must ensure the transparency of any relationship with the tobacco industry, and must see to it that the information required or transmitted by the tobacco industry is transparent and precise.

Art. 7. In situations of relationships with the tobacco industry, members of CONICQ must take into consideration the following guidelines:

- i. Requests for a meeting must be addressed to the public servant, in writing, via fax or e-mail, containing the following:
 - a. the identification of the applicant, including the address, email and phone and fax numbers;
 - b. date and time on which he wishes to be heard, and as appropriate, the reasons for urgency;
 - c. the subject to be addressed;
 - d. the interest of the applicant with regard to the matter to be addressed;
 - e. identification of companions, if any;

(continued)

Box 6.3 (continued)

- ii. The meeting shall always have an official character, and is preferably to be conducted at the main office of the agency;
- iii. Public officials responsible for receiving the tobacco industry for meetings should be accompanied by at least one other public servant; and
- iv. A specific record is to be made of the meeting, with a list of the persons present and the matters addressed.

§ 1. When a meeting occurs unexpectedly, it must be retroactively formalized, with a memorandum "for the file," the identification of the participants, the matters addressed and the decisions made.

§ 2. The minutes for the meeting are to be subsequently sent to the Executive Secretary of CONICQ, to be kept on file.

§ 3. The guidelines established in this article seek to ensure transparency in this process and guarantee the clarity of positions, pursuant to what is set forth in Art. 3 of the Code of Conduct and in Decree 4.334 of 12 August 2002."

An unofficial English translation of Administrative Rule 713 is available at <http://www.tobaccocontrolaws.org/files/live/Brazil/Brazil%20-%20Ord.%20No.%20713.pdf>. The rule is available in the original Portuguese at http://bvsm.sau.de.gov.br/bvs/sau.delegis/gm/2012/prt0713_17_04_2012.html.

Periodic tobacco industry reporting. To help ensure transparency of the tobacco industry's operations and activities, Article 5.3 implementing measures should impose comprehensive reporting requirements on the industry (Article 5.3 Guidelines, Recommendations 5, 5.2, and 5.3). Periodic reports should be required to contain information mandated under both Article 5.3 and other WHO FCTC articles, either in one report or in separate reports. They should also include, but not be limited to, information that government needs in order to:

- Raise public awareness about tobacco-related harms and tobacco industry operations pursuant to WHO FCTC Article 12 and the Article 5.3 Guidelines, Recommendation 1;
- Monitor the tobacco industry's expenditures and other information related to tobacco advertising, promotion, and sponsorship not banned or not yet banned, as required by WHO FCTC Article 13.4(d), as provided in the Article 13 Guidelines (WHO 2009b); and
- Understand the contents and emissions of tobacco products, as required by WHO FCTC Article 10, in order to inform product regulation.

Disclosure of information that will help the government recognize tobacco industry tactics for undermining and interfering with tobacco control policies should also be required. This includes, for example, disclosure of:

- The identities of, payments to, and activities of lobbyists, front groups, and others working to further the interests of the tobacco industry with respect to tobacco control policy development or implementation;
- The identities of, payments to, and activities of scientists, economists, trade experts, and other individuals and entities who conduct research, publish papers, or undertake other activities that support the industry's positions;
- Policy-related conferences, seminars, and other forums for which the tobacco industry provided funding or was otherwise involved in planning, organizing, or execution;

- Interactions, contacts, and communications with public office holders; and
- Other industry tactics, such as those detailed by WHO (2000, 2008, 2012).

The legislation template in Chapter 9 of this manual contains a comprehensive list of information and items that might be required in tobacco industry reports. The government should be required to make information in these reports readily available to the public (Article 5.3 Guidelines, Recommendation 5.5). Certain information may be excluded from the public access requirement, however, such as information protected by law and misleading or promotional information that may be contained in the reports.

Registration of tobacco industry lobbyists. The Article 5.3 Guidelines provide that disclosure or registration of tobacco industry entities, affiliated organizations, and individuals acting on their behalf, including lobbyists, should be required (Recommendation 5.3). As mentioned, any generally applicable lobbying registration law that may exist in a given country likely will cover tobacco industry lobbyists. Such a law should be checked to see whether any additional legal measures are required.

Box 6.4 In Practice: Registration

United States

The Lobbying Disclosure Act of 1995 requires entities with one or more lobbyists and organizations employing in-house lobbyists to file a registration with the Secretary of the Senate or the Clerk of the US House of Representatives no later than 45 days after a lobbyist first makes a lobbying contact or is employed or retained to make a lobbying contact, subject to meeting or exceeding specified threshold lobbying income or expense amounts.

The Lobbying Disclosure Act is available at <http://lobbyingdisclosure.house.gov/>.

Other transparency requirements. Other documentation and disclosure requirements on the part of government and the tobacco industry arise in the context of preventing conflicts of interest, discussed below.

6.2.3.3 Preventing and managing tobacco-related conflicts of interest

Tobacco-related conflicts of interest within government can arise in a variety of circumstances, including (but not limited to) undertaking current, recent past, or near future tobacco-related occupational activities; holding shares of tobacco company stock; solicitation or acceptance, by public office holders, of contributions, gifts, favors, or perks from the tobacco industry; and solicitation or acceptance, by government institutions or bodies, of contributions from the tobacco industry. Conflict of interest would not apply to payments that are mandated by law, such as (but not limited to) tax payments or payments from legal settlements. In addition to enacting measures that prohibit conflicts of interest, governments should impose transparency requirements to help prevent conflicts of interest and reveal them if they occur; outline criteria for determining the circumstances under which conflicts of interest are considered to exist; and establish specific safeguards to protect against them and remedy them if they do arise (Article 5.3 Guidelines, Recommendation 4).

The WHO FCTC and recommendations in the Article 5.3 Guidelines call for the following measures, at a minimum, to prevent and address tobacco-related conflicts of interest:

- Prohibit tobacco industry representatives as voting members or observers on government bodies, boards, or commissions with responsibility for tobacco control, and require disclosure of any conflict of interest or potential conflict of interest (e.g., occupational activity with the tobacco industry, tobacco stock holdings, or tobacco-related business relationships or other interests) by persons under consideration for such representation (Recommendation 4.8);
- Prohibit tobacco industry representation on delegations to meetings of the Conference of the Parties, its subsidiary bodies, or any other COP-established body (Recommendation 4.9), or on any other international delegation where the scope of work includes policies or issues involving, relevant to, or related to tobacco control,⁷ and require disclosure of any conflict of interest by persons under consideration for such representation (Recommendation 4.9);
- Require applicants for government employment or service, including contract tenderers, to disclose any conflicts of interest (Recommendations 4.5 and 4.6);
- Prohibit public office holders from engaging in occupational activities, tobacco holdings, or other specified relationships or activities with the tobacco industry while serving in government in any capacity in a position with responsibility for tobacco control Recommendation 4.8);
- Impose disclosure requirements for public office holders who intend to undertake post-government occupational activity with the tobacco industry during a specified time after leaving government service (Recommendation 4.4), and prohibit such activity during the covered period⁸;
- Prohibit the tobacco industry from making or offering payments, services, gifts, favors, or perquisites to any public office holder, whether or not that person has responsibility for tobacco control (WHO FCTC Articles 13.2 and 13.4(f)), prohibit acceptance of any such offers (Recommendation 4.10), and require disclosure of any such offers and/or acceptances if they do occur⁹;
- Prohibit the tobacco industry from making or offering any contributions to government institutions or bodies (WHO FCTC Articles 13.2 and 13.4(f)),¹⁰ prohibit acceptance of any such offers (Recommendation 6.4),¹¹ and require disclosure of any such offers and/or acceptances if they do occur;
- Prohibit the tobacco industry from making or offering any contributions to political parties, candidates, or campaigns, prohibit acceptance of any such contributions, and require disclosure of any such offers/and or acceptances if they do occur (Recommendation 4.11); and
- Prohibit government investment or other financial interest in any business in the tobacco industry, and require disclosure and divestiture of any such investments (Recommendation 7.2).

⁷ Although the Article 5.3 Guidelines only address delegations to the COP, consideration should be given to including delegations to other international forums relevant to tobacco control.

⁸ Although Recommendation 4.4 only speaks of disclosure, a prohibition on gainful activity with the tobacco industry within a specified period after leaving government service can be inferred from the language in Recommendation 4.1, which provides that Parties should “mandate a policy on the disclosure and management of conflicts of interest” (emphasis added).

⁹ The Guidelines do not specifically require disclosure of offers or acceptance of payments, services, gifts, etc. from the tobacco industry, but such a requirement could be inferred from Guidelines Recommendation 4.1, which provides that Parties should “mandate a policy on the disclosure and management of conflicts of interest . . .”

¹⁰ The offer or provision of contributions to government would fall under the prohibition on sponsorships.

¹¹ This would not apply to compensations due to legal settlements, to those mandated by law, or to those arising from legally binding and enforceable agreements.

Box 6.5

In Practice: Preventing and managing conflicts of interest caused by the “revolving door”

United Nations Convention Against Corruption (UNCAC)

Article 12(2)(e) of the UNCAC provides for imposing restrictions, for a reasonable period of time after leaving government service, on the professional and occupational activities of former public officials (defined broadly to include any persons who perform a public function or provide a public service) where the activities relate directly to the functions they held or supervised during their government tenure.

The UNCAC is available at http://www.unodc.org/pdf/crime/convention_corruption/signing/Convention-e.pdf.

Canada

Canada's Conflict of Interest Code is an example of a domestic law containing a prohibition on public office holders consistent with the UNCAC provisions noted above. The Code (sec. 28) prohibits public office holders, within one year after leaving office (two years for ministers), from accepting services contracts, appointment to a board of directors, or employment with an entity with which they had direct and significant official dealings during the period of one year immediately prior to the termination of their service in public office.

The Conflict of Interest Code is available at <http://pco-bcp.gc.ca/index.asp?lang=eng&page=information&sub=publications&doc=c ode/code-conflict-eng.htm#cataloguing>.

Brazil

Administrative Rule 713 addresses the management of conflicts of interest for the members of CONICQ in sections I and V of the ethical guidelines. Conflicts of interest based on property, business, and relationship interests are prohibited. The ethical guidelines emphasize conflict disclosure and removal from CONICQ membership during the period in which the conflict exists, recusal from policy debates and decisions, and refraining from consulting with the tobacco industry while serving CONICQ. A four-month cooling-off period after leaving CONICQ is recommended before undertaking employment or consulting with the tobacco industry.

Section I. Conflicts of Interest

“Art. 3. Representatives of CONICQ must avoid conflicts of interest and, should they arise, must declare their existence, pursuant to the form indicated in sub-paragraph XIII of Art. 11 of Administrative Rule nº 1.083/GM/MS, 12 May 2011.

Sole paragraph. The following situations, among others, may give rise to conflicts of interest:

- i. property interests;
- ii. family relationships;
- iii. friendship; and
- iv. professional relationships.”

“Art. 4. With the aim of preventing situations that have the potential to give rise to conflicts of interest, CONICQ members must do the following:

- i. Cease to act as a member of CONICQ for as long as the situation likely to give rise to conflicts of interest persists; and
- ii. In the event of a specific and transitory conflict of interest, communicate its occurrence to one's immediate superior and to the Executive-Secretary of CONICQ, abstaining from taking part in the debate on the matter and from voting in any possible group decisions.”

(continued)

Box 6.5 *(continued)*

“Art. 5. In relationships with government agencies, institutions and public servants, members of CONICQ must explain the existence of any and all private interests or circumstances that may give rise to a conflict of interest, whether it is apparent, potential or actual.

Sole paragraph. For the purposes of what is stated in the ‘heading,’ members of CONICQ should declare themselves disqualified from taking part in any decision making process.”

Section V. Employment Proposals

“Art. 13. Members of CONICQ may not provide, formally or informally, consulting services for the tobacco industry or its affiliates, in the face of potential characterization as a conflict of interest.

Art. 14. It is recommended that public officials refrain from employment, including consulting activities, that are incompatible with the duties they performed at CONICQ, for a period of 4 (four) months, counting from the date of their ceasing to function as a member of CONICQ.”

An unofficial English translation of Administrative Rule 713 is available at <http://www.tobaccocontrolaws.org/files/live/Brazil/Brazil%20-%20Ord.%20No.%20713.pdf>. The rule is available in the original Portuguese at http://bvsmms.saude.gov.br/bvs/saudelegis/gm/2012/prt0713_17_04_2012.html.

6.2.3.4 Prohibiting unenforceable agreements and acceptance of voluntary codes of conduct

By establishing its own voluntary codes and agreements with governments, such as memoranda of understanding, the tobacco industry has been able to successfully argue that government regulations are not necessary. Experience and scientific evidence had demonstrated the ineffectiveness of such measures to advance tobacco control. According to an internal Philip Morris document, these codes “can be used as both a lobbying lever and an argument against not [sic] introducing formal legislation” (Philip Morris Asia 1994). Article 5.3 implementing measures should prohibit acceptance of voluntary, unenforceable agreements in place of legally binding and enforceable tobacco control measures (Article 5.3 Guidelines, Recommendations 3.1 and 3.3).

6.2.3.5 Prohibiting preferential treatment of the tobacco industry

Implementing measures should prohibit the government from granting any kind of special assistance, incentives, privileges, or benefits to tobacco companies to establish or run their businesses, including preferential tax treatment and subsidies (Article 5.3 Guidelines, Recommendations 7.1 and 7.3). The Article 5.3 Guidelines remind Parties that they should respect their commitments to tobacco control, suggesting that any such incentives, privileges, or benefits granted, even if applied to businesses at large, should not apply in the case of the tobacco industry (Recommendation 7).

6.2.3.6 Requiring the government to raise awareness about tobacco-related harms, the operations of the tobacco industry, and its interference tactics

Awareness-raising campaigns can be carried out in conjunction with WHO FCTC Article 12 (on education, communication, training, and public awareness). Such campaigns should target all branches of government and the public, informing them, at a minimum, about:

- The wide-ranging tobacco-related harms and risks;

- Front groups the tobacco industry uses to advance its influence and interference tactics; and
- Tobacco industry tactics for undermining public health and tobacco control policies, especially the tobacco industry's commercially driven use of "corporate social responsibility" programs and activities, undertaken to improve its image and to prevent, delay, and undermine effective tobacco control policies and programs (Oliver 1998).

While media and public awareness campaigns highlighting the role of the industry have been successful, they could be better developed by making use of the information that must be disclosed to government under Article 5.3. This information would enrich public and governmental officials' understanding of how far the industry is willing to go to subvert the role of government and manipulate public opinion in order to continue manufacturing and marketing its deadly and addictive products.

6.2.3.7 Requiring government to denormalize and regulate the industry's "corporate social responsibility" activities

The tobacco industry's "corporate social responsibility" (CSR) programs and activities, which fall under the FCTC definition of "tobacco sponsorship," are also discussed in Chapter 5 of this manual. All tobacco industry CSR contributions should be prohibited pursuant to WHO FCTC Article 13 and Article 5.3. This prohibition should apply to contributions both to government bodies and to nongovernmental entities, such as community, and humanitarian, and other groups.

Tobacco industry contributions to government are a documented strategy undertaken to influence tobacco control policy, as highlighted in Chapter 5, section 5.1.1.4. Such contributions also create a conflict of interest, and their acceptance by government could be perceived as signaling a government–tobacco industry partnership and government endorsement of the company making the contribution. In addition, government acceptance of tobacco industry contributions would imply underlying unnecessary government–tobacco industry interactions and would otherwise run afoul of both WHO FCTC Article 5.5 and Article 13 and their Guidelines (Article 5.3 Guidelines, Recommendation 6.4; Article 13 Guidelines, Recommendation following para. 28).

Contributions to nongovernmental entities should be prohibited as part of a comprehensive tobacco sponsorship ban under WHO FCTC Article 13, because the aim, effect, or likely effect of such a contribution is to promote a tobacco product or tobacco use either directly or indirectly (WHO 2009b), as well as to gain legitimacy for the tobacco industry in the eyes of the public and the government. In the event tobacco sponsorships in any given jurisdiction are not comprehensively banned, or are not yet banned, regulation of tobacco industry CSR should, at a minimum, prohibit public disclosure of any tobacco industry CSR activities and funding, except to the extent this information is legally required to be reported, such as in annual reports (Article 5.3 Guidelines, Recommendation 6.3).

6.2.3.8 Applying all of the above measures equally in the case of State-owned tobacco industries

Even though there are no State-owned tobacco companies in Latin America and the Caribbean, it is worth noting that the above measures apply to government-owned tobacco businesses. Where tobacco companies are State-owned, the Article 5.3 Guidelines provide that implementing measures should require, at a minimum, a separation of the regulatory functions related to tobacco control policy development and implementation from those related to overseeing or managing the tobacco business (Recommendation 8.2). In addition, all other requirements and prohibitions contained in the Article 5.3 Guidelines recommendations should apply equally to any State-owned tobacco industry.¹²

¹² This would be subject to the exception noted in Recommendation 4.7 with regard to government financial interests in the tobacco industry.

6.2.4 Impose legal duties of compliance

Legal duties of compliance should be imposed on all businesses in the tobacco industry and all lobbyists, trade groups, front groups, and other entities and individuals working on the industry's behalf. On the government side, most duties of compliance will only apply to government institutions, bodies, and public office holders with responsibility for tobacco control. Some duties of compliance should apply government-wide, however. An example would be the prohibitions on accepting contributions and granting preferential treatment to the tobacco industry.

6.2.5 Provide effective enforcement mechanisms

The Article 5.3 Guidelines provide that Parties should put in place enforcement mechanisms or, to the extent possible, use existing enforcement mechanisms to meet their obligations under Article 5.3 and its Guidelines. Duties of any oversight body or bodies charged with implementing Article 5.3 might include: providing regulations and/or policies and guidelines for implementing the Article 5.3 measures, especially the prohibitions against unnecessary government–tobacco industry interactions and conflicts of interest; monitoring and investigating compliance; receiving required disclosures and reports and making them publically accessible; and similar matters.

Many jurisdictions have established national tobacco control coordinating mechanisms pursuant to WHO FCTC Article 5.2(a). These bodies may be able to serve an oversight function with regard to Article 5.3 implementation if they have independent status that prevents them from being beholden to any one ministry or branch of government, if they have clear legal authority to conduct oversight activities and investigations across all of government, and if they have the technical, human, and financial capacity to undertake such a role.

Many jurisdictions also have established anti-corruption commissions pursuant to the United Nations Convention against Corruption. Where they have been established, these commissions may already have responsibility for some portion of Article 5.3 implementing measures that have been enacted or adopted, especially those addressing contributions, gifts, and perks to public office holders and other conflicts of interest. Otherwise, leading anti-corruption commissions, human rights commissions, and similar bodies may be a source of guidance for establishing an overarching Article 5.3 implementing body, with appropriate adaptation.

If it is not possible for one overarching body to monitor and investigate for compliance, develop regulations, policies, and/or guidelines, receive required disclosures and reports, and fulfill other duties, it may be necessary to create multisectoral committees or bodies and/or structures within each branch of government (WHO 2012a).

Box 6.6 In Practice: Oversight body

Hong Kong

Hong Kong's Independent Commission Against Corruption Ordinance creates the Independent Commission Against Corruption (ICAC). The ICAC is empowered with a strong, clear, and effective legal framework and has three functional departments: investigation, prevention, and community relations. The investigation department investigates alleged law violations and refers violations for prosecution. The prevention department helps identify strategies for preventing corruption, funds studies of corruption, conducts seminars, and regularly reviews laws, suggesting revisions on the basis of conclusions from its studies. The community relations department builds awareness of the dangers of corruption through public campaigns and publicizes the investigation and apprehension of corrupt officials.

The ICAC submits regular reports following clear procedural guidelines to Hong Kong's Special Regional Administrator, the ICAC director, and three oversight committees. Each of these oversight committees corresponds to the three ICAC departments. In particular, the operations review committee examines reports of investigations and of specified cases, enforcing accountability through its supervisory and advisory role.

The ICAC homepage is at http://www.icac.org.hk/en/about_icac/os/index.html.

Also see John R. Heilbrunn, *Anti-Corruption Commissions: Panacea or Real Medicine to Fight Corruption?* (Washington, DC: World Bank, 2004). Available at <http://siteresources.worldbank.org/WBI/Resources/wbi37234Heilbrunn.pdf>.

6.2.6 Provide a range of deterrents and proportionate penalties

The Article 5.3 Guidelines are silent on sanctions for noncompliance with Article 5.3 implementing measures. For Article 5.3 measures enacted by law, the full range of civil and criminal penalties, as recommended in the Guidelines to Articles 8, 11, and 13, should apply. For measures that take the form of policies governing public sector institutions and bodies and public office holders, employment disciplinary measures may be the applicable penalties, unless additional penalties can be written into employment agreements. It may also be the case that applicable penalties already exist in another law, such as a corruption or conflict of interest code or lobbying law. As is the case with other WHO FCTC articles, sanctions for violations should be sufficiently large to deter violations, they should be proportionate to the nature and seriousness of the violation and the duties of the violator, and they should increase for repeat violations.

6.2.7 Provide a role for civil society

The Article 5.3 Guidelines encourage Parties to establish mechanisms for complaint procedures, such as an ombudsman system, and to provide protection to persons who report legal violations or other wrongdoing. Civil society can play an important role in the creation and monitoring of an ombuds office or other complaint mechanism. Additionally, civil society organizations can play essential roles in helping raise awareness about tobacco industry interference and tracking reported information and disclosures required by Article 5.3 implementing measures, using information available through the transparency measures established to hold duty bearers accountable. As with other FCTC articles, members of the public and civil society organizations should be given the authority to initiate complaints and legal action to compel compliance where this is possible.

6.2.8 Grant broad regulatory power to the appropriate authority to address implementation details

The appropriate authority or authorities should be granted power to address a broad range of matters in regulations and/or policies, including, but not limited to:

- Criteria for determining whether a government–tobacco industry interaction is necessary and how any necessary interaction must be conducted;
- Any additional content to be included in mandated tobacco industry reports, and the form, manner, and frequency of the reports;
- Additional transparency requirements;
- Requirements for disclosure;
- Requirements for the prevention and management of tobacco-related conflicts of interest;
- Procedures and requirements for making mandated disclosures and reports readily accessible to the public;
- Procedures to prevent government–tobacco industry partnerships and nonenforceable agreements; and
- Any other necessary or appropriate matter.

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Additional resources

This section lists additional publications and other resources to complement the information in Chapter 6 and its references. More examples of tobacco industry interference in specific areas are included in each of the chapters in this manual.

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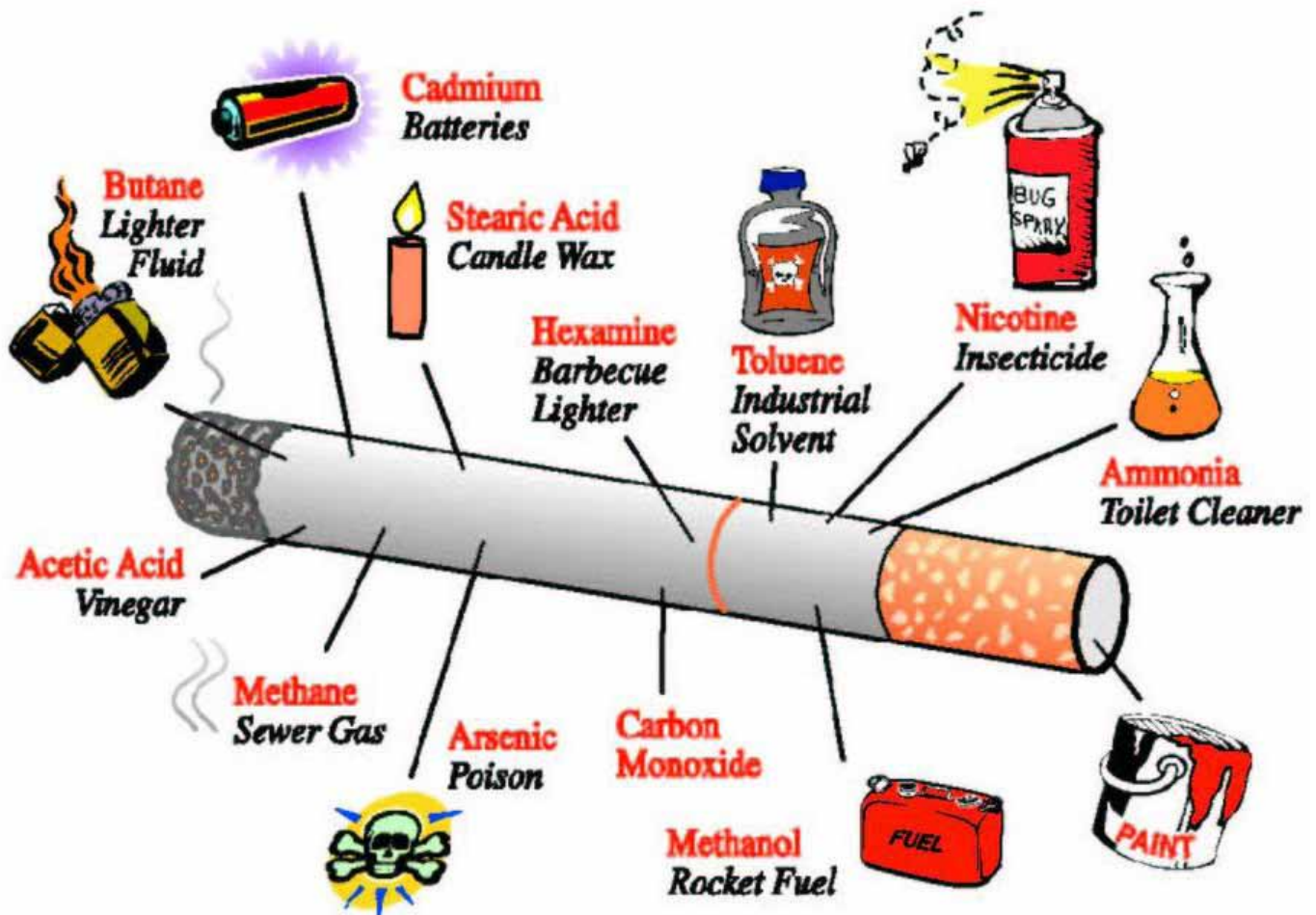
The Library of the University of California at San Francisco (UCSF) is a repository for a large collection of tobacco industry materials. The UCSF Tobacco Control Archives homepage is at

<http://www.library.ucsf.edu/tobacco>. Of special note is Research into Tobacco Industry Activity, <http://www.library.ucsf.edu/tobacco/activity>.

The WHO Tobacco Free Initiative maintains a tobacco industry monitoring database at <http://www.who.int/tobacco/industry/monitoring/en/index.html>.

Chapter 7

Regulation of the Contents of Tobacco Products and of the Reporting of Constituents and Emissions



7. Regulation of the Contents of Tobacco Products and of the Reporting of Constituents and Emissions

7.1 Background

7.1.1 Evidence and rationale

Cigarettes and other tobacco products are highly engineered products (WHO 2010a). Their toxicity and addictiveness are related to their contents, designs, and emissions. The contents and designs affect the consumer appeal or attractiveness of the product and thus have a direct bearing on the initiation and persistence of tobacco use (Talhout, Opperhuizen, and van Amsterdam 2006; Wayne and Connolly 2004). The tobacco industry has a long history of manipulating contents, designs, and other factors related to consumer appeal in order to increase tobacco use and dependence (Rabinoff et al. 2007). From the perspective of public health, there is no justification for permitting the use of ingredients that help make tobacco products attractive, such as added flavoring or coloring agents or aromas. Regulation of contents and emissions is consistent with other measures of the World Health Organization Framework Convention on Tobacco Control (WHO 2003; hereafter, WHO FCTC) that seek to reduce the attractiveness of tobacco products, such as measures related to packaging and to advertising, promotion, and sponsorship (WHO FCTC Articles 11 and 13).

Despite the fact that cigarettes kill a third to a half of regular users if used as intended by the manufacturers, cigarettes and other tobacco products have not been required to meet the health and safety standards that are applied to other consumer products, including food, beverages, and medicines. Regulation of tobacco products has the potential to contribute to reducing tobacco-attributable disease and premature death by reducing the appeal of tobacco products, reducing their addictiveness (or dependence liability), and reducing their overall toxicity. In addition, regulation that requires testing and disclosure of test results to health authorities and the public serves to provide more complete information on tobacco products' potential health hazards, which in turn can inform decision making surrounding tobacco use.

Regulation that covers the contents and emissions of tobacco products, with requirements for testing and disclosure of test results, should be viewed as an important element in a comprehensive tobacco control strategy and is mandated by the WHO FCTC in Articles 9 and 10. WHO FCTC Article 9 directs the Conference of the Parties (COP) to propose guidelines for testing, measuring, and regulating the contents and emissions of tobacco products. Parties are then required to adopt and implement effective measures to carry out these tasks. WHO FCTC Article 10 requires Parties to adopt effective measures requiring tobacco product manufacturers and importers to disclose information on the contents and emissions of tobacco products to government authorities, and requiring public disclosure of information on constituents and emissions.

A set of partial guidelines for the implementation of Articles 9 and 10 was adopted by the Parties at the fourth and fifth sessions of the COP (WHO 2010b; hereafter, Articles 9 and 10 Partial Guidelines). These primarily address the regulation of tobacco products to reduce their palatability and attractiveness and the disclosure of ingredients to governmental authorities. Additional sections of the Articles 9 and 10 Guidelines will be proposed in a step-by-step process.

The Guidelines define the term “ingredients” as follows: “tobacco, components (e.g. paper, filter), including materials used to manufacture those components, additives, processing aids, residual substances found in tobacco (following storage and processing), and substances that migrate from the packaging material into the product (contaminants are not part of the ingredients).” The Guidelines also stipulate that information on ingredients used in the manufacture of tobacco products should be disclosed to the government at specified intervals, by product type and for each brand within a brand category, as opposed to disclosure of a single list of ingredients or the maximum quantity or total quantity of each ingredient.

7.1.2 Regional situation

Globally, there is limited country experience to date with implementing measures that regulate the contents, designs, and emissions of tobacco products. In many regions, including the Region of the Americas, the task is made more difficult by the amount of technical and financial resources required for tobacco product regulation.

Nonetheless, some relevant legislation is in place in several countries in the Region. For example, Canada, the United States, and Brazil have laws at the national or subnational level addressing, among other things, the attractiveness of tobacco products. Canada and the United States also regulate the ignition propensity of tobacco products. Canada amended its Tobacco Act in 2009 to ban the use of most flavoring agents in the manufacture of cigarettes, little cigars, and blunt wraps. Other countries, especially in Latin America, have begun to advance in this area as well. Some countries, including Costa Rica, Ecuador, and Uruguay, have at least granted authority to the national health authority to regulate tobacco products and impose some restrictions on additives.

Of particular note is the achievement of Brazil in banning all additives—except sugar—starting in 2016.¹ Continuous and updated regulation of tobacco products in Brazil is necessary given the frequent launching of new products onto the market. In November 2010, Brazil’s National Health Surveillance Agency (ANVISA) published draft regulations banning the use of all additives in tobacco, including additives such as sugar and other sweeteners, flavors, aromatizers, spices, seasonings, caffeine, and anything else that imparts aroma or flavor to the product. The draft provisions followed the normal procedure for adoption of regulations, including a public comment period and public hearings. As a result of tobacco industry pressure, the use of sugar during the tobacco curing process was authorized, conditional upon the industry disclosing such information to the regulatory agency, ANVISA. The creation of a working group to further study how to regulate sugar has been discussed.

Other countries in the Region have passed legislation stipulating maximum levels for nicotine, tar, and other ingredients. So far, there is no scientific evidence to support any limit as safer from the public health perspective, however.

7.2 Strategies against effective regulation of tobacco products

7.2.1 Countering tobacco industry arguments

A number of countries, including several in Latin America, have encountered difficulties in effectively implementing WHO FCTC Articles 9 and 10 due to tobacco industry pressure. In Brazil, for example, the tobacco industry opposed ANVISA’s proposed regulations, using three main arguments that will be discussed here.

¹ See ANVISA Resolution RDC No. 14 of 15 March 2012. An unofficial English translation is available at http://www.tobaccocontrolaws.org/files/live/Brazil/Brazil%20-%20RDC%20No.%2014_2012.pdf.

7.2.1.1 Argument: Banning additives will drastically increase illicit trade

The tobacco industry argues that banning additives will result in an increase in illicit trade in tobacco products, which in turn will hamper regulation and increase consumption of these products (Fundação Getulio Vargas 2011). There is no evidence to support this allegation. A study by the World Bank (1999) found that the level of illicit trade in tobacco products tends to increase in tandem with the general level of corruption in a country.

7.2.1.2 Argument: Regulation of tobacco products will result in lost jobs

The tobacco industry argues that regulation of the contents of tobacco products will result in lost jobs and negative effects on local economies. This has motivated some tobacco growers to act as an industry front group against tobacco product regulation. However, the above-mentioned World Bank study also found that the potential impact of tobacco control policies on jobs and the economy was often greatly overstated. It found that in most countries, except for a few agrarian countries, there would be no net loss of jobs. Tobacco-dependent economies would have years to adjust to declining demand. Moreover, there would be potential job gains if tobacco consumption fell, because money spent on tobacco would be spent on other goods and services, generating more jobs (World Bank 1999: 67–68). It should be kept in mind that the regulation of additives or other contents does not ban any tobacco products, but only regulates the use of additives. Tobacco manufacturers can modify or reformulate tobacco products to meet new regulatory requirements.

7.2.1.3 Argument: Sugar and other additives have no effect on the general toxicity or addictiveness of tobacco products

The industry argues that sugars and other additives have no effect on the toxicity or addictiveness of cigarettes (Fundação Getulio Vargas 2011; Roemer et al. 2012). From a public health perspective, the pertinent issue is not whether sugar makes cigarettes more toxic or addictive, but that sugar makes tobacco products more attractive and palatable to first-time users, who are usually young people (INCA/PAHO 2010).

7.2.1.4 Argument: Banning the addition of sugar will mean that certain types of tobacco can no longer be used, causing financial harm to tobacco growers

Most of the cigarettes sold in the world are either flue-cured (or Virginia) tobacco cigarettes or American-blend cigarettes. The tobacco industry argues that they cannot make American-blend cigarettes without sugar or other additives, but according to industry internal documents, this is not true (Brown & Williamson 1994). American-blend cigarettes usually contain flue-cured tobacco, Burley tobacco, and, often, Oriental tobacco, as well as a large quantity of additives.

Because of the way it is cured, Burley tobacco contains very low levels of sugar, while flue-cured tobacco is higher in natural sugars.

The industry claims that if the addition of sugar is no longer allowed, manufacturers will use only flue-cured tobacco, resulting in lower demand for Burley tobacco and putting growers of this tobacco out of business. The experience of Canada suggests otherwise, however, as the marketing of American-blend cigarettes continued in that country even after the use of sugars (except for starch) was banned in 2010.

7.2.2 Experiences with legal challenges to product regulation

In June 2009, the United States passed the Family Smoking Prevention and Tobacco Control Act. One of the new provisions under this law was a total ban on the production and sale of flavored cigarettes, except for menthol cigarettes (which are

domestically produced). Indonesia, the world's main producer of clove cigarettes, challenged this provision, as clove cigarettes could no longer be shipped to the US market. Claiming that the ban on clove cigarettes was both discriminatory and unnecessary, Indonesia requested the establishment of a World Trade Organization (WTO) panel to determine whether the US law violated the Agreement on Technical Barriers to Trade and the General Agreement on Tariffs and Trade (GATT 1994).

The WTO panel rejected the argument that the prohibition on clove cigarettes was not necessary for protecting public health. However, it determined that the United States had treated products of a WTO member country, namely Indonesia, less favorably than its own domestic products. The panel concluded that menthol and clove cigarettes are "similar products" in terms of the objective of the regulation and that both types of cigarette have a flavor that reduces the harshness of tobacco and attracts young people. The US government agreed to implement recommendations from the panel in a manner that protects public health and respects its WTO obligations, but stated that it would need a reasonable period of time to do so. The agreed-upon period of 15 months will expire on 24 July 2013.²

7.3 Implementing WHO FCTC Articles 9 and 10 at the domestic level: Drafting effective measures on tobacco product regulation

The science is still evolving to support practical applications for regulating the addictiveness and the carcinogenic and toxic properties of tobacco products to serve individual and public health goals. As already noted, the Partial Guidelines for the implementation of Articles 9 and 10 are being developed in a stepwise approach, in tandem with advancing scientific knowledge and country experience. Continued progress at the country level depends on adequate human and financial resources as well as on specialized technical and scientific expertise. Under the circumstances, governments may wish to concentrate first on enacting and implementing other effective measures for tobacco control embodied in several other WHO FCTC articles, primarily Articles 5.3, 8, 11, and 13, while providing broad regulatory authority in legislation for product regulation that can be exercised at the appropriate time. This is the approach taken in the legislative template in Chapter 9.

There are, however, areas of product regulation where there is already some country experience. This experience was taken into account in shaping the Articles 9 and 10 Partial Guidelines adopted by the COP. The Partial Guidelines recommend:

- Prohibiting or restricting ingredients that may be used to increase the palatability of tobacco products;
- Prohibiting or restricting ingredients that have coloring properties (except those used for tax marking and for health warnings);
- Prohibiting ingredients in tobacco products that may create the impression that they have a health benefit; and
- Prohibiting ingredients associated with energy and vitality, such as stimulant compounds.

To date, several jurisdictions have taken steps to regulate the ingredients that may increase the attractiveness of tobacco products; they include, in addition to Brazil as noted above, Australia, Canada, France, Singapore, Thailand, and the United States. Their experiences can be instructive for jurisdictions that are considering enacting measures for this purpose. In

² A summary of the dispute settlement is available on the WTO website at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds406_e.htm.

addition, some jurisdictions, such as the European Union, South Africa,³ Canada,⁴ Australia,⁵ and all US states,⁶ have enacted regulations that require cigarettes to meet reduced ignition propensity (RIP) standards in order to reduce fire risk.

The COP, at its fourth session, mandated that the working group on Articles 9 and 10 examine the regulation of cigarette ignition propensity for possible insertion in the Guidelines to these articles. At the fifth COP, the Parties adopted guidelines on reduced ignition propensity.

At present, the best approach to legislation on product regulation and disclosure is to provide the Ministry of Health or other appropriate agency with authority to regulate tobacco products, including specifying the testing methods and requiring manufacturers and importers to report on product contents and emissions using prescribed testing methods. If program funding is limited, it would also be important to establish the financing mechanism for these functions, since implementing and administering effective tobacco product regulation typically requires the allocation of significant resources.

Health authorities should ensure that laboratories used by tobacco product manufacturers and importers to test products pursuant to product regulation and disclosure requirements follow appropriate testing methods and are able to meet international competence standards. It is therefore recommended that preliminary measures be taken to ensure laboratory capacity in the Region, with a recognized accreditation body that can accredit laboratories performing tobacco testing to ensure that they meet international laboratory competency standards for the purposes of testing and disclosure to the government (Articles 9 and 10 Partial Guidelines).

Box 7.1 provides examples of legislation from different countries. As discussed in Chapter 3, perfectly written laws are rare, but these examples approach the standard. Fully incorporating WHO FCTC Articles 9 and 10 and their Guidelines provides the best means of ensuring best-practice legislation.

³ Regulations Relating to the Standard for Manufacturing of Reduced Ignition Propensity (RIP) Cigarettes, Government Notice No. R. 429, 16 May 2011.

⁴ Cigarette Ignition Propensity Regulations (2005). Available at: <http://www.gazette.gc.ca/archives/p2/2005/2005-06-29/html/sor-dors178-eng.html>.

⁵ Trade Practices (Consumer Product Safety Standard) (Reduced Fire Risk Cigarettes) Regulations 2008. Available at: <http://www.comlaw.gov.au/Details/F2009C00252>.

⁶ Examples include Colorado (24-33.5-1214,C.R.S.); New Hampshire (NH RSA 339-F); Ohio (37 Revised Ohio Code 3739); Oregon (Oregon Administrative Rules, Dept. of Oregon State Police, Office of State Fire Marshal, Division 35); and New York (Fire Safety Standards for Cigarettes, Part 429, Chapter XII, Title 19 of the New York Code of Rules and Regulations, <http://government.westlaw.com/linkedslice/default.asp?SP=nycrr-1000>).

Box 7.1

In Practice: Examples of legislation regulating the contents of tobacco products and information disclosure

Uruguay

Law 18.256 establishes reporting requirements and grants the Ministry of Public Health the authority to ban the use of additives or other substances that increase consumer harm or risk. The second paragraph of the excerpt below requires manufacturers and importers to go directly to the “principal communications media” in the country and disclose information on toxins and emissions. However, it is preferable that the reports go to the ministry, which would then be responsible for disclosure to the public. This way, the Ministry of Public Health can ensure that the information released is not misleading or promotional in nature.

“Article 6. (Information). Tobacco product manufacturers and importers must render an account to the Ministry of Public Health, under the conditions established by regulation, of all the information judged necessary concerning the tobacco products’ contents and emissions.

Manufacturers and importers of tobacco products sold in the country are required to disclose information in the principal communications media, every three months, about the toxic components of tobacco products and the emissions they can produce.

Regulations issued by the Executive Branch, based on guidelines recommended by the Conference of the Parties (Article 9 of the WHO Framework Convention on Tobacco Control), will establish the rules on the circulation of information concerning additives and substances incorporated into tobacco and their effects on users’ health. Regulations may also ban the use of additives or substances that increase the damage or risk to the consumer of such products.”

An unofficial English translation of Law 18.256 is available at <http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Law%20No.%2018.256.pdf>. The law is available in the original Spanish at <http://www.parlamento.gub.uy/leyes/ AccesoTextoLey.asp?Ley=18256&Anchor>. Excerpt above is an unofficial translation by the authors.

Regulations for Law 18.256 are contained in Ministerial Decree 284/2008. The regulations establish some reporting requirements and elaborate on public disclosure of the reported information. In addition, the regulations define “additive” and prohibit ammonia as an additive in tobacco products.

“Article 6: Companies doing preparation and exportation must file a sworn statement with the Ministry of Public Health every quarter that is directed to the National Tobacco Control Program of the Office of Secretary of State in which a report is given on the presence of the toxic substances established by the Ministry of Public Health. Dissemination of the information mentioned earlier will be made through print publications in two newspapers in the capital.

An ‘additive’ is defined as any substance, with the exception of tobacco leaves or another natural and unprocessed part of the tobacco plant, that is used in preparing a tobacco product and that is present in the final product, even when its form has been altered, including paper, filters, print, and adhesives. The products included in Article 1 of the Decree may not contain any ammonia.”

An unofficial English translation of Decree 284/2008 is available at http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Decree%20No.%20284_008.pdf. The decree is available in the original Spanish at http://archivo.presidencia.gub.uy/_web/ decretos/2008/06/CM496__00001.PDF. Excerpt above is an unofficial translation by the authors.

(continued)

Box 7.1 *(continued)*

Ecuador

The Organic Law for the Regulation and Control of Tobacco (2011) is a good example of a law that provides the appropriate health agency with the authority to issue regulations to implement WHO FCTC Articles 9 and 10.

"Article 10. Competencies. The National Health Authority shall have the follow competencies: [. .]

- a. Monitor the components of tobacco products and other accessories and related products within the scope of its competency;
- b. Establish methods of analysis to verify that the manufacture of tobacco products and their accessories is done according to the applicable technical and legal provisions;
- c. Determine the information that manufacturers are required to provide to the pertinent authorities and the general public with respect to tobacco products and their harmful effects. . . ."

An unofficial English translation of the tobacco control law is available at <http://www.tobaccocontrolaws.org/files/live/Ecuador/Ecuador%20-%20Organic%20Law%20for%20TC.pdf>. The law is available in the original Spanish at <http://www.legal.gen.ec/Ley-Organica-Regulacion-Control-Tabaco>. Excerpts above are unofficial translations by the authors.

Brazil

Resolution RDC 14 of 15 March 2012 imposes an extensive ban on additives.

Chapter IV. Additives

"Art. 6. It is prohibited to import or sell in Brazil tobacco products that contain any of the following additives:

- i. synthetic and natural substances in any form (pure substances, extracts, oils, distillates, balms, among others), with flavoring properties that can impart, intensify, modify, or enhance the flavor of the product, including additives identified as flavoring agents:
 - a. by the Joint FAO/WHO Expert Committee on Food Additives (JECFA); or
 - b. by the Flavor and Extract Manufacturers Association (FEMA).
- ii. processing aids for flavorings;
- iii. additives with nutritional properties, including:
 - a. amino acids;
 - b. vitamins;
 - c. essential fatty acids; and
 - d. minerals, except for those that are demonstrably essential to the manufacture of the tobacco products.
- iv. additives associated with alleged stimulating or invigorating properties, including taurine, guaraná, caffeine, and glucuronolactone;
- v. pigments (or coloring agents);
- vi. fruits, vegetables, or any product originating from the processing of fruits and vegetables, except activated charcoal and amides;
- vii. sweeteners, honey, molasses, or any other substance that can impart a sweet flavor, apart from sugars;
- viii. seasonings, herbs and spices, or any substance that can impart a flavor of seasonings, herbs and spices;
- ix. ameliorants; and
- x. ammonia or any of its compounds and derivatives.

(continued)

Box 7.1 *(continued)*

Art. 7. The use of the following additives is permitted in tobacco products:

- i.** sugars, exclusively for the restitution of the sugar originally present in tobacco leaf prior to the curing process;
- ii.** adhesives;
- iii.** binders;
- iv.** combustion agents;
- v.** processing aids that are not for flavorings;
- vi.** pigments (or coloring agents) used to whiten the paper or the filter, to imitate a cork pattern in the wrapping of the filter tip, and those used to print logos or brand names;
- vii.** glycerol and propylene glycol; and
- viii.** potassium sorbate.

§ 1 The addition of sugars indicated in sub-paragraph I is subject to the declaration of losses and the need for restitution, to be submitted by the companies when applying for Registration or Renewal of Registration of the Tobacco Product—Registration Data or Alteration of Data.

§ 2 The Collegiate Directorate may, through issuance of its own regulatory provisions, approve the use of other additives, considering the justifications submitted by companies concerning their necessity for the manufacture of the tobacco product, as long as they do not alter its flavor.”

Chapter V. Final and Transitory Provisions

“Art. 8. A period of 18 (eighteen) months is granted, counting from the date of publication of this Resolution, to allow manufacturers and importers of tobacco products that are already registered in compliance with Article 5.

§ 1 At the end of the period indicated in the caput, products that are not in compliance with Article 5 can be sold on a retail basis for a period of 6 (six) months.

§ 2 At the end of the period established in § 1, the products must be taken off the market by manufacturers, importers, distributors, and retailers.

§ 3 The periods set forth in this Article do not apply to cigarettes.

Art. 9. A period of 18 (eighteen) months is granted, counting from the date of publication of this Resolution, to allow manufacturers and importers of tobacco products that are already registered in compliance with Article 6.

§ 1 At the end of the period indicated in the caput, products that are not in compliance with Article 6 can be sold on a retail basis for a period of 6 (six) months.

§ 2 At the end of the period established in § 1, the products must be taken off by manufacturers, importers, distributors and retailers.

Art. 10. Any alteration in the composition, packaging, or brand name of the product for purposes of compliance with Articles 5 and 6 of this Resolution must be implemented through the application form entitled ‘Alter Data’ or the application form entitled ‘Renewal of Registration of a Tobacco Product – Registration Data.’

Art. 11. Failure to comply with the provisions contained in this Resolution constitutes a health violation pursuant to the terms of Law 6.437, of 20 August 1977, without impairment to such civil, administrative, and criminal liabilities as may be applicable.”

(continued)

Box 7.1 *(continued)*

An unofficial English translation of RDC 14 is available at http://www.tobaccocontrolaws.org/files/live/Brazil/Brazil%20-%20RDC%20No.%2014_2012.pdf. The resolution is available in the original Portuguese at http://bvsmms.saude.gov.br/bvs/saudelegis/anvisa/2012/rdc0015_15_03_2012.html. Excerpts above are unofficial translations by the authors.

Canada

The Cracking Down on Tobacco Marketing Aimed at Youth Act, 2009 (also known as an Act to amend the Tobacco Act), added new provisions dealing with the issue of attractiveness for cigarettes, little cigars, and blunt wraps to the 1997 Tobacco Act, including the addition of a

Schedule of Prohibited Additives:

"2. . . 'additive' means an ingredient other than tobacco leaves. . . 'ingredient' means tobacco leaves and any substance used in the manufacture of a tobacco product or its components, including any substance used in the manufacture of that substance. [. .]

5.1(1) No person shall use an additive set out in column 1 of the schedule in the manufacture of a tobacco product set out in column 2.

(2) Subsection (1) does not prohibit the use of a colouring agent to depict a trade-mark on a tobacco product or to display a marking required under this or any other Act of Parliament or of the legislature of a province or for any other prescribed purpose. [. .]

5.2(1) No person shall sell a tobacco product set out in column 2 of the schedule that contains an additive set out in column 1.

(2) Subsection (1) does not prohibit the sale of a tobacco product by reason only that the product contains a colouring agent used for a purpose referred to in subsection 5.1(2)."

The list of prohibited additives in the accompanying schedule is quite extensive, and includes the following: additives that have flavoring properties or that enhance flavor, amino acids, caffeine, probiotics, sugars and sweeteners, and vitamins.

The Cracking Down on Tobacco Marketing Aimed at Youth Act is available in English and French at http://laws-lois.justice.gc.ca/PDF/2009_27.pdf.

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Additional resources

This section lists additional publications and other resources to complement the information in Chapter 7 and its references.

Scientific Committee on Emerging and Newly Identified Health Risks. 2010. Addictiveness and Attractiveness of Tobacco Additives. Brussels: European Commission.

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenih_r_o_031.pdf.

The WHO Tobacco Free Initiative offers studies on tobacco product regulation available at

http://www.who.int/tobacco/publications/prod_regulation/en/index.html.

The WHO Tobacco Laboratory Network (TobLabNet) is a global network of government, academic, and independent laboratories established to strengthen capacity for testing and research on the contents and emissions of tobacco products, pursuant to Article 9 of the WHO FCTC. Objectives and proceedings of meetings are available at

http://www.who.int/tobacco/global_interaction/toblabnet/history/en/index.html

Chapter 8

WHO FCTC Articles 12 and 14 as Components of an Integrated, Multisectoral Tobacco Control Strategy



Source: Shutterstock.

8. WHO FCTC Articles 12 and 14 as Components of an Integrated, Multisectoral Tobacco Control Strategy

8.1 Background

8.1.1 Rationale and evidence

The World Health Organization Framework Convention on Tobacco Control (WHO 2003; hereafter, WHO FCTC) addresses tobacco control from the perspectives of both supply and demand. Articles 12 and 14 are two of the many measures in the Convention relating to the reduction of tobacco demand.

Article 12 addresses education, communication, training, and public awareness. The Guidelines for Implementation of Article 12 (WHO 2010a; hereafter, Article 12 Guidelines) call for “the use of all available communication tools to promote and strengthen public awareness of tobacco-control issues.” Article 14 addresses tobacco dependence and cessation. The Guidelines for Implementation of Article 14 (WHO 2010b; hereafter, Article 14 Guidelines) call for measures to support and promote tobacco cessation and provide adequate treatment for tobacco dependence.

Implementing measures for either of these articles alone, or even for both, cannot accomplish the Convention’s overall goal of decreasing tobacco consumption. Rather, each article should be one element in an integrated national tobacco control strategy. It is essential that implementation of each article complement and build upon other tobacco control policies in order to maximize their impact, as was discussed in Chapter 1.

For example, WHO FCTC Article 11 requires Parties, among other things, to inform the public and consumers about the harmfulness of tobacco products and exposure to tobacco smoke through required health warnings on tobacco packaging and labeling (WHO 2009b); this is complemented by the implementation of Article 12, calling for broader communication efforts. Also, the Article 11 Guidelines call for Parties to set up “quit lines,” toll-free telephone numbers to provide consumers with information on cessation services (WHO 2009b); therefore, the smoking cessation and dependence treatment measures included in Article 14 should be in place in order to complement and work synergistically with Article 11 mandates. The Article 14 Guidelines state that counseling and treatment services should be implemented in conjunction with population-level interventions, including raising public awareness pursuant to Article 12. However, even in the absence of other tobacco control interventions, mass media campaigns have been shown to be effective on their own when they are well designed and planned (WHO 2011b).

Like the other WHO FCTC articles, Articles 12 and 14 should be implemented through a comprehensive, multisectoral approach, as stated in WHO FCTC Articles 4.4 and 5.2(a), and with the active participation of civil society, as stated in Article 4.7. Toward this end, the Article 12 Guidelines and Article 14 Guidelines call for a focal point or other coordinating mechanism to be identified and given the requisite authority for effective implementation, monitoring, and evaluation. In this process, steps should be taken to protect the coordinating body from tobacco industry interference, as recommended in WHO FCTC Article 5.3 and its Guidelines (WHO 2009a).

Guiding principles that underpin the implementation of Articles 12 and 14 invoke fundamental human rights and freedoms. These include, but are not limited to, the right to life, the right to the highest attainable standard of health, and the right to education.¹ Prevention and treatment of tobacco addiction are important components of the right to health, a right understood as containing both freedoms and entitlements. According to the United Nations Committee on Economic, Social and Cultural Rights, “The freedoms include the right to control one’s health and body . . . By contrast, the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health” (CESCR 2000: 8).

Access to treatment, along with public education about the harms of tobacco and the benefits of cessation, is necessary for the realization of the highest attainable standard of health. States should offer broad and comprehensive support to ensure that treatment is widely available, accessible, and affordable (Article 14 Guidelines).

Although their population-wide impact may not be as great, individual smoking cessation interventions have a significant impact on individual health and are extremely cost-effective compared with many other health system activities (Cromwell et al. 1997). People who quit smoking, regardless of their age, smoking history, or health status, experience immediate and profound health benefits and can reduce most smoking-associated risks within a few years of quitting (Doll et al. 2004; HHS 1990). The Article 14 Guidelines state that “there is clear scientific evidence that tobacco dependence treatment is effective and that it is a cost-effective health-care intervention, and thus that it is a worthwhile investment for health-care systems.”

The rights to life, the highest attainable standard of health, and to education, as noted in Chapter 1, permeate the Convention. Governments should, therefore, adopt and implement effective legislative, executive, administrative, and other measures to protect individuals from threats to their fundamental rights and freedoms.

8.1.1.1 Education, communication, training, and public awareness: WHO FCTC Article 12

Article 12 of the WHO FCTC requires Parties to promote and strengthen public awareness of tobacco control issues, using all appropriate and available communication tools. In order to fulfill that goal, the Article 12 Guidelines state that each Party must implement effective legislative, executive, administrative, and other measures necessary to “successfully educate, communicate with and train people on the health, social, economic and environmental consequences of tobacco production, consumption and exposure to tobacco smoke.” Parties should also inform the public about the strategies used by the tobacco industry to undermine tobacco control measures.²

Research-based programming. The Article 12 Guidelines identify education, communication, and training as the “three pillars of public awareness” needed to promote social and environmental change. Implementing legislation should mandate that these three pillars be carried out. Research-based evidence³ and best practices tailored to the circumstances in each country are fundamental to the elaboration, management, and implementation of education, communication, and training programs aimed at raising public awareness of tobacco control issues. Legislation should require that programs

¹ These rights are recognized in many international legal instruments, including Articles 3 and 25 of the Universal Declaration of Human Rights, the Preamble to the Constitution of the World Health Organization, the Convention on the Rights of the Child, the Convention on the Elimination of All Forms of Discrimination against Women, and the International Covenant on Economic, Social and Cultural Rights. They are formally incorporated into the Preamble of the WHO FCTC and are recognized in the constitutions of many countries. The right to education is specified in Article 13 of the International Covenant on Economic, Social and Cultural Rights and in the United Nations Economic and Social Council General Comment No. 13 (E/C.12/1999/10).

² See also Article 5.3 Guidelines, Recommendation 5.2 (WHO 2009a).

³ The term “research-based” refers to “the use of rigorous, systematic, and objective methodologies to obtain reliable and valid knowledge relevant to education, communication, and training activities and programmes” (Article 12 Guidelines, n. 6).

to implement Article 12 be research-based and that they address the entire population, while also taking into account key differences between population groups.

According to the Guidelines, special attention should be paid to the populations most affected by marketing and rising tobacco use and to those that are often neglected, such as people who are poor, illiterate, or undereducated. Priority should also be given to individuals who serve as role models, such as health, educational, and media professionals, as well as to pregnant women, parents, teachers, and educators. Because most smokers begin using tobacco as adolescents, it is important to inform young people about the harms of tobacco use before they start. As noted in Chapter 1, there is a prevalent belief that youth should be addressed differently than adults, but comprehensive tobacco control efforts designed to reach all age groups have been more effective in influencing youth behavior than outreach specifically to youth (NCI 2008). Anti-tobacco programs directed at children are politically popular and have broad public appeal, but they do not contribute substantially to reducing youth smoking experimentation or initiation when conducted as part of health education classes in schools (Wiehe et al. 2005; Thomas and Perera 2006). Focusing anti-tobacco educational initiatives on children could also weaken a more comprehensive population-wide approach that would have a greater long-term impact (Warner 2000; WHO 2011b). Exposure to effective anti-tobacco mass media campaigns has similar effects on adults and youth, with adult smokers more likely to quit and youth less likely to become established smokers than their counterparts not exposed to anti-tobacco campaigns (McVey and Stapleton 2000; Siegel and Biener 2000).

A sustainable infrastructure. The Article 12 Guidelines also provide detailed recommendations on creating a sustainable infrastructure for raising public awareness, engaging civil society, running effective programs, and strengthening international cooperation.

As is the case with various WHO FCTC articles, sufficient resources should be devoted to the implementation of Article 12. To address resource needs, the Article 12 Guidelines urge Parties to take into account existing funding sources and to explore other potential funding sources, including raising tobacco excise taxes, introducing dedicated taxes, and imposing licensing fees, all of which would require a legislative mandate. Where appropriate, Parties can also make use of bilateral and multilateral funding mechanisms, as set out in Articles 5.6 and 26 of the Convention.

8.1.1.2 Demand reduction measures concerning tobacco dependence and cessation: WHO FCTC Article 14

Article 14.1 of the WHO FCTC provides that “each Party shall develop and disseminate appropriate, comprehensive and integrated guidelines based on scientific evidence and best practices, taking into account national circumstances and priorities, and shall take effective measures to promote cessation of tobacco use and adequate treatment for tobacco dependence.” Implementing legislation can require the government to ensure a sustainable infrastructure that “motivates attempts to quit, ensures wide access to support for tobacco users who wish to quit, and provides sustainable resources to ensure that such support is available,” as provided in the Article 14 Guidelines.

The Guidelines identify the key components of a system to help tobacco users quit, including approaches with a broad reach (e.g., telephone quit lines, brief advice provided by primary care practitioners) and more individualized approaches (e.g., medication, behavioral support).⁴ Implementing legislation could require these components to be established, or strengthened, as the case may be, and require them to be inclusive, taking into account factors such as gender, culture, religion, age, educational background, literacy, socioeconomic status, disability, and the needs of groups with the highest rates of tobacco use. If possible, treatment should be tailored to the needs of individual tobacco users.

⁴ Notably, nicotine replacement therapies, such as chewing gum and the transdermal patch, are listed on the WHO Model List of Essential Medicines (WHO 2011a).

Finally, to address funding support for cessation programs, legislation could provide for designated tobacco taxes, licensing fees, tobacco product registration fees, and similar funding mechanisms, as recommended in the Guidelines. Through mechanisms such as these, the tobacco industry and retailers will bear the costs of cessation support and services.

8.1.2 Regional situation

According to the WHO FCTC progress reports from 18 Parties in the Region (two- and five-year reports), all of them had implemented some sort of educational and public awareness programs. Twelve had also implemented training programs addressed to health workers.⁵

However, the most recent WHO report on the global tobacco epidemic shows that only nine countries from the Region conducted at least one national mass media campaign during 2009 or 2010, and less than half of them had an outcome evaluation to assess the media campaign's effectiveness (WHO 2011b, Table 2.3.2). These findings may be related to the usually high cost associated with mass media campaigns.

Health care institutions and health care personnel are particularly well suited to conduct programs promoting cessation of tobacco use and treatment of tobacco dependence. However, global findings on the use of health care institutions to carry out such programs indicate that these opportunities are not being sufficiently utilized (WHO 2010c). The situation is no different in the Region of the Americas, where only four countries report having a national quit line and covering the costs of both some cessation services and nicotine replacement therapies (WHO 2011b). An additional 10 countries in the Region offer some cessation services and/or nicotine replacement therapies, at least one of which is cost-covered. In most other countries in the Region, some cessation services and/or nicotine replacement therapies are offered, but the cost is not covered by government.

8.2 Tobacco industry strategies to weaken implementation of WHO FCTC Articles 12 and 14

It is critical that Parties bear in mind WHO FCTC Article 5.3 when seeking funding for and planning public awareness and education programs. Specifically, Parties may not accept any kind of collaboration, financial or otherwise, direct or indirect, with the tobacco industry. For further details, see the Article 12 Guidelines and the Article 5.3 Guidelines, Recommendation 3.2.⁶

A favored strategy of the industry has been to sponsor youth smoking prevention programs while simultaneously engaging in marketing and promotional activities targeting youth (Assunta and Chapman 2004; Landman, Ling, and Glantz 2002). Internal industry documents show that companies launch these prevention programs in order to gain political favor with policy makers and portray themselves as concerned corporate citizens (Assunta and Chapman 2004, Sebríe and Glantz 2007). However, industry-sponsored youth smoking prevention programs are ineffective at best and harmful at worst. In the first place, the industry does not utilize the strategies that are scientifically proven to be successful in influencing youth not to smoke (Landman, Ling, and Glantz 2002). In addition, industry-sponsored programs undermine anti-smoking messages by portraying smoking as an "adult choice," increasing many teens' desire to smoke (Landman, Ling, and Glantz 2002). These programs also fail to adequately address the health consequences of exposure to tobacco smoke and tobacco use. For example, they never state that nicotine is addictive (Landman, Ling, and Glantz 2002).

⁵ This information is available in the WHO FCTC Implementation Database, http://www.who.int/fctc/reporting/implement_database/en/index.html.

⁶ Article 5.3 Guidelines, Recommendation 3.2: "Parties should not accept, support or endorse the tobacco industry organizing, promoting, participating in, or performing, youth, public education or any initiatives that are directly or indirectly related to tobacco control" (WHO 2009a).

In seeking to counter government-sponsored tobacco control actions in some places, the tobacco industry has created its own “anti-tobacco campaigns.” Generally these campaigns are thinly disguised product advertisements; as such, they are ineffective in reducing smoking and may even increase smoking, especially among youth for the reasons discussed above (WHO 2011b; Wakefield et al. 2006; Henriksen et al. 2006; Biener 2002).

8.3 Implementing WHO FCTC Articles 12 and 14 at the domestic level: Drafting effective demand reduction measures

“In Practice” boxes in this section present practical examples of good-practice legislation in different countries. Legislative development and legislative drafting are both a science and an art, and they occur within a political context. Achieving best-practice legislation often takes time; the examples highlighted in the boxes either achieve or approach this standard. The best means of ensuring best-practice legislation with respect to tobacco demand reduction is to fully incorporate WHO FCTC Articles 12 and 14 and their Guidelines.

8.3.1 Implementing WHO FCTC Article 12

WHO FCTC Article 12 can be implemented either by law or by policy. However, a legal requirement for conducting education, communication, training, and public awareness may help ensure sustainability, especially if a legal mandate creates an obligation to fund these programs. Some jurisdictions have enacted legislative mandates in order to ensure access to some of the funding resources suggested by the Guidelines, such as mandates directing that a portion of tobacco taxes be used to fund health promotion, including tobacco control programs.⁷ When drafting legislation or policies for the implementation of Article 12, it should be noted that the Guidelines provide annexes with checklists and indicative lists that may be very useful.

⁷ See, for example, Iceland’s Tobacco Control Act, 2002 (as amended), Sec. 15, <http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/19484>. See also Thailand’s Health Promotion Act 21110 (2001), http://www.hpfoundations.net/sites/default/files/page/2010/08/thai_health_promotion_foundation_act_2001.pdf.

Box 8.1

In Practice: Examples of education, communication, training, and public awareness

Uruguay

Law 18.256 (2008):

Article 10. Promotion

“The Executive Branch must design, carry out, and assess the various anti-tobacco consumption programs, projects, and campaigns.”

Excerpt above is from an unofficial English translation of Law 18.256 at <http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Law%20No.%2018.256.pdf>. The law is available in the original Spanish at <http://www0.parlamento.gub.uy/leyes/ AccesoTextoLey.asp?Ley=18256&Anchor=>.

Ecuador

Organic Law for the Regulation of Tobacco Control (2011):

Article 4. Responsibility for Educational Matters

“Through the Health and Education Ministries, and in coordination with other public and private institutions, the State shall develop sporting, health promotion, and educational activities as well as tobacco consumption prevention, detection, and intervention activities.”

Excerpt above is from an unofficial English translation of the law at <http://www.tobaccocontrolaws.org/files/live/Ecuador/Ecuador%20-%20Organic%20Law%20for%20TC.pdf>. The law is available in the original Spanish at <http://www.legal.gen.ec/Ley-Organica-Regulacion-Control-Tabaco>.

8.3.2 Implementing WHO FCTC Article 14

Like Article 12, WHO FCTC Article 14 can be implemented either by law or by policy. Again, a legal requirement for implementation may help ensure sustainability, especially if it creates an obligation to fund smoking cessation programs. Legislation could simply include a requirement for the implementation and funding of evidence-based tobacco cessation programs, giving the Ministry of Health the mandate to define and develop policies and the necessary programs to accomplish them. Additionally, if existing legislation creates unnecessary barriers to access to cessation medications, these barriers will need to be addressed through subsequent legislative measures (Article 14 Guidelines).

Box 8.2

In Practice: Examples of demand reduction measures concerning tobacco dependence and cessation

Uruguay

Law 18.256 (2008):

Article 10. Promotion

"Public and private health services shall incorporate tobacco dependency diagnosis and treatment into their national primary health care programs, plans, and strategies by promoting rehabilitation and dependency treatments. They shall also properly publish the basic services available for tobacco dependency treatment, including pharmaceutical products, be they drugs, products used to administer medications, or diagnostic methods, as the case may be."

Excerpt above is from an unofficial English translation of Law 18.256 at <http://www.tobaccocontrolaws.org/files/live/Uruguay/Uruguay%20-%20Law%20No.%2018.256.pdf>. The law is available in the original Spanish at <http://www0.parlamento.gub.uy/leyes/AccesoTextoLey.asp?Ley=18256&Anchor=>.

Panama

Ministry of Health Executive Decree 230 (2008):

Article 21

"Institutions providing health services that make up the Ministry of Health and Social Security Administration's network of services shall provide smoking cessation programs. For such purposes the following actions shall apply:

- a. The Department of Public Health shall actively design a Comprehensive Program for Smoking Cessation. This program will be presented to the competent authorities within no more than three (3) months from when this Order takes effect.
- b. The Ministry of Health's Provision of Services Office and the Social Security Administration's Office of Medical Services and Benefits shall adopt the measures needed for optimal functioning of the cessation clinics in mobile facilities for primary and secondary care throughout the country as well as at entities specializing in managing addictions within a period of no greater than six (6) months after approval of the Comprehensive Program for Smoking Cessation to which this article's subparagraph refers. These clinics will offer comprehensive treatments to members of the smoking public who demand their services.
- c. Corresponding teaching units will carry out the qualification and training of personnel required for the good performance of these clinics. These must have at least one doctor, a psychologist, a social worker, and a nurse.
- d. Health dispensaries, posts, and subcenters shall develop only the component for the promotion of smoking cessation contained in the program under comment.
- e. Public health officials shall have access to the cessation clinics pursuant to the provisions of Article 165 of Law 9 of 1994."

Article 22

"In order to ensure intersectoral articulation in formulating smoking cessation policies, the Ministry of Health and the Social Security Administration shall consolidate strategic alliances to join forces and resources with nongovernmental organizations related to the topic of tobacco control, pursuant to the provisions of Numeral 3, Article 5 of Law 40 of July 7, 2004, to develop the Comprehensive Program for Smoking Cessation."

Excerpt above is from an unofficial English translation of Decree 230 at <http://www.tobaccocontrolaws.org/files/live/Panama/Panama%20-%20EO%20No.%20230.pdf>. The decree is available in the original Spanish at http://www.gacetaoficial.gob.pa/pdfTemp/26356_B/20281.pdf.

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Additional resources

This section lists additional publications and other resources to complement the information in Chapter 8 and its references.

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The World Health Organization offers a resource list of materials to promote the implementation of WHO FCTC Article 12 and its guidelines at

http://www.who.int/fctc/protocol/guidelines/adopted/article_12res/en/index.html. Reference materials concerning the of implementation Article 14 and its guidelines are available at <http://www.who.int/fctc/A14reference.pdf>.

The World Lung Foundation offers resources for tobacco control campaigns at

<http://www.worldlungfoundation.org/ht/d/sp/i/5835/pid/5835>.

Chapter 9

Template for a Tobacco Control Act



Legislation

Legislation, regarded as government, which are of to regulate, to proscribe, to sanction, to authorize, separation of powers.

Tobacco Control Act of _____ [or other name for the Act]

A Bill for an Act to protect present and future generations from the devastating harms of tobacco use and exposure to tobacco smoke in accordance with the WHO Framework Convention on Tobacco Control, its Protocols, and its Guidelines for implementation, and for related purposes.

CHAPTER I — PRELIMINARY

1. Short title

This Act may be cited as _____.

2. Commencement date

Each provision of this Act shall come into operation on _____, unless otherwise specified in the Act.

3. Objects of the Act

The objectives of this Act are to protect present and future generations from the devastating health, social, economic, and environmental consequences of tobacco use and exposure to tobacco smoke through a range of supply and demand, measures aimed at improving the health of the population by eliminating or substantially reducing their consumption of tobacco products and exposure to tobacco smoke. In fulfilling these objectives, the State gives effect to the obligations it has undertaken to provide effective protection against tobacco-related harms and to promote health and other human rights as a Party to the WHO Framework Convention for Tobacco Control and to other relevant treaties, such as the Convention on the Rights of the Child, the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, and the Convention on the Elimination of All Forms of Discrimination Against Women, under relevant regional treaties, and under the Constitution. *[Note: Inclusion of this phrase will depend on the treaties to which the country is a party and whether the constitution protects the right to health or other related human rights.]*

[Note: In addition to the overall objectives expressed above, topic-specific objectives are expressed in the different Chapters of the Act. In the event legislation is being drafted covering only some FCTC topics, applicable objectives can be pulled from the relevant Chapters of this template to supplement the overall objectives.]

CHAPTER II—DEFINED TERMS

4. Definitions

In this Act, unless the context otherwise requires-

“conflict of interest” involves a conflict between the public duties and private interests of any person working in any capacity in or on behalf of government where that person has tobacco-related interests which could improperly influence the performance of his or her official duties or responsibilities.

“cross-border” with respect to tobacco advertising, promotion, and sponsorship means that which originates within the territory of _____ and enters another territory or could be received in another territory, including by means such as, but not limited to, placement on the Internet or through broadcasts or other communications technologies, as well as that which originates outside the territory of _____ and enters or is designed to enter the territory.

“enclosed” or “indoor” means any space covered by a roof or one or more walls or sides, regardless of the type of material used and regardless of whether the structure is permanent or temporary.

“government” or “government authority” includes any governmental or semi- or quasi-governmental institution, body, board, commission, committee, work group, or other entity.

“health warnings and messages” means government-prescribed text and accompanying full color pictures required to be displayed on tobacco packaging and labelling conveying the health consequences of tobacco use and exposure to tobacco smoke and any other messages as may be prescribed by the Ministry. *[Note: It is not necessary to include in the definition that the warnings consist of text and full color pictures, as this should also be specified in the provisions prescribing the warning requirements. Putting it in the definition may reinforce the requirement, however.]*

“Minister” means Minister of Health *[Note: or other appropriate Ministry]*.

“Ministry” means Ministry of Health *[Note: or other appropriate Ministry]*.

“occupational activity” includes any kind of employment, contract, consulting, or other work or service activity, whether it is gainful or not, and whether it is full-time, part-time, occasional, temporary, or permanent.

“open space” or “outdoor space” means any space that is not “enclosed” or “indoor”, as those terms are defined in this Act.

“outside packaging and labelling”, with respect to tobacco products, means packaging and labelling used in the retail sale of the products.

“person” includes any natural and any legal person.

“person responsible for the premises” means the owner, manager, or other person in charge of a public place, workplace, or means of public transport.

“public office holder” means an appointed or elected government official, representative, employee, or advisor within any branch of government at the national level or at any sub-national level of government.

“public place” means any place accessible to the general public or place for collective use, regardless of ownership or right of access.

“public transport” means any vehicle used for carriage of members of the public, usually for reward or commercial gain.

“publish” means to make public to one or more persons by any means.

“relevant or related to tobacco control” means any policies, laws, regulations, programs, or initiatives that affect or are likely to affect the development or implementation of tobacco control policy, such as but not limited to, tax, price, trade, and agricultural policies.

“responsible for tobacco control”, “responsibility for tobacco control”, or “role in tobacco control” includes being involved in or contributing to, or being in a position to be involved in or contribute to tobacco control policies, or those relevant or related to tobacco control, within any branch of government at the national or sub-national levels.

“seller” with regard to tobacco products means any person that sells tobacco products at import, wholesale, export, or retail.

“smoking” includes being in possession or control of a lit tobacco product regardless of whether the smoke is being actively inhaled or exhaled.

“subsidiary” means a tobacco manufacturer, importer, or wholesaler in which another tobacco manufacturer, importer, or wholesaler has a controlling share and includes any corporation organized and chartered under the laws of another State.

“tobacco advertising and promotion” means any form of commercial communication, recommendation, or action with the aim, effect, or likely effect of promoting a tobacco product or tobacco use directly or indirectly.

“tobacco control” means a range of supply, demand, and harm reduction strategies that aim to improve the health of the population by eliminating or reducing the consumption of tobacco products and exposure to tobacco smoke.

“tobacco control policy” includes the formulation, development, implementation, administration, or enforcement of any tobacco control policy, law, regulation, program, or initiative, and any policy, law, program, or initiative relevant or related to tobacco control.

“tobacco industry” means tobacco manufacturers, wholesale distributors, and importers.

“tobacco products” means products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.

“tobacco sponsorship” means any form of contribution to any event, activity, organisation, or individual that has the aim, effect, or likely effect of promoting a tobacco product or tobacco use directly or indirectly.

“unit packaging and labelling” means the packaging and labelling in which a tobacco product is directly placed.

“workplace” means any place used by one or more persons during their paid or unpaid employment or work, including all associated or attached areas commonly used in or incidental to the course of work, as well as work vehicles.

CHAPTER III – ADMINISTRATION

[Note: Provisions on administration of the Act are country specific and do not lend themselves well to a template. Below are descriptions of what should be included, at a minimum, in provisions for administration.]

5. Implementation and administration authorities and their duties; powers

[Note: Provisions should be included that: (1) specify which ministry or ministries or other government authorities have rule-making powers and other responsibilities and authorities for carrying out the Act (normally the Ministry or authority with responsibility for assuring the highest degree of protection of health of the population for most topics covered by the law, though other ministries also will have a role, such as with prevention of illicit trade, tax, etc.); (2) specify which ministries/authorities have the powers and duties to inspect, investigate complaints, and take enforcement action, and how different ministries/authorities and different levels of government are to cooperate and coordinate (as worked out among the relevant ministries and authorities before inserting into the bill); and specify the powers of inspectors.

If a Tobacco Control Board or other national coordinating mechanism will be established by law, provisions for it could be provided in this Part. FCTC Article 5.2(a) requires parties to establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control. This may be done through the creation of a multi-sectorial tobacco control board that includes civil society representation, or through another mechanism. If a Board is to be established, this may be done by either law or policy, depending on the powers to be given to it.]

CHAPTER IV— SMOKE-FREE ENVIRONMENTS

6. Objects of the Chapter; interpretation

(1) The objectives of this Chapter are to:

(a) provide effective, evidence-based measures to protect against exposure to the hazards of tobacco smoke, in order to promote and protect the population’s rights to health, life, physical integrity, safe and healthy workplaces, and other rights adversely impacted by tobacco smoke exposure. *[Note: the rights enumerated here will depend largely on the constitution and treaties to which the State is a party];*

(b) provide protection to all workers and members of the public by completely prohibiting smoking in all indoor workplaces, all indoor public places, on all means of public transport, and in outdoor public spaces where smoking would create a hazard or would otherwise undercut any objectives of the Act;

(c) provide equal protection for all workers, regardless of where they work, and all population groups;

(d) discourage smoking initiation, encourage quitting, and reduce tobacco consumption through behavior and norm changes brought about by smoke-free environments as well as through the various other measures provided in the Act; and

(e) reduce the economic costs attributable to exposure to tobacco smoke and smoking.

(2) To ensure that all people are effectively and equally protected from exposure to tobacco smoke in all indoor public and workplace settings, including public transport, and in the outdoor public spaces specified in the Act and in any implementing regulations, any question that may arise as to whether smoking is permitted in any given place or situation shall be resolved in favor of protecting the health of all workers and members of the public from exposure to tobacco smoke.

7. Protection from exposure to tobacco smoke in indoor public places, indoor workplaces, public transport, and specified outdoor public spaces

(1) No person shall smoke in any part of any indoor work place or public place, anywhere on any means of public transport, or in the outdoor places specified in sub-paragraph 2.

[Note: Because apartment and condominium buildings have aspects of private dwellings, workplaces, and possibly public places, and because smoke can enter one dwelling unit from another, it may be advisable to specify exactly where smoking is prohibited (e.g., in common areas or in both common areas and individual dwelling units). If smoking is not prohibited by law in individual dwelling units, it should be clear that nothing in the law prevents the person responsible for the premises, or any governing body, from prohibiting smoking anywhere on the premises.]

(2) In addition to any outdoor space that is designated as a no-smoking area by the person responsible for the premises, no person may smoke in any outdoor space that is--

- (a) within ___ meters of any doorway, operable window, or air intake mechanism of any public place or workplace;
- (b) within ___ meters of any waiting area or queue, including but not limited to public transport stops;
- (c) anywhere on the premises of any child care facility or educational facility at any level of instruction;
- (d) anywhere on the premises of any health care facility;
- (e) a playground, amusement park, plaza, public park, or other public gathering space;(f) a stadium, arena, or any kind of performance space;(g) a space for the service or consumption of food or drink; and(h) any other outdoor public or work space as may be specified in regulations.

[Note: If electronic nicotine delivery systems (ENDS), such as e-cigarettes, are not banned or their use is not regulated under another law, careful consideration could be given to whether a provision should be included here that applies the smoking ban to ENDS products.]

8. Duties of the person responsible for the premises

Persons responsible for the premises specified in the previous article shall have a continuous duty to--

- (a) prominently post “no smoking” signs, which shall be prescribed by the Ministry with regard to format, content, design, size, display, location, and all other details *[Note: if there is concern that there may be delay in promulgating regulations, the law could specify the basic requirements for signage and authorize the Ministry to supplement those requirements];*
- (b) remove all ashtrays from all indoor areas of the premises and any outdoor areas where smoking is prohibited;
- (c) supervise observance of the smoking ban;
- (d) take reasonable steps to discourage and stop any person who appears to be preparing to smoke or who is smoking from continuing to do so where it is prohibited, including asking the person not to smoke, discontinuing service, asking the person to leave the premises or public transport vehicle when it is safe to do so, and contacting law enforcement or other appropriate authority where necessary; and
- (e) investigate complaints and take any necessary action to ensure compliance.

9. Penalties for non-compliance

A person who violates any provision of this Chapter shall be subject to any one or combination of penalties provided in Article 43, **Application of penalties for non-compliance**, as applicable. Any fine that may be applied for a violation of this Chapter shall be as follows--(a) against the person responsible for the public place, workplace, or means of public transport, a fine of no less than ___ and no more than ___ and ___ times the previous amount for any subsequent violation, up

to an amount of ____; *[Note: Consideration could be given to applying different fine amounts for violations of different duties imposed under Article 8.]* and

(b) against any person who smokes where smoking is prohibited, a fine of no less than ____ and no more than __ and __ times the previous amount for any subsequent violation, up to an amount of _____. *[Note: Fine amounts should normally be lower for smokers than for persons responsible for the premises.]*

CHAPTER V— PROHIBITION ON TOBACCO ADVERTISING, PROMOTION, AND SPONSORSHIP

10. Objects of the Chapter; interpretation

(1) The objective of this Chapter is to prevent commercial messages, cues, and other inducements that directly or indirectly encourage people, especially minors and young adults, to begin using tobacco products, reassure users about continuing their use, or that otherwise undermine quitting.

(2) To ensure that all people are protected from commercial inducements to begin or continue using tobacco products, any question that may arise as to whether any commercial communication, recommendation, or action constitutes a form or manner of tobacco advertising, promotion, or sponsorship prohibited under the Act shall be resolved in favor of protecting public health.

11. Comprehensive ban on all tobacco advertising, promotion, and sponsorship

(1) All forms, methods, and means of tobacco advertising, promotion, and sponsorship are prohibited and no person shall--

(a) initiate;

(b) produce;

(c) publish or place; or

(e) disseminate, when the person is aware of or in a reasonable position to become aware of the content and in a position to reasonably be able to control it, any tobacco advertising or promotion.

(2) No person shall engage or participate in tobacco sponsorship as a media or event organizer, sports person, celebrity, or other performer, as a recipient of any sponsorship contribution, or as an intermediary that facilitates any such contribution.

(3) Sub-articles 1 and 2 include any commercial communication, act, or practice that is intended to promote, promotes, or is likely to promote a tobacco manufacturer, wholesale distributor, or importer directly or indirectly.

(4) A person involved in the dissemination of communications content through analogue or digital media and communications, including but not necessarily limited to any content host, content navigator, and access provider, shall have fulfilled the requirement of sub-article (1)(d) if after becoming aware of any tobacco advertising, promotion, or sponsorship, the person removes the content or, when technically possible, takes reasonable efforts to disable access to it.

(5) This Article applies to all domestic and cross-border tobacco advertising, promotion, and sponsorship.

(6) Without limiting in any way the broad application of this Article, Schedule 1 provides, for illustrative purposes only, non-exhaustive examples of tobacco advertising, promotion, and sponsorship prohibited under the Act. The Ministry shall have the authority to expand the examples in the Schedule as it deems appropriate and useful.

[Note: For the small number of countries with constitutions that may preclude a complete APS ban, the provisions of this article and the items listed in the Schedule will need to be modified, taking into account constitutional requirements.]

In addition, FCTC Article 13.3 and 13.4 require that where a party has not yet enacted a comprehensive ban, or has not enacted a comprehensive ban due to its constitutional principles, it must, among other things: apply restrictions to all tobacco advertising, promotion, and sponsorship; prohibit all forms of tobacco 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; require accompanying warnings/messages on tobacco advertising, promotion, and sponsorship; and require tobacco manufacturers, importers, and wholesalers to disclose their expenditures on tobacco advertising, promotion, and sponsorship.]

12. Exclusions

The following, even if they have an incidental promotional effect, shall not be considered tobacco advertising, promotion, or sponsorship subject to the provisions of Article 11--

- (a) a plain black-and-white only price list made available where tobacco products are legally sold, provided the list contains nothing more than the tobacco product brand name, package quantity, price, and any other government required or authorized information;
- (b) depiction of tobacco products or tobacco use in media where—
 - (i) the depiction is purely incidental or is justified by reasons of historical accuracy or legitimate journalistic or artistic expression, or where the depiction is required for educational purposes and
 - (ii) no payment, other consideration, or anything else of value was offered or made by a tobacco manufacturer or seller, or any person acting on their behalf in exchange for the depiction;
- (c) genuine political, social, editorial, academic, or scientific commentary about tobacco products or tobacco use provided no payment, other consideration, or anything else of value was offered or made in exchange for the commentary;
- (d) information that is necessary for business administration or for required corporate reporting, but only to the extent access is limited to the person(s) who need to receive it for business administration or require it to be reported;
- (e) product information made accessible to persons within the tobacco trade who need the information for trading decisions, but only to the extent access is limited to those persons; and

(f) tobacco manufacturers' newsletters destined for and distributed only to the manufacturers' employees, contractors, suppliers, and other tobacco-related business partners, and only to the extent their distribution is limited to such persons.

13. Penalties for non-compliance

A person who violates any provision of this Chapter shall be subject to any one or combination of the penalties provided in Article 43. Any fine that may be applied for a violation of this Chapter shall be as follows—

(a) against any entity for initiating tobacco advertising, promotion, or sponsorship, a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____;

(b) against any entity that produces, publishes, or places advertising, promotion, or sponsorship, a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____;

(c) against any entity that disseminates tobacco advertising, promotion, or sponsorship that has failed to fulfil its duties under Article 11(1)(d) or (4), a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____; and

(d) against any person that engages or participates in tobacco advertising, promotion, or sponsorship as specified in Article 11(2), a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____.
[Note: Consideration could be given to applying different fine amounts for violations of different articles under this Chapter.]

CHAPTER VI – TOBACCO PRODUCT PACKAGING AND LABELLING

14. Objects of the Chapter; interpretation

(1) The objectives of this Chapter are to-

(a) inform consumers of the health consequences, addictive nature, and mortal threat posed by tobacco consumption and exposure to tobacco smoke and provide other relevant information, including on the true risks and specific harms of tobacco use and exposure to tobacco smoke, and about the benefits of quitting;

(b) discourage tobacco use and to encourage cessation among users at the time of purchase and the time of use; and

(c) ensure tobacco product packaging and labelling and the product itself do not mislead consumers or undermine or detract from health warnings and messages or other required information in any way, or undercut any other objectives of the Act. *[Note: If plain packaging will be directly required in the legislation, rather than giving the MOH the authority to require it, as is done in this template, this objective could include the phrase “promote tobacco use or use of the product” to replace the phrase “or undercut any other objectives of the Act”.*

(2) Provisions of this Chapter shall be interpreted as prohibiting any means or methods whatsoever used in connection with tobacco product packaging and labelling, or in connection with the product itself, that are likely to directly or indirectly create an erroneous impression about the product's characteristics, health effects, hazards and emissions, undermine or detract from health warnings and messages or other required information in any way, or undercut any other objectives of the Act.

15. Health warnings and other information required on tobacco product packaging and labelling

(1) The Ministry [*Note: or other appropriate authority*] shall prescribe a set of at least ___ health warnings and messages and these shall be permanently displayed on each principal display area of the unit and outside packaging and labelling of all tobacco products for sale in the territory.

(2) Warnings and messages from this set shall appear on unit and outside packaging and labelling for a period of no longer than ___ months, as specified in regulations. [*Note: The Article 11 Guidelines (para. 22) provide that a period between 12 and 36 months should be an appropriate period for the display of a set of warnings/messages before they are required to be replaced with a new set.*]

(3) For subsequent periods of no longer than ___ months each, the Ministry [*Note: or other appropriate authority*] shall prescribe a new set of warnings and messages that shall be used to replace the previous set. The Ministry may authorize the use of some warnings and messages from previous sets.

(4) During each specified period, each of the different health warnings and messages in the set shall appear on tobacco product packaging and labelling concurrently so that each of the warnings or messages appears on an equal number of retail packages for each brand within each brand family for each package size and type.

(5) The health warnings and messages shall be displayed on tobacco product unit and outside packaging and labelling in accordance with the following:

(a) The text and pictures comprising the warnings and messages shall appear together and shall occupy no less than ___% [*Note: The Guidelines (paras. 12 and 13) provide that the percentage should be at least 50% or more since the larger the warnings, the more effective they are*] of each principal display area of the package, not counting the space taken up by any border surrounding the health warnings and messages that may be required in regulations. [*Notes: 1) Drafters should be familiar with the different types of packaging on the market in order to determine how warnings will be best displayed for the different kinds of packaging, unless standardized packaging will be required. 2) The Article 11 Guidelines recommend that the warnings/messages be placed in the top portion of the principal display areas (PDAs). This can be specified in the law or left to the regulations and the electronic source document specifying how the warnings/messages are to be displayed on the pack.*]

(b) The text of the health warnings and messages shall be in the _____ language. [*Note: If there is more than one principal language, the principal languages should be specified, along with how the warnings/messages are to be displayed (for example, the picture and text in the first language on one PDA and the picture and text in the second language on the other PDA, for packs with only two PDAs and two principal languages).*]

(6) The visibility of the warnings and messages must not be, and must not be susceptible at any time to being, damaged, concealed, obstructed, obscured, disrupted, covered, or changed by other required

packaging and labelling information, markings, or stamps, by any package design feature or opening or other mechanism, or by anything supplied by the manufacturer or seller; provided that in the case of flip top packages, it shall not be a violation if warnings and messages required to be placed at the top of the principal display areas are incidentally and temporarily separated upon normal opening of the package.

(7) In addition to the required health warnings and messages, the unit and outside packaging and labelling of all tobacco products shall provide the descriptive only information on constituents and emissions prescribed by the Ministry [*Note: or other appropriate authority*] in regulations.

(8) The Ministry shall prescribe the content, colors, size, font, print quality, layout, design, placement, display, and all other details related to the health warnings and messages, constituent and emissions information, and any other information required to be displayed in connection with tobacco product packaging and labelling. [*Note: Development of the warnings and messages, constituent and emissions information, and other required information should be undertaken during the legislative drafting process so that the regulations and any electronic source document (See the following sub-paragraph) can be published at the time or shortly after the law is enacted.*]

(9) The Ministry is authorized to provide electronic samples of the health warnings and messages, constituents and emissions information, and any other information required for tobacco product packaging and labelling. The samples must be reproduced and displayed by manufacturers and importers on packaging and labelling as closely as technologically possible.

(10) (1) After the date specified in regulations, which shall be no later than ___ days [*Note: for example, up to 365 days*] from the date of publication of the regulations in the Official Gazette, tobacco manufacturers and sellers shall only supply tobacco products, packaging, and labelling for sale in the territory that comply with the provisions of this Section, and commercial purchasers shall not buy tobacco products that fail to comply with the provisions of this Chapter.

[Note: The electronic samples authorized in Article 15(10) will need to be made available at the time of publication of the regulations in the Gazette for this date to work.] Any tobacco product packaging and labelling or products contained therein that do not comply with the requirements of this Chapter found in the possession or under the control of a tobacco manufacturer or seller or any person acting on their behalf after that date shall be subject to confiscation and destruction, in addition to any penalties or other corrective action authorized.

(2) For subsequent periods when health warnings and messages are required to be replaced with new warnings and messages, as described in sub-article (3), unit and outside packaging and labelling already in circulation with the old health warnings and messages may continue to be sold along with unit and outside packaging and labelling with the new warnings and messages for a period of no longer than ___ days [*Note: This should be a relatively short period, for example, 60 days*]. At the end of the ___ days, in addition to any penalty or other corrective action to which the responsible manufacturer and/or seller may be subject, any non-compliant packaging and labelling and any products contained therein found in the possession or under the control of a tobacco manufacturer or seller or any person acting on their behalf shall be subject to confiscation and destruction.

16. Prohibition on misleading packaging, labelling, and product design; regulation of promotional features

(1) The unit and outside packaging and labelling, and the tobacco product itself, must not promote the product by any means that are false, misleading, deceptive or likely to create an erroneous impression about the product's characteristics, health effects, hazards or emissions, including using any term, descriptor, trademark, figurative, color, or other sign of any kind in whole or in part that directly or indirectly creates or is likely to create the false impression that a particular tobacco product is less harmful than others. Prohibited terms include, but are not limited to, "low tar", "light", "ultra-light" or "mild", "extra", "ultra", and other terms in any language that are likely to mislead consumers, including when used as part of a brand name or trademark.

(2) Quantitative information on emissions shall not be displayed anywhere on or inside the product's unit or outside packaging or labelling, or on the product itself, including when used as part of a brand name or trademark.

(3) The Minister shall have the authority to specify additional prohibitions and requirements to prevent the promotion of tobacco products in any misleading manner, and to prohibit or restrict any promotional features, including but not limited to –

(a) the use of logos, colors, brand images, and other promotional items or features on, in, or as part of tobacco product packaging and labelling, and on or as part of the product itself, other than brand name, manufacturer name, product name and specified product information, displayed in a specified color and font, as may be prescribed in regulations;

(b) any features of the retail packaging designed to change after retail sale, including, but not limited to:

(i) heat activated inks;

(ii) inks or embellishments designed to appear gradually over time, including on the product itself;

(iii) inks that appear fluorescent in certain light, including on the product itself;

(iv) panels designed to be scratched or rubbed to reveal an image or text;

(v) removable or hidden tabs or panels; or

(vi) fold-out tables or panels; and

(c) any other misleading or promotional features or design of the packaging, labeling, or product.

[Note: As an alternative to sub-paragraph 3, provisions for directly requiring plain packaging could be provided in the legislation. See Australia's Tobacco Plain Packaging Act, 2011, for example. Available at <http://www.tobaccocontrolaws.org/legislation/country/australia>.]

(4) (a) In addition to any other requirements or prohibitions authorized in this Chapter or elsewhere in the Act, the Minister shall have the authority to prescribe requirements and prohibitions with regard to the physical features, such as but not limited to shape, size, opening or other moving mechanisms, and

other features of unit and outside tobacco product packaging, including their inside and outside surfaces and anything contained in or placed on the package. *[Note: Alternatively, provisions for standardized packaging could be required in the legislation. See Australia’s Tobacco Plain Packaging Act, 2011, Sec. 16(b), for example.]*

(b) The authority specified in sub-paragraph (a) shall extend also to the physical features, including but not limited to, the design, shape, and size, such as length and mass, of the product itself.

17. Designation of legal place of sale

The legal place of sale shall be visibly displayed on the unit and outside packaging and labelling of all tobacco products for sale in the territory, conveyed as follows: “Sales allowed only in _____”. *[Note: or other appropriate wording provided by the government.]* The information on legal place of sale shall be displayed on the package as specified in regulations. *[Note: This requirement could be part of legislative provisions implementing WHO FCTC Article 15 or in packaging and labelling provisions.]*

18. Duties not diminished by compliance with this Part

Fulfilling the requirements of this Part does not remove or diminish any duty of a tobacco manufacturer or seller, including, but not limited to, the duty to warn consumers about the health hazards arising from tobacco use and exposure to tobacco smoke.

19. Penalties for non-compliance

A person who violates any provision of this Chapter shall be subject to any one or combination of penalties provided in Article 43. Any fine that may be applied for a violation of this Chapter shall be as follows--

(a) against any tobacco manufacturer, importer, or wholesale distributor, a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____; and

(b) against a retailer *[Note: or exporter, if exports are covered under the Chapter]*, a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____.*[Note: Consideration could be given to applying different fine amounts for violations of different articles under this chapter.]*

CHAPTER VII – TOBACCO PRODUCT SALES

20. Objects of the Chapter

The objectives of this Chapter are to—

- (1) prevent the accessibility of tobacco products to young people, and
- (2) prevent the retail environment and sales practices from undercutting any of the objectives of the Act.

21. Prevention of youth access to tobacco products and related measures

(1) No seller shall sell a tobacco product to a person under ___ years of age *[Note: Since most tobacco users initiate tobacco use as youth or young adults, consideration should be given to setting a minimum age that might be higher than the age of majority if the age of majority is 18 or lower]* or employ or use a

person under ___ years of age to sell or handle a tobacco product. Prior to any tobacco product sale, the seller shall verify the age of the purchaser by checking a reliable form of identification.

(2) Retail sellers of tobacco products must display at their places of sale signage stating that tobacco sales to minors [*Note: or to persons below a specified age if that age is higher than the age of majority*] are not allowed, as may be prescribed in regulations.

(3) Tobacco products shall not be directly accessible to consumers at retail sales outlets prior to the sales transaction.

(4) No person shall sell or arrange for tobacco products to be sold through vending machines or other automated devices, and any tobacco product vending machines found for use within the territory shall be subject to confiscation, forfeiture, and destruction, in addition to any other penalties and corrective action authorized.

(5) No person shall sell or arrange for the retail sale of tobacco products, or enable or facilitate such sale, including by facilitating payment or delivery services, by any means by which the purchaser and seller are not in the same physical location. This includes but is not limited to, sales by mail, through the Internet, or other remote means.

(6) Sellers of tobacco products shall ensure that these products are not visible at the place of sale other than momentarily pursuant to a sales transaction.

(7) No person shall sell a tobacco product unless it is in an intact package containing the specified number of sticks or consisting of the specified weight, as applicable.

(a) Smoked tobacco product unit packages shall contain a minimum number of 20 sticks [*Note: An different number may be appropriate for cigars*].

(b) Smokeless tobacco product unit packages shall contain a minimum of 30 grams [*Note: or other minimum weight*] of smokeless tobacco.

(8) Any packages of tobacco products that do not meet the minimum size or weight requirements and any unpackaged tobacco products found in the possession or control of a seller or any person acting on its behalf shall be subject to confiscation, forfeiture, and destruction, in addition to any other penalties and corrective action authorized.

(9) The Ministry [*Note: or other appropriate authority*] may prescribe additional requirements and prohibitions related to tobacco product sales as necessary or appropriate to prevent youth access and to prevent sales methods that contravene or undermine any objectives of the Act.

22. Penalties for non-compliance

A person who violates any provision of this Chapter shall be subject to any one or combination of penalties provided in Article 43. Any fine that may be applied for a violation of this Chapter shall be as follows--

(a) for failing to post required signage, a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____;

(b) for a violation of Article 21(4) or (6), the applicable fine amount provided in Article 13 shall apply;(c) for violation of any other provision of Article 21, a fine of no less than ___ and no more

than ____ and __ times the previous fine amount for any subsequent violation, up to a maximum amount of _____. *[Note: Consideration could be given to applying different fine amounts for violations of different sub-paragraphs of Article 21.]*

CHAPTER VIII – REGULATION OF TOBACCO PRODUCTS; TOBACCO PRODUCT CONTENTS AND EMISSIONS DISCLOSURES

23. Objects of the Chapter

The objectives of this Chapter are to—

(1) ensure tobacco products are not designed in a way that makes them more addictive or attractive, especially to young persons, or in ways that undercut any objectives of the Act, and

(2) ensure the Ministry *[Note: or other appropriate authority]* has broad authority to regulate tobacco products and their testing and to require the disclosure of information about tobacco products to the government in order to effectively exercise its regulatory powers.

24. Regulation of tobacco products

(1) No person shall manufacture or sell any tobacco product that does not meet all product requirements prescribed by the Ministry *[Note: or other appropriate authority]* in implementing regulations, as tested by the method and in the manner prescribed.

(2) Tobacco products exported from the territory shall meet the requirements of the importing territory. *[Note: If possible and appropriate, the legislation might provide that if no such requirements exist, the products must meet the requirements imposed in this Chapter.]*

(3) Any non-compliant tobacco products found in the possession or under the control of a tobacco manufacturer or seller or any person acting on their behalf, or bound for the market place after the date specified for compliance in regulations shall be subject to confiscation and destruction, in addition to the application of any penalties and other corrective action authorized.

[Note: The FCTC Article 9 and 10 Guidelines address some, but not all, aspects of product regulation as of September 2012. Several countries have passed legislation governing select aspects of product regulation. For example, Brazil's RDC No. 14 of March 15, 2012 bans additives in tobacco products and several jurisdictions impose requirements for reduced ignition propensity (RIP). An unofficial English translation is available at http://www.tobaccocontrolaws.org/files/live/Brazil/Brazil%20-%20RDC%20No.%2014_2012.pdf. The National Fire Protection Association of the U.S. provides a model RIP law, available at <http://www.nfpa.org/itemDetail.asp?categoryID=2260&itemID=53335&URL=Safety>. These examples could be used to inform the development of legislative provisions for regulating additives and reduced ignition propensity, if desired.]

25. Product content and emissions reporting

(1) Tobacco manufacturers and importers shall submit reports to the Ministry *[Note: or other appropriate authority]*, periodically and upon request, on tobacco product contents and emissions, which shall be tested by the method and in the manner prescribed in regulations. Reports shall be submitted at the frequency and in the manner prescribed in regulations as to content, format, and all other details.

(2) The Chief Executive Officer or Chair of the Board of the tobacco manufacturing or importing company, as applicable, shall verify the information contained in the reports and, as part of the report, attest to the accuracy and completeness of the information supplied.

(3) The Ministry shall make information from these reports readily accessible to the public while taking reasonable action necessary to prevent disclosure of any information that may be protected by law and any information that may be misleading or promotional.

26. Penalties for non-compliance

A person who violates any provision of this Chapter shall be subject to any one or combination of penalties provided in Article 43. Any fine applied for a violation of this Chapter shall be as follows--

(a) against a manufacturer or importer, a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____;

(b) against any other seller of tobacco products who is aware or in a position to be aware of a product's noncompliance with product requirements, a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____; and

(c) against any person who supplies false, misleading, or inaccurate information in a report required by Article 25, including the person verifying and attesting to the report, a fine of no less than ___ and no more than ___ and ___ times the previous fine amount for any subsequent violation, up to a maximum amount of _____.

[Note: Consideration could be given to applying different fine amounts for violations of the different articles under this chapter.]

CHAPTER IX— PROTECTION OF TOBACCO CONTROL POLICIES FROM THE COMMERCIAL AND OTHER VESTED INTERESTS OF THE TOBACCO INDUSTRY

Note: Because many of the provisions for implementing FCTC Article 5.3 can take the form of either policy or law, or both, options for the different provisions below are noted in blue font.

27. Preliminary

In this Chapter, unless otherwise provided in any particular provision, reference to-

(1) “government” or “government authority” includes any person working on behalf of or to further the interests of government. Where the context requires, reference to “government” also refers to the public office holders and other persons representing government;

(2) “public office holder” includes any person or entity working on behalf of or to further the interests of the office holder; and

(3) “tobacco industry” or “entity in the tobacco industry” includes any person or entity working on behalf of or to further the interests of the tobacco industry.

28. Objects of the Chapter; interpretation

(1) The objectives of this Chapter are to:

(a) fulfill the State's obligation under Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC) to protect tobacco control policies from the commercial and other vested interests of the tobacco industry on account of the inherent and irreconcilable conflict of interests between the goals of public health policies for tobacco control and the interests of the tobacco industry, arising from the deadly nature of tobacco products;

(b) insulate tobacco control policy making and implementation from the tobacco industry's actions to subvert and undermine effective tobacco control policy development and the role of government in implementing effective tobacco control policies; and

(c) enact the most protective measures to guard against tobacco industry influence and interference with tobacco control policy development and implementation since this interference jeopardizes the government's ability to enact and implement the effective tobacco control measures required by the various articles of the FCTC.

(2) Because of the longstanding practice of the tobacco industry subverting and undermining tobacco control policy development and implementation through a variety of overt and covert means, any interpretation questions that might arise in applying the requirements and prohibitions under this Act shall be made in favor of insulating the government from tobacco industry influence and interference and in favor of full transparency of any interactions between government and the tobacco industry.

29. Limitation on interactions between government and the tobacco industry

[Note: The provisions of this article could take the form of policy rather than legal measures. Enacting these provisions through law, however, will lend strength to them, and these provisions are central to effectively insulating government from tobacco industry influence and interference.]

(1) Interactions between government and the tobacco industry shall be limited to only those strictly necessary for effective regulation of the tobacco industry or tobacco products.

(2) (a) When any interaction between government and the tobacco industry is strictly necessary for effective regulation, and whenever there is an interaction of any kind or contact between the government and the tobacco industry, regardless of which party initiates it, the appropriate government authority shall ensure transparency of the interaction or the contact.

(b) Transparency of tobacco industry-government interactions and contacts shall require, at a minimum-

(i) conducting any interaction between the government and the tobacco industry in public, such as through public hearings, unless doing so would jeopardize effective regulation or would not be legally possible, as, for example, in the case of inspections or investigations or litigation interactions;

(ii) providing, for any interaction, timely advance notice and an agenda to the public and to the _____ *[Note: This would be the designated government oversight authority or authorities]*, unless doing so would jeopardize effective regulation or would not be

legally possible, as, for example, in the case of inspections or investigations or litigation interactions;

(iii) requiring minutes or other documentation of all interactions, whether face-to-face or through some other means of communication, and contacts that provide sufficient detail to identify, at a minimum, the parties involved, matters discussed or considered, any decisions taken, any follow-up action planned or anticipated, the date, location, and method of the interaction or contact, and any other details as may be prescribed in regulations and/or policies;

(iv) forwarding all documentation to ____ [*Note: this would be the designated government oversight authority or authorities*] within no more than ____ days and making all records of and documents related to interactions, communications, and contacts readily accessible to the public, unless public disclosure would not be legally possible or timeliness of public accessibility would jeopardize effective regulation, such as in the case of ongoing investigations; and

(v) any other transparency measures as may be prescribed in regulations and/or policies.

(3) Any necessary interaction with the tobacco industry must be carried out in a manner that avoids the creation of any perception of a partnership or collaboration. In the event such a perception is created, the government shall act promptly to correct it.

30. Prohibition on partnerships and endorsements of the tobacco industry, tobacco industry involvement in tobacco control initiatives

[Note: The provisions in this article could take the form of policy rather than legal measures, and in fact these should be elaborated in regulations or policies pursuant to Article 29 since all of the things prohibited in this Article arise from government-tobacco industry interactions that are not strictly necessary for effective tobacco control. As policy measures alone, however, the provisions probably would not be enforceable through legal action.]

Government shall not participate in, support, endorse, or accept:

(a) any proposals, drafts, or offers of assistance with the development or implementation of any tobacco control policies by the tobacco industry;

(b) partnerships of any kind with the tobacco industry, including with respect to initiatives or activities of the tobacco industry described, characterized, implied, or likely to be perceived as “socially responsible”;

(c) any non-binding or non-enforceable agreement, memorandum of understanding, voluntary arrangement, or tobacco industry code of conduct in the place of legally enforceable tobacco control measures; or

(d) any tobacco industry involvement in any manner in any initiative, campaign, program, or activity directly or indirectly related to tobacco control or public health, including but not limited to, any youth access or education program, public education campaign, or other initiative.

31. Prohibition on voluntary contributions from the tobacco industry

[Note: The provisions in this article that prohibit the tobacco industry from making contributions would have to be enacted as legal measures since government policies would only apply to the conduct of the government entities and public office holders. The prohibitions on government acceptance of tobacco industry contributions in this article would be more enforceable as legal measures than as policy measures.]

(1) No person in the tobacco industry shall offer or make any voluntary contribution of any kind, financial or otherwise, to a government entity; provided that a contribution from the tobacco industry resulting from legal requirements or settlement of litigation shall not be considered a voluntary contribution. No government institution, body, board, commission, committee, work group, organ, or other government entity shall accept such voluntary contribution.

(2) No person in the tobacco industry shall offer or make any financial or other contribution of any kind, including any gift, favor, or perquisite, to any public office holder. No public office holder shall solicit or accept any such financial or other contribution of any kind, including any gift, favor, or perquisite from a person in the tobacco industry.

(3) No person in the tobacco industry shall offer or make to any political party, candidate, or campaign, or any person or entity acting on their behalf, any financial or other contribution of any kind. No political party, candidate, or campaign, or any person or entity acting on their behalf, shall solicit or accept any such financial or other contribution of any kind from a person in the tobacco industry.

(4) Any person who offers, makes, solicits, receives, accepts, or facilitates a contribution covered under this Article shall report the same to _____ within ___ days of the offer, solicitation, acceptance, receipt, or facilitation, as applicable. *[Note: Reports could be required to go to an over-arching oversight body, if one exists or will be created under the law, and/or to the heads of the various government institutions involved, or this could be dealt with in some other way in an implementing policy.]* The _____ shall make information from these reports publically accessible in a timely manner.

32. Prevention and management of conflicts of interest

[Note: The provisions in this article could take the form of policy rather than legal measures. They lend themselves well to policy measures if the government has the political will to adhere to them. As legal measures, they would be more enforceable. Regardless of whether these provisions are enacted as policy or legal measures, it will be necessary to provide detailed guidance, for example, on exactly what disclosures are required and in what manner, determining when a conflict of interest arises or may arise, on how to handle conflicts of interest, how disclosures and other records are to be made publically accessible, procedures for orderly divestment, termination of prohibited relationships, and other matters.]

(1) Before engaging any person to undertake any paid or voluntary government work or service of any kind involving the development or implementation of tobacco control policy, the person under consideration must be required to make appropriate disclosures about any current or prior affiliation with the tobacco industry or other tobacco-related conflict of interest, as specified in (a) – (c). No person shall be hired, awarded a contract, or otherwise retained or engaged to work or serve in any capacity with responsibility for tobacco control policy if that person:

- (a) is currently engaging in occupational activity with the tobacco industry, including serving as a member of a board of directors for a business in the tobacco industry;

(b) has engaged in occupational activity with the tobacco industry within the 24-month period *[Note: or other period]* prior to the month the disclosure was submitted; or

(c) has or had during the relevant period any other tobacco-related conflict of interest, as determined by the hiring authority.

(2) Any public office holder who intends to engage in occupational activity, including serving as a member of a board of directors for an entity in the tobacco industry, upon leaving government service or within 24 months *[Note: or other period]* after leaving government service, shall disclose such intent to _____ within ___ days of agreeing with the entity to undertake such activity. *[Note: Reports could be required to go to an over-arching oversight body, if one exists or will be created under the law, and/or to the heads of the various government institutions involved, or this could be dealt with in some other way in an implementing policy.]*

(3) Any person required to make disclosures pursuant to this Article shall truthfully and fully disclose all information required and do so in the time specified.

(4) Any public office holder who engaged in significant activity in relation to tobacco control policy during the 24 month period *[Note: or other period]* immediately prior to the termination of his or her government service shall be prohibited from accepting occupational activity, including appointment to a board of directors, with any entity in the tobacco industry for a period of at least ___ after leaving government service. In addition, the public office holder and shall be bound by confidentiality with respect to disclosing any matter involving tobacco control policy development or implementation for a period of ___ years *[Note: or from ever disclosing such information.]*

(5) The relevant authority or authorities in each government branch, institution, or body shall establish effective directives, policies and procedures, guidelines, and/or other measures necessary or appropriate for preventing and addressing any tobacco-related conflicts of interest pursuant to this Article and any implementing regulations.

[Note: If there is or will be an over-arching government-wide oversight body with authority over all of government, it could be charged with developing regulations, directives, policies, procedures, and/or guidelines under sub-paragraphs 1-5, or with providing guidance to the branches, institutions, bodies, or other organs to ensure consistency of directives, policies and procedures, guidelines, and/or other measures policies they develop.]

33. Tobacco industry reporting

(1) Tobacco manufacturers, wholesale distributors, and importers shall submit reports to the Ministry *[Note: and/or to another relevant authority, such as an over-arching oversight body, focal point, or working group with the mandate to coordinate and oversee the implementation of FCTC Article 5.3]* periodically, as prescribed by the Ministry *[Note: or other relevant authority]*, and upon request. These reports shall contain the following information, to the extent applicable to the entity submitting the report, for the period covered by the report--

- (a) tobacco product revenues and profits, broken down by region and sector and, in the case of tobacco manufacturers, by wholesaler and retailer;
- (b) locations, addresses and corporate names of all tobacco and non-tobacco subsidiaries, affiliates, joint ventures, partners, suppliers, and licensees;

- (c) litigation in which the corporation or a subsidiary of the corporation, or the officers or directors of either, is or was at any time during the litigation a party to the litigation;
- (d) any and all legal violations committed or prosecuted against the corporation or any of its officers or directors and the outcome or status of any prosecutions;
- (e) corporate taxes owed and paid;
- (f) domestic and global market shares for all brands and brand families in all markets in the territory, including market shares by age and sex;
- (g) information on tobacco product imports into and exports out of the territory, as specified in regulations, and import and export partners and locations [*Note: This information may already be required to be reported to a trade or finance ministry*];
- (h) all activities and actions attempted or undertaken by the reporting entity or any third party engaged by the reporting entity to influence the formulation or implementation of any tobacco control or public health policy;
- (i) (1) identification of lobbying firms, lobbyists, advocacy organizations, advocates, and all other persons, including the employees of the manufacturer, wholesaler, or importer, used for the purpose of taking or attempting action to influence the formulation or implementation of any tobacco control or public health policy, including issue advocacy advertising, and
 (2) itemization of all costs incurred and payments or other consideration of any kind made in regard to these activities, dates the costs were incurred and the payments or other consideration were made, if any, and identification of the policy that was the subject of the lobbying;
- (j) membership in any trade or business associations or membership organizations;
- (k) payments or other consideration of any kind made to any trade or business associations or membership organizations, including not-for-profit associations, and the purpose(s) of any such payments;
- (l) identification of any trade, business, or membership organizations, including not-for-profit associations, established or operating pursuant to any degree of direction from or control by the reporting entity;
- (m) any conferences, seminars, workshops, training events, and other forums concerning tobacco control policy, tobacco products, or tobacco control organized, funded, or supported in some other way in whole or in part;
- (n) any conferences, seminars, workshops, training events, and other forums concerning tobacco control policy, tobacco products, or tobacco control attended by any person employed by or acting on behalf of the reporting entity;
- (o) any offers of or payments made to scientists, researchers, journalists, and any other persons as may be specified in regulations, and the purposes, amounts, and dates of the offers or payments;

- (p) any payments, gifts, contributions of any kind, or perquisites offered or given, directly or indirectly, to any public office holder having any responsibility for tobacco control, the dates and amounts offered or given, and the purposes;
- (q) any contributions or payments of any kind offered or given to any government institution, body, board, commission, committee, work group, and other government organ or entity, the amount, date, and the purposes of the contributions or payments;
- (r) any charitable, philanthropic, civic, or similar contributions or payments of any kind offered or given to any persons and the amount and date of the contributions or payments;
- (s) any contacts or communications of any kind initiated and all interactions of any kind with any public office holder having any responsibility for tobacco control, along with a description of the identity of the office holder, the date, the purpose, matters raised or discussed, and any outcome;
- (t) any offers or payments made to any political party, candidate, campaign, or any person acting on their behalf, along with a description of the identity of the political party, candidate, or campaign, the date, and the amount; and
- (u) any other information as may be prescribed by the Ministry [*Note: or other appropriate authority*] in regulations.

(2) The Chief Operating Officer or Chair of the Board of the entity submitting the report shall, under penalty of perjury, verify and attest to the accuracy and completeness of the information reported.

(3) The report shall be submitted at the frequency and in the manner as may be prescribed by the Ministry in regulations as to content, format, method of reporting, and all other details.

(4) The Ministry shall maintain the reports for a period of at least ___ years and shall make information from the reports readily accessible to the public in a timely manner, which shall be no later than ___ days after receipt of the report; provided that the Ministry shall take reasonable action necessary to prevent disclosure of any information that may be protected by law and any information that may be misleading or that may promote tobacco use, tobacco products, or the tobacco business making the report.

34. Awareness raising and public education

The Ministry [*Note: and/or any tobacco control board or over-arching body with responsibility for tobacco control*] shall ensure that all branches of government are made aware of, at a minimum, the addictive and harmful nature of tobacco products, the need to protect tobacco control policies from the commercial and other vested interests of the tobacco industry, and of the strategies, tactics, and front groups and other surrogates used, openly or covertly, by the tobacco industry to undermine or subvert the development and implementation of effective tobacco control policies, including by making philanthropic contributions to public and private organizations.

35. Prohibition on incentives or privileges to tobacco businesses

[Note: If there are already privileges or incentives granted by a pre-existing law, that law would need to be amended or superseded by new legal provisions, as below. Additionally any new laws generally granting subsidies, tax benefits, government procurement benefits, foreign direct investments, or the like,

would need to exclude application of those benefits to the tobacco industry. Otherwise, the prohibition on granting incentives or privileges to tobacco businesses could be undertaken as a matter of policy if the government has the political will to adhere to such a policy.]

Government shall not provide any incentive or privilege to any person to establish or run a tobacco manufacturing, wholesale, import, or retail business, or any incentive or privilege related to any phase of the production or marketing of tobacco products or growing of tobacco. This includes but is not necessarily limited to, subsidies, investment incentives, direct investments or loans, tax exemptions or reductions, or any other form of favourable tax treatment, and research and development grants or loans.

36. Implementation of this Chapter

(1) The _____ shall have the authority to specify additional requirements and prohibitions to protect tobacco control policies from the commercial and other vested interests of the tobacco industry, and shall have authority to promulgate any implementing regulations necessary or appropriate for achieving the objectives of this Chapter.

[Note: If there is or will be an over-arching government-wide oversight body with authority over all of government, that body could be given the regulatory power. If there is not and will not be such an over-arching body, regulatory authority may need to be given to multiple ministries or authorities.]

(2) Application of this Chapter to a retailer that sells tobacco products, either exclusively or among other products, shall be triggered if the retailer acts in any way in contravention of this Chapter when any such act was undertaken with the aim or has the effect or likely effect of influencing tobacco control policy directly or indirectly.

(3) The heads of government institutions, bodies, and/or other organs shall adopt and periodically monitor and evaluate policies, procedures, directives, guidelines, codes of conduct, and/or standards to ensure proper administration of the provisions of the Chapter.

37. Penalties

(1) A person violating any provision of this Chapter shall be subject to any one or combination of penalties provided in Article 43, as applicable. Any fine that may be applied for a violation of this Chapter shall be as follows--

(a) in the case of violation by a political candidate, party, or campaign, a fine of no less than _____ and no more than _____ and ___ times the previous fine amount for any subsequent violation, up to a maximum of _____;

(b) in the case of a violation by an entity in the tobacco industry or a retailer as specified in Article 36(2), a fine of no less than _____ and no more than _____, and ___ times the previous fine amount for any subsequent violation, up to a maximum of _____;

(c) in the case of a violation by a public office holder, a fine of no less than _____ and no more than _____, and ___ times the previous fine amount for any subsequent violation, up to a maximum of _____; and

(d) in the case of a violation by any other person, a fine of no less than _____ and no more than _____, and ___ times the previous fine amount for any subsequent violation, up to a maximum of _____.

[Notes: 1) Consideration could be given to applying different fine amounts for violations of different articles under this chapter. 2) The ban on tobacco industry contributions is also covered by the ban on sponsorship in Article 11(a) of Chapter V, so penalties imposed for violating the ban on tobacco industry contributions in this chapter should be consistent with any such penalties provided in Chapter V.]

CHAPTER X – MISCELLANEOUS

38. Power to make regulations

(a) In addition to any matter in the various Chapters for which this Act requires or authorizes the Minister and any other government authority to make regulations, policies, procedures, and other measures, the Ministry and any other authority specified under the Act are authorized to make regulations prescribing any matter or thing that is necessary or appropriate to fulfil the objectives of the Act and its Chapters and for the effective administration of the Act.

(b) Regulations, policies, procedures, and other measures required or necessary under this Act pursuant to Articles 8(a), 15(1) and (7), 32(5), 33(1) and (3), and 36(3) shall be enacted no later than ___ days from the effective date of the Act, provided that the Ministry or other authority shall have the authority to revise regulations and make new regulations for these and any other articles at any time.

39. Evaluation

The Minister *[Note: or other authority or authorities]* shall be required to evaluate the effectiveness of the Act and the effectiveness of the inspection and enforcement program. Evaluation shall include an assessment of the impact with respect to different population groups and vulnerable groups such as women, youth, and low-income populations. This information shall be readily accessible to the public.

40. Sub-national authority to enact legal measures

Sub-national authorities may enact and implement legal measures that are more protective of the public's health than those provided under this Act. *[Note: This may not be applicable in some jurisdictions.]*

41. Protection from retaliation

It shall be unlawful for the government, any business or entity, or any other person to retaliate or discriminate against any employee, applicant, contractor, or other person because such person made a complaint, reported, disclosed, or opposed any conduct, activity, or practice that reasonably could be construed to be a violation of any provision of this Act or implementing regulations or policies, or who brought a legal action, testified in any proceeding or hearing, or assisted or participated in any way in any investigation brought pursuant to this Act.

42. Application of penalties for non-compliance(1) In addition to the application of any fine that provided in the different Chapters of this Act, any person who violates any provision of this Act or implementing regulations shall be subject to any one or combination of the following penalties, as applicable:

(a) a warning for a first time, unintentional violation [*Note: or prescribe other circumstances that justify a warning*];

(b) public notification of the violation and accompanying court [*Note: or, as applicable, administrative*] decision, with any costs associated with publication cast against the violator(s);

(c) licensure suspension or revocation; and

(d) imprisonment of up to ____ [*Note: specify time period*].

(2) In addition to any penalty authorized in sub-article 1 and in any Chapter of this Act, corrective action may be ordered, with the cost of the corrective action borne or reimbursed to the government by the violator(s). Corrective action includes any corrective measures provided in any Chapter of this Act and, as applicable, any one or combination of the following:

(a) an order to cease and desist from any conduct that violates any provision of the Act or implementing regulations or policies;

(b) recall, removal, or blockage of tobacco advertising, promotion, or sponsorship content and confiscation and destruction of any advertising, promotion, or sponsorship materials and any items containing such content or materials, including tobacco product vending machines;

(c) invalidation of any contract, agreement, or arrangement concerning tobacco advertising, promotion, or sponsorship and forfeiture of any contribution accepted from the tobacco industry that is prohibited under Chapter V or IX;

(d) recall, removal, and confiscation and destruction of any product that fails to meet the requirements specified in Chapters V, VI, or VII.

(e) recall, removal, and confiscation and destruction of any product for which no report was filed or for which false or incomplete information was filed pursuant to Article 25;

(f) forfeiture and destruction of illicitly traded products;

(g) forfeiture of ill gotten gains; and

(h) any other corrective action ordered.

(3) In the case of a violation by a corporation, partnership, firm or other entity, the managers, directors, officers and/or their legal representatives, as appropriate, shall bear responsibility for any penalty imposed, for any costs associated with any enforcement or corrective action, and for any term of imprisonment ordered, unless otherwise specified.

(4) Any fines collected [*Note: or a specified portion of fines collected*] pursuant to this Act shall be used for funding tobacco control programs and/or activities.

43. Public awareness and civil society participation

(1) In implementing this Act, the Ministry [*Note: or other authority or authorities*] shall promote and strengthen public awareness of tobacco control issues and promote the full participation of civil society not affiliated with the tobacco industry.

(2) Any person may file a complaint about any violation of the Act or implementing regulations or policies and the Ministry *[Note: or other authority or authorities]* shall establish institutional channels for the presentation of and action upon such complaints.

(3) Any person may commence a civil action before the appropriate court *[Note: or if applicable, before the appropriate administrative authority]* against any person for violation of any provision of this Act. It shall not be necessary for the person instituting the action to prove harm as a result of the alleged violation or that he or she has any special interest in the action, save for the enforcement of the Act. An action instituted under the provisions of this section shall be exempt from any filing fees.

[Note: Where possible in a given jurisdiction, it might be advisable to allow the person bringing the action, if successful, to also recover the costs of bringing the action, including attorneys' fees, and to recover statutory damages, if applicable in the jurisdiction.]

44. Severability

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

45. Repeals

All laws or parts thereof that are in conflict or are inconsistent with any provision of this Act are hereby repealed or modified accordingly. *[Note: Depending on the way repeals are handled in the jurisdiction, laws or parts of laws that conflict with any provisions in the Act may need to be specified here or amended or repealed separately to remove the offending provisions.]*

SCHEDULE

Indicative (Non-Exhaustive) List of the Forms, Media, and Means of Tobacco Advertising, Promotion, and Sponsorship Prohibited Under the Act

1. Communication through audio, visual or audiovisual means, such as print (for example, newspapers, magazines, pamphlets, leaflets, flyers, letters, billboards, posters, signs), television and radio (including terrestrial and satellite), films, DVDs, videos and CDs, games (such as computer games, video games and online games), other digital communication platforms (such as the Internet, mobile phones, and mobile phone applications), and theatre and other live performance;
2. Brand-marking, including in entertainment venues and retail outlets and on vehicles and equipment, such as by use of words, designs, images, sounds or colors, including brand names, trademarks, logos, names of tobacco manufacturers, importers, or wholesalers, colors or schemes of colors in whole or part, and any other indicia associated or likely to be associated with tobacco products, manufacturers, importers, or wholesalers;
3. Display or visibility, other than incidental to an immediate sales transaction, of tobacco products at points of sale and any other commercial display of tobacco products;
4. Sales of tobacco products through vending machines;
5. Sales of tobacco products through the Internet;
6. Use of a tobacco brand name, emblem, trademark, logo, trade insignia, or any other distinctive feature, in whole or in part, including color combinations, on or in connection with a non-tobacco product or service in such a way that the tobacco product and the non-tobacco product or service are likely to be associated;
7. Use of a brand name, emblem, trademark, logo, trade insignia, or any other distinctive feature, in whole or in part, including color combinations, of a non-tobacco product or service in connection with a tobacco product or tobacco manufacturer, importer, or wholesaler in such a way that the tobacco product or company and the non-tobacco product or service are likely to be associated;
8. Product placement, such as the inclusion of or reference to a tobacco product, service or trademark in the context of communication in return for payment or other consideration;
9. Provision or offer of gifts or discounted products, such as key rings, T-shirts, baseball caps, cigarette lighters, CDs, or other trinkets or tobacco products, in connection with the purchase of tobacco products;
10. Supply or offer of free samples of tobacco products, including in conjunction in connection with marketing surveys and taste testing;
11. Incentive promotions or loyalty schemes, such as redeemable coupons provided with purchase of tobacco products;
12. Competitions associated with tobacco products or brand names, whether requiring the purchase of a tobacco product or not;

13. Direct communications with individuals using promotional material, including informational material, that is aimed at having or is likely to have a promotional effect, such as through direct mail, telemarketing, “consumer surveys” or “research”, or person-to-person conversation;
14. Promotion of discounted products;
15. Sale or supply of toys or sweets or other non-tobacco products that resemble tobacco products;
16. Payments or other contributions of any kind to retailers aimed at encouraging or inducing them, or having the likely effect of encouraging or inducing them, to sell tobacco products, including retailer incentive programs, such as those that provide rewards to retailers for achieving certain sales volumes;
17. Promotional packaging and product design features that have been prohibited or restricted in regulations;
18. Payment or other consideration in exchange for the exclusive sale or prominent display of a particular product or particular manufacturer’s product in a retail outlet or at a venue or an event;
19. Sale, supply, placement, or display of tobacco products at educational establishments or at hospitality, sporting, entertainment, music, dance and social venues or events;
20. Provision of financial or other support to events, activities, individuals or groups, such as sporting or arts events, individual sportspeople or teams, individual artists or artistic groups, welfare and other public interest organizations, government institutions or organizations, politicians, political candidates, and political parties, whether or not in exchange for attribution, acknowledgement, or publicity, including corporate social responsibility activities of any kind;
21. Provision of financial or other support to venue operators, such but not limited to as pubs, clubs, and other recreational venues, in exchange for building or renovating or decorating premises to promote a tobacco product or the use or provision of awnings, sunshades and similar items that promote a tobacco product; and
22. Any other tobacco advertising, promotion, or sponsorship in any form and by any method or means.



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