

Chapter 8

Smokeless Tobacco Regulation and Policy

Chapter Contents

The Role of Regulation and Policy	255
The Global Community and Smokeless Tobacco Regulation	255
Key Provisions of the FCTC	256
Warning Labels on Product Packaging	257
Toxicant Testing	257
Illicit Trade	258
Description and Analysis of Key Tobacco Control Policy Interventions	259
Education and Awareness Efforts	259
Excise Taxes and Pricing Policies	260
Bans on Smokeless Tobacco	260
Regulatory Experience of Countries and WHO Regions	261
The South-East Asia and Western Pacific Regions	261
The European Region	261
The Americas Region	262
United States	262
Canada	262
Brazil	262
The Eastern Mediterranean Region	263
The African Region	263
Challenges and Recommendations for Regulation and Policy	263
Smokeless Tobacco Product Heterogeneity and Novelty	263
Testing Challenges	264
The Evidence Base and Information Gaps	264
Information Dissemination	265
Smokeless Tobacco Product Regulation	265
References	267
Figure	
Figure 8-1 Camel Snus advertisement	256

The Role of Regulation and Policy

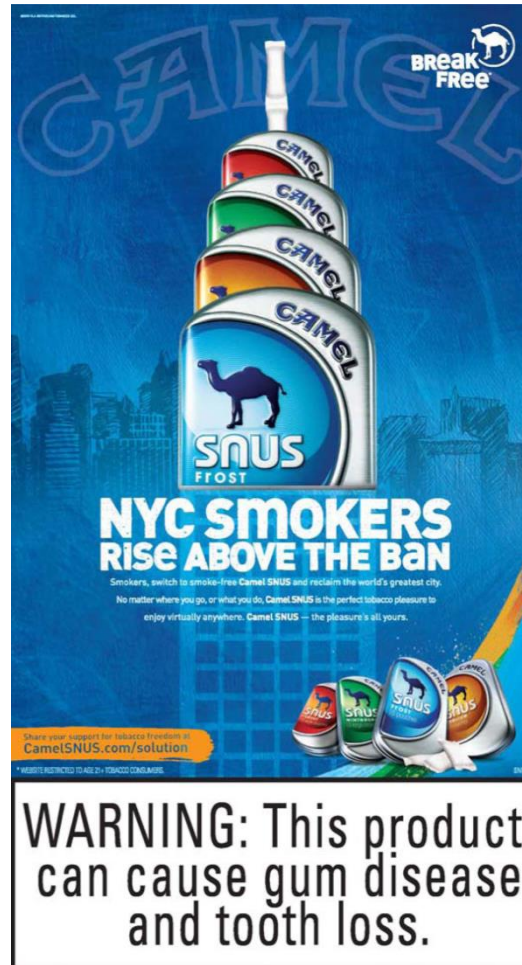
Regulatory and policy actions on the part of governments and international organizations are vital to addressing the global tobacco epidemic and protecting human health. One of the principal requirements of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) is to “adopt and implement effective legislative, executive, administrative, and/or other measures...at the appropriate governmental level to protect all persons from exposure to tobacco smoke.”¹ Furthermore, according to the WHO FCTC, “the consumption of smokeless tobacco is a global concern and not limited to a few countries. During the negotiations leading to the WHO FCTC, Parties agreed to address concerns relating to all forms of tobacco, not only the smoking forms.”^{2,p.4} The need for regulation guided by effective policy can be seen in the measures the FCTC calls for: taxation and pricing, regulation of tobacco product contents, product packaging and labeling requirements, restricting marketing and advertising, as well as prohibiting sales to minors, preventing illicit trade, and others.

The key to successful use of regulatory tools is that they be grounded in scientific evidence. In recognition of this basic principle, the FCTC calls on the Parties to the Convention to develop and promote research in the field of tobacco control.³ Through evidence-based regulation, governments can reduce their populations’ exposure to harmful toxicants in smokeless tobacco (ST) products. Youth initiation of ST use can also be reduced through restrictions on advertising, marketing, and promotion, and through aggressive enforcement of restrictions on youth access to tobacco products.

The Global Community and Smokeless Tobacco Regulation

The global public health community has long focused primarily on cigarette smoking. Smokeless tobacco use has received less attention because it imposes a comparatively smaller burden on human health, and because it has been seen as confined to a few South Asian countries, Sweden, and the United States, and therefore not of worldwide concern. However, the reality is that ST use is not simply a local or regional problem but a major challenge facing a large percentage of the world’s population. In addition, several factors suggest that the public health impact of ST use is likely to intensify. First, major cigarette companies have moved into the ST market by purchasing ST manufacturing companies, and have expanded their operations (see chapters 2 and 6). Second, the tobacco industry is promoting ST use as a short-term substitute for smoking in countries that have made good progress in ensuring smoke-free environments (Figure 8-1).⁴ Third, ST use has been promoted by some as a cessation aid and a harm-reduction tool for cigarette smokers, although there is insufficient evidence for the effectiveness of ST as a cessation aid.⁵

Figure 8-1. Camel Snus advertisement



Note: This advertisement appeared after New York City amended its smoke-free law in 2003 to include all restaurants and bars. Caption says, "Smokers, switch to smoke-free Camel Snus and reclaim the world's greatest city. No matter where you go, or what you do, Camel Snus is the perfect tobacco pleasure to enjoy virtually anywhere. Camel Snus—the pleasure's all yours."

Key Provisions of the FCTC

The WHO FCTC was negotiated between 1999 and 2003 and came into force in 2005. During the negotiations, some WHO member states opposed including ST in the Framework Convention. It was argued that the body of evidence was insufficient for a concerted global action against ST, and that ST use was at most a regional concern in Asia that should be addressed by a regional policy. However, the majority view on the harms associated with ST use prevailed, and ST was incorporated into the FCTC.

Although the FCTC covers all tobacco products, many of the strategies developed under the Convention to date are focused on cigarettes only. However, in recognition of the emerging global threat from ST, the fourth session of the Conference of the Parties discussed the issue and requested a comprehensive report on the Parties' experience with smokeless tobacco.⁶ The fifth session of the Conference of the Parties further discussed efforts to control smokeless tobacco and electronic cigarettes, and the Parties

will continue to review evidence on ST and the prevention and control of e-cigarette use, and report on this review during the sixth session of the Conference of the Parties,⁷ which convenes as this report goes to press.

The following paragraphs describe measures called for by the FCTC (warning labels, toxicant testing, and illicit trade) as they relate to ST, and how these measures have been implemented by the Parties.

Warning Labels on Product Packaging

Parties to the treaty often apply WHO FCTC requirements differently to smokeless forms of tobacco as compared with cigarettes. For example, Article 11 sets standards for warning messages to be displayed on tobacco product packaging,⁸ but many Parties have lower standards for ST packaging than for cigarette packages. Most European Union (EU) countries, the Russian Federation, and other countries allow health warnings to cover a smaller proportion of the principal display area of ST packages than of cigarette packages. Some countries (e.g., Thailand, Bangladesh, Venezuela, and Pakistan) have mandated that health warnings appear at the top of the principal display area for cigarettes but not for ST. In addition, many countries (e.g., the United Kingdom, Turkey, Sweden, and Vietnam) mandate alternating health warnings for cigarettes but not for ST products. Similarly, countries such as Australia, Canada, Malaysia, Switzerland, Jordan, and Djibouti require graphic/pictorial warnings for cigarettes but not for ST products.

The issue of package warnings also illustrates how evidence regarding ST use provided to governments and decisionmakers can lead to policy change. Data from the 2009–2010 Global Adult Tobacco Survey (GATS) for India showed an alarming increase in the prevalence of ST use in India. This evidence aroused great concern in the Indian government, which then formulated a requirement for pictorial health warnings for ST products.⁹ (This requirement went into effect in December 2011.) The more current data on the prevalence of ST use that has been furnished by the GATS and other national surveys attracts greater policy attention to smokeless tobacco.

Toxicant Testing

Articles 9 and 10 of the FCTC stipulate the testing and measurement of contents and emissions of tobacco products. The numerous different ST products contain widely varying levels of toxicants and include some products with very high amounts of toxic substances. In view of this variability, the WHO Study Group for Tobacco Product Regulation (TobReg) has recommended mandating upper limits for toxicants in ST products.^{10,11} The TobReg Study Group produced a review, published in two technical reports, of the available global data on toxicant levels in ST products, with emphasis on two carcinogens, tobacco-specific nitrosamines (TSNAs) and benzo(*a*)pyrene (BaP). The Study Group recommended setting an upper limit for both *N*'-nitrosonornicotine (NNN) and 4(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) at 2 micrograms per gram of dry weight tobacco, and an upper limit for BaP at 5 nanograms per gram of dry weight tobacco. These recommendations were based upon extensive review of the evidence on methods to reduce these carcinogens and the feasible limits to which they can be reduced in available products. Although not formally adopted by the Conference of the Parties, the Study Group's recommendations can serve as a basis for future regulations or can be adopted by countries where ST use is highly prevalent and constitutes a major public health problem.¹²

Importantly, TobReg emphasized that “regulators must assume responsibility to ensure that consumers are not told directly or indirectly or led to believe that ST products that meet the carcinogen limits established pursuant to this proposal are less hazardous than similar products, have been approved by the government or meet government-established health or safety standards.”^{11,p.34-35}

The WHO established the Tobacco Laboratory Network (TobLabNet), an international collaborative network of testing laboratories, to validate testing methods for selected ingredients in tobacco products and emissions in smoked tobacco products. The experience gained in testing smoked products is clearly important in informing future regulatory efforts aimed at ST and other tobacco products.¹³ As of September 2014, TobLabNet has successfully completed the validation of testing for nicotine and humectants in cigarettes, and BaP, TSNAs, and carbon monoxide in mainstream cigarette smoke. Validation of ammonia in cigarette tobacco filler, and volatile organic compounds (VOCs) and aldehydes in mainstream cigarette smoke is currently under way.

Illicit Trade

To further develop the provisions of Article 15 of World Health Assembly Resolution 56.1 on preventing illicit trade, the second WHO FCTC Conference of the Parties established the Intergovernmental Negotiating Body (INB) on a Protocol to Eliminate Illicit Trade in Tobacco Products, which met five times between 2008 and 2012. Despite an INB consensus that strong supply chain measures are critical to eliminating illicit trade in tobacco products, some Parties cited domestic or regional/legal constraints and opposed stringent measures, such as unique identification markings and tracking and tracing (T&T) of ST products.¹⁴ After extensive negotiation, the Parties agreed to put a T&T mechanism in place for cigarettes within 5 years of the Protocol’s entry into force and within 10 years for all other tobacco products.¹⁴

The decision to delay T&T for ST highlights the need to expand the ST evidence base not only for health and economic implications, but also for trade and financial transactions. In some regions not much is known about the nature and volume of ST trade transactions within countries and across borders. Sharing trade information as well as trend analysis data on illicit trade detected by governmental enforcement authorities would do much to reduce this lack of information. It is equally important to engage with other relevant intergovernmental organizations, such as the World Customs Organization and World Trade Organization, and intelligence organizations such as the European Commission Anti-Fraud Office and others.

During the fifth session of the Conference of the Parties, the Protocol to Eliminate Illicit Trade in Tobacco Products, the first of its kind for the Convention, was developed. The Protocol states that the Parties “shall adopt and implement effective measures to control or regulate the supply chain covered by this Protocol in order to prevent, deter, detect, investigate and prosecute illicit trade.”^{15,p.7} The Protocol also calls for control of tobacco licensure for tobacco retailing, manufacture, and growth; for Parties to track and trace tobacco manufacture, sale, and shipments; and for ensuring legislative action on unlawful or illicit activities.

Description and Analysis of Key Tobacco Control Policy Interventions

Changing trends in the use of ST products make it even more important for countries to develop comprehensive tobacco control programs that address the use of smokeless tobacco. Intervention strategies must fit the context of the local society, its tobacco use rates, and trends in consumption of tobacco products including smokeless tobacco. Interventions may include: health warnings on product packaging; comprehensive bans on advertising, promotions, and sponsorships as well as bans on ST product sales, trade, and use; restrictions on sale to minors; training and capacity building; tax and pricing policies that discourage ST use; and information, education, and communication strategies and campaigns to increase awareness of the harmful health effects of ST use. Social, cultural, and economic factors are central to how individuals perceive the health risks of smokeless tobacco. This section highlights several measures that have successfully addressed these considerations.

Education and Awareness Efforts

The effectiveness of health warnings and comprehensive bans on cigarette advertising, promotions, and sponsorships^{16–18} strongly suggests these steps will be successful in curbing the demand for smokeless tobacco. Given the lack of awareness of the hazards of ST, some countries have launched mass media and other awareness-building campaigns. A long-term investment by governments in sustained mass media campaigns will bring a high degree of awareness and create change in social norms.

An example of this kind of effort was the “Mukesh campaign” conducted by the Ministry of Health in India in 2009–2010, acting in concert with Tata Memorial Hospital in Mumbai and the World Lung Foundation (WLF). The campaign consisted of media spots that followed a 24-year-old male ST user, Mukesh Harane, from his diagnosis with throat cancer caused by ST use, through his treatment and eventual death. An evaluation by the WLF in 2010 showed that viewers had a high degree of recall of the media spots, as well as a significantly enhanced appreciation for the devastating effects of smokeless tobacco use.^{19,20} Another positive result of the campaign was that an advertisement that included pictures of the damage oral cancer wreaks on the human body was aired nationwide in 12 vernacular languages. At that time, the country did not have pictorial warnings on ST labels. This campaign served as a useful tool to communicate the harmful effects of smokeless tobacco to a large audience.

The availability of accurate data has been instrumental in initiating policy change. For example, the 2009 Bangladesh GATS report indicated a very high level of ST use among women in rural Bangladesh.²¹ This finding prompted the government to request the WHO Tobacco Free Initiative (TFI) to provide technical assistance on developing a strategy for tackling the problem. Likewise, following India’s release of its 2009–2010 GATS report,⁹ the government of India increased funding for media campaigns against ST use in 2010–2012 and announced a stronger set of health warnings.²² Smokeless tobacco cessation has been included in the Indian government’s national guidelines on tobacco dependence treatment as well as in training modules for doctors and health workers.

In some cultures, ST is mistakenly believed to have beneficial effects—for example, that oral tobacco cures toothache (India) or that ST cures morning sickness during pregnancy (Bangladesh). The high prevalence of ST use among women in South-East Asian countries is associated with low levels of awareness regarding its harmful effects, which include addiction, especially when such products are

promoted as a dentifrice. Use of ST to clean the teeth is common in some countries, especially among women, and it is important not only to raise public awareness, but also to target and educate women, schoolteachers, dentists, health workers, and others on the risks associated with use of ST products.

Excise Taxes and Pricing Policies

Because ST products are cheaper and easier to access than cigarettes in some countries, with high social acceptance rather than stigma attached to their consumption, the young and the poor may predominantly consume ST instead of smoked tobacco. Given the price sensitivity of these groups, raising prices by raising excise and other taxes on ST is, therefore, one of the most effective measures to reduce demand. However, any efforts to levy taxes must also be fully supported by well-managed tax administration and compliance systems.

Administering taxation on ST products is especially challenging because of the high likelihood of illicit trade and tax evasion with these products. Smokeless tobacco products are easy to manufacture with small machines in limited spaces, and it is easy to trade these products illegally and avoid paying taxes on them. In addition, because products in some countries are made in traditional markets and by individuals for their own use, it is difficult to determine how taxation systems would be implemented and enforced in these countries. To better regulate ST products, securing the supply chain is essential in order to guarantee taxes are paid. For example, in response to rampant tax evasion, the Indian government changed the excise tax collection on gutka and other ST to a system of presumptive tax (compounded levy per manufacturing machine). The resulting fourfold increase in excise collection since 2009 indicates ST's tax potential if proper taxation systems are put in place.

Bans on Smokeless Tobacco

The sale of several types of oral tobacco is banned in all EU countries except Sweden.²³ Smokeless tobacco has also been banned at various levels in New Zealand, Australia, Turkey, Israel, Taiwan, Thailand, Singapore, Hong Kong, and the United Arab Emirates (UAE).²⁴ Specifically, the UAE bans the importation of ST, and Israel, Taiwan, Thailand, Singapore, and Hong Kong ban the manufacture, sale, and import of ST products. Turkey, Australia, and New Zealand limit ST sales and supply. By law, the government of Bhutan has banned the cultivation, sale, and purchase of all tobacco products, including ST, making it the first country to introduce such a comprehensive ban.

In India, a national-level group of experts convened by the Ministry of Health in April 2011 strongly recommended that the government ban the sale of gutka and all other smokeless forms of tobacco nationwide, based on India's current laws. Many Indian states, territories, and subregions have subsequently banned the sale, manufacture, distribution, and storage of these products.

A ban on ST tobacco products, however, is difficult to implement if it is the sole tobacco control measure in place in a given country. If a ban is accompanied by a comprehensive tobacco control program that includes tobacco dependence treatment and education on the danger of using ST, it may further enable existing users to quit. Setting up a comprehensive program requires strong will among decisionmakers and a consensus among the majority of the population, as well as an environment amenable to legislation and the administrative capacity to fully implement the ban.

Not only is it difficult to implement ST bans in isolation from a comprehensive program of tobacco control measures within a country, it may be also difficult to enforce a ban on ST in only one country, given the trend toward elimination of non-tariff barriers to trade between countries. In the case of Bhutan, illicit trade and smuggling of tobacco products from neighboring countries reportedly have increased, thereby keeping up the supplies of tobacco products, including ST products, which Bhutan has banned. The example of Bhutan clearly exemplifies the difficulties in enforcing bans and illustrates the need to take cross-border issues and international policies into consideration before implementing these types of measures.

A further concern related to banning ST, particularly in countries with substantial ST use, is whether or not such a ban would result in ST users switching to cigarettes or initiating cigarette smoking, which would result in higher tobacco-related mortality and morbidity.

Regulatory Experience of Countries and WHO Regions

The South-East Asia and Western Pacific Regions

Some Asian countries have begun regulating and banning ST products to keep pace with industry developments and to take steps to preempt the entry and spread of products in local markets. For example, under the Tobacco (Control of Advertisements and Sale) Act, Singapore has banned chewing tobacco since 1993.²⁵ In July 2010, an amendment was passed that expanded the scope of this act. Novel and emerging forms of tobacco products, such as tobacco derivatives (dissolvable tobacco) and nicotine-based products, are now subject to the same regulatory control as existing ST products, and the Minister for Health is empowered to ban a wider array of products, including more types of smokeless tobacco. Singapore has a lab for testing contents and emissions of cigarettes and measuring nicotine content in ST products such as chewable tobacco, betel quid, and khaini. However, other Asian economies including the countries where the ST burden is extremely high—India, Bangladesh, and Myanmar—generally lack laboratory capacity to test ST products.²⁵

The European Region

Regulations governing the use of ST vary widely within Europe. In EU member countries, ST is regulated under EU Tobacco Products Directive 2001/37/EC, which prohibits the sale of tobacco for oral use. The EU Directive defines “tobacco for oral use” as “all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco...particularly those presented in sachet portions or porous sachets, or in a form resembling a food product” (Directive 2001/37/EC, Article 2: Definitions²³).

As a result of negotiations at the time Sweden entered the EU, Sweden was exempted from this regulation, and the manufacturing, sale, and marketing of snus are legal within its borders. This form of tobacco is traditional in Sweden and represents a major proportion of the tobacco consumed in that country.²⁶

In many Eastern European countries, ST use is rare.²⁷ In many of these countries, ST is subjected to regulations regarding advertising and health warnings similar to those of smoked tobacco products. Because of the high prevalence of use of smoked tobacco products in the region, many Eastern

European countries have undertaken aggressive tobacco control measures. The Russian Federation has set a timetable to put into effect all FCTC articles by 2015. Such measures will also restrict the use of smokeless tobacco. Moreover, several Eastern European countries have joined the EU (or are in the process of joining) and consequently must observe the existing EU directive regarding ST use.

The Americas Region

United States

The Family Smoking Prevention and Tobacco Control Act, enacted in 2009, set in motion a new regulatory regime for tobacco products in the United States. This law enables the U.S. Food and Drug Administration (FDA) to regulate the manufacture, sale, and distribution of tobacco products, including ST products. Provisions of the law include manufacturer registration and product listing requirements, warning labels, and enforcement of a minimum-age-of-sale restriction. The FDA has authority to set tobacco product standards including, for example, imposing limits on the amounts of nicotine, toxicants, and/or additives that will be permitted in ST products.²⁸ The FDA is also examining the public health impact of novel smokeless/dissolvable tobacco products.

Canada

Generally, the prohibitions and requirements for tobacco products defined in Canada's Federal Tobacco Act apply to ST products, including the prohibition of selling tobacco to youth, restrictions on promotion, and requirements for reporting by manufacturers.

The labeling regulations, known as the 2000 Tobacco Products Information Regulations, also apply, but only to chewing tobacco, nasal snuff, and oral snuff. For these classes of products, the regulations require text-based health warnings that occupy at least 50% of the principal display surfaces.²⁹ In 2011, the Canadian House of Commons passed requirements, applicable only to cigarettes and little cigars, that limit the addition of flavorings, restrict the use of color packages (to make them less appealing to children), call for graphic health warnings on packages, and mandate that minimum quantities be purchased rather than single items (e.g., cigarettes must be sold in packs with a quantity of 20; sales of "loose" cigarettes are prohibited).³⁰⁻³² Smokeless tobacco products, however, will continue to be regulated under the 2000 regulations.

Brazil

Although at the forefront of tobacco product regulation, Brazil mainly targeted cigarettes for many years. Despite the low consumption of smokeless products in Brazil,³³ regulatory authorities have detected a slight increase in the use of other tobacco products, including ST products, since the passage of a 2007 law, Regime Diferenciado de Contratações Públicas (better known as "RDC") 090/07.³⁴ Tobacco companies or importers must submit information about tobacco product contents and emissions, packaging, and design features.³⁴ Brazil requires that ST products be registered with the Brazilian health surveillance agency, ANVISA (Agência Nacional de Vigilância Sanitária), in order to be sold within the country, but as of 2012 no ST products are registered, which means that they cannot be legally sold (and thus are effectively banned); labels on illegally marketed products do not display health warnings. In 2010, a regulatory task force conducting surveillance in the small municipality of

Maringá in southern Brazil seized the unique ST product rapé, which often contains agents such as tonka bean that have very high levels of coumarin, a liver toxicant (personal communication, Andre Oliveira). Tonka bean and coumarin are both banned in food for human consumption in the United States.²⁸

The Eastern Mediterranean Region

Well-structured interventions and regulatory policies regarding ST product use are for the most part absent in the Eastern Mediterranean region. Only Bahrain and the UAE have introduced policies banning ST and ST sales. In 2009 the government of Bahrain introduced strong antismoking regulations and a law that prohibits the importation of ST products.³⁵ In 2008, Ajman Municipality in the UAE banned the sale, import, storage, and possession of ST and imposes heavy fines on violators.³⁶

The African Region

Despite increasing prevalence of ST use, the countries of Sub-Saharan Africa have limited ST regulations and programs. Since ST is primarily produced by cottage industry in this region, distribution and marketing of these products often takes place on a local rather than national or international scale. Collating relevant data and information about importation and use of ST in African countries is important to helping these countries develop their capacity to regulate ST products.

Challenges and Recommendations for Regulation and Policy

Smokeless Tobacco Product Heterogeneity and Novelty

One of the challenges to creating and implementing any regulatory framework is the heterogeneity of ST products from country to country and within countries. Added ingredients and levels of nicotine and other toxic constituents vary widely among the various types of ST products, and forms of ST that are produced using non-standardized methods often pose the greatest risk to health because of the levels of toxicants they contain.

The wide variety of products and methods of manufacturing and distribution within a country make it more difficult for the country to set up regulatory means of dealing with them, and a wide variety of products across countries makes international cooperation on tobacco control more difficult. These difficulties are encountered especially in countries where products are manufactured and distributed in informal, cottage-industry-like settings that are less amenable to a conventional regulatory system of product registration, inspection, and enforcement.

The situation is further complicated by the fact that the novel forms of ST products introduced into some markets over the past decade—such as dissolvable tobacco sticks, strips, and lozenges—are unlike most of the oral ST products that preceded them. These products also pose new questions about use, especially because in some countries they are explicitly marketed to be used along with cigarettes. This dual use of ST with smoked tobacco, or any other form of tobacco, presents a further risk to the health of individuals and populations.

Understanding the toxicity and addictiveness profiles of the diverse and novel ST products requires thorough scientific evaluation. The research community could increase its efforts to provide data on

these products, their contents and toxicant levels, in order to help governments in countries and regions create effective systems for regulation. Dual use of smoked and smokeless products must be evaluated for its potential impact on quitting intentions, quitting behavior, and initiation of use; dual use of ST products and other tobacco products must also be addressed in developing cessation strategies and programs for smokeless tobacco.

Testing Challenges

Laboratory testing of tobacco products is a major challenge in regulating tobacco products. Although validated methods have been identified for measuring some constituents, most countries have not yet adopted specific product standards or testing regimens, and further development is needed in this area. Additionally, countries differ in their capacity to test tobacco products. Countries with limited budgets face significant challenges in acquiring costly equipment and in securing resources for technical training of staff.

The global tobacco testing network coordinated by the WHO Tobacco Free Initiative (TFI), TobLabNet, is validating standard operating procedures for testing the contents and emissions of tobacco products. Though time-consuming and costly, this effort is essential to global regulatory efforts. Although progress has been made in building capacity in a few selected laboratories in developing countries, regional and reference laboratories are still being relied on to assist in the technical training of staff in individual country laboratories. Regional efforts to consolidate tobacco product testing are ongoing and are exemplified by the European Network of Government Laboratories for Tobacco and Tobacco Products, and by the work of Brazil's ANVISA to coordinate testing activities and procedures in Latin America. The WHO TFI, the Centers for Disease Control and Prevention, the Netherlands National Institute for Public Health and the Environment, and other laboratories have been providing training and technical assistance to laboratories in low- and lower middle-income countries.

Further research is needed on the development of additional standardized testing methods that can be used to set limits on the allowable levels of toxicants in ST products.

Coordinated testing by region is valuable because of the unique characteristics of ST products in South-East Asian, North African, and Gulf countries. Although there are recognized inter-country differences in these products, coordinated testing can be useful for countries that have limited funding for independent testing. TobLabNet continues to explore the feasibility of scaling up lab capacities in low- and middle- income countries. A centralized website could serve as a source of validated information on tobacco product contents and emissions. It is also important that global partners help countries develop the capacity to identify counterfeit ST tobacco products in addition to counterfeit cigarettes.

The Evidence Base and Information Gaps

Effective policies to tackle the challenges posed by ST require quantification of the risks associated with ST use, including the burden on health, the economy, and the environment, and the social costs of increasing ST use by young people. There has been very little study or documentation of the adverse health care costs and the economic costs of ST use.³⁷ The WHO, government agencies, and academic

institutions have important roles to play in generating data and developing a body of evidence about the individual and societal risks of ST use.

A clearer picture of these risks could be achieved by disaggregating ST-related data from existing Global Tobacco Surveillance System studies such as the Global Youth Tobacco Survey (GYTS) and GATS, as well as from the WHO STEPwise Approach to Surveillance (WHO STEPS) and other national surveys. Valuable information could be obtained from investigations by academic and research institutions on the local factors responsible for high rates of ST use in some communities, as well as many other aspects of smokeless tobacco.

Current information-gathering tools should be adapted to collect more information on smokeless tobacco. Some deficits of information about ST reflect a lack of attention paid to ST by these instruments. For example, the *WHO Report on the Global Tobacco Epidemic, 2011* (GTCR) provides a qualitative assessment of progress made by countries in implementing the MPOWER package, which is a list of demand-reduction measures formulated by the WHO as guidance for countries implementing the FCTC's tobacco control guidelines.¹⁸ The GTCR covers smokeless as well as smoked tobacco products, but the report does not contain ST-specific information regarding relative progress on interventions such as package warnings and labeling, taxation, or enforcement of bans on advertising, promotion, and sponsorship.¹⁸ Similarly, the reporting instrument of the Conference of the Parties captures the progress made by Parties to the FCTC, but it does not include questions specifically on smokeless tobacco. Volunteering specific information on ST is left to the discretion of the individual Parties.

Information Dissemination

Smokeless tobacco products have a high degree of social acceptance in many countries, and their low cost and widespread availability make them easily accessible, especially for vulnerable groups such as youth and women. Much of the world's population is unaware of the dangers of using these products, and marketing efforts by the tobacco industry further distort the dangers. Even in high-income countries where information about the harms of tobacco use is more widely available, the tobacco industry has been marketing ST products as a safer substitute for cigarettes among adult smokers and adolescent initiators, particularly for use in situations where smoking is not allowed or where the smoker wants to use tobacco discreetly.³⁸

Increasing public awareness of the risks and consequences of using ST products is critical to safeguarding public health. Depending on the country or region, this can mean combating long-held local customs as well as industry marketing efforts by delivering accurate information to dispel myths about ST use and explain the hazards of dual use of ST and cigarettes. Adolescent, school health, and maternal-child health programs are valuable means of educating the public about ST use.

It is essential that information and evidence about smokeless tobacco use be disseminated among policymakers, researchers, and other professionals in order to establish programs to combat ST use and ameliorate its effects. Nongovernmental organizations (NGOs) could play an important role in generating international awareness of the hazards of ST use through all relevant forums, such as the

WHO FCTC, the World Conference on Tobacco or Health, and other international conferences. NGOs could also share best practices for advocacy efforts and for building local, NGO, and country-level capacity. As part of the global tobacco control effort, the Conference of the Parties to the WHO FCTC should consider extending its efforts to coordinate the dissemination of product information on ST products. It is critical that these organizations and institutions continue to provide policymakers with the evidence necessary for ST control, surveillance, training of health professionals, and capacity building for cessation initiatives for smokeless tobacco.

Smokeless Tobacco Product Regulation

In addition to granting higher priority to the control of ST use, the global community can advance evidence-based ST regulation and policy in a number of ways.

- *Providing technical assistance.* Given the limited knowledge and expertise in the area of ST, it is important for global partners to develop their ability to deliver technical assistance in building the capacity to regulate ST in each country. The partners could assist governments by providing information on global best practices and by developing the ability to monitor and regulate the ST industry by carrying out all the key provisions of the Protocol to Eliminate Illicit Trade, including, for example, mandating secure supply chain controls. This international cooperation is especially important to protecting young people and assisting countries that have inadequate resources.
- *Developing and disseminating testing protocols and product standards.* Companies and organizations with advanced laboratory capacity can assist in developing product testing capacity where it is needed. They can also assist in disseminating basic product manufacture and handling standards—for example, by indicating the manufacturing date on packages and controlling temperature conditions until sale to prevent further increases in carcinogens during storage. Additionally, WHO's TobLabNet and TobReg have developed common testing protocols and recommended specific limits for some known constituents.
- *Revising existing tobacco control programs to better address smokeless tobacco.* A comprehensive tobacco control program that deals with ST and smoking on an equal footing is critical for the effective regulation of smokeless tobacco. Such a program would include legislative and administrative measures that address issues such as advertising, cross-country trade, Internet purchases, tax evasion by industry, and low levels of taxation on ST products. In regard to taxation, the global community should focus on building the capacity to administer taxes on all tobacco products, including ST products, especially in low- and lower middle-income countries. High-income countries with more mature tobacco control programs may want to review their policies in light of the latest evidence on ST use. Countries that have been successful in controlling the tobacco epidemic and are experiencing a decline in smoking prevalence should examine whether ST use is replacing smoking in a manner that is causing net harm at the population level.

References

1. World Health Organization. World Health Assembly Resolution 56.1—Part II: Objective, guiding principles and general obligations. Article 4: Guiding principles. Geneva: World Health Organization; 2003. Available from: http://www.who.int/tobacco/framework/final_text/en/index4.html
2. World Health Organization. Control and prevention of smokeless tobacco products and electronic cigarettes. Conference of the Parties to the WHO Framework Convention on Tobacco Control, fourth session, 15–20 November 2010. Report by the Convention Secretariat. Punta del Este, Uruguay: World Health Organization; 2010. Available from: http://apps.who.int/gb/fctc/PDF/cop4/FCTC_COP4_12-en.pdf
3. World Health Organization. World Health Assembly Resolution 56.1—Part VII: Scientific and technical cooperation and communication of information. Article 20: Research, surveillance and exchange of information. Geneva: World Health Organization; 2003. Available from: http://www.who.int/tobacco/framework/final_text/en/index9.html
4. Mejia AB, Ling PM. Tobacco industry consumer research on smokeless tobacco uses and product development. *Am J Public Health*. 2010 January;100(1):78–87.
5. Tomar SL, Fox BH, Severson HH. Is smokeless tobacco use an appropriate public health strategy for reducing societal harm from cigarette smoking? *Int J Environ Res Public Health*. 2009 January;6(1):10–24. doi: 10.3390/ijerph6010010
6. World Health Organization. Conference of the Parties to the WHO Framework Convention on Tobacco Control: fourth session. Decisions. Punta del Este, Uruguay: World Health Organization; 2010. Available from: <http://www.who.int/fctc/copdecisionrevone.pdf>
7. World Health Organization. Conference of the Parties to the WHO Framework Convention on Tobacco Control: fifth session. Decision: control and prevention of smokeless tobacco products and electronic nicotine delivery systems, including electronic cigarettes. Seoul, Republic of Korea: World Health Organization; 2012. Available from: [http://apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5\(10\)-en.pdf](http://apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5(10)-en.pdf)
8. World Health Organization. Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (packaging and labelling of tobacco products). Geneva: World Health Organization; 2009. Available from: http://www.who.int/fctc/guidelines/article_11.pdf
9. International Institute for Population Sciences, Ministry of Health and Family Welfare, Government of India. Global Adult Tobacco Survey India (GATS India), 2009–2010. New Delhi, India: Ministry of Health and Family Welfare; Mumbai: International Institute for Population Sciences; 2010. Available from: <http://whoindia.org/EN/Section20/Section25-1861.htm>
10. Stanfill SB, Connolly GN, Zhang L, Jia LT, Henningfield JE, Richter P, et al. Global surveillance of oral tobacco products: total nicotine, unionised nicotine and tobacco specific *N*-nitrosamines. *Tob Control*. 2011;20(3):e2. Epub 2010 Nov 25. doi: 10.1136/tc.2010.037465
11. WHO Study Group on Tobacco Product Regulation. 3. Report on setting regulatory limits for carcinogens in smokeless tobacco. In: Report on the scientific basis of tobacco product regulation. Third report of a WHO study group. WHO technical report series no. 955. Geneva: World Health Organization; 2009. p. 23–38.
12. WHO Study Group on Tobacco Product Regulation. 1. Advisory note on smokeless tobacco products: health effects, implications for harm reduction and research. In: Report on the scientific basis of tobacco product regulation. Second report of a WHO study group. WHO Technical Report Series No. 951. Geneva: World Health Organization; 2008. p. 1–16.
13. Rutqvist LE, Curvall M, Hassler T, Ringberger T, Wahlberg I. Swedish snus and the GothiaTek standard. *Harm Reduct J*. 2011;8:11.
14. WHO. Conference of the Parties: Intergovernmental Negotiating Body on a Protocol on Illicit Trade in Tobacco Products. Analysis of the available technology for unique markings in view of the global track-and-trace regime proposed in the negotiating text for a protocol to eliminate illicit trade in tobacco products. Note by the Convention Secretariat. Geneva: World Health Organization; 2010. Available from: http://apps.who.int/gb/fctc/PDF/it4/FCTC_COP_INB_IT4_ID1-en.pdf
15. World Health Organization. Conference of the Parties to the WHO Framework Convention on Tobacco Control: fifth session. Decision: protocol to eliminate illicit trade in tobacco products. Seoul, Republic of Korea: World Health Organization; 2012. Available from: [http://apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5\(10\)-en.pdf](http://apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5(10)-en.pdf)
16. Hammond, D. Health warning messages on tobacco products: a review. *Tob Control*. 2011;20(5):327–37. doi: 10.1136/tc.2010.037630

17. Hammond D, Wakefield M, Durkin D, Brennan E. Tobacco packaging and mass media campaigns: research needs for Articles 11 and 12 of the WHO Framework Convention on Tobacco Control. *Nicotine Tob Res.* 2013 Apr;15(4):817–31. Epub 2012 Oct 4. doi: 10.1093/ntr/nts2022012
18. World Health Organization. WHO report on the global tobacco epidemic, 2011. Warning about the dangers of tobacco. Geneva: World Health Organization; 2011. Available from http://whqlibdoc.who.int/publications/2011/9789240687813_eng.pdf
19. Gupta S. Anti tobacco campaign India. In: Cancer mission blog. Posted by K. Chandramohan. 2011 Apr 3 [cited 2012 Oct 10]. Available from: <http://www.cancermission.com/2011/04/anti-tobacco-campaign-india.html>
20. Mullin S, Prasad V, Kaur J, Turk T. Increasing evidence for the efficacy of tobacco control mass media communication programming in low- and middle-income countries. *J Health Commun.* 2011;16(Suppl 2):49–58.
21. World Health Organization, Country Office for Bangladesh. Global Adult Tobacco Survey: Bangladesh report 2009. Dhaka, Bangladesh: World Health Organization, Country Office for Bangladesh; 2009 [cited 2012 June 21]. Available from: http://www.who.int/tobacco/surveillance/global_adult_tobacco_survey_bangladesh_report_2009.pdf
22. World Lung Foundation. India health communications campaign. New York: World Lung Foundation; c2012 [cited 2012 Oct 10]. Available from: <http://worldlungfoundation.org/ht/d/sp/i/11219/pid/11219>
23. The European Parliament and the Council of the European Union. Directive 2001/37/EC of the European Parliament and of the Council (5 June 2001) on the approximation of the laws, regulations and administrative provisions of the member states concerning the manufacture, presentation and sale of tobacco products. *Official Journal of the European Communities.* 2001 Jul 18. L194/26–34. Available from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:194:0026:0034:EN:PDF>
24. International Agency for Research on Cancer. Smokeless tobacco and some tobacco-specific *N*-nitrosamines. IARC monographs on the evaluation of carcinogenic risks to humans. Vol. 89. Lyon, France: World Health Organization, International Agency for Research on Cancer; 2007 [cited 2012 April 24]. Available from: <http://monographs.iarc.fr/ENG/Monographs/vol89/index.php>
25. Health Sciences Authority (Singapore). Smoking (Control of Advertisements and Sale of Tobacco) Act, Chapter 309. 1993 May 31 [cited 2010 Sept 15]. Available from: [http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/health_products_regulation/legislation/smoking_control_of.Par.0416.File.dat/SMOKING%20\(CONTROL%20OF%20ADVERTISEMENTS%20AND%20SALE%20OF%20TOBACCO\)%20ACT%202010.pdf](http://www.hsa.gov.sg/publish/etc/medialib/hsa_library/health_products_regulation/legislation/smoking_control_of.Par.0416.File.dat/SMOKING%20(CONTROL%20OF%20ADVERTISEMENTS%20AND%20SALE%20OF%20TOBACCO)%20ACT%202010.pdf)
26. Foulds J, Ramstrom L, Burke M, Fagerström K. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tob Control.* 2003;12(4):349–59.
27. World Health Organization. WHO report on the global tobacco epidemic, 2011. Appendix VIII—Table 8.2: Crude smokeless tobacco prevalence in WHO member states. Geneva: World Health Organization; 2011. Available from: http://www.who.int/tobacco/global_report/2011/en_tfi_global_report_2011_appendix_viii_table_2.pdf
28. U.S. Food and Drug Administration. Coumarin. C.F.R. (Title 21, Volume 3), Sect. 189.130. 2012 Apr 1. Available from: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=189.130>
29. Health Canada. Tobacco products information regulations. JUS-601413. 2000 Jun [cited 2012 Oct 10]. Ottawa, Ontario, Canada: Health Canada; 2000. Available from: <http://hc-sc.gc.ca/hc-ps/pubs/tobac-tabac/rc/index-eng.php>
30. Parliament of Canada, House of Commons. 41st Parliament, 1st session. Standing Committee on Health. 2011 June 20. Available from: <http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=5100652&Language=E&Mode=1&Parl=41&Ses=1>
31. Prime Minister of Canada: Stephen Harper. Cracking Down on Tobacco Marketing Aimed at Youth Act. 2009 Oct 26 [cited 2012 Oct 4]. Available from: <http://pm.gc.ca/eng/media.asp?id=2915>
32. Department of Justice, Canada. Tobacco products labelling regulations (cigarettes and little cigars). SOR 2011-177. Ottawa, Ontario, Canada: Department of Justice; 2012 [cited 2012 Oct 10].
33. Ministério da Saúde (Brazil). Global Adult Tobacco Survey: Brazil report. Rio de Janeiro: Ministério da Saúde, Instituto Nacional de Câncer, Pan American Health Organization; 2010. Available from: http://www.who.int/tobacco/surveillance/en_tfi_gats_2010_brazil.pdf
34. Brazil's reporting instrument of the WHO Framework Convention on Tobacco Control. 2011 Aug 9. Available from: http://www.who.int/fctc/reporting/party_reports/Brazil_5y_report_final.pdf
35. Time Out Bahrain Staff. Smoking ban in Bahrain. *Time Out Bahrain.* 2009 Apr 28 [cited 2012 Oct 10]. Available from: <http://www.timeoutbahrain.com/knowledge/features/8573-smoking-ban-in-362bahrain>
36. Bowman, J. Chewing tobacco outlawed. *Arabian Business.* 2008 May 19 [cited 2012 Oct 10]. Available from: <http://www.arabianbusiness.com/chewing-tobacco-outlawed-49783.html>

37. World Health Organization. The world health report 2002: reducing risks, promoting healthy life. Geneva: World Health Organization; 2002. Available from: <http://www.who.int/whr/2002/en>
38. Carpenter CM, Connolly GN, Ayo-Yusuf OA, Wayne GF. Developing smokeless tobacco products for smokers: an examination of tobacco industry documents. *Tob Control*. 2009 Feb;18(1):54–9.

