Control and prevention of smokeless tobacco products

Report by the Convention Secretariat

INTRODUCTION

1. At its fourth session, the Conference of the Parties (COP), taking note of the report by the Convention Secretariat on smokeless tobacco products (SLT) and electronic cigarettes (document FCTC/COP/4/12), requested the Convention Secretariat to prepare jointly with WHO’s Tobacco Free Initiative a comprehensive report based on the experience of Parties on the matter of SLT products, for consideration by the COP at its fifth session.1

2. Document FCTC/COP/4/12 reviewed the types, carcinogenic compound content, presentation and prevalence of SLT use globally and regionally. Furthermore, the report highlighted the need for further research in several areas related to SLT including cost-effective strategies for prevention and cessation of use, standardized testing methods, training, capacity building and information programmes, and combating SLT use via taxation and control of the supply chain. The report concluded that “owing to the scale of the [SLT] epidemic, comprehensive legislative, technical, administrative and other measures and greater international cooperation will be needed for effective prevention and control of smokeless tobacco products”.

3. This report builds on document FCTC/COP/4/12 and follows the guidance provided in decision FCTC/COP4(14). It is primarily based on a review of the available literature and international developments concerning SLT prevention and control, as well as relevant research. The other important source of information was an exercise coordinated by the Convention Secretariat in early 2012, in which Parties were requested, by means of a questionnaire, to provide their experiences of implementing policies and measures to prevent and control SLT use. Thirty-eight Parties completed the questionnaire. Information from the regular implementation reports of the Parties has also been taken into account.

1 See decision FCTC/COP/4(14).
BACKGROUND

4. The WHO Framework Convention on Tobacco Control (WHO FCTC) defines “tobacco products” as those entirely or partly made of leaf tobacco as raw material and that are manufactured to be used for smoking, sucking, chewing or snuffing. Furthermore, Article 4.4 of the Convention also establishes that comprehensive measures to reduce consumption of all tobacco products are essential to prevent the incidence of diseases, premature disability and mortality due to tobacco use.

5. Although cigarette smoking is the dominant form of tobacco use in most parts of the world, SLT use accounts for a significant and growing share of tobacco use in a number of countries in Asia, Africa, the Middle East and northern Europe, and is an emerging problem in a number of other countries, especially given the dwindling share of smoking tobacco use. Moreover, dual use of smoking and smokeless tobacco products and promotion of the use of SLT as a cessation aid can also be seen in several countries.

6. SLT has been proved to be a major cause of disease, disability and death in countries with high prevalence of SLT use. One recent study\(^1\) reported a fivefold increase in mortality from oral cancers among tobacco chewers compared to never chewers, and also provided further evidence that tobacco chewing is a major cause of disease and disability in South Asia by demonstrating the increased mortality risk from upper airway, digestive tract, and cervical cancers and an increased risk of heart attacks.

7. Globally, policy-makers and researchers have generally paid little attention to SLT. While certain groups have been identified as being at increased risk for SLT use, few data are available on the factors associated with initiation of SLT use by particular populations. The research on SLT products has been mainly limited to snus and snus-like products, focusing on Sweden and the United States of America.

8. The importation and sale of SLT products have been banned in 40 countries and areas around the world, in line with the WHO recommendation that “countries with no established smokeless tobacco habit should consider a ban on the manufacture, importation, sale and promotion of smokeless tobacco products before they are introduced to market or become an established habit”.\(^2\) However most of these bans are partial.

PREVALENCE OF SMOKELESS TOBACCO USE

9. Information on the prevalence of SLT use is collected through various international data collection mechanisms, including the Global Adult Tobacco Survey and the Global Youth Tobacco Survey, and the WHO STEPwise approach to Surveillance of NCD Risk Factors. The majority of national health, public health and morbidity surveys and the Demographic and Health Survey also include questions on SLT use.

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10. Parties to the Convention are required to report regularly, through the Convention reporting instrument, on the latest available information that they have concerning SLT use by adults, young people and ethnic groups.\(^1\)

11. According to figures published in the *2010 global progress report on implementation of the WHO FCTC*,\(^2\) the weighted averages calculated from the data submitted by Parties showed that globally, among adults, 27% of males and 9% of females used SLT, while among young people, 15% of boys and 7% of girls used SLT. The figures showed that SLT use was unevenly spread across regions and countries.\(^3\)

12. A monograph recently published by the International Agency for Research on Cancer (IARC)\(^4\) provides a snapshot of recent data concerning SLT use. According to these findings, large variations can be observed by country and by gender within countries. The countries with a high reported prevalence (≥ 10%) of SLT use in one or both gender groups include Bangladesh (26% in men, 28% in women), Benin (13% in men), Cambodia (7–12.7% in women), India (33% in men, 11–18% in women), Madagascar (23% in men, 20% in women), Mauritania (28% in women), Myanmar (51.4% in men, 16.1% in women), Nepal (31–38% in men), Norway (17% in men), South Africa (11% in women), Sri Lanka (24.9% in men), Sweden (26% in men), Timor-Leste (25.4% in men), Uzbekistan (22.5% in men), and Yemen (15% in men); the following countries have medium prevalence (between 5% and 10%): Finland, Iceland, Kyrgyzstan, Mali, Mauritania, Swaziland, Tunisia, United States of America, and Zimbabwe in men; and Cape Verde, Malawi, and Thailand in women.

13. In most countries, current prevalence of SLT use is higher among men than among women. Some exceptions include: Bangladesh, Barbados, Cambodia, Cape Verde, Malaysia, Mauritania, South Africa, Thailand, and Viet Nam.

14. Among young people, according to the figures published in the IARC Monograph, prevalence of SLT use in both boys and girls is highest in Bhutan, Barbados, Congo, the Cook Islands, Djibouti and Timor-Leste. Most countries reported higher prevalence of SLT among boys than girls, although in several countries, prevalence was reported as being similar or higher among girls. It is also noteworthy that in several countries, prevalence of SLT use is higher among 13–15 year olds than that among adult men and women (aged 15 years or more).

**SMOKELESS TOBACCO PRODUCTS: KEY FACTS**

15. SLT products are a non-homogenous group of products that vary widely in appearance and composition, are used in various parts of the world, and include both tobacco and non-tobacco constituents. Data are not available for all countries. A wide variety of SLT products are available in some countries and instances of products migrating with relocation of people are recorded.

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\(^1\) Parties are also required to report information on the licit supply of SLT products, seizures of illicit SLT products, and taxation and prices of SLT products.


\(^3\) New figures concerning SLT indicators included in the reporting instrument of the WHO FCTC, based on the figures reported by Parties in the 2012 reporting period, will be available in the 2012 global progress report on implementation of the Convention submitted for consideration by the COP at its fifth session.

16. The heterogeneity of SLT products also applies to their production, which includes both manufacturing and hand preparation, resulting in products with very different levels of toxicity and carcinogenic compounds. This explains the varying health risks associated with the use of different products. When taking into account their production, SLT products can be broadly divided into pre-made and custom-made products as described below.

17. **Pre-made SLT products:** either manufactured or cottage industry products.
   
   (a) Manufactured SLT products are made for sale in a manufacturing environment and are packed in sealed packages. These are generally consumed as purchased. Examples include: moist snuff, plug, creamy snuff, dissolvables, dry snuff, gul, loose leaf, red tooth powder, snus, chimo, guthka, khaini, gudakhu, zarda, quiwam.

   (b) Cottage industry SLT products are usually handmade in non-traditional production environments (e.g. market stalls, shops, etc.) and intended for sale, often placed in non-commercial packaging, and unlabelled. Examples include: dohra, tuibur, nasway, naas/naswar, shammah, betel quid, toombak.

18. **Custom-made SLT products:** these are not intended for sale but for use by individuals or their family members. They are prepared and used in homes or social gatherings, and are consumed shortly after preparation. Examples include pan (betel quid), Iq’mik, Nasway, Naas/Naswar, Shammah, Mishri, Tapkeer, Tombol. Some manufactured and cottage industry products can be used as ingredients in custom-made products, for example Zarda, Quiwam or Toombak.

19. The IARC monograph provides a brief overview of the various SLT products, their modes of use and main ingredients, and some specification of the countries in which the product is used most commonly or specifically.¹

20. The variety of manufacturing practices, together with the heterogeneity of SLT products, are potential challenges with regard to the establishment and operation of an effective system to regulate the supply chain of SLT products.

**CONSTITUENTS OF SMOKELESS TOBACCO**

21. The nicotine in SLT products is responsible for their addictive properties. Besides tobacco, SLT products also contain ingredients such as alkaline agents (e.g. slaked lime, calcium carbonate, sodium bicarbonate, magnesium carbonate, alkaline ashes), areca nut, tonka bean, camphor and other plants containing toxins and carcinogens that have additional health effects.

**HEALTH CONDITIONS ASSOCIATED WITH SMOKELESS TOBACCO PRODUCTS**

22. The varieties of SLT differ considerably in their composition and carcinogenic potential. The IARC has indicated the presence of 28 potential or known carcinogens in SLT, the most important of which were listed in document FCTC/COP/4/12.

23. The IARC monograph provides a comprehensive review of the available literature on the interrelationship between SLT use and cancers in humans and experimental animals. The monograph

concludes that there is “sufficient evidence” in humans for the carcinogenicity of SLT, which causes cancer of the oral cavity, oesophagus and pancreas.

24. The use of SLT is also associated with several oral premalignant lesions/conditions, e.g. leukoplakia, erythroplakia, submucous fibrosis and lichen planus. It also causes a number of non-cancerous conditions. Most of the evidence comes from the chewing varieties of SLT. Their use can result in inflammation of the buccal and gingival mucosa, gingival recession, dental caries and decay and excessive tooth wear.

25. Several constituents of cigarette smoke that cause cardiovascular disease are also present, although in differing amounts, in SLT products. Such constituents include nicotine, polycyclic aromatic hydrocarbons and heavy metals such as cadmium. The evidence that SLT use is associated with the development of insulin resistance, metabolic syndrome and diabetes is limited, but plausible. Some studies suggest that an increased risk of non-fatal cardiovascular disease is associated with the use of SLT products, including snuff, chewing tobacco, paan, and mishri. There is also evidence to suggest that infants born to women who use smokeless tobacco, including snus, paan, and mishri, during pregnancy have a higher risk of several adverse outcomes such as stillbirth, preterm birth and low birth weight. Men who use smokeless tobacco have reduced semen volume, count, and motility and increased frequency of abnormal spermatozoa.

26. The WHO Study Group on Tobacco Product Regulation (TobReg), in a report published in 2008,1 concluded on the basis of current scientific evidence that all SLT products are hazardous to health and are addictive, recognizing at the same time that the composition and manner in which SLT products are used vary widely. Furthermore, the paper refers to the fact that risks for disease associated with SLT products also vary according to product, pattern of use and geographical region. Another TobReg report, published in 2009,2 recommends that “all products that deliver nicotine for human consumption should be regulated”, and that “smokeless tobacco products should be regulated by controlling the contents of the products”. The report also provides recommendations for the upper limit of concentrations of three hazardous components.

NEW AND EMERGING SMOKELESS TOBACCO PRODUCTS

27. Tobacco manufacturers have recently introduced a new generation of novel smokeless tobacco products, both in developed countries and in emerging markets, that may have even broader consumer appeal owing to the use of attractive flavourings, such as mint or fruit flavours, and new delivery methods, such as lozenges or small pouches that eliminate the need to spit. Additives or flavourings may be added to mask the poor quality of some products or in targeting certain population groups.3 In Canada 20 new SLT products have been launched since 2009, and there has been an increase in sales of SLT by 10% over the past five years.

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28. Major multinational cigarette companies have introduced snus products carrying brand names previously used for smoking tobacco products, as part of a marketing drive by these companies to promote SLT products, for example in the United States of America. The increased marketing of these products will have an adverse population health impact, particularly among young people, new users and women.

29. Since 2000, several tobacco companies that have traditionally marketed cigarettes have introduced novel SLT products called “dissolvables”, which are essentially tobacco pressed into tablets, rods, or flat strips that fully dissolve in the mouth. Tobacco-coated toothpicks that are sucked to liberate nicotine have also been introduced. These products contain tobacco-related compounds, flavours, alkaline agents, coatings, fatty acids, fatty acid esters, acids, antioxidants, etc.

ECONOMICS AND ENVIRONMENTAL ASPECTS OF SMOKELESS TOBACCO

30. Economic analysis of the SLT market is relatively undeveloped, as that market is largely heterogeneous and non-consistent compared with the cigarette market. Euromonitor International, however, reported an 11% growth in the value of SLT sold in 2010. The sales volumes of chewing tobacco increased between 2005 and 2010 by 25.7% in India, 12.9% in Venezuela and 8% in Norway. During the same period, the reported increase in sales volumes of snuff was 76.4% in Norway, 36.4% in Algeria and 28.9% in the United States of America; According to Euromonitor International, the projected rise in global SLT sales volumes in the next five years is 24%, compared with only 7% for cigarettes.

31. The SLT markets in low- and middle-income countries are not yet dominated by multinational tobacco companies, and the products consumed in these countries are often homemade or manufactured within a fragmented network of small locally owned businesses. On the other hand, the SLT market in many developed economies has recently undergone a transition towards a higher degree of concentration, with multinational tobacco companies owning the largest share.

32. There are not many existing data on SLT prices, or on tax structures and levels applied to SLT products. Knowledge about the extent to which higher taxes on SLT products translate into higher prices and how these prices affect the affordability of SLT products is also limited.

33. Besides the well-documented environmental effects related to tobacco cultivation, production and packaging, there is growing concern in high-prevalence countries about the plastic packaging of SLT products, which leads to the generation of solid waste. For example, the Supreme Court of India directed SLT manufacturers to refrain from using plastic material in sachets of gutkha, tobacco and pan masala with effect from 1 March 2011.
EXPERIENCE OF THE PARTIES TO THE CONVENTION WITH RESPECT TO SLT PRODUCTS

34. As explained earlier in this report, Parties were requested to respond to a questionnaire in early 2012 on their experiences regarding the implementation of measures to control SLT use. A brief summary of the responses of the 38 Parties\textsuperscript{1} that provided information is given below.

35. Most of the 38 Parties responded affirmatively when asked if SLT is covered, along with smoking tobacco products, in their tobacco-control legislation.

36. In response to the question asking whether they implement any specific strategies and policies to address the matter of SLT, most of the Parties that responded reported that they did not have any such strategies. However, nine Parties\textsuperscript{2} reported that they had imposed a ban on the sale, promotion or importation of SLT, but that such bans were, in the majority of cases, only partial; for example, some products were exempted from the ban or limited importation was allowed for personal use. The European Union's tobacco products Directive requires Member States to prohibit the placing on the market of tobacco for oral use.\textsuperscript{3} Parties also reported having in place mandatory health warnings for SLT products as applicable to other tobacco products, but that these were mainly textual warnings. Five Parties\textsuperscript{4} also reported that they ban sales of SLT products to minors (persons aged less than 18 years). This is an important measure to reduce or minimize the access of minors to SLT. Some Parties reported that they apply licensing and taxation measures to control SLT. Norway reported increasing the tax rates for SLT products at a higher rate than in the case of other tobacco products in order to decrease the large difference in taxes between them. Spain reported that it regulates the contents of SLT products. Australia reported that research is being undertaken to examine the options for further regulation of SLT. India has developed its National Guidelines for Tobacco Dependence Treatment that give due emphasis to cessation of SLT use.

37. Parties were also asked about any recent efforts by the tobacco industry aimed at promoting the use of SLT products through, for example, enhanced marketing and promotional activities as well as the introduction of new products. Several Parties reported that new SLT products and brand variants had been introduced with attractive packages and flavours. It was also reported by Norway and Finland that SLT products with different tastes and colourful boxes were being promoted by the industry, with special appeal to young people and women. Australia reported that its Department of Health and Ageing had received complaints regarding Indian smokeless tobacco products being advertised at sports grounds, in breach of Australian legislation banning tobacco advertising.

38. When asked about the challenges involved in the prevention and control of smokeless tobacco in their country and/or region, some Parties indicated that there is limited information and understanding about the range of SLT products. Furthermore, there are limited data available on consumption, manufacturing practices, contents, harmful effects and sociocultural factors associated

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\textsuperscript{1}Australia, Austria, Azerbaijan, Belgium, Benin, Brazil, Bulgaria, Canada, Congo, Côte d’Ivoire, Cyprus, Denmark, Egypt, Finland, France, Georgia, Germany, Hungary, Iran (Islamic Republic of), Ireland, Japan, Kenya, Kuwait, Lithuania, Malta, Netherlands, Norway, Philippines, Serbia, Singapore, Spain, Swaziland, Sweden, Tonga, Tunisia, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, and United Republic of Tanzania. Information for India was also made available through expert advice.

\textsuperscript{2}Australia, Austria, Denmark, Finland, France, Germany, Kuwait, Serbia, and the United Kingdom.


\textsuperscript{4}France, Japan, Norway, Singapore, and the United Kingdom.
with the use of SLT products, which is hindering the development of strategies for control of these products. The identification and classification of many SLT products available on the market was also reported to be a challenge by Parties. Parties also reported: that there is unclear and inadequate documentation of the harmful effects of SLT products; the difficulties of combating the promotion of SLT as a harm-reduction product; the cost of awareness raising campaigns regarding the harmful effects of SLT; the difficulty of implementing full bans on sales/imports; and the problem of the illicit trade in SLT products. A few Parties also mentioned the sale and promotion of SLT through the Internet as being a major challenge. A recent study covering 10 Member States of the European Union showed that out of 43 Internet-based test purchases of snus, 41 were successfully made.1

39. Parties were also asked if they cooperate with other Parties in the area of prevention and control of SLT use. Experience in this area seems to be largely lacking. However, some instances of regional cooperation were mentioned, and some Parties expressed an interest in cooperating with others; for example, Australia declared its willingness to share the results of research on options for further regulation of SLT. The United Kingdom indicated that it had posted on the Internet a recently developed comprehensive web based “directory of niche tobacco products”.2 Several Parties also proposed international collaboration in this area, through measures such as the introduction of a comprehensive ban on such products or banning Internet sales and promotion of SLT.

SUMMARY OF CHALLENGES, NEEDS AND OPPORTUNITIES LINKED TO SMOKELESS TOBACCO PREVENTION AND CONTROL

40. The knowledge base, evidence and capacity for research in the areas of SLT use, prevention and control all need to be strengthened. Research on SLT is limited in general, and significant research gaps exist in regard to identifying the ingredients, additives, and toxicities of SLT products. There is also a lack of information in many countries concerning the types, variation, heterogeneity (including identification of the product itself) and composition of SLT products. The added ingredients, levels of nicotine and other toxic and/or carcinogenic constituents vary widely among the many types of SLT products, resulting in different levels and types of harmful health effects related to their consumption. Parties to the Convention, as part of their tobacco surveillance systems established in line with the requirements of Article 20 of the Convention, need to build capacity for regular monitoring of the use of SLT in their jurisdictions. There is also a need to strengthen data collection and reporting on matters related to production, trade (licit and illicit), taxation, pricing, policies on SLT control, and their enforcement.

41. Little evidence on trends in SLT prevention strategies and no evidence at all on the susceptibility of young people to SLT is available in Parties’ reports. The information collected in the future should be regularly reported to the COP via the reporting system of the WHO FCTC. The reporting instrument needs to allow for structured communication of actions taken to prevent and control the use of SLT products.

42. Due to the low cost of manufacturing these products and, in addition, the lower taxation rates applied to SLT products (compared with smoking tobacco products), SLT products are relatively inexpensive and hence affordable, especially in comparison with smoking tobacco products. This is one of the main reasons why such products are so accessible to minors, in addition to the high

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sociocultural acceptance of custom-made and traditional SLT products in many countries. Some countries, faced with the magnitude of the problem, have started using taxation as a tool to reduce consumption of SLT products, especially through harmonization of taxes between smoking and smokeless tobacco products.

43. Differences in the content and presentation of SLT products used in different geographical areas might explain the different health outcomes observed in regard to their use. The prevalence outcomes indicate the public health benefits of regulation. Laboratory testing of tobacco products to determine their contents is not only a challenge for many countries owing to lack of capacity, but also at the regional and global levels. Standards and validation methods to test the contents of SLT products are lacking. The heterogeneity and prevalence of custom-made and traditional SLT products in developing countries pose an additional challenge to regulation and testing. TobReg has recommended that initial regulatory efforts be focused on large manufacturers and importers of SLT that can change products rapidly. The more complex problem of limiting the levels of carcinogens in products produced by cottage industries should not be used as an excuse to allow higher levels than needed in manufactured products.

44. There is a need for more evidence concerning licit and illicit trade, including the nature and volume of the SLT trade within and between countries. It is widely recognized that strong supply chain measures are critical to eliminate illicit trade in SLT products, but Parties have reported difficulties in implementing such measures. In addition, since SLT products are easy to manufacture with small machines and in a limited space, there is high potential for tax evasion and smuggling.

45. Novel SLT products are appearing on the market and are often effectively promoted. As mentioned above, some of these products are sold as small lozenges or pouches that prevent the need to spit. Countries like Canada and Finland, which have experienced a decline in smoking prevalence after decades of implementation of strong tobacco-control measures, now face the challenge of new SLT products being introduced onto their domestic markets.

46. Multinational tobacco companies invest in SLT products via acquisition and product development. These companies have now entered the SLT market and are branding their SLT products as an extension of cigarette brands, which can be used despite the application of smoke-free legislation. Full implementation of Article 8 of the Convention is likely to create pressure on smokers remaining addicted to nicotine to seek out alternative nicotine delivery systems. Understanding this “dual-use” consumption pattern will be essential in developing an appropriate regulatory structure for smokeless tobacco.

47. Arguments are being put forward that certain low nitrosamine SLT products can be used by smokers as alternatives to cigarettes. In this regard, two primary concerns emerge: (1) encouragement of novices (particularly young people) to take up SLT use, including the more toxic forms; and (2) dual use of cigarettes and SLT. A commonly expressed concern is that young people may be attracted to SLT products, but eventually move to use of cigarettes and other tobacco products (i.e. SLT can act as a “gateway” to smoking). Dual or simultaneous use of cigarettes and SLT could sustain nicotine addiction, delay cessation and contribute to a compensation of the reduced quantity of cigarettes smoked. Another related concern is that if smokers turn to SLT when they are unable to smoke, the effect of smoking bans on encouraging smoking cessation may be diminished. Dual users tend to have higher nicotine dependence, and although it is unclear whether this is an antecedent or consequence of dual use, it poses a public health challenge.

48. Targeted interventions are required to address the need for services that help SLT users to quit. Experience shows that there is very limited support available for cessation of SLT use, not least
because the majority of national treatment guidelines developed by countries cater to the needs of smokers. In addition, countries and societies with high prevalence of SLT use usually lack the necessary capacity and access to affordable treatment for SLT dependence. The dual use of SLT with smoking tobacco and a poor understanding of the addictiveness potential of SLT also make it more difficult to develop a suitable tobacco cessation strategy for SLT. There is a need to promote cost-effective interventions and sharing of information, knowledge and tools for SLT dependence treatment among developing countries with high prevalence of SLT; some of these high-burden countries have already developed appropriate tobacco dependence treatment guidelines.

49. The formulation, adoption, implementation and enforcement of specific policies and interventions to address SLT use still need to be prioritized as part of the full implementation of the Convention in the majority of Parties, especially through the integration of SLT prevention and control into all tobacco-control measures. In addition, while the guidelines adopted by the COP provide for detailed action to control all tobacco products, there is still room to extend their application to the framing of policies and actions that specifically target SLT products.

50. While the potential for cooperation among the Parties in the scientific and technical fields in implementation of the WHO FCTC at country, regional and global levels is recognized, there is still a need to develop regional and international cooperation mechanisms for the identification of best practices and promotion of strategies to prevent and control SLT use. Parties facing challenges related to SLT will also need to be supported in building capacity to formulate SLT-specific policies and in the implementation of those policies.

ACTION BY THE CONFERENCE OF THE PARTIES

51. The COP is invited to note this report and provide further guidance.