

COMMENTS ON REPORTS OF SMOKELESS TOBACCO PRODUCTS AND E-CIGARETTES

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**Asian Center for WTO and International Health Law and Policy
National Taiwan University College of Law**

<http://www.law.ntu.edu.tw/center/wto/index.asp>

The increasing availability of smokeless tobacco products and various kinds of electronic cigarettes in the markets of many countries are posing threats to the current approach of tobacco control under the FCTC. We are delighted to see that the FCTC Secretariat issued its latest report on “*Control and Prevention of Smokeless Tobacco Products*” (FCTC/COP/5/12) and “*Electronic Nicotine Delivery Systems, Including Electronic Cigarettes*” (FCTC/COP/5/13) to assist countries in discussing and deciding the policies and approaches for dealing with the common problems arising from the use of these new forms of products. As a constant observer of the development of international regime for the control of tobacco, we would like to provide Taiwan’s practical situations and its regulatory approaches on these products. These might help Parties to have better understanding of the conditions in different jurisdictions. Also, we would like to offer our opinions concerning the possible approaches that the FCTC might consider while regulating such products. We sincerely hope that our inputs could facilitate the international community’s further discussions and deliberations on these important issues to enhance effective tobacco control.

I. Regulatory Approaches of Smokeless Tobacco Products and E-cigarettes in Taiwan

Taiwan’s tobacco control regimes are mainly established by the Tobacco Hazards Prevention Act (hereinafter the Act), based on the FCTC. Under the Act, a range of tobacco control measures, such as tobacco taxes, smoke-free public places,

bans on sale for under-ages and the pregnant, health warnings and information disclosure have been put in place. According to the definition in Article 2.1.1 of the Act, tobacco products refer to “cigarettes, cut tobacco, cigars and other products entirely or partly made of the leaf tobacco or its substitute as raw material which are manufactured to be used for smoking, chewing, sucking, snuffing or other methods of consuming.” Given such broad definition, smokeless tobacco products (such as chewing tobacco) are included and considered as general tobacco products, subject to the same level of regulations in regard to traditional smoked tobacco.

E-cigarettes (a more precise term is electronic nicotine delivery systems) are excluded from the scope of the Act since they are not entirely or partly made of the leaf tobacco as raw material. In accordance with the Pharmaceutical Affairs Act, e-cigarettes could be treated as medical devices and subject to higher level of obligations. More specifically, for the purpose of having e-cigarettes subject to regulations which are stricter than those under the rules governing tobacco products, the health authority in Taiwan (i.e. Department of Health, hereinafter DOH) uses the pharmaceutical regulatory framework to regulate the marketing of e-cigarettes. Under such regulatory approach, manufacturers of e-cigarettes are not allowed to claim or imply that e-cigarettes are of therapeutic effects without the approval of the DOH. E-cigarette advertisements shall be submitted to DOH for scrutiny and approval. Such advertisements shall not warrant the efficacy or functions by making use of materials or information from a book or publications, by releasing an interview or news report, or by publicizing in any other illegitimate manners. In addition, E-cigarettes shall not be made in cigarette-like forms.

II. Recommendations on the Regulation of Smokeless Tobacco Products under the FCTC

According to Article 1(f) of the FCTC, tobacco products are defined 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.” Under this definition, smokeless tobacco products, which are made of tobacco leaf as raw material, fall under this definition and are regulated by the FCTC. For the purpose of the

implementation of the FCTC, we suggest Parties to consider the following aspects:

1. *Health warnings on SLT packages*: Although the issue concerning scientific evidence on the causal link between SLT and certain illnesses is unsettled, it is still widely established by solid scientific evidences that the use of SLT will cause some serious harms to health, such as oral cancer, esophageal cancer, pancreatic cancer, and addiction. To promote and strengthen public awareness of the harmfulness of the use of SLT, Parties should require that the tobacco industry places relevant text health warnings (and graphic warnings where appropriate in terms of the size of SLT) on the packages of the SLT.
2. *Bans on SLT use in schools*: Banning the use of SLT in public places might be difficult. Nevertheless, we are of the view that at least SLT should be banned in schools so as to protect young persons' health. In this regard, both the *Yukon Smoke-Free Places Act* in Canada and the *Oklahoma Statutes on Smoking in Public Places and Indoor Workplaces* in the United States prohibiting SLT use in campus could provide useful references.
3. *Disclosure of SLT ingredients and constituents*: More and more various SLT products with large differences appear in the markets. We are of the view that FCTC should further develop and establish specific regulations for SLT ingredients and constituents to ensure states' consistent practices. At current stage, Parties shall require tobacco companies, based on the FCTC, to disclose relevant ingredients and constituents on the package of SLT as required in Article 11.2.

III. Recommendations on the Regulation of E-Cigarettes under the FCTC

E-cigarettes are devices to deliver nicotine to the respiratory system of the users. The FCTC, as its current cigarette-centric form, might not fully address the issue of e-cigarettes since it limits the definition of tobacco products to those made of tobacco leaves. Currently, e-cigarettes are often promoted and alleged by the tobacco companies as safer or less harmful and are perceived as useful alternatives to tobacco smoking or even as a smoking cessation. The special concern regarding the attractiveness of e-cigarettes to young person, and subsequent tobacco smoking

and nicotine addiction would also arise. We thought that the FCTC should give immediate response to this emerging issue.

The modification of the texts under the FCTC would be too complicated as required in Article 28 of the FCTC. Also, the current guidelines and protocol have been to focus on the control of smoked tobacco. We suggest that the FCTC should have separate guideline specifically designed for the characteristics of e-cigarettes. That is to say, current FCTC might take into account broadening its scope and having e-cigarette subject to multilateral regulations. On the basis of changing the cigarette-centric approach, the FCTC and its guideline need to be refined and clarified to cope with the regulatory needs of e-cigarettes. For instance, there must be recognition that the promotion of such products being safer is directly or indirectly creating “false impressions” and thus they should be prohibited. The explicit and implied promotion or indication of e-cigarettes being the alternative should be considered as advertising or promotional activities and need to be prohibited.¹

Parties should be encouraged to adopt rules that might be stricter than those suggested in the guideline, such as banning the production and distribution of e-cigarettes as applied in some countries. Also, practically, for regulatory purpose, e-cigarettes should be subject to higher extent of obligations under national laws. For instance, the advertisement and promotion activities of e-cigarettes might be subject to tighter regulations. No distribution is allowed without the pre-market approval of competent authorities.

¹ See Chang-fa Lo, *Uneasy Task of WHO FCTC to Regulate Smokeless Tobacco and E-Cigarettes: Different Legal Options to Tighten the Control beyond Cigarette-Based Model*, 2012 International Conference on FCTC, organized by Bureau of Health Promotion, Department of Health and the Asian Center for WTO and International Health Law and Policy, National Taiwan University College of Law, Taipei, Taiwan, 23-24 October 2012.