



## **INFORMATION NOTE**

### **on classification of novel and emerging tobacco products**

#### **Secretariat of the WHO Framework Convention on Tobacco Control**

This note aims to inform Parties on developments related to novel and emerging tobacco products in accordance with decision FCTC/COP8(22), including customs classification of these products.

#### **Tobacco products**

Article 1 of the WHO Framework Convention on Tobacco Products (WHO FCTC) defines tobacco products as “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 is a unique product in the sense that it is the only legal consumer product that kills up to half of its regular users when used as recommended by the manufacturer. Tobacco consumption and exposure to second-hand smoke are associated to higher prevalence of the leading causes of morbidity and mortality in the world, especially Non-Communicable Diseases (NCDs).

In this regard, the WHO FCTC and the Protocol to Eliminate Illicit Trade in Tobacco Products (the Protocol) provide a solid foundation and guidance for controlling the tobacco epidemic and promoting health through the regulation of tobacco products and protecting present and future generations. Tobacco is the only NCD risk factor that is covered by an international convention, and the Parties to this Convention have also elaborated a Protocol related to illicit trade of these products.

#### **Tobacco industry**

Based on the latest reports on the implementation of the WHO FCTC completed by its Parties,<sup>1</sup> tobacco industry interference, combined with the emergence of new and novel tobacco products, is considered a common challenge and the most serious barrier to progress. Moreover, some Parties have specifically mentioned that the target of the tobacco industry interference is the non-health sectors.

Article 5.3 of the WHO FCTC aims at protecting public health policies from commercial and other vested interests of the tobacco industry. The Guidelines for Implementation of Article 5.3 of the Convention recommends Parties to interact with the tobacco industry only when strictly necessary, and calls for transparency of such interactions, reducing or avoiding tobacco industry’s efforts to undermine tobacco control initiatives. The obligations acquired by the State Parties are applicable

---

<sup>1</sup> [https://www.who.int/fctc/reporting/WHO-FCTC-2018\\_global\\_progress\\_report.pdf](https://www.who.int/fctc/reporting/WHO-FCTC-2018_global_progress_report.pdf)

to all government sectors and departments. The different government sectors and departments require to follow a coherent policy when interacting with the tobacco industry, as provided for in Article 5.3 of the WHO FCTC, and its Guidelines. The policy coherence also implies that Parties to the WHO FCTC, when represented in various international organizations and bodies, should stand for and act in the spirit of their obligations under the Convention.

The need for coherence is also reflected in the “Model policy for agencies of the United Nations system on preventing tobacco industry interference”, which aims at ensuring that efforts to protect tobacco control from commercial and other vested interests of the tobacco industry are comprehensive, effective and consistent across the United Nations system including its funds, programmes, specialized agencies, other entities and related organizations.

The Convention Secretariat operates a Knowledge Hub for Article 5.3, and has contributed to the establishment and operations of three tobacco industry monitoring centres (observatories), which inform policy makers and governments of the tobacco industry’s interests and tactics, and provide strategies and tools to counter such interference, promoting policy coherence in tobacco control at all levels.

## **Terms, definitions and product categories**

### Electronic nicotine delivery systems

In a statement of January 2017, WHO describes electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) as *“battery powered devices that heat a solution (e-liquid) to create an aerosol which frequently contains flavourants, usually dissolved into Propylene Glycol or/and Glycerin. All ENDS (but not ENNDS) contain nicotine. Electronic cigarettes, the most common prototype, are devices that do not burn or use tobacco leaves but instead vaporise a solution the user then inhales. The main constituents of the solution, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavouring agents. ENDS solutions and emissions contain other chemicals, some of them considered to be toxicants.”*

At COP6, decision FCTC/COP6(9), invited Parties *“to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products,<sup>2</sup> medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health”*.

In terms of their current classification, in the annex to the International Convention on the Harmonized Commodity Description and Coding System,

- cartridges (e-liquids) for ENDS do not have a specific customs code and fall under the subheading of “other” in chapter 38, which concerns “miscellaneous chemical products” (3824.90); and
- devices of ENDS do not have a specific customs code and fall under the subheading of “other machines and apparatus” (8543.70) in chapter 85, which concerns electrical machinery.

---

<sup>2</sup> Tobacco products are defined in Article 1 of the WHO FCTC as “products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing.”

## Heated tobacco products

In the WHO information sheet dated May 2018, *“heated tobacco products are tobacco products that produce aerosols containing nicotine and other chemicals, which are inhaled by users, through the mouth. They contain the highly addictive substance nicotine (contained in the tobacco), which makes HTPs addictive. They also contain non-tobacco additives, and are often flavoured. HTPs mimic the behaviour of smoking conventional cigarettes, and some make use of specifically designed cigarettes to contain the tobacco for heating.”*

In the preamble of decision FCTC/COP8(22) dated 6 October 2018, the Parties to the WHO FCTC recognized that *“heated tobacco products are tobacco products, and are therefore subject to the provisions of the WHO FCTC”*.

The heated tobacco units (units that contain tobacco), are heated by a device that requires charging, and the user draws on the mouthpiece at intervals to inhale volumes of the aerosol through the mouth, which is then taken into the body.

In terms of their current classification, in the annex to the International Convention on the Harmonized Commodity Description and Coding System,

- heated tobacco units do not have a specific customs code and fall under the subheading of “other” (2403.99) in chapter 24 of the International Convention on the Harmonized Commodity Description and Coding System, which addresses tobacco products;
- devices used to heat tobacco units (heated tobacco products) do not have a specific customs code and fall under the subheading of “other machines and apparatus” (8543.70) in chapter 85, which concerns electrical machinery.

## **Relevant decisions of the Conference of the Parties and other COP documents**

Several COP decisions have covered novel and emerging tobacco products such as ENDS and HTPs, in parallel with specific attention to the analysis and recommendations on the control and prevention of ENDS/ENNDS.

Decision FCTC/COP3(9)<sup>3</sup> requested the Convention Secretariat to invite WHO to elaborate a report identifying best practices in reporting to regulators as regards contents, emissions and product characteristics, including electronic systems, best practices in informing the public, submitted to the following COP (FCTC/COP/4/INF.DOC./2)<sup>4</sup>.

The Convention Secretariat presented document FCTC/COP/4/12<sup>5</sup> at COP4, related to the Control and prevention of smokeless tobacco products and electronic cigarettes, responding to an agenda item. Decision FCTC/COP4(14)<sup>6</sup> requested the Convention Secretariat to prepare jointly with WHO a report based on the experience of Parties on the matter of smokeless tobacco products and

---

<sup>3</sup> [http://apps.who.int/gb/fctc/PDF/cop3/FCTC\\_COP3\\_DIV3-en.pdf](http://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_DIV3-en.pdf)

<sup>4</sup> [http://apps.who.int/gb/fctc/PDF/cop4/FCTC\\_COP4\\_ID2-en.pdf](http://apps.who.int/gb/fctc/PDF/cop4/FCTC_COP4_ID2-en.pdf)

<sup>5</sup> [http://apps.who.int/gb/fctc/PDF/cop4/FCTC\\_COP4\\_12-en.pdf](http://apps.who.int/gb/fctc/PDF/cop4/FCTC_COP4_12-en.pdf)

<sup>6</sup> [http://apps.who.int/gb/fctc/PDF/cop4/FCTC\\_COP4\\_DIV6-en.pdf](http://apps.who.int/gb/fctc/PDF/cop4/FCTC_COP4_DIV6-en.pdf)

nicotine delivery systems including electronic cigarettes, submitted to the following COP (FCTC/COP/5/13)<sup>7</sup>.

Decision FCTC/COP5(6) invited WHO to monitor and follow closely the evolution of new tobacco products, including products with potentially “modified risks”, reported in a document submitted to the following COP (FCTC/COP/6/14)<sup>8</sup>, including criteria to define “new” or “novel” tobacco products and a monitoring of the market of these products. Decision FCTC/COP5(10)<sup>9</sup> requested the Convention Secretariat to invite WHO to identify options for the prevention and control of ENDS and to examine emerging evidence on the health impacts of ENDS use. Subsequently, WHO submitted the report on ENDS to the following COP (FCTC/COP/6/10 Rev.1)<sup>10</sup>.

Decision FCTC/COP6(9)<sup>11</sup> invited Parties to take measures, such as the recommended in document FCTC/COP/6/10 Rev.1, in order to prevent initiation of ENDS/ENNDS by non-smokers and youth; minimize potential health risks to its users and protect non-users; prevent unproven health claims from being made; and protect tobacco-control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry. Additionally, COP invited Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate. Following this decision, an expert report was submitted by WHO to the following COP (FCTC/COP/7/11)<sup>12</sup>.

At COP7, decision FCTC/COP7(9)<sup>13</sup> invited Parties to apply regulatory measures, such as the recommended in document FCTC/COP/7/11, to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate. Moreover, the Convention Secretariat was requested to invite Parties to monitor and report on scientific, regulatory and market developments such as initiation, cessation, advertising and promotion, and to invite WHO to report on the development of methods by regional and international standards-development organizations for the testing and measuring of contents and emissions of these products.

Decision FCTC/COP7(14) requested the Convention Secretariat to invite WHO to continue to monitor and examine market developments and usage of novel and emerging tobacco products, such as “heat-not-burn” tobacco products. WHO presented to COP8 the document FCTC/COP/8/8<sup>14</sup>. In parallel, the Convention Secretariat submitted to COP8 the document FCTC/COP/8/10<sup>15</sup>, on the progress on regulatory and market developments on ENDS and ENNDS, in response to a request from the Bureau.

The latest COP decision on the matter, FCTC/COP8(22)<sup>16</sup>, recognizes that heated tobacco products are to be classified as tobacco products and are therefore subject to the provisions of the WHO

---

<sup>7</sup> [http://apps.who.int/gb/fctc/PDF/cop5/FCTC\\_COP5\\_13-en.pdf](http://apps.who.int/gb/fctc/PDF/cop5/FCTC_COP5_13-en.pdf)

<sup>8</sup> [http://apps.who.int/gb/fctc/PDF/cop6/FCTC\\_COP6\\_14-en.pdf](http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_14-en.pdf)

<sup>9</sup> [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)

<sup>10</sup> [http://apps.who.int/gb/fctc/PDF/cop6/FCTC\\_COP6\\_10Rev1-en.pdf](http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf)

<sup>11</sup> [http://apps.who.int/gb/fctc/PDF/cop6/FCTC\\_COP6\(9\)-en.pdf](http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6(9)-en.pdf)

<sup>12</sup> [https://www.who.int/fctc/cop/cop7/FCTC\\_COP\\_7\\_11\\_EN.pdf](https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf)

<sup>13</sup> [https://www.who.int/fctc/cop/cop7/FCTC\\_COP7\\_9\\_EN.pdf](https://www.who.int/fctc/cop/cop7/FCTC_COP7_9_EN.pdf)

<sup>14</sup> [https://www.who.int/fctc/cop/sessions/cop8/FCTC\\_COP\\_8\\_8-EN.pdf](https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP_8_8-EN.pdf)

<sup>15</sup> [https://www.who.int/fctc/cop/sessions/cop8/FCTC\\_COP\\_8\\_10-EN.pdf](https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP_8_10-EN.pdf)

<sup>16</sup> [https://www.who.int/fctc/cop/sessions/cop8/FCTC\\_COP8\(22\).pdf](https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8(22).pdf)

FCTC. Additionally, the Convention Secretariat was requested to examine the possible challenges posed by these products to the implementation of the WHO FCTC, and to advise on the adequate classification of these products to support regulatory efforts and the need to define new product categories.

### **Classification of novel and emerging tobacco products by the World Customs Organization**

In decision FCTC/COP8(22), the COP requested the Convention Secretariat “*to advise, as appropriate, on the adequate classification of novel and emerging tobacco products such as heated tobacco products to support regulatory efforts and the need to define new product categories*”. Upon this mandate, the Convention Secretariat has duly informed the Permanent Missions to the United Nations Office in Geneva of the Parties to the WHO FCTC and to the Protocol about the ongoing process for the amendment of harmonized customs codes concerning tobacco and nicotine products at the World Customs Organization (WCO).

In March 2019, the HS Committee will meet at the WCO to consider a proposal to establish a new HS Code heading 24.04 to cover “*products containing tobacco, reconstituted tobacco, nicotine or tobacco or nicotine substitutes, intended for inhalation without combustion; other nicotine containing products intended for the intake of nicotine into the human body*”. The Convention Secretariat and WHO have expressed concerns during the negotiation of the amendments, and propose that some additional elements are put forward during the discussions. These elements, with some explanations, are provided below:

**Element 1:** heated tobacco products should not be referred to as products intended for “inhalation without combustion”, as this might unintentionally suggest that heated tobacco products do not produce smoke (as has been argued by tobacco companies).

**Explanation:** The discussion on whether heated tobacco products (HTPs) produce smoke or not, should not be brought to the WCO, since the topic is still under discussion for the next COP, and the categorization of this condition may vary among products and countries' regulations. However, the Convention Secretariat, following the recommendations from the COP and the reports from WHO, in order to promote and contribute to the implementation of the WHO FCTC, would like to emphasize to Parties that the classification of the HTPs should fall under a category that allows to enhance the Parties' capacity to monitor the import and export of novel and emerging tobacco products (HTPs among them), but also to implement effective tobacco product regulations. In this regard, the classification of HTPs in the aforementioned category could affect, for example, the exclusion of these products under smoke-free regulations.

**Element 2:** nicotine replacement therapies should sit in separate sub-headings from heated tobacco products and ENDS to ensure that these categories are easily distinguished for customs and tax purposes.

**Explanation:** Nicotine replacement therapy (NRT) are placed on the WHO Model List of Essential Medicines, and it is recommended that Parties include them in their national list. These products should be considered in a separated sub-chapter from HTPs and ENDS, given their irreconcilable difference in nature. However, the classification of HTPs and ENDS would be acceptable either under chapter 24 or 38 of the Harmonized System Code, as it stands at the moment. Accordingly, the separation of these products from NRTs would

allow Parties to implement adequate taxes or regulations (including banning) on HTPs and ENDS, as recommended by the COP.

**Element 3:** devices used for heated tobacco products and ENDS should also have separate customs codes or be grouped on a category such as “tobacco related products”, to support application of tobacco control laws to devices.

**Explanation:** These are the devices used for heating, and otherwise consuming, the cartridges, e-liquid vials, etc in case of electronic nicotine delivery systems and the heated tobacco units in case of heated tobacco products. In contrast with the consumable parts, the separation of the devices will give the opportunity for a different application of existing and relevant laws to these devices, for example the tobacco control laws, where applicable.

Although the HS Code is not intended to affect domestic regulation, in practice, customs codes are used for controlling the entry and exit of goods at the border, for purposes of levying excise taxes, and may also affect how different products are categorized under domestic laws, such as tobacco control laws. There is also potential for tobacco companies to misuse customs codes in lobbying to resist regulation or taxation of new products, such as heated tobacco products.

### **Next steps**

The Convention Secretariat will:

- Participate in the WCO meeting of the HS Committee, calling the attention to these elements listed in the NV sent to Parties on 4 February 2019.
- Call for actions included in operative paragraphs 2-6 of decision FCTC/COP8(22), including additional research on novel and emerging products.
- Prepare an information note, including the outcome of negotiations under the auspices of the WCO, on harmonized customs codes and their potential impacts on the implementation of the WHO FCTC.
- Remind Parties, through additional resources and NVs as appropriate, on their obligations under the WHO FCTC when addressing the challenges posed by novel and emerging tobacco products.
- Strengthen the monitoring of market developments and the use of novel and emerging products through the WHO FCTC reporting instrument and other appropriate surveys and reports.
- Submit to COP9 recent developments related to novel and emerging tobacco products and guide further actions.

Geneva, 15 March 2019

===