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Challenges posed by and classification of novel and emerging tobacco products

Report by the Convention Secretariat

Purpose of the document

This report examines the challenges that novel and emerging tobacco products are posing for the comprehensive application of the WHO Framework Convention on Tobacco Control, in particular those articles and guidelines referring to definitions and terminology and to tobacco smoke, and provides information on the adequate classification of such products, such as heated tobacco products, to support regulatory efforts, as requested in paragraph 3 of decision FCTC/COP8/(22).

Action by the Conference of the Parties

The Conference of the Parties is invited to note the report and provide further guidance.

Contribute to the Sustainable Development Goals (SDGs), if applicable: Target 3.a and Goal 3.

Link to the workplan and budget item: 1.1.1.3, 1.1.2.1, 1.1.3.1, 1.1.3.2.

Additional financial implications if not included in the workplan and budget: None.

Related document(s): FCTC/COP/9/8; FCTC/COP/9/9; Previous COP decisions concerning novel and emerging tobacco products.

BACKGROUND

1. The Eighth session of the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC) adopted decision FCTC/COP8 (22)¹ on novel and emerging tobacco products. The decision recognizes that heated tobacco products (HTPs) are tobacco products and therefore subject to the provisions of the WHO FCTC, further noting that there is currently limited guidance to Parties on the classification and regulation of HTPs. Moreover, in the same decision, Parties were reminded of their commitments under the WHO FCTC and invited to consider prioritizing certain measures in accordance with the WHO FCTC in addressing the challenges posed by novel and emerging tobacco products, such as heated tobacco products (HTPs) and devices designed for consuming such products.

2. In operative paragraph 3 of decision FCTC/COP8(22), the COP requested the Convention Secretariat: “(a) to examine possible challenges these products are posing for the comprehensive application of the WHO FCTC and in particular those articles and guidelines referring to definitions/terminology and to tobacco smoke, while considering the need to adapt these guidelines; (b) 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”. In responding to these requests, the Convention Secretariat commissioned the following three reports:

- Possible challenges posed by novel and emerging tobacco products in implementing WHO FCTC articles and guidelines referring to tobacco smoke.
- Possible challenges posed by novel and emerging tobacco products in implementing WHO FCTC articles and guidelines referring to definitions/terminology.
- Classification of novel and emerging tobacco products to support regulatory efforts and the need to define new product categories.

INTRODUCTION

3. Novel and emerging tobacco products are heterogeneous, increasing in number and have a variety of design features that raise questions concerning the application of product definitions, categorization or descriptions.²

4. Among the novel and emerging tobacco products, HTPs were introduced by the tobacco industry with unproven claims of “reduced harm” to the user and are often marketed as alternatives to smoked tobacco products. The most widely used HTPs are composed of an accessory device that contains an external energy source that heats the tobacco and an insert containing processed tobacco. Both components are necessary for the use of HTPs. The device then provides the energy that would allow the release of – among other substances – nicotine, the addictive substance in tobacco, at temperatures typically less than 350°C. The heat source can be manipulated in its intensity to satisfy the user, primarily

¹ [https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8\(22\).pdf](https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8(22).pdf).

² For the definition of novel and emerging tobacco products see: WHO TobReg: report on the scientific basis of tobacco product regulation: 5th report of a WHO study group (available at https://apps.who.int/iris/handle/10665/161512?search-result=true&query=WHO+TobReg%3A+report+on+the+scientific+basis+of+tobacco+product+regulation%3A+5th+report+of+a+WHO+study+group&scope=&rpp=10&sort_by=score&order=desc).

in its nicotine dosing.¹ In less commonly used products, the heat source is integrated internally in the design of the product but with a rechargeable energy source.

5. The knowledge of these novel and emerging tobacco products has been rapidly increasing, but information on their long-term health effects is limited because of the relative recent availability of this new generation of products in global markets, and the fact that the industry regularly introduces new products with added design features that pose a challenge in conducting studies. Independent (that is, not funded or produced by the manufacturers) data on the health and environmental impact of these novel tobacco products is incipient.² Despite some gaps in the science about these products, adequate information has become available to make recommendations to Parties, as per the request made of the Secretariat of the WHO FCTC, that pertain to their categorization/classification and the applicability of the obligations in the WHO FCTC to their regulation.

POSSIBLE CHALLENGES POSED BY NOVEL AND EMERGING TOBACCO PRODUCTS IN IMPLEMENTING WHO FCTC ARTICLES AND GUIDELINES REFERRING TO TOBACCO SMOKE

6. Smoke is a type of aerosol, defined as a system consisting of particles suspended in a gas.³ Aerosol particles may be liquids, solids or a combination thereof. Aerosols may be classified by their sources. For example, aerosols generated by mechanical disintegration are considered “dusts”; those generated by atomization are termed “mists”; those produced by condensation of a vapor⁴ due to cooling are termed “fog”; and those generated by chemical reactions involving heat are termed “smoke”,⁵ as is the case in tobacco smoking.

7. Combustion, pyrolysis and pyrosynthesis are categories of thermochemical reactions that often occur simultaneously when conventional tobacco products are used. Some of the chemical reaction products are the result of combustion in which an oxidant (typically oxygen) accepts an electron from the oxidized fuel to form carbon dioxide (CO₂) and/or carbon monoxide (CO), and thermal energy. Burning of solid carbon in charcoal, as is the case in water-pipe smoking, is an example of these thermochemical reactions. Other chemical reaction products are largely formed by pyrolysis and pyrosynthesis reactions in the oxygen-starved region of the chemical reaction.⁶

8. Combustion is an exothermic (or heat-releasing) chemical reaction. Pyrolysis is an endothermic reaction (a reaction that consumes heat) in which a parent molecule subjected to heat is cracked into more elementary (lower molecular mass) components, usually in an inert atmosphere (environment without risk of contamination from reactive gases that exist in air, such as oxygen). These elementary

¹ WHO study group on tobacco product regulation. Report on the scientific basis of tobacco product regulation: Seventh report of a WHO study group (available at: <https://www.who.int/publications-detail/who-study-group-on-tobacco-product-regulation-report-on-the-scientific-basis-of-tobacco-product-regulation-seventh-report-of-a-who-study-group>).

² WHO study group on tobacco product regulation: Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group. 4 May 2021 (available at: <https://www.who.int/publications/i/item/9789240022720>).

³ <https://www.merriam-webster.com/dictionary/aerosol>.

⁴ A vapor is physical state of a gas, when that gas is below the critical pressure, and therefore can condense to become a liquid.

⁵ Torikai K et al: Effects of temperature, atmosphere and pH on the generation of smoke compounds during tobacco pyrolysis. *Food and Chemical Toxicology* 42 (2004) 1409–1417.

⁶ Mastral A et al. A Review on Polycyclic Aromatic Hydrocarbon (PAH) Emissions from Energy Generation. *Environmental Science & Technology* 2000; 34 (15):3051–3057.

molecules may recombine to form new, larger molecules that were not previously present, in a process known as pyrosynthesis. Polycyclic aromatic hydrocarbons (PAHs) are a class of chemicals commonly formed through a pyrolysis–pyrosynthesis sequence.¹

9. In many systems, such as conventional cigarettes, the source of heat driving pyrolysis and pyrosynthesis is combustion in an atmosphere involving oxygen, but these reactions can also be driven by external heat sources, including electrical heating, even without the presence of combustion.

10. The term “tobacco smoke” is commonly used to refer to the aerosol emitted from a tobacco-containing system or product that is undergoing combustion. The generated smoke often contains products of thermochemical reactions, as well as unreacted material from the parent “fuel” – tobacco in this case. Some components in tobacco smoke are produced primarily by combustion reactions – for example, CO₂, CO and water (H₂O) – by pyrolysis and pyrosynthesis reactions (for example, PAH and aldehydes), and by non-reactive transfer from the heated tobacco filler into the air passing through the smoked device, for example, nicotine, tobacco-specific nitrosamines (TSNAs), propylene glycol, lead, arsenic and solanesol. It should be noted that the third category, which is non-reacted products, account for more than 75% of the mass of cigarette tobacco smoke and only a small fraction is derived by chemical reaction processes.²

Can the aerosols of novel and emerging tobacco products qualify as “tobacco smoke”?

11. Yes. In general, smoke is produced whenever substances are heated beyond a temperature at which pyrolysis occurs, whether such temperatures are achieved through combustion or other means. For example, heating cooking oil to high temperatures in a cooking vessel can cause pyrolysis reactions that emit aerosols visible to the naked eye, even if the cooking vessel was heated on an electric stove, that is without combustion. The temperature at which a particular oil begins to undergo pyrolysis when it is heated is known as the “smoke point” and international standard methods exist to measure the smoke-point temperatures of lubricating oils, fuel oils and cooking oils.³ Aerosols emitted by heated cooking oil are a health concern because they include toxic thermal degradation products, such as volatile aldehydes, which are produced via degradation of intermediate degradation products, such as glycerol.⁴ Another example is provided by electrical cables that are overloaded; the aerosol emitted by the insulating plastic is called “smoke”, even when no fire is present. Thus, strictly speaking, visible aerosols deriving in whole or in part from thermally driven chemical reactions qualify as “smoke”, even when combustion is not involved in the process.

¹ Atal A et al. On the survivability and pyrosynthesis of PAH during combustion of pulverized coal and tire crumb. *Combustion and Flame*. 1997; 110(4):462–478.

² Hoffmann D et al. The less harmful cigarette: a controversial issue. A tribute to Ernst L. Wynder. *Chem Res Tox*. 2000; 14(7):767–90.

³ <https://www.astm.org/Standards/D1322>.

⁴ Katragadda H et al. Emissions of volatile aldehydes from heated cooking oils. *Food Chemistry*. 2010; 120(1):59–65.

12. Novel and emerging tobacco products, particularly HTPs, emit pyrolysis products such as volatile aldehydes;^{1,2} therefore, these aerosols are clearly within the scientific definition of “smoke”, and any smoke emitted by HTPs is unambiguously “tobacco smoke”.

POSSIBLE CHALLENGES POSED BY NOVEL AND EMERGING TOBACCO PRODUCTS IN IMPLEMENTING WHO FCTC ARTICLES AND GUIDELINES REFERRING TO DEFINITIONS AND TERMINOLOGY

13. Decision FCTC/COP8(22) on “Novel and emerging tobacco products” reminds Parties to the Convention that these products are tobacco products and, therefore, subject to the provisions of the WHO FCTC, and the decision invites Parties to prioritize the following measures: prevention of initiation; protection of people from exposure to their emissions by including these products in the scope of the smoke-free legislation; prevention of unproven health claims; prohibition of advertising, promotion and sponsorship; regulation of contents and disclosure of contents; and protection of tobacco control policies from commercial and other vested interests related to these products. The decision also requests Parties to consider whether to “regulate, including restrict, or prohibit, as appropriate the manufacture, importation, distribution, presentation, sale and use of novel and emerging tobacco products” and to apply the aforementioned measures to the devices designed for consuming these products.

14. At the national level, Parties have taken different approaches to classifying HTPs (see Annex 1). Such classification may also carry importance for tax and regulatory purposes.

15. *General challenges to implementation.* In the context of HTPs, there are a number of potential challenges Parties may face in implementing the WHO FCTC through pre-existing domestic tobacco control laws. For example:

- where laws apply to tobacco products, the question of whether those laws are broad enough to apply to HTP devices might arise; and
- where existing laws apply differently to different categories of tobacco products, the question of how to classify HTPs might arise.

16. *Overcoming these challenges.* On the question of classification, Parties should consider regulating HTPs akin to conventional cigarettes, or any other tobacco product category where a higher level of health protection is achieved.

With respect to devices, Parties should consider:

- whether existing laws govern HTP devices as tobacco products or tobacco accessories, for example, because devices are sold together with tobacco sticks or are integral for their use, and if not, whether existing laws applicable to devices for tobacco use (such as pipes and water pipes) apply to HTP devices; and

¹ Williams M et al. Elements including metals in the atomizer and aerosol of disposable electronic cigarettes and electronic hookahs. *PLoS ONE*. 2014; 12(4): e0175430.

² Salman R et al. Free-Base and Total Nicotine, Reactive Oxygen Species, and Carbonyl Emissions From IQOS, a Heated Tobacco Product. *Nicotine Tob Res*. 2019; 21(9):1285–1288.

- in light of this analysis, whether amendments are necessary to ensure that HTP devices cannot be used to circumvent or undermine existing tobacco control laws.

17. The challenges detailed above, and other potential challenges, arise in a context of tobacco industry interference in policy-making, with tobacco companies arguing that HTPs should be subject to lighter regulation than conventional cigarettes. Industry arguments for relatively light regulation revolve around the distinct product features of HTPs, as compared to conventional cigarettes. In this respect, tobacco companies emphasize that HTPs heat tobacco without burning it or involving combustion. This assertion then underpins a number of arguments, including claims that HTPs are “reduced risk” products relative to conventional cigarettes, can be used as part of an approach to tobacco “harm reduction” and that HTPs aerosols do not constitute tobacco smoke.

18. Tobacco companies use a number of tactics in pursuing relatively light regulation for HTPs, including downplaying and ignoring health risks from HTPs, conflating HTPs and electronic nicotine delivery systems (ENDS) in ways that confuse the evidence around risk where it is expedient to do so, lobbying parliamentarians directly in order to bypass health authorities, and funding front groups to push a “harm reduction” narrative and make claims that companies themselves may not be permitted to make under laws governing misleading conduct.¹

19. *Overcoming these challenges.* To overcome these challenges relating to industry interference, Parties should consider:

- taking a precautionary approach to the health risks posed by HTPs, ensuring that they are regulated akin to conventional cigarettes;
- strictly enforcing prohibitions on tobacco advertising, promotion and sponsorship, including by enforcing those laws with respect to public or consumer facing claims that are designed to promote HTP use or create perceptions of safety;
- strictly enforcing laws relating to misleading or deceptive claims, including by prohibiting unfounded public or consumer facing claims that imply that HTPs reduce health risks relative to conventional cigarettes, such as reduced exposure claims; and
- applying Guidelines for Implementation of Article 5.3 to their full extent.

20. *Article 6.* Upon introduction of HTPs to a market, many Parties have confronted the question of whether and how existing tax laws apply. This challenge arises partly because different tax rates and structures are often applied to different categories of tobacco products. These categories can be established through definitions in the tax laws themselves, or more often, by a cross-reference to customs codes that define product categories for customs purposes. Where tax laws clearly apply to HTPs, or are reformed to do so, a related challenge arises of how best to tax the products, in the context of existing approaches to different product categories.

¹ For further information see <https://www.who.int/fctc/mediacentre/news/2019/remain-vigilant-towards-novel-new-nicotine-tobacco-products/en/>; https://exposetobacco.org/pmi-uncovered/?fbclid=IwAR1gu0a755q3ziT7Bm31QWaYdJQZF-vWHZ3hP_hhz-kWeW5Z9qLKN82S3_4; <https://www.rappler.com/newsbreak/investigative/252521-truth-behind-philip-morris-international-cigarette-free-future?fbclid=IwAR2IJsVBIJrPsoiTsn9108qrskdBGUCZ0BtA8GmUk2dZ8hqBPMbHvhSc1Wc>; Elias J at al. Invisible smoke: third-party endorsement and the resurrection of heat-not-burn tobacco products. *Tob Control*. 2018; 27(Suppl 1):s96-s101.; https://www.theguardian.com/society/2020/feb/24/philip-morris-drew-up-plan-for-1bn-tobacco-transition-fund?fbclid=IwAR0xwqziFv1c7LGv44PFrhc3aFGe_exbWxAbkPW3xMevcEj--DQd9LK7bmo.

21. *Overcoming these challenges.* Parties should consider:

- establishing new product categories in domestic tax laws or customs codes for HTPs at the earliest legislative opportunity, such as when annual budgetary legislation is passed, or relevant customs codes are reformed (see below);
- taxing HTPs at the same level as conventional cigarettes on a per unit basis, regardless of the total tobacco content; and
- taxing HTP devices and any other accessories to deter HTP use.

22. *Article 8.* The evidence on exposure to emissions from novel tobacco products is emerging, but there is evidence that non-users are exposed to toxicants.¹ Nonetheless, as noted above, questions may arise concerning whether definitions in existing smoke-free laws are broad enough to govern HTP use. Additionally, enforcement challenges may arise if ENDS use is permitted in smoke-free areas because of the challenge in distinguishing between ENDS and HTPs.

23. *Overcoming these challenges.* Parties should consider:

- treating HTP aerosols as smoke, and treating HTP use as smoking, where existing laws permit, or reforming those laws or regulations to treat them accordingly; and
- implementing decision FCTC/COP7/(9) to prohibit ENDS use within smoke-free areas.

24. *Articles 9 and 10.* Understanding the risks posed by HTPs presents a number of challenges for Parties, including with respect to attaining comprehensive data regarding the contents, emissions and design features of individual products, verification of such information, evaluation and subsequent product regulation. In this respect, there are no internationally validated standard methods for testing HTP contents and emissions. However, there is ongoing work by international standardization bodies, countries and the World Health Organization (WHO) Tobacco Laboratory Network (TobLabNet) to assess and validate existing TobLabNet methods for testing these products.

25. In keeping with Articles 9 and 10 of the WHO FCTC, Parties should consider:

- requiring comprehensive disclosure of contents, emissions and design features of HTPs;
- monitoring priority harmful compounds in HTP emissions such as nicotine, aldehydes and carbon monoxide and requiring their reduction, as appropriate, taking into account WHO recommendations and the national context;
- using the methods developed and validated by WHO TobLabNet to measure priority toxicants in HTP contents and emissions; and
- regulating the contents, emissions and design features of HTPs and requiring product disclosures as part of a comprehensive approach to tobacco control; and

¹ Simonavicius E at al. Heat-not-burn Tobacco Products: A Systematic Literature Review. *Tob Control*. 2019; 28(5):582–594.

- restricting the use of flavours that appeal to minors and implementing the recommendations in the Partial Guidelines for Implementation of Articles 9 and 10.

26. *Article 11.* One challenge in implementing Article 11 concerns the specificity of warning messages. Other than applying warning labels related to addiction and toxicants, as well as general warnings regarding harm to health, warning labels that are disease specific may be distinct for these products and may change as knowledge of disease risk develops. Another challenge is that HTPs have a device that is indispensable for their use, but often sold separately, raising questions of whether or in what circumstances packaging and labelling laws, including those requiring health warnings as well as standardized packaging, apply to devices.

27. *Overcoming these challenges.* Parties should consider:

- sharing existing and new health warnings with the WHO FCTC Secretariat and WHO, to make them readily available to other Parties; and
- whether existing packaging and labelling laws (including those requiring health warnings) that govern tobacco products, or accessories, also govern HTP devices, and if not, amending those laws to ensure their application to HTP devices.

28. *Article 13.* A range of marketing strategies are being used to promote HTPs, often with claims of reduced risk if conventional cigarette smokers switch completely from cigarettes to HTPs. The tobacco industry has used social media,^{1,2} as well as traditional media,³ including billboards, in advertising campaigns that glamourize these products.⁴ The tobacco industry has also used extensive point-of-sale advertisement, as well as specific retail stores, to promote these products.⁵ To circumvent existing tobacco control laws, tobacco companies have also advertised and promoted devices separately from tobacco inserts, the advertising and promotion of which is clearly prohibited.

29. *Overcoming these challenges.* Parties should consider:

- treating advertising, promotion and sponsorship of HTP devices as tobacco advertising, promotion and sponsorship, given the link between the device and the tobacco stick intended for use in the device; and
- prohibiting point-of-sale advertising and point-of-sale display of HTPs and HTP devices.

30. *Article 14.* As HTPs are tobacco products, switching from conventional cigarettes to HTPs does not constitute tobacco cessation under Article 14 and its Guidelines for Implementation. The Guidelines for Implementation of Article 14 define “tobacco cessation” as the “process of stopping the use of any

¹ <https://www.reuters.com/article/us-philipmorris-ecigs-instagram-exclusiv/exclusive-philip-morris-suspends-social-media-campaign-after-reuters-exposes-young-influencers-idUSKCN1SH02K>.

² Dagli E et al. Heated tobacco product marketing: internet platforms undermine regulations. *European Respiratory Society*. 2019; 54: PA1693.

³ Bialous SA et al. Heated tobacco products: another tobacco industry global strategy to slow progress in tobacco control. 2018; 27(Suppl 1): s111-s117.

⁴ <https://scopeblog.stanford.edu/2020/02/26/exposing-the-effort-to-glamorize-heated-tobacco/>.

⁵ <https://www.tobaccofreekids.org/assets/factsheets/0404.pdf>.

tobacco product”. However, broader reduced-risk claims made by industry may have the effect of encouraging existing smokers to switch product categories rather than make quit attempts.

31. *Overcoming this challenge.* Parties should consider:

- strictly enforcing laws to prevent unfounded claims concerning the relative risks of HTPs as compared to conventional cigarettes; and
- providing the public with information concerning the health risks associated with HTP use.

32. *Article 16.* Laws prohibiting sales to and by minors apply to novel and emerging tobacco products. Enforcement remains a concern, especially since the marketing message may make these products more appealing to youth.^{1,2}

33. *Overcoming this challenge.* Parties should consider:

- strictly enforcing minimum age laws for the purchase of such products, in coordination with implementation and enforcement of other aspects of Article 16 intended to protect minors; and
- implementing other articles and guidelines that limit access by minors, especially those focused on product attractiveness (for example, Partial Guidelines for Implementation of Article 9 and 10 and Guidelines for Implementation of Articles 11 and 13).

34. *Article 20.* Parties must continue sharing best practices and developing evidence, based on surveillance and on population-based and clinical research, on the impact of novel and emerging tobacco products on health and the implementation of policies to reduce tobacco use. This is particularly important in light of the rapidly changing context in which HTPs are sold and marketed, and the fact that much of the available research on them is industry funded. In addition, there is limited data available on uptake of HTPs by adolescents, as well as former smokers and non-smokers.

35. *Overcoming these challenges.* Parties should consider:

- ensuring that HTPs are included in representative national, regional and global tobacco monitoring and surveillance programmes;
- ensuring that data collected on HTPs reflects the products available on the market and describes them clearly; and
- conducting surveys related to HTP use and uptake to ensure regular monitoring and better enable timely regulatory interventions, such as conducting them over shorter time intervals and using smaller sample sizes.

¹ McKelvey K et al. Heated Tobacco Products Likely Appeal to Adolescents and Young Adults. *Tob Control*. 2018; 27(Suppl 1):s41-s47.

² Lee Y et al. Association of Alcohol and Drug Use With Use of Electronic Cigarettes and Heat-Not-Burn Tobacco Products Among Korean Adolescents. *PLoS One*. 2019; 14(7):e0220241.

CLASSIFICATION OF NOVEL AND EMERGING TOBACCO PRODUCTS TO SUPPORT REGULATORY EFFORTS AND THE NEED TO DEFINE NEW PRODUCT CATEGORIES

36. Parties that have not banned novel and emerging tobacco products have adopted several approaches to classify or regulate them (see Annex 1). As is reflected in COP decision FCTC/COP8(22), under the WHO FCTC, HTPs are tobacco products. In implementing the WHO FCTC and determining how these tobacco products may be further classified under domestic tobacco control laws, Parties might also have a secondary consideration concerning how they are classified under customs codes and tax laws.

37. Parties separately classify HTPs under domestic customs codes when the products are imported, and where tax laws refer to customs codes for purposes of product classification. In this respect, the Harmonized System Committee of the World Customs Organization (WCO) has adopted a number of proposed new customs subheadings relevant to customs classification of novel and emerging tobacco products and nicotine products.¹ Customs codes serve multiple purposes, such as in controlling import and export of goods, and levying customs duties.

38. Chapter 24 of the Harmonized System (HS) Nomenclature² (codes related to tobacco products) was amended (see Annex 2) during the negotiations of the Harmonized System Committee, and they will come into effect on 1 January 2022. In essence, Chapter 24 of the HS Nomenclature creates a new heading (24.04) and subheadings covering some novel and emerging tobacco products and nicotine products (including nicotine replacement therapies).³

39. Heading 24.04 includes products intended for inhalation without combustion. The expression “inhalation without combustion” was defined as inhalation through heated delivery or other means, without combustion. There is no operational definition of “combustion” in the HS Code for the purpose of this categorization, leaving the issue to be further clarified through official Explanatory Notes, or Classification Opinions (in the case of individual products).

40. A new code in Chapter 85 (electrical machinery, equipment and parts) was created for Electronic Nicotine Delivery Systems/Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) and personal vaporizers (8543.40).

41. Creation of new headings and subheadings in Chapter 24 will be replicated by Parties in changes to their own customs codes. To advance tobacco control, Parties could take steps such as ensuring that HTPs are subject to taxes equivalent to cigarettes and ensuring that nicotine products listed as essential medicines are not subjected to customs duties or other taxes. Parties may also wish to consider establishing a national eight-digit subheading under Subheading 8543.40 to create separate categories for the devices of novel and emerging tobacco products, including HTPs, as compared to ENDS/ENNDS devices.

¹ <http://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs-nomenclature-2022-edition.aspx>.

² https://www.usitc.gov/tariff_affairs/wco/wco_recommendation_june282019_to_hts.pdf.

³ Consequential amendments were made to other chapters of the Code that previously included nicotine products. For example, specific notes were added to Chapter 21 on miscellaneous edible preparations, Chapter 30 on pharmaceutical products, and Chapter 38 on miscellaneous chemical products to exclude anything that has already been classified under Chapter 24.

CONCLUSIONS

42. Smoke is a type of aerosol that is produced when a substance is heated sufficiently to produce noxious chemical reaction products. Smoke can be generated under a wide range of temperatures, with or without the presence of combustion. Heating tobacco at temperatures commonly used in novel and emerging tobacco products, including HTPs, produces an aerosol that contains toxic thermal degradation products that were not originally present in the tobacco before it was heated. The aerosols emitted by HTPs thus fall under the definition of smoke. Since the source of this smoke is a tobacco product, the emissions of most novel and emerging tobacco products – including HTPs – are tobacco smoke.

43. All articles of the WHO FCTC and their guidelines for implementation can be applied to novel and emerging tobacco products, including HTPs, and extended to the devices needed for their use if they are not covered by national legislation, in those Parties that have allowed these products in their jurisdiction.

44. The recently introduced amendments to the coding system of the Harmonized System Committee of WCO provide a scheme of categorization and classification that serve to control import and export of tobacco products. At the country level, it may be used in levying taxes and in assisting in identification of tobacco products and the devices needed for their use that should be subjected to tobacco control laws. Parties should consider implementing the policy options mentioned above in paragraph 41 in response to these changes.

ACTION BY THE COP

45. The COP is invited to note the present report and provide further guidance.

ANNEX 1

**EXAMPLES OF REGULATION OF HEATED TOBACCO PRODUCTS (HTPS)
IN SELECTED COUNTRIES (AS OF 30 DECEMBER 2020:
TAX DATA AS OF 31 JULY 2020)¹**

Country	Advertisement/marketing	Packaging/health warning	Tax	Use in public places
Canada	Heated tobacco products (HTPs) are legally sold and distributed. HTPs cannot be advertised or promoted.	HTPs subject to plain packaging requirements.	*	No federal laws regulate the use of HTPs; provincial legislation may do so.
Israel	HTPs are legally sold and distributed. HTPs subject to the same advertising restrictions as other tobacco products.	Plain packaging enforced on all tobacco products, including HTPs, as of 8 January 2020.	HTPs subject to same tax rate as conventional cigarettes.	Existing smoke-free legislation applies to HTPs.
Japan	HTPs are legally sold and distributed.	HTPs subject to specific warning requirements.	Taxed by number of sticks, using a conversion method from conventional cigarettes.	Existing smoke-free legislation applies to HTPs.
New Zealand	HTPs are legally sold and distributed. HTPs cannot be advertised or promoted.	HTPs subject to same warning requirement as for smokeless tobacco products.	HTPs taxed by weight.	Existing smoke-free legislation applies to HTPs.
Republic of Korea	HTPs are legally sold and distributed. HTPs subject to same advertising restrictions as other tobacco products.	HTPs subject to same graphic warning requirements as smoked tobacco.	Individual consumption tax rate for HTPs is 89% of the tax levied on conventional cigarettes.	Existing smoke-free legislation applies to HTPs.
Switzerland	HTPs are legally sold and distributed. HTPs can be marketed like other tobacco products and are subject to the same advertising restrictions.	HTPs subject to same warning requirement as smokeless tobacco products.	HTPs subject to an ad valorem tax, unlike conventional cigarettes, which face a mixed system and a higher rate overall.	No federal laws regulate the use of HTPs; subnational legislation may do so.
United Kingdom of Great Britain and	HTPs are legally sold and distributed. HTPs subject to same advertising restrictions as other tobacco products.	Health warning labels are required.	Taxed by weight (243.95 pounds sterling per kg).	Existing smoke-free legislation does not apply to HTPs.

¹ The data presented in this Annex are based on a legal desk review and have not been reviewed and validated by the Parties.

Country	Advertisement/marketing	Packaging/health warning	Tax	Use in public places
Northern Ireland				
European Union** (EU)	HTP inserts are considered to be tobacco products, and they are legally sold and distributed subject to EU bans on advertising and sponsorship.	The provisions of the EU Tobacco Products Directive, including on health warning labelling, apply to HTPs.	No EU-wide tax.	No EU-wide legislation.
Austria	HTPs are legally sold and distributed. HTPs are subject to same advertising restrictions as other tobacco products.	Health warning labels required.	Taxed by weight (€144 per kg).	Existing smoke-free legislation applies to HTPs.
Czech Republic	HTPs are legally sold and distributed, classified as smokeless tobacco products. HTPs are subject to same advertising restrictions as other tobacco products.	Health warning labels required, same as for smokeless tobacco products.	Taxed by weight, with a rate equivalent to the rate on smoking tobacco.	Existing smoke-free legislation, applies to HTPs.
Germany	HTPs are legally sold and distributed. HTPs are subject to same advertising restrictions as other tobacco products.	In accordance to the EU Tobacco Products Directive, health warnings on packaging are required for HTPs.	HTPs are taxed like pipe tobacco (mixed system, lower than conventional cigarettes).	No federal laws regulate the use of HTPs.
Italy	HTPs are legally sold and distributed. HTPs are subject to same advertising restrictions as other tobacco products.	HTPs subject to same warning requirement as smokeless tobacco products.	HTPs taxed per stick, subject to 25% of tax applied to conventional cigarettes.	Existing smoke-free legislation does not apply to HTPs.
Lithuania	HTPs are legally sold and distributed. HTPs are subject to same advertising restrictions as other tobacco products	Health warning labels required.	HTPs are currently taxed by weight (€60.24 per kg).	Existing smoke-free legislation applies to HTP.
Netherlands	HTPs are legally sold and distributed. HTPs are subject to same advertising restrictions as other tobacco products.	In accordance with the EU Tobacco Products Directive, health warning labels are required for HTPs.	HTPs are currently taxed by weight (€99.25 per kg).	Existing smoke-free legislation applies to HTPs.
Poland	HTPs are legally sold and distributed. HTPs are subject to same advertising restrictions as other tobacco products.	In accordance to EU Tobacco Products Directive, health warning labels are required for HTPs.	HTPs taxed by weight (155.79 zlotys or €34.24 per kg) and 32.05% ad valorem tax.	Existing smoke-free legislation applies to HTPs.

Country	Advertisement/marketing	Packaging/health warning	Tax	Use in public places
Portugal	HTPs are legally sold and distributed. HTPs are subject to same advertising restrictions as other tobacco products.	HTPs subject to same warning requirement as smokeless tobacco products.	Taxed both by weight (€83.70/ kg) and ad valorem (15% of retail price).	Existing smoke-free legislation applies to HTPs.
Romania	HTPs are legally sold and distributed. HTPs are subject to same advertising restrictions as other tobacco products.	Health warning labels required.	Taxed by weight (411.15 Romanian leu per kg).	Existing smoke-free legislation does not apply to HTPs.

* Information not found.

** The countries listed below the European Union (EU) row are EU members. Some EU Member States apply additional requirements to HTPs; examples are listed in reference to the relevant Party.

ANNEX 2

**CHAPTER 24 IN THE 2017 AND 2022 EDITIONS OF
THE HARMONIZED SYSTEM (HS) NOMENCLATURE**

2017	2022
<p>Chapter 24</p> <p>Title: Tobacco and manufactured tobacco substitutes</p> <p>Note</p> <p>1. This Chapter does not cover medicinal cigarettes (Chapter 30).</p> <p>Subheading note</p> <p>1. For the purposes of subheading 2403.11, the expression “water pipe tobacco” means tobacco intended for smoking in a water pipe and which consists of a mixture of tobacco and glycerol, whether or not containing aromatic oils and extracts, molasses or sugar, and whether or not flavoured with fruit. However, tobacco-free products intended for smoking in a water pipe are excluded from this subheading.</p> <p>Code</p> <p>24.01 Unmanufactured tobacco; tobacco refuse. 2401.10 Tobacco, not stemmed/stripped 2401.20 Tobacco, partly or wholly stemmed/stripped 2401.30 Tobacco refuse</p> <p>24.02 Cigars, cheroots, cigarillos and cigarettes, of tobacco or of tobacco substitutes. 2402.10 Cigars, cheroots and cigarillos, containing tobacco 2402.20 Cigarettes containing tobacco 2402.90 Other</p> <p>24.03 Other manufactured tobacco and manufactured tobacco substitutes; “homogenised” or “reconstituted” tobacco; tobacco extracts and essences.</p> <p>Smoking tobacco, whether or not containing tobacco substitutes in any proportion:</p>	<p>Chapter 24</p> <p>Title [new]: Tobacco and manufactured tobacco substitutes; products, whether or not containing nicotine, intended for inhalation without combustion; other nicotine-containing products intended for the intake of nicotine into the human body [text replaced]</p> <p>Notes [new]</p> <p>“2. Any products classifiable in heading 24.04 and any other heading of the Chapter are to be classified in heading 24.04. 3. For the purposes of heading 24.04, the expression “inhalation without combustion” means inhalation through heated delivery or other means, without combustion.” [text added]</p> <p>Code [new]</p> <p>24.04 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.</p> <p>Products intended for inhalation without combustion:</p> <p>2404.11 Containing tobacco or reconstituted tobacco 2404.12 Other, containing nicotine 2404.19 Other</p> <p>Other</p> <p>2404.91 For oral application 2404.92 For transdermal application 2404.99 Other [text added]</p>

2017	2022
2403.11 Water pipe tobacco specified in Subheading Note 1 to this chapter 2403.19 Other Other 2403.91 “Homogenised” or “reconstituted” tobacco 2403.99 Other	
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