



WHO FRAMEWORK CONVENTION  
ON TOBACCO CONTROL

CONFERENCE OF THE PARTIES TO THE  
WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

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## **Progress report on technical matters related to Articles 9 and 10 of the WHO FCTC (Regulation of contents and disclosure of tobacco products, including waterpipe, smokeless tobacco and heated tobacco products)**

**Report by the World Health Organization**

### **Purpose of the document**

This report provides an update for the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC) on the progress made by the World Health Organization (WHO) in work related to tobacco product regulation, in pursuance of implementation of Articles 9 and 10 of the WHO FCTC. It responds to requests made by the Conference of the Parties (COP) at its Seventh and Eight Sessions related to decisions FCTC/COP7(9), FCTC/COP7(14), FCTC/COP8(21) and FCTC/COP8(22).

### **Action by the Conference of the Parties**

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

Contribute to the 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/9/9; FCTC/COP/9/10; previous COP decisions regarding electronic nicotine delivery systems/electronic non-nicotine delivery systems; smokeless tobacco; water-pipe tobacco; novel and emerging tobacco products; as well as on implementation of Articles 9 and 10 of the WHO FCTC.

## INTRODUCTION

1. The World Health Organization (WHO) provides support to its Member States, including Parties to the WHO Framework Convention on Tobacco Control (WHO FCTC), to reduce the overall burden of tobacco use. This is achieved within the context of the Thirteenth General Programme of Work 2019–2023,<sup>1</sup> the bedrock of which are the Triple Billion targets that call for: (a) one billion more people to benefit from universal health coverage; (b) one billion more people to be better protected from health emergencies; and (c) one billion more people to enjoy better health and well-being.

2. Globally, tobacco use accounts for more than 8 million deaths annually, with more than 7 million of those deaths attributable to direct tobacco use and approximately 1.2 million deaths the result of the exposure of non-smokers to second-hand tobacco smoke.<sup>2</sup> The WHO FCTC, an international legally binding treaty, provides a framework for its Parties to implement tobacco control measures. MPOWER,<sup>3</sup> a technical package introduced by WHO, includes a set of tobacco demand-reduction measures from the WHO FCTC that serve as an entry point for full implementation of the Convention. While the implementation of the WHO FCTC has been advancing and MPOWER has contributed to combating the tobacco epidemic, there is a need to further accelerate the implementation of the WHO FCTC to meet the global voluntary target to reduce by 30% the prevalence of adult current tobacco use by 2025, as well as to meet Target 3.a of the Sustainable Development Goals, which calls for strengthening implementation of the WHO FCTC, as appropriate.<sup>4</sup>

3. As part of that effort, WHO works across its three levels (country offices, regional offices and headquarters) and its various networks to identify scientific, policy and regulatory gaps and to build the evidence and capacity to support implementation of Articles 9 and 10 of the WHO FCTC and their Partial Guidelines.<sup>5</sup> Poor implementation of Articles 9 and 10 – which call for the regulation of contents and disclosures of tobacco products, including water-pipe, smokeless tobacco and heated tobacco products (HTPs) – represents a missed opportunity, as tobacco product regulation is a valuable tool that complements other tried and tested tobacco control interventions as part of a comprehensive tobacco control programme to drive down the demand for tobacco.

4. WHO work on tobacco product regulation is led by the WHO No Tobacco Unit (also known by its WHO Unit name, TFI), of the Health Promotion Department, with support from other technical teams at headquarters (Fiscal Policies for Health, and Public Health Law and Policies), WHO regional and country offices and WHO technical advisory groups on product regulation. These technical advisory groups include: the WHO Study Group on Tobacco Product Regulation (TobReg); the WHO Tobacco Laboratory Network (TobLabNet); WHO collaborating centres; and independent experts. The No Tobacco Unit has undertaken a range of activities, including addressing the relevant requests of the

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<sup>1</sup> Thirteenth Global Programme of Work (GPW) (<https://www.who.int/about/what-we-do/thirteenth-general-programme-of-work-2019---2023>).

<sup>2</sup> Tobacco Factsheet (2020). <https://www.who.int/news-room/fact-sheets/detail/tobacco> (accessed 21 June, 2021).

<sup>3</sup> World Health Organization (2008). WHO Report on the Global Tobacco Epidemic, 2008: the MPOWER package. World Health Organization (<https://apps.who.int/iris/handle/10665/43818>).

<sup>4</sup> United Nations General Assembly (2015). Resolution adopted by the General Assembly on 25 September 2015. Sustainable Development Goals and Targets ([https://www.un.org/ga/search/view\\_doc.asp?symbol=A/RES/70/1&Lang=E](https://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E)).

<sup>5</sup> Partial Guidelines on Articles 9 and 10. Geneva). Partial Guidelines on Implementation of the WHO Framework Convention on Tobacco Control. Geneva. World Health Organization (2012) ([https://www.who.int/fctc/guidelines/Guideliness\\_Articles\\_9\\_10\\_rev\\_240613.pdf](https://www.who.int/fctc/guidelines/Guideliness_Articles_9_10_rev_240613.pdf), accessed 21 June 2021).

Conference of the Parties (COP) to the WHO FCTC, as well as publication of WHO Public Health Goods (which are initiatives developed or undertaken by WHO that are of collective benefit to countries and partner organizations).<sup>1</sup>

5. This progress report provides an update on WHO work on product regulation, pursuant to Articles 9 and 10 of the WHO FCTC, as well as the activities related to decisions FCTC/COP7(9), FCTC/COP7(14), FCTC/COP8(21) and FCTC/COP8(22).

### **DEVELOPMENT OF METHODS BY REGIONAL AND INTERNATIONAL STANDARDS-DEVELOPMENT ORGANIZATIONS FOR THE TESTING AND MEASURING OF THE CONTENTS AND EMISSIONS OF ENDS AND ENNDS (paragraph 3 of decision FCTC/COP7(9))**

6. At its Seventh session (COP7), the COP, in Paragraph 3 of decision FCTC/COP7(9) on electronic nicotine delivery systems and electronic non-nicotine delivery systems, requested the Convention Secretariat “to invite Parties to monitor and report on scientific regulatory and market developments such as initiation, cessation, advertising and promotion, and 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, at either the eighth or the ninth session of the COP, as applicable”.

7. To address this request, WHO commissioned a paper, which was discussed at the 10th WHO TobLabNet working group meeting at the National Institute for Public Health and the Environment in Bilthoven, Netherlands, in February 2020. The paper identified existing standardized methods for the determination of contents and emissions of electronic nicotine delivery systems (ENDS) and/or electronic non-nicotine delivery systems (ENNDS). These include the method for the determination of nicotine, propylene glycol and glycerol in e-liquids using gas chromatography flame ionization detection (GC-FID) and the method for the determination of glycerine, propylene glycol, water and nicotine in e-cigarette aerosol, also using gas chromatography.

8. In addition to that commissioned paper, WHO drafted a questionnaire to gather evidence from WHO TobLabNet member laboratories on the methods being used in their laboratories to determine the contents and emissions of ENDS and ENNDS. This questionnaire was circulated to regulators via EZcollab (a restricted online platform for WHO TobLabNet members) for completion, and only one laboratory reported using additional methods.

9. Following an extensive review of literature and other published materials, the paper reported that the components of interest in the contents and emissions of e-liquids are: (1) nicotine; (2) glycerol; (3) propylene glycol; (4) tobacco-specific nitrosamines (TSNAs); (5) benzo[a]pyrene; (6) carbonyls; (7) phenolic compounds; (8) volatile organic compounds (VOCs); (9) metals; and (10) flavours. Collaborative efforts are ongoing in a few national, regional and international standardization bodies to propose, develop or validate methods for the determination of some of these components in e-liquids. Examples include Association Française de Normalisation (AFNOR); the British Standards Institute; the European Committee for Standardization (CEN); the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA), a body dominated by the tobacco industry; and the International

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<sup>1</sup> Thirteenth General Programme of Work 2019–2023. Geneva: World Health Organization; 2019 (<https://apps.who.int/iris/bitstream/handle/10665/324775/WHO-PRP-18.1-eng.pdf>, accessed 22 July 2021).

Organisation for Standardisation (ISO). Details of the methods available and under development can be obtained from the paper on the WHO website, upon publication.<sup>1</sup>

10. TobReg proposed a priority list of toxic contents and emissions of tobacco products, as reported in Table 4 of document FCTC/COP6/14<sup>2</sup> and recommended that this list be extended to other products. While the list may not be applicable to ENDS and ENNDS, toxic constituents or constituents with carcinogenic, mutagenic and reprotoxic properties, as well as those that enhance the addictiveness or attractiveness of ENDS and ENNDS, should be prioritized for method development. In this regard, different road maps can be followed for prioritizing methods for testing ENDS/ENNDS, based on attractiveness, addictiveness or potentially reducing the toxicity of the products based on the compounds of interest.

11. At COP7, a report submitted by WHO (FCTC/COP/7/11)<sup>3</sup> presented some broad regulatory objectives, including options which Parties that have not banned the importation, sale and distribution of ENDS/ENNDS may consider. These objectives include:

- (i) prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups;
- (ii) minimize as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions;
- (iii) prevent unproven health claims being made about ENDS/ENNDS; and
- (iv) protect tobacco control activities from all commercial and other vested interests related to ENDS/ENNDS, including interests of the tobacco industry.

12. These options remain valid and the first regulatory objective provides that Parties that have not banned the importation, sale and distribution of ENDS and ENNDS may consider “banning or restricting the use of flavours that appeal to minors” to prevent the initiation of ENDS/ENNDS by non-smokers and youth, with special attention to vulnerable groups; whereas the second regulatory objective provides that Parties that have not banned the importation, sale and distribution of ENDS/ENNDS may consider “(i) testing heated and inhaled flavourants used in the e-liquids for safety, and banning or restricting the amount of those found to be of serious toxicological concern such as diacetyl, acetyl propionyl, cinnamaldehydes or benzaldehyde; and (ii) requiring the use of ingredients that are not a risk to health and are, when allowed, of the highest purity” to minimize as far as possible potential health risks to ENDS/ENNDS users and protect non-users from exposure to their emissions.

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<sup>1</sup> Development of methods by regional and international standards-development organizations for the testing and measuring of contents and emissions of ENDS/ENNDS (2021) ([https://www.who.int/health-topics/tobacco#tab=tab\\_1](https://www.who.int/health-topics/tobacco#tab=tab_1)).

<sup>2</sup> WHO Work in progress in relation to Articles 9 and 10 of the WHO FCTC. Priority list of toxic contents and emissions of tobacco products. Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Sixth session, FCTC/COP6/14. 2014. [https://apps.who.int/gb/fctc/PDF/cop6/FCTC\\_COP6\\_14-en.pdf](https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_14-en.pdf) (accessed July 23, 2021).

<sup>3</sup> WHO. Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Seventh session, FCTC/COP/7/11 (2016) ([https://www.who.int/fctc/cop/cop7/FCTC\\_COP\\_7\\_11\\_EN.pdf?ua=1](https://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf?ua=1), accessed July 21, 2021).

13. Considering the evidence that flavourings and sugars play a key role in user selection of ENDS/ENNDS e-liquids, especially by young people, thus contributing to the appeal of these products, the testing for these components should be prioritized for method development.<sup>1</sup>

14. The published and validated WHO TobLabNet methods for the determination of nicotine, TSNAs, aldehydes, VOCs and benzo[a]pyrene in cigarette emissions can be adapted for the determination of these components in e-cigarette emissions. However, the trapping efficiency, measurement range, interferences, and product variability and stability will need to be further investigated specifically for e-liquids. Additionally, the puffing topography used for cigarette emission testing can be used for e-liquid testing; however, due to the product diversity of ENDS/ENNDS, the WHO TobLabNet standard operating procedure (SOP) for intense smoking of cigarettes (WHO TobLabNet SOP-01) will require some modifications. The main items to be adapted or added to this SOP (or included in a dedicated SOP for ENDS/ENNDS emission generation) are:

- connection of e-cigarettes to a smoking/vaping machines
- activation of e-cigarettes, when needed
- puffing topography, depending on product type (for example, cig-a-like, POD, MOD).

15. There are methods for testing the contents and emissions of ENDS/ENNDS, and these can be adapted and validated by WHO TobLabNet for regulatory purposes. For addictiveness, the method for the determination of nicotine in emissions should be prioritized for validation by WHO TobLabNet; and for attractiveness, methods for the determination of flavours and sugars in e-liquids should be prioritized, especially to protect young people. These methods should be developed and validated independently from product manufacturers. This is particularly important to ensure that marketed products are in compliance with regulatory requirements.

#### **TECHNICAL AND SCIENTIFIC ASSISTANCE ON ENDS/ENNDS (Paragraph 4 of FCTC/COP7(9))**

16. Also, at COP7, the COP requested the Convention Secretariat, in Paragraph 4 of FCTC/COP7(9), to invite “WHO to continue to provide technical and scientific assistance on ENDS/ENNDS upon request by the Parties or the Convention Secretariat”. WHO continues to provide technical and scientific assistance to its Member States not only on ENDS/ENNDS, but also on other products, including novel and emerging nicotine and tobacco products, and conventional tobacco products. WHO also published the *Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group* (Eighth report of TobReg), which is available on the website of WHO<sup>2</sup> and contains evidence-based recommendations, specifically on ENDS, ENNDS and heated tobacco products (HTPs). These recommendations were tabled at the 148th WHO Executive Board as part of a summary of the full report of TobReg in January 2021.<sup>3</sup>

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<sup>1</sup> Supra, note 7 (Development of methods by regional and international standards-development organizations for the testing and measuring of contents and emissions of ENDS/ENNDS (2021) ([https://www.who.int/health-topics/tobacco#tab=tab\\_1](https://www.who.int/health-topics/tobacco#tab=tab_1)).

<sup>2</sup> WHO study group on tobacco product regulation. Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group. Geneva: World Health Organization; 2021 (WHO Technical Report Series, No. 1029).

<sup>3</sup> EB148/47 (2021). Report on meetings of expert committees and study groups ([https://apps.who.int/gb/ebwha/pdf\\_files/EB148/B148\\_47-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_47-en.pdf)).

17. To build intelligence to continue providing timely technical and scientific assistance to countries on ENDS/ENNDS, WHO commissioned four systematic reviews in 2020 to update its 2016 systematic reviews that had informed the development of WHO's report to COP7 on ENDS/ENNDS. The four systematic reviews will cover the following:

- (i) Prevalence of electronic nicotine delivery systems and electronic non-nicotine delivery systems use among children and adolescents.
- (ii) Association between electronic nicotine and non-nicotine delivery systems with initiation of tobacco use in individuals aged < 20 years.
- (iii) Efficacy of ENDS and ENNDS as cessation aids.
- (iv) Health effects of ENDS and ENNDS.

18. In addressing the first topic, the use of ENDS and/or ENNDS by children and adolescents is of international concern, especially given the availability of flavoured products that appeal to this age group, which has led to an increase in the use of these products in some countries.<sup>1</sup> Therefore, evidence describing the prevalence of use of these products among children and adolescents is necessary to inform global efforts to address ENDS and/or ENNDS use in this age group. A systematic review of global data<sup>2</sup> looking at the use of ENDS and/or ENNDS by children and adolescents below 20 years of age found the following:

- “Ever use” of ENDS and/or ENNDS ranged from 2% to 52%, with a combined pooled estimate across all countries and territories of 17% in children and adolescents.
- Current use of ENDS and/or ENNDS ranged from 1% to 33%, with a combined pooled estimate across all countries and territories of 8% in children and adolescents.
- Use of ENDS and/or ENNDS tended to be higher for males than females in children and adolescents.
- Use of ENDS and/or ENNDS by children and adolescents tended to be higher in high-income countries than for higher-middle- and lower-middle-income countries.

19. For the second topic, there are some concerns about the association between the use of ENDS and ENNDS by children and adolescents below the age of 20 and the later use of tobacco. Some previous research suggests that there is an association, whereas other research does not. Based on country requests, there was a clear need to address questions relating to the use of different ENDS and/or ENNDS products with the risk of later tobacco use and the link with flavours. Previous reviews describing this association included research mainly from the United States of America; however, this

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<sup>1</sup> WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

<sup>2</sup> Yoong SL, Hall A, et al. Prevalence of electronic nicotine delivery systems and electronic non-nicotine delivery systems in children and adolescents: a systematic review and meta-analysis. *Lancet Public Health*. 2021 Jul 15:S2468-2667(21)00106-7. doi: 10.1016/S2468-2667(21)00106-7. Epub ahead of print. PMID: 34274048.

systematic review investigated this possible link and took into account studies from outside the United States of America. The review<sup>1</sup> found the following:

- (i) Non-smoking children and adolescents, below the age of 20 who use ENDS and/or ENNDS have over two times the increased risk of tobacco use at 6–24 months follow-up.
- (ii) There are few studies assessing whether ENNDS or flavoured ENDS/ENNDS use increases risk of cigarette smoking. This warrants further investigation.

20. These findings highlight the need for public health policies and measures to address the use of ENDS and/or ENNDS in children and adolescents. Countries should, therefore, enact policies and launch public health initiatives aimed at reducing ENDS and ENNDS use in children and adolescents, including by restricting the availability and accessibility of ENDS and/or ENNDS to this age group. Work is ongoing on the third and fourth topics, on which WHO will provide updates in future COP sessions.

### **MARKET DEVELOPMENTS AND USAGE OF NOVEL AND EMERGING TOBACCO PRODUCTS (Paragraph 5a of decision FCTC/COP7(14))**

21. In Paragraph 5a of decision FCTC/COP7(14), COP requested the Convention Secretariat to invite WHO to undertake, among other tasks, the following work: “to continue to monitor and examine market developments and usage of novel and emerging tobacco products, such as ‘heat-not-burn’ tobacco products. This might cover available scientific data on attractiveness, addictiveness and toxicity; health risk impact analysis of the products; their potential role in initiation and cessation of tobacco consumption; and to collect further scientific information, especially in relation to nicotine and other toxicants, including those arising from emissions; and to report progress to the future sessions of the COP”.

22. WHO continues to monitor and examine market developments and usage of these products as requested by the COP. At the Eighth Session of the COP (COP8), WHO reported on market developments in document FCTC/COP8/8,<sup>2</sup> which provided an update on technical matters related to Articles 9 and 10 (Regulation of contents and disclosure of tobacco products, including water-pipe, smokeless tobacco and heated tobacco products). This report also provided information on the global sales of these products, sales forecast until 2021 and referred readers to WHO’s *Heated Tobacco Products Market Monitoring Information Sheet*,<sup>3</sup> which outlined the various strategies employed by the industry to market HTPs.

23. The tobacco industry continues to reinvent itself, adding newer tactics to expand its market, not just in conventional products, such as cigarettes, but also in novel and emerging tobacco products such as HTPs, as well as on ENDS and ENNDS. WHO examined these tactics in the recently published

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<sup>1</sup> Yoong SL, Hall A, Leonard A, McCrabb S, Wiggers J, Tursdan d’Espaignet E, et al. Association between electronic nicotine delivery systems and electronic non-nicotine delivery systems with initiation of tobacco use in individuals aged <20 years – a systematic review and meta-analysis. PLOS. 2021 [In press].

<sup>2</sup> FCTC/COP8/8 (2018). Progress report on technical matters related to Articles 9 and 10 (Regulation of contents and disclosure of tobacco products, including waterpipe, smokeless tobacco and heated tobacco products). [https://www.who.int/fctc/cop/sessions/cop8/FCTC\\_COP\\_8\\_8-EN.pdf?ua=1](https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP_8_8-EN.pdf?ua=1) (accessed on 21 June 2021).

<sup>3</sup> Heated tobacco products: market monitoring information sheet (2018). <https://www.who.int/publications/i/item/WHO-NMH-PND-18.7> (accessed 22 July 2021).

Eighth report of TobReg, which described a wide range of marketing strategies used to promote HTPs, often targeting adolescents and young adults. Some of these strategies are outlined below:

- Advertisements, including online, television, radio, newspapers and magazines, billboards and posters, dedicated retail stores for HTPs, and bars and pubs.
- Emphasis on similarities to cigarettes.
- Acknowledgement of the harms of cigarettes, while presenting HTPs as “cleaner alternatives”.
- Use of brand “ambassadors” (in person and on social media) and demonstrations.
- Product design, including sleek, high-tech appearance, rapid charging, less odour, customization with colours and limited-edition designs.
- Sponsorship, including sporting events, art shows, concerts, and food and wine festivals.
- Pricing strategies, such as “bait-and-hook” pricing – discounted prices for devices and recurrent cost for specially designed refills or inserts – and free samples.
- Customer service, such as call centre support, dedicated brand retail stores and websites, and software applications to help customers locate nearby stores and to troubleshoot their device.
- Marketing to young people, including placement of HTPs near youth-oriented merchandise at points of sale and sponsorship of youth-oriented events (for example, Tel Aviv’s TLV Student Day).
- Funding front groups (for example, Foundation for a Smoke-Free World).
- Lobbying.
- Corporate social responsibility to boost the industry’s image.

24. The market for these products continues to grow. Their global sales generated US\$ 6.3 billion in 2018 but is expected to reach a market value of US\$ 22 billion by 2024. This projected rapid growth in sales, coupled with the increasing use of these products in some jurisdictions, is a concern for regulators. In 2018, Japan had the largest share of HTP revenue at 85% of the global HTP market, whereas the Republic of Korea had the fastest growth rate in HTP revenue. There is thus a need to continually monitor the marketing and use of these products to ensure they do not derail tobacco control. TobReg’s report, which is summarized in document FCTC/COP9/9,<sup>1</sup> contains detailed evidence-based recommendations on HTPs, following an extensive review of literature by independent experts, members of the Study Group and WHO.

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<sup>1</sup> FCTC/COP9/9 – Comprehensive report on research and evidence on novel and emerging tobacco products, in particular heated tobacco products. (In response to Paragraphs 2(a)–(d) of decision FCTC/COP8(22)).

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**FINALIZATION OF THE STANDARD OPERATING PROCEDURES FOR SMOKELESS AND WATER-PIPE TOBACCO AND BUILDING CAPACITY FOR PRODUCT TESTING (Paragraph 5b of decision FCTC/COP7(14) and decision FCTC/COP/8(21))**

25. The WHO Tobacco Laboratory Network (TobLabNet) makes methods available to countries in furtherance of the implementation of Articles 9 and 10 of the WHO FCTC. TobLabNet develops and validates methods to test the contents and emissions of nicotine and tobacco products and supports WHO in building testing capacity in WHO Member States, including conducting training workshops in countries on tobacco product testing. TobLabNet also works in unison with TobReg, under the leadership of WHO, to advance product regulation towards comprehensive implementation of the WHO FCTC.

26. At its Third session in 2008, the COP, in decision FCTC/COP3(9)<sup>1</sup> on the Elaboration of guidelines for implementation of Articles 9 and 10 (Regulation of the contents of tobacco products and Regulation of tobacco product disclosures), requested the Convention Secretariat to invite WHO to “validate, within five years, the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities” in document FCTC/COP/3/6, using the two smoking regimens set out in paragraph 18 of that report, and inform the COP through the Convention Secretariat on a regular basis of the progress made.

27. Pursuant to this, WHO validated 10 methods, which are available on the WHO TFI website and reported in the *Information sheet on WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products*.<sup>2</sup> This information sheet highlights the importance of developing methods that are independent of the tobacco industry for tobacco product regulation, provides guidance on reducing tobacco product appeal and use, and describes the role tobacco product regulation plays in the wider context of tobacco control.

28. In furtherance of this work, the COP requested the Convention Secretariat to invite WHO to “assess, within two years, whether the standard operating procedures for nicotine, tobacco-specific N-nitrosamines (TSNAs) and B[a]P in cigarette contents and emissions are applicable or adaptable, as appropriate, to tobacco products other than cigarettes, including smokeless tobacco and water-pipe smoke;” in decision FCTC/COP6(12) 2(b)(ii).<sup>3</sup>

29. Following this assessment and report by WHO on this work, which can be found in document FCTC/COP7/(9),<sup>4</sup> the COP requested the Convention Secretariat to invite WHO to “(b) to collaborate with the Knowledge Hub on smokeless tobacco by assisting tobacco testing laboratories; (ii) to finalize

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<sup>1</sup> FCTC/COP3(9) – [https://apps.who.int/gb/fctc/PDF/cop3/FCTC\\_COP3\\_DIV3-en.pdf](https://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_DIV3-en.pdf).

<sup>2</sup> 20 Information sheet on WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products. <https://www.who.int/publications/i/item/WHO-HEP-HPR-2020.1>.

<sup>3</sup> FCTC/COP6(12) 2(b)(ii); Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC(2014) ([https://apps.who.int/gb/fctc/PDF/cop6/FCTC\\_COP6\(12\)-en.pdf](https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6(12)-en.pdf)).

<sup>4</sup> FCTC/COP7/(9) – Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). Decision by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Seventh session, (2016). [https://www.who.int/fctc/cop/cop7/FCTC\\_COP7\\_9\\_EN.pdf?ua=1](https://www.who.int/fctc/cop/cop7/FCTC_COP7_9_EN.pdf?ua=1) (accessed 21 June 2021).

the standard operating procedures for measuring nicotine, tobacco specific nitrosamines (TSNAs) as requested by decision FCTC/COP6(12) 2(b)(ii)", in decision FCTC/COP7(14).<sup>1</sup>

30. WHO continues to work through TobLabNet to finalize the methods for the determination of nicotine and TSNAs in smokeless tobacco and water-pipe tobacco. The method for testing nicotine in smokeless tobacco was optimized to include the determination of pH and moisture content of smokeless tobacco, which are key parameters influencing nicotine delivery capacities of the products. This method, which is being finalized, will be published before the Ninth session of the COP (COP9) and will be available for use by countries for the determination of nicotine, pH and moisture in smokeless tobacco for regulatory purposes. Methods for the determination of TSNAs in smokeless tobacco and in water-pipe tobacco, as well as nicotine in water-pipe tobacco, are under development.

31. In addition to the methods for smokeless tobacco and water-pipe tobacco, decision FCTC/COP8(21)<sup>2</sup> on the Implementation of Articles 9 and 10 of the WHO FCTC requested the Convention Secretariat to invite WHO to "continue to provide support in synergy with other WHO FCTC work in facilitating take-up of the WHO Tobacco Laboratory Network resources and capacity-building activities, upon the request of Parties".

32. Following several requests by Parties to make methods available for the determination of key contents and emissions in novel and emerging tobacco products and nicotine products, WHO published WHO *TobLabNet Official Method SOP11 – Standard Operating Procedure for Measuring Nicotine, Glycerol and Propylene Glycol in e-Liquids* in April 2021.<sup>3</sup> This method was prepared by WHO and TobLabNet in cooperation with member laboratories of the European Joint Action on Tobacco Control (JATC).

33. WHO TobLabNet SOP11 is a WHO Public Health Good, which will support countries to strengthen nicotine and tobacco product regulation and thus implementation of Articles 9 and 10 of the WHO FCTC. This is in response to Member States' request to WHO to provide technical leadership in tobacco product testing. The SOP operationalizes the recommendation of TobReg.

34. To further facilitate take-up of the TobLabNet resources and build capacity for testing as requested in decision FCTC/COP8(21), WHO also launched two courses: one on the basics of Tobacco Product Regulation<sup>4</sup> and the other on Building Laboratory Testing Capacity.<sup>5</sup> These courses are now available in English and French, and more languages are to follow to encourage wider uptake by Parties.

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<sup>1</sup> FCTC/COP7(14). – Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC (Regulation of the contents of tobacco products and Regulation of tobacco product disclosures) (2016) [https://www.who.int/fctc/cop/cop7/FCTC\\_COP7\(14\)\\_EN.pdf?ua=1](https://www.who.int/fctc/cop/cop7/FCTC_COP7(14)_EN.pdf?ua=1) (accessed on 21 June 2021).

<sup>2</sup> FCTC/COP8(21) – Implementation of Articles 9 and 10 of the WHO FCTC (Regulation of contents and disclosure of tobacco products, including water pipe, smokeless tobacco and heated tobacco products) (2018) [https://www.who.int/fctc/cop/sessions/cop8/FCTC\\_\\_COP8\(21\).pdf?ua=1](https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8(21).pdf?ua=1) (accessed 21 June 2021).

<sup>3</sup> WHO TobLabNet SOP11 (2021). Standard operating procedure for determination of nicotine, glycerol and propylene glycol in e-liquids. <https://www.who.int/publications/i/item/9789240022744> (accessed 21 June 2021).

<sup>4</sup> Tobacco product regulation courses. Geneva: World Health Organization (2020). Tobacco product regulation: Basic handbook. <https://openwho.org/courses/TPRS-tobacco-product-regulation-handbook>.

<sup>5</sup> Tobacco product regulation courses. Geneva: World Health Organization (2020). Tobacco product regulation: Building laboratory testing capacity. <https://openwho.org/courses/TPRS-building-laboratory-testing-capacity>.

35. SOPs are also being developed for the contents and emissions of HTPs, on which WHO will report at future sessions of the COPs. WHO's *Information sheet on measuring priority emissions in heated tobacco products (HTPs) – importance for regulators and significance for public health*<sup>1</sup> provides further information on the methods proposed for development for HTP emissions.

### **OVERVIEW OF THE LATEST SCIENTIFIC EVIDENCE ON THE IMPACT OF CIGARETTE VENTILATION ON CIGARETTE USE (Paragraph 8 of decision FCTC/COP8(21))**

36. COP8 requested the “Convention Secretariat in cooperation with WHO to hold a face-to-face meeting on cigarette ventilation, with a wide range of relevant experts, Party representatives and observers accredited to the COP independent from the tobacco industry, to gain an overview of the latest scientific evidence on the impact of cigarette ventilation on cigarette use and report back their findings to the Ninth session of the COP”.

37. WHO addressed the technical component of the request and commissioned experts to develop background papers for the face-to-face meeting, in line with the terms of reference defined for these papers, which were designed to answer the question posed by the COP. The meeting report, which informed the development of the report to COP9 on the scientific evidence on the impact of cigarette ventilation on cigarette use, is available for Parties' information.<sup>2</sup> Further details of how this request was addressed by experts at the face-to-face meeting and the key findings, following synthesis of evidence on cigarette ventilation, is provided in document FCTC/COP9/7.

### **COMPREHENSIVE REPORT ON RESEARCH AND EVIDENCE ON NOVEL AND EMERGING TOBACCO PRODUCTS, IN PARTICULAR HEATED TOBACCO PRODUCTS, REGARDING THEIR HEALTH IMPACTS (Paragraph 2 of decision FCTC/COP8(22))**

38. COP8, in paragraph 2 of decision FCTC/COP8(22)<sup>3</sup> on novel and emerging tobacco products, requested the Convention Secretariat “to invite WHO and, as appropriate, the WHO Tobacco Laboratory Network (TobLabNet):

(a) to prepare a comprehensive report, with scientists and experts, independent from the tobacco industry, and competent national authorities, to be submitted to the Ninth Session of the COP on research and evidence on novel and emerging tobacco products, in particular heated tobacco products, regarding their health impacts including on non-users, their addictive potential, perception and use, attractiveness, potential role in initiating and quitting smoking, marketing including promotional strategies and impacts, claims of reduced harm, variability of products, regulatory experience and monitoring of Parties, impact on tobacco control efforts and research

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<sup>1</sup> WHO Information Sheet (2021). Information sheet on measuring priority emissions in heated tobacco products (HTPs) – importance for regulators and significance for public health. (To be published).

<sup>2</sup> The summaries of the background papers and the final meeting report are published in the WHO FCTC implementation database (<https://untobaccocontrol.org/impldb/article-9/>, under “Resources”: “Report of the meeting to review the latest available scientific evidence on the impact of cigarette ventilation on cigarette use”).

<sup>3</sup> FCTC/COP8(22) (2018). Novel and emerging tobacco products [https://www.who.int/fctc/cop/sessions/cop8/FCTC\\_\\_COP8\(22\).pdf?ua=1](https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8(22).pdf?ua=1) (accessed 21 June 2021).

gaps, and to subsequently propose potential policy options to achieve the objectives and measures outlined in paragraph 5 of the present decision;

(b) to examine the chemical and physical processes these products are undergoing during use, including the characterization of emissions;

(c) to assess whether the available standard operating procedures for contents and emissions are applicable or adaptable to heated tobacco products;

(d) to advise, as appropriate, on suitable methods to measure the contents and emissions of these products”.

39. The request is addressed in the Eighth Report of TobReg, the policy brief on research and evidence on novel and emerging tobacco products,<sup>1</sup> in particular HTPs, in the updated information sheet on HTPs<sup>2</sup> and in document FCTC/COP9/8 – Comprehensive report on research and evidence on novel and emerging tobacco products, in particular heated tobacco products.

40. WHO continues to monitor evidence and conduct research on novel and emerging tobacco products, including through TobReg and through TobLabNet and the Global Tobacco Regulators’ Forum, and will provide further updates, including on marketing, regulation, science, promotion and use of these products at future sessions of the COP.

## **POLICY OPTIONS AND WHO FCTC IMPLEMENTATION APPROACHES**

41. The following (i.e. paragraphs 42–45) is a non-exhaustive list of regulatory options that Parties might consider in accordance with their national laws, to achieve a high level of protection for human health.

42. **ENDS/ENNDS:** In light of WHO’s recent work on ENDS and ENNDS, as articulated in paragraphs 6–16 and 17–21 of the present document, the options below might be considered by Parties for ENDS and ENNDS:

(a) Where the importation, sale and distribution of ENDS are not banned, governments should:

(i) ban these products to children and adolescents to prevent uptake and/or reduce use of ENDS and ENNDS in this age group;

(ii) prevent the availability and marketing of the products to children and adolescents to ensure that tobacco control efforts are not undermined; and

(iii) monitor the use of both ENDS and/or ENNDS among children and adolescents and subsequent uptake of smoking by conducting the relevant national surveys, which will

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<sup>1</sup> Policy brief on heated tobacco products (2021) ([https://www.who.int/health-topics/tobacco#tab=tab\\_1](https://www.who.int/health-topics/tobacco#tab=tab_1)). – To be published.

<sup>2</sup> Updated Information Sheet on HTPs (2021) ([https://www.who.int/health-topics/tobacco#tab=tab\\_1](https://www.who.int/health-topics/tobacco#tab=tab_1))– To be published.

ensure accurate data collection on the prevalence of ENDS and ENNDS use to inform regulatory decisions to protect children and adolescents.

(b) WHO should work through TobLabNet and its networks to further develop methods for testing the identified toxicants in e-liquids and prioritize the methods for addictiveness and attractiveness. For addictiveness, methods for nicotine content and emissions should be prioritized for validation, and for attractiveness, methods for the determination of flavours and sugars in e-liquids should be prioritized, especially to protect young people. These methods should be developed and validated independently from product manufacturers.

43. **Marketing of novel and emerging tobacco products:** Based on the evidence discussed in paragraphs 22–25 of the present document and TobReg’s recommendation on HTPs, where countries have not banned the importation, sale and distribution of novel and emerging tobacco products, governments should consider banning all commercial marketing of novel and emerging tobacco products, including in social media and through organizations funded by and/or associated with the tobacco industry.

44. **Methods in furtherance of Articles 9 and 10 of the WHO FCTC:** In light of its ongoing work articulated in paragraphs 26–36 of the present document, WHO, through WHO TobLabNet and its other networks, should continue building capacity for product testing, including but not limited to the following:

(a) finalize the SOPs for measuring nicotine and TSNAs, as requested by decisions FCTC/COP6(12)2(b)(ii) and FCTC/COP7(14);

(b) promptly make methods available to Parties for HTPs, based on the preliminary work done by TobLabNet and in line with the recommendations of the *Information sheet on measuring priority emissions in heated tobacco products (HTPs) – importance for regulators and significance for public health*;

(c) facilitate the use of these methods in countries for regulatory purposes; and

(d) build and strengthen capacity for the testing of the contents and emissions of nicotine products and tobacco products to strengthen Parties’ implementation of Articles 9 and 10 of the WHO FCTC.

45. **Research and evidence of novel and emerging tobacco products:** Recognizing that HTPs are tobacco products, Parties that have not banned their importation, sale and distribution should fully apply the provisions of the WHO FCTC, as well as follow the implementation approaches enumerated in documents FCTC/COP9/8 and FCTC/COP9/10.

## **ACTION BY THE CONFERENCE OF THE PARTIES**

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

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