



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

In accordance with decision FCTC/COP9(2), the present report is an updated version of document FCTC/COP/9/8 submitted to the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC) on the progress made by World Health Organization (WHO) in work related to tobacco product regulation, in pursuance of implementation of Articles 9 and 10 of the WHO FCTC.

Action by the Conference of the Parties

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

Contribution to the Sustainable Development Goals (SDGs): All SDGs; in particular, SDG 3 and Target 3.a.

Link to 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/10/10; FCTC/COP/10/9; 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; *Disposable electronic cigarettes (D-ENDS) in selected countries and their characteristics. A short overview of the available evidence* (Supplementary information); and *Flavours in Nicotine Pouches* (Supplementary information).

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 2019–2023,¹ 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.² The WHO FCTC, an international legally binding treaty, provides a framework for its Parties to implement tobacco control measures. MPOWER,³ 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.⁴

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.⁵ 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's 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)⁶; the WHO Tobacco

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

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

³ 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>).

⁴ United Nations General Assembly (2015). Resolution adopted by the General Assembly on 25 September 2015. Sustainable Development Goals and Targets (https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_RES_70_1_E.pdf).

⁵ 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://fctc.who.int/publications/m/item/regulation-of-the-contents-of-tobacco-products-and-regulation-of-tobacco-product-disclosures>, accessed 21 June 2021).

⁶ WHO Study Group on Tobacco Product Regulation (<https://www.who.int/groups/who-study-group-on-tobacco-product-regulation>).

Laboratory Network (TobLabNet)¹; WHO collaborating centres²; and independent experts. The No Tobacco Unit has undertaken a range of activities, including addressing the relevant requests of the Conference of the Parties (COP) to the WHO FCTC, as well as publication of WHO Technical Products (formerly referred to as WHO Public Health Goods, which are initiatives developed or undertaken by WHO that are of collective benefit to countries and partner organizations).

5. This progress report provides an update on WHO's 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).³

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 paper⁴, 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 the 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)**

¹ WHO Tobacco Laboratory Network (TobLabNet) (<https://www.who.int/groups/who-tobacco-laboratory-network/about>).

² WHO Collaborating Centres (<https://www.who.int/about/collaboration/collaborating-centres>).

³ 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).

⁴ Supplementary documentation – Development of methods by regional and international standards-development organizations for the testing and measuring of contents and emissions of ENDS/ENNDS.

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

10. TobReg proposed a priority list of toxic contents and emissions of tobacco products, as reported in Table 4 of document FCTC/COP6/14² 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)³ 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,

¹ Development of methods by regional and international standards organizations for testing and measuring the contents and emissions of electronic nicotine and non-nicotine delivery systems (2023) (<https://www.who.int/publications/i/item/9789240086968>).

² 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, accessed 23 July 2021).

³ 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://fctc.who.int/publications/m/item/fctc-cop-7-11-electronic-nicotine-delivery-systems-and-electronic-non-nicotine-delivery-systems-\(ends-ennds\)](https://fctc.who.int/publications/m/item/fctc-cop-7-11-electronic-nicotine-delivery-systems-and-electronic-non-nicotine-delivery-systems-(ends-ennds))).

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.

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.¹

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 (see item 8, Annex 2) 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

¹ Development of methods by regional and international standards organizations for testing and measuring the contents and emissions of electronic nicotine and non-nicotine delivery systems (2023) (<https://www.who.int/publications/i/item/9789240086968>).

full report of TobReg in January 2021.¹ Two of the key recommendations to policy-makers and all other interested parties are: (1) “to prohibit the sale of ENDS and ENNDS in which the user can control device features and liquid ingredients (that is, open systems) and (2) to prohibit the addition of pharmacologically active substances such as cannabis and tetrahydrocannabinol (in jurisdictions where they are legal), other than nicotine in ENDS, to ENDS and ENNDS”.

17. To build intelligence to continue providing timely technical and scientific assistance to countries on ENDS/ENNDS, WHO commissioned four systematic reviews to update its 2016 systematic reviews that had informed the development of WHO’s report to COP7 on ENDS/ENNDS. The four systematic reviews 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.² 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 data³ 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.

¹ EB148/47 (2021). Report on meetings of expert committees and study groups, para. 29. (https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_47-en.pdf).

² 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.

³ 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.

19. It is to be noted that since this publication, the use of ENDS among young people has been reported to be of great public health concern by several countries.^{1,2,3,4} A number of surveys, such as the Global Youth Tobacco Survey, the European School Survey Project on Alcohol and Other Drugs are closely monitoring the use of these products by adolescents. A recent report by the University of Waterloo summarized findings among youth respondents aged 16 – 19 in three countries, including trends between 2017 and 2022.⁵

20. For the second topic, there are serious 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, the WHO commissioned systematic review investigated this possible link and took into account studies from outside the United States of America. The review 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.

21. Since publication of this systematic review, a number of studies as well as systematic reviews have been published which show an association between the use of electronic cigarettes among non-smoking young people and progression to the use of tobacco. This updated research has similarly reported more than three times increased risk, as compared with non-users of electronic cigarettes among youth and young people.^{6,7,8}

22. 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

¹ Jongenelis, M.I. E-cigarette product preferences of Australian adolescent and adult users: a 2022 study. *BMC Public Health* 23, 220 (2023) (<https://doi.org/10.1186/s12889-023-15142-8>).

² Karlijn A.H.J. Thoonen, Michelle I. Jongenelis, Perceptions of e-cigarettes among Australia, adolescents, young adults, and adults, *Addictive Behaviors*, Volume 144, 2023 (<https://doi.org/10.1016/j.addbeh.2023.107741>).

³ Cooper, M et al., “E-Cigarette Use Among Middle and High School Students—United States, 2022,” *MMWR*, 71(40): 1283-1285, October 7, 2022 (<https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf>).

⁴ Wiley ER, Seabrook JA. Nicotine and Nicotine-Free Vaping Behavior among a Sample of Canadian High School Students: A Cross-Sectional Study. *Children*. 2023; 10(2):368 (<https://doi.org/10.3390/children10020368>).

⁵ Hammond D, Reid JL, Burkhalter R, Hong D. Trends in smoking and vaping among young people: Findings from the ITC youth survey. April 2023; University of Waterloo (<https://profglantz.files.wordpress.com/2023/06/2023-itc-canengus-ecig-youth-report-hammond-et-al.pdf>).

⁶ Baenziger O, Ford L, Yazidjoglou A, et al. E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis. *BMJ Open* 2021; 11: e045603. (Meta-analyses of 25 longitudinal studies) (<https://pubmed.ncbi.nlm.nih.gov/33785493/>).

⁷ Parnham JC, Vrinten C, Radó MK, Bottle A, Filippidis FT, Lavery AA. Multistate transition modelling of e-cigarette use and cigarette smoking among youth in the UK. *Tob Control*. 2023 Mar 10;tc-2022-057777. doi: 10.1136/2022-057777. Epub ahead of print. PMID: 36898842 (<https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2023/03/09/tc-2022-057777.full.pdf>).

⁸ O’Brien, D., Long, J., Quigley, J. et al. Association between electronic cigarette use and tobacco cigarette smoking initiation in adolescents: a systematic review and meta-analysis. *BMC Public Health* 21, 954 (2021).

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.

23. On the third systematic review (Efficacy of ENDS and ENNDS as cessation aids) and fourth (Health effects of ENDS and ENNDS), work is still ongoing and WHO will provide updates on these topics in future sessions of the COP. However, in recent times, there have been a few published systematic reviews and studies on these topics. Therefore, a non-exhaustive summary is provided in paragraphs 24–28 based on these reviews to highlight the key points and the current state of knowledge, in relation to these topics.

24. *Efficacy of ENDS and ENNDS as cessation aids*: Overall, the certainty of the evidence across the studies and reviews is often rated as “low” or “insufficient”.^{1,2,3} Firstly, the published findings have a wide range of study designs⁴ and reliable evidence is limited. Secondly, given the diverse nature of ENDS, more evidence is needed to examine various device types and varying nicotine delivery profiles.^{5,6,7} Thirdly, the studies often involve insufficient length of follow-up in order to properly assess subsequent cigarette use, potentially as a dual user, or the duration for which a person continues to use ENDS.⁸ Lastly, and perhaps most significantly, there is a critical need across the studies to uniformly define ‘cessation’, and whether a person who has switched from conventional cigarettes to ongoing use of ENDS can be considered to have successfully “quit”.^{9,10}

25. It has to be highlighted that across the published evidence, there is incongruity in the findings, and at this time, there are still a number of unknown factors, which means that ENDS and ENNDS cannot be recommended as cessation aids at the population level.

¹ Yazidjoglou A, Ford L, Baenziger O, Brown S, Martin M, Zulfiqar T, Joshy G, Beckwith K, Banks E. Efficacy of e-cigarettes as aids to cessation of combustible tobacco smoking: updated evidence review. Final report prepared for the Australian Government Department of Health: Online version, September 2021. Available at: <https://openresearch-repository.anu.edu.au/>.

² Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.

³ Pound C, Zhang J, Kodua A, Sampson M. Smoking cessation in individuals who use vaping as compared with traditional nicotine replacement therapies: a systematic review and meta-analysis. *British Medical Journal BMJ Open*. 2021 Feb 22;11(2):e044222. doi: 10.1136/bmjopen-2020-044222.

⁴ Liber A, Knoll M, Cadham C, Issabakhsh M, Oh H, Cook S, Warner K, Mistry R, Levy D. The role of flavored electronic nicotine delivery systems in smoking cessation: A systematic review. *Drug Alcohol Depend Rep*. 2023 Mar 16;7:100143. doi: 10.1016/j.dadr.2023.100143.

⁵ Tatten-Birch H, Kock L, Brown J, Beard E, Bauld L, West R, Shahab L. E-cigarettes to Augment Stop Smoking In-person Support and Treatment With Varenicline (E-ASSIST): A Pragmatic Randomized Controlled Trial. *Nicotine & Tobacco Research*, Volume 25, Issue 3, March 2023 (<https://doi.org/10.1093/ntr/ntac149>).

⁶ Irish Health Research Board 2020. Electronic cigarettes and smoking cessation: An evidence review (https://www.hrb.ie/fileadmin/2._Plugin_related_files/Publications/2020_publication-related_files/2020_HIE/Evidence_Centre/Electronic_cigarettes_and_smoking_cessation_systematic_evidence_review.pdf).

⁷ Quigley J, Walsh C, Lee C, Long J, Kennelly H, McCarthy A, Kavanagh P. Efficacy and safety of electronic cigarettes as a smoking cessation intervention: A systematic review and network meta-analysis. *Tob Prev Cessation*. 2021; doi: 10.18332/tpc/143077.

⁸ *Supra*, notes 6 and 7.

⁹ *Supra*, notes 1 and 2.

¹⁰ 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.

26. At this time, given the low level of certainty of the evidence, the uncertainty of the long-term health effects of ENDS, the likelihood of becoming a dual user, as well as some evidence of ENDS hindering cessation in some individuals by prolonging or increasing addiction to nicotine, people who smoke should be supported with approved smoking cessation aids. WHO recommends nicotine replacement therapies (gums and patches) and pharmacotherapies, with established safety, quality and efficacy, and which must be approved by each country's regulatory authority before they can be made available in that country.^{1,2}

27. *Health effects of ENDS and ENNDS:* While the evidence of some health effects of ENDS has not yet been established, there is *conclusive* evidence that e-cigarettes cause poisoning, injuries and burns and immediate toxicity through inhalation, including seizures.³ Further, there is conclusive evidence that ENDS use leads to addiction, as well as increases airborne particulate matter in indoor environments, potentially harming bystanders. Additionally, there is *strong* evidence that e-cigarettes increase conventional cigarette uptake, particularly among youth, by approximately three-fold. There is *moderate* evidence that among smokers, the use of e-cigarettes increases heart rate, systolic and diastolic blood pressure and arterial stiffness acutely after use.⁴ There is sufficient evidence that ENDS are harmful, particularly to young people.

28. The long-term health effects of these products are unknown and the health impacts of dual use with cigarette smoking are not yet fully understood, but some studies suggest that dual use is at least as, or probably even more, harmful than exclusive smoking of conventional cigarettes.^{5,6} Considerations that can have additional implications and potentially further alter the health impacts on users of ENDS and ENNDS are accounting for the wide range of ENDS design, possible custom alterations of ENDS devices, variance in nicotine concentrations, presence of nicotine salt products and flavours.⁷

Country and Global Consultation(s) on novel and emerging nicotine and tobacco products

29. With the emergence of ENDS and ENNDS as a major public health challenge for regulators in many countries, WHO has received numerous requests for technical assistance and has held a number of country, regional and Global Consultations between 2021–2023. These Consultations highlight the need to protect young people, build the capacities of countries to effectively regulate (including ban, where deemed appropriate) these products, translate evidence into policy, as well as simplify current knowledge and evidence. Furthermore, it was apparent that the regulatory approach adopted by a

¹ 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.

² Kaplan B, Galiatsatos P, Breland A, Eissenberg T, Cohen J. Effectiveness of ENDS, NRT and medication for smoking cessation among cigarette-only users: a longitudinal analysis of PATH Study wave 3 (2015-2016) and 4 (2016-2017), adult data. *Tob Control*. 2023 May;32(3):302-307. doi: 10.1136/tobaccocontrol-2020-056448.

³ Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.

⁴ Ibid.

⁵ Pisinger C, Rasmussen SKB. The Health Effects of Real-World Dual Use of Electronic and Conventional Cigarettes versus the Health Effects of Exclusive Smoking of Conventional Cigarettes: A Systematic Review. *Int J Environ Res Public Health*. 2022 Oct 21;19(20):13687. doi: 10.3390/ijerph192013687. PMID: 36294263; PMCID: PMC9603628.

⁶ WHO Report on the Global Tobacco Epidemic, 2021, (<https://www.who.int/publications/i/item/9789240032095>).

⁷ Yazidjoglou A, Ford L, Baenziger O, Brown S, Martin M, Zulfiqar T, Joshy G, Beckwith K, Banks E. Efficacy of e-cigarettes as aids to cessation of combustible tobacco smoking: updated evidence review. Final report prepared for the Australian Government Department of Health: online version, September 2021. Available at: <https://openresearch-repository.anu.edu.au/>.

particular country based on its regulatory environment and its population may not necessarily be suitable in other regulatory contexts. Countries should therefore make regulatory decisions factoring in their unique circumstances.

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

30. 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*”.

31. 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/COP8/8,¹ 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,² which outlined the various strategies employed by the industry to market HTPs.

32. The tobacco industry continues to add newer tactics to expand its market, not just for conventional products, such as cigarettes, but also in new and emerging tobacco products such as HTPs, as well as on ENDS and ENNDS. WHO examined these tactics in the 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.

¹ 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://fctc.who.int/publications/m/item/fctc-cop-8-8-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://fctc.who.int/publications/m/item/fctc-cop-8-8-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)) (accessed 21 June 2021).

² Heated tobacco products: market monitoring information sheet (2018) (<https://www.who.int/publications/i/item/WHO-NMH-PND-18.7>, accessed 22 July 2021).

- 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.

33. The market for HTPs continues to grow. Their global sales generated US\$ 32.4 billion in 2022 but are expected to reach a market value of US\$ 77.2 billion by 2027. This projected rapid growth in sales, coupled with the increasing use of these products in some jurisdictions, is a concern for regulators. Phillip Morris has the predominantly largest company share of HTPs, at 67.4%, followed with British American Tobacco at 16.5%, and Japan Tobacco International at 5.1% (Euromonitor). 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.

34. 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 Eighth report (see item 8, Annex 2), which is summarized in document FCTC/COP10/10,¹ contains detailed evidence-based recommendations on HTPs, following an extensive review of literature by independent experts, members of the Study Group and WHO.

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))

35. 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. To date, fifteen methods have been published on WHO’s website and are available to countries to strengthen implementation of Articles 9 and 10 of the WHO FCTC. These are also provided in Annex 1 for easy reference. TobLabNet also works in unison with TobReg,

¹ FCTC/COP10/10 – 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).

under the leadership of WHO, to advance product regulation towards comprehensive implementation of the WHO FCTC.

36. At its Third session in 2008, the COP, in decision FCTC/COP3(9)¹ 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.

37. 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*.² 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.

38. 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).³

39. Following this assessment and report by WHO on this work, which can be found in document FCTC/COP7(9),⁴ 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 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).⁵

40. WHO continues to work through TobLabNet to finalize the methods for the determination of 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 resulted in the

¹ FCTC/COP3(9) – https://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_DIV3-en.pdf. (accessed 9 July 2023).

² 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> (accessed 9 July 2023).

³ 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) (accessed 9 July 2023).

⁴ 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://fctc.who.int/publications/m/item/fctc-cop7\(9\)-electronic-nicotine-delivery-systems-and-electronic-nonnitotine-delivery-systems](https://fctc.who.int/publications/m/item/fctc-cop7(9)-electronic-nicotine-delivery-systems-and-electronic-nonnitotine-delivery-systems) (accessed 9 July 2023).

⁵ 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://fctc.who.int/publications/m/item/fctc-cop7\(14\)-further-development-of-the-partial-guidelines-for-implementation-of-articles-9-and-10-of-the-who-fctc-\(regulation-of-the-contents-of-tobacco-products-and-regulation-of-tobacco-product-disclosures\)](https://fctc.who.int/publications/m/item/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)) (accessed 9 July 2023).

publication of three standard operating procedures for smokeless tobacco in all UN languages, in April 2022, as follows (see Annex 1 for links):

- (i) WHO TobLabNet SOP 12 – Standard operating procedure for determination of nicotine content in smokeless tobacco products;
- (ii) WHO TobLabNet SOP 13 – Standard operating procedure for determination of moisture content in smokeless tobacco products; and
- (iii) WHO TobLabNet SOP14 – Standard Operating Procedure for Determination of the pH of Smokeless Tobacco Products.

41. These methods are now available for use by countries for the determination of nicotine, pH and moisture in smokeless tobacco for regulatory purposes. Methods for the determination of TSNA in smokeless tobacco and in water-pipe tobacco, as well as nicotine in water-pipe tobacco, are also planned, with further updates expected to be provided in future sessions of the COP.

42. In addition to the methods for smokeless tobacco and water-pipe tobacco, decision FCTC/COP8(21)¹ 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*”.

43. Following several requests by Parties to make methods available for the determination of key contents and emissions of 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 March 2021 (see Annex 1). This method was prepared by WHO and TobLabNet in cooperation with member laboratories of the European Joint Action on Tobacco Control (JATC).

44. 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. The recommendations made by TobReg to date are available in Annex 2 for easy reference.

45. 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 Regulation² and the other on Building Laboratory Testing Capacity.³ These courses are now

¹ 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://fctc.who.int/who-fctc/governance/working-and-expert-group/fctc-cop8\(21\)-implementation-of-articles-9-and-10-of-the-who-fctc-\(regulation-of-contents-and-disclosure-of-tobacco-products-including-water-pipe-smokeless-tobacco-and-heated-tobacco-products\)](https://fctc.who.int/who-fctc/governance/working-and-expert-group/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)) (accessed 9 July 2023).

² Tobacco product regulation courses. Geneva: World Health Organization (2020). Tobacco product regulation: Basic handbook. <https://openwho.org/courses/TPRS-tobacco-product-regulation-handbook>. (accessed 9 July 2023).

³ 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>. (accessed 9 July 2023).

available in English, French and Russian, and more languages are to follow to encourage wider uptake by Parties.

46. In accordance with decision FCTC/COP8(22), WHO is also working through TobLabNet to develop SOPs for the contents and emissions of HTPs. This led to the publication of the *Standard operating procedure for the determination of nicotine, glycerol and propylene glycol content in the tobacco of heated tobacco products (HTPs)*, in the third quarter of 2023 (see Annex 1). WHO continues to work via TobLabNet to prioritise and develop methods for nicotine products, as well as tobacco products, based on the requests received from its Member States to provide guidance on the testing of the priority contents and emissions of HTPs. These include those proposed for prioritization in HTP emissions (Nicotine, Carbon monoxide and Aldehydes) in an information sheet published by WHO in December 2021. This WHO *Information sheet on measuring priority emissions in heated tobacco products (HTPs) – importance for regulators and significance for public health* provides information on why it is important to measure and regulate HTP emissions.¹

47. Given the demand from WHO Member States and interested parties, including civil society organizations, for standardized analytical testing methods for nicotine and tobacco products, which are devoid of tobacco industry involvement, WHO continues to develop methods for these products, including for flavours and will report at future sessions of the COP. WHO is also working on developing online training modules to make the SOPs more accessible to regulators to facilitate implementation of Articles 9 and 10 of the WHO FCTC and thus strengthening of tobacco control at national level. Further information on this will also be provided at future sessions of the COP.

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

48. 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”.

49. 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.² 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.

¹ WHO Information Sheet (2021). Information sheet on measuring priority emissions in heated tobacco products (HTPs) – importance for regulators and significance for public health. <https://www.who.int/publications/i/item/WHO-HEP-HPR-TFI-2021.1> (accessed 9 July 2023)

² 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”).

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))

50. COP8, in paragraph 2 of decision FCTC/COP8(22)¹ 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 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”.

51. The request is addressed in the Eighth Report of TobReg, the policy brief on research and evidence on novel and emerging tobacco products,² in particular HTPs, and in document FCTC/COP9/8 – Comprehensive report on research and evidence on novel and emerging tobacco products, in particular heated tobacco products, now updated in document FCTC/COP10/10.

52. 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.

¹ FCTC/COP8(22) (2018). Novel and emerging tobacco products [https://ftc.who.int/publications/m/item/ftc-cop8\(22\)-novel-and-emerging-tobacco-products](https://ftc.who.int/publications/m/item/ftc-cop8(22)-novel-and-emerging-tobacco-products) (accessed 21 June 2021).

² Heated tobacco products: Summary of research and evidence of health impacts (2023) (<https://www.who.int/publications/i/item/9789240042490>).

EMERGING AND ONGOING ISSUES IN PRODUCT REGULATION (FLAVOURS, NICOTINE POUCHES, AND DISPOSABLE ENDS)

Nicotine Pouches:

53. In the last decade, newer forms of nicotine and tobacco have entered global markets and proliferated in many jurisdictions.¹ These products are quite diverse, available in a variety of types and flavours and marketed in ways that are inconsistent with public health goals. In the past 20 years, many countries have ratified the WHO FCTC, which is an evidence based global public health treaty negotiated under the auspices of WHO to combat the tobacco epidemic. This has led to the acceleration of tobacco control, thus saving lives.

54. In response to this and changes to consumer behaviour, transnational tobacco companies are diversifying their product lines to sustain profitability.² Nicotine pouches are among the products introduced to several markets, circa 2018. These products are also referred to as “white pouches”, “tobacco leaf-free pouches”, “tobacco-free nicotine pouches”, and “tobacco-derived nicotine pouches”. They are pre-proportioned pouches that contain nicotine, and are similar in some regard to snus, which are conventional smokeless tobacco products.³ This similarity in appearance to conventional products poses serious regulatory challenges to countries. Therefore, WHO Member States have sought technical assistance from WHO on how to address these products, which are currently not regulated in many countries. This prompted WHO to commission some work on nicotine pouches, which includes a paper in the Ninth TobReg report on the “characteristics, use, harmfulness and regulation of nicotine pouches”, as well as a report on “flavours in nicotine pouches”.

55. The paper noted that nicotine pouches have attractive properties, such as appealing flavours, and can be used discretely without the stigma of smoking. They also deliver sufficient nicotine to induce and sustain nicotine addiction. Based on this paper and its review of evidence on nicotine pouches, the study group made a number of recommendations to policy makers and all other interested parties. Detailed information can be found in Chapter 4 and Chapter 7 (*Overall Recommendations*) of TobReg’s Ninth report.

56. The other paper commissioned by WHO set out to provide relevant information on flavours in nicotine pouches, and touches on how these products are advertised and promoted. The paper is available on the WHO FCTC website as supplementary information to this report.

57. The paper noted that nicotine pouches are offered in a wide variety of sweet and fruity flavours, which are known to have a differential appeal to youth. Nicotine pouch brands further target youth, primarily advertising on social media channels, crossing national boundaries, and amplifying the visibility of pouch promotion globally, even in countries in which such marketing is illegal. Nicotine pouch brands also sponsor a wide variety of events such as music concerts, auto racing, sporting events,

¹ 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. <https://www.who.int/publications/i/item/9789240032095>.

² Edwards R, Hoek J, Karreman N, Gilmore A. Evaluating tobacco industry ‘transformation’: a proposed rubric and analysis Tobacco Control 2022;31:313-321.

³ WHO study group on tobacco product regulation. Report on the scientific basis of tobacco product regulation: ninth report of a WHO study group. Geneva: World Health Organization; 2023 (WHO Technical Report Series, No. 1047). Licence: CC BY-NC-SA 3.0 IGO. <https://www.who.int/publications/i/item/9789240079410>.

and poker competitions. To recruit new users, pouch brands make heavy use of free or heavily discounted samples distributed by attractive, young “brand ambassadors”.

58. Analysis of marketing campaigns found that most nicotine pouch advertisements recapitulate themes typical of 20th century cigarette marketing, while some pouch advertising themes diverge, with themes such as: freedom to use anywhere, rule breaking, innovative/modern/high tech, stealthy/discrete to use, no smell/teeth stains, and as a means of smoking cessation. In a worrisome trend, pouch brands are co-marketed with the tobacco company’s flagship cigarette brands in a manner intended to encourage dual or poly use with nicotine and/or tobacco products.

59. In many countries, nicotine pouches are either unregulated or lightly regulated, a permissive environment which facilitates their rapid growth. Lack of regulatory limitation has enabled companies to globally implement sophisticated and pervasive marketing campaigns to promote their newly introduced nicotine pouches. The rapid rise in sales of pouches show how effective aggressive marketing has been in growing a market over an impressively short timeline. The paper is also available on the WHO FCTC website as supplementary information to this report, which contains the relevant references.

Disposable ENDS

60. ENDS, with the most common prototype being electronic cigarettes, and ENDS, have been addressed by WHO and the COP. To this end, TobReg has provided numerous recommendations based on the evaluation of evidence, and the *WHO Report on the Global Tobacco Epidemic 2021* chronicles the COP’s work to date – from COP4 (2010) to COP8 (2018) – on these products. Some updates of WHO’s work are provided in this report and WHO, as it continues to monitor evidence, will provide further updates in future sessions of the COP.

61. In its review of evidence, interactions with its Member States and international experts, as well as its monitoring of market trends and prevalence of use of nicotine and tobacco products, WHO notes that disposable ENDS (D-ENDS), which were introduced around 2018–2019 and began circulating on global markets, are fast becoming a global public health challenge. They are discarded after the e-liquid content is consumed, which means that all device components (plastic, metal casing, lithium battery, heating element, e-liquid, etc.) are intended to be used only once and thrown away. Given the popularity of these products among children and adolescents and the alarming trends among young people in a number of countries, including Australia, Switzerland, the United Kingdom of Great Britain and Northern Ireland, and the United States of America, WHO commissioned a background paper on the characteristics, marketing, challenges of D-ENDS, as well as the regulatory considerations in order to be better informed and to provide authoritative guidance to its Member States. Key highlights from the paper, which is available as supplementary information on the WHO FCTC website, as well as other relevant information on D-ENDS, are provided in paragraphs 62 and 64 of the present report.

62. The background paper, which provides the bibliographic references to the evidence contained in this report, noted the huge diversity of products on global markets, with over 550,000 different D-ENDS available from some markets. Markets in Europe are seeing steep growth curves (up 2200% for 2022 in Switzerland) and the market is also growing in the Middle East and Africa. Furthermore, the paper noted that although monitoring and surveillance of D-ENDS are insufficient, the prevalence of use, especially among younger users, is rising in all surveys to date. These products aggressively target children and adolescents, particularly flooding social media channels, with child friendly images, cartoon characters and attractive flavours and packaging to lure children. Increasing evidence of the negative health impacts of D-ENDS is emerging and further, components, notably the casing, the lithium-ion battery and toxic chemical residue, are discarded after single use, thereby creating serious risks to the environment. The

industry continues to lobby for weaker regulations for newer products, including D-ENDS, relative to conventional products, with claims and arguments, which are as yet unsubstantiated.

63. Generally, only limited regulation exists, and enforcement is often weak. To date, 47 countries or territories have some form of ban on ENDS and a few countries are contemplating a specific ban on D-ENDS. The French overseas territory of New Caledonia, in 2022, was the first jurisdiction to ban D-ENDS, followed more recently, with Australia, in 2023.¹ Several other countries are deliberating on taking similar measures.

64. These products require urgent attention by countries, the COP and WHO to safeguard the health of the younger generation and protect the environment. Countries, in addressing the challenges presented by these products, could consider very strong regulations, which could include a ban. The paper is also available on the WHO FCTC website as supplementary information to this report, which contains the relevant references.

Flavours and flavouring agents

65. The tobacco industry has pioneered the integration of flavour science and technology to increase product appeal and expand global market reach.² Historically, tobacco companies have been known to manipulate the flavour experience for users, mitigating the bitterness of tobacco, reducing the harshness, facilitating inhalation, playing an integral role in building perceptions of “healthier” products, relative to non-flavoured products, and attracting new users. In recent times, the tobacco industry has continued to employ its well-known strategies, while developing newer approaches to exponentially enhance the flavour experience and capture the attention of new users, particularly the young.³ The evidence on flavours is well documented and three recent publications from STOP,^{4, 5, 6} a global tobacco industry watchdog, simplify the key points. Flavours are often cited as the primary reason for youth to try a tobacco or nicotine product, serving as a path from experimentation to regular use, and perpetuating the global tobacco epidemic. Further, there has been a proliferation of newer nicotine and tobacco products on global markets, such as electronic cigarettes, heated tobacco products and nicotine pouches, and the number and variety of documented flavours for these products is staggeringly high.

66. The *Partial guidelines for implementation of Articles 9 and 10*⁷ of the WHO FCTC recognize that “from the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive”. They further recommend that “Parties should regulate, by prohibiting or restricting, ingredients that may be used to increase palatability in tobacco products”. To facilitate this, TobReg has made several recommendations on

¹ Media release. Taking action on smoking and vaping. 2 May 2023, <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/taking-action-on-smoking-and-vaping>.

² Krishnan-Sarin S, O'Malley SS, Green BG, Jordt SE. The science of flavour in tobacco products. World Health Organ Tech Rep Ser. 2019 Oct 24;1015:125-142. PMID: 36743396; PMCID: PMC9896977.

³ Krishnan-Sarin S, O'Malley SS, Green BG, Jordt SE. The science of flavour in tobacco products. World Health Organ Tech Rep Ser. 2019 Oct 24;1015:125-142. PMID: 36743396; PMCID: PMC9896977.

⁴ Next Generation Addiction. Flavored Tobacco: 3 Ways It Hooks Young People. 17 May 2023, <https://exposetobacco.org/news/flavored-tobacco/>.

⁵ Next Generation Addiction. Why the Industry Loves—and Protects—Tobacco Flavors. 24 May 2023.

⁶ Next Generation Addiction. Is PMI Really Creating a ‘Smoke-Free Future’? 10 May 2023.

⁷ Partial guidelines for implementation Articles 9 and 10: Regulation of the contents of tobacco products and regulation of tobacco product disclosures, <https://fctc.who.int/publications/m/item/regulation-of-the-contents-of-tobacco-products-and-regulation-of-tobacco-product-disclosures>.

flavours, since its fifth report in 2015 and in every subsequent report thereafter.^{1,2,3,4} These include a recommendation to prohibit flavours in new products. Evaluations of the impact of flavour bans across countries, globally, note the associated reduced sales of flavoured products and the increase in successful quit attempts, but also reveal a cautionary tale of the necessity of a comprehensive ban which covers all tobacco products to prevent switching of products and to eliminate potential loopholes for the industry to exploit.⁵ The present landscape of nicotine and tobacco products is bursting with flavours, and the formulation of effective and futuristic counter strategies is pivotal for the maximum protection of public health, especially of young people.

67. In response to numerous requests for technical assistance, WHO has been engaging with, countries, regions, international experts and non-governmental organization to address the pertinent issues related to the use of flavours in nicotine and tobacco products. These engagements facilitated the sharing of country experiences, exchange of knowledge on the science of flavours, as well as the sharing of information on the strategies used to promote flavours. This is in order to formulate counter strategies to close regulatory loopholes around flavours to protect young people and strengthen tobacco control. These engagements highlight the need for a comprehensive ban or otherwise comprehensive regulation of flavouring agents in all nicotine and tobacco products to protect the youth.

POLICY OPTIONS AND WHO FCTC IMPLEMENTATION APPROACHES

68. The following (i.e., paragraphs 69–75) 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.

69. **ENDS/ENNDS:** In light of WHO’s recent work on ENDS and ENNDS, as articulated in paragraphs 6–15 and 16–23 of the present document, as well as the current state of knowledge in paragraphs 24 – 28 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

¹ WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: fifth report of a WHO study group. Geneva: World Health Organization; 2015 (WHO Technical Report Series, No. 989)

² WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: sixth report of a WHO study group. Geneva: World Health Organization; 2017 (WHO technical report series; no. 1005). Licence: CC BY-NC-SA 3.0 IGO

³ WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: seventh report of a WHO study group. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1015). Licence: CC BY-NC-SA 3.0 IGO.

⁴ 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). Licence: CC BY-NC-SA 3.0 IGO.

⁵ Next Generation Addiction. Is PMI Really Creating a ‘Smoke-Free Future’? 10 May 2023, <https://exposetobacco.org/news/pmi-smoke-free-future/>.

(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 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.

(c) At the current time, the evidence does not support the use of ENDS or ENNDS as cessation aids at the population level. Tobacco users who want to quit should use proven methods to quit tobacco: advice from healthcare workers, toll-free quit lines, mobile and digital cessation services, approved nicotine replacement therapy (gums and patches) and where recommended, pharmacotherapies.

70. Marketing of novel and emerging tobacco products: Based on the evidence discussed in paragraphs 30–34 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.

71. Methods in furtherance of Articles 9 and 10 of the WHO FCTC: In light of its ongoing work articulated in paragraphs 35–47 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 additional 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.

72. Use of WHO TobLabNet Standard Operating Procedures: Parties are encouraged to use the tobacco industry independent methods (Annex 1) to facilitate implementation of Articles 9 and 10 of the WHO FCTC, including but not limited to specifying these methods in their national laws.

73. 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.

74. **Nicotine pouches:** Based on the evidence described in the Ninth TobReg report (see item 9, Annex 2) and the background paper on nicotine pouches (paragraphs 53 – 59), as well the growing market of these products, Parties should consider the recommendations of TobReg in its Ninth report, as follows:

(a) establish or extend surveillance of products and their users, including demographics, use of other tobacco and related products, brand, type and flavour used in nicotine pouches to acquire knowledge and assess the prevalence of use and user profiles;

(b) regulate nicotine pouches to prevent all forms of marketing and take all other action necessary to minimize: young people's access to them, their appeal to young people and initiation of use by young people;

(c) regulate non-therapeutic nicotine products in the same manner as products of similar appearance, content and use; and

(d) ensure that nicotine pouches are not classified as pharmaceutical products unless they are proven to be nicotine replacement therapies by following stringent pharmaceutical pathways for licensing as nicotine replacement therapies, as prescribed by the appropriate national regulatory authority.

75. **Disposable ENDS:** In addressing the challenges presented by these products, Parties should consider very strong regulations, which could include a ban, to protect children and adolescents. This should be done in the context of its regulatory environment, while maintaining focus on evidence-based tobacco control through full implementation of the WHO FCTC.

ACTION BY THE CONFERENCE OF THE PARTIES

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

ANNEX 1

**LIST OF PUBLISHED WHO TOBACCO LABORATORY NETWORK
STANDARD OPERATING PROCEDURES**

WHO TobLabNet SOP 01 - Standard operating procedure for intense smoking of cigarettes,
https://apps.who.int/iris/bitstream/handle/10665/75261/9789241503891_eng.pdf?sequence=1.

WHO TobLabNet SOP 02 - Standard operating procedure for validation of analytical methods of tobacco product contents and emissions,
<https://apps.who.int/iris/bitstream/handle/10665/254998/9789241512060-eng.pdf;sequence=1>.

WHO TobLabNet SOP 03 - Standard operating procedure for determination of tobacco-specific **nitrosamines** in mainstream cigarette smoke under ISO and intense smoking conditions,
http://apps.who.int/iris/bitstream/handle/10665/136000/9789241506663_eng.pdf;jsessionid=D3B8754511DCFE3AB3918CEB7921E3AA?sequence=1.

WHO TobLabNet SOP 04 - Standard operating procedure for determination of nicotine in cigarette tobacco filler,
https://apps.who.int/iris/bitstream/handle/10665/102318/9789241503907_eng.pdf?sequence=1.

WHO TobLabNet SOP 05 - Standard operating procedure for determination of benzo[a]pyrene in mainstream cigarette smoke under ISO and intense smoking conditions,
https://apps.who.int/iris/bitstream/handle/10665/174003/9789241508322_eng.pdf?sequence=1.

WHO TobLabNet SOP 06 - Standard operating procedure for determination of humectants in cigarette tobacco filler,
<https://apps.who.int/iris/bitstream/handle/10665/246228/9789241510479-eng.pdf;sequence=1>.

WHO TobLabNet SOP 07 - Standard operating procedure for determination of ammonia in cigarette tobacco filler,
<https://apps.who.int/iris/bitstream/handle/10665/250089/9789241510462-eng.pdf?sequence=1>.

WHO TobLabNet SOP 08 - Standard operating procedure for determination of aldehydes in mainstream cigarette smoke under ISO and intense smoking conditions,
<https://apps.who.int/iris/bitstream/handle/10665/275357/9789241514767-eng.pdf?ua=1>.

WHO TobLabNet SOP 09 - Standard operating procedure for determination of volatile organics in mainstream cigarette smoke under ISO and intense smoking conditions,
<http://apps.who.int/iris/bitstream/handle/10665/275344/9789241514774-eng.pdf?ua=1>.

WHO TobLabNet SOP 10 - Standard operating procedure for determination of nicotine and carbon monoxide in mainstream cigarette smoke under intense smoking conditions,
<https://apps.who.int/iris/bitstream/handle/10665/252615/9789241511810-eng.pdf?sequence=1&isAllowed=y>.

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

WHO TobLabNet SOP12 - Standard operating procedure for determination of nicotine content in smokeless tobacco products,
<https://www.who.int/publications/i/item/9789240044661>.

WHO TobLabNet SOP13 - Standard operating procedure for determination of moisture content in smokeless tobacco products,
<https://www.who.int/publications/i/item/9789240044685>.

WHO TobLabNet SOP14 - Standard operating procedure for determination of the pH of smokeless tobacco products,
<https://www.who.int/publications/i/item/9789240044708>.

WHO TobLabNet SOP15 - Standard operating procedure for determination of nicotine, glycerol and propylene glycol content in the tobacco of heated tobacco products (HTPs),
<https://www.who.int/publications/i/item/9789240079304>.

ANNEX 2

**LIST OF REPORTS TO DATE BY THE WHO STUDY GROUP
ON TOBACCO PRODUCT REGULATION**

1. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: report of a WHO study group. Geneva: World Health Organization; 2007 (WHO technical report series; no. 945). Licence: CC BY-NC-SA 3.0 IGO,
<https://www.who.int/publications/i/item/the-scientific-basis-of-tobacco-product-regulation-report-of-a-who-study-group>.
2. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: second report of a WHO study group. Geneva: World Health Organization; 2008 (WHO technical report series; no. 951). Licence: CC BY-NC-SA 3.0 IGO,
https://apps.who.int/iris/bitstream/handle/10665/43997/TRS951_eng.pdf?sequence=1&isAllowed=y.
3. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: third report of a WHO study group. Geneva: World Health Organization; 2009 (WHO technical report series; no. 955). Licence: CC BY-NC-SA 3.0 IGO,
<https://fctc.who.int/publications/i/item/who-study-group-on-tobacco-product-regulation-third-report-on-the-scientific-basis-of-tobacco-product-regulation>.
4. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: fourth report of a WHO study group. Geneva: World Health Organization; 2012 (WHO technical report series; no. 967). Licence: CC BY-NC-SA 3.0 IGO,
https://apps.who.int/iris/bitstream/handle/10665/44800/9789241209670_eng.pdf?sequence=1.
5. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: fifth report of a WHO study group. Geneva: World Health Organization; 2015 (WHO technical report series; no. 989). Licence: CC BY-NC-SA 3.0 IGO,
<https://www.who.int/publications/i/item/who-study-group-on-tobacco-product-regulation-report-on-the-scientific-basis-of-tobacco-product-regulation-fifth-report-of-a-who-study-group>.
6. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: sixth report of a WHO study group. Geneva: World Health Organization; 2017 (WHO technical report series; no. 1001). Licence: CC BY-NC-SA 3.0 IGO,
<https://www.who.int/publications/i/item/who-study-group-on-tobacco-product-regulation-report-on-the-scientific-basis-of-tobacco-product-regulation-sixth-report-of-a-who-study-group>.
7. WHO Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: seventh report of a WHO study group. Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1015). Licence: CC BY-NC-SA 3.0 IGO,
<https://www.who.int/publications/i/item/who-study-group-on-tobacco-product-regulation-report-on-the-scientific-basis-of-tobacco-product-regulation-seventh-report-of-a-who-study-group>.

8. 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). Licence: CC BY-NC-SA 3.0 IGO, <https://www.who.int/publications/i/item/9789240022720>.

9. WHO study group on tobacco product regulation. Report on the scientific basis of tobacco product regulation: ninth report of a WHO study group. Geneva: World Health Organization; 2023 (WHO Technical Report Series, No. 1047). Licence: CC BY-NC-SA 3.0 IGO, <https://www.who.int/publications/i/item/9789240079410>.

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