EUROPEAN
COMMISSION

Strasbourg, 17.9.2024
COM(2024) 55 final

2024/0230 (NLE)

Proposal for a

COUNCIL RECOMMENDATION

on Smoke- and Aerosol-Free Environments replacing Council Recommendation 2009/C 296/02

{SWD(2024) 55 final} - {SWD(2024) 56 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

Introduction

In Europe's Beating Cancer Plan, the Commission announced its intention to update the Council Recommendation on smoke-free environments[1]. One of the plan's tobacco-related objectives is to help create a 'Tobacco-Free Generation' where less than 5% of the population uses tobacco by 2040, compared to around 25% today. The revision of the Council Recommendation on smoke-free environments is an initiative which aims to positively contribute towards this goal, fulfil the objective of better protecting people in the Union from second-hand smoke originating from combustible tobacco products and second-hand aerosols originating from the use of emerging products, and promote smoking cessation and the denormalisation of smoking and nicotine use.

The current Council Recommendation (2009/C 296/02) sets out recommendations for Member States to implement the World Health Organization Framework Convention on Tobacco Control (FCTC) and thus provides guidance for them to comply with their legal commitments to protect people from second-hand smoke in all indoor workplaces, public transport, and indoor public places. Its scope includes traditional tobacco products, perceived to be the main issue at the time, and some public spaces, covered based on a case-by-case hazard assessment.

However, at present, the current Council Recommendation cannot fully achieve its protective purpose due to the lack of coverage of outdoor spaces and because of market developments related to emerging products, which may emit smoke and/or aerosols, for example heated tobacco products, electronic cigarettes, whether containing nicotine or nicotine-free, and tobacco surrogates, and any other smoke and/or aerosol emitting products, which were not originally included. The objective of the proposed revision of the Council Recommendation is therefore two-fold, namely, to cover emerging products and specific outdoor spaces. With that, it will better address the risks of second-hand exposure to aerosols from emerging products as well as the risk of second-hand exposure to both smoke and aerosols in certain outdoor spaces. A revision of the Recommendation on these two aspects is thus needed to achieve the objective of better protecting people, in particular children and young people, in the Union from exposure to second-hand smoke and aerosols. The proposal for a revised Council Recommendation, in addition, aims to indirectly support the denormalisation of the use of both tobacco and emerging products and, in this way, contribute to the goal of achieving a tobacco-free generation.

The proposed revision of the Council Recommendation includes an extension of its coverage to certain emerging products and outdoor spaces. A major driver for this extension is the rapid market growth and appeal of emerging products, especially among young people, since 2009 and the currently significant exposure to second-hand smoke and aerosols in certain outdoor spaces. In 2009, heated tobacco products had not yet entered the EU market and electronic cigarettes only to a minor extent; the current Recommendation therefore only targets traditional tobacco products by referring to 'tobacco smoke', meaning that it does not cover all emerging products. However, since 2009, emerging products such

[1] Council Recommendation of 30 November 2009 on smoke-free environments (OJ C 296, 5.12.2009, p. 4).

as electronic cigarettes and heated tobacco products have increased their market shares. Among respondents to the 2023 Eurobarometer on the attitudes of Europeans towards tobacco and related products, 3% are current users of electronic cigarettes compared to 2% in 2020. A particularly concerning aspect of the uptake of emerging products in recent years has been their appeal among children and young people; in fact, 54% of current and past smokers start smoking before the age of 19 and 14% start before the age of 15 [2].

Evidence from research shows that second-hand emissions from emerging products can have potentially harmful health impacts. In its opinion on electronic cigarettes, the European Commission's advisory committee known as Scientific Committee on Health, Environment and Emerging Risks (SCHEER) concluded that there is weak to moderate evidence of risks of respiratory, cardiovascular, and carcinogenic damage due to second-hand exposure to electronic cigarette aerosols[3]. The EU-funded TackSHS project showed that the burden of second-hand smoke continues to be substantial, quantified the health risk and economic costs for several Member States and proposed interventions aiming to decrease second-hand smoke exposure to decrease disease burden among children and adults[4]. The World Health Organization[5,6,7,8] recently highlighted, among other concerns related to emerging products, the negative health effects of exposure to second-hand aerosols. For example, there is evidence that exposure to second-hand emissions from heated tobacco products is associated with significant respiratory and cardiovascular abnormalities in bystanders[9,10,11,12,13,14]. In addition, second-hand aerosols from electronic cigarettes, both with or without nicotine, expose bystanders to quantifiable levels of

2 Special Eurobarometer 539. 2023. Attitudes of Europeans towards tobacco and related products. ISBN: 978-92-68-07599-9.

3 SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). Opinion on electronic cigarettes. 16 April 2021.

4 https://www.tackshs.eu/wp-content/uploads/2019/10/TackSHS-leaflet_20191023.pdf

5 World Health Organization. Report on the global tobacco epidemic 2021: addressing new and emerging products. 2021. ISBN: 978 92 4 003209 5, p. 30-38.

6 World Health Organization. Report on the global tobacco epidemic 2023: protect people from tobacco smoke. 2023. ISBN: 978-92-4-007716-4, p. 31-32.

7 World Health Organization. Technical note on the call to action on electronic cigarettes. 2023. p.3-4. https://www.who.int/publications/m/item/technical-note-on-call-to-action-on-electronic-cigarettes

8 World Health Organization. Electronic cigarettes call to action. 2023. https://www.who.int/publications/m/item/electronic-cigarettes---call-to-action

9 World Health Organization. Heated tobacco products: summary of research and evidence of health impacts. 2023. p. 12-13. https://www.who.int/publications/i/item/9789240042490

10 World Health Organization: WHO study group on tobacco product regulation: Report on the scientific basis of tobacco product regulation: eighth report of a WHO study group. 2021. https://www.who.int/publications/i/item/9789240022720

11 Yoshioka T, Shinozaki T, Hori A, Okawa S, Nakashima K, Tabuchi T. Association between exposure to secondhand aerosol from heated tobacco products and respiratory symptoms among current non-smokers in Japan: a cross-sectional study. BMJ Open. 2023;13:e065322. doi: 10.1136/ bmjopen-2022-065322

12 Imura Y, Tabuchi T. Exposure to secondhand heated-tobacco-product aerosol may cause similar incidence of asthma attack and chest pain to secondhand cigarette exposure: the JASTIS 2019 study. Int J Environ Res Public Health. 2021;18(4):1766. doi: 10.3390/ijerph18041766

13 Uguna CN, Snape CE. Should IQOS emissions be considered as smoke and harmful to health? A review of the chemical evidence. ACS Omega. 2022;7(26):22111–24. doi: 10.1021/ acsomega.2c01527.

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particulate matter and key toxicants and contaminants [15,16,17,18,19,20,21]. For context, the World Health Organization considers that electronic cigarettes with nicotine are highly addictive and harmful to health[7,8]. It also highlights that no level of side-stream exposure is safe or acceptable and that a careful approach should be taken[5]. Moreover, in order to achieve higher protection levels from second-hand smoke and aerosols, smoke-free legislation should be comprehensive and cover emerging products in its provisions[6]. Several Member States have already taken protective measures including banning smoking in indoor and outdoor places or banning the use of emerging products in public places. [22]

Given the above, and while continuous development of the current evidence base will be pursued, a revision of the Council Recommendation to include emerging products is justified and appropriate to address the risk of exposure to second-hand smoke and aerosols in view of ensuring a high level of public health protection. This approach is also aligned with the Communication from the Commission on the precautionary principle[23].

The proposed extension of the scope of the Recommendation is a major step towards de-normalising smoking and the use of emerging products which might mimic the action of smoking which is a crucial element of achieving a tobacco-free generation in the Union by 2040. This extension of scope is particularly important given the fact that the use of emerging products especially those that contain nicotine and particularly by young people, might become a starting point for the subsequent use of traditional combustible tobacco products. This can result in 'dual use' where users consume both conventional tobacco and emerging products at the same time and often switch between the two depending on where smoke-free rules apply[24,25,26,27,28].

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15 Fernández E, Ballbè M, Sureda X, Fu M, Saltó E, Martínez-Sánchez JM. Particulate matter from electronic cigarettes and conventional cigarettes: a systematic review and observational study. Curr Environ Health Rep. 2015;2(4):423–9. doi: 10.1007/s40572- 015-0072-x.

16 Li L, Lin Y, Xia T, Zhu Y. Effects of electronic cigarettes on indoor air quality and health. Annu Rev Public Health. 2020;41(1):363–80. doi: 10.1146/ annurev-publhealth-040119-094043.

17 Hess I, Lachireddy K, Capon A. A systematic review of the health risks from passive exposure to electronic cigarette vapour. Public Health Research & Practice. 2016;26(2).

18 Borgini A, Veronese C, De Marco C, Boffi R, Tittarelli A, Bertoldi M et al. Particulate matter in aerosols produced by two last generation electronic cigarettes: a comparison in a real-world environment. Pulmonology. 2021.

19 Exposure to aerosols from smoking-proxy electronic inhaling systems: a systematic review. Barcelona: Tobacco Control Unit, Institut Català d'Oncologia; 2016.

20 Lerner CA, Sundar IK, Yao H, Gerloff J, Ossip DJ, McIntosh S et al. Vapors produced by electronic cigarettes and e-juices with flavorings induce toxicity, oxidative stress, and inflammatory response in lung epithelial cells and in mouse lung. PLoS One. 2015;10(2):e0116732

21 Glantz, S.A., Nguyen, N., & Oliveira da Silva, A.L. (2024). Population-Based Disease Odds for E-Cigarettes and Dual Use versus Cigarettes. NEJM Evidence, 3(3). DOI: 10.1056/EVIDoa2300229.

22 Some examples of Member States that have already taken protective measures include Spain, Latvia and Sweden (Staff working document accompanying the Council Recommendation on Smoke- and Aerosol-Free Environments replacing Council Recommendation 2009/C 296/02).

23 Communication from the Commission on the precautionary principle (COM/2000/0001 final).

24 Special Eurobarometer 506. 2021. Attitudes of Europeans towards tobacco and electronic cigarettes. ISBN: 978-92-76-27171-0, p. 10.

25 World Health Organization. Report on the global tobacco epidemic 2021: addressing new and emerging products. 2021. ISBN: 978 92 4 003209 5, p. 36.

26 Kalkhoran S, Glantz SA. E-cigarettes and smoking cessation in real-world and clinical settings: a systematic review and meta-analysis. Lancet Respiratory Medicine. 2016;4(2):116–28.

27 Felicione NJ, Ozga-Hess JE, Ferguson SG, Dino G, Kuhn S, Haliwa I et al. Cigarette smokers' concurrent use of smokeless tobacco: dual use patterns and nicotine exposure. Tobacco Control. 2021;30(1):24–29.

Regarding the outdoor spaces not explicitly covered by the current Recommendation, there is at present significant exposure to second-hand smoke and aerosols in places such as the outdoor spaces of hospitality venues and outdoor spaces intended for use by children and adolescents. In fact, 74% of Eurobarometer respondents say that they have experienced people smoking in outdoor terraces in the past 6 months and 71% of respondents say they have experienced people using electronic cigarettes and heated tobacco products in the same places. 42% of respondents say that people were smoking in outdoor places intended for use by children and adolescents and 49% of respondents say that they experienced people using electronic cigarettes and heated tobacco products in the same places[2]. The proposal to extend the coverage of the current Council Recommendation to include specific outdoor spaces aims to better protect people, in particular children and young people, from exposure to second-hand smoke and aerosols.

Commission supportive actions

The proposed Council Recommendation contains recommendations to Member States to better address the risks from exposure to second-hand smoke and aerosols in certain outdoor spaces. The Commission is planning to carry out a series of measures to support countries in implementing the recommendations.

First, the Commission intends to encourage and/or reinforce cooperation between Member States on the exchange of best practices on strengthening and/or developing comprehensive smoke- and aerosol-free policies, programmes, and strategies, and support the design and piloting of ambitious and efficient approaches towards achieving smoke and aerosol-free environments. Second, the Commission envisages to provide support, through existing EU programmes, discussion fora and collaboration tools, for the implementation of the Recommendation by Member States and for the enforcement of tobacco and nicotine control measures.

The Commission also intends to support tobacco and nicotine control, and prevention of addiction, by further promoting research. These research efforts are envisaged to encompass emerging products that emit smoke or aerosols, including heated tobacco products, electronic cigarettes, whether containing nicotine or nicotine-free, and tobacco surrogates that emit smoke or aerosols[29], and any other smoke and/or aerosol emitting product, and nicotine-releasing products and products resembling the use of nicotine-releasing products. The Commission also intends to strengthen international cooperation, including on research, on the topics covered by this Recommendation.

Finally, the Commission intends to develop a prevention toolkit supporting the better protection of the health of children and young people in the most vulnerable and formative years of their lives, including a focus on prevention from smoking and nicotine addiction, and addressing the interlinks between mental and physical health and key health determinants.

The Commission intends to implement all supportive actions in close cooperation with Member States.

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[28] Wang JB, Olgin JE, Nah G, Vittinghoff E, Cataldo JK, Pletcher MJ et al. Cigarette and e-cigarette dual use and risk of cardiopulmonary symptoms in the Health eHeart Study. PLoS One. 2018;13(7):e0198681.

[29] In the context of this proposal for a Council Recommendation, tobacco surrogates are non-tobacco products that emit smoke or aerosols that can be used at the same time as tobacco products or can mirror the use of tobacco products.

- **Consistency with existing policy provisions in the policy area**

  This proposal is complementary to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC[30]. This Directive lays down rules for tobacco and related products on the EU market. It provides a regulatory framework for, among others, heated tobacco products and electronic cigarettes. The Directive aims to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for people in the Union.

  This proposal will also contribute towards the tobacco-related objectives of Europe's Beating Cancer Plan, notably the objective of achieving a tobacco-free generation. Working in close synergy with the Plan, the EU Mission on Cancer[31] supports this objective by generating new evidence around prevention and behavioural changes, building on research on tobacco supported through the Horizon 2020 and Horizon Europe programmes.[32]

  This proposal is complementary to the Healthier Together- EU non-communicable diseases initiative which aims to tackle risk factors common to cancer and other non- communicable diseases, including tobacco use. Among other things, this proposal deals with health determinants. Through various measures under the EU4Health Programme, it provides Union funding for measures on health determinants aimed at addressing risk factors related to various non-communicable diseases and developing interventions on major cross-cutting themes such as tobacco control.

  This proposal is complementary to, but has a broader scope, than the global tobacco control measures laid down in the WHO Framework Convention on Tobacco Control (FCTC), which is an international treaty, to which the European Union and its Member States are Parties, with the main objective of fostering international cooperation to bring about an effective, appropriate, and comprehensive international response to the spread of the global tobacco epidemic. More specifically, this revision is complementary to Article 8 of the FCTC which deals with the protection from exposure to tobacco smoke.

- **Consistency with other Union policies**

  This initiative is consistent with the Zero Pollution action plan[33] which, under the European Green Deal, sets out the objective of reducing, by 2050, air, water and soil pollution to levels no longer harmful to human health and natural ecosystems and that respect the boundaries our planet can cope with, thus creating a toxic-free environment. The revision of the Council Recommendation on smoke-free environments may have a positive environmental impact by reducing smoke and aerosols originating from the use of emerging products, and by reducing waste and littering from the disposal of cigarette butts, plastic filters and devices, most notably disposable devices, used in association with emerging products. In addition, the consumption of traditional tobacco and emerging products can be an environmental fire and safety hazard.

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30 OJ L 127, 29.4.2014, p. 1.

31 https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en

32 Under the Horizon 2020 and Horizon Europe programmes, more than 55 projects related to research on tobacco were funded, with a total budget of around EUR 110 million.

33 Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' (COM/2021/400 final)).

This proposal is also consistent with the EU strategy on the rights of the child[34], which highlights that the EU and Member States must respect, protect, promote and fulfil children's rights. In one of its thematic areas, the strategy refers to the right to good living, education, and health for all children in the EU. The revision of the Council Recommendation on smoke-free environments aims in particular to protect children and young people from exposure to second-hand smoke and aerosols.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

This proposal is based on Article 168(6) of the Treaty on the Functioning of the EU (TFEU) according to which the Council, on a proposal from the Commission, may adopt recommendations for the purposes set out in Article 168, which concerns the protection of public health. The primary objective of this proposal is to better protect people in the Union in particular children and young people from exposure to second-hand smoke and aerosols. This proposal for a Council Recommendation may thus be adopted on the basis of Article 168(6) TFEU.

- **Subsidiarity (for non-exclusive competence)**

This proposal will help increase the levels of human health protection from second-hand smoke and aerosol exposure both between and within Member States. Union action, that would complement national policies, would bring clear added value to national efforts by providing Member States that have not yet implemented comprehensive smoke-free legislation with recommendations for doing so. The proposed Council Recommendation respects the responsibility of Member States for the definition of their health policy.

- **Proportionality**

This proposal for a Council recommendation based on Article 168(6) TFEU takes into account that EU action, which, as set out in Article 168(1) TFEU, shall complement national policies, shall be directed towards improving public health. The objective of this proposal is to better protect people in the Union from second-hand smoke and aerosols, with a focus on including emerging products and specific outdoor spaces in its scope. The proposed revision of the current Council Recommendation[1] is suitable to achieve the intended objective and does not go beyond what is necessary and proportionate because it would result in increased positive health benefits. In addition, the economic impacts are overridden by the public health benefits and the expected savings for healthcare systems and reduced environmental costs.

- **Choice of the instrument**

The policy instrument for this revision, a proposal for a Council Recommendation, remains unchanged and fully respects the principles of subsidiarity and proportionality in the field of public health. It is a non-binding instrument that allows Member States to adapt their approaches to their national needs.

[34] EU strategy on the rights of the child (COM/2021/142 final)

3. RESULTS OF *EX-POST* EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACTASSESSMENTS

- ***Ex-post* evaluations/fitness checks of existing legislation**

  N/A

- **Stakeholder consultations**

  Input and feedback for this initiative was gathered through a call for evidence[35] and various targeted consultation activities (targeted surveys, targeted interviews and focus groups). The following stakeholder groups were consulted: 1) representatives of Member States competent authorities; 2) civil society organisations; 3) representatives from the tobacco and related products industry; 4) representatives from the HORECA sector; 5) other relevant stakeholders, such as those in education and sports associations. Input on the revisions was also gathered through a meeting of the Expert Group on Tobacco Policy on 3 May 2023. Finally, written feedback on the proposed revisions of the Recommendation was received from the Joint Action on Tobacco Control (JATC-2).

  The call for evidence, was open for contribution from 22 June to 20 July 2022 and prompted 207 responses[36]. The majority of Non-Governmental Organisations, academic/research institutions, and representatives of national competent authorities largely supported the proposed updates to the 2009 Recommendation. Some of the points which were highlighted concern the importance of adding emerging products (including nicotine-free products) and the positive impact that the updates to the Recommendation would have in tackling the rising popularity, advertising, and use of emerging products, notably among children and young people. Moreover, the importance of ensuring the harmonisation of smoke- and aerosol-free laws across Member States was highlighted. The feedback received from businesses largely opposes any updates to the Recommendation.

  During the targeted consultation activities, most representatives of national competent authorities highlighted that the proposed amendments to the Recommendation would help to protect the public from exposure to second-hand smoke and aerosols. They noted that it would have a positive effect in terms of harmonisation of smoke-free rules within and across Member States and that the resultant economic impact and administrative burden would be minor and outweighed by the health benefits. Possible enforcement and compliance challenges were highlighted.

  Most civil society organisations that were consulted agreed that the proposed extension to cover emerging products and outdoor spaces would have a positive impact in reducing exposure to second-hand smoke/aerosols and that this would consequently help to protect people, in particular children, adolescents, and other more vulnerable people, for instance citizens with chronic diseases or other pre-existing conditions, or pregnant women. They also noted that revising the Recommendation would contribute to the denormalisation of smoking and use of emerging products. Some organisations highlighted the importance of 'futureproofing' the revised Recommendation against possible developments and trends in emerging tobacco products. Several organisations also pointed to environmental benefits against a background of significant concern about the negative environmental impacts of

[35] Have Your Say. Smoke-free environments- updated recommendation. Call for evidence. 22 June 2022- 20 July 2022.

[36] Replies were received from EU citizens (101), businesses, consumer, and trade organisations (47), Non-Governmental Organisations (28), academic/research institutions (6) and Member State Public authorities (4).

smoking and use of emerging products, such as cigarette butts discarded as litter, disposable/single use 'vapes' and discarded batteries. Finally, most civil society organisations saw industry interference and lobbying, enforcement, and compliance as challenges related to the revision.

Representatives from the tobacco and related products industry who were consulted were mostly opposed to changes to the current Recommendation regarding the inclusion of emerging products and outdoor spaces. They highlighted that emerging products should not be subject to the same level of restrictions as traditional combustible tobacco products in the context of smoke-free rules. However, some tobacco industry representatives also agreed that extending the rules to outdoor spaces where children and adolescents are present might help to protect them from second-hand smoke and aerosols.

Representatives from the HORECA sector had varying views. Some largely supported the proposed amendments with regard to the scope of both products and spaces; they noted it would have a positive effect on the health of employees in the sector as it would help to protect them from exposure to second-hand smoke and aerosols. Others expressed a certain level of reservation to the proposed revision of the Recommendation, in particular to the measure of including the outdoor spaces of hospitality establishments. In particular, representatives from HORECA businesses highlighted their concerns about losing customers, their fear that they might potentially have to spend resources on adjusting to new measures and that, in the case of the hotel industry, their customers could shift to the short-term rental sector, resulting in unfair business competition. No quantitative information or factual estimations were provided to support the negative economic impacts that were mentioned. In contrast, representatives of employees in the HORECA sector thought that the economic impact would be neutral and negligible.

Representatives from the tobacco industry mentioned that the initiative would lower demand for both traditional tobacco products and emerging products such as electronic cigarettes which would also adversely impact employment in the tobacco and emerging products industry.

The Expert Group on Tobacco Policy and the Joint Action on Tobacco Control (JATC-2) supported the inclusion of emerging products and outdoor spaces.

The input, suggestions and recommendations of Member States and other stakeholders were analysed and taken into account as much as possible and in line with relevant and available scientific evidence. The detailed outcomes of all the consultation activities and how these were taken into account are described in the accompanying staff working document.

- **Collection and use of expertise**

As mentioned above, to support this Recommendation, several consultation activities targeting relevant stakeholder groups were organised to gather opinions and evidence.

- **Impact assessment**

An impact assessment was not considered necessary because the proposed initiative is a non-binding recommendation for Member States and leaves room for different national approaches. This initiative aims to update the former 2009 Recommendation in response to technological developments since 2009 regarding emerging products and to avoid a case-

by-case approach when applying smoke-free rules to public spaces. The 2021 study[37] on smoke-free environments and advertising of tobacco and related products showed that the revision is expected to have a positive health and social impact and that the magnitude of the negative economic impacts economic operators might face are limited and/or insignificant. The supporting evidence and conclusions from the study are presented in the accompanying staff working document.

- **Regulatory fitness and simplification**

  N/A.

- **Fundamental rights**

  […]

4. BUDGETARY IMPLICATIONS

N/A

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

  The Commission intends to report on the progress made in implementing this Recommendation, on the basis of the information provided by Member States, within 5 years after its adoption.

- **Explanatory documents (for directives)**

  N/A

- **Detailed explanation of the specific provisions of the proposal**

  N/A

[37] European Commission, Directorate-General for Health and Food Safety. Study on smoke-free environments and advertising of tobacco and related products. 2021. ISBN: 978-92-76-42343-0.

2024/0230 (NLE)

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COUNCIL RECOMMENDATION

on Smoke- and Aerosol-Free Environments replacing Council Recommendation 2009/C 296/02

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(6) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) According to the World Health Organization, exposure to second-hand tobacco smoke is a widespread source of mortality, morbidity, and disability in the Union. Such exposure is associated with tobacco consumption which remains the leading cause of preventable cancers with 27% of all cancers being attributed to the use of tobacco.

(2) The use of tobacco remains widespread globally and throughout the Union. In 2023, 24% of the European Union population are estimated to be smokers[1].

(3) The global annual economic cost of smoking was estimated at US$ 1.4 trillion in 2012, equivalent to 1.8% of the global gross domestic product (GDP). In the EU, already in 2009, tobacco smoking cost €544 billion which is about 4.6% of the EU27 combined GDP.[2]

(4) It is appropriate to contribute towards the reduction of the smoking level in the Union, in line with the objective of Europe's Beating Cancer Plan[3] to achieve a tobacco-free generation where only 5% of the Union population uses tobacco products compared to the 24% of today.

(5) The World Health Organization Framework Convention on Tobacco Control (FCTC) was developed with the aim of fostering an effective and comprehensive international response to the spread of the global tobacco epidemic. Article 8 of the FCTC requires its parties to provide effective protection from second-hand tobacco smoke in workplaces, public transport and indoor places; the annexed guidelines aim to assist parties in meeting their obligations under Article 8 of the FCTC.

(6) The European Strategy on Tobacco Control adopted by the World Health Organization Regional Committee for Europe in September 2002 recommended that WHO Member States ensure the citizens' right to a smoke-free environment by, inter alia, making public places, workplaces and public transport smoke-free, banning smoking outdoors in all educational institutions for minors, in all places of healthcare delivery and at

1 Special Eurobarometer 539. 2023. Attitudes of Europeans towards tobacco and related products. ISBN: 978-92-68-07599-9.

2 Health Promotion (who.int), Tobacco and Smoking | Knowledge for policy (europa.eu)

3 Communication from the Commission on the Europe's Beating Cancer Plan, COM/2021/44 final.

public events, as well as classifying environmental tobacco smoke (ETS) as a carcinogen[4].

(7) The second-hand emissions of emerging products can have potentially harmful health impacts. The World Health Organization highlights that second-hand emissions from emerging products can expose people to potentially harmful levels of particulate matter and key toxicants.

(8) The World Health Organization[5,6,7] has highlighted, among other issues related to emerging products, the negative health effects of exposure to second-hand aerosols. For example, recent evidence has indicated that exposure to second-hand emissions from heated tobacco products were associated with significant respiratory and cardiovascular abnormalities in bystanders[8,9,10,11,12,13]. In addition, second-hand aerosols from electronic cigarettes, including both ones that do and do not contain nicotine, expose bystanders to quantifiable levels of particulate matter and key toxicants and contaminants [14,15,16,17,18,19,20].

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4 World Health Organization. 2002. European Strategy for Tobacco Control. https://iris.who.int/handle/10665/107455

5 World Health Organization. Report on the global tobacco epidemic 2023: protect people from tobacco smoke. 2023. ISBN: 978-92-4-007716-4, p. 31-32.

6 World Health Organization. Technical note on the call to action on electronic cigarettes. 2023. p. 3-4. https://www.who.int/publications/m/item/technical-note-on-call-to-action-on-electronic-cigarettes

7 World Health Organization. Electronic cigarettes call to action. 2023. https://www.who.int/publications/m/item/electronic-cigarettes---call-to-action

8 World Health Organization. Heated tobacco products: summary of research and evidence of health impacts. 2023. p. 12-13. https://www.who.int/publications/i/item/9789240042490

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16 Hess I, Lachireddy K, Capon A. A systematic review of the health risks from passive exposure to electronic cigarette vapour. Public Health Research & Practice. 2016;26(2).

17 Borgini A, Veronese C, De Marco C, Boffi R, Tittarelli A, Bertoldi M et al. Particulate matter in aerosols produced by two last generation electronic cigarettes: a comparison in a real-world environment. Pulmonology. 2021.

18 Exposure to aerosols from smoking-proxy electronic inhaling systems: a systematic review. Barcelona: Tobacco Control Unit, Institut Català d'Oncologia; 2016.

19 Lerner CA, Sundar IK, Yao H, Gerloff J, Ossip DJ, McIntosh S et al. Vapors produced by electronic cigarettes and e-juices with flavorings induce toxicity, oxidative stress, and inflammatory response in lung epithelial cells and in mouse lung. PLoS One. 2015;10(2):e0116732

(9) The World Health Organization considers that no level of side-stream exposure is safe or acceptable[4] thus, a careful approach should be taken. The World Health Organization recommends applying tobacco control measures, including protection from exposure, to electronic cigarettes[21, 4,5].

(10) In its 2021 opinion on electronic cigarettes[22], the Scientific Committee on Health, Environment and Emerging Risks (SCHEER) concluded that there is weak to moderate evidence of risks of respiratory, cardiovascular, and carcinogenic damage due to second-hand exposure to aerosols from electronic cigarettes.

(11) Smoke- and aerosol-free environments are a globally recognised and proven approach to adequately protect the health of people from the effects of second-hand tobacco smoke and aerosols.

(12) In recent years, emerging products such as electronic cigarettes and heated tobacco products have consolidated their market shares and their uptake is increasing. Based on Eurobarometer data, the prevalence of electronic cigarettes use across the Union is 3% and the prevalence of heated tobacco products use is 2%.

(13) An issue of specific concern in relation to the market developments of emerging products, such as electronic cigarettes and heated tobacco products, is their particular uptake and appeal among children and young people.

(14) Exposure to second-hand smoke and aerosols could be particularly dangerous to children and adolescents and could increase the likelihood of them taking up smoking habits [4,5,6].

(15) In 2023, 54% of current and past smokers are estimated to have started regularly smoking before the age of 19; 14% start before the age of 15, during childhood[1].

(16) The use of emerging products which contain nicotine, in particular by young people, is associated with addiction and might become a starting point for the later use of traditional tobacco products[4].

(17) It is important to take into consideration not only the recent market and technological developments related to emerging products but also to better coordinate and future-proof the national smoke- and aerosol-free regulatory frameworks.

(18) At present, the second-hand exposure to smoke and aerosols in places such as the outdoor spaces of hospitality venues and outdoor spaces intended for use by children and adolescents is significant. Based on 2023 Eurobarometer data, 74% of Eurobarometer respondents say that they have experienced people smoking in outdoor terraces in the past 6 months and 71% of respondents say they have experienced people using electronic cigarettes and heated tobacco products in the same places. 42% of respondents say that people were smoking in outdoor places intended for use by

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20 Glantz, S.A., Nguyen, N., & Oliveira da Silva, A.L. (2024). Population-Based Disease Odds for E-Cigarettes and Dual Use versus Cigarettes. NEJM Evidence, 3(3). DOI: 10.1056/EVIDoa2300229.

21 "Applying tobacco control measures to e-cigarettes, including the supply and demand reduction measures of the WHO FCTC" (page 3, https://cdn.who.int/media/docs/default-source/tobacco-hq/regulating-tobacco-products/ends-call-to-action.pdf?sfvrsn=ea4c4fdb_12&download=true , referring to the Framework Convention on Tobacco Control (page 8, https://iris.who.int/bitstream/handle/10665/42811/9241591013.pdf?sequence=1).

22 SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). Opinion on electronic cigarettes. 16 April 2021.

children and adolescents and 49% of respondents say that they experienced people using electronic cigarettes and heated tobacco products in the same places[1].

(19) Several Member States have taken protective measures including banning smoking in indoor and outdoor places or banning the use of emerging products in public places[23,24].

(20) It is therefore appropriate to extend the scope of the Recommendation to include specific outdoor spaces in order to better protect people in the Union, in particular children, young people and vulnerable people, for instance citizens with chronic diseases or other pre-existing conditions, or pregnant women from exposure to second-hand smoke and aerosols from emerging products, for example heated tobacco products, electronic cigarettes, whether containing nicotine or nicotine-free, and tobacco surrogates, and any other smoke and/or aerosol emitting products.

(21) In support of the revision of the Recommendation, a call for evidence was launched from June until July 2022 and representatives of Member States' competent authorities, civil society organisations, relevant economic operators and other relevant stakeholders were consulted through targeted consultation activities from March-May 2023.

(22) The Commission intends to support Member States in the effective implementation of the Recommendation through existing EU programmes and collaboration tools.

(23) In particular, the Commission envisages to help strengthen research in this field. These research efforts should encompass emerging products (such as electronic cigarettes, whether containing nicotine or nicotine-free, and heated tobacco products); tobacco surrogates that emit smoke or aerosols and any other smoke and/or aerosol emitting product; nicotine releasing products and products resembling the use of nicotine-releasing products. International cooperation, including on research, on the topics covered by this Recommendation, is also envisaged to be strengthened.

(24) The Commission intends to develop a prevention toolkit supporting the better protection of the health of children and young people in the most vulnerable and formative years of their lives, including a focus on prevention from smoking and nicotine addiction, and addressing the interlinks between mental and physical health and key health determinants.

(25) The annexed 'Guidelines on protection from exposure to tobacco smoke, as adopted by the Second Conference of the Parties to the WHO Framework Convention on Tobacco Control' should be taken into account. Member States should be encouraged to expand and go beyond the measures contained in those guidelines.

(26) This Recommendation covers a wider scope than Recommendation 2009/C 296/02 and replaces it, with the objective of better protecting people in the Union from second-hand smoke and aerosols, positively contributing to the tobacco-related objectives of Europe's Beating Cancer Plan and contributing to the reduction of prevalence and de-normalisation of smoking and use of emerging products

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23 Staff working document accompanying the Council Recommendation on Smoke- and Aerosol-Free Environments replacing Council Recommendation 2009/C 296/02, [reference]

24 Study on smoke-free environments and advertisement of tobacco and related products, 2021

HEREBY RECOMMENDS THAT MEMBER STATES:

1. Provide effective protection from exposure to tobacco smoke in indoor workplaces, indoor public places and public transport as stipulated by Article 8 of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) and based on the Guidelines on protection from exposure to tobacco smoke in the Annex that were adopted by the Second Conference of the Parties to the FCTC.

2. Provide effective protection in indoor workplaces, indoor public places, and public transport from exposure to second-hand emissions originating from the use of emerging products that emit smoke or aerosols, for example heated tobacco products, electronic cigarettes, whether containing nicotine or nicotine-free, and tobacco surrogates, and any other smoke and/or aerosol emitting products.

3. Provide effective protection from exposure to second-hand smoke and aerosols in designated outdoor recreational areas, especially where children may often be present. These should include public playgrounds, amusement parks, swimming pools, zoos, and other similar outdoor spaces.

4. Provide effective protection from second-hand smoke and aerosols in any outdoor or semi-outdoor (e.g. partially covered, walled, fenced or otherwise delineated areas next or close to an establishment, including rooftops, balconies, porches or patios) areas associated with service establishments. These should include outdoor spaces of restaurants, bars, cafes, and outdoor spaces of other similar premises.

5. Provide effective protection from second-hand smoke and aerosols in any outdoor or semi-open areas related to public transportation, including at bus, tram and train stops and airports.

6. Provide effective protection from second-hand smoke and aerosols in any outdoor area associated to a place of work.

7. Provide effective protection from second-hand smoke and aerosols in any outdoor area of premises related to healthcare. These should include hospitals, clinics, health centres, nursing homes and other similar premises.

8. Provide effective protection from second-hand smoke and aerosols in any outdoor area of premises that provide education and training to children and young people. Such areas should include pre-school childcare institutions, primary and secondary schools, vocational educational and training institutions, universities, youth centres and other similar premises.

9. Consider the inclusion of other outdoor areas in which members of the public, including children, minors or vulnerable people, are likely to congregate, in complementary actions preventing tobacco and nicotine use and addiction, and contributing to comprehensive smoke- and aerosol-free environments. Such spaces could include among others outdoor areas where events are organised, auditoriums and spectator areas at public events, and spaces associated with buildings open to the public that are likely to see heavy foot traffic (e.g. entrances to shopping malls, courtyards of buildings open to the public).

10. Consider the inclusion of other areas, such as private cars where children, minors or vulnerable people, are present, in complementary actions preventing tobacco and nicotine use and addiction, and contributing to comprehensive smoke- and aerosol-free environments.

11. Develop and/or strengthen smoke- and aerosol-free environments policies namely by:

    a) Developing national strategies and programmes to ensure effective protection from exposure to second-hand smoke and aerosols.

    b) Applying and/or developing prevention, smoking cessation and awareness-raising campaigns such as educational, outreach and information campaigns to ensure compliance with smoke and aerosol-free measures. Such campaigns could also be part of initiatives to reduce addiction. They could be based on and/or supplement prevention initiatives included in Europe's Beating Cancer Plan.

    c) Ensuring that appropriate structures and mechanisms are in place to promote compliance and applying and/or developing best-practices which can improve the implementation and enforcement of smoke- and aerosol-free environments measures.

12. Work together on the exchange of best practices on developing new or strengthening existing smoke and aerosol-free policies, programmes and strategies to ensure they are comprehensive, and on the design and piloting of ambitious and efficient approaches towards achieving smoke- and aerosol-free environments.

13. Cooperate closely among themselves and with the Commission to develop a coherent framework of definitions, benchmarks, and indicators for the effective implementation of this Recommendation, and monitor, evaluate and update its measures, as appropriate.

14. Report to the Commission, namely to the Public Health Expert Group and the Expert Group on Tobacco Policy, on the implementation and progress of the measures taken initially 3 years after the adoption of this Recommendation and every 5 years thereafter.

Recommendation 2009/C 296/02 is replaced by this Recommendation.

Done at Strasbourg,

For the Council
The President