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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Council Recommendation on smoke- and aerosol-free environments replacing Council Recommendation 2009/C 296/02 (legal basis proposed by the Commission: Article 168(6) TFEU) - <i>Adoption</i>

1. On 18 September 2024, the European Commission submitted to the Council a proposal for a Council Recommendation on smoke- and aerosol-free environments replacing Council Recommendation 2009/C 296/02¹, based on Article 168(6) TFEU with the objective of better protecting people in the Union from second-hand smoke and aerosols.
2. The proposal updates the current provisions and extends the scope of the Recommendation to address new products emitting smoke and aerosols and their use in indoor and specific outdoor spaces in light of new evidence and product developments. This Council Recommendation forms part of Europe's Beating Cancer Plan.
3. The Working Party on Public Health examined the proposal at its meetings on 25 September and 10 October 2024 followed by an informal written consultation concluded on 24 October.
4. On 6 November 2024, the Permanent Representatives Committee confirmed the agreement reached in the Working Party on Public Health and agreed to submit the corresponding text² to the EPSCO Council of 3 December 2024 for adoption.

¹ 13519/24 + ADD 1-3

² 14603/24

5. The Council is invited:
- a) to adopt, at its session on 3 December 2024, the Council Recommendation on smoke- and aerosol-free environments replacing Council Recommendation 2009/C 296/02, as set out in the Annex to this note, and
 - b) to enter into the minutes of the Council the statement in the addendum to this note.
6. After the Recommendation has been adopted, it will be published in the Official Journal of the European Union.
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Proposal for a

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 (WHO), 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, 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 were estimated to be smokers¹.
- (3) The global annual economic cost of smoking was estimated at USD 1.4 trillion in 2012, equivalent to 1.8 % of the global gross domestic product (GDP). In 2009, tobacco smoking already cost the EU EUR 544 billion, which is about 4.6 % of the EU27's combined GDP².

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).

- (4) It is appropriate to contribute to reducing smoking rates in the Union, in line with the objective of Europe's Beating Cancer Plan³ to achieve a tobacco-free generation where less than 5 % of the Union population uses tobacco products by 2040.
- (5) The WHO 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 Guidelines annexed to the FCTC aim to assist parties in meeting their obligations under that Article.
- (6) The European Strategy on Tobacco Control adopted by the WHO Regional Committee for Europe in September 2002 recommended that WHO Member States ensure 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 public events, as well as classifying environmental tobacco smoke (ETS) as a carcinogen⁴.
- (7) Second-hand emissions from emerging products can have potentially harmful health impacts. The WHO highlights that second-hand emissions from emerging products can expose people to potentially harmful levels of particulate matter and key toxicants.

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

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

- (8) The WHO^{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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- 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>
- ⁹ 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>
- ¹⁰ 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
- ¹¹ 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
- ¹² 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.
- ¹³ Auer R, Concha-Lozano N, Jacot-Sadowski I, Cornuz J, Berthet A. Heat-not-burn tobacco cigarettes: smoke by any other name. *JAMA Intern Med*. 2017;177(7):1050–2. doi: 10.1001/jamainternmed.2017.1419.
- ¹⁴ 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.
- ¹⁵ 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.
- ¹⁶ Hess I, Lachiredy 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
- 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.

- (9) The WHO considers that no level of side-stream exposure is safe or acceptable⁴, so a careful approach should be taken. The WHO recommends applying tobacco control measures, including protection from exposure, to electronic cigarettes^{21,4,5}.
- (10) In its 2021 opinion on electronic cigarettes²², 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 development of emerging products, such as electronic cigarettes and heated tobacco products, is their particular uptake and appeal among children and young people.

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.

- (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, it was estimated that 54 % of current and past smokers had started regularly smoking before the age of 19, and 14 % before the age of 15, during childhood¹.
- (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 products⁴.
- (17) It is important not only to take into consideration recent market and technological developments related to emerging products but also to better coordinate and future-proof national smoke- and aerosol-free regulatory frameworks.
- (18) At present, there is significant 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. In the 2023 Eurobarometer survey, 74 % of respondents said that they had experienced people smoking in outdoor terraces in the past six months, and 71 % of respondents said they had experienced people using electronic cigarettes and heated tobacco products in such places. 42 % of respondents said that they had experienced people smoking in outdoor places intended for use by children and adolescents, and 49 % of respondents said that they had experienced people using electronic cigarettes and heated tobacco products in such places¹.

- (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 and pregnant women, from exposure to second-hand smoke and aerosols from emerging products such as heated tobacco products; electronic cigarettes, whether containing nicotine or nicotine-free; tobacco surrogates; and any other smoke and/or aerosol emitting products such as herbal products for smoking or heated herbal products.
- (21) In support of the revision of the Recommendation, a call for evidence was launched from June to 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 Council takes note that the Commission intends to support Member States in the effective implementation of the Recommendation through existing Union programmes and collaboration tools.

²³ Staff working document accompanying the Council Recommendation on Smoke- and Aerosol-Free Environments replacing Council Recommendation 2009/C 296/02, 13519/24 ADD2

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

- (23) In particular, the Council takes note that the Commission envisages helping to 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; and 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 Council also takes note that the Commission intends to develop a prevention toolkit supporting better protection of the health of children and young people in the most vulnerable and formative years of their lives, including a focus on the prevention of smoking and nicotine addiction, and addressing the interlinks between mental and physical health and key health determinants.
- (25) The Council also takes note that the Commission intends to report on the progress made in implementing this Recommendation, on the basis of the information provided by Member States, within five years of its adoption.

- (26) 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 on and go beyond the measures contained in those Guidelines.
- (27) This Recommendation covers a broader 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.
- (28) De-normalising smoking and reducing smoking prevalence and the use of emerging products demands a comprehensive set of actions at Union level. Therefore it is important that this Recommendation is coupled with intense work on the evaluation and revision of EU tobacco legislation, notably addressing concerns about young people’s access to novel tobacco and nicotine products.

HEREBY RECOMMENDS THAT MEMBER STATES, having regard to national competences and specificities relating to implementation:

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 FCTC and based on the annexed Guidelines on protection from exposure to tobacco smoke 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; tobacco surrogates; and any other smoke and/or aerosol emitting products such as herbal products for smoking (hereinafter referred to, together with exposure to tobacco smoke, as ‘exposure to second-hand smoke and aerosols’).
3. Provide effective protection from exposure to second-hand smoke and aerosols in designated outdoor recreational areas, especially where children, young and vulnerable people may often be present. These should include public playgrounds, amusement parks, swimming pools, beaches, zoos, and other similar outdoor spaces.
4. Provide effective protection from second-hand smoke and aerosols in outdoor or semi-outdoor areas associated with service establishments (e.g. partially covered, walled, fenced or otherwise delineated areas next or close to an establishment, including rooftops, balconies, porches or patios). 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 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 outdoor areas associated with a place of work.
7. Provide effective protection from second-hand smoke and aerosols in outdoor areas associated with premises related to healthcare. Such premises should include hospitals, clinics, health centres, nursing homes and other similar premises.
8. Provide effective protection from second-hand smoke and aerosols in outdoor areas associated with premises that provide education and training to children and young people. Such premises 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 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 to 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, where applicable in the context of already existing obligations, on the implementation and progress of the measures taken initially three years after the adoption of this Recommendation and every five years thereafter.

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

Done at Brussels,

For the Council
The President
