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COMMISSION STAFF WORKING DOCUMENT

Accompanying the document

Proposal for Council Recommendation

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

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

1. Introduction and context

This report is an informative document supporting the revision of the 2009 Council Recommendation on smoke-free environments¹ and explains its potential health, social, environmental, and economic impacts.

The 2009 Council Recommendation on smoke-free environments was adopted on 30 November 2009 following a consultation process which showed a clear support for the introduction of smoke-free rules. It recommended that EU Member States act in three main areas: 1) Adopt and implement rules to fully protect their citizens from exposure to tobacco smoke in enclosed public places, workplaces and public transport; 2) Enhance smoke-free laws with supporting measures such as protecting children, encouraging efforts to give up tobacco use and pictorial warnings on tobacco packages; 3) Strengthen cooperation at EU level by setting up a network of national focal points for tobacco control.

The Recommendation was also adopted in line with and with the aim of supporting the implementation of the WHO Framework Convention of Tobacco Control (WHO FCTC) to which the Union and all Member States are parties. Article 8 of the FCTC requires its parties to tackle exposure to tobacco smoke in workplaces, public transport and indoor places. The guidelines for its implementation² aim to assist parties in meeting their obligation under Article 8 of the FCTC.

The 2009 Council Recommendation called on Member States to introduce smoke-free environments by November 2012. To follow up on this, in 2013, the Commission published an Implementation Report³ presenting the state of implementation of the Council Recommendation (2009/C 296/02). The report found that all Member States had adopted measures to protect citizens against exposure to tobacco smoke, but that the national measures or policies differed considerably in their extent and scope. As a result of the measures taken, the exposure rates from tobacco smoke dropped from 2009 to 2012. The report also found that the health effects of smoke-free environments are immediate and include a reduction in the incidence of heart attacks and improvements in respiratory health, while the economic effect of smoke-free environments is positive or neutral.

The Council Recommendation on smoke-free environments included only traditional tobacco products, which were perceived to be the main issue at the time, and some public spaces, such as indoor and enclosed spaces, in its scope. Other spaces, including specific outdoor spaces, were only covered based on a case-by-case hazard assessment. In 2009, heated tobacco products had not yet entered the EU market and electronic cigarettes only to a minor extent. The Recommendation therefore targeted only traditional smoking tobacco products by referring to 'tobacco smoke', meaning that it cannot currently be directly applied to emerging products.

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

² WHO Framework Convention on Tobacco Control: <u>Guidelines for implementation of Article 8</u>

³ Report on the implementation of the Council Recommendation of 30 November 2009 on Smoke-free Environments (2009/C 296/02)

The information and evidence presented in this report is based on:

- The 2009 impact assessment accompanying the Council Recommendation (2009/C 296/02), which will be referred to simply as the 'impact assessment' throughout this report⁴
- The 2021 evaluative study on smoke-free environments and advertising of tobacco related products⁵, commissioned by the European Commission's Directorate-General for Health and Food Safety (DG SANTE). It serves as an important document that identifies some shortcomings and gaps of the existing Council Recommendation. It also provides an analysis of the progress made since the earlier 2013 report on the implementation of the 2009 Council Recommendation on smoke-free Environments and analyses the various impacts of smoke-free rules. This study will be referred to simply as 'evaluative study' throughout this report.
- The 2021 WHO Report on the global tobacco epidemic: addressing new and emerging products⁶.
- The 2021 Scientific Opinion of the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) on electronic cigarettes⁷.
- The 2023 Special Eurobarometer report on 'Attitudes of Europeans towards tobacco and electronic cigarettes. This survey report is the most recent in a series and aims to assess the prevalence of tobacco use and exposure to tobacco smoke in public places, to explore the motivations for smoking, and to help identify measures to reduce the number of smokers in the EU and address issues related to electronic cigarettes and heated tobacco products⁸.
- The 2023 WHO Report on the global tobacco epidemic: protect people from tobacco smoke 9
- The 2023 WHO Technical note on the call to action on electronic cigarettes¹⁰
- The 2023 WHO Call to action on electronic cigarettes ¹¹
- The Weight of Evidence paper for the evidence supporting the expansion of Smoke and Aerosol Free Environments (SAFE) in the EU: Assessment of barriers, opportunities, and best practices for SAFE¹². This report is a deliverable of the Work Package 8 of the Joint Action on Tobacco Control (JATC-2)¹³ and aims to

⁴ Accompanying document to the Proposal for a Council recommendation on smoke-free environments - Impact assessment (SEC/2009/0894 final)

⁵ 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

⁶ World Health Organization. Report on the global tobacco epidemic 2021: addressing new and emerging products. 2021. ISBN: 978 92 4 003209 5

⁷ SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). Opinion on electronic cigarettes. 16 April

Special Eurobarometer 539. 2023. Attitudes of Europeans towards tobacco and related products. ISBN: 978-92-68-07599-9 ⁹ World Health Organization. Report on the global tobacco epidemic 2023: protect people from tobacco smoke. 2023. ISBN: 978-92-4-007716-4

¹⁰ World Health Organization. Technical note on the call to action on electronic cigarettes. 2023. https://www.who.int/publications/m/item/technical-note-on-call-to-action-on-electronic-cigarettes

¹¹ World Health Organization. Electronic cigarettes call to action. 2023. https://www.who.int/publications/m/item/electroniccigarettes---call-to-action

¹² Carnicer-Pont, D., et al. 2023. Weight of Evidence (WoE) paper for the evidence supporting the expansion of Smoke and Aerosol Free Environments (SAFE) in the EU: Assessment of barriers, opportunities and best practices. JATC-2. https://jaotc.eu/wp-content/uploads/2023/10/D8.1-Weight-of-eviedence-paper-on-the-evidence-for-supporting-theexpansion-of-smoke-free-environments.pdf

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provide up to date information and address questions on barriers, opportunities, and best practices to support the expansion of smoke- and aerosol-free environments in Member States.

• The Workshop report "Novel tobacco and nicotine products and their effects on health" 14. This document outlines the results of a workshop conducted by the ENVI committee health working group in the European Parliament.

This report also presents the outcomes of the consultation activities conducted in support of the revision. Namely:

- Feedback from 207 responses resulting from the call for evidence on the 'Have your say' platform from 22 June until 20 July 2022¹⁵, through which the Commission invited the public and stakeholders to provide feedback and other relevant input regarding the revision of the Council Recommendation on Smoke-free Environments. Responses were received from citizens (52%), Non-Governmental Organisations (13.5%), business associations, business organisations and trade associations (19%), consumer organisations (3.9%), academic/research institutions (2.9%) and Member State Public authorities (1.9%) and other respondents (7.2%).
- Results of the targeted consultation activities gathering input from the following relevant stakeholder groups: 1) representatives of Member State competent authorities; 2) civil society organisations; 3) Economic Operators in the tobacco and related products industry; 4) representatives from the HORECA sector; 4) other relevant stakeholders such as those in education and sports associations. The targeted consultation activities consisted of a targeted survey, targeted interviews, and focus groups.
- Input and feedback from representatives of Member States competent authorities (26 EU Member States plus Iceland and Norway) who participated in a meeting of the Expert Group on Tobacco Policy organised on 3 May 2023¹⁶.

2. Problem definition and objectives

Problem 1: Emerging products and the risk of exposure to second-hand aerosols is not considered in the current Recommendation

Since 2009, emerging products such as electronic cigarettes and heated tobacco products have consolidated their market shares and their appeal, in particular to young consumers and their use is rapidly becoming a trend among young people in the EU. Based on Eurobarometer data from 2023, the prevalence of electronic cigarette use across the EU is 3% and the prevalence of heated tobacco products use is 2%. A particularly concerning aspect of the uptake of emerging products in recent years has been their appeal among children and young people. The Eurobarometer from 2023 also highlighted that 54% of current and past smokers start regularly before the age of 19 and 14% start before the age of 158.

Second-hand emissions from emerging products have potentially harmful health impacts. The World Health Organization highlights that second-hand emissions from emerging

¹⁴ European Parliament, Directorate-General for Internal Policies of the Union. <u>Novel tobacco and nicotine products and their effects on health.</u> 2023. ISBN: 978-92-848-0226-5

¹⁵ Have Your Say. Smoke-free environments- updated recommendation. <u>Call for evidence</u>. 22 June 2022- 20 July 2022

¹⁶ Flash report of the 20th Meeting of the Expert Group on Tobacco Policy

products expose bystanders to quantifiable levels of particulate matter and key toxicants, albeit at a lower level than from second-hand smoke of traditional tobacco products. In its opinion on electronic cigarettes, a 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. The World Health Organization considers that electronic cigarettes with nicotine are highly addictive and are harmful to health and all tobacco measures should be applied to them ¹⁰ and that no level of exposure is safe or acceptable and that a careful approach should be taken. Given this situation, the revision of the Council Recommendation to include emerging products is justified and appropriate to ensure proper public health protection.

Problem 2: The coverage of outdoor spaces is not specific in the current Recommendation

In the current Council Recommendation (2009/C 296/02) 'indoor' (or enclosed) areas are defined very broadly, i.e. any space covered by a roof or enclosed by one or more walls or sides, regardless of the type of material used for the roof, wall or sides, and regardless of whether the structure is permanent or temporary. Places where groups of people gather, regardless of ownership or right of access, which include outdoor and quasi-outdoor spaces, are only covered based on a case-by-case assessment of possible health hazards by the individual Member States. This means that certain outdoor spaces are not necessarily specifically covered by the Recommendation, despite the risk of possible hazardous exposure to second-hand smoke and aerosols.

In conclusion and given the market developments since 2009, the current situation undermines the objectives of the 2009 Council Recommendation, as it cannot sufficiently address the risks from emerging products or from exposure to second-hand smoke and aerosols in certain outdoor spaces. Therefore, the revision of the 2009 Council Recommendation on Smoke-free Environments is necessary and appropriate in order to contribute to the better protection of people in the EU from second-hand smoke and aerosols, to discourage the uptake of related products and addiction, and to resist any normalisation of such products and behaviour.

Objectives of the new Council Recommendation on Smoke- and Aerosol-free Environments

In response to the issues identified in the above sections, the revision of the current Council Recommendation has the following objectives:

Objective 1

To strengthen the protection of people in the Union from the risks related to the exposure to second-hand smoke originating from the use of traditional tobacco products and second-hand aerosols originating from the use of emerging products.

Objective 2

To encourage current smokers and users of emerging products to quit, which will contribute to the reduction of the prevalence of smoking and use of emerging products. In addition, the Recommendation aims to support the denormalisation the use of traditional tobacco products and the use of emerging products, and fight addiction, especially among young people and discouraging its general social acceptance.

Objective 3

To positively contribute towards the tobacco-related objective set out in Europe's Beating Cancer Plan which is the achievement of a 'Tobacco-Free Generation' where less than 5% of the EU population uses tobacco by 2040, compared to around 24% today.

3. Suggested revisions of the Recommendation

3.1 Specific revisions

The revised Council Recommendation would include the following specific revisions adding towards the already existing ones:

Extension of the scope to specifically include the following emerging products

- Emerging products that emit smoke or aerosols. For example, heated tobacco products and electronic cigarettes (whether containing nicotine or nicotine-free)
- Tobacco surrogates and any other smoke and/or aerosol emitting products

Given the above revisions, the title of the Recommendation has been adapted to include aerosol-free environments.

Extension of the coverage to specifically include the following specific outdoor spaces

- 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;
- 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 to service establishments. These should include outdoor spaces of restaurants, bars, cafes, and outdoor spaces of other similar premises.
- Any outdoor or semi-open areas related to public transportation, including at bus, tram and train stops and airports;
- Any outdoor area associated to a place of work;
- Any outdoor area of premises related to healthcare. These should include hospitals, clinics, health centres, nursing homes and other similar premises;
- 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 institutions, universities, youth centres and other similar premises;

The Recommendation complementarily refers to the following spaces in order to encourage a comprehensive approach:

- Other outdoor areas in which members of the public, including children and minors, are likely to congregate. 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)
- Other areas, such as private cars where children and minors are present.

3.2 Rationale for the revisions

Inclusion of emerging products in the scope

Emerging products emit aerosols and thus expose people, in particular children and young people, to second-hand aerosols. As described under problem 1, these products were not relevant and/or not considered in the 2009 Council Recommendation. The WHO, in its reports on the global tobacco epidemic, highlights those second-hand emissions from emerging products expose bystanders to quantifiable levels of particulate matter and key toxicants, even if at a lower level than from second-hand smoke of traditional tobacco products. There is variation in the conclusions of studies analysing the harms of second-hand exposure to aerosols originating from the use of emerging products. Some studies show that users and bystanders who were exposed to heated tobacco products were exposed to reduced levels of harmful substances, such as tobacco-specific N-nitrosamines, cadmium, polycyclic aromatic hydrocarbons and carbon monoxide, compared to conventional cigarette smoke. However, other studies show that emissions of heated tobacco products may contain higher concentrations of potentially toxic substances, including carcinogenic substances, in higher amounts than in conventional cigarette smoke¹⁷. In addition, the WHO^{6,9,10,11}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 18,19,20,21,22,23. In addition, second-hand aerosols from electronic cigarettes, both with and without nicotine, expose bystanders to quantifiable levels of particulate matter and key toxicants and contaminants 24,25,26,27,28,29,30. For context, the WHO considers that electronic cigarettes with nicotine are highly addictive and harmful to health 10,11.

¹⁷ European Parliament, Directorate-General for Internal Policies of the Union. <u>Novel tobacco and nicotine products and their effects on health.</u> 2023. ISBN: 978-92-848-0226-5

¹⁸ World Health Organisation. Heated tobacco products: summary of research and evidence of health impacts. 2023. p. 12-13. https://www.who.int/publications/i/item/9789240042490

¹⁹ World Health Organisation: 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

²⁰ 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

²¹ 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

²² 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.

²³ Auer R, Concha-Lozano N, JacotSadowski 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.

²⁴ 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.

²⁵ 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.

²⁶ 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).

²⁷ 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.

²⁸ Exposure to aerosols from smoking-proxy electronic inhaling systems: a systematic review. Barcelona: Tobacco Control Unit, Institut Català d'Oncologia; 2016.

²⁹ 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

³⁰ 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.

In its opinion on electronic cigarettes, the SCHEER concluded that there is weak to moderate evidence of risks of respiratory, cardiovascular and carcinogenic damage due to second-hand exposure to e-cigarette aerosols. For second-hand exposed persons, the overall weight of evidence is moderate for risks of local irritative damage to the respiratory tract mainly due to exposure to glycols; the overall weight of evidence for risks of systemic cardiovascular effects in second-hand exposed persons due to exposure to nicotine is weak to moderate; the overall weight of evidence for carcinogenic risk due to cumulative exposure to nitrosamines is weak to moderate. In addition, in a recently published call to action, the WHO highlights that electronic cigarettes with nicotine are highly addictive and are harmful to health and all tobacco control measures should be applied to them ¹⁰. Electronic cigarettes are relatively new in terms of exposure to humans and a continuous development of research and of the evidence base should be pursued, in particular on their long-term health effects.

In addition to this, emerging products are often marketed and promoted by the tobacco industry as 'safer' alternatives to conventional tobacco products and thus as useful smoking cessation tools. However, the evidence on the use of emerging products as a cessation aid is inconclusive. In fact, in its opinion on electronic cigarettes the SCHEER concluded that "There is a lack of robust longitudinal data on the effect of electronic cigarettes on smoking cessation. Until such research is available, electronic cigarettes should only be considered to support smoking cessation for a limited time and under supervision". Moreover, the WHO report on the global tobacco epidemic highlights that, in some cases, emerging products containing nicotine could hinder smoking cessation efforts in some individuals by prolonging or increasing their addiction to nicotine. Data from the 2023 Eurobarometer report show that for 42% of the respondents, using electronic cigarettes or any similar devices did not result in a decrease of their tobacco consumption.

Taking into consideration the scientific assessment of the SCHEER and the WHO reports, it is clear that second-hand exposure to aerosols from emerging products is potentially harmful. The WHO considers that no level of exposure that is safe or acceptable. Taking into consideration the EU's precautionary principle³¹, which can be applied in cases where potentially dangerous effects from a product, among other things, have been identified, and where scientific evaluation does not allow the risk to be determined with sufficient certainty, it is important that the current Recommendation is updated to specifically include emerging products in its scope to fulfil its main objective of protecting people from the harms of second-hand smoke and aerosol exposure.

Some emerging products may contain nicotine which is a highly addictive substance which poses a risk of addiction. Nicotine can have harmful impacts in particular on brain development, leading to long-term consequences for children and adolescents. Given that many emerging products are marketed to be attractive to young people, they have been taken up by many adolescents and children in the Union. Young people who experiment with emerging products are more likely to progress to regular use of conventional tobacco products than those who do not^{32,7} In addition, emerging products are often used as complements to cigarette smoking and not as substitutes, especially in the smoke-free environments where their use is banned. This can result in 'dual use' where many users of emerging products use both these products and conventional tobacco products, such as cigarettes³³, moreover, this can result in

³¹ Communication from the Commission on the precautionary principle (COM/2000/0001 final)

³² According to the 2020 Eurobarometer, among 15-24-year-olds who were users of electronic cigarettes, 16.9% transitioned to regular users. The SCHEER opinion refers to a study showing that the pooled probabilities of cigarette smoking initiation were 30.4% for baseline electronic cigarette users while it was 7.9% for baseline never electronic cigarette users.

³³ According to the 2020 Eurobarometer, 59% of users of electronic cigarettes were dual users.

situations where dual 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 ^{6,34,35,36}. This pattern of consumption may also sustain prolonged nicotine dependence and is associated with increased risk of respiratory and cardiovascular conditions relative to single use⁶.

It is important to note that, in some cases, the use of emerging products has also been linked to physical injuries, including burns from explosions or malfunctions. In addition, accidental exposure to high nicotine concentrations in the e-liquid and accidental ingestion of the e-liquid are also some concerns associated with their use^{6,7}.

The proposed Council Recommendation on Smoke- and Aerosol-free Environments includes an extension to emerging products which may not contain nicotine. Although some emerging products, specifically electronic cigarettes, do not contain nicotine, they may still contain various flavours which can increase their palatability and aid in their marketing towards children and young people. Some of the flavours used within these products have been shown to increase their toxicity in their aerosols⁵. In addition, it is important to note that while some electronic cigarettes are said not to contain nicotine, in practice many e-liquids marked as containing "zero-nicotine" have been found to contain nicotine when tested⁶. Moreover, the WHO highlights that there are health concerns related to the e-liquid contained in electronic cigarettes, which might contain potentially harmful components, which when inhaled may have long-term health impacts. In addition, the act of using emerging products, even those that do not contain nicotine, mimics the use of conventional cigarettes, which is a behavioural pattern that can prevent those trying to quit tobacco from doing so successfully; it may even contribute to the renormalisation of smoking leading to non-smokers, particularly children and young people, taking up the use of conventional tobacco products, such as cigarettes⁶. Given this evidence, if not included in smoke- and aerosol-free rules these emerging products can potentially generate loopholes and could be exploited by commercial interests.

Although some Member States already include emerging products in their smoke- and aerosol-free policies, the level of coverage and approach of inclusion of these products differs considerably among the Member States. Some Member State approaches may not comprehensively cover electronic cigarettes that contain nicotine (e.g. Bulgaria) or electronic cigarettes without nicotine (e.g. Ireland) while others do not encompass tobacco surrogates that may emit smoke or aerosols (e.g. Spain, Lithuania). Other national approaches include all nontobacco oral nicotine products as part of smoking bans (e.g. Netherlands). Moreover, countries report that a major related challenge in this area is the need to "denormalise" the use of all types of tobacco and nicotine products. This was mentioned as being helpful for the enforcement of legislation (e.g. Latvia). An additional challenge with emerging products is that they are more difficult to detect (e.g. Belgium), even as their use especially among young people, becomes an increasing concern (e.g. Denmark).

Inclusion of specific outdoor spaces in the scope of the proposed Council Recommendation

³⁴ 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.

³⁵ 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

³⁶ 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.

At present, there is a significant exposure to second-hand smoke and aerosols in various outdoor spaces such as the outdoor spaces of hospitality venues, outdoor spaces intended for children and outdoor spaces of public spaces. In addition, the level of protection from exposure to second-hand smoke and aerosols in indoor spaces varies in Member States.

The level of coverage of smoke-free rules varies greatly based on the type of smoke-free environments, and the general level of coverage of outdoor spaces in smoke-free policies is low. The level of coverage also varies based on the product considered: while the implementation is good for traditional products for smoking, it is less the case for heated tobacco products and electronic cigarettes. Overall, Member States which have stricter rules for tobacco products also have stricter rules for emerging products⁵. A few Member States have a comprehensive approach of including outdoor spaces in national smoking bans (e.g. Latvia broadly protects educational and healthcare premises, outdoor recreational areas, public spaces, outdoor spaces of work areas, restaurant terraces and public transportation hubs). Many Member States, however, have narrower approaches, explicitly covering only a limited set of outdoor spaces (e.g. Slovakia). Member States report challenges related to implementation and enforcement of bans in outdoors spaces (e.g. open public transportation hubs in Sweden) and note that these increase if different rules apply to different products (e.g. Finland).

Based on 2023 Eurobarometer data, 74% of respondents said that they have experienced people smoking in outdoor terraces in the past 6 months and 71% of respondents have experienced people using electronic cigarettes and heated tobacco products in the same places. 42% of respondents said that people were smoking in outdoor places intended for use by children and adolescents and 49% of respondents experienced people using electronic cigarettes and heated tobacco products in the same places.

Various studies show that the use of emerging products raises airborne concentrations of particulate matter above baseline levels when measured indoors. The levels of nicotine, particulate matter and potential carcinogens in second-hand aerosols exceed the maximum recommended levels set out in the WHO FCTC guidelines. This is of importance because exposure to particulate matter generated through the use of emerging products has been associated with increased risk of heart and lung disorders^{6,9}. The 2021 evaluative study highlights that the locations with the highest exposure to electronic cigarettes and heated tobacco products are workplaces, public parks and bars.

A literature review conducted within the context of the Joint action for Tobacco Control (JACT-2) found that several studies using environmental markers to assess second-hand smoke exposure in various places including in the hospitality sector, work areas and outdoor settings indicate high second-hand smoke exposure in these settings¹². These figures show that people in the EU, especially children and young people, can be better protected from second-hand smoke and second-hand aerosols.

The 2023 Eurobarometer results highlight that two thirds of the respondents in the EU (66%) are in favour of banning the use of electronic cigarettes or heated tobacco products in places where smoking is prohibited. The proposed extension of coverage of the existing Recommendation to the outdoor spaces mentioned in this section of this report would extend the protection of people through a more comprehensive Council Recommendation.

4. Impacts of the proposed measures of the revision

Health and Social impact

By reducing exposure to second-hand smoke and aerosols, the revised Council Recommendation on Smoke and Aerosols free environments is expected to have positive impacts on health and result in reduced morbidity and mortality associated to the consumption and exposure of smoking tobacco and emerging products. The impact assessment for the 2009 Council Recommendation on smoke-free environments³⁷ showed that smoke-free policies may reduce smoking prevalence and result in health benefits. In addition, due to the inclusion of emerging products and specific outdoor spaces, there will be less risk of unintended exposure to second-hand smoke and aerosols which results in maximising protection of people in the EU from hazardous exposure.

This positive impact was expressed by the majority of respondents during the consultation activities for the revision and in the responses to the call for evidence for this initiative, particularly by representatives of Member States competent authorities and civil society organisations who highlighted the positive impact of the initiative in protecting children and adolescents from exposure to second-hand smoke and aerosols. Representatives of employees of the HORECA sector highlighted the positive impact of this initiative on the health and wellbeing of their employees. Additionally, representatives of Member States competent authorities, during the meeting of the Expert Group on Tobacco Policy, highlighted that this initiative is a timely measure given its particular benefit to children and young people. In contrast, the response from industry regarding the health impacts of the revision of the Recommendation was different: only a minority believed that the revision would have a positive health impact.

The 2021 evaluative study on smoke-free environments and advertising of tobacco related products highlights that smoke-free legislation results in a significant decrease in smoking. Smoking cessation is likely to increase among smokers who are exposed to a smoke-free law, a systematic review found a 6.4% increase in smoking cessation among smokers exposed to a smoke-free law³⁸. The evaluative study also highlights that positive impacts appear promptly after starting to implement smoke-free legislation (for example, reduction in the incidence of heart attacks in the general population and improvements in respiratory health) and enacting national legislative smoking bans leads to improved health outcomes for smokers and non-smokers in terms of cardiovascular, respiratory, perinatal health outcomes and reduced mortality. A systematic review demonstrated that across 21 countries, enacting national legislative smoking bans, there were improved health outcomes for smokers and non-smokers in terms of cardiovascular, respiratory, and perinatal health outcomes³⁹. In Ireland, which was the first country in the world to implement a national workplace smoking ban in March 2004, the smoking ban was associated with reductions in early mortality⁴⁰. Similarly in Belgium, a study showed that smoking ban interventions were associated with reductions in the population

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³⁷ Accompanying document to the Proposal for a Council recommendation on smoke-free environments - <u>Impact assessment (SEC/2009/0894 final)</u>

³⁸ Hopkins, D. P., Razi, S., Leeks, K. D., Priya Kalra, G., Chattopadhyay, S. K., & Soler, R. E. (2010). Smokefree policies to reduce tobacco use: A systematic review. Cochrane Database of Systematic Reviews, (2), CD005992

³⁹ Frazer, K., Callinan, J. E., McHugh, J., van Baarsel, S., Clarke, A., Doherty, K., & Kelleher, C. (2016). Legislative smoking bans for reducing harms from secondhand smoke exposure, smoking prevalence and tobacco consumption. Cochrane Database of Systematic Reviews, (2), CD005992

⁴⁰ Stallings-Smith, S., Zeka, A., Goodman, P., Kabir, Z., & Clancy, L. (2013). Reductions in cardiovascular, cerebrovascular, and respiratory mortality following the national Irish smoking ban: interrupted time-series analysis. PLOS ONE, 8(6), e62063

rate of myocardial mortality, with public health gains even before and during the middle-age period of life ⁴¹.

Comprehensive smoke-free legislation has increased benefits in comparison to partial smoke-free bans (comprehensive smoke-free legislation or policies means without exemptions or permission to smoke/use emerging products in certain spaces). Comprehensive laws have a positive effect on quit attempts and quit success while partial smoke-free laws have no such impacts⁴². In addition, the introduction of comprehensive smoke-free policies results in increased public support for such smoke-free rules: a study from France, Germany and the Netherlands indicated that support for smoke-free rules increases once they are in place, and that this effect is more pronounced with comprehensive compared to partial smoke-free policies⁴³. This points to the likelihood that more comprehensive smoke- and aerosol-free rules might be a beneficial policy option.

Smoke-free rules can also reduce health disparities between socio-economic groups although the results of some studies are mixed in some cases⁵. Voluntary regional or partial smoke-free policies are more likely to have negative equity impact in comparison to national and comprehensive smoke-free policies and rules⁴⁴. The effect of non-comprehensive and differing smoke-free rules among the Member States is seen in the existing inequalities among the Member States. Some representatives of Member States competent authorities, during the meeting of the Expert Group on Tobacco Policy expressed the importance of smoke- and aerosol- free rules being uniform across Member States in order to reduce inequalities in the exposure and consequently in health outcomes. In the consultation activities, representatives from Member States and civil society organisations have also highlighted that this initiative will also result in better public support for the expansion of smoke- and aerosol-free rules at the national level. In connection to this, during the meeting of the Expert Group on Tobacco Policy and in the responses to the call for evidence, it was highlighted that the revision of the 2009 Council Recommendation would be helpful in Member States to overcome political challenges. This initiative would therefore offer an important opportunity to coordinate smokeand aerosol-free legislation both within and between Member States and help introduce more comprehensive and ambitious smoke- and aerosol-free policies. As a result, this comprehensive approach will have a positive impact on the denormalisation of smoking and use of emerging products as well as help in the fight against nicotine addiction, especially among young people.

Economic impact

The economic analysis included in the impact assessment accompanying the 2009 Council Recommendation is largely still valid even if the proposal for a revised Recommendation has an extended scope and coverage in terms of products and spaces. The impact assessment accompanying the 2009 Council Recommendation and the 2021 evaluative study both showed that for the 2009 Recommendation the potential negative impact was outweighed by the

⁴¹ Cox B, Vangronsveld J, Nawrot TSImpact of stepwise introduction of smoke-free legislation on population rates of acute myocardial infarction deaths in Flanders, BelgiumHeart 2014;100:1430-1435.

⁴² Nagelhout, G. E., de Vries, H., Boudreau, C., Allwright, S., McNeill, A., van den Putte, B., Fong, G. T., & Willemsen, M. C. (2012). Impact of smoke-free legislation on smoking cessation in three European countries. European Journal of Public Health, 22(suppl 1), 4-9

⁴³ Mons, U., Nagelhout, G.E., Guignard, R., McNeill, An. Van de Putten, B., Willemsen, M.C., Brenner, H., Potschke-Lange, M., & Breitling, L.P. (2012). Comprehensive smoke-free policies attract more support from smokers in Europe than partial policies. European Journal of Public Health, 22(suppl_1), 10-16

⁴⁴ Brown, T., Platt, S., & Amos, A. (2014). Equity impact of population-level interventions and policies to reduce smoking in adults: A systematic review. Drug and Alcohol Dependence, 138, 7-16. https://doi.org/10.1016/j.drugalcdep.2014.03.001

positive economic impact. 45 The consultation activities carried out in preparation of the proposal for a revised Recommendation confirm this finding.

The impact assessment highlights that there will be reductions in medical costs as a result of smoke-free rules. This assessment is also confirmed by the 2021 evaluative study and the consultation activities. Throughout the consultation activities, the positive long-term health gains resulting from the revision were further highlighted.

The 2021 evaluative study highlighted that any lost taxation revenue due to a decrease in smoking levels would be offset by the alternative investments and expenditures of the disposable income of households. Throughout the consultation activities, the loss of taxation revenue was not an issue which was particularly highlighted by the Member States. When this was mentioned, it was rather highlighted as one of the possible challenges that could be raised by the national Ministries of finance when trying to implement the revised provisions of the smoke- and aerosol-free environments at the national level. Some civil society organisations highlighted that the long-term reduction of mortality and morbidity from tobacco related diseases, the subsequent reduction of the cost to treat tobacco-related diseases and the substantial environmental benefits (such as reduction in waste and the reduction of deforestation as a result of tobacco growing) will outweigh any loss of income from tobacco taxation.

The impact assessment highlights several potential microeconomic benefits of smoke-free rules, including reducing cleaning, maintenance, redecorating, and fire damage costs and highlights its total savings. The 2021 evaluative study also reached a similar conclusion, it points to research showing that businesses that allow smoking experience higher cleaning and maintenance costs than those that are smoke-free^{46, 47}. The consultation activities show that this conclusion is also corroborated by Member States' representatives, civil society organisations and some representatives from the HORECA sector. Another impact highlighted in the impact assessment is the potential productivity gains that could be expected from a reduced number of smoking breaks due to the introduction of smoke-free bans. This aspect was also highlighted by the 2021 evaluative study which shows that a few Member States reported an increase in workers productivity related to smoking breaks. In addition, that study also shows the views from a representative from the hospitality sector who noted that smoke-free rules had a positive health impact on the health of the employees and in turn on their productivity and presenteeism. However, the impact assessment and the evaluative study also note that there might be a loss of productivity due to the time spent by smoking workers or employees to find an appropriate place to smoke or their ability to concentrate less due to the reduced opportunities to smoke.

Regarding the economic impact of the initiative, the 2021 evaluative study highlights that the overall economic impact of smoking bans on the hospitality and tobacco industry is limited, and that smoke-free policies had either limited negative economic impact or a positive impact. This analysis is to a large extent still valid for the proposal for a revised Recommendation.

The impact assessment showed that there would be no negative economic impact from the introduction of smoke-free policies in restaurants and bars. This conclusion is corroborated by

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⁴⁵ European Commission, Directorate-General for Health and Food Safety. <u>Study on smoke-free environments and</u>

advertising of tobacco and related products. 2021. ISBN: 978-92-76-42343-0 (p. 157-162).

46 Ekpu, V. U., & Brown, A. K. (2015). The Economic Impact of Smoking and of Reducing Smoking Prevalence: Review of Evidence. Tobacco Use Insights, 8, 1-35

⁴⁷ Javitz, H. S., Zbikowski, S. M., Swan, G. E., & Jack, L. M. (2006). Financial burden of tobacco use: an employer's perspective. Clinics in Occupational and Environmental Medicine, 5(1), 9-29

the results of the evaluative study which shows that the economic impact of smoking bans on the restaurant/hospitality sector is limited (neutral or positive)⁴⁸. During the consultation activities supporting this initiative, two representatives from the hospitality sector participated and shared opposing views about the economic impact on hospitality businesses: while one highlighted that the extension of scope of the Recommendation might result in loss of customers in premises such as hotels, bars and restaurants, the other highlighted that some of the concerns related to the negative economic impact for hospitality businesses are 'unfounded' and that it is likely that it would not have any major negative economic impacts. The 2021 evaluative study provides some national examples: in Norway, where the ban on smoking was extended to all drinking and eating establishments in 2004, the smoke-free law had no longterm impact on the revenue of these establishments even if there was a short-term negative effect ⁴⁹. Similarly, in Hungary an amendment strengthening the Protection of Non-Smokers Act came into effect in 2012 in an effort to minimise exposure to second-hand smoke. This amendment was followed by an increase in the number of hospitality venues (i.e. restaurants, confectioneries, drink shops, music clubs), an increase in the income of the hospitality industry, as well as an increase in guest flow and income from accommodation charges. Finally, in Belgium the smoking ban came to effect in January 2007 and no negative impacts were observed in terms of the number of restaurants and the revenues for the hospitality sector.

The impact assessment showed that the expected negative impact of introducing smoke-free rules would be relatively small despite the potential reduction in the sales of tobacco or related products. This is demonstrated through the revenue loss estimation done as part of the impact assessment. The 2021 evaluative study highlights potential job losses due to the introduction of smoke-free rules in some Member States, however, these losses can be offset by increased employment in other sectors as the money once spent on cigarettes is spent on other goods and services. During the consultation activities, the response from representatives of the tobacco industry was that the revision of the Recommendation and its extension of scope would result in a reduction of demand for both traditional tobacco products as well as emerging products such as electronic cigarettes which would also lead to reduced employment levels in the tobacco and emerging products sector. Nevertheless, no quantitative or factual estimation information was provided in support the mentioned negative effects and concerns. Throughout the consultation activities, particularly throughout the targeted survey, a common pattern of responding with 'don't' know or can't answer' was observed for questions related to the economic impact of the initiative.

The impact assessment highlights that the implementation and enforcement costs, which might arise as a result of smoke-free bans for both public authorities and private actors, are likely to be small compared to the costs savings achieved through the health benefits from the reduction of medical costs related to tobacco-related issues. The potential implementation and enforcement costs were an issue raised by Member State representatives during the consultation activities. Although representatives from Member States competent authorities throughout the consultation activities have noted that they might experience higher costs in the short term, the long-term public health and societal benefits would outweigh these costs.

Environmental impact

The WHO notes that second-hand exposure to e-cigarette vapour is a new air contamination source for particulate matter, including fine and ultrafine particles, as well as some heavy

⁴⁸ Brown, T. J., Platt, S., & Amos, A. (2014). Systematic review and meta-analysis of the economic impact of smoking bans in restaurants and bars. Addiction, 109(5), 720-727

⁴⁹ Melberg, H. O., & Lund, K. E. (2012). Do smoke-free laws affect revenues in pubs and restaurants? European Journal of Health Economics, 13(1), 93-99

metals⁶. Smoke-free rules may improve air-quality, this fact was corroborated by several representatives of civil society organisations and Member State representatives during the consultation activities.

The 2021 evaluative study highlights that, for example, the level of air pollution inside smoke-free Irish pubs was 93% lower than the level found in Irish pubs where smoking was permitted ⁵⁰. Similarly, in New Zealand, it was found that air quality improved in hospitality venues following a smoke-free law in 2004⁵¹. In Greece, hospitality venues were assessed for their indoor concentrations of particulate matter (PM2.5), before and after the smoke-free legislation implemented in 2010. Indoor air levels of PM2.5 attributable to second-hand smoke dropped by more than a third following the transition from a partial to a complete ban⁵². In Spain, after the 2011 Spanish smoking ban, both nicotine and PM2.5 concentrations decreased by more than 90% in indoor hospitality venues in three Spanish regions⁵³.

The proposed inclusion of specific outdoor spaces in the Council Recommendation would result in environmental benefits by reducing emissions, thus having a positive impact on air quality and by reducing waste. In particular, by reducing littering and the use and disposal of single-use plastics. Moreover, when consulted on the proposed revisions, the Joint Action on Tobacco Control noted that the mention of open outdoor spaces such as parks is relevant as these places suffer from the environmental pollution caused by all kinds of tobacco products (cigarette butts, plastic filters from Roll Your Own and disposable devices from electronic cigarettes). They also highlighted that smoking combustible tobacco products in natural areas is a well characterised risk factor for fires which creates a hazardous situation for environmental safety.

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⁵⁰ Connolly, G. N., Carpenter, C. M., Travers, M. J., Cummings, K. M., Hyland, A., Mulcahy, M., & Clancy, L. (2009). How smoke-free laws improve air quality: a global study of Irish pubs. Nicotine & Tobacco Research, 11(6), 600-605 ⁵¹ Edwards, R., Thomson, G., Wilson, N., Waa, A., Bullen, C., O'Dea, D., Gifford, H., Glover, M., Laugesen, M., & Woodward, A. (2008). After the smoke has cleared: evaluation of the impact of a new national smoke-free law in New Zealand. Tobacco Control, 17(1), e2

⁵² Vardavas, C. I., Anagnostopoulos, N., Patelarou, E., Minas, M., Nakou, C., Dramba, V., Giourgouli, G., Bagkeris, E., Gourgoulianis, K., Pattaka, P., Antoniadis, A., Lionis, C., Bertic, M., Dockery, D., Connolly, G. N., & Behrakis, P. K. (2012). Five-year trends of second-hand smoke exposure in Greece: a comparison between complete, partial, and prelegislation levels. Tobacco Control, 21(5), 473-477

⁵³ María J. López PhD, Esteve Fernández PhD, Mónica Pérez-Rios PhD, Jose M. Martínez-Sánchez PhD, Anna Schiaffino MPH, Iñaki Galán PhD, Albert Moncada BsC, Marcela Fu PhD, Agustín Montes PhD, Esteve Saltó MPH, Manel Nebot PhD. "Impact of the 2011 Spanish Smoking Ban in Hospitality Venues: Indoor Secondhand Smoke Exposure and Influence of Outdoor Smoking." Nicotine & Tobacco Research, vol. 15, no. 5, 2013, pp. 992–996