



Council of the
European Union

196681/EU XXVII. GP
Eingelangt am 18/09/24

Brussels, 18 September 2024
(OR. en)

Interinstitutional File:
2024/0230(NLE)

13519/24
ADD 1

SAN 522
SOC 659

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	18 September 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2024) 55 final
Subject:	ANNEXES to the Proposal for a COUNCIL RECOMMENDATION on Smoke- and Aerosol-Free Environments replacing Council Recommendation 2009/C 296/02

Delegations will find attached document COM(2024) 55 final.

Encl.: COM(2024) 55 final



EUROPEAN
COMMISSION

Strasbourg, 17.9.2024
COM(2024) 55 final

ANNEX

ANNEXES

to the

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}

ANNEX

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

PURPOSE, OBJECTIVES AND KEY CONSIDERATIONS

Purpose of the guidelines

1. Consistent with other provisions of the WHO Framework Convention on Tobacco Control and the intentions of the Conference of the Parties, these guidelines are intended to assist Parties in meeting their obligations under Article 8 of the Convention. They draw on the best available evidence and the experience of Parties that have successfully implemented effective measures to reduce exposure to tobacco smoke.
2. The guidelines contain agreed upon statements of principles and definitions of relevant terms, as well as agreed upon recommendations for the steps required to satisfy the obligations of the Convention. In addition, the guidelines identify the measures necessary to achieve effective protection from the hazards of second-hand tobacco smoke. Parties are encouraged to use these guidelines not only to fulfil their legal duties under the Convention, but also to follow best practices in protecting public health.

Objectives of the guidelines

3. These guidelines have two related objectives. The first is to assist Parties in meeting their obligations under Article 8 of the WHO Framework Convention, in a manner consistent with the scientific evidence regarding exposure to second-hand tobacco smoke and the best practice worldwide in the implementation of smoke-free measures, in order to establish a high standard of accountability for treaty compliance and to assist the Parties in promoting the highest attainable standard of health. The second objective is to identify the key elements of legislation necessary to effectively protect people from exposure to tobacco smoke, as required by Article 8.

Underlying considerations

4. The development of these guidelines has been influenced by the following fundamental considerations:
 - (a) The duty to protect from tobacco smoke, embodied in the text of Article 8, is grounded in fundamental human rights and freedoms. Given the dangers of breathing second-hand tobacco smoke, the duty to protect from tobacco smoke is implicit in, inter alia, the right to life and the right to the highest attainable standard of health, as recognised in many international legal instruments (including the Constitution of the World Health Organisation, the Convention on the Rights of the Child, the Convention on the Elimination of all Forms of Discrimination against Women and the Covenant on Economic, Social and Cultural Rights), as formally incorporated into the preamble of the WHO Framework Convention and as recognised in the constitutions of many nations.
 - (b) The duty to protect individuals from tobacco smoke corresponds to an obligation by governments to enact legislation to protect individuals against

threats to their fundamental rights and freedoms. This obligation extends to all persons, and not merely to certain populations.

- (c) Several authoritative scientific bodies have determined that second-hand tobacco smoke is a carcinogen. Some Parties to the WHO Framework Convention (for example, Finland and Germany) have classified second-hand tobacco smoke as a carcinogen and included the prevention of exposure to it at work in their health and safety legislation. In addition to the requirements of Article 8, therefore, Parties may be obligated to address the hazard of exposure to tobacco smoke in accordance with their existing workplace laws or other laws governing exposure to harmful substances, including carcinogens.

STATEMENT OF PRINCIPLES AND RELEVANT DEFINITIONS UNDERLYING PROTECTION FROM EXPOSURE TO TOBACCO SMOKE

Principles

- 5. As noted in Article 4 of the WHO Framework Convention, strong political commitment is necessary to take measures to protect all persons from exposure to tobacco smoke. The following agreed upon principles should guide the implementation of Article 8 of the Convention.

Principle 1

- 6. Effective measures to provide protection from exposure to tobacco smoke, as envisioned by Article 8 of the WHO Framework Convention, require the total elimination of smoking and tobacco smoke in a particular space or environment in order to create a 100 % smoke-free environment. There is no safe level of exposure to tobacco smoke, and notions such as a threshold value for toxicity from second-hand smoke should be rejected, as they are contradicted by scientific evidence. Approaches other than 100 % smoke-free environments, including ventilation, air filtration and the use of designated smoking areas (whether with separate ventilation systems or not), have repeatedly been shown to be ineffective and there is conclusive evidence, scientific and otherwise, that engineering approaches do not protect against exposure to tobacco smoke.

Principle 2

- 7. All people should be protected from exposure to tobacco smoke. All indoor workplaces and indoor public places should be smoke free.

Principle 3

- 8. Legislation is necessary to protect people from exposure to tobacco smoke. Voluntary smoke-free policies have repeatedly been shown to be ineffective and do not provide adequate protection. In order to be effective, legislation should be simple, clear and enforceable.

Principle 4

- 9. Good planning and adequate resources are essential for successful implementation and enforcement of smoke-free legislation.

Principle 5

10. Civil society has a central role in building support for and ensuring compliance with smoke-free measures, and should be included as an active partner in the process of developing, implementing and enforcing legislation.

Principle 6

11. The implementation of smoke-free legislation, its enforcement and its impact should all be monitored and evaluated. This should include monitoring and responding to tobacco industry activities that undermine the implementation and enforcement of the legislation, as specified in Article 20.4 of the WHO Framework Convention.

Principle 7

12. The protection of people from exposure to tobacco smoke should be strengthened and expanded, if necessary; such action may include new or amended legislation, improved enforcement and other measures to reflect new scientific evidence and case study experiences.

Definitions

13. In developing legislation, it is important to use care in defining key terms. Several recommendations as to appropriate definitions, based on experiences in many countries, are set out here. The definitions in this section supplement those already included in the WHO Framework Convention.

‘Second-hand tobacco smoke’ or ‘environmental tobacco smoke’

14. Several alternative terms are commonly used to describe the type of smoke addressed by Article 8 of the WHO Framework Convention. These include ‘second-hand smoke’, ‘environmental tobacco smoke’, and ‘other people's smoke’. Terms such as ‘passive smoking’ and ‘involuntary exposure to tobacco smoke’ should be avoided, as experience in France and elsewhere suggests that the tobacco industry may use these terms to support a position that ‘voluntary’ exposure is acceptable. ‘Second-hand tobacco smoke’, sometimes abbreviated as ‘SHS’, and ‘environmental tobacco smoke’, sometimes abbreviated ‘ETS’, are the preferable terms; these guidelines use ‘second-hand tobacco smoke’.
15. Second-hand tobacco smoke can be defined as ‘the smoke emitted from the burning end of a cigarette or from other tobacco products usually in combination with the smoke exhaled by the smoker’.
16. ‘Smoke-free air’ is air that is 100 % smoke free. This definition includes, but is not limited to, air in which tobacco smoke cannot be seen, smelled, sensed or measured¹

‘Smoking’

17. This term should be defined to include being in possession or control of a lit tobacco product regardless of whether the smoke is being actively inhaled or exhaled.

‘Public places’

18. While the precise definition of ‘public places’ will vary between jurisdictions, it is important that legislation define this term as broadly as possible. The definition used should cover all places accessible to the general public or places for collective use, regardless of ownership or right to access.

¹ It is possible that constituent elements of tobacco smoke may exist in air in amounts too small to be measured. Attention should be given to the possibility that the tobacco industry or the hospitality sector may attempt to exploit the limitations of this definition.

‘Indoor’ or ‘enclosed’

19. Article 8 requires protection from tobacco smoke in ‘indoor’ workplaces and public places. Because there are potential pitfalls in defining ‘indoor’ areas, the experiences of various countries in defining this term should be specifically examined. The definition should be as inclusive and as clear as possible, and care should be taken in the definition to avoid creating lists that may be interpreted as excluding potentially relevant ‘indoor’ areas. It is recommended that ‘indoor’ (or enclosed) areas be defined to include 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.

‘Workplace’

20. A ‘workplace’ should be defined broadly as ‘any place used by people during their employment or work’. This should include not only work done for compensation, but also voluntary work, if it is of the type for which compensation is normally paid. In addition, ‘workplaces’ include not only those places at which work is performed, but also all attached or associated places commonly used by the workers in the course of their employment, including, for example, corridors, lifts, stairwells, lobbies, joint facilities, cafeterias, toilets, lounges, lunchrooms and also outbuildings such as sheds and huts. Vehicles used in the course of work are workplaces and should be specifically identified as such.
21. Careful consideration should be given to workplaces that are also individuals' homes or dwelling places, for example, prisons, mental health institutions or nursing homes. These places also constitute workplaces for others, who should be protected from exposure to tobacco smoke.

‘Public transport’

22. Public transport should be defined to include any vehicle used for the carriage of members of the public, usually for reward or commercial gain. This would include taxis.

THE SCOPE OF EFFECTIVE LEGISLATION

23. Article 8 requires the adoption of effective measures to protect people from exposure to tobacco smoke in (1) indoor workplaces, (2) indoor public places, (3) public transport, and (4) ‘as appropriate’ in ‘other public places’.
24. This creates an obligation to provide universal protection by ensuring that all indoor public places, all indoor workplaces, all public transport and possibly other (outdoor or quasi- outdoor) public places are free from exposure to second-hand tobacco smoke. No exemptions are justified on the basis of health or law arguments. If exemptions must be considered on the basis of other arguments, these should be minimal. In addition, if a Party is unable to achieve universal coverage immediately, Article 8 creates a continuing obligation to move as quickly as possible to remove any exemptions and make the protection universal. Each Party should strive to provide universal protection within five years of the WHO Framework Convention's entry into force for that Party.
25. No safe levels of exposure to second-hand smoke exist, and, as previously acknowledged by the Conference of the Parties in decision FCTC/COP1(15),

engineering approaches, such as ventilation, air exchange and the use of designated smoking areas, do not protect against exposure to tobacco smoke.

26. Protection should be provided in all indoor or enclosed workplaces, including motor vehicles used as places of work (for example, taxis, ambulances or delivery vehicles).
27. The language of the treaty requires protective measures not only in all ‘indoor’ public places, but also in those ‘other’ (that is, outdoor or quasi-outdoor) public places where ‘appropriate’. In identifying those outdoor and quasi-outdoor public places where legislation is appropriate, Parties should consider the evidence as to the possible health hazards in various settings and should act to adopt the most effective protection against exposure wherever the evidence shows that a hazard exists.
28. Raising awareness among the public and opinion leaders about the risks of second-hand tobacco smoke exposure through ongoing information campaigns is an important role for government agencies, in partnership with civil society, to ensure that the public understands and supports legislative action. Key stakeholders include businesses, restaurant and hospitality associations, employer groups, trade unions, the media, health professionals, organisations representing children and young people, institutions of learning or faith, the research community and the general public. Awareness-raising efforts should include consultation with affected businesses and other organisations and institutions in the course of developing the legislation.
29. Key messages should focus on the harm caused by second-hand tobacco smoke exposure, the fact that elimination of smoke indoors is the only science-based solution to ensure complete protection from exposure, the right of all workers to be equally protected by law and the fact that there is no trade-off between health and economics, because experience in an increasing number of jurisdictions shows that smoke-free environments benefit both. Public education campaigns should also target settings for which legislation may not be feasible or appropriate, such as private homes.
30. Broad consultation with stakeholders is also essential to educate and mobilise the community and to facilitate support for legislation after its enactment. Once legislation is adopted, there should be an education campaign leading up to implementation of the law, the provision of information for business owners and building managers outlining the law and their responsibilities and the production of resources, such as signage. These measures will increase the likelihood of smooth implementation and high levels of voluntary compliance. Messages to empower non-smokers and to thank smokers for complying with the law will promote public involvement in enforcement and smooth implementation.

ENFORCEMENT

Duty of compliance

31. Effective legislation should impose legal responsibilities for compliance on both affected business establishments and individual smokers, and should provide penalties for violations, which should apply to businesses and, possibly, smokers. Enforcement should ordinarily focus on business establishments. The legislation should place the responsibility for compliance on the owner, manager or other person

in charge of the premises, and should clearly identify the actions he or she is required to take. These duties should include:

- (a) a duty to post clear signs at entrances and other appropriate locations indicating that smoking is not permitted. The format and content of these signs should be determined by health authorities or other agencies of the government and may identify a telephone number or other mechanisms for the public to report violations and the name of the person within the premises to whom complaints should be directed;
- (b) a duty to remove any ashtrays from the premises;
- (c) a duty to supervise the observance of rules;
- (d) a duty to take reasonable specified steps to discourage individuals from smoking on the premises. These steps could include asking the person not to smoke, discontinuing service, asking the person to leave the premises and contacting a law enforcement agency or other authority.

Penalties

- 32. The legislation should specify fines or other monetary penalties for violations. While the size of these penalties will necessarily reflect the specific practices and customs of each country, several principles should guide the decision. Most importantly, penalties should be sufficiently large to deter violations or else they may be ignored by violators or treated as mere costs of doing business. Larger penalties are required to deter business violators than to deter violations by individual smokers, who usually have fewer resources. Penalties should increase for repeated violations and should be consistent with a country's treatment of other, equally serious offences.
- 33. In addition to monetary penalties, the legislation may also allow for administrative sanctions, such as the suspension of business licences, consistent with the country's practice and legal system. These 'sanctions of last resort' are rarely used, but are very important for enforcing the law against any businesses that choose to defy the law repeatedly.
- 34. Criminal penalties for violations may be considered for inclusion, if appropriate within a country's legal and cultural context.

Enforcement infrastructure

- 35. Legislation should identify the authority or authorities responsible for enforcement, and should include a system both for monitoring compliance and for prosecuting violators.
- 36. Monitoring should include a process for inspection of businesses for compliance. It is seldom necessary to create a new inspection system for enforcement of smoke-free legislation. Instead, compliance can ordinarily be monitored using one or more of the mechanisms already in place for inspecting business premises and workplaces. A variety of options usually exists for this purpose. In many countries, compliance inspections may be integrated into business licensing inspections, health and sanitation inspections, inspections for workplace health and safety, fire safety inspections or similar programmes. It may be valuable to use several such sources of information gathering simultaneously.
- 37. Where possible, the use of inspectors or enforcement agents at the local level is recommended; this is likely to increase the enforcement resources available and the

level of compliance. This approach requires the establishment of a national coordinating mechanism to ensure a consistent approach nationwide.

38. Regardless of the mechanism used, monitoring should be based on an overall enforcement plan, and should include a process for effective training of inspectors. Effective monitoring may combine regular inspections with unscheduled, surprise inspections, as well as visits made in response to complaints. Such visits may well be educative in the early period after the law takes effect, as most breaches are likely to be inadvertent. The legislation should authorise inspectors to enter premises subject to the law and to collect samples and gather evidence, if these powers are not already established by existing law. Similarly, the legislation should prohibit businesses from obstructing the inspectors in their work.
39. The cost of effective monitoring is not excessive. It is not necessary to hire large numbers of inspectors, because inspections can be accomplished using existing programmes and personnel, and because experience shows that smoke-free legislation quickly becomes self-enforcing (that is, predominantly enforced by the public). Only a few prosecutions may be necessary if the legislation is implemented carefully and active efforts are made to educate businesses and the public.
40. Although these programmes are not expensive, resources are needed to educate businesses, train inspectors, coordinate the inspection process and compensate personnel for inspections of businesses outside of normal working hours. A funding mechanism should be identified for this purpose. Effective monitoring programmes have used a variety of funding sources, including dedicated tax revenues, business licensing fees and dedicated revenues from fines paid by violators.

Enforcement strategies

41. Strategic approaches to enforcement can maximise compliance, simplify the implementation of legislation and reduce the level of enforcement resources needed.
42. In particular, enforcement activities in the period immediately following the law's entrance into force are critical to the law's success and to the success of future monitoring and enforcement. Many jurisdictions recommend an initial period of soft enforcement, during which violators are cautioned but not penalised. This approach should be combined with an active campaign to educate business owners about their responsibilities under the law, and businesses should understand that the initial grace period or phase-in period will be followed by more rigorous enforcement.
43. When active enforcement begins, many jurisdictions recommend the use of high-profile prosecutions to enhance deterrence. By identifying prominent violators who have actively defied the law or who are well known in the community, by taking firm and swift action and by seeking maximum public awareness of these activities, authorities are able to demonstrate their resolve and the seriousness of the law. This increases voluntary compliance and reduces the resources needed for future monitoring and enforcement.
44. While smoke-free laws quickly become self-enforcing, it is nevertheless essential that authorities be prepared to respond swiftly and decisively to any isolated instances of outright defiance. Particularly when a law first comes into force, there may be an occasional violator who makes a public display of contempt for the law. Strong responses in these cases set an expectation of compliance that will ease future efforts, while indecisiveness can rapidly lead to widespread violations.

Mobilise and involve the community

45. The effectiveness of a monitoring-and-enforcement programme is enhanced by involving the community in the programme. Engaging the support of the community and encouraging members of the community to monitor compliance and report violations greatly extends the reach of enforcement agencies and reduces the resources needed to achieve compliance. In fact, in many jurisdictions, community complaints are the primary means of ensuring compliance. For this reason, smoke-free legislation should specify that members of the public may initiate complaints and should authorise any person or non- governmental organisation to initiate action to compel compliance with measures regulating exposure to second-hand smoke. The enforcement programme should include a toll-free telephone complaint hotline or a similar system to encourage the public to report violations.

MONITORING AND EVALUATION OF MEASURES

46. Monitoring and evaluation of measures to reduce exposure to tobacco smoke are important for several reasons, for example:
- (a) to increase political and public support for strengthening and extending legislative provisions;
 - (b) to document successes that will inform and assist the efforts of other countries;
 - (c) to identify and publicise the efforts made by the tobacco industry to undermine the implementation measures.
47. The extent and complexity of monitoring and evaluation will vary among jurisdictions, depending on available expertise and resources. However, it is important to evaluate the outcome of the measures implemented, in particular, on the key indicator of exposure to second-hand smoke in workplaces and public places. There may be cost-effective ways to achieve this, for example through the use of data or information collected through routine activities such as workplace inspections.
48. There are eight key process and outcome indicators that should be considered²: ⁽²⁾

Processes

- (a) Knowledge, attitudes and support for smoke-free policies among the general population and possibly specific groups, for example, bar workers;
- (b) enforcement of and compliance with smoke-free policies;

Outcomes

- (a) reduction in exposure of employees to second-hand tobacco smoke in workplaces and public places;
- (b) reduction in content of second-hand tobacco smoke in the air in workplaces (particularly in restaurants) and public places;
- (c) reduction in mortality and morbidity from exposure to second-hand tobacco smoke;
- (d) reduction in exposure to second-hand tobacco smoke in private homes;
- (e) changes in smoking prevalence and smoking-related behaviours;

² The publication 'WHO policy recommendations: protection from exposure to second- hand tobacco smoke' (Geneva, World Health Organisation, 2007) provides references and links to monitoring studies conducted elsewhere on all of these indicators.

- (f) economic impacts.