

Brussels, September 10, 2024

To:

Commissioner Margaritis Schinas
Vice President Promoting our European Way of Life
Rue de la Loi / Wetstraat 200
B - 1049 Brussels, Belgium

Cc:

Mr Chris Uregian, Member of Cabinet
Ms Maria Krikou, Member of Cabinet (Relations with Ombudsman)

Subject: Tobacco Europe Letter to Commissioner Schinas on Smokefree Environment

Dear Commissioner Margaritis Schinas,

Tobacco Europe¹ has been following the ongoing discussions regarding the revision of the Recommendation on Smoke-free Environments. We understand it may be addressed on the 17th of September, and we greatly appreciate the chance to engage with you on this topic.

While we assume the publication of a proposal will not be on the agenda due to the ongoing consultation process, we would like to seek your clarity. As you may be aware, the Commission had committed to publishing a 'synopsis report' summarizing the input from stakeholders at the conclusion of the consultation. However, to date, this report remains unpublished and thus we are led to assume the consultation is still ongoing:

At the end of the consultation process, a synopsis report summarising all consultation activities will be published.²

We believe the timely publication of the report, well in advance of any proposal and in line with the process the Commission outlined to stakeholders, is crucial for transparency and ensuring the input of over 200 entities, including the Tobacco Europe members, is adequately considered. If there is intention to withhold it, we would greatly appreciate your help in reconsidering this, in the spirit of openness the Commission champions and its duty to justify such decisions.

¹ [Tobacco Europe](#) AISBL is the umbrella organisation representing the three largest tobacco and nicotine products manufacturers, namely British American Tobacco, Imperial Brands and Japan Tobacco International.

² Call for Evidence, Ref. Ares(2022)458672, page 3. To date only a summary of the contributions to the Call for Evidence was published (Ref. Ares(2023)661571).

We also trust you agree public scrutiny is essential. Without an evaluation or impact assessment performed, the consultation is the main source of primary and timely data for this revision. Unfortunately, some studies the Commission relies on are outdated (some of which date from the 1990s!), which raises concerns about the evidence-base related to today (please see the Annex our remarks on the revision process).

We are aware DG SANTE is navigating complex challenges, including the management and verification of conflict-of-interest allegations involving the contractor supporting this revision consultation. As stakeholders, we are not privy to this process, but we trust your experience and help to ensure it proceeds with the integrity expected by all parties.

Particularly, we would appreciate your consideration of whether it aligns with the principles of Better Regulation to base policy decisions on deliverables authored by contractors subject to unresolved conflict of interest allegations. Unfortunately, it is unclear to us whether due diligence and thorough reviews were conducted on those deliverables. Furthermore, the Commission previously mentioned the need for “further work” and additional “evidence gathering.” We are left uncertain whether those observations, or the delay in the publication of the consultation report, are linked to the conflict-of-interest concerns in any way.

In the UK, similar discussions have sparked significant public debate, which we believe serves as a valuable lesson. We hope the Commission will rely on comprehensive, transparent, and up-to-date data to base any decisions.

Tobacco Europe members remain fully committed to participating in the consultation process. With the publication of the ‘Draghi report’ emphasizing the regulatory burden of businesses and the definition of Commissioner portfolios, we believe that crucial aspects, such as competitiveness, which were not sufficiently addressed in previous questionnaires, should now be given proper attention.

Thank you very much for your attention to these matters,

Yours Sincerely,

A handwritten signature in blue ink, appearing to read 'Darge', with a blue horizontal line underneath.

Nathalie Darge,
Director General Tobacco Europe

Annex - General comments on the process

It is unclear whether an evaluation of the revised Recommendation was ever performed in line with the Commission's Better Regulation guidelines. A formal evaluation should have been made but to our knowledge, it seems the Commission limited itself to Implementation Reports.

The Commission developed the 2021 Rand report based on both a questionnaire and desktop research on the implementation of the 2009 Council Recommendation on smoke-free environments. This report was meant to be the basis in 2022 for a Commission proposal in 2023.

The Commission is considering the 2021 RAND report on the Tobacco Advertising Directive and Smokefree environments as an “evaluative study”. However, this report does not follow the evaluation structure imposed by the Better Regulation Principles.

In addition, the Commission has so far refrained from carrying out an impact assessment (IA), claiming that the initiative “does not substantially change the scope of the 2009 Recommendation” and the IA carried out in 2008 and published in 2009 remains valid. We find this perturbing as:

- The Commission itself has acknowledged on two occasions, the scientific challenges of such an update, particularly Commissioner Kyriakides who called it “a particularly challenging task” and whose services have stated “it requires further work and evidence gathering”;
- The 2009 IA cites studies dating back to the 1990s and is itself over 15 years old;
- The IA does not assess the impact of restrictions in outdoor and quasi-outdoor spaces, such as terraces of restaurants and bars. At the time, the Commission’s goal was to improve indoor air quality. Its findings are irrelevant to the Commission’s current goals;
- The IA included a subsidiarity test to justify EU action against smoke exposure. No such test has been conducted for this initiative. The 2023 Progress Report on the implementation of the FCTC shows a 95% implementation rate for its Article 8 (protection from exposure to tobacco smoke). This is the highest for any Article and suggests very limited need for EU intervention;
- The 2009 IA examined the impact of five alternative policy options.³ This time no alternative options are being considered, nor there is any input from the Regulatory Scrutiny Board, which provided substantial input at the time;
- The IA fails to address the specific impact on small and medium-sized

³ No change from status quo; open method of coordination in respect of Member States’ smoke free policies; Commission or Council Recommendation; combination of the two, etc.).

enterprises (SMEs). This omission is troubling given President Ursula Von der Leyen's emphasis on SMEs being the "heart of our economy" in her candidacy speech.

- The 2009 IA did not cover emerging products. Whereas the Commission justifies the update on the need to keep pace with "technological change and technological development", the legal basis for the Recommendation (Articles 153, 168, and 292 TFEU) does not support such a rationale.

According to the latest Eurobarometer 539 survey⁴, more than half of respondents reported that vaping and heated tobacco products helped them reduce or quit smoking. Therefore, these conclusions must be considered by the Commission. TE believes that extending the scope of Smoke-Free environments to outdoor spaces would send the wrong message to consumers who wish to quit smoking by using potentially reduced risk alternatives, as these would be treated the same as combustible tobacco products.

Therefore, we believe that the Commission should carry out an Impact Assessment to inform the proposal, by carrying out a new analysis of evidence and ensuring a consultation with relevant stakeholders.

Conclusion

- Tobacco Europe encourages the Commission to act in accordance with the principles of Better Regulations and first develop an Impact Assessment prior to considering any changes to the review of the Council's "Recommendation on smoke-free environments (2009/C 296/02)".
- Tobacco Europe believes that measures to restrict smoking and vaping in outdoor public places such as the outdoor terraces of bars and restaurants are not supported by any scientific evidence.
- Considering the lack of scientifically based evidence and of consistency used in the assessment methodology, Tobacco Europe does not support the extension of the Recommendation to emerging products nor the extension of its current scope to additional outdoor spaces.
- All in all, in a liberal society, the state's responsibility is to regulate for safety, not to make choices on behalf of their citizens, nor to tell them how to live their lives. We view that nanny state interference should not prevail, but rather uphold the respect of individual autonomy and personal responsibility.

⁴ <https://europa.eu/eurobarometer/surveys/detail/2995>