



To : Sandra Gallina
Director-General, Directorate-General for Health and Food Safety
European Commission
Rue de la Loi 200
B - 1049 Bruxelles

Cc : Secretariat-General
European Commission
Rue de la Loi 200
B - 1049 Bruxelles

Brussels, 27 October 2023

RE: Procedural shortfalls identified in the public consultation on the Evaluation of The Legislative Framework for Tobacco Control in line with the Better Regulation Guidelines and other applicable frameworks

Dear Ms. Gallina,

Following the response from DG SANTE (28 July) to Tobacco Europe's letter (June 19) outlining procedural shortfalls identified in the Public Consultation on the evaluation of the Tobacco Control Acquis, we would like to provide you with additional observations based on your feedback.

1. Access to the relevant data:

In your answer to our letter, you replied that: *'During the preparation of the public consultation questionnaire as well as in any other stages of the evaluation process, the Commission took and will continue to take active steps to ensure that the contractors adhere to ethical, transparency and accountability standards, including by providing access to the relevant data.'*

However, we have noted that a MEP published online¹ extracts of a document which was reportedly shared by your contractor with Member State authorities. This document was, however, never presented to economic operators, in spite of outlining preliminary findings that contradicted and differed from what was presented to economic operators. We therefore find it difficult to understand why economic operators are not provided with the same views, data and considerations as provided to Member States, and vice versa, in line with your commitment to ensure that contractors act transparently, "including by providing access to the relevant data".

2. Conflicts of interest:

As regards conflicts of interest, the reply provided in your answer states that: *"contractors are requested to provide a declaration of honour with respect to absence of conflict of interest in the field of tobacco, in line with the provisions of article 5.3 of the WHO Framework Convention on Tobacco Control of which the EU is a party. They also commit to take all the necessary measures to prevent any*

¹ <https://pouchforum.eu/2023/10/02/breaking-confidential-document-distributed-by-commissions-consultant-recommends-a-ban-on-nicotine-pouches/>



situation of conflict of interest during the implementation of the contract, to notify of any situation that could constitute a conflict of interest, and to take immediate action to rectify that situation as appropriate.”.

Please note that one of the subcontractors, the European Network for Smoking Prevention (ENSP), reportedly stated in an article in Euractiv², that the “*very concept*” of conflict of interest is not applicable to a non-profit organisation with “*no economic interest whatsoever in the tobacco business*”, which clearly illustrates that their understanding of the concept is biased. The fact that this advocacy group has won a €3 million tender for research services funded by European taxes could give rise to allegations that DG SANTE and HaDEA apply a double standard when assessing the interests of stakeholders. In light of this declaration, and with regards to the common understanding of the concept of conflict of interest, we believe their declaration should not be considered as valid or, at least, sufficient.

Furthermore, in accordance with Article 61(1) of the EU Financial Regulation (EU, Euratom 2018/1046) and the ‘Guidance on avoidance of conflict of interests under the Financial Regulation’ (2021/C 121/01), authorising officers and those involved or in charge of award procedures as well as those involved in the preparation, opening and evaluation phases, shall take appropriate measures to prevent a conflict of interest from arising in the functions under their responsibility and to address situations with may ‘objectively be perceived’ as a conflict of interests. Thus, members of an evaluation committee must be able to impartially and objectively assess the proposals and are obligated to take any action required under Article 61(1), to respect the principles of sound financial management.

Rather than blaming and shaming singular ideas or vested interests, it should be acknowledged that everybody has inherent interests. Only a constant discourse of all interests in a transparent and rules-based manner can help define the best outcome for the common public interest. Involvement of all stakeholders is critical to ensuring that regulation is effective, proportionate, workable, and supported by credible evidence. The benefits of full stakeholder participation are widely recognized as they bring everyone’s expertise, perspectives, and ideas into the policy-making process.

In our view, consultation activities carried out by the Commission should be designed and implemented in line with the objectives, principles and standards established in the Better Regulation Guidelines.

We would therefore welcome receiving clarity on both concerns highlighted above.

Yours sincerely,

Nathalie Darge
Director, Tobacco Europe

² <https://www.euractiv.com/section/politics/news/stakeholders-bicker-over-eu-tender-on-tobacco-control-policy/>