



Secretariat-General  
European Commission  
Rue de la Loi 200/ Wetstraat 200  
1049 Bruxelles/Brussel  
Belgium

Brussels, 19 June 2023

**Subject: 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. Juhansone,

We<sup>1</sup> are writing to you today to draw your attention to the procedural shortfalls identified in the public consultation on the Evaluation of The Legislative Framework For Tobacco Control<sup>2</sup>.

Public consultations are a cornerstone of the rule of law and pivotal to improve transparency, efficiency, and effectiveness of regulations. Good public consultations are understood as a continuous dialogue to facilitate the drafting of higher quality regulation. As per the OECD guidelines, public consultation processes help to bring the expertise and perspectives of those directly affected, help balance different interests, identify unintended effects, provide quality checks as well as serve as a participatory tool for the public at large to ensure EU policymaking is evidence-based, to simplify laws and involve all stakeholders to foster trust in both policymaking processes and outcomes.

In our view, this public consultation was not designed and implemented in line with the above objectives nor with the principles and standards established in the Better Regulation Guidelines (hereafter 'Guidelines').

Tobacco Europe supports the evaluation of the legislative framework for tobacco control although it should be pointed out that many measures of the existing framework have not been fully implemented and it is therefore premature to properly assess the overall impact on the smooth functioning of the internal market and public health protection.

We believe that the design of the questionnaire will not allow the Commission to obtain sufficient evidence on the concrete impacts of the TPD and TAD, hindering the Commission's ability to formulate an accurate understanding of the issues at hand. In this regard we also would like to point out concerns expressed by Members of the European Parliament.<sup>3</sup>

Whilst the questionnaire claims that it intends to collect "perceptions" from stakeholders, the questions address the "adequacy" or the impact of specific provisions from the Tobacco Products Directive ("TPD") and the Tobacco Advertising Directive ("TAD") – not perceptions or impressions, even more so when academic institutions, consumer organizations or economic operators are consulted.

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<sup>1</sup> [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.

<sup>2</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13481-Evaluation-of-the-legislative-framework-for-tobacco-control/public-consultation_en)

<sup>3</sup> <https://twitter.com/jessicapolfjard/status/1649337954656043010>



Moreover, the questions are highly technical and not straightforward for someone unfamiliar with the TPD and TAD regulatory framework. Therefore, the questions are likely to be unclear to an average adult consumer or non-specialist citizens who wish to express their views. The Guidelines require all consultation documents to be *clear and concise* and include *all necessary information to facilitate responses*. Additionally, the Guidelines recommend that *questionnaires that are very technical in nature include a set of more general questions for non-specialists*.

Furthermore, the Guidelines require the preparation of laws to be carried out in an open, objective and transparent manner, to be consulted as widely as possible and to be based on the best available evidence. We believe that the required transparency and objectivity has been compromised by the participation, in the consortia supporting the Commission to conduct this consultation, of the European Network for Smoking Prevention (ENSP). ENSP is an interest representative registered in the Transparency Register, with a clear agenda to influence EU tobacco control legislation, notably by currently lobbying the Commission for additional tobacco control measures through a European Citizens Initiative<sup>4</sup> of which they are the lead funders.

The fact that this advocacy group has won a 3-million-euro tender for research services, could give rise to allegations that DG SANTE is not interested in conducting genuinely independent research. The parties to this tender are obliged to demonstrate they have no conflict of interest, yet this seems to have been disregarded in this instance. In the EURACTIV article<sup>5</sup>, ENSP mentioned that the concept of conflict of interest was not applicable to a non-profit organisation, whereas it is generally accepted that all stakeholders should be scrutinised.

#### 1. NEUTRALITY AND TRANSPARENCY OF THE QUESTIONNAIRE

The questionnaire states that its objective is to “collect stakeholders’ *perceptions* on the current legislative framework for Tobacco Control in the EU” with the aim to “evaluate the extent to which the framework has fulfilled its established goals and objectives”.

However, throughout the questionnaire, the formulation of questions is rather misleading in nature, casting doubt on the neutrality and objectivity of the consultation process.

Examples:

- Wording such as asking to rate the level of “threat” of different new nicotine product categories is clearly suggestive in nature. Civil stakeholders should have a right to respond to the consultation free from the bias one can detect in the way this question has been framed.
- The phrasing of the question concerning an exemption from the ban on characterising flavours is unclear. It is difficult to determine whether the European Commission would like for the feedback to focus on the adequacy of exempting categories from the characterising flavours ban, or on the substantial changes of circumstances clause provided in this exemption.
- Asking about a future EU’s objective of a tobacco-free generation is not related in any way to the evaluation of the present framework but, in our opinion, is rather of suggestive and insinuating political nature. Moreover, we question what the added value is for the European Commission to try to scrutinize the business models of economic operators.

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<sup>4</sup> <https://eci.ec.europa.eu/029/public/#/screen/home>

<sup>5</sup> <https://www.euractiv.com/section/politics/news/stakeholders-bicker-over-eu-tender-on-tobacco-control-policy/>



## 2. EXAMPLES OF THE TECHNICAL NATURE OF THE QUESTIONS

As an example, an average adult consumer or non-specialist citizen could contribute on how they see the implementation of the tobacco control framework in their daily life/consumption (e.g., an average consumer could express their views on the possibility to buy certain products in certain EU Member States but not others without having specific knowledge of exact provisions of the TPD). However, it is likely to be challenging for them to reply to the question addressed in the questionnaire about whether TPD provisions like the ban of characterising flavours '*contribute to reducing health risk from tobacco and related products*', issues that are better suited to be addressed via evidence, data, facts and scientific methodology.

The distinction between 'very inadequate' and 'inadequate' and 'adequate' and 'very adequate' in the range of answers is likely to leave the respondents puzzled. Linguistically, it is unclear how something can be considered worse than 'inadequate' or better than 'adequate'.

Formulations including double negation render it difficult to understand the questions and to respond properly, as an example, '*to what extent do you believe the following TPD provisions were adequate to facilitate the smooth functioning of the internal market – not harmonising additional aspects of electronic cigarettes or refill containers (e.g. adopting rules on flavours)*'.

We would like to highlight the importance for the Commission to consider the wealth of scientific evidence that is currently publicly available, including those of the industry, and to rely on the best available evidence in the policy making process.

Furthermore, it is our view that the wordings of the questions do not aim at ascertaining the specific challenges faced by small and medium sized enterprises in the value chain, notably retailers, distributors and farmers. In our opinion, this may hinder the Commission's ability to obtain all the information required to evaluate the tobacco control framework in a holistic and comprehensive manner and therefore, violate the principle of participation required in the Guidelines and the objectives of this public consultation.

To conclude, public consultations as opposed to targeted consultations should foster transparency and accountability and ensure the broadest public validation and support for an initiative. This questionnaire may deter or limit the ability of certain stakeholders to participate in this public consultation which, in our view, violates the principle of participation enshrined in the Guidelines. Violation of the principle of participation will further exacerbate the growing gap between public institutions and citizens.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Darge", with a horizontal line drawn through it.

Nathalie Darge  
Director Tobacco Europe

Cc: Sandra Gallina, Director-General, Directorate-General for Health and Food Safety  
Regulatory Scrutiny Board