



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

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Sent by e-mail:
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Subject: Procedural shortfalls identified in the public consultation on the evaluation of the legislative framework for tobacco control

Dear Ms Darge,

I refer to your letter of 19 June addressed to the Secretary-General, concerning the public consultation on the evaluation of the legislative framework for tobacco control. The Secretary-General has asked me to reply on her behalf. In your letter, you expressed the view that DG SANTE disregarded a number of rules outlined in the ‘Better Regulation’ guidelines and toolbox, notably on the neutrality of the questionnaire.

First of all, this retrospective evaluation process, and any next steps decided upon its findings, are fully carried out in line with the Commission better regulation guidelines. This evaluation comes at a time where a rapid rise in emerging products, new technologies and continuously evolving markets, require a thorough assessment of the functioning of the legislation for tobacco control in relation to products’ toxicity, addiction and attractiveness, together with an appraisal how those products are being presented and promoted to the public.

The Commission’s consultation system provides stakeholders and the public with many opportunities to contribute to informing the decision-making process at different stages. The consultation activities related to the evaluation of the legislative framework for tobacco control include: the call for evidence open for feedback in June 2022, the public consultation open from the 21 February to 16 May 2023, the targeted survey of Member States, civil society organisations and economic operators currently on-going and to which Tobacco Europe was invited to participate, and the interviews with key stakeholders that will take place shortly.

A consultation strategy, providing an outline of how the Commission intended to consult stakeholders featured already in the call for evidence, with a view to inform all stakeholders and to invite them to provide feedback. This aimed to ensure broad and

representative participation and transparency throughout the process. The feedback and responses received will be taken into account in the evaluation process.

The public consultation received more than 17 000 responses. The Commission services, assisted by an external consultant and in line with the 'Better Regulation' guidelines, prepared the questionnaire to gather views on how well the current legislative framework is working and to what extent it is ready to withstand market, scientific and technical developments. 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.

With regard to the formulation of the questions, it is important to note that all questions in the questionnaire for the public consultation provided a full scale of options for response, for example from "strongly agree" to "strongly disagree" or from 'not a threat at all' to 'very threatening', ensuring its neutrality and transparency. This allowed respondents to express any views they might have on any of the topics in a clear and measurable way. In addition, a dedicated entry area provided the opportunity to insert any additional comments or suggestions as free text and there was also a possibility to attach supporting evidence. As you mention in your letter, a reply on this same issue was already provided to the Members of the European Parliament Ms Polfj rd and Mr Warborn on 7 June 2023.

Concerning the technical nature of the questions, the questionnaires were adapted in order to cover a broad audience as much as possible and included questions on 'perception' and others requiring more factual and evidence-based replies.

As regards potential conflicts of interest, 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 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. In the case of framework contracts, the declaration of honour with respect to absence of conflict of interest needs to be reconfirmed for each specific contract concluded under the framework contract.

Yours faithfully,

Sandra GALLINA