



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

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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,

Thank you for your letter of 30th October 2023, concerning the public consultation on the evaluation of the legislative framework for tobacco control and the application of the Commission Better Regulation guidelines.

In your letter, you provided additional observations in reaction to DG SANTE correspondence dated 28th July 2023. In your view, DG SANTE disregarded a number of rules outlined in the better regulation guidelines, notably on transparency with regard to documents presented to different stakeholders and on conflict of interest in a framework contract.

First of all, as outlined in prior correspondence, the evaluation is being conducted in strict adherence to better regulation guidelines amidst significant developments in new products and technologies. The overall evaluation framework has been designed to offer numerous opportunities for public and stakeholder engagement at various stages. These include a call for evidence, public consultations, targeted surveys, and interviews with major stakeholders. This approach provided a direct opportunity for Tobacco Europe and their opinions to be involved. The consultation strategy aims to inform and invite comprehensive feedback, ensuring broad and representative participation and transparency throughout the process. The feedback received is an important aspect of the evaluation.

It is important to note that the Commission, with assistance from an external consultant, developed a strategy to solicit opinions on the current legislation. The documents provided to stakeholders in the evaluation process are managed with a commitment to ethical standards, transparency, and data accessibility for accountability purposes. The purpose of these documents circulated in parallel to the three stakeholders' groups was to summarise the preliminary views of the specific groups and to validate the position of each stakeholder group, based on the different contributions collected within them. Even though the structure and length of the three documents provided to the groups were basically identical, they reflected differences in their views or they might have been presented in a different context. More specifically, whereas nicotine pouches were a noteworthy issue raised by a

number of Member States, this matter appeared to raise less attention in the replies from economic operators.

In both the background documents for Economic operators and Member States, the following statement was included in the ‘Relevance’ section: *“While the ban on oral tobacco (TPD article 17) remains important to meet public health objectives, this is undermined by the rise of ‘new products’ such as nicotine pouches. Economic operators believe that extending the ban also to nicotine pouches will be detrimental for users intending on switching ‘to safer alternatives.’”*

Additionally, the background document for Member states contained the following comment in the ‘Effectiveness’ section, which Member States had stressed in their replies to the consultation, unlike the economic operators: *“The ban on tobacco for oral use has been found to be highly successful in improving the internal market and ensuring a high level of health protection, even if some challenges are posed by new products as covered under the relevance criterion that require the ban to be extended to nicotine containing oral products.”*

As regards potential conflicts of interest, contractors involved in a framework contract on a broad range of tobacco-related issues declared their absence of conflict of interest in the field of tobacco in accordance with Better Regulation guidelines as well as with article 5.3 of the WHO Framework Convention on Tobacco Control. The role of the European Network for Smoking Prevention (ENSP) in the evaluation procedure, as one member of the contractual consortium, would be facilitating the necessary contacts with experts, when relevant, for the different specific contracts. ENSP, as part of a joint tender, signed a Declaration on honour and an additional absence of conflict of interest in the field of tobacco. These documents were fully assessed during the evaluation of the tenders before awarding the contract.

Regarding your concerns about the wide reflection on discourse of all interests in the evaluation framework, stakeholders’ participation through multiple channels is considered of primary importance for ensuring objective and evidence-based findings in line with the Better Regulation guidelines. The involvement of Tobacco Europe demonstrates the strategy is centred on garnering extensive feedback, promoting wide-ranging involvement and transparency, which are fundamental to the integrity of the evaluation.

Yours faithfully,

Sandra GALLINA