Director-General of Health and Food Safety
European Commission DG SANTE
Rue de la Loi/Wetstraat 200
1049 Brussels
Belgium

Subject: Request for Inclusion in Ongoing Targeted Consultation and Concerns Regarding the Public Consultation and Targeted Stakeholders' Consultation on Tobacco Control

Dear Director-General,

On behalf of the Greek Vaping Industry Association (S.E.E.P.A.), we are writing to express our concerns about the recent public consultation conducted by the European Commission (DG SANTE) and to request our participation in the ongoing targeted stakeholders' consultation. Additionally, we would like to emphasize the importance of conducting a SME-test as part of the evaluation process, particularly for small and medium-sized enterprises (SMEs) like ours.

S.E.E.P.A. is the single body of Greek companies engaged in the field of electronic cigarettes. Originally founded in 2011 as the Association of Greek Electronic Cigarette Businesses (S.E.H.E.T.), our organization aims to contribute our perspectives to the regulation of this growing market, provide public information, and ensure quality, safety standards, and transparency in the realm of e-cigarettes.

1. Criticism of the Questionnaire Quality

We raise profound concerns regarding the inadequate quality of the questions in the Public Consultation. Firstly, the questionnaire failed to facilitate a comprehensive assessment of the expected impacts on affected groups and neglected to reference the Impact Assessment conducted for TPD2. Instead, it heavily relied on subjective questions and questions that raise certain concerns and can have a significant impact on SMEs, such as the following example: "Given the policy objective of achieving a 'tobacco-free generation' by 2040 in the European Union, do you feel that your organization is prepared for a smooth exit from the market (e.g., strategic plans to transition to a different sector)?" The inclusion of such a question created frustration among SME businesses, as it presupposed their readiness to exit the market without considering alternative scenarios or the potential for harm reduction strategies.
This lack of quality in the questionnaire raises concerns about the Commission's commitment to **Better Regulation** and the **Inter-institutional Agreement on Better Law Making**. We question whether these commitments are merely empty rhetoric. Moreover, the consultation did not adequately consider the input and follow-up from the Call for Evidence, making it difficult for respondents to actively participate.

**-Low-Quality Questionnaire Hindering Evidence-Based Policy Making**

Furthermore, we found biased and unclear questions throughout the consultation. Many questions relied on subjective opinions, personal beliefs, or perceptions, rather than objective data. Additionally, numerous questions allowed for answers that could be interpreted both negatively and positively. Some questions were phrased in a manner that restricted respondents from providing negative responses. Furthermore, the questionnaire included references to young people without separate specific inquiries dedicated to addressing their unique concerns. The language employed in certain questions was harsh, leading, and potentially misleading. This might have influenced respondents to make subjective judgments, undermining the reliability of the collected data. Additionally, some questions assumed a prerequisite of policy and EU expertise from respondents, which may have excluded valuable perspectives. The questionnaire also included questions unrelated to stakeholder expertise and lacked evidence-based decision-making inquiries.

To ensure the quality of the consultation, we believe it is necessary to conduct a thorough **quality control and/or review by the Secretary General**. The consultation should have better incorporated the input and follow-up from the Call for Evidence, ensuring ease of participation for all stakeholders.

**-Lack of Distinction Between Tobacco and Nicotine Products**

Another pressing concern is the lack of clear differentiation between tobacco and nicotine products within the evaluation questionnaire. This oversight hampers a comprehensive assessment of these distinct product categories and their respective impacts. It is imperative to acknowledge and address the concept of Tobacco Harm Reduction, which holds significant relevance for the vaping industry.

In conclusion, we kindly request that the European Commission (DG SANTE) urgently address our concerns regarding the questionnaire's quality in the public consultation. We further implore you to grant our association active involvement in the ongoing targeted stakeholders' consultation, enabling us to contribute valuable insights based on our practical expertise. Lastly, we emphasize the imperative need for a comprehensive SME assessment to ensure a thorough evaluation process that considers the specific impacts on small and medium-sized enterprises.

We greatly appreciate your attention to these concerns and eagerly await your actions in addressing them. Thank you for your unwavering commitment to evidence-based policy making and for prioritizing the needs and perspectives of all stakeholders.

### 2. Request to Participate in the Ongoing Targeted Stakeholders’ Consultation

We have been informed that the ongoing process involves a targeted stakeholders’ consultation, which is currently underway. As a stakeholder directly impacted by the vaping industry, we kindly request our participation in this consultation. We strongly believe that our practical experience in implementing the existing...
legislation can contribute valuable insights to the policy-making process. It is crucial to ensure that the targeted stakeholders' consultation is inclusive and incorporates a wide range of perspectives to develop a well-informed approach.

3. Request for a SME-Test as Part of the Evaluation

The Better Regulation Guidelines include a significant requirement known as the SME Test, which examines the potential impact of EU regulations and proposals on small and medium-sized enterprises (SMEs). However, there is a lack of substantial evidence within the questions of the Public Consultation indicating the application of this crucial SME Test.

We are concerned about the lack of attention given to small and medium-sized enterprises (SMEs) and related sectors in the recent public consultation. The questionnaire did not address the specific issues affecting SMEs, growers, and the supply chain, and there was no mention or use of an 'SME test' to assess the impact of EU regulations and proposals on SMEs. It is crucial that the European Commission conducts a thorough assessment specifically tailored to SMEs in the ongoing evaluation of the Tobacco Product Directive. The public consultation failed to adequately consider the impact on SMEs, and the connection between the question asked and its impact on small businesses was unclear. Considering the goal of achieving a 'tobacco-free generation' by 2040 in the European Union, it is important to assess the potential consequences for SMEs and ensure the development of effective and feasible regulations. We recommend a systematic approach that includes input from affected individuals and businesses, active participation in the targeted consultation, a realistic and comprehensive analysis of practical impacts, and exploration of alternative options to replace lost revenue, thereby avoiding unnecessary future costs.

In conclusion, we kindly request the European Commission (DG SANTE) to address our concerns regarding the quality of the public consultation questionnaire. We also seek our association’s inclusion in the ongoing targeted stakeholders’ consultation to provide valuable input based on our practical expertise. Lastly, we emphasize the necessity of conducting an SME-test to ensure that the evaluation process adequately considers the impact on small and medium-sized enterprises.

We appreciate your attention to our concerns and requests and look forward to your prompt response. Thank you for your commitment to creating evidence-based and fair regulations that prioritize public health while considering the needs of all stakeholders.

Yours sincerely,