Complaint to DG SANTE

Concerning the design of the European Commission's public consultation on the revision of the EU rules on tobacco products and tobacco advertising (Initiative 17612, DG SANTE)

I. Subject of the complaint

This complaint concerns an instance of maladministration in the design of a public consultation, not the substance of the policy it supports. The complainant takes no issue with the Commission's competence to legislate on tobacco and nicotine products, nor with its right to pursue a high level of health protection.

The complaint is that the consultation questionnaire issued by DG SANTE is not an objective or impartial instrument. Its wording, and the way it groups respondents and products, systematically steers respondents toward the most restrictive answers and, in a substantial number of questions, offers no means of expressing disagreement on the substance. In doing so the instrument fails to comply with the binding standards of objectivity and impartiality that govern the Commission's administrative conduct and its own Better Regulation framework. A consultation so constructed cannot produce evidence that fairly represents stakeholder views, yet its results are intended to inform a legislative proposal scheduled for adoption in 2026.

II. Background and facts

1. DG SANTE is preparing a revision of the Tobacco Products Directive (2014/40/EU) and the Tobacco Advertising Directive (2003/33/EC). As part of that process the Commission opened a public consultation, the questionnaire for which ("Public consultation questionnaire – Revision of the EU rules on tobacco products and tobacco advertising") is the subject of this complaint.
2. The questionnaire contains 22 substantive questions. The complainant has assessed each of them for framing bias. Those relevant to the assessment are detailed in this complaint. A majority of the questions embed a contested conclusion in their premise, and that two design choices, described below, distort the instrument as a whole.
3. The consultation is open at the time of this complaint and its results are intended to feed directly into the forthcoming legislative proposal. The defects are therefore live and capable of correction.

III. The standards that apply

The Commission is bound, when consulting the public, by the following standards. They are the benchmark against which the Ombudsman assesses maladministration.

a) The right to good administration and the duty of objectivity

- Article 41 of the Charter of Fundamental Rights guarantees every person the right to have their affairs handled impartially and fairly by the institutions of the Union.
- The European Code of Good Administrative Behaviour requires officials to act impartially and independently (Article 8), objectively (Article 9), and fairly (Article 11).

- The European Ombudsman's Public Service Principles (Principle 3, Objectivity) require civil servants to be impartial, open-minded, guided by evidence, and willing to hear different viewpoints.

b) The Better Regulation framework for consultation

- Article 11 TEU requires the Commission to give citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of Union action.
- The Better Regulation Guidelines (SWD(2021) 305), Chapter 2 and Box 3, set out the general principles and minimum standards for consultation — participation, openness and accountability, effectiveness and coherence — together with minimum standards including clarity of the consultation. These derive from the Commission's own general principles and minimum standards (COM(2002) 704).
- The Better Regulation Toolbox, Tools #51–#54 (consulting stakeholders; consultation strategy; conducting consultation activities; analysing data and informing policymaking), governs the construction of consultation questionnaires and the duty to design questions that elicit, rather than pre-empt, stakeholder views.

Taken together, these instruments establish that a Commission consultation must be a genuine tool for considering alternative policy options, not an exercise for confirming a predetermined outcome. A questionnaire that is constructed to elicit a particular answer is, according to the Commission's own standards, not a valid consultation.

IV. The specific defects in the consultation

Defect 1 — Two structural design choices distort every relevant question

Respondent grouping. The questionnaire defines "young people" as everyone aged 10 to 24. This single band combines children, and 16- and 17-year-olds who cannot lawfully purchase these products anywhere in the EU, with adults aged 18 to 24 who are lawful consumers in every Member State. Questions on initiation age, access channels, appeal and flavours are read throughout as child-protection matters, even though responses for the band will be materially driven by lawful adult behaviour. The instrument cannot distinguish a 13-year-old from a legal adult, yet draws child-protection conclusions from the aggregate. A 13 year old should not be using nicotine. A 24 year old may be a smoker who would benefit from a safer alternative. The policy responses to this situation should not be grouped together.

Product grouping. Combustible cigarettes, heated tobacco, nicotine e-cigarettes, nicotine-free e-cigarettes and nicotine pouches are repeatedly presented as a single regulatory category in questions about bans and restrictive measures. These products differ markedly in established harm. Grouping them implies equivalence in harm, appeal and regulatory need, so that a measure restricting a nicotine-free product is presented on the same footing as one restricting a cigarette. No question allows a respondent to distinguish between them.

Defect 2 — A majority of questions presuppose their own conclusion

In a substantial number of questions the premise asserts a contested proposition as established fact, and the response options permit the respondent only to agree on the scope

of action, never to contest whether action is warranted. Examples drawn from the questionnaire:

- **Q1** invites agreement that protective measures are “beneficial for society.” Disagreement reads as opposition to public health, suppressing critical responses at the outset. Complainants would like to express that they agree that protective measures regarding combustible products (such as cigarettes) are beneficial, but such measures when applied to other categories like e-cigarettes or pouches could have unintended consequences and therefore be harmful. They are unable to do so.
- **Q8** front-loads large market-growth multiples and then asks respondents to agree that use has risen “particularly among young people.” The statistics anchor agreement before the question is read; the parallel fact that combustible tobacco sales fell over the same period — consistent with adults switching to lower-risk products — is not presented.
- **Q9–Q10** assume that promotion “influences” uptake and that further action “is needed,” presupposing both causation and a regulatory gap, with no option to record that the evidence is weak.
- **Q13** lists only restrictive measures and asks respondents to rate their effectiveness, with no option to indicate that a measure could be counterproductive. Many complainants would like to express support for such measures for combustible products (cigarettes) but not for others (e-cigarettes, pouches) due to harmful unintended consequences. They are unable to do so.
- **Q14–Q16** treat the scope as having “not kept pace” and the rules as “needing” fast-track powers, with no option to call the current scope adequate.
- **Q18–Q20** ask only whether plain packaging and flavour bans would “strengthen” health and the internal market. The verb “strengthen” frames the outcome as self-evident; there is no option to record that a measure could cause net harm.
- **Q21–Q22** treat the expansion of traceability and enforcement as the default, with no option to state that the current level is adequate.

Defect 3 — Q20 states contested claims as fact and excludes the countervailing case

Q20 is the clearest single instance. Its premise states as an established fact that flavours “seem to play a key factor” in youth initiation and that they “create the impression” the product is less harmful. Whatever the merits of those propositions — and they are contested in the primary literature — the defect is procedural: the question presents a disputed causal claim as settled, and then offers respondents no option to register the well-documented countervailing risk that banning flavours may drive adult e-cigarette users back to combustible cigarettes, producing a net increase in harm. Complainants hold that view and cannot express it. The question is built to return support for a ban.

V. The consultation as it stands constitutes maladministration

A consultation instrument that (i) conflates children with lawful adults, (ii) treats products of materially different risk as one category, and (iii) in most of its questions permits agreement only on the scope of restriction, cannot return data that objectively represents the range of

stakeholder views. It will tend toward the most restrictive conclusion whatever respondents actually think.

That outcome is incompatible with the duty of objectivity and impartiality in Articles 8, 9 and 11 of the Code of Good Administrative Behaviour and with Article 41 of the Charter; with Principle 3 of the Ombudsman's Public Service Principles; and with the Commission's own Better Regulation Guidelines and Toolbox, which require a consultation to be a genuine instrument for weighing options rather than a means of validating a predetermined result. Designing and deploying a consultation that fails these standards, and presenting its results as an evidence base for legislation, is maladministration within the Ombudsman's settled meaning: a failure by an institution to act in accordance with the rules and principles binding upon it.

The defect is not cured by the eventual publication of responses. The bias operates at the point of data collection; it shapes what the published data can show, and a synopsis report drawn from a skewed instrument will carry the skew forward into the legislative proposal.

VI. Remedies

Since this is an open consultation, there remains time to correct the error and ensure the consultation is designed appropriately and in accordance with Better Regulation standards, but only if swift action is taken. Complainants request that DG SANTE undertake to do the following by 30 June 2026.

- To open an inquiry into whether the design of the consultation questionnaire for Initiative 17612 complies with the duty of objectivity and impartiality and with the Better Regulation consultation standards.
- To relaunch the consultation with the following corrections: disaggregate "young people" into lawful and non-lawful age groups; distinguish products by category; and, in its synopsis report (Toolbox Tool #54), expressly identify and weight the framing limitations of the questions when interpreting the responses.
- To ensure that the Commission states in any future consultation instrument, for each closed question, a balanced range of response options that permits substantive disagreement.

VII. Signatories

Complainants are groups representing consumers of safer nicotine products and their authorized signatories:

- Asociación Española de Usuarios de Vaporizadores Personales (Anesvap, Spain), represented here by Ángeles Muntadas-Prim Lafita
- Heated Community Hub (Italy), represented here by Francesco Luongo
- Stichting Acvoda (Netherlands), represented here by Hans Molenaar
- Asociația Consumatorilor de Produse Alternative cu Nicotină (ACPAN, Romania), represented here by Alex Gogana
- EU4Snus (Sweden), represented here by Bengt Wiberg
- Association Indépendante des Utilisateurs de Cigarette Électronique (AIDUCE, France), represented here by Claude Bamberger.