Complaint to the European Ombudsman

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), and the handling of the complainants' correspondence concerning it

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To: The European Ombudsman, 1 avenue du Président Robert Schuman, CS 30403, F-67001 Strasbourg Cedex, France

Complaint submitted under: Article 228 TFEU and Article 43 of the Charter of Fundamental Rights of the European Union.

Request for expedited handling: the public consultation under complaint closes on 14 August 2026. The complainants respectfully ask the Ombudsman to consider whether the case can be handled with urgency while the defects remain capable of remedy.

Complainant details

Complainants: Asociación Española de Usuarios de Vaporizadores Personales (Anesvap, Spain); Heated Community Hub (Italy); Stichting Acvoda (Netherlands); Asociația Consumatorilor de Produse Alternative cu Nicotină (ACPAN, Romania); EU4Snus (Sweden); Association Indépendante des Utilisateurs de Cigarette Électronique (AIDUCE, France).

Lead contact: Hans Molenaar, info@acvoda.nl

Institution concerned

European Commission: Directorate-General for Health and Food Safety (DG SANTE), as author of the consultation questionnaire and of the reply of 15 July 2026.

I. Subject of the complaint

This complaint concerns maladministration in (a) the design of a public consultation and (b) the handling of the complainants' correspondence about it. It does not concern the substance of tobacco policy. The complainants take 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; that DG SANTE's reply of 15 July 2026, far from answering the complaint, confirms its central elements; and that DG SANTE failed to reply to the original complaint within the period required by the Commission's Code of Good Administrative Behaviour. The consultation closes on 14 August 2026 and its results are intended to inform a legislative proposal.

II. Background and chronology

1. DG SANTE is preparing a revision of the Tobacco Products Directive (2014/40/EU) and the Tobacco Advertising Directive (2003/33/EC) (Initiative 17612). The public consultation questionnaire under complaint is enclosed at Annex 1. The complainants' question-by-question assessment of it is enclosed at Annex 2.

2. **10 June 2026:** the complainants wrote to the Director-General of DG SANTE setting out the defects in the questionnaire and requesting a response by 30 June 2026 (Annex 3). The letter was copied to the Secretary-General, the Chair of the Regulatory Scrutiny Board, the Deputy Director-General of DG SANTE, and the Cabinet of the Commissioner for Health and Animal Welfare.
3. **30 June 2026:** the deadline passed without any reply, substantive or holding.
4. **7 July 2026:** the complainants wrote to the Secretary-General (Annex 4), noting the absence of any reply, identifying the non-response as a breach of the Code of Good Administrative Behaviour, and requesting that the Secretariat-General, as institutional owner of the Better Regulation framework, require the withdrawal and re-issuance of the consultation.
5. **15 July 2026:** the Director-General of DG SANTE replied (Ares(2026)7082585; Annex 5), stating that the reply also addressed the letter of 7 July to the Secretary-General. The reply declined to revise the questionnaire. Its content is analysed in section V below.
6. No reply has been received from the Secretary-General at any point.
7. **23 July 2026:** the complainants sent a closing letter to the Director-General recording the points on which the reply of 15 July confirmed or failed to engage with the complaint (Annex 6).

III. The standards that apply

a) The right to good administration

- Article 41 of the Charter of Fundamental Rights: the right to have one's affairs handled impartially, fairly and within a reasonable time.
- The European Code of Good Administrative Behaviour: impartiality and independence (Article 8), objectivity (Article 9), fairness (Article 11).
- The Commission's Code of Good Administrative Behaviour for Staff in their Relations with the Public (OJ L, 8 March 2024): a reply within 15 working days of receipt by the responsible service, or a holding reply indicating when a substantive reply may be expected.
- The European Ombudsman's Public Service Principles, Principle 3 (Objectivity).

b) The Better Regulation framework for consultation

- Article 11 TEU: citizens and representative associations must be given 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: general principles and minimum standards for consultation, deriving from COM(2002) 704.
- The Better Regulation Toolbox (December 2025 edition, in force at the launch of this consultation), Tool #53, section 2.1.3 ("Question design"): questions "need to be designed in a neutral manner, meaning that they should not 'push' respondents to answer in any way," using "a balanced answer scale, such as a five-point scale with two positive answer options, two negative answer options and a neutral option," and ensuring that "respondents can always appropriately answer the question," with "other"

and “I do not know / Not applicable” options. The same tool recommends that draft questionnaires be piloted, i.e. tested with selected respondents before use.

- The Better Regulation Toolbox, Tool #54 (Analysing data and informing policymaking): the presentation of stakeholder views must be “clear, complete, neutral, unbiased, and balanced across all groups.”
- European Court of Auditors, Special Report No 14/2019: questionnaire quality identified as a weakness of Commission consultations, with a recommendation for better-tailored questions.

IV. The defects in the consultation instrument

Defect 1 — Respondent grouping

The questionnaire defines “young people” as everyone aged 10 to 24, combining children and 16–17-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, although 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. This matters. A person aged 18 to 24 may well be a legal-age smoker seeking a safer product; on the harm-reduction evidence their switching to a lower-risk product may be a net benefit to public health, yet the consultation frames it as the opposite.

Defect 2 — 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, although they differ markedly in established harm. No question allows a respondent to distinguish between them: a respondent who supports a restrictive measure for cigarettes but opposes it for a non-combustible or nicotine-free product cannot say so.

Defect 3 — Leading premises and response format

A majority of the substantive questions use an agree/disagree format, which the survey-methodology literature identifies as the response format most prone to acquiescence bias, with premises that state contested propositions as established fact. Question 20 is the clearest instance: it asserts that flavours “seem to play a key factor” in youth initiation and “create the impression” the product is less harmful, and then asks only whether a flavour ban would “strengthen” health and the internal market, with no option to record that a ban could produce net harm. Annex 2 sets out the assessment question by question, and is incorporated into this complaint.

V. The reply of 15 July 2026 confirms the complaint

The complainants draw the Ombudsman’s attention to four features of DG SANTE’s reply (Annex 5).

1. On the age band, the reply states that the definition “follows the nomenclature defined by the WHO,” citing WHO’s categories of “adolescents” (10–19) and “youth” (15–24).

This does not answer the objection, and in two respects deepens it. First, none of the WHO age categories — including "young people" (10–24), the umbrella term the questionnaire in fact uses — is defined by, or tracks, the legal boundary between those who may lawfully purchase these products and those who may not. The WHO categories are developmental and health-research constructs; the objection is that a category of that kind is the wrong analytical unit for questions whose regulatory significance turns on lawful versus unlawful conduct. Adopting a correct WHO label does not make the resulting data fit for that purpose. Second, WHO maintains "adolescents" (10–19) and "youth" (15–24) as distinct categories precisely because the 10–24 span is heterogeneous; the questionnaire adopted the single coarsest umbrella and disaggregated neither by those sub-categories nor by the legal boundary. On its own chosen authority's terms, the design used the least granular option available, and the reliance on WHO makes the failure to distinguish lawful from unlawful use harder, not easier, to justify.

2. On product grouping, the reply states that the questionnaire "is not intended to establish a ranking or comparative assessment of the relative harm of different product categories" and does not "differentiate between levels of risk at this stage." This is an express confirmation of the design choice complained of. The reply defends the choice as policy; it does not answer the methodological objection that an instrument designed not to differentiate between materially different risks cannot generate objective evidence about their appropriate regulation.
3. On neutrality, the reply asserts that the questionnaire "strictly follows the principle of neutrality" but supplies no design methodology, no record of piloting or cognitive testing, and no reference to the survey-methodology literature. It further states that the questionnaire's propositions were "guided" by the results of the prior evaluation of the tobacco control framework — that is, that the premises of the questions embed the conclusions of a prior document, with which respondents are then invited to agree. That is a description of a leading instrument.
4. The reply relies on the option to upload supporting documents as a cure. It is not one. Closed-question responses are what the synopsis report will quantify and what the impact assessment will cite; uploaded documents are treated as qualitative background. The reply does not address the closing date of 14 August 2026, which falls within the institutional summer break, and refuses the requested remedy ("no need to revise the questionnaire") without engaging with the grounds on which it was sought.

VI. The handling of the correspondence

A further instance of maladministration arises from the handling of the complainants' letters.

DG SANTE did not reply to the letter of 10 June 2026 within 15 working days, and issued no holding reply. The first response of any kind came on 15 July 2026, five weeks after the letter was sent and only after escalation to the Secretary-General. That is a breach of the Commission's Code of Good Administrative Behaviour for Staff in their Relations with the Public.

VII. Why this 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. Designing and deploying such an instrument, and presenting its results as an evidence base for legislation, breaches the standards that govern the Commission's consultations in four specific respects.

First, the instrument breaches a named, mandatory design rule in the Commission's own current Toolbox. Tool #53, section 2.1.3 requires that questions be "designed in a neutral manner, meaning that they should not 'push' respondents to answer in any way," and that answer scales be balanced — "two positive answer options, two negative answer options and a neutral option" — so that respondents "can always appropriately answer the question." The questions identified in section IV do the opposite: they push toward agreement and offer no balanced means of substantive disagreement. This is not a departure from the spirit of the framework but from a specific rule the Commission published in December 2025, before this consultation was launched.

Second, the Guidelines require that "the results of the consultation should be presented in an objective, unbiased way … recording all views, including dissenting ones" (SWD(2021) 305, Chapter II, section 5.2.4), and Tool #54 requires the presentation of views to be "clear, complete, neutral, unbiased, and balanced across all groups." A questionnaire that does not collect dissenting views on the substance cannot have them recorded; the standard is breached at source. That the Guidelines are, by their own terms, internal instructions rather than rules enforceable by outside parties is no answer: an institution's departure from its own published administrative standards is a settled ground of maladministration before the Ombudsman, whatever its status before a court.

Third, the results of this consultation are intended to feed the impact assessment supporting the legislative proposal. Under the Better Regulation system an impact assessment must rest on reliable evidence, and its synopsis of consultation results must be balanced and unbiased. Data generated by a leading instrument is not reliable for that purpose; presenting it as an evidence base carries the design defect forward into the proposal and misrepresents the state of stakeholder opinion to the Regulatory Scrutiny Board, to the College, and to the co-legislators.

Fourth, above these specific standards sits the duty of good administration in Article 41 of the Charter and the duty of objectivity in Article 9 of the Code of Good Administrative Behaviour: the Commission must handle matters impartially and must not, through the design of its own fact-finding instrument, predetermine the outcome it is ostensibly consulting upon. A consultation constructed to return a particular answer is not impartial fact-finding; it is the appearance of consultation used to ratify a conclusion already reached. That is the substance of the maladministration alleged.

The defect operates at the point of data collection and is irreversible after it. A response given to a question about a fused 10–24 age band cannot subsequently be separated into what the respondent thought about minors and what they thought about lawful adults; a response given to a question about a bundled product category cannot subsequently be attributed to any one product within it. The distinctions were never collected, and no analysis of the responses can recover them. It follows that the defects cannot be cured by

commentary in a synopsis report or by any downstream treatment of the data, and that re-issuance of the consultation with a corrected instrument is the only complete remedy.

The handling failures compound the substantive defect: a five-week silence in breach of the Code's reply standards, followed by a reply that confirms the design choices complained of.

VIII. Prior administrative approaches and admissibility

The approaches required by Article 2(4) of the Statute have been made and exhausted: a substantive complaint to the responsible Director-General (10 June); an escalation to the Secretary-General upon non-response (7 July); a substantive reply refusing the remedy (15 July); and a closing letter recording the unresolved points (Annex 6). The Secretary-General has not replied. The complaint is brought within two years of the facts. The complainants are legal persons established in Member States. No court proceedings are pending on the matter.

IX. What the complainants ask the Ombudsman to do

- To open an inquiry, handled with urgency in view of the consultation closing date of 14 August 2026, into (a) the design of the consultation questionnaire for Initiative 17612 and (b) the handling of the complainants' correspondence by DG SANTE.
- To find that DG SANTE committed maladministration in deploying a consultation instrument that is not objective or impartial.
- To find that DG SANTE committed maladministration in failing to reply to the letter of 10 June 2026 within the period required by the Code of Good Administrative Behaviour.
- Principally: to recommend that the Commission withdraw the public consultation on Initiative 17612 and re-issue it with a properly constructed instrument that complies with the Better Regulation Guidelines and Toolbox. As set out in section VII, the response data cannot be disaggregated after collection; re-issuance is the only remedy that fully addresses the defects.
- In the alternative, and without prejudice to the principal request: to recommend that the Commission (a) conduct a targeted supplementary consultation, before the impact assessment is finalised, using corrected questions that distinguish minors from lawful adult consumers and distinguish between product categories; (b) commit that the results of the affected closed questions will not be relied upon, in the synopsis report (Toolbox Tool #54) or in any impact assessment, to support conclusions distinguishing minors from adults or between product categories, and that the framing limitations of the questionnaire will be expressly identified and weighted; and (c) publish the full anonymised response data set so that independent analysis is possible.

Enclosures

- Annex 1 — The public consultation questionnaire (Initiative 17612).
- Annex 2 — Question-by-question assessment of framing bias, prepared by European Tobacco Harm Reduction Advocates (ETHRA).
- Annex 3 — Letter to the Director-General of DG SANTE, 10 June 2026.
- Annex 4 — Letter to the Secretary-General, 7 July 2026.

- Annex 5 — Reply of the Director-General of DG SANTE, 15 July 2026 (Ares(2026)7082585).
- Annex 6 — Closing letter to the Director-General of DG SANTE, 24 July 2026.