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Date: Tue, 07 Jul 2026 20:22:13 +0200
From: hans@acvoda.nl
To: Ilze.Juhansone@ec.europa.eu
Cc: Leopoldo.Rubinacci@ec.europa.eu, Claire.Bury@ec.europa.eu, cab-varhelyi-contact@ec.europa.eu, sandra.gallina@ec.europa.eu
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=?UTF-8?Q?=29_=E2=80=94request_for_institutional_intervention=?
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Dear Secretary-General,

On 10 June 2026, the signatory consumer associations wrote to Sandra Gallina, Director-General of DG SANTE, setting out a complaint concerning the design of the public consultation questionnaire for Initiative 17612. The letter, copied to your office, identified three defects: the use of a single "young people" category spanning ages 10 to 24, combining children with adults who are lawful consumers in every Member State; the treatment of products of materially different established harm as a single regulatory category in questions concerning restrictive measures; and the use of an agree/disagree response format in a majority of substantive questions, with premises that state contested propositions as established fact. The letter asked DG SANTE to respond by 30 June 2026. The full text of the letter and its supporting annex are enclosed for reference.

As of the date of this letter, no reply has been received from DG SANTE. The consultation closes on 14 August 2026, inside the institutional summer break. The standard reply timeline cannot deliver a remedy within the period during which the defects remain capable of correction.

The failure to reply is itself a matter for the Secretariat-General. The Commission's Code of Good Administrative Behaviour for Staff in their Relations with the Public (OJ L, 8 March 2024) requires a reply within 15 working days of receipt of correspondence by the responsible service or, where a substantive reply is not possible in that period, a holding reply indicating the date by which a substantive reply may be expected. That period has now been exceeded. Neither a substantive nor a holding reply has been received. This non-response constitutes a further and distinct instance of maladministration, and one for which the Secretariat-General has direct institutional responsibility.

We write to you in your capacity as Secretary-General and institutional owner of the Better Regulation framework on which the 10 June complaint is based. The defects identified are structural. They concern the response format used across the questionnaire, the definition of respondent categories, and the categorisation of products. They cannot be remedied by adjustments to individual questions or by retrospective commentary in a synopsis report. Data collection at the front end determines what analysis at the back end can show; a synopsis report cannot recover information the instrument was not designed to elicit. The only remedy that gives effect to the Commission's duty of objectivity is the withdrawal of the present consultation and its

re-issuance with a properly constructed instrument.

We accordingly ask that the Secretariat-General require DG SANTE to withdraw the public consultation on Initiative 17612 and to re-issue it with a questionnaire that complies with the Better Regulation Guidelines and Toolbox and with the survey-methodology principles those instruments incorporate.

We are aware that withdrawal and re-issuance has consequences for the legislative timetable. The timetable cannot be a defence to maladministration. A consultation that does not meet the standards of objectivity required of Commission consultations cannot be relied upon as an evidence base for legislation, and proceeding on its results would carry the procedural defect forward into the proposal itself.

The signatories intend, if the matter is not satisfactorily resolved within the consultation period, to file a complaint with the European Ombudsman. This letter, together with the 10 June letter to DG SANTE, is intended to constitute the full administrative approach contemplated by Article 2(4) of the Statute of the European Ombudsman.

We would welcome a substantive response before the start of the institutional summer break.

Yours sincerely,
Hans Molenaar
Boardmember, Acvoda
Info@acvoda.nl

- 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.

----- Oorspronkelijke bericht -----

Onderwerp: Complaint concerning the design of the public consultation on the revision of the EU tobacco rules (Initiative 17612)

Datum: 2026-06-10 13:43

Afzender: info@acvoda.nl

Ontvanger: sandra.gallina@ec.europa.eu

Kopie: Ilze.Juhansone@ec.europa.eu, Leopoldo.Rubinacci@ec.europa.eu, Claire.Bury@ec.europa.eu, cab-varhelyi-contact@ec.europa.eu

Dear Director-General Gallina,

I write on behalf of the consumer associations listed in section VII of the enclosed complaint – representing users of safer nicotine products in Spain, Italy, the Netherlands, Romania, Sweden and France – to submit a formal complaint concerning the design of the public consultation questionnaire for Initiative 17612.

The complaint identifies three defects in the questionnaire's design: the grouping of children with lawful adults under a single "young people" band; the treatment of products of materially different risk as a single regulatory category; and the use of leading premises and one-directional response options across a majority of the substantive

questions. It does not contest DG SANTE's competence on this file or the policy direction the revision is pursuing.

The objection is that the instrument as designed cannot return data that objectively represents stakeholder views, and that this is incompatible with Article 41 of the Charter, the Code of Good Administrative Behaviour, and the Commission's own Better Regulation Guidelines and Toolbox.

Because the consultation is open, the defects remain capable of correction. The signatories ask DG SANTE to consider the remedies set out at section VI and to respond by 30 June 2026. We are available to discuss how the corrections might be made without disrupting the legislative timetable.

This letter is intended as the prior administrative approach contemplated by Article 2(4) of the Statute of the European Ombudsman. It is copied to the Secretary-General of the Commission, 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, to place the correspondence on the institutional record.

Yours sincerely,

Hans Molenaar
Boardmember Acvoda
Info@acvoda.nl, +31643024265

Enclosures

Complaint to DG SANTE concerning Initiative 17612
Question-by-question assessment of framing bias produced by European Tobacco Harm Reduction Advocates

Copied to

Ilze Juhansone, Secretary-General, European Commission
Leopoldo Rubinacci, Director-General and Chair of the Regulatory Scrutiny Board
Claire Bury, Deputy Director-General, DG SANTE
Cabinet of Commissioner Olivér Várhelyi
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