



European Policy
Innovation Council



Testing the Evidence Trail in the TPD2 Revision Process:

An Assessment of the Public Consultation
Questionnaire

September 2026



European Policy Innovation Council

This report has been prepared by the European Policy Innovation Council (EPIC) as an independent policy assessment of the European Commission's Evaluation of the EU tobacco control framework, with a focus on Better Regulation, methodological robustness, proportionality and the forthcoming Impact Assessment process.

EPIC does not take a position on the consumption of tobacco or nicotine products. EPIC recognises the importance of public health objectives, including the reduction of smoking-related harm and the protection of minors. The purpose of this report is not to assess product-specific policy choices, but to examine whether the Evaluation provides a sufficiently robust analytical basis for future regulatory decisions. This report was prepared with the support of Tobacco Europe. The analysis, conclusions and wording are the responsibility of EPIC.

EPIC is registered in Brussels, Belgium, as a nonprofit (BE1016989669) and under the EU Transparency Register (REG 683253994641-35).

© European Policy Innovation Council, 2026

EPIC accepts no responsibility for the persistence or accuracy of URLs for external or third-party websites referenced in this publication and does not guarantee that any content on such websites is, or will remain, accurate or appropriate.

Executive Summary

Purpose. This assessment is part II in a broader review of the Commission's process for revising the EU tobacco control framework. Part I assessed the TPD2 Evaluation. This output assesses the public consultation questionnaire as the next stage in the evidence-to-regulation chain.

Central finding. In several areas, the questionnaire creates an Evaluation-to-Public Consultation leap: it shifts to questions about specific, more ambitious regulatory interventions, for which the Evaluation did not clearly establish whether the relevant existing TPD framework is ineffective, inadequately enforced, or no longer fit for purpose. In those cases, the Impact Assessment must now supply the missing evidence trail before such measures are advanced.

Key Better Regulation question: In cases where the public consultation tests interventions that go beyond the shortcomings clearly established in the Evaluation, will the Impact Assessment supply the missing evidence trail by demonstrating whether the existing TPD framework is ineffective, insufficiently enforced, or no longer fit for purpose?

Live examples. The leap is most visible in pack inserts with cessation information; standardisation of the form and size of vape tanks, refill containers, and

cartridges; standardised packaging format for new-generation products; additional vape device safety rules; and restrictions on device design and appeal.

Main recommendation. The Impact Assessment should not treat consultation responses as proof that these measures are already necessary or proportionate. For each intervention, it should establish a clear evidence trail from the existing rule to the proven shortcoming, the available policy options, the expected impacts and the proportionality of EU action.

Series Note: Testing the TPD2 Regulatory Process

This assessment is part of a broader review of the regulatory process underpinning the revision of the EU tobacco control framework. The purpose of the series is not to determine the final policy outcome in advance, but to test whether the Commission's process meets the standards of evidence, neutrality, proportionality and analytical completeness required under the EU Better Regulation framework. Each part examines a different stage of the policy cycle: evaluation, consultation, impact assessment and legislative proposal.

Consultation as a Regulatory Evidence Gate

The European Commission's public consultation on the revision of the EU tobacco control framework is an important procedural step in the preparation of future legislation. In such a file, the questionnaire is not a neutral administrative formality. The way questions are framed, the product categories used, the response options offered and the trade-offs explored will influence the type of evidence the Commission receives and, ultimately, the quality of the future Impact Assessment.

The questionnaire rightly identifies several legitimate subjects for consultation, including youth protection, novel products, flavours, packaging, product safety, digital promotion, traceability and internal market divergence. The concern is narrower and procedural: in several areas, the questionnaire moves from broad diagnosis to specific regulatory interventions without first showing a visible evidence trail from the Evaluation.

This matters because Part I identified a risk that the Evaluation moves from a constrained evidence base toward a relatively strong forward-looking narrative on regulatory adaptation. The OPC questionnaire is the next procedural step in that chain. If it reinforces the same direction without sufficiently testing evidence, enforcement, product-specific distinctions, impacts and proportionality, the future IA may inherit assumptions that should remain open for analysis.

The Evaluation-to-Public Consultation Leap

The main concern raised by the questionnaire is not that it asks about irrelevant issues. Many of the issues covered are legitimate. The concern is that, for a number of measures, the questionnaire moves directly to specific restrictions or new regulatory layers in areas where the Evaluation did not clearly establish that the relevant existing TPD framework is ineffective, inadequately enforced,

or no longer fit for purpose. The Impact Assessment must therefore test that missing link measure by measure.

A robust Better Regulation sequence should normally include **the existing rule; identified shortcomings; evidence of ineffectiveness or enforcement failure; policy options; impact assessment; and proportionality test.**

In the questionnaire, this sequence is not always visible. Some questions appear to move from broad concern to specific intervention. This creates an Evaluation-to-Public Consultation leap. The point is not that the measures should be excluded from the IA. The point is that the IA must make the case for them measure by measure, rather than treating their inclusion in the consultation as evidence that the need for intervention has already been established.

Evidence-Trail Matrix: Five Examples

The following examples show where the public consultation appears to test interventions that go beyond the specific regulatory shortcomings visibly established by the Evaluation. The table uses row-level references because several major interventions are bundled inside broad matrix questions, especially Q13 and Q19. Where those questions recur, this is part of the critique: the OPC places several distinct regulatory moves inside omnibus effectiveness grids rather than building a separate evidence trail for each measure.

OPC measure and precise question reference	Existing TPD baseline	Missing Evaluation finding	IA risk / corrective requirement
Pack inserts with cessation information across product categories Primary: Q19, row "Leaflets/inserts with quitting information". Objective context: Q12, row "Supporting the cessation of use".	For smoking tobacco products, cessation information is already embedded in combined health warnings. For e-cigarettes, Article 20 requires a leaflet with information on use, storage, contraindications, adverse effects, addictiveness and toxicity.	The Evaluation does not clearly show that existing warning and leaflet arrangements are ineffective, that consumers do not engage with them, or that separate cessation inserts would provide an additional demonstrated benefit.	The IA should not move to a broader information obligation without first testing whether the current information architecture is failing and whether inserts would add measurable value.
Standardisation of the form and size of vape tanks, refill containers and cartridges Primary: Q13, row "Standardising the form and size of tanks, refill containers and cartridges for e-cigarettes". Secondary: Q19 repeats the same item in the labelling/packaging grid.	The TPD already harmonises this space through capacity limits for refill containers, tanks and cartridges, notification of components and refill mechanisms, and leak-free refilling requirements.	The Evaluation does not clearly establish that existing capacity limits or refill-mechanism rules are failing, or that differing physical formats create a demonstrated safety, interoperability or internal-market problem.	The IA should distinguish between a proven safety/internal-market problem and a preference for more prescriptive product standardisation.
Standardised packaging form or format for new-generation products (NGPs) Primary: Q18, mandatory plain packaging. Secondary: Q19, row "Plain or standardised packaging". Scope context: Q15 on currently uncovered products and devices.	For combustibles, the TPD contains detailed rules on pack dimensions, shape and minimum pack size, while allowing Member States further room for packaging standardisation. For e-cigarettes and other NGPs, the framework focuses more on product information, warnings and misleading features than on common pack format.	The Evaluation does not clearly show why the existing category-specific balance is no longer adequate, what concrete problem is created by current NGP packaging formats, or why common EU rules on form or format are necessary.	The IA should avoid generalising packaging-standardisation logic across product categories without a product-specific evidence trail.

OPC measure and precise question reference	Existing TPD baseline	Missing Evaluation finding	IA risk / corrective requirement
Additional vape device-safety rules on leakage, overheating and battery safety Primary: Q13, row "Strengthening product standards for device safety". Scope context: Q15, row on devices, accessories and items used for consumption.	Article 20 already requires e-cigarettes and refill containers to be protected against breakage and leakage, to ensure leak-free refilling, and to address unsafe or non-compliant products through correction, withdrawal or recall. Member States can also act where products present a serious health risk.	The Evaluation does not visibly establish that the current safety architecture is not working in practice through incident data, adverse-effect reports, recalls, enforcement failures or divergent national requirements.	The IA should determine whether the problem is rule design, compliance, enforcement, market surveillance or lack of data before adding a new regulatory layer.
Restrictions on device design and appeal, including appearance, lighting, toy-like features, screens and gamification Primary: Q13, row "Introducing product design requirements to reduce appeal". Appeal context: Q2 and Q3 on product attractiveness. Related: Q19, row on promotional or misleading packaging elements.	The TPD already restricts promotional communications and limits misleading product presentation and packaging. These tools address appeal and consumer perception, though they do not prescribe detailed physical design rules.	The Evaluation does not clearly identify evidence that these particular physical design features drive uptake or appeal, explain why existing tools are inadequate, or show why EU-wide design restrictions are necessary.	The IA should test evidence on uptake and appeal, assess enforcement feasibility, and compare targeted alternatives before moving to detailed product-design regulation.

OPC-to-Impact Assessment Risk Map

The risk is not that the questionnaire raises these measures. The risk is that consultation responses may later be read as procedural validation for options whose evidence trail has not yet been established. The IA should therefore treat the OPC as a signal of possible regulatory directions, not as proof of necessity, effectiveness or proportionality.

Risk arising from the questionnaire	Why it matters for the IA	Corrective requirement
Specific interventions are tested without a clearly established Evaluation finding	The IA may inherit options that appear procedurally validated but lack a demonstrated evidence trail.	For each measure, identify the existing rule, the proven shortcoming and the evidence of failure.
The questionnaire does not consistently distinguish ineffective rules from insufficient enforcement	The IA may propose new legislation where implementation, market surveillance or enforcement would be more appropriate.	Distinguish rule-design failure, enforcement failure and market/technological obsolescence.
The questionnaire moves across product categories	The IA may generalise measures from combustibles to e-cigarettes, heated tobacco, heated herbal products or nicotine pouches without sufficient justification.	Assess each product category separately and justify any cross-category extension.
Restrictive measures are tested without equivalent testing of alternatives	The IA may treat stricter regulation as the default pathway.	Compare less restrictive, targeted, enforcement-led and product-specific options.
Agreement-scale responses may not explain why respondents support measures	The IA may overread broad support as evidence of effectiveness or proportionality.	Supplement OPC data with targeted evidence, technical analysis and stakeholder interviews.

Recommendations for the Impact Assessment

The Impact Assessment should address the limitations of the public consultation questionnaire by applying five safeguards.

1. **Evidence trail.** For each proposed measure, the IA should establish the link from the existing TPD provision to the identified shortcoming and then to the proposed intervention.
2. **Problem type.** The IA should distinguish between rules that are ineffective by design, rules that are inadequately enforced, and rules that may no longer be fit for purpose because of market or technological developments.
3. **Product specificity.** Measures relevant to combustible tobacco products should not be automatically extended to e-cigarettes, heated tobacco products, heated herbal products, nicotine pouches or other new-generation products without a product-specific justification.
4. **Alternatives.** The IA should compare less restrictive and more targeted alternatives, including enforcement-led approaches, market surveillance, clearer guidance, consumer information, age-verification measures and product-specific standards.
5. **Use of OPC evidence.** The IA should treat OPC responses as one source of evidence, not as proof that the measures tested in the questionnaire are necessary, effective or proportionate.

Conclusion

The public consultation questionnaire is useful as an issue-mapping instrument. It identifies topics that are relevant to the future revision of the EU tobacco control framework and may help the Commission understand stakeholder views on possible regulatory directions.

However, the questionnaire does not, on its own, demonstrate that the measures it tests are necessary, evidence-based, enforceable or proportionate. In several areas, it moves beyond the regulatory shortcomings visibly established in the Evaluation and asks about more ambitious interventions without first establishing whether the existing TPD framework is ineffective, insufficiently enforced or no longer fit for purpose.

This is why the forthcoming IA must play a corrective role. It should not treat the Evaluation and OPC as confirmation of a predetermined regulatory pathway. It should test, measure by measure, whether there is a clear evidence trail from the existing rule to the problem, from the problem to the available options, and from the preferred option to a proportionate EU intervention.

The conclusion is not that further EU action is unwarranted. The conclusion is that further EU action must be justified through a process that clearly defines the problem, tests the evidence, distinguishes between product categories and affected groups, assesses enforcement and economic impacts, compares genuine alternatives and demonstrates proportionality.



European Policy Innovation Council

About EPIC

EPIC is a thinking movement that combines the research capacity of traditional think tanks with the community engagement and mobilisation of political movements. By blending classic initiatives such as policy papers and conferences with innovative digital formats and on-site tours, EPIC is building a large community of policymakers, industry leaders, experts, activists, and influencers in Europe. Together, we aim to become Europe's first public policy influencer, shaping the future of competitiveness, sustainability, and democratic resilience.

Transparency and Legal Notice

EPIC is a nonprofit registered under Belgian law as an ASBL (BE.1016.989.669) and the EU Transparency Register (REG 683253994641-35). All opinions and publications represent the views of the respective authors and do not necessarily reflect the positions of EPIC or any affiliated organizations or individuals.

Contact Information

European Policy Innovation Council (EPIC) asbl
Rue du Chatelain, 8, Box 4
1000 Brussels, Belgium

2026 © European Policy Innovation Council

www.thinkepic.eu



2026 © European Policy Innovation Council