

Tobacco Europe contribution to the European Commission Call for Evidence on the modernisation of the Better Regulation Framework

3 February 2026

Tobacco Europe¹ welcomes the opportunity to contribute to the Commission's call for evidence in preparation of its forthcoming Communication on Better Regulation and wishes to provide the following observations.

1) How could the Commission better reconcile the need for evidence-based policies and urgent action in the conduct of its better regulation activities?

Tobacco Europe has consistently underlined that evidence-based policymaking can be strengthened by greater reliance on real-world evidence and market surveillance data, particularly where policy measures have significant market, consumer, and enforcement implications. Practical experience from Member States (for example, Sweden²) can provide timely and policy-relevant insights that complement academic or model-based studies.

In addition, Tobacco Europe has highlighted a fragmented or selective integration of scientific evidence in certain policy processes. A genuinely evidence-based approach requires that all relevant scientific inputs are assessed holistically and transparently. Past experiences, such as the limitations identified in the preparation of scientific opinions (e.g. SCHEER), illustrate the risk that incomplete integration of evidence can undermine both policy quality and stakeholder trust.

Impact assessments, in line with the competitive checks, should systematically assess impacts on competitiveness, innovation capacity and investment conditions, including the effects of regulatory choices on incentives for product development, compliance planning and long-term business investment within the EU. Such analysis is essential to ensure that urgent action does not inadvertently undermine the EU's broader economic and industrial policy objectives.

In this context, Tobacco Europe underlines that impact assessments are not optional procedural tools, but a mandatory prerequisite for the adoption of any legislative proposal with significant economic, social, market or enforcement implications. This requirement flows directly from the Commission's own Better Regulation Guidelines³ and from the

¹ Tobacco Europe is the European umbrella organisation representing the three largest tobacco and nicotine products manufacturers, namely British American Tobacco, Imperial Brands and Japan Tobacco International.

² Sweden has achieved one of the lowest smoking prevalence rates in the EU, with daily smoking levels at around 5-6% of the adult population, reflecting a sustained long-term decline.

³ https://commission.europa.eu/law/law-making-process/better-regulation/better-regulation-guidelines-and-toolbox_en;

Interinstitutional Agreement on Better Law-Making⁴ and should be applied consistently across all policy areas.

Impact assessments must be completed and be subject to appropriate quality control before the publication of a legislative proposal. In the exceptional cases of derogations from the requirement to conduct an impact assessment on grounds of urgency, accelerated timelines may lead to adjustments in scope or depth, but cannot justify the absence, postponement, or retroactive publication of an impact assessment report or staff working document.

Publishing proposals before the underlying impact assessment or analytical work is completed reverses the logic of Better Regulation, undermines evidence-based decision-making, and deprives co-legislators and stakeholders of the information needed for meaningful scrutiny. Such practices weaken legal certainty, reduce the credibility of the legislative process, and increase the risk of implementation and enforcement failures.

Beyond procedural compliance, Better Regulation should also safeguard policy-making predictability and legal certainty. Frequent changes to regulatory timelines, subsequent compressed timelines or policy options introduced without sufficient evidence increase uncertainty for economic operators and authorities alike, complicating compliance, enforcement and policy processes.

Tobacco Europe therefore considers that strict adherence to the principle “no proposal without an impact assessment” is essential to uphold proportionality, accountability, and the Commission’s commitments under the Better Regulation framework.

2) How could the Commission ensure a holistic approach to stakeholder consultations with a view to implementing a more efficient and effective manner to gathering essential information, including possibly across policy fields?

Tobacco Europe has highlighted that effective information-gathering depends on inclusive, impartial, and well-balanced consultation processes. While formal invitations to stakeholders are welcome, the credibility and effectiveness of consultations can be weakened when key work is delegated to external consultants whose approach lacks perceived neutrality. This concern has already been raised by Tobacco Europe in previous exchanges and has been also reflected in issues subject to scrutiny in the context of a complaint lodged to the European Ombudsman⁵.

Moreover, Tobacco Europe has called for greater clarity and proportionality in the interpretation and application of Article 5.3 WHO Framework Convention on Tobacco Control (FCTC), to ensure that it does not lead to the systematic exclusion of legitimate stakeholders from

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:41997A0625%2801%29;>

⁵https://www.ombudsman.europa.eu/en/decision/en/199130?utm_source=BenchmarkEmail&utm_campaign=March_2025_News_Copy&utm_medium=email;

technical and evidence-gathering phases. This is even more relevant in light of the current Commissioners' mission, which explicitly emphasise the importance of stakeholder involvement and of hearing all affected parties⁶.

A holistic consultation approach should also ensure continuity of stakeholder engagement throughout the policy cycle, including during the preparation of delegated or implementing measures and during substantive amendments introduced by co-legislators. This would improve the quality, relevance and completeness of the information used for decision-making

3) What practical steps could be undertaken to make EU laws simpler and easier to implement in practice (for example as regards the legal instruments, the use of delegated and implementing acts, or the application of digital tools, etc.)?

From a Better Regulation perspective, Tobacco Europe has constantly stressed the importance of simplification across policy frameworks. In this context, it is notable that the evaluation of Tobacco Products Directive (TPD) has not been included in DG SANTE's current simplification efforts, despite its complexity and the significant challenges it poses for implementation, enforcement, and compliance.

Tobacco Europe also underlines that Better Regulation should help ensure that EU legislation commands broad public support, which requires transparency not only in procedures but also in how evidence and public opinion are considered. For example, Eurobarometer data indicating that around half of EU citizens do not support flavour bans⁷ should be transparently reflected in impact assessments and policy deliberations, alongside scientific and enforcement considerations.

Better Regulation should apply equally to delegated and implementing acts, particularly where such measures establish technical requirements, product specifications or market access conditions with significant economic or enforcement implications. Appropriate transparency, stakeholder involvement and, where relevant, impact analysis should accompany such acts to avoid regulatory gaps and unintended consequences.

Tobacco Europe also calls for more diligent scrutiny to ensure that delegated powers are strictly limited to non-essential elements of legislation, which may only be supplemented or amended without altering the core policy direction established in the primary act. Robust necessity assessments, grounded in the principles of proportionality and subsidiarity, should be systematically conducted *ex ante* to avoid regulatory duplication. Where delegation is considered warranted, it should be narrowly circumscribed, clearly defined and, where appropriate, subject to a precise time frame. This is essential to safeguard legal certainty.

⁶ Commissioner Dobrovskis mission letter: https://commission.europa.eu/document/download/71c3190f-0886-4202-846e-5750f188f116_en?utm_source=chatgpt.com

⁷ https://europa.eu/eurobarometer/surveys/detail/2995?utm_source=chatgpt.com;

prevent undue discretion regarding when and how such powers are exercised, and ensure full accountability to the co-legislators.

Finally, EU legislation should systematically include monitoring, evaluation and review mechanisms, allowing rules to be reassessed in light of new evidence, real-world experience and market developments. This is particularly important in policy areas characterised by evolving science and consumer behaviour.

Overall, Tobacco Europe underlines the importance of making the evidence-based principle a practical reality through robust impact assessments that capture all relevant economic and social impacts, including employment effects. Early and structured stakeholder consultation would support this objective, while simplifying legislation, ensuring internal coherence, and clearly explaining how evidence and societal views are weighed would strengthen both the effectiveness and legitimacy of EU law.