To : Ms Ilze Juhansone
Secretariat-General European Commission
Rue de la Loi 200/ Wetstraat 200
1049 Bruxelles/Brussel

Subject: Observations on the Evaluation Report of the Tobacco Products Directive and Tobacco Advertising Directive (2 April 2026)

18 May 2026

Dear Ms Juhansone,

On behalf of Tobacco Europe[1], I would like to share our observations on the Commission's Evaluation Report published on 2 April 2026 on the Tobacco Products Directive (TPD) and Tobacco Advertising Directive (TAD)[2]. Given its central role in informing the forthcoming Impact Assessment and the ongoing revision process, we consider it important to raise a number of concerns regarding its analytical robustness.

As a preliminary matter, we note that shortcomings in the evaluation process had already been observed during earlier stages, including in the context of an Ombudsman inquiry concerning a framework contract on tobacco control policy[3]. That case highlighted weaknesses in how the Commission addressed stakeholder concerns and explained its assessment of interests relevant to the evaluation exercise. The Ombudsman, while closing the inquiry, underlined the importance of transparency, clear reasoning and rigorous conflict-of-interest assessments on a contract-specific basis—principles that are equally relevant to evaluations intended to underpin major policy revisions.

Furthermore, while the Commission has formally addressed the Regulatory Scrutiny Board's recommendations[4] in the revised evaluation report, we remain concerned that certain underlying weaknesses persist, as further outlined below. In particular, despite the revisions made, the evaluation report continues to provide a limited evidentiary and analytical basis for forward-looking policy discussions, notably in relation to causality, EU added value and proportionality. Also, the evaluation does not meet the principles and minimum standards required under the Better Regulation framework[5].

First, the report does **not establish a robust causal link between the measures introduced under the TPD/TAD and observed outcomes**. Despite recognizing evidentiary gaps and methodological limitations, it proceeds to draw broad conclusions on effectiveness of the Directives (for example, in relation to the impact of certain product restrictions), without clearly demonstrating how those outcomes can be attributed to those measures, thereby weakening the reliability of the analysis.

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[11] 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] 4913f646-f22d-463f-8678-3a82c3e84fc2_en
[3] https://www.ombudsman.europa.eu/en/decision/en/199130
[4] Register of Commission Documents - SEC(2026)111
[5] Better regulation: guidelines and toolbox

Second, the **evaluation does not sufficiently assess the EU added value of the intervention**. The evaluation report addresses EU added value in general and descriptive terms, by stating that EU action contributed to harmonisation, avoided fragmentation and supported cross-border coordination. However, it does not systematically analyse whether and to what extent outcomes could have been achieved through national policies alone, nor does it meaningfully compare the effectiveness of pre-existing or parallel national measures (for example, why – despite EU intervention – some countries have achieved Directives' objectives and some not). This limits the evaluation's ability to demonstrate the necessity and added value of EU-level intervention, an issue that is closely linked to subsidiarity considerations and echoes several of the RSB's observations on the need for a clearer intervention logic and counterfactual analysis.

Third, the **scope of the evaluation is incomplete** as it does not adequately assess how have the Directives affected economic operators across the value chain, including SMEs, retailers, processors and primary producers, nor does it quantify regulatory costs, administrative burden or implications for competitiveness. These are core elements required for a balanced assessment.

Fourth, the report provides **limited insight into how the framework operates in practice and its effectiveness**. In particular, while it documents divergences in national tobacco control measures across several policy areas (including taxation, flavour regulation and smoke-free environments), it does not analyse how these differences affect the effectiveness of the TPD/TAD as a whole, nor does it clarify whether observed shortcomings stem from the design of the EU legislation or from implementation and enforcement at Member State level. It does not meaningfully assess enforcement challenges, the functioning and effectiveness of existing instruments such as traceability systems, or the interaction between regulation and the persistence of illicit and non-compliant markets. The Better Regulation framework requires evaluations to explain why an intervention is or is not effective, including by distinguishing between structural shortcomings and operational or enforcement-related issues, an aspect that is not clearly addressed in the report

Fifth, there are **shortcomings in the handling and use of collected evidence**. As already highlighted by the RSB, which stated that the "*evidence base is insufficient to draw informed conclusions*", the report does not set out a clear methodology explaining which evidence was retained, weighted or excluded, and on what basis. This results in selective reliance on certain evidence, while other relevant strands appear to be downplayed or dismissed, without the conclusions fully acknowledging these limitations.

Finally, the evaluation **does not clearly distinguish between shortcomings in the design of the legislation and divergences in national implementation**, nor does it sufficiently analyze variations in outcomes across Member States and their underlying drivers. In this context, the report appears to rely on a **selective use of the internal-market rationale**, whereby more restrictive national measures adopted by some Member States are implicitly treated as positive benchmarks, while less restrictive approaches are characterised as sources of distortion. However, the report does not seem to assess whether such more restrictive national practices may themselves create internal market barriers, nor does it demonstrate their marginal effectiveness. This asymmetrical approach is difficult to reconcile with Better Regulation principles that require internal market fragmentation to be demonstrated and not presumed.

More broadly, the evaluation appears to **point towards further regulatory intervention without first establishing whether the current framework has delivered its objectives, where specific deficiencies lie, and whether divergences stem from EU-level design choices of from national implementation.** This creates a risk that future measures may not be sufficiently targeted or proportionate.

As already outlined, these shortcomings were formally identified by the Commission's Regulatory Scrutiny Board, whose negative opinion concluded that the scope of the evaluation was too limited to support a comprehensive assessment of tobacco control measures and that the evidence base was insufficient to draw informed policy conclusions.

As the RSB is mandated to provide central quality control of evaluations and to ensure that political decision-making is supported by the best available evidence, such a finding constitutes a serious procedural warning. Looking ahead to the upcoming Impact Assessment, we believe it will be essential to address these gaps through a comprehensive and methodologically sound analysis, including by:

- Establishing clear causality between measures and outcomes;
- Assessing the added value of EU intervention compared to national action;
- Providing a full and quantified assessment of impacts on economic operators, including SMEs, employment, investment, innovation and the internal market;
- Assessing effectiveness in practice;
- Providing clarification on how evidence is assessed, treated and reflected in the findings;
- Assessing regulatory costs, compliance burdens and enforcement realities; and
- Evaluating potential unintended consequences, including the expansion of illicit markets and distortions affecting compliant businesses.

We trust that these concerns will be taken into due consideration by the Commission as it progresses towards the forthcoming Impact Assessment, which will shape the revision ofthe EU's future tobacco and nicotine legislative framework. In view of these matters, we respectfully request your perspective on the following areas, which are essential for establishing a comprehensive understanding of all relevant policy-making aspects:

1. In light of the Regulatory Scrutiny Board's finding that the evidence base was insufficient to draw informed conclusions, can the Commission confirm whether the forthcoming Impact Assessment will include a revised and transparent evidence-assessment methodology, including an explanation of which evidence is retained, weighted or excluded as mentioned in the RSB opinion, and on what basis?
2. What steps will be taken to provide a comprehensive and quantified assessment of impacts on economic operators – including SMEs, employment, agricultural regions, investment, innovation, and the internal market – as well as to clarify how evidence is assessed and weighted in the findings?

3. Can the Commission confirm whether the Impact Assessment will include a quantified assessment of regulatory costs, compliance burdens and economic impacts across the full value chain, including SMEs, retailers, processors and primary producers, together with an assessment of unintended consequences such as the expansion of illicit markets and distortions affecting compliant businesses? In addition, can the Commission explain how these impacts will be reflected in the assessment of proportionality?

We remain at your disposal to contribute constructively to this process and to support the assessment on how an evidence-based, proportionate and effective regulatory framework should look like.

Yours sincerely,

Nathalie Darge,

Director General, Tobacco Europe

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