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TPD2 Evaluation Assessment:

Procedural Alignment with EU Better Regulation Standards

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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.

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Introduction: Evaluation as the Foundation of Policy

The revision of the EU tobacco control framework comes at an important moment for both public health policy and EU regulatory governance. The Tobacco Products Directive and Tobacco Advertising Directive sit at the intersection of two central EU objectives: the smooth functioning of the internal market and the achievement of a high level of human health protection, particularly for young people. The Commission's Evaluation of the tobacco control framework is therefore not merely a technical exercise. It is a key procedural step that will help shape the evidentiary basis for any future legislative revision.

The Evaluation assesses the Tobacco Products Directive, the Tobacco Advertising Directive and related tobacco control policies as a single policy intervention, applying the standard Better Regulation criteria of effectiveness, efficiency, relevance, coherence and EU added value. It draws on a broad evidence base, including stakeholder consultations, scientific and expert studies, survey data, legal analysis and supporting studies. It also identifies significant market developments since the adoption of the current framework, including the growth of novel tobacco and nicotine products, changing consumption patterns and the increasing role of digital marketing.

At the same time, the Evaluation acknowledges important analytical limitations. These concern data availability, the quantification of costs and benefits, attribution of observed outcomes to individual measures, and the difficulty of distinguishing the effects of the EU tobacco control framework from other factors such as taxation, national measures, behavioural trends and market developments. These limitations matter because the Evaluation also moves toward a clear directional narrative: that the current framework has been outpaced by market developments and that regulatory adaptation is required.

This creates the central question for this assessment: Does the Commission Evaluation meet the analytical standard required to inform a robust, proportionate and evidence-based Impact Assessment for any future revision of the EU tobacco control framework?

This question is particularly important because evaluation and impact assessment perform distinct functions in the EU policy cycle. An evaluation should assess the performance of existing rules. An impact assessment should

define the problem for future intervention, identify and compare policy options, assess likely impacts and test proportionality. Where an evaluation moves beyond retrospective assessment and begins to frame future regulatory conclusions, the boundary between evaluation and impact assessment risks becoming blurred.

The Commission's own quality-control process underlines the relevance of this concern. The draft Staff Working Document was submitted to the Regulatory Scrutiny Board on 10 November 2025, discussed on 9 December 2025, and received a negative opinion on 12 December 2025. The published Evaluation sets out how the Commission addressed the Board's recommendations, including on attribution, product scope, Member State variation, uncertainty and the need to avoid conclusions going beyond the evidence.

Against this background, this assessment does not seek to contest the public health objectives of the EU tobacco control framework, nor does it assess the desirability of any future regulatory option. Its purpose is narrower and procedural: to examine whether the Evaluation provides a sufficiently robust, balanced and methodologically transparent basis for the subsequent Impact Assessment phase.

Analytical Framework: Benchmarking Against Better Regulation Standards and Practice

EU Better Regulation Guidelines, OECD Principles, and the 2026 Better Regulation Communication

The appropriate benchmark for assessing the Evaluation is not whether it supports one stakeholder's preferred policy outcome. The benchmark is whether it satisfies the standards that the European Commission applies to its own policy cycle.

The Commission's Better Regulation Guidelines and Toolbox set out the principles to be followed when preparing new initiatives, managing existing legislation, conducting evaluations and carrying out impact assessments. These standards apply across the law-making cycle and are intended to ensure that EU action is evidence-informed, proportionate, transparent and based on a clear understanding of problems, impacts and policy alternatives.[1]

[1] EU Better Regulation Guidelines, OECD Principles, and the 2026 Better Regulation Communication; European Commission, *Better Regulation Guidelines*, SWD(2021) 305 final, November 3, 2021.

For evaluations specifically, the Better Regulation framework requires an evidence-based judgement of the extent to which an intervention has been effective, efficient, relevant, coherent and has delivered EU added value. The Commission's evaluation guidance also stresses the need to design evaluations carefully, define appropriate questions, identify impacts, and be transparent about limitations and uncertainty.

For impact assessments, the Better Regulation framework requires a clear problem definition, assessment of drivers and affected parties, identification of objectives, development of policy options, analysis of economic, social and environmental impacts, and comparison of options. The Toolbox also contains dedicated tools on proportionality, problem analysis, identification of policy options, competitiveness, SMEs, employment, health impacts, consumers, territorial impacts and internal market effects.[2]

This distinction matters. An evaluation should not substitute for an impact assessment. It may identify implementation issues, performance gaps and emerging developments. It may also point to areas where further analysis is required. But the assessment of future regulatory choices, including their proportionality, distributional consequences and likely impacts, belongs to the Impact Assessment stage.

The OECD regulatory policy framework reinforces the same logic. OECD principles emphasize evidence-based decision-making, stakeholder engagement, ex post evaluation, regulatory impact assessment and the need to integrate regulatory tools across the policy cycle. In particular, regulatory impact assessment and ex post evaluation should be connected but not conflated: each serves a distinct function in ensuring high-quality regulation.[3]

This assessment therefore applies a process- and methodology-driven framework. The question is not whether stronger regulation may or may not ultimately be justified. The question is whether the Evaluation provides a sufficiently robust analytical foundation for determining that question through a future Impact Assessment.

[2] European Commission, *Better Regulation Toolbox*, 2023 edition.

[3] OECD, *Recommendation of the Council on Regulatory Policy and Governance* (Paris: OECD, 2012).

Insights from the EU Better Regulation Literature

The assessment framework used in this report is not specific to tobacco control. It reflects a wider and well-established literature on the quality of EU Better Regulation, impact assessment and evaluation practice. That literature points to three relevant conclusions.

First, Commission impact assessment practice has improved over time, but persistent structural weaknesses remain. Recent analysis by the European Parliament's Ex-Ante Impact Assessment Unit of the European Parliamentary Research Service examined 143 Commission impact assessments from the 2019–2024 term and found average quality to be satisfactory, with improvement over time but recurring weaknesses in areas such as quantification, transparency, impact assessment depth and policy options.[4] Earlier scorecard-based research by Fritsch, Radaelli, Schrefler and Renda similarly found gradual improvement in Commission impact assessment quality, linking this to learning effects and regulatory oversight.[5]

Second, the most persistent weaknesses identified in the literature correspond closely to the criteria used in this assessment. These include limited quantification and causal attribution, uneven treatment of economic, social and environmental impacts, insufficient transparency over evidence use, weaknesses in explaining how stakeholder input is selected and incorporated, and difficulties in presenting genuinely distinct policy options. The issue is therefore not whether the Commission follows formal procedures, but whether those procedures generate sufficiently robust analysis to support policy choices.[6]

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4 European Parliamentary Research Service, *Quality Analysis of European Commission Impact Assessments: Developments during the 2019–2024 Term* (Brussels: European Parliament, February 2025).

5 Oliver Fritsch, Claudio M. Radaelli, Lorna Schrefler, and Andrea Renda, *Regulatory Quality in the Euro-pean Commission and the UK: Old Questions and New Findings*, CEPS Working Document No. 362 (Brussels: Centre for European Policy Studies, Janu ary 2012).

6 Claudio M. Radaelli, "Measuring Policy Learning: Regulatory Impact Assessment in Europe," *Journal of European Public Policy* 16, no. 8 (2009): 1145–1164; Jacopo Torriti, "Impact Assessment in the EU: A Tool for Better Regulation, Less Regulation or Less Bad Regulation?," *Journal of Risk Research* 10, no. 2 (2007): 239–276; Paul Stephenson, "Exploring the Throughput Legitimacy of European Union Policy Evaluation: Challenges to Transparency and Inclusiveness in the European Commission's Consultation Procedures and the Implications for Risk Regulation," *European Journal of Risk Regulation* 14, no. 2 (2023): 351–370.

Third, regulatory scrutiny matters. Research on the Regulatory Scrutiny Board characterizes it as an active quality–control mechanism within the Commission's policy cycle, whose opinions are taken seriously by Commission services and can lead to substantive revisions. The fact that the draft Evaluation received a negative opinion from the Board is therefore institutionally significant. It does not invalidate the final Evaluation, but it confirms that concerns about attribution, product scope, Member State variation, uncertainty and conclusions going beyond the evidence were material enough to be raised through the Commission's own scrutiny process.[7]

This literature also supports a balanced approach. Quality assessment should not be reduced to a mechanical checklist. Complex files may legitimately require different methods, evidence sources and analytical choices. However, flexibility does not remove the need for transparency, causal discipline, clear problem definition, proportionate conclusions and a genuine separation between evaluation and impact assessment.[8]

Weaknesses in impact assessment and consultation are not merely procedural defects. They can affect the legitimacy, credibility and durability of regulatory outcomes. Research on stakeholder consultation suggests that inclusive and balanced consultation can increase acceptance of regulatory decision–making, while unequal participation can reduce perceived legitimacy, even where the final policy outcome appears substantively defensible. More broadly, studies of EU impact assessment practice warn that when assessments become instruments for justifying preexisting choices rather than testing alternatives, they may weaken both policy design and public trust in the regulatory process.[9]

The six criteria used in this report therefore reflect both the Commission's formal Better Regulation framework and wider evidence on recurring quality challenges in EU policy analysis. They provide a structured way to assess whether the TPD2 Evaluation offers a sufficiently robust foundation for the next stage of the policy cycle.

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7 Roman Senninger and Jens Blom-Hansen, "Meet the Critics: Analyzing the EU Com mission's Regulatory Scrutiny Board through Quantitative Text Analysis," *Regulation & Governance* 15, no. 4 (2021): 1436–1453.

8 Diana Danciu, Bertin Martens, and Wim Marneffe, "Assessing the Quality of European Impact Assessments," *European Journal of Risk Regulation* (2024).

9 Jennifer Beyers and Sarah Arras, "Stakeholder Consultations and the Legitimacy of Regulatory Decision-Making: A Survey Experiment in Belgium," *Regulation & Gover nance* 15, no. 1 (2021): 167–186; Anne Rasmussen and Stefanie Reher, "(Inequality in) Interest Group Involvement and the Legitimacy of Policy Making," *British Journal of Political Science* 53, no. 1 (2023): 45–64; Manuel Souto-Otero, "Is 'Better Regulation' Possible? Formal and Substantive Quality in the Impact Assessments in Education & Culture of the European Commission," *European Journal of Education* 48, no. 4 (2013): 513–529.

Assessment Criteria

The assessment applies six core criteria derived from EU Better Regulation standards, OECD regulatory governance principles, and typical methodological risks in policy evaluation. These criteria are used to assess whether the Evaluation provides a sufficiently robust basis for the subsequent Impact Assessment phase.

Assessment criterion	What a robust evaluation requires	Relevance for the TPD2 Evaluation
1. Problem Definition and Intervention Logic	A clear distinction between the original objectives of the intervention, the problems it was designed to address, and new or evolving problems identified during the evaluation period.	The Evaluation assesses a framework originally designed to harmonize tobacco and related product rules while ensuring a high level of health protection. Since then, the market has evolved significantly. The analysis must therefore distinguish between design gaps, implementation or enforcement issues, national divergence, and developments outside the original scope of the legislation.
2. Evidence Base and Causal Attribution	A clear explanation of the strength, relevance and limitations of the evidence used, including the distinction between direct evidence, indirect evidence, stakeholder views, modelling assumptions and expert judgement.	The Evaluation links the tobacco control framework to changes in smoking prevalence, mortality, market developments and product uptake. Where multiple factors may have contributed to these outcomes, including taxation, national rules, consumer preferences and wider public health trends, conclusions about the specific contribution of the TPD and TAD must be qualified.

3. Stakeholder Consultation and Evidence Integrity	Transparent explanation of how consultation responses were collected, weighted, interpreted and used, with a clear distinction between stakeholder perception and empirical evidence.	The Evaluation draws on large consultation exercises, including a call for evidence and public consultation with tens of thousands of contributions. It also acknowledges that consultation responses are not representative samples and that campaign-driven responses and stakeholder asymmetries were present.
4. Economic Impacts and Value-Chain Considerations	Assessment of economic, administrative and distributional impacts, including costs to public authorities, compliance costs for operators, SMEs, employment, competitiveness, enforcement burdens and wider value-chain effects.	The Evaluation discusses costs and benefits, including administrative costs for Member States and implementation costs for economic operators. However, it also acknowledges limitations in the quantitative data available, particularly on costs incurred by economic operators and the ability to verify the information submitted.
5. Proportionality and Options Logic	Identification of shortcomings and analytical needs without narrowing the range of future policy choices before the Impact Assessment has assessed options and proportionality.	The Evaluation identifies gaps in the current framework, including product scope, digital marketing, flavours, labelling, enforcement and national divergence. These findings may justify further assessment, but should not imply that a particular regulatory response is already established.
6. Interface with the Impact Assessment Phase	Preservation of the distinct role of the Impact Assessment, which should define the problem, assess affected groups, establish the baseline, compare options, analyse impacts, test proportionality and address subsidiarity.	The Evaluation should provide inputs into the future IA, not conclusions that narrow it in advance. Where the Evaluation identifies uncertainty, gaps or limitations, these should become explicit analytical requirements for the IA.

On this basis, the following sections assess whether the Commission Evaluation meets these standards across the main analytical dimensions: problem definition, evidence and causality, stakeholder consultation, economic and value-chain impacts, proportionality, and the interface with the Impact Assessment phase.

Assessment of the Evaluation

The Commission Evaluation is broad, detailed and structured around the standard Better Regulation criteria. It provides a substantial account of market developments since 2012, the evolution of tobacco and nicotine product use, the implementation of the TPD and TAD, and the emergence of new regulatory challenges linked to digital promotion, product scope and divergent national rules. In that respect, it represents a useful diagnostic document.

At the same time, the Evaluation's main strength lies in the breadth of information it compiles rather than in the precision of its causal analysis or the proportionality of its forward-looking conclusions. The Evaluation itself acknowledges important limitations, including difficulties in quantifying costs, attributing outcomes to specific measures, isolating the contribution of the TPD and TAD from other policy instruments, and assessing the long-term effects of novel products.

The scale and duration of the process make these limitations more consequential. This was not a preliminary scan or a light-touch review: the Evaluation followed a multi-year process, was supported by **a €3 million EU-funded framework contract**, and still received a negative opinion from the Regulatory Scrutiny Board at draft stage.[10] This does not invalidate the Evaluation, but it reinforces the need to examine carefully whether the final document fully addresses the methodological concerns identified during scrutiny.

[10] The Evaluation process began with the Call for Evidence in May 2022 and culminated in the publication of the Staff Working Document in April 2026. It involved several consultation exercises, targeted surveys, interviews, expert studies and inter-service coordination. The supporting framework contract, "HADEA/2022/OP/0011 – Single Framework Contract for Support Actions in the Field of Tobacco Control," had a total value of EUR 3,000,000 and was awarded to a consortium including Open Evidence SL, the European Network for Smoking Prevention, and University of Crete. The contract award notice also records that only one tender was received and that the framework contract was changed from cascade to single because only one tender was evaluated above threshold. See European Health and Digital Executive Agency (HaDEA), "HADEA/2022/OP/0011 – Single Framework Contract for Support Actions in the Field of Tobacco Control," Contract Award Notice, *Supplement to the Official Journal of the European Union*, 2023/S 017-048118, 24 January 2023.

This point requires some procedural clarification. Unlike an Impact Assessment, an Evaluation may still be finalised and published following a negative RSB opinion, provided the lead service takes the Board's recommendations into account. In this case, the final Evaluation explains how the RSB's comments were addressed, but the published record does not indicate that the revised document received a second RSB opinion. This makes the adequacy of the revisions an important point of analytical scrutiny.

Regulatory Scrutiny Board scrutiny: why it matters

The draft Evaluation received a negative opinion from the Regulatory Scrutiny Board in December 2025. The final Staff Working Document includes a table explaining how the Commission addressed the Board's recommendations. This does not invalidate the Evaluation. However, it confirms that several of the issues assessed in this report — including attribution, scope, Member State variation, uncertainty, effectiveness, efficiency and the limits of the evidence base — were also central to the Commission's own internal quality-control process.

RSB concern	Commission response in the final SWD	Remaining analytical question
The Evaluation should better distinguish the TPD/TAD intervention from other factors affecting consumer behaviour, including taxation and national measures.	The final SWD added explanations on other EU legislation, external factors and consumer behaviour drivers.	Does the revised Evaluation sufficiently prevent forward-looking conclusions from relying on outcomes that cannot be clearly attributed to the TPD/TAD?
The Evaluation should better substantiate effectiveness with evidence on individual measures and ensure that conclusions do not go beyond the evidence.	The final SWD added evidence on selected measures and revised the conclusions to reflect uncertainty.	Do the remaining conclusions still imply a stronger regulatory direction than the evidence base can fully support?

RSB concern	Commission response in the final SWD	Remaining analytical question
The Evaluation should better analyse Member State differences and clarify whether observed problems stem from the design of the EU intervention or from national enforcement.	The final SWD added Member State–level prevalence data and explanations on design versus enforcement.	Does the analysis sufficiently distinguish regulatory gaps from implementation or enforcement problems?
The Evaluation should explain whether monitoring and evaluation data provide a sufficient evidence base.	The final SWD added further discussion of data limitations.	If the evidence base remains limited, which issues must remain open for the Impact Assessment phase?

This reinforces the central point of the assessment. The question is not whether the Evaluation identifies relevant issues — which it clearly does — but whether the revisions made after RSB scrutiny are sufficient to support strong forward-looking regulatory conclusions. The following scorecard therefore assesses whether the Evaluation provides a sufficiently robust analytical basis for future regulatory decisions.

Evaluation Robustness Scorecard

Assessment criterion	Assessment	Rationale
1. Problem Definition and Intervention Logic	**Partially robust**	The Evaluation correctly identifies the original objectives of the framework and provides a detailed account of market evolution. However, it tends to bring together different types of problems — design gaps, enforcement issues, national divergence, scope limitations and market developments — under a broad narrative of regulatory insufficiency. This weakens analytical precision.
2. Evidence Base and Causal Attribution	**Constrained**	The Evaluation draws on a broad evidence base, including surveys, scientific studies, JRC reports, market data, consultations and expert studies. However, it acknowledges that the contribution of individual measures cannot be quantitatively isolated and that other factors, including taxation and national policies, influenced outcomes. The evidence base is broad, but causal attribution remains constrained.
3. Stakeholder Consultation and Evidence Integrity	**Partially robust**	The consultation process was extensive, with more than 24,000 call-for-evidence contributions and more than 17,000 public consultation responses. However, the Evaluation acknowledges that consultation responses are not representative, that campaign-driven responses were present, and that some groups were overrepresented. Consultation input is useful, but its evidentiary status requires careful qualification.
4. Economic Impacts and Value-Chain Considerations	**Constrained**	The Evaluation includes an efficiency analysis and discusses administrative costs, implementation burdens and public health benefits. However, it also acknowledges that data on industry compliance costs were limited, scattered, inconsistent and not independently verified. The treatment of SMEs, retailers, growers, employment, competitiveness and value-chain impacts remains insufficiently granular.

Assessment criterion	Assess-ment	Rationale
5. Proportionality and Options Logic	**Constrained**	The Evaluation identifies relevant gaps and shortcomings, including product scope, digital marketing, flavours, labelling, enforcement and national divergence. However, its forward-looking language risks moving from diagnosis to implied regulatory direction before policy options have been fully assessed. The proportionality question remains open.
6. Interface with the Impact Assessment Phase	**Requires further substantiation**	The Evaluation should provide inputs into the next stage of the policy cycle, not narrow it in advance. Yet the document sometimes blurs the boundary between retrospective assessment and forward-looking policy framing. The negative opinion issued by the Regulatory Scrutiny Board reinforces the importance of addressing this boundary carefully.

The Evaluation is strongest as a diagnostic mapping exercise. It identifies real and relevant developments in the tobacco and nicotine market, including the rise of novel products, digital marketing, national divergence and implementation challenges.

Its limitations arise when it moves from diagnosis to policy direction. The Evaluation is transparent about uncertainty in several places, but its conclusions sometimes move further than the underlying evidence can fully support.

This issue is particularly relevant in light of the distinction between an evaluation and an impact assessment. The Call for Evidence launched in May 2022 already referred to the need to consider the "main economic impacts of the options". Such language is not unusual in Commission practice: Impact Assessments are expected to compare policy options and assess their likely economic, social and environmental impacts, including costs, benefits, administrative burden, competitiveness effects and impacts on affected groups.

However, in the present file, this distinction matters. The Evaluation is a retrospective exercise. Its purpose is to assess the performance of the existing framework against the Better Regulation criteria of effectiveness, efficiency,

relevance, coherence and EU added value. The assessment of future policy options belongs to the Impact Assessment phase. The use of options-oriented language early in the process therefore reinforces the need to preserve a clear analytical separation between the Evaluation's diagnostic function and the IA's prospective role.

Where an Evaluation moves beyond identifying performance gaps and begins to frame the direction of future regulatory adaptation, it risks narrowing the analytical space that should remain open for the Impact Assessment. This is not a procedural irregularity in itself, but it is a methodological risk. It underlines why the next phase should include a robust, comprehensive and proportionate assessment of alternative options before any major regulatory choices are advanced.

The main analytical weaknesses are therefore not that the Evaluation ignores relevant issues. Rather, they concern:

- the aggregation of distinct problems into a broad regulatory narrative;
- limited causal attribution;
- reliance on consultation evidence whose representativeness is qualified;
- insufficiently granular economic and value-chain analysis;
- and the partial blurring of the boundary between evaluation and impact assessment.

On this basis, the Evaluation provides an important starting point for future policy discussion, but not a sufficiently robust analytical basis for major regulatory decisions without further assessment.

Implications for the Impact Assessment Phase

The Evaluation should be treated as an important diagnostic input into the future Impact Assessment, not as a substitute for it. Its value lies in mapping the evolution of the tobacco and nicotine market, identifying regulatory gaps, and highlighting areas where the existing framework may no longer operate as intended.

However, the scorecard above shows that the Evaluation's robustness varies across the six assessment criteria. Several limitations are acknowledged by the Evaluation itself, including constrained causal attribution, incomplete quantitative data, consultation representativeness issues, limited granularity on economic and value-chain impacts, and uncertainty regarding the long-term effects of novel products.

These limitations do not invalidate the Evaluation. They do, however, create specific risks for the next phase of the policy cycle. The Impact Assessment will need to test the Evaluation's findings independently, rather than simply inherit its forward-looking conclusions.

This is particularly important because the draft Staff Working Document received a negative opinion from the Regulatory Scrutiny Board. The published Evaluation records that the draft was submitted to the Board on 10 November 2025, discussed on 9 December 2025, and received a negative opinion on 12 December 2025. The Board's recommendations concerned several issues directly relevant to the future IA, including attribution, product scope, Member State variation, the distinction between the EU intervention and other factors affecting consumer behaviour, and the need to avoid conclusions going beyond the evidence.

The following risk map connects each assessment criterion to the corresponding risk for the Impact Assessment phase.

Impact Assessment Risk Map

Assessment criterion	Assess-ment	Risk for the Impact Assessment
1. Problem Definition and Intervention Logic	**Partially robust**	**Risk of problem misspecification.** The IA may begin from an overly general problem definition, treating the framework as "outdated" without sufficiently distinguishing between problems requiring new EU legislation, better enforcement, targeted harmonisation, or further evidence-gathering.
2. Evidence Base and Causal Attri-bution	**Con-strained**	**Risk of weak causal foundations.** The IA may as-sume that observed trends justify specific regu-latory measures without fully demonstrating the causal pathway between the problem, the pro-posed intervention and the expected outcome.

Assessment criterion	Assessment	Risk for the Impact Assessment
3. Stakeholder Consultation and Evidence Integrity	**Partially robust**	**Risk of consultation over-weighting.** The IA may rely too heavily on stakeholder perceptions or consultation salience as evidence of effectiveness, proportionality or causal impact, without sufficient validation against objective data.
4. Economic Impacts and Value-Chain Considerations	**Constrained**	**Risk of incomplete impact assessment.** The IA may underestimate distributional impacts across the tobacco and nicotine value chain, particularly for SMEs, retailers, growers, enforcement authorities and Member States.
5. Proportionality and Options Logic	**Constrained**	**Risk of pre-selected policy options.** The IA may treat regulatory strengthening as the default pathway rather than comparing a full range of options, including enforcement, targeted amendments, non-legislative tools, product-specific measures and broader revision.
6. Interface with the Impact Assessment Phase	**Requires further substantiation**	**Risk of procedural compression.** The IA may risk becoming confirmatory rather than exploratory, translating the Evaluation's directional narrative into legislative options without fully reopening problem definition, evidence, alternatives, impacts and proportionality.

The Commission Evaluation provides an important starting point, but not a sufficient endpoint. The risk analysis indicates that the Impact Assessment must perform an independent analytical function. It should test the Evaluation's findings, clarify the problem definition, strengthen the evidence base, assess economic and distributional impacts, compare genuine alternatives and demonstrate proportionality before any legislative proposal is advanced. This is a condition for credible, evidence-based and legally robust EU policymaking.

Conclusions: Why Analytical Robustness Matters

The Commission Evaluation provides a substantial and useful overview of the EU tobacco control framework. It brings together a wide range of evidence on market developments, implementation issues, public health trends, emerging products, digital marketing, internal market fragmentation and the evolution of national regulatory approaches. It also identifies several areas where the current framework may no longer operate as originally intended.

However, the Evaluation should be understood as a diagnostic document, not as a sufficient basis for future regulatory choices.

Its own analysis repeatedly acknowledges important methodological constraints, including limited causal attribution, gaps in quantitative data, uncertainty around the long-term health impacts of novel products, difficulties in assessing costs for economic operators, and the influence of other policy instruments such as taxation and national measures. These limitations are particularly relevant given that the draft Evaluation received a negative opinion from the Regulatory Scrutiny Board, with recommendations relating to attribution, product scope, Member State variation, uncertainty and conclusions going beyond the available evidence.

The central concern is therefore not that the Evaluation identifies irrelevant issues. On the contrary, many of the issues it raises are legitimate subjects for further policy assessment. The concern is that the Evaluation moves from a constrained and partially non-attributable evidence base toward a relatively strong directional narrative on the need for regulatory adaptation.

This matters because the forthcoming revision of the EU tobacco control framework will not regulate a marginal or purely technical file. It will shape policy in a highly sensitive area where public health, internal market rules, consumer behaviour, enforcement capacity, economic activity and public finances intersect.

At stake is the EU's ability to reduce smoking prevalence in the most effective way possible, using all credible and evidence-based tools available. It is also the ability to protect minors from nicotine initiation, address the growth of illicit and unregulated markets, reduce avoidable healthcare costs, and ensure that

future regulation is targeted at real risks rather than driven by assumptions or broad category-based approaches.

At the same time, the framework affects a large and complex value chain, including manufacturers, SMEs, retailers, distributors, growers, enforcement authorities and Member States.[11] Future policy choices may have implications for employment, investment certainty, fiscal revenues, administrative burdens, legal compliance and the functioning of the internal market. These impacts are unlikely to be distributed evenly across the EU. They may vary significantly between Member States, regions, rural and urban economies, and different parts of the value chain, including small retailers, growers, logistics operators and national enforcement authorities. Social and regional discrepancies are therefore not secondary considerations: they are part of the proportionality assessment required for durable and enforceable regulation.

The Evaluation also appears to point towards a number of possible regulatory directions that correspond to issues of particular importance for the sector, including flavours, product scope, labelling, digital promotion, emissions and the potential reconsideration of tar, nicotine and carbon monoxide (TNCO) measurement rules. In several of these areas, the Evaluation identifies regulatory gaps or scientific uncertainty but nonetheless frames the need for further regulatory adaptation. This is especially relevant for novel products, where the long-term evidence base is still developing and where divergent peer-reviewed evidence on comparative risk, switching behaviour and product differentiation should be assessed transparently. These impacts and uncertainties do not override public health objectives, but they must be properly examined if future regulation is to be effective, proportionate, legally robust and durable.

The sensitivity of the file also makes analytical discipline especially important. Tobacco and nicotine policy is an area marked by strong normative positions, entrenched institutional preferences and competing stakeholder interests. Precisely for that reason, Better Regulation standards matter. They provide a common framework for separating evidence from assumption, stakeholder preference from public interest, and policy objectives from the proportionality of the means chosen to pursue them.

[11] Bob Flanagan, Ian Chin, and Dan McLaughlin, *The Economic Footprint of Traditional Tobacco and New Nicotine Products: Contributions to the EU-27 in 2021* (S&P Global Market Intelligence, May 2023), 3–4; European Policy Innovation Council, *The End of Smoking? How Europe Can Save Millions of Lives while Boosting Economic Growth*, EPIC Report (Brussels: European Policy Innovation Council, 2025).

Comparative experience from other complex EU regulatory files reinforces this point. In areas such as sustainability reporting, chemicals regulation, taxation and regulatory simplification, methodological weaknesses have not remained confined to process. Where problem definition is broad, causal evidence is

Comparative reference	Why it matters	Lesson for the TPD2 process
EPRS review of Commission Impact Assessments, 2019–2024	Provides the broadest recent institutional benchmark of Commission IA quality. It shows improvement over time, but also persistent weaknesses in quantification, transparency, options analysis and impact-assessment depth.	The weaknesses identified in the TPD2 Evaluation — attribution, consultation weighting, economic granularity and options logic — correspond to known Better Regulation risk points, not isolated concerns.
REACH / chemicals regulation	A complex health-protection and internal-market file involving scientific uncertainty, industry costs, long-term benefits and strong political contestation.	Where evidence is uncertain and impacts are unevenly distributed, methodological clarity is essential. Uncertainty should be carried into the IA as an analytical question, not smoothed over by broad policy direction.
CSRD / sustainability reporting and simplification debate	A complex internal-market file with major compliance, SME, reporting and value-chain implications, where process quality and regulatory burden became part of the legitimacy debate.	Complex EU files require granular assessment of affected groups, compliance burdens and proportionality. Otherwise, rules may become more politically fragile and more vulnerable to later correction or simplification.
Regulatory Scrutiny Board practice	The RSB is the Commission's internal quality-control mechanism for impact assessments and major evaluations. Research shows it can act as an active watchdog and that its opinions can lead to substantive revisions.	The negative RSB opinion on the draft TPD2 Evaluation is institutionally significant. It confirms that concerns about attribution, product scope, Member State variation and conclusions going beyond evidence were material quality issues.

uncertain, consultation is contested, or economic impacts are insufficiently granular, the resulting policy debate can become more politically fragile and more vulnerable to later correction, contestation or simplification. The lesson is not that tobacco control is comparable in substance to these files. Rather, it is that complex EU regulation is most vulnerable when broad objectives substitute for disciplined analysis.

These references do not provide substantive analogies to tobacco control. Their relevance lies in the Better Regulation lesson they illustrate: complex EU files are most vulnerable when broad objectives substitute for disciplined analysis. For the TPD2 revision, this means that public health ambition must be matched by analytical precision, transparent evidence use, granular impact assessment and genuine options analysis.

The consequences of weak analytical process are not limited to the quality of the file on paper. Poorly specified problems, weak causal reasoning, insufficiently balanced consultation or premature narrowing of options can reduce the perceived legitimacy of the regulatory process, particularly among stakeholders or citizens already sceptical of the policy direction. They can also produce rules that are less durable, more contested and more likely to require later correction, simplification or litigation. The point of Better Regulation is therefore not procedural perfection for its own sake, but the production of rules that are more effective, more legitimate and more resilient over time.

A weak analytical process risks producing rules that are less effective, less targeted and more vulnerable to unintended consequences. Measures that do not distinguish properly between products, users and risk pathways may fail to support the most effective pathways for reducing smoking prevalence, while strengthening illicit or unregulated markets. Measures that do not assess economic and enforcement impacts may impose disproportionate burdens on parts of the value chain while failing to deliver the intended public health gains.

The Evaluation therefore reinforces, rather than reduces, the need for a full, open and rigorous Impact Assessment before any legislative proposal is advanced.

Such an Impact Assessment must not simply inherit the Evaluation's forward-looking narrative. It must test it. It should define the problems precisely, distinguish evidence from assumptions, address causal uncertainty, assess economic and value-chain impacts, compare genuine policy options, test proportionality, and clearly explain why EU-level action is necessary.

The credibility of the next phase will depend on whether these analytical steps are carried out fully. A credible revision of the EU tobacco control framework requires more than a broad diagnosis of regulatory gaps. It requires a transparent, proportionate and evidence–based assessment of the choices available.

The Evaluation identifies issues that merit further analysis, but it does not yet provide a sufficiently robust analytical basis for major regulatory decisions. Given what is at stake for public health, minors, enforcement, economic activity, public finances and the integrity of the internal market, the forthcoming Impact Assessment must play a substantive, independent and corrective role in the policy process.

European Policy Innovation Council

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