

Towards an EU framework for tobacco and smokeless products that delivers on all Union objectives

Imperial Brands' contribution to the Call for Evidence on the revision of the Tobacco Products Directive and Tobacco Advertising Directive

Imperial Brands* supports a high level of health protection, strong protection of minors, robust action against illicit actors, and a well-functioning internal market. These objectives are mutually reinforcing.

The revision should be assessed as a horizontal regulatory intervention, across the full range of policy areas it affects. Future measures should be evidence-based, proportionate and enforceable. They should preserve the legal, taxed and supervised market, and the legal value chain through which regulation operates.

Structure: Six questions for the Impact Assessment

This submission is structured around six questions that should guide the Impact Assessment.

Area	Question for the Impact Assessment
Cross-policy framework	Do regulatory options take into account how they will be implemented across the full range of policy areas they affect?
Legal market functioning	Do regulatory options preserve or weaken control by keeping demand within the legal, taxed and supervised market?
Value-chain competitiveness	Do regulatory options ensure the legal value chain can adapt, comply and compete, or risk disrupting the legal market and shifting demand outside it?
Evidence base	Is the intervention supported by EU-relevant, product-specific and sufficiently robust evidence on product use and consumer behaviour?
Enforcement design	Are the measures enforceable in practice, given where the problem arises and how the market operates?
Legal coherence	Can the measure be reconciled with internal-market principles, proportionality, legal certainty and the wider EU legal framework?

1. The revision is a horizontal file and requires a cross-policy assessment

Takeaway: The TPD/TAD revision is not a narrow health file. It is a horizontal intervention requiring coordinated input across Commission services and across Member State administrations, reflecting the breadth of policy areas affected.

The revision of the TPD and TAD is a horizontal regulatory intervention. Regulatory options need to be assessed across the policy areas they will affect.

Those areas include the internal market, taxation, customs enforcement, anti-illicit trade policy, digital regulation, consumer information, competitiveness, employment, SMEs, innovation, environmental policy and Member State administrative capacity.

If these systems are not considered together, measures risk being designed in a silo. An assessment that separates policy design from implementation conditions risks producing measures that are formally aligned with their objective but operationally ineffective.

The Impact Assessment therefore needs to be constructed as a cross-policy assessment, with coordinated input from the Commission services and Member State authorities responsible for implementation, enforcement and supervision.

Annex I sets out additional non-exhaustive questions to support a structured assessment of how the revision would operate across the wider regulatory ecosystem.

2. The legal, taxed and supervised market is central to policy effectiveness

Takeaway: Regulation is effective when demand is met within the legal market – not outside it.

The effectiveness of the TPD and TAD depends on the continued functioning of the legal, taxed and supervised market. It is through that market that product standards are applied, compliance is monitored, traceability operates, fiscal revenues are collected and public authorities can exercise effective control.

Increasingly, a reduction in legal sales does not, in itself, demonstrate reduced consumption.

Across Member States, recent and consistent evidence shows that product and flavour bans do not eliminate demand, but redirect it towards informal cross-border purchasing, illegal imports, non-compliant operators or unregulated online channels.

Each option therefore needs to be assessed against its effect on this system: **does it strengthen control through the legal market as the channel through which regulation is applied, or does it increase the risk of displacement towards illicit and non-compliant supply?**

When this occurs, public authorities lose visibility, lose control and lose revenue. Current market conditions illustrate the scale of activity already taking place outside the regulated framework:

- Illicit cigarette consumption in the EU27 is estimated at 10.3% of total consumption, corresponding to approximately €16.7 billion in lost revenues, and more than 40 billion cigarettes remaining outside of regulatory control.¹
- Approximately 50% of the EU e-cigarette market is estimated to be illegal and non-compliant.²
- In the Netherlands, estimates suggest that 87% of e-cigarette consumers use illegal e-cigarettes or e-cigarettes obtained outside the legal market.³

3. Effective regulation depends on a competitive legal value chain

Takeaway: Regulation cannot be effective if the value chain that implements it cannot adapt, comply and compete.

Regulatory measures can only be effective if they are workable for the legal value chain. That value chain is the infrastructure through which products are produced, adapted, tested, packaged, distributed and sold in compliance with EU and national rules.

These actors already operate under structural constraints common to European industry, including high energy costs, competitiveness pressures, investment uncertainty and exposure to external competition.

If the legal value chain cannot adapt and compete within realistic conditions, measures will not deliver as intended – disrupting the legal market instead and increasing the existing advantage of non-compliant supply.

Aggregate EU-level effects are insufficient. For each measure, the assessment needs to establish whether the legal value chain can comply within realistic costs, timelines and technical constraints, and who is affected, where and over what timeframe.

¹ KPMG LLP, Illicit cigarette and heated tobacco consumption, and oral nicotine share in Europe: 2025 results, 20th annual report, commissioned by Philip Morris Products S.A., 3 June 2026.

² Uwe Veres-Homm and Daniel Reich, Fraunhofer IIS, in partnership with Horst Manner-Romberg and Jörg Storz, MRU GmbH, The Irregular Market for E-Cigarettes in Europe: Market Structures, Quantification and Supply Chains, February 2026.

³ Emily Berger, Emma Derksen, Christa Dinnissen and Juno van Esseveldt, *Donkere wolven: Een eerste verkenning van illegale vapehandel in Nederland*, Bureau Beke, Bekereeks, 2026, commissioned by the Dutch Ministry of Health, Welfare and Sport.

Tests that should be built into the Impact Assessment

Test	Assessment question
SME test	Whether SMEs and specialised operators can comply within realistic costs, timelines and technical constraints.
Agricultural test	Whether measures affect growers, processors, rural supply networks, sourcing, crop-specific dependencies and regional agricultural activity.
Competitiveness proofing	Whether measures affect the ability of legal operators to invest, innovate, adapt production systems and compete within the regulated market.
Regional and distributional test	Whether impacts are concentrated in specific Member States, regions, border areas, rural communities or market segments.
Employment and transition test	Whether effects on jobs, skills and adjustment capacity are manageable over time.
Cumulative and sequencing test	Whether multiple measures can be absorbed simultaneously without overloading the same operators, suppliers, retailers, laboratories or regions.

Analysis of the structure, scale and economic contribution of the legal value chain is provided in Tobacco Europe's submission.⁴

4. The evidence base needs to be strengthened before options are taken forward

Takeaway: Regulatory options should be based on the full body of evidence, including primary research and real-world and population-level evidence.

The Impact Assessment cannot rely on assumptions that have not been robustly established by the Evaluation. The Regulatory Scrutiny Board identified serious shortcomings in the evidence base, including the attribution of effects to the Directives and the role of Member State measures.

Tobacco control outcomes are shaped by multiple interacting factors, including taxation, national measures, enforcement, consumer behaviour and illicit trade.

Where Member States such as Sweden have achieved much faster reductions in smoking prevalence, the drivers need to be assessed, including the availability and role of non-combustible ('smokeless') products.

Smokeless products differ materially from combustible tobacco and cannot be assessed only in isolation. **Their health effects should be assessed in relation to continued smoking, as the relevant real-world comparator.**

Market experience indicates that disproportionate restrictions on smokeless alternatives may affect consumer behaviour, including switching and substitution.

- In the Netherlands, findings indicate that 6% of e-cigarette users report initiating cigarette smoking following the flavour ban on e-cigarettes;
- and 10% of pre-ban smokers report increased cigarette consumption following the same measure.⁵
- EU population data do not support a gateway from smokeless products to smoking. Over the same period, smoking prevalence declined from 28% to 24%, with underage smoking reaching historic lows in Member States.⁶

⁴ F33486881.

⁵ Hellmich, I. M., Havermans, A., Pauwels, C. G. G. M., Boesveldt, S., & Talhout, R. (2026). *Reduced vaping and smoking prevalence among people using e-cigarettes after implementation of an e-cigarette flavour ban in the Netherlands*. *Tobacco Control*. Advance online publication. <https://doi.org/10.1136/tc-2025-059567>

⁶ Attitudes of Europeans towards tobacco and related products (June 2024) Eurobarometer survey.

For each regulatory option, the analysis should explain

- the specific problem being addressed;
- the product and user group concerned;
- the evidence supporting intervention, including whether evidence is EU-relevant, product-specific and sufficiently robust;
- the expected effect on consumer behaviour, including switching and substitution; and possible unintended effects;
- the uncertainties and data limitations that remain;
- the indicators through which effectiveness would be measured over time.

Further analysis of the scientific and evidentiary basis for the revision, including relevant Joint Research Centre publications, is provided in a separate Imperial Brands contribution to this Call for Evidence.

5. Measures must be designed for effective enforcement

Takeaway: Measures that cannot be effectively enforced where the problem arises risk overburdening the legal value chain while strengthening non-compliant supply.

Many enforcement challenges in the tobacco and nicotine market are driven by actors operating outside the legal market, including illicit imports, illegal online sellers, non-compliant products and informal cross-border supply, who do not comply with product standards, sales restrictions or other regulatory requirements.

The Impact Assessment must demonstrate how the proposed measure would reach those actors in practice.

Measures applied through the legal market affect operators already subject to regulatory control. **On their own, they do not address enforcement gaps outside that market.**

Poorly-targeted obligations increase the burden on the legal value chain, **create uneven application across Member States and strengthen the relative advantage of illicit and non-compliant suppliers.**

Where new obligations are proposed, the assessment should also identify the competent authorities, legal powers, data requirements, cooperation mechanisms and administrative resources required for enforcement, and whether Member States have the administrative capacity to apply them consistently in practice.

6. Legal coherence and proportionality must be built into the design of each option

Takeaway: Measures that are legally uncertain, difficult to apply, or inconsistent with adjacent EU frameworks are less likely to be enforceable, proportionate or stable over time.

The assessment needs to test each option against the wider EU legal framework:

Wider EU legal framework to be tested

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| <ul style="list-style-type: none"> • non-discrimination • fundamental rights • freedom to conduct a business • consumer access to lawful information • trademark and intellectual property rights | <ul style="list-style-type: none"> • data protection • consumer law • digital law • environmental law • international trade obligations under the WTO |
|--|--|

The assessment should distinguish between binding international obligations and non-binding recommendations or guidelines. **International commitments and guidance cannot replace the need to demonstrate EU competence, internal-market necessity, proportionality and evidence-based effectiveness.**

A measure that is difficult to reconcile with the wider EU framework creates legal uncertainty for authorities and the legal value chain, increases litigation risk, complicates enforcement and weakens the stability of the legal market.

Conclusion: towards a framework that delivers on all Union objectives

The revision of the TPD and TAD is an opportunity to build an effective EU framework for tobacco and smokeless products that protects minors, supports public health, preserves the functioning of the internal market and keeps demand within legal, taxed and supervised channels.

Taken together, the questions set out in this submission identify the priorities for a proportionate, enforceable and legally coherent framework.

Priorities for an effective and proportionate framework

(1) Treat the revision as a horizontal regulatory intervention.	An effective framework should reflect the full range of policy areas affected by the revision. Measures are more likely to deliver stable outcomes where policy design, implementation conditions and enforcement responsibilities are assessed together from the outset.
(2) Preserve the function of the legal, taxed and supervised market	An effective framework should preserve the functioning of the legal market as the channel through which regulation is applied. Measures that only weaken legal supply without reducing overall demand risk moving consumption even more towards illicit, non-compliant or unsupervised channels.
(3) Start from the right problem definition and the full body of evidence	Combustible tobacco is already subject to one of the most comprehensive regulatory frameworks in the consumer goods market. For smokeless products, the assessment should also consider their role in relation to continued smoking as the relevant real-world comparator. Measures on smokeless products should be assessed against their likely effects on smoking reduction, switching, substitution, with uncertainties and data limitations clearly identified.
(4) Protect minors through effective and enforceable measures	Under-age access prevention is essential. Restrictions should be tested against the routes through which minors access products, the behaviour they are intended to address, and their likely effects on lawful adult use and non-compliant supply. Minors protection is more likely to be effective where rules can be enforced in practice and do not unintentionally weaken the supervised channels through which age controls and compliance obligations operate.
(5) Design measures that are workable for authorities and the legal value chain	An effective framework should be workable for authorities and the legal value chain. Legal certainty supports compliance, product quality, investment, lawful innovation and effective supervision.

* **Imperial Brands** is a significant participant in the EU's legal, taxed and supervised tobacco and nicotine market. Across the Union, our activities include and support manufacturing, procurement, product stewardship, regulatory compliance, logistics, distribution, innovation and cooperation with retailers and suppliers. In the EU alone, Imperial Brands works with around 100 European suppliers and contributes to employment, including 7,416 direct jobs across Europe, as well as tax revenues, investment and the practical implementation of regulatory obligations throughout the legal value chain.

Annex I: Cross-policy questions for the Impact Assessment

The following non-exhaustive questions are intended to support a structured assessment of the revision as a whole regulatory ecosystem.

Dimension	Question to test
Internal market	<p>Does the option address a genuine internal-market problem, or does it primarily pursue a public-health preference better addressed at national level?</p> <p>Could the measure create a market in which only illicit, non-compliant, cross-border or third-country operators can continue supplying products consumers seek?</p>
Taxation and public revenues	<p>If legal sales decline after a measure is introduced, how will the assessment distinguish genuine demand reduction from displacement into untaxed, illicit, cross-border or non-compliant channels?</p> <p>How will the assessment ensure that assumptions on legal sales, illicit trade, cross-border purchasing and tax revenues are consistent with the tax revenue ambitions of the Tobacco Taxation Directive revision?</p> <p>How will the combined effect of product restrictions, excise increases, tax differentials and Article 32 cross-border acquisition rules be modelled?</p> <p>Could the measure reduce Member State revenues while leaving underlying demand partly intact through untaxed channels?</p> <p>How will the assessment align with the Tobacco Taxation Directive's parallel interpretation of smokeless products?</p>
Customs and anti-illicit trade	<p>If a measure restricts lawful availability or product features, would it increase the profitability of illicit supply, counterfeit products, illicit whites, small-parcel imports or informal cross-border purchasing?</p> <p>If a measure increases the profitability of illicit tobacco or nicotine-product supply, how will the Impact Assessment reflect the security dimension, not only the health and revenue dimensions?</p> <p>If the problem is linked to raw tobacco diversion, clandestine factories or third-country supply, would downstream product restrictions address the problem, or would targeted upstream controls be more effective?</p>
Digital and online channels	<p>If under-age access is linked to social media, messaging apps, informal online supply or third-country platforms, how will the assessment test whether restrictions on legal operators actually reach those channels?</p> <p>What role would the Digital Services Act, trusted flaggers, platform cooperation, takedown mechanisms and cross-border enforcement play in removing illegal offers online?</p> <p>If the concern is exposure through digital channels, how will the Impact Assessment distinguish between unlawful promotion, lawful commercial communication, lawful non-commercial communication, consumer discussion and peer-to-peer content?</p> <p>Would restrictions on lawful distance sales or online communication push adult consumers towards informal digital channels with no age checks, product standards or tax obligations?</p>
Consumer information	<p>If materially different product categories are labelled, warned or communicated in the same way, could this mislead consumers about differences in product characteristics, use patterns or risk profiles?</p> <p>How will the assessment distinguish between unlawful communication clearly directed at minors and lawful information for adult consumers, to avoid creating an information deficit for adults seeking lawful, accurate and product-specific information?</p> <p>Could more accurate product-specific information achieve the objective with fewer restrictions than broad bans on presentation or communication?</p>

Dimension	Question to test
Competitiveness and innovation	<p>If product features, formats, flavours, packaging elements or communication channels are removed, what lawful competitive parameters remain available to operators?</p> <p>Could rigid rules deter lawful innovation in product quality, safety, testing, sustainability or alternatives to combustible products?</p> <p>How will the competitiveness check account for competition not only between legal EU operators, but also between legal operators and illicit suppliers?</p> <p>Would the measure reduce investment, productivity or value added in the legal EU value chain while demand is partly served by actors outside the legal market?</p>
SMEs and specialised operators	<p>How will the SME Test quantify fixed compliance costs such as reformulation, testing, packaging-line adaptation, stock write-offs, notification costs, laboratory costs, staff training and transition costs?</p> <p>Would the measure increase barriers to entry or accelerate market concentration because fixed costs are easier for larger operators to absorb?</p> <p>Are transition periods realistic for smaller operators, or would SMEs exit the market before compliance becomes possible?</p>
Agriculture and regional impact	<p>Which ingredient, product-standard or product-composition options would affect the usability of EU-grown Burley, Oriental or other tobacco varieties?</p> <p>Would any proposed restriction indirectly favour imported tobacco or third-country supply over EU-grown tobacco?</p> <p>What rural-proofing evidence shows whether affected regions have realistic alternatives within the proposed transition period?</p> <p>Would the measure worsen territorial disparities by concentrating costs in regions with limited diversification capacity and fewer alternative jobs?</p> <p>Would the measure have different effects in border regions, external-border Member States, tourist regions, high-illicit-trade regions?</p>
Employment and transition	<p>If legal-market contraction is expected, how will the assessment distinguish jobs lost through genuine demand reduction from jobs lost because activity moves into illicit, informal or third-country channels?</p> <p>Which workers are most exposed across growing, processing, manufacturing, logistics, laboratories, wholesale, retail and hospitality?</p> <p>Are the impacts concentrated in regions or occupations where skills are not easily transferable?</p> <p>If legal operators downsize or close, what happens to jobs covered by legal employment conditions, collective agreements, social protection and workplace standards?</p> <p>What transition assumptions, mitigation measures or sequencing would be required to avoid disproportionate social impacts?</p>
Administrative capacity	<p>Would the measure produce uneven real-world outcomes because some Member States lack the capacity, legal powers or systems to enforce it?</p> <p>Could targeted enforcement of existing rules deliver more than new obligations that Member States cannot realistically supervise?</p> <p>If the measure cannot be enforced consistently across Member States, should it be redesigned, sequenced differently or replaced by a more enforceable alternative?</p>
Legal coherence	<p>For each major option, what is the precise legal basis and internal-market rationale, and how is it distinct from a general preference for stricter public-health rules?</p> <p>If the measure restricts lawful adult access, product presentation, trade marks, communication or differentiation, why would a narrower measure targeted at minor access prevention, or action</p>

Dimension	Question to test
Evidence, monitoring and future evaluation	<p>against illegal sellers or non-compliant channels not achieve the objective?</p> <p>How will the assessment distinguish binding international obligations from non-binding recommendations or guidelines?</p> <p>If a measure imposes product standards, ingredient restrictions, packaging rules, testing requirements, authorisation conditions or distance-sales restrictions, what is the WTO/TBT necessity analysis?</p> <p>How will the assessment separate the effects of the TPD/TAD from taxation, national measures, enforcement intensity, product innovation, consumer preferences, price changes and illicit trade?</p> <p>What consumer-substitution model will determine whether consumers stop using a product, switch to another lawful product, return to combustible products or move to illicit supply?</p> <p>What early-warning indicators will detect policy failure, such as rising illicit share, online availability, non-compliant imports, under-age access through informal channels or legal-market contraction without prevalence decline?</p> <p>Under what conditions would a measure be reviewed, adjusted or withdrawn if it does not deliver its intended effect?</p>