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BRIEFING PAPER

The TPD Revision and Europe's Innovation Economy: A Review of the Evidence

A Data-Driven Look at the Case for Proportionate Regulation

July 2026

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Key Messages at a Glance

90%+	~2%	138	43
critical of all submissions	express support	countries represented	countries represented in academic input

Submissions cluster around 5 issue areas – while the topics within each area differ markedly by stakeholder group

1	2	3	4	5
Freedom of Choice	Health Gains & Product Differentiation	Fiscal Stability & Illicit Trade	Jobs, Investment & Innovation	Proportionate, Evidence-Based Rules

What the consultation tells us

1 **Near-unanimous opposition.** Of more than 80,000 submissions, over 90% raise at least one substantive objection to the Commission's trajectory and only around 2% express support.

2 **A cross-border, cross-disciplinary consensus.** Submissions span 138 countries, and academic and research input alone comes from 43 countries. Resistance is neither geographically isolated nor confined to a single discipline.

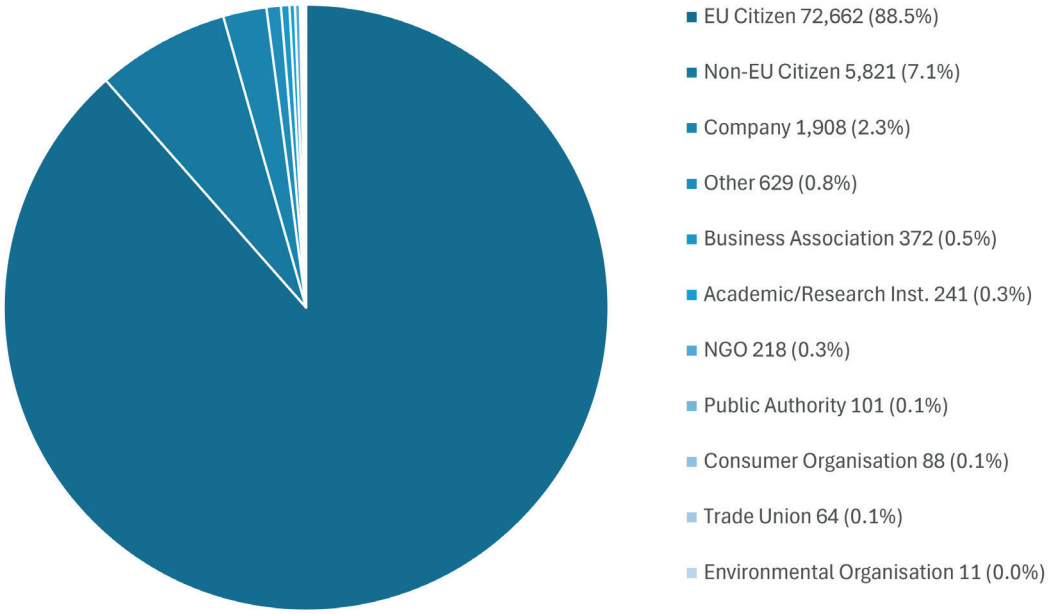
3 **Opposition deepens with expertise.** 96% of academic and research submissions, 94% of companies, NGOs and other organisations, and 93% of EU and non-EU citizens are critical of a revision.

4 **A wide variety of topics raised.** Citizens stress adult choice and access; companies, NGOs and others stress jobs, value chains, excise revenue and illicit-market risks; academia stresses the combustion-driven risk continuum and health-system sustainability.

5 **One common thread – innovation and competitiveness.** Uncalibrated regulation raises fixed compliance costs, erodes innovation incentives and adds a regulatory-uncertainty premium. A defensible revision must rest on risk differentiation, explicit innovation-cost assessment, and causal evidence meeting the RSB 2025 standards.

Submissions by Group

+80,000	+91 %	~96 %
submissions	critical – all respondents	critical – academic



Executive Summary: What the Consultation Reveals

While the public consultation on the Tobacco Products Directive (TPD) focuses on tobacco and nicotine markets, the response, particularly from academia and institutional stakeholders, points to broader structural questions for the EU economy. The Commission's regulatory approach carries implications that reach well beyond a single sector.

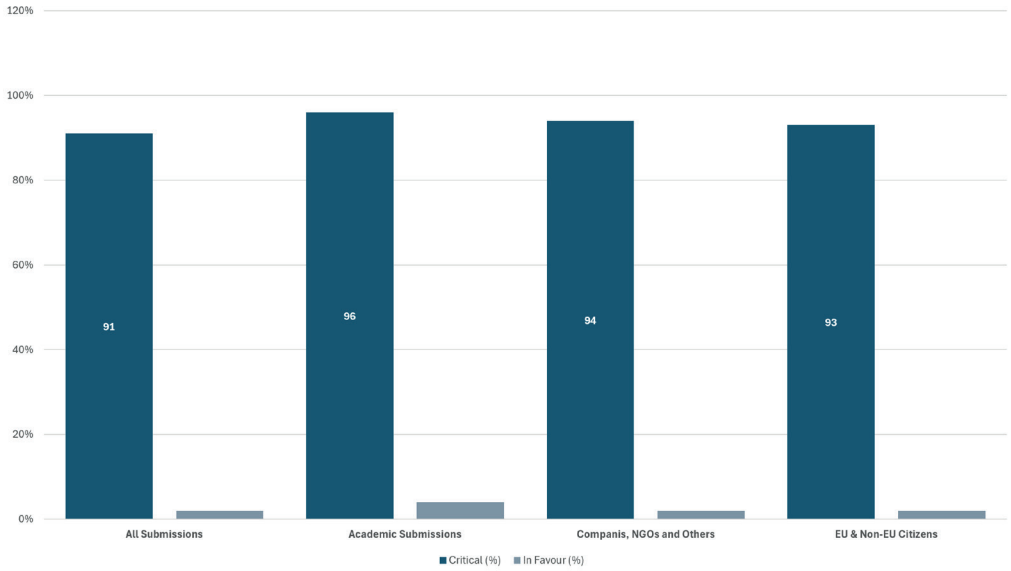
A regulatory approach that adds cost to technological progress, relies on evidence that has not kept pace with the market, and unsettles investment timelines risks weakening the EU's competitiveness. This publication examines what the consultation reveals about the wider EU economic and market environment, and sets out where WAI believes the revision should be strengthened.

Overview of the Call for Evidence

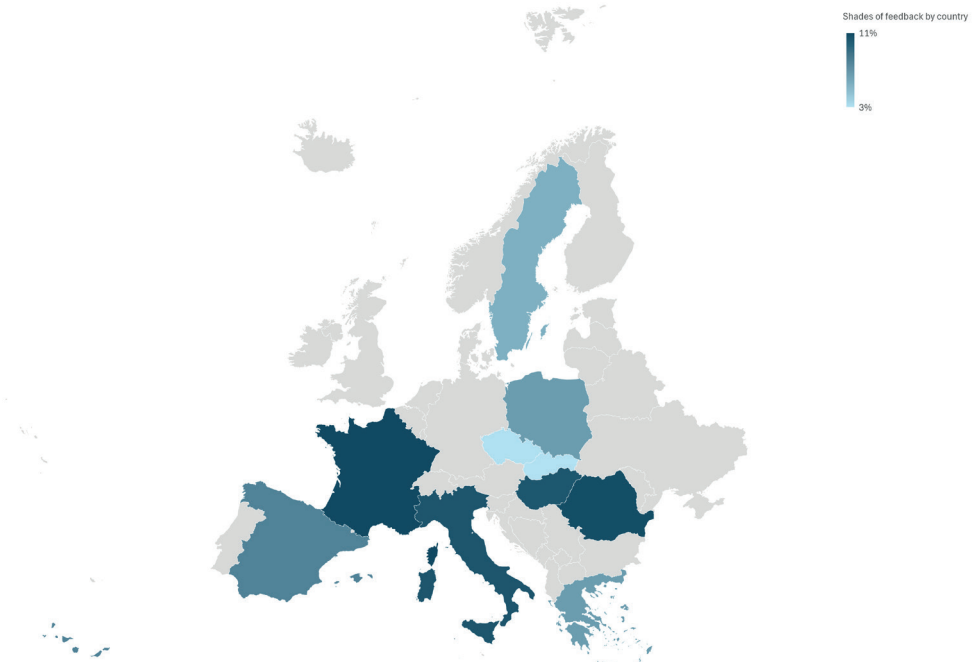
To evaluate the structural alignment between European regulatory intent and empirical market realities, this analysis examines the stakeholder feedback submitted during the European Commission's Call for Evidence (CfE) on the Tobacco Products Directive (TPD) and Tobacco Advertising Directive (TAD). Running from May 18 to June 15, this consultation sought to gather evidence and data to inform a forthcoming legislative impact assessment, with the stated objectives of ensuring a smoothly functioning internal market and upholding a high level of human health protection. Our review of the consultation record points to a considerable gap between the Commission's proposed direction and the views expressed by respondents. The planned revisions have drawn substantial pushback from the scientific community, industrial stakeholders, and tens of thousands of individual citizens.

Of more than 82,000 submissions received, over 90% raise at least one substantive objection to the Commission's trajectory: equal regulatory treatment for all products (including non-tobacco nicotine products, e-cigarettes and heated products), further restrictions on flavours and labelling, and product bans, as signalled in the Commission's public statements, Evaluation report and supporting study, while only a marginal 2% express outright support. This pattern holds across stakeholder groups: objections appear in 96% of academic and research submissions, 94% of submissions from companies, NGOs and other organisations, and 93% of submissions from individual EU and non-EU citizens. Submissions span 138 countries, with academic and research input alone drawn from 43 countries, suggesting that concerns about the proposed direction are not confined to a single constituency or discipline. It is worth noting, however, that "critical" submissions do not all point in the same direction: most argue the proposal is too restrictive, though a smaller number, illustrated further below, argue it should go further still. France, Romania, Italy, Hungary, and Spain provided the highest number of submissions, followed by Poland, Greece, Sweden, the Czech Republic, and Slovakia.

How Stakeholder Groups Responded to the Proposal



Top 10 Countries by Submission Volume



The Consultation Demographics: Themes and Perspectives

The consultation profile shows a broad mobilization. **EU and non-EU citizens account for 95.6% of responses, industry and organizational stakeholders comprise 4.1%, and academic and research institutions 0.3%.** Despite differences in perspective, the feedback converges around a small set of core topics. **For citizens, the dominant topic is freedom of choice.** Many object to restrictions on access to certain products or limits to adult consumers' ability to choose between different nicotine and tobacco alternatives. Their topics are often framed around individual autonomy, proportionality, and the fear that regulation may reduce rather than improve practical, legal options for consumers. Other major concerns include potential bans and restrictions on novel tobacco and nicotine products as less risky switching tools, the personal and family livelihoods tied to local retail, and the fear that bans and taxes will fuel the black market and erode tax revenue.

For companies, the strongest topics relate to industrial policy, innovation, competitiveness, and regulatory predictability. Submissions emphasise investment certainty, compliance costs, and the EU's position as a market for innovation, alongside the ability to operate viable product portfolios. Many warn that disproportionate or unpredictable regulation could weaken investment in lower-risk alternatives and constrain retail viability. While corporate priorities are anchored in jobs and value chains across manufacturers and retail, they intersect deeply with excise-revenue and illicit-market risks, the case for proportionate, risk-tiered regulation of smoke-free alternatives, and adult consumer choice at the point of sale.

For academia and research institutions, the central theme is the relative risk of products along a combustion-driven risk continuum. Academic submissions place considerable emphasis on aligning legislative frameworks with empirical evidence on relative product risks, the dynamics of consumer substitution, and the need for robust methodological design. This perspective generally sits alongside broader questions of health economics, industrial policy, and state-level governance. A minority of submissions, mostly from public-health and medical bodies, argue for tighter rules still. One example, from the roughly 2% of submissions that favour a more restrictive approach, reads:

"We call on the European Commission to fully include all novel nicotine products in the strict regulatory framework. There is a need for mandatory health authorisation procedures, the mandatory declaration of free nicotine and pH values, restrictive unit packaging and an EU-wide ban on nicotine pouches and youth-affined flavourings."
– Austrian Society for Pneumology, Austria

This minority position, taken as a whole, focuses on closing perceived legal loopholes and strengthening controls over product authorisation, testing protocols, flavour rules, standardised packaging, and warning labels. It also places emphasis on supply-side and marketing restrictions, including online sales, social media marketing, digital advertising, and youth access.

Leading Topics Across Citizens, Companies, and Academia

EU & NON-EU CITIZENS	COMPANIES, NGOS & OTHERS	ACADEMIA & RESEARCH INSTITUTIONS
Adult autonomy against paternalistic nicotine bans	Jobs and value chains across manufacturers and retail	Combustion-driven toxicity and the continuum of risk
Viewing alternative products as a way to switch away from cigarettes and potentially improve health outcomes	Excise revenue loss and illicit-market displacement of legal trade	Health-system sustainability and avoidable disease burden
Personal and family livelihoods tied to local retail	Proportionate, risk-tiered regulation of smoke-free alternatives	Regulatory incentive design for innovation and EU competitiveness

Bans and taxes fuel the black market and erode tax revenue	Adult consumer autonomy and product range at point of sale	Illicit-market substitution and enforce-ability of fiscal controls
Existing rules suffice; call for evi-dence-based, proportionate revision	Regulatory predictability and propor-tionate burden on compliant operators	Causal identification, counterfactuals and impact-assessment validity

Issue area colours: 1. Freedom of Choice 2. Health Gains & Product Differentiation 3. Fiscal Stability & Illicit Trade 4. Jobs, Investment & Innovation 5.Proportionate, Evidence-Based Rules

Issue Areas and Their Costs to Society, by Stakeholder Group

1 · Freedom of Choice

Cost to society: over-restriction drives adults toward illicit or more harmful products.

Topic description within issue area by stakeholder group

EU & Non-EU Citizens	Informed adults want to decide for themselves; further bans are felt as paternalistic interference in private lifestyle choices
Companies, NGOs & Others	Adult customers' demand for a range of legal products and the retailer's ability to offer them.
Academia & Research Institutions	Support for informed adult choice, but within proportionate, evidence-based regu-lation.

2 · Health Gains & Product Differentiation

Cost to society: treating all products alike keeps smokers on cigarettes, forgoing avoidable health gains.

EU & Non-EU Citizens	Many recount that vaping / heated tobacco / pouches helped them quit or cut down, and fear losing a tool that improved their health.
Companies, NGOs & Others	Rules should scale to relative risk, so lower-risk alternatives are not regulated like cigarettes.
Academia & Research Institutions	Harm comes mainly from combustion; products sit on a risk continuum – linked to long-term population health and healthcare costs.

3 · Fiscal Stability & Illicit Trade

Cost to society: demand shifts to the black market, draining tax revenue and safety oversight.

EU & Non-EU Citizens	Bans and higher taxes will push consumers to the black market / cross-border sources – bad for safety and tax revenue.
Companies, NGOs & Others	Over-regulation diverts legal sales into illicit channels – lost tax revenue and legiti-mate business.
Academia & Research Institutions	Analysis of how restrictions can be substituted by illicit markets and whether fiscal/ enforcement measures are actually workable.

4 · Jobs, Investment & Innovation *Cost to society: investment, jobs and value creation move outside the EU.*	
EU & Non-EU Citizens	Personal stake: their own job or local shop threatened by restrictions.
Companies, NGOs & Others	Employment and the value chain (manufacturers, retailers) plus investment and competitiveness are at stake.
Academia & Research Institutions	Focus on how regulatory design shapes incentives for innovation/R&D and the EU's competitiveness.
5 · Proportionate, Evidence-Based Rules *Cost to society: regulatory churn and weak evidence raise costs and produce counterproductive policy.*	
EU & Non-EU Citizens	The sector is already heavily regulated; any revision should be proportionate and evidence-based rather than adding more restrictions.
Companies, NGOs & Others	Legal certainty and no disproportionate compliance burden on compliant operators.
Academia & Research Institutions	Whether the evidence base and impact assessment can establish causal effects before measures are adopted.

Evaluating Submissions Through an Innovation Lens

Read through the lens of innovation and competitiveness, the priorities raised across the consultation's stakeholder groups converge on a shared concern: that the Commission's proposed framework could act as a barrier to technological progress. **Submissions consistently warn that an uncalibrated regulatory architecture slows development pipelines and weakens Europe's ability to compete in technology-intensive segments.** In knowledge-based economies, regulatory design is a meaningful factor in where R&D is funded, where intellectual property is generated, and where manufacturing capacity is built. Stakeholders place this concern within the wider debate on the EU's innovation gap, rising compliance costs, and the conditions needed for high-growth firms to scale. The underlying logic is fairly direct: regulation tends to support innovation when it allows room for experimentation, rewards incremental improvement, and offers a stable legislative horizon for long-term investment. It tends to hold innovation back when it raises fixed costs, limits lawful product differentiation, and adds ongoing uncertainty, a pattern that consultation respondents argue the current proposal risks reinforcing.

"The critical question for the upcoming revision is whether the legal architecture preserves core incentives for lawful product improvement […] The next regulatory iteration must explicitly evaluate whether proposed measures catalyze further technical optimization or inadvertently contract its scope. A sound impact assessment should include effects on product development and incremental innovation within a clear public health framework. *– IE University, Spain*

Cost is one of the clearest channels through which uncalibrated regulation can slow progress. Submissions describe how regulatory adjustment requires capital for technical redesign, relabelling, reformulation, legal review, notifica-

tion, and compliance infrastructure. These costs are largely fixed and front-loaded, meaning firms absorb them well before any commercial return. Respondents report that, under constrained budgets, compliance spending can crowd out discretionary research and development, with a corresponding effect on product development and quality iteration. Respondents describe this effect as falling hardest on small and medium-sized enterprises and on new market entrants.

A second theme in the consultation concerns the erosion of innovation incentives. Submissions argue that technological progress depends on expected returns, and that firms invest when better engineering can be reflected in market share through visible quality differentiation. A framework that limits this differentiation, respondents argue, weakens the commercial case for investing in product refinement, and shifts competition toward price, compliance capacity, and scale rather than innovation. Several submissions suggest this dynamic tends to favour large incumbents, low-cost imports, and non-compliant suppliers over European operators seeking to innovate within the legal framework.

"Regulatory uncertainty discourages R&D investment; a differentiated approach that acknowledges the spectrum of risk supports quality, innovation, and investor confidence."
– Northeastern University London, United Kingdom

A third theme raised in the feedback concerns market expectations and the effect of regulatory uncertainty on long-horizon projects. Technological innovation requires long development cycles and significant upfront investment, both of which depend on a stable legislative outlook. A regulatory trajectory that is unclear or subject to repeated revision raises downside risk, and can lead firms to narrow their pipelines, delay launches, or hold back capital until the environment stabilises. Northeastern University London notes that regulatory uncertainty discourages R&D investment, while a differentiated approach that reflects the spectrum of risk supports quality, innovation, and investor confidence. The University of Delaware adds that when long investment cycles coincide with regulatory reopening, the cost of capital can rise across the wider innovation economy, a signal that reaches investors well beyond this sector.

"The wider and more important concern is signalling beyond tobacco: when long investment cycles and regulatory reopening occur simultaneously, the cost of capital rises across the entire innovation economy."
– University of Delaware, United States

Taken together, these three channels (cost, incentives, and uncertainty) can compound one another, leading firms to prioritise short-term regulatory compliance over long-horizon research and development. Rather than reducing consumer demand, an uncalibrated approach risks displacing technological development and investment outside the European Union. It may also, by limiting the domestic development of lower-risk alternatives, leave more room for unregulated supply chains that do not meet European safety and youth-protection standards. In WAI's view, the upcoming impact assessment should treat this revision as a meaningful factor in Europe's wider innovation environment, alongside its core public health objectives. These innovation concerns are consistent with the broader pattern seen across the consultation: citizens, academia, and industry each raise distinct concerns, yet converge on a shared call for regulation that is proportionate and evidence-based. We believe the Commission has an opportunity to address these concerns through a risk-differentiated approach, one that can support both public health goals and Europe's economic competitiveness.

Our Conclusions Derived from Stakeholder Evidence

Based on our review of the consultation submissions, we see five priorities that should guide a legally and economically sound revision of the framework. WAI's own research on innovative nicotine products points in the same direction, and we highlight below where that evidence aligns with what respondents raised.

Risk differentiation must form the foundation: respondents across public opinion, industry, and academia converge on the view that regulation should reflect relative risk, in line with proportionality and Better Regulation standards. This is consistent with independent findings on the risk continuum among nicotine products.

"Switching from cigarettes to nicotine pouches could represent a reduction of a smoking individual's health risk."
– Germany's Federal Risk Assessment Institute (BfR), 2022 assessment.

Innovation costs must be explicitly assessed: our analysis suggests innovation costs should be explicitly and dynamically assessed. We note that the Commission's current impact assessment does not appear to account for the R&D disincentive effects that can follow from mid-cycle regulatory uncertainty. In our view, these costs are measurable, material, and relevant to the proportionality assessment.

Economic and employment impacts must be weighed: respondents consistently note that disproportionate rules could reduce investment, affect jobs across manufacturers and retail, and shift value creation outside the EU. We believe these effects merit explicit quantification in the impact assessment.

Effects on illicit trade must be anticipated: respondents caution that equal treatment of all products, tighter flavour and labelling rules and product bans risk diverting consumer demand into unregulated and illicit channels. Because these channels bypass European safety and quality standards, this displacement must be assessed and mitigated.

Causal evidence standards must be met before adoption: in our view, causal evidence standards should be fully satisfied before final policy adoption. We would point to the Regulatory Scrutiny Board's 2025 review standards as a relevant benchmark, one that can help ensure a credible, evidence-based outcome that limits market distortions and capital outflow while supporting the Commission's public health objectives.

Methodology

Data source and extraction. The analysis draws on the public feedback submitted to the European Commission's Call for Evidence "Tobacco products and tobacco advertising – revision of EU rules" on the Have Your Say portal. For each submission, the user type, country, organisation, feedback text and date were extracted. Duplicate submissions were identified and removed prior to analysis. The dataset comprises more than 82,000 submissions from 138 countries.

Stakeholder groups. Based on user type, submissions were grouped into EU and non-EU citizens, companies, NGOs and other organisations, and academic and research institutions.

Sampling and reading. The analysis was conducted on random samples drawn within each group, together with the academic and research submissions, with each text read in full and assessed in context; non-English submissions were translated. The reading and classification were carried out with the assistance of a large language model (LLM) under the definitions set out below.

Position coding. Each submission was classified according to its position toward the proposed revision and toward stricter or undifferentiated regulation. Four categories were used: Critical – raises at least one substantive objection, reservation or warning, even where it also endorses public-health aims; In favour – clearly supports stricter rules, prohibitions or an ambitious revision without substantive objection; Unclear – no determinable stance; and Excluded – empty submissions. For academic and research submissions, attachments were reviewed manually and included in the assessment. Negation was interpreted in context; for example, "no further restrictions are needed" was coded as Critical.

Issue and topic coding. The substantive concerns raised in each submission were first recorded in the respondent's own terms. These issue statements were then clustered into broader thematic areas across the sample. Each submission was assigned to one dominant topic, based on the main argument or concern expressed in the text, so that topic shares sum to 100% within each stakeholder group. The five most frequent topics were then identified and ranked separately for each stakeholder group.

Quotations. Quotes used throughout this briefing are reproduced verbatim from coded submissions, with no paraphrasing or editing beyond minor formatting.

PATH TO SMOKE-FREE

Path to Smoke-Free is a comprehensive analytical platform developed by We Are Innovation that reveals how countries can harness innovation to defeat smoking and accelerate their journey toward smoke-free status. Drawing from Sweden's remarkable success in dramatically reducing smoking rates far below global averages—we identified three key elements: Accessibility, Acceptability, and Affordability of innovative nicotine products. Our platform combines comprehensive policy data with real insights from Swedish ex-smokers, offering interactive tools to compare how countries are harnessing innovation to defeat smoking. The platform features powerful forecasting charts that project smoking prevalence and when countries will reach smoke-free status under three scenarios: current policy trajectories, outcomes if countries matched Sweden's success rate, or results following the combined pace of leading nations. Policymakers, researchers, and health professionals can explore evidence-based strategies that could help their countries reach smoke-free targets faster, guided by proven success stories.
Discover how your country could accelerate its journey to smoke-free status at https://pathtosmokefree.global/.

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