

IEVA's Contribution to TRIS Notification 2025/044/ES

IEVA - the **Independent European Vape Alliance** - as the umbrella organisation representing national associations, manufacturers, distributors, and specialised retailers of vaping products across the EU, would like to express its **serious concerns** regarding the impact of Spain's proposed **Royal Decree amending RD 579/2017**, regulating certain aspects relating to the manufacture, presentation and marketing of tobacco and related products, notified under the TRIS reference <u>2025/044/ES</u>.

This initiative, if adopted, would set a dangerous precedent for regulatory fragmentation and threaten the integrity of the EU Single Market.

While IEVA supports robust public health policy and effective regulation, we believe that the Spanish proposal - particularly the blanket flavour ban and lack of a reasonable transitional period - constitutes a disproportionate and unjustified barrier to trade, in violation of Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU). It also risks distorting competition and undermining the competitiveness of SMEs, a sector the EU itself has committed to supporting.

This is not an isolated national issue. Measures like Spain's proposed Royal Decree, if replicated across Member States, would fragment the internal market and jeopardise the EU's goals of regulatory harmonisation and strategic industrial autonomy.

1. A flavour ban will lead to a rise in smoking rates and will threaten public health

Many independent and publicly funded studies have highlighted the harm reduction potential of vaping products: a report commissioned by Public Health England found that vaping is 95% less harmful than smoking combustible cigarettes, and a study financed by the prestigious Institut Pasteur confirmed that vaping is significantly less carcinogenic than smoking and constitutes an acceptable replacement for traditional tobacco. Other sources pointing to the harm reduction potential in vaping can be found in studies by the Royal College of Physicians or published in the British Medical Journal. Overall, vaping products reduced the risk of cancer for smokers.



Vaping products also play a **critical role in helping adult smokers to quit traditional tobacco**. Peer reviewed studies by the <u>American Journal of Public Health</u> and research led by the <u>University of Oxford</u> highlight the smoking cessation potential of vaping. The European Parliament considered in two separate reports - the report on <u>strengthening Europe in the fight against cancer</u> (2022) and the report on <u>non-communicable diseases</u> (2023) - that "electronic cigarettes could allow some smokers to progressively quit smoking".

Vaping products' flavours moreover constitute an **essential motivation for smokers trying to switch to a less harmful alternative**. A <u>peer-reviewed article</u> published in the *Journal of the American Medical Association* showed that adults vaping non-tobacco flavoured products were more likely to quit smoking than those vaping tobacco flavours (which are commonly exempted from flavour bans in countries that implemented them).

For these reasons, we can expect that implementing a flavour ban will push smokers away from a safer alternative and lead to a rise in tobacco smoking rates: current smokers will lose an incentive to quit, and consumers of flavoured products will revert back to smoking. As an example, in Denmark, a country with similarly harsh vaping legislation, the e-liquid flavour ban implemented in 2020 lead to an increase in the smoking rates. The <u>Danish Health Authority</u> highlighted that the percentage of 15-29 year-olds who smoked tobacco cigarettes went from 23% in 2020 to 25% in 2022.

This decree will therefore do more harm to Spanish public health than good.

2. The Royal Decree Violates the Free Movement of Goods in the EU

The proposed Royal Decree would unilaterally ban all non-tobacco flavours in vaping products. This ban targets goods that are **lawfully marketed in most other EU**Member States and contradicts the principles of mutual recognition and free movement of goods as laid out in Articles 34 and 36 TFEU.

Article 34 prohibits measures that directly or indirectly restrict trade within the EU. A flavour ban would effectively block imports of otherwise compliant products from other Member States. Article 36 allows public health exceptions only if they are



strictly justified and proportionate. The Spanish government has not met this burden of proof.

Moreover, under Directive 2014/40/EU (TPD), national deviations from harmonised regulation require detailed justification. No empirical evidence has been presented that clearly links flavoured vaping products to increased underage use, nor have less restrictive alternatives been considered.

IEVA stresses that this approach undermines the coherence of EU regulation and poses a risk of cascading protectionist measures that will disrupt the Single Market. We urge the Commission to consider this case not only in the context of Spain, but as a test case for the integrity of EU regulatory alignment.

3. The Decree Undermines EU Industrial Policy and SME Competitiveness

The Spanish proposal stands in **direct contradiction to EU strategies aimed at boosting industrial resilience**, such as the SME Strategy, the EU Industrial Strategy, and the Clean Transition Industrial Deal. These policies recognise the central role of small and medium-sized enterprises in Europe's economic fabric.

By targeting SMEs disproportionately, the flavour ban would **threaten the viability of hundreds of independent producers and retailers**. According to analysis by Analistas Financieros Internacionales (AFI), the measure could lead to a **65% loss in turnover for these businesses in Spain alone**.

This scenario also undermines cross-border investment and pan-European supply chains. The vaping sector, which is rapidly innovating in harm reduction, had projected over €1.5 billion in EU-wide investments by 2030. Measures like this jeopardise such projections and send a chilling signal to the broader innovation economy.



4. The Decree Will Fuel the Illicit Market and Endanger Public Health

Blanket flavour bans have consistently led to unintended public health consequences and increased illicit market activity. The Spanish case would be no exception. Evidence from Estonia and the Netherlands has shown that prohibitions on flavoured products have driven consumers to black-market alternatives, undermining regulatory goals and exposing consumers to dangerous, unregulated substances.

IEVA highlights that these products - often sold through online platforms outside EU jurisdiction - frequently contain untested chemical compounds and bypass age verification, taxation, and labelling requirements. The resulting market distortion penalises compliant operators while eroding consumer safety. In Spain, the Guardia Civil has already seized over 150,000 illicit vaping products. With the adoption of a flavour ban, such seizures will likely rise, overwhelming enforcement capacity and undermining legal channels.

This is not a theoretical risk: it is a predictable and documented consequence of poorly calibrated policy. IEVA urges the Commission to consider the real-world implications of Spain's proposal and promote a regulatory framework that is proportionate, evidence-based, and enforceable.

5. Inadequate Transitional Period and Regulatory Disproportionality

The proposed transitional period - 10 months for manufacturing and importation, and 12 months for final sale - **is not aligned with EU regulatory norms**. Previous transitions of comparable scope within the EU have ranged from 24 to 48 months.

This timeline is particularly burdensome for SMEs, which **lack the scale and capital flexibility of multinational firms**. Reformulating products, relabelling, and restructuring distribution networks in under a year is unrealistic and likely to result in widespread product shortages, job losses, and supply chain disruptions.

IEVA calls for a realistic and harmonised approach that allows legal industry stakeholders to adapt without undue burden.



Conclusion

IEVA strongly supports proportionate and evidence-based regulation that safeguards both public health and the functioning of the EU Single Market.

We respectfully call on the European Commission and Member States, through the TRIS procedure, to:

- **Reject the proposed Spanish flavour ban in its current form** and encourage less restrictive, better-targeted alternatives (e.g., stricter point-of-sale regulation, improved labelling, and robust age verification systems).
- Request from the Spanish government a detailed, evidence-backed justification demonstrating the necessity and proportionality of the measure.
- Recommend an extended transitional period in line with best practices observed in other Member States, ensuring continuity and legal certainty for businesses.
- As the European representative body for the independent vaping industry, IEVA remains committed to supporting EU-wide policies that protect consumers, foster innovation, and uphold the principles of the internal market.

About IEVA

The Independent European Vape Alliance (IEVA) is a European trade body that unites small and medium-sized producers and retailers of vaping products, as well as European countries' national vaping associations. The vast majority of vaping companies are run by self-funded entrepreneurs who saw a problem in society cigarette smoking - and created vaping products as part of the solution. We are independent and not influenced by tobacco companies.

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