

## **Disproportionate restrictions on nicotine products in Spain's draft regulation resulting in obstacles to the free movement of goods (TRIS notification 2025/0044/ES)**

### **Introduction:**

On 24 January 2025, the Ministry of Health of Spain submitted [via TRIS](#) the *Draft Royal Decree amending Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and marketing of tobacco and related products ('draft regulation')*,<sup>1</sup> which heavily penalizes EU businesses manufacturing, distributing and importing electronic cigarettes and refill containers with or without nicotine, nicotine pouches and heated herbal products into Spain.

If adopted in its current form, these products will be subject to heavy-handed, disproportionate and, in several instances unlawful restrictions, which will **breach the right to the free movement of goods in the EU internal market**.

As imports, including from Member States, account for the largest share of these products in the Spanish market, **such restrictions amount to *de facto* discrimination on imports which is forbidden by EU law**, as specified in Articles 34 and 36 TFEU, as measures are not justified given their lack of necessity and proportionality.

Tobacco Europe represents the views of major European-based tobacco and nicotine products manufacturers such as British American Tobacco (BAT), Imperial Brands (IMB), and Japan Tobacco International (JTI), located in Brussels.

With this contribution, Tobacco Europe would hereby like to call on the Commission and Member States to consider our concerns outlined in the below, notably related to the free movement of goods in the EU.

Please see below further details on the measures proposed by Spain in the draft regulation and the concerns they raise in relation to the free movement of goods in the EU.

### **1. *De facto* ban on nicotine pouches and heavy-handed restrictions on heated herbal products.**<sup>2</sup>

Article 52 of the draft regulation prohibits the placing on the market of nicotine pouches containing more than 0.99 mg of nicotine per pouch. Such **proposed maximum limit of 0.99 mg of nicotine per pouch constitutes a *de facto* ban on nicotine pouches**, as no product with such low concentration exist on the market nor would be commercially viable.

Whilst Article 24 of the TPD allows Member States to introduce further national measures on tobacco and related products if they are justified by public health concerns, they must **comply with EU law and be justified, necessary and proportionate** to their aim and **do not constitute an arbitrary discrimination or disguised restriction on trade between Member States**.

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<sup>1</sup> 2025/0044/ES.

<sup>2</sup> "It shall be prohibited to place on the market, sell, distribute, or offer free of charge, nicotine pouches containing a) more than 0.99 mg of nicotine per pouch".

The communication does not provide the substantiated evidence required by EU law to justify such measure on public health grounds. It relies on general claims but **fails to demonstrate a concrete public health risk that would necessitate such measure**. Moreover, the selective reference to policy in neighbouring countries does not constitute an objective, evidence-based assessment of the actual public health situation. To date, nicotine pouches use in Spain remains low and no nicotine pouch or heated herbal product has ever been withdrawn from the Spanish market and flagged on Safety Gate – the system for dangerous non-food consumer goods.

Even if a specific public health concern was identified, **the measure goes beyond what is necessary, in breach of the principle of proportionality**, requiring measures to be suitable, necessary and not imposing an excessive burden in relation to the objective sought.<sup>3</sup>

In this sense, It should be noted that existing studies indicate that **nicotine pouches present a lower health risk compared to combustible tobacco**<sup>4</sup>. Additionally, a study by the [Bundesinstitut für Risikobewertung \(BfR\)](#), Germany's Federal Institute for Risk Assessment, shows that **16.6 mg of nicotine per pouch would be the equivalent nicotine dose to smoking a cigarette**. This standard has been considered for legislation in Italy and other Member States. As such, the proposed maximum level of nicotine content seems unreasonable and unnecessary.

Finally, even if the measure was proven to be necessary, it should be proportionate and not impose excessive burdens in relation to the objective. The availability of **other conceivable measures**, such as a potential prohibition of sale to minors, shall be considered as they **would be less restrictive, and equally effective** in the pursue of the public health goal.

## **2. Flavour ban fails the proportionality test and no evidence of its effectiveness.**

Furthermore, the proposed regulation also imposes restrictions to the flavours allowed in e-cigarettes, nicotine pouches and herbal nicotine sticks.

In principle, this measure is **prohibited under Articles 34 and 36 of the TFEU**, as it restricts the placement on the market of products that are lawfully sold in most Member States. The TPD itself clarifies that **"[for electronic cigarettes] any prohibition of such flavoured products would need to be justified"**.

To be deemed valid, a justification must demonstrate a **clear link** between the **proposed measure** and **intended objective** as well as evidence to support its efficiency and if alternative, less restrictive measures were considered. **Spain did not provide evidence to that effect.**

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<sup>3</sup> According to the courts, "A national rule or practice cannot therefore benefit from the derogation provided for in Article 36 of the Treaty if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade" (Judgment of 11 July 2000, *Toolex*, C-473/98, EU:C:2000:379, paragraph 40).

<sup>4</sup> Clinical studies of Altria's "on!" brand of nicotine pouches, which show reduced exposure to harmful and potentially harmful compounds when switching from combustible tobacco products to nicotine pouches. See Rensch, J., Edminston, J., Wang, J., Jin, X., Sarkar, M. (2023). "A Randomized, Controlled Study to Assess Changes in Biomarkers of Exposures Among Adults Who Smoke That Switch to Oral Nicotine Pouch Products Relative to Continuing Smoking or Stopping All Tobacco Use." Available at: <https://pubmed.ncbi.nlm.nih.gov/37322571/>.

Data from the latest **2023 Eurobarometer survey casts doubt on the effectiveness of such ban**,<sup>5</sup> as it shows that the consumption of flavoured electronic cigarettes in countries where a ban is in place, is similar or even higher than in countries without such restrictions (Annex I).

**3. Disproportionate labelling and product presentation rules harm legitimate EU businesses to the benefit of illicit actors.**<sup>6</sup>

The restriction on colors and elements that “*may attract the attention or particular interest*” has **no precedent in the EU**. It is a highly disproportionate restriction on trade, amounting to a **de facto prohibition on the use of registered trademarks, logos and branding features** by EU businesses importing goods into Spain.

It is also ambiguous, lacking legal certainty and **subject to individual and arbitrary interpretation**.

Under the principle of **mutual recognition**, goods legally sold in one Member State must be accepted in other Member States unless an overriding public interest justifies restrictions. **No evidence** is shared on the suitability of this measure or whether alternative, less restrictive options were considered.

By banning distinctive elements, the measure **will facilitate illicit trade**, allowing illegal products to enter the internal market more easily, harming legitimate EU businesses, eroding tax revenue and undermining human health protection.

In its current formulation, the draft regulation challenges amongst others:

- Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), protecting the **free movement of goods** within the internal market;
- Articles 16 and 17 of the **Charter of Fundamental Rights**, which protects the freedom to conduct business and to property, including trademarks, logos and branding features. The **lack of legal certainty** on which elements or colours can be used hampers EU businesses’ operations.
- **Article 20 (4) of the Tobacco Products Directive (TPD)** allowing EU businesses to include information on nicotine content and other product features on packaging, often conveyed through elements or images. The rule risks making even legal information unlawful, putting businesses in an impossible legal position where compliance with EU law results in a violation of domestic law.
- The **WTO TRIPS agreement**, which is binding on Member States, and forbids trademark limitations save exceptional cases backed by strong evidence—which Spain did not provide.

**4. Disproportionate pre-market notification stifles innovation, discourages trade and leads to internal market fragmentation.**<sup>7</sup>

<sup>5</sup> Eurobarometer: Attitudes of Europeans towards tobacco and related products (2023).

<sup>6</sup> “The unit packet, the outside packaging, and the device may not include images, with the exception of the mandatory pictograms. Likewise, elements and combinations of colours that, due to their content or design, are likely to attract the attention or particular interest of consumers, especially minors, may not be used”.

<sup>7</sup> “Manufacturers or importers intending to place on the market electronic cigarettes, **nicotine-free electronic** cigarettes or refill containers **with or without nicotine** shall, to the Directorate-General for Public Health and Health Equity, through the EU-CEG Portal, and following the format set out in Commission Implementing. The communications referred to in Paragraphs 1 and 2 shall be made:[...], six months before the date of their placing on the market.

TPD Article 20 (2) requires manufacturers and importers of electronic cigarettes and refill containers to submit a notification six months before placing on the market. This notification is made via EU-CEG, in line with the format in Commission Implementing Decision (EU) 2015/2183<sup>8</sup>.

The draft regulation extends the requirement to **nicotine-free electronic cigarettes and refill containers**, as well as to **nicotine pouches** and **heated herbal products**, which are not covered by the TPD.

Such requirements **were never designed or intended** for such products by the co-legislators. Imposing them without justification **constitutes a direct restriction on trade and on the freedom to conduct business** – a fundamental right protected under **Article 16 of the Charter**.

It also harms **EU businesses heavily invested into these nascent product categories**, stifling innovation and imposing trade burdens without evidence of the necessity, particularly when **less than 1% of nicotine users in Spain ever used nicotine pouches**<sup>9</sup>, and heated herbal products are too novel for genuine data.

Additionally, the information storage would occur at **Spain's own risk**, not the Commission's, which carries **data security and confidentiality** risks. No safeguards are provided by the Spanish authorities, in a violation of **Article 17 of the Charter** protecting the right to property.

Lastly, **no guidance** has been issued—or is planned<sup>10</sup>—on how EU businesses should comply with this measure. This further exacerbates legal uncertainty, making compliance unnecessarily complex and burdensome for EU businesses, reinforcing barriers to trade.

##### **5. The transition period contradicts EU case law, rendering it unlawful.**<sup>11</sup>

The draft regulation sets an **unreasonable transition period of only 10 months** for electronic cigarettes and refill containers, whether containing nicotine or not, with mandatory **market clearance by month 12**. In parallel, **no transitional period is given for nicotine pouches and heated herbal products**, meaning the requirements may apply upon entry into force. **Such a short transition period contradicts established EU case law and is therefore unlawful.**<sup>12</sup>

Compliance with the above rules will **require substantial time for adaption**. EU businesses will be forced to **reformulate products, modify production lines and implement changes to labelling, packaging and product presentation** – all of which cannot be reasonably completed within 10 months.

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<sup>8</sup> Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers.

<sup>9</sup> Eurobarometer: Attitudes of Europeans towards tobacco and related products (2023)

<sup>10</sup> In accordance with the communication under TRIS 2025/0044/ES.

<sup>11</sup> “[...] the following shall be allowed to continue to manufacture or put into free circulation up to **10 months** after the entry into force of this Royal Decree: b) electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with and without nicotine. 2. The products referred to in the previous paragraph may continue to be marketed up to **12 months** after the entry into force of this Royal Decree”.

<sup>12</sup> “[...] the following shall be allowed to continue to manufacture or put into free circulation up to **10 months** after the entry into force of this Royal Decree: b) electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with and without nicotine. 2. The products referred to in the previous paragraph may continue to be marketed up to **12 months** after the entry into force of this Royal Decree”.

The EU Court of Justice has ruled that **failing to provide a reasonable transition period constitutes a restriction** on the free movement of goods (C-309/02, Radlberger). Such rulings are binding on the Member States; however, the draft regulation disregards the obligation to provide a longer period.

Precedent shows that **major regulatory changes in tobacco legislation** have been accompanied by **extended transitional periods**. For instance, the prohibition of **certain tobacco products for smoking with a characterising flavour** allowed for a **four-year adaptation period**—a stark contrast to the **timeframe proposed** in the draft regulation.

### ***Conclusion***





























As better clarified above, the measures proposed in the draft regulation create obstacles to the free movement of goods within the internal market. These restrictions amount to *de facto* discrimination against imports, which is prohibited under Articles 34 and 36 TFEU, as they are neither necessary nor proportionate to achieving the stated objectives.

In light of this, Tobacco Europe and its members kindly request the Commission to carefully examine carefully this draft technical regulation to ensure that any resulting barriers to these fundamental freedoms are removed at the source.

\*\*\*ENDS\*\*\*

**Annex I**

\*The countries marked with boxes enforce a ban on flavours other than tobacco.

May 2023		Fruit flavour (for example cherry or strawberry flavour)	
Diff. May 2023 - Aug/Sep 2020			
EU27		48	5
BE		91	15
BG		30	13
CZ		63	-2
DK		54	20
DE		78	27
EE		49	-36
IE		43	-3
EL		23	15
ES		36	-14
FR		48	2
HR		49	20
IT		14	14
CY		74	-26
LV		70	14
LT		57	19
LU		75	32
HU		52	1
MT		61	-39
NL		61	19
AT		36	0
PL		52	5
PT		0	-100
RO		34	12
SI		64	25
SK		31	31
FI		23	-15
SE		61	50