

**Subject:** Tobacco Europe contribution to the TRIS notification 2025/0110/FR of the Decree on the prohibition of products for oral use containing nicotine

## Background

On 24 February 2025, the Ministry of Health of France submitted via the Technical Regulation Information System (TRIS) the Decree on the prohibition of products for oral use containing nicotine (Draft Decree), which heavily penalises EU businesses manufacturing, distributing and importing nicotine pouches.

Following the submission of the draft decree to the French Council of State in late 2024, the Council of State issued, in January 2025, an unfavourable opinion on the proposed ban, finding it disproportionate and unnecessary.<sup>1</sup> Nevertheless, the new government decided to proceed with the ban, which was then notified to the European Commission via TRIS.

Nicotine pouches are tobacco-free products that contain nicotine compounds and other ingredients. They are used by placing them between the gum and the lip, and, as they do not involve combustion or tobacco, they potentially lower consumers' exposure to harmful substances. The main ingredients include microcrystalline cellulose, water, flavours and nicotine, ingredients used widely within the pharmaceutical industry and all of which are pharmaceutical or food grade. Prohibiting the use of such products prevents consumers from using valid and risk-reduced alternatives to traditional tobacco products and creates barriers to free movement of products within the internal market.

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.

Tobacco Europe would hereby like to share its views on the TRIS notification 2025/0110/FR (France) of the Decree on the prohibition of products for oral use containing nicotine.

## The decree:

- Introduces a measure equivalent to a quantitative restriction that is not necessary. Under EU law, a Member State wanting to introduce national

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<sup>1</sup> Conseil d'État, Délibération 408971, 28 Janvier 2025.

provisions that could hinder intra-EU trade is required to provide substantial evidence and data to justify such measures. However:

- The French government has failed to provide any scientific studies demonstrating that nicotine pouches pose a genuine and significant public health risk or that their consumption acts as a gateway or promotes addiction to illicit substances. This view was also confirmed by the Council of State in the above-cited Opinion.
- The French government refers to data on intoxication cases reported by poison control centres. However, it must be taken into account that the vast majority of poisoning cases in 2022 is related to accidental/unintended consumption by infants while no public data was shared to explain which oral nicotine products were involved, the number of units ingested, nor the nicotine levels per unit. This highlights a need for preventive measures (like secure product storage) rather than defining it a direct public health risk from nicotine pouches as such.
- Introduces a measure equivalent to a quantitative restriction that is not proportionate (Article 5 TEU). If the objective is to prevent youth access to nicotine pouches and mitigate health risks, several more proportionate regulatory measures exist, including regulating nicotine pouches like vaping products, banning sales to minors, limiting sales to tobacconists to enhance age-control, strengthened product safety requirements and control (e.g. child-proof packaging).
- Jeopardizes recent progress in providing less harmful alternatives to conventional cigarettes. Scientific evidence indicates that some new nicotine products, like oral nicotine pouches, carry a lower health risk compared to combustible cigarettes<sup>2</sup>, offering a viable option for smokers not ready to quit nicotine entirely. Additionally, a study by the [Bundesinstitut für Risikobewertung \(BfR\)](#), Germany's Federal Institute for Risk Assessment, concluded that while nicotine pouches are not risk-free, *"switching from cigarettes to nicotine pouches could represent a reduction in health risks for a*

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<sup>2</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/> .

*person who smokes*".<sup>3</sup> Currently, 2.6 million citizens across the EU Member States<sup>4</sup> have transitioned from smoking to using these pouches in pursuit of a reduced risk experience. Prohibiting nicotine pouches would remove an important harm-reduction tool and force adult smokers to continue using more harmful combustible products, as well as undermine Europe's Beating Cancer Plan that sets the goal of creating a tobacco-free generation by 2040.

- Undermines investments and increases negative impact on retailers and manufacturers. Denmark, Estonia, Lithuania, Latvia, Hungary, Italy, Poland, and Sweden are the countries where pouches are developed/manufactured and then exported to many other Member States. A ban would hinder the free movement of goods (Article 34 TFEU) and create fragmentation in the internal market, affecting 76,000 physical retail stores and 137 websites that sell these products across the Union.<sup>5</sup>
- Pre-empts the process for revising the EU Tobacco Products Directive (2014/40/EU). According to article 6(3) of the TRIS Directive, Member States should postpone the adoption of a legislative act for twelve months if the Commission *intends* to propose or adopt EU regulation on the matter. The Commission has already started the process of the revision of Tobacco Product Directive II, intending to regulate new and emerging nicotine products, including oral nicotine pouches. A ban would undermine this review process and prevent from reaching an approach common to the 27 Member States. Furthermore, a draft proposal from 2022, for a revised Directive on the structure and rates of excise duty applied to tobacco and tobacco related products, illustrates that the EU Commission intends to introduce a common definition and enforce an EU-wide minimum level of taxation on nicotine pouches, showcasing that a harmonised approach does not contemplate banning pouches in their entirety.
- Introduces disproportionate sanctions. By linking the penalties for the violation of the ban on nicotine pouches (including possession) to the ones provided in the Code of Public Health for poisonous substances,<sup>6</sup> the decree provides for imprisonment up to five years and EUR 375.000 fines for violations, potentially exposing consumers that legally purchased nicotine pouches in other EU

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<sup>3</sup> Bundesinstitut für Risikobewertung. (2022). Health Risk Assessment of Nicotine Pouches: Updated BfR Opinion No. 023/2022 of 7 October 2022. In *BfR-Stellungnahmen* (Vol. 2022, Issue 23). Bundesinst. für Risikobewertung.

<sup>4</sup> TobaccoIntelligence.com, 2023

<sup>5</sup> TobaccoIntelligence.com

<sup>6</sup> [Article L5432-1 - Code de la santé publique - Légifrance](#)

Member States and imported them to France to heavy and disproportionate sanctions.

- Creates fragmentation and favours illicit trade. Banning nicotine pouches risks fragmenting the market by creating a regulatory gap between these products and their regulated counterparts, driving consumers to seek alternatives through illicit channels and/or cross-border purchases, and expose themselves to unregulated products that undermine their safety.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Darge', with a long horizontal stroke extending to the right.

Nathalie Darge

Secretary General Tobacco Europe