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Subject: Tobacco Europe contribution to the TRIS notification 2022/417/B (Belgium) of the Royal Decree prohibiting the manufacture and placing on the market of certain similar products

Background

The Belgian government is proposing to prohibit the placing on the market of oral nicotine pouches. These products do not contain tobacco; they are intended as potentially less harmful alternative consumption products for smokers to traditional cigarettes. Consisting of a small sachet/pouch, it is placed under the lip by the consumer for around 30 minutes to allow the nicotine to be delivered via the oral mucosa (i.e. membrane lining the mouth). The main ingredients include microcrystalline cellulose, water, flavours and nicotine.

The draft Decree was TRIS notified on the 16th of June, with the standstill period expiring on the 16th of September 2022.

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 TRIS notification 2022/417/B (Belgium) of the Royal Decree prohibiting the manufacture and placing on the market of certain similar products. The decree:

- Constitutes an arbitrary discrimination of these products. The ban treats oral nicotine pouches much more strictly than cigarettes, which still would be available for sale. The available peer-reviewed scientific evidence shows that oral nicotine pouches contain significantly less toxicants than cigarettes¹ and product extracts trigger no toxic response in human cell cultures². The proposed ban is therefore discriminatory as it unjustifiably restricts the freedom of trade to the detriment of consumers as well as producers. Thus, the Royal Decree would infringe Article 36 TFEU.
- Incorrectly classifies oral nicotine pouches as a “similar product” to snus. Contrary to what the draft Decree states, oral nicotine pouches are not like snus – they are fundamentally different in that they do not contain tobacco leaf and are lawfully sold in the vast majority of EU Member States as a general consumer good.
- Violates the principle of proportionality (Article 5 TEU). Belgium is seeking to justify the ban based on the precautionary principle. This is disproportionate under CJEU case law (e.g. Kanavape decision) because:

¹ Azzopardi D, Liu C, Murphy J. Chemical characterization of tobacco-free "modern" oral nicotine pouches and their position on the toxicant and risk continuums. *Drug Chem Toxicol.* 2021 May 25:1-9. doi: 10.1080/01480545.2021.1925691

² Bishop E, East N, Bozhilova S, Santopietro S, Smart D, Taylor M, Meredith S, Baxter A, Breheny D, Thorne D, Gaca M. An approach for the extract generation and toxicological assessment of tobacco-free 'modern' oral nicotine pouches. *Food and Chemical Toxicology*, Volume 145, 2020. ISSN 0278-6915, <https://doi.org/10.1016/j.fct.2020.111713>



- the available scientific evidence demonstrates that oral nicotine pouches have 1) a potentially lower risk profile than tobacco-based products; and 2) do not cause increased smoking or tobacco use among youth.
- Risks undermining recent advancement in the offer of alternatives which have the potential to reduce harm caused by conventional cigarettes. It is scientifically acknowledged that certain new tobacco or nicotine products (such as nicotine pouches) are potentially less harmful compared to conventional, combustible cigarettes. As such, they provide an alternative for smokers who do not want to, stop smoking completely. Oral nicotine pouches are currently consumed by 1.4 million citizens across 25 EU Member States. The overwhelming majority of these consumers have transitioned to nicotine pouches from smoking cigarettes as they seek a potentially less harmful way of consuming nicotine. If existing options to cigarettes, such as nicotine pouches, are banned, smokers are prevented from switching to alternative products with a lower risk profile.
- Goes against recent development in other Member states. Belgium's measure is not justified to that extent because of recent legislation in a number of Member States that have regulated, but not banned, oral nicotine pouches. The Czech Republic, Denmark and Sweden have introduced bespoke regulation for oral nicotine pouches, which seeks to strike a balance between ensuring their availability for adult smokers who are looking for alternatives, while guarding against use by non-smokers and youth. Estonia, Hungary, Italy, Latvia and Sweden also apply excise tax, and derive revenues from, oral nicotine pouches.
- Undermines investments and increases stress on retailers and manufacturers. Oral nicotine pouches are developed/manufactured in Denmark, Hungary, Italy and Sweden, and exported to many other Member States. A ban would violate the free movement of goods (Article 34 TFEU). An estimated 76,000 physical retail stores and 137 websites sell these products across the Union.³
- Pre-emptes 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 12 months if the Commission *intends* to propose or adopt EU regulation on the matter. The Commission has already voiced the need to regulate new and emerging nicotine products, including oral nicotine pouches. A ban would undermine this review process.
- Incentivises illicit trade/cross border sales, including from non-EU countries where the products are potentially unregulated. This would undermine consumer safety and has budgetary consequences.

We therefore urge the European Commission to take clear action, i.e. block the Royal Decree and issue a detailed opinion expressing its concerns about the obstacles to the free movement of goods within the internal market created by the Royal Decree.

Sincerely,

Nathalie Darge
Director Tobacco Europe

³ TobaccoIntelligence.com