# Reply from Nordic Nicotine Pouches Alliance (NNPA) Regarding TRIS Notification: [2024/0444/LU](https://technical-regulation-information-system.ec.europa.eu/en/notification/26151) (Luxembourg)

*Projet de loi modifiant la loi modifiée du 11 août 2006 relative à la lutte antitabac*

## Nordic Nicotine Pouches Alliance (NNPA)



## The Nordic Nicotine Pouches Alliance (NNPA) is a Brussels-based platform for stakeholders advocating for nicotine pouches as an essential part of harm reduction among adult nicotine users within the EU. We promote responsible, effective, and harmonised European legislation that establishes clear guidelines for this product category to achieve specific goals, such as banning extreme nicotine levels or reducing usage among minors. Our main focus is information dissemination, but we continuously work to build support for our position from stakeholders who are representatives of a responsible value chain. NNPA is funded by European (and Swedish) industry actors.

## Summary of our position:

NNPA strongly object to the restrictions with the motivation that justification criteria cannot be met for the proposed restrictions. We also consider that the proposed restrictions preempt the revision of the Tobacco Products Directive, violate the principle of non-discrimination and the freedom of trade and industry (Article 36 TFEU) and that they without due justification contradict legislation recently introduced in other EU Member States.

# NNPA’s opinion on the Luxembourg de facto ban on nicotine pouches

The Luxembourgish government is updating its law on tobacco control and has notified the European Commission of the proposed changes. While the bill addresses a broader range of tobacco and nicotine products, the proposed rules for nicotine pouches provide a worrying development. In article 7.4 the proposal takes an unexpected turn and bans the marketing and sales of nicotine pouches containing more than 0.048mg of nicotine per pouch. Given that 0.048 mg per pouch is a fraction of the typical range (approximately 200-400 times lower than the legal requirements of other Member States), it would be insufficient to raise blood nicotine levels to a noticeable or effective concentration for any user and even less so for someone accustomed to the higher doses received from smoking, rendering the product category useless as a smoking cessation aid as well as a consumer product.

For the NNPA the most obvious objection to the notified restrictions is that **there is no public health benefit to be made from an unduly low nicotine cap**. NNPA does advocate for a nicotine cap in order to limit extreme products with potentially harmful levels of nicotine, but this level must be set in context with scientific evidence and without undue thresholds that could disincentivize smokers from switching to nicotine pouches.

## Relative risk

The relative risk of nicotine pouches compared to cigarettes is unanimously recognized as significantly lower. **Nicotine pouches do not contain tobacco, they are not burned, heated or in any other way chemically altered when used**. The nicotine is absorbed by exposing a few square centimeters of the oral mucosa to nicotine. Absorption through the oral mucosa bypasses the lungs and directly enters the bloodstream, but it takes longer to reach peak levels due to the slower release as opposed to cigarettes that expose the alveoli that are directly connected to the capillaries and normally have an area of 70 to 100 square meters. The effective exposure of the lungs varies but the exposed area would be between 100 000 and 300 000 times larger. **This difference in exposed area is critical not only for understanding the relative safety of nicotine pouches but also for determining a reasonable nicotine cap, as the slower, limited absorption through the oral mucosa requires different standards than those set for inhaled products**

The main three risks connected to smoking cigarettes are **cancer, pulmonary disease and cardiovascular risk**. These are well-established facts within the scientific and medical communities including the European Commission’s Knowledge for Policy resource and the World Health Organization (WHO) who both identify these as the primary consequences of smoking cigarettes.

Since nicotine pouches do not **contain carcinogenic substances** and are not chemically altered when used, the risk in the context of cancer would be **negligible**.

Since nicotine pouches do not emit any byproducts of combustion and the **lungs are not exposed** the risk for pulmonary disease would also be **negligible.**

While both products contain nicotine that can contribute to elevated blood pressure, increased heart rate and vascular constriction, **the main risk of cardiovascular disease of smoking cigarettes does not derive from the nicotine content** but rather from byproducts of combustion i.e. carbon monoxide and oxidizing chemicals that significantly increases the risk of atherosclerosis, blood clot formation and chronic inflammation. **While nicotine pouches may carry a minimal cardiovascular risk relative to non-use, they are far safer for the cardiovascular system than smoking.**

While not risk free, **the placing of nicotine pouches on the internal market does not contribute to any significant risk to public health[[1]](#footnote-2)**[[2]](#footnote-3)[[3]](#footnote-4) On the contrary, statistics from countries that have available and affordable nicotine pouches indicate that their presence on the market provides a viable and attractive alternative for adult smokers and that the benefits on a societal level are massive. According to EU statistics, Sweden has around the same percentage of nicotine users as the average in the union, but all indicators of tobacco-related harm including lung cancer, Chronic Obstructive Pulmonary Disease (COPDand general mortality rates related to tobacco use are significantly lower than in all other Member States (typically 40-50 percent lower)

It also appears irrational for Luxembourg to apply a maximum nicotine limit that originates from the area of food regulation. The EFSA report referenced by the authorities was intended to address the question of the maximum ingestible nicotine threshold in food (i.e. 0.0008 mg/kg of body mass, or 0.048 mg per day for a person weighing 60 kg). However, nicotine pouches are not ingested and should thus not be regulated accordingly. This was further confirmed by the European Commission in its [Communication](https://europa.eu/webtools/rest/html2m/output/html2m-1730140593-ohrlt.pdf) to TRIS notification [2023/0019/CZ](https://technical-regulation-information-system.ec.europa.eu/en/notification/16379) in relation to a draft law regulating nicotine pouches. The Commission asked the Czech authorities to ensure that "the provisions of the notified draft do not equate nicotine pouches with 'food' as defined in Regulation (EC) No 178/2002"; and to not imply that "procedures applicable to food would apply to nicotine pouches."

## Other concerns and objections

We find the proposed restrictions to be completely unjustified and in violation of the principle of free movement of goods. Nicotine pouches are consumed daily by around 1.4 million citizens across 25 EU Member States. **The overwhelming majority of these consumers have switched away from smoking traditional tobacco cigarettes** as pouches offer an alternative and less risky way of consuming nicotine. It’s to be noted that Czech Republic, Denmark, Slovakia, Hungary, Romania, and Sweden have introduced bespoke regulation for nicotine pouches, allowing a higher nicotine level and responsible use of flavors. Finland, Italy, and Lithuania are in the process of doing so. The proposed Law in Luxembourg is far more restrictive and discards the success of appropriate regulation in Sweden which has led to the lowest smoking rate in the EU (5.8%) and the lowest levels of smoking-related disease and death[[4]](#footnote-5), in large part due to the use of nicotine pouches.

Production is largely concentrated in Hungary, Sweden, Denmark, and Italy, but nicotine pouches are manufactured in several countries and widely exported across the EU and beyond. The industry contributed just over €1 billion to the EU economy in 2021, with an extensive network of around 76,000 retail stores, many of which are SMEs, alongside 137 websites offering these products across Europe.[[5]](#footnote-6)Hungary, Czechia, Denmark, Slovakia, Sweden, Estonia and Italy have introduced category specific regulations and / or apply excise tax to the products. As such, and in view of the above, the proposed restrictions breach EU law on the free movement of goods, as they will restrict the sale and use of nicotine pouches that can be lawfully sold in other Member States. It should also be noted that the market for nicotine pouches is highly dynamic and holds considerable growth potential, **largely driven by increasing consumer demand for harm-reduction products**. The proposed restrictions would not only dampen investments and limit the free movement of goods within the Single Market, but could also close off significant export markets, stifling a sector with undeniable economic and public health potential.

We consider the legislative approaches taken in Belgium and the Netherlands to be similarly misguided. As such, the bans in Belgium and the Netherlands do not serve as sound precedents but rather highlight the risks of adopting overly restrictive measures without a comprehensive assessment. By relying on an interpretation that contradicts both the broader body of scientific evidence and the more balanced approaches taken by other EU Member States, these laws fail to align with the EU’s objectives of proportional, evidence-based policy, internal market rules as well as EU targets for a smoke free Europe

Conclusions

As such, with the above as the basis for our motivation, we conclude that the justification criteria cannot be met for the proposed restrictions and that the draft Law will restrict the free movement of goods (Article 34 TFEU)

* *There are no public health risks that could justify restrictions on the free movement of nicotine pouches. On the contrary, such restrictions are likely to have the opposite effect by reducing access to reduced risk alternatives beneficial to smokers as recognized by Bfr, COT and RIVM (footnote 1, 2 and 3)*
* *The ban is not proportionate since there is no scientific evidence or even statistical indications that suggests that nicotine users would be exposed to higher risk by placing nicotine pouches on the market. The Member States that clearly excel at reducing tobacco harm have products with approximately 400 times higher nicotine concentration available on the market showing that Luxembourg could achieve even more ambitious health objectives without this completely unwarranted and disproportionate interpretation of the precautionary principle.*
* *It is also obvious to us that there are significantly less invasive measures that can be used to tackle real and present issues related to the consumption of tobacco and/or nicotine, instead of direct or indirect bans. (The NNPA proposes a number of ways to regulate in a way that will optimize the benefit for public health. This includes a nicotine cap at a more purposeful level but also a reasonable way of pinpointing the possible problem areas for underage access and how to restrict unsuitable designs, marketing and flavor descriptors.)*

We consider that the proposed restrictions preempt the revision of the Tobacco Products Directive, violate the principle of non-discrimination and the freedom of trade and industry (Article 36 TFEU), and that they without due justification contradict legislation recently introduced in other EU Member States.

In conclusion, we strongly oppose the proposed restrictions.

För NNPA, Robert Casinge

Senior partner, regulatory affairs

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1. <https://www.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf> [↑](#footnote-ref-2)
2. <https://cot.food.gov.uk/sites/default/files/2023-04/Publishable%20%20COT%20Oral%20nicotine%20pouches%20-%20final%20v1-0%20Acc%20V.pdf> [↑](#footnote-ref-3)
3. <https://www.rivm.nl/publicaties/nicotineproducten-zonder-tabak-voor-recreatief-gebruik> [↑](#footnote-ref-4)
4. Global Burden of Disease, survey: [VizHub - GBD Compare](https://vizhub.healthdata.org/gbd-compare/) [↑](#footnote-ref-5)
5. TobaccoIntelligence.com [↑](#footnote-ref-6)