

Reply from GINN (Global Institute for Novel Nicotine) Regarding the Draft Royal Decree amending Royal Decree 579/2017

CONTRIBUTION TO TRIS NOTIFICATION

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ABOUT GINN

The Global Institute for Novel Nicotine (GINN) represents independent European manufacturers of nicotine pouches, distinct from the tobacco industry. GINN is registered in the European Union Transparency Register (ID: 207263897934-45) and advocates for evidence-based regulation that promotes public health, respects internal market principles, and supports the competitiveness of European businesses offering reduced-risk nicotine products.

SUMMARY OF OUR POSITION:

GINN expresses serious concerns regarding the Spanish Ministry of Health's proposed nicotine limit of 0.99 mg per pouch. This limit would amount to a de facto ban on nicotine pouches, undermining public health objectives, fragmenting the EU internal market, and severely impacting the competitiveness of independent European producers. It would be the first de facto ban across the EU and probably across the world.

We assert that:

- The proposed limit is disproportionate and lacks a scientific foundation.
- It infringes upon the free movement of goods within the European Union (Articles 34-36 TFEU).
- It contradicts existing regulations in several Member States where higher nicotine levels are permitted thus attacking the harmonisation goal of the Tobacco Products Directive, which regulates these products across the EU.
- It undermines harm reduction strategies crucial for achieving the EU's public health targets.

GINN'S PERSPECTIVE ON THE PROPOSED NICOTINE CONTENT LIMIT

The proposed nicotine limit would neutralize the effectiveness of nicotine pouches as a smoking cessation and harm reduction tool. Existing scientific evaluations, including the German Federal Institute for Risk Assessment (BfR), recommend a maximum nicotine content of up to 20 mg per pouch. This level supports adult smokers in switching to less harmful alternatives without posing undue health risks.

Setting a limit at 0.99 mg per pouch would make nicotine pouches ineffective for smokers, removing an essential harm reduction tool and pushing users towards riskier nicotine consumption methods. Additionally, no substantive scientific evidence has been presented to justify such a restrictive threshold.

Several EU Member States (e.g., Czech Republic, Slovakia, Hungary, Romania) have introduced nicotine limits significantly higher than the one proposed by Spain, typically allowing up to 16 mg per pouch. Spain's proposal would, therefore, isolate its market, creating a barrier to trade and undermining EU internal market principles.

IMPACT ON INTERNAL MARKET AND EU PRINCIPLES

The proposed measure is likely to:

- Create unjustified obstacles to the free movement of goods.
- Fragment the internal market.
- Disrupt harmonization efforts currently underway at EU level.

By imposing an excessively low nicotine threshold, Spain risks undermining the functioning of the internal market and violating the proportionality principle embedded within the TFEU. The proposal also risks setting a precedent for arbitrary national barriers to trade.

PUBLIC HEALTH CONSIDERATIONS:

Nicotine pouches offer adult smokers a substantially less harmful alternative compared to combustible tobacco products. Sweden, where reduced-risk products are widely available, boasts the lowest smoking rates and tobacco-related mortality rates in the EU. Public health policies should encourage smokers to transition to reduced-risk alternatives. A de facto ban on nicotine pouches contradicts these goals and may inadvertently sustain higher levels of tobacco-related morbidity and mortality. While nicotine is not risk-free, the health risks associated with nicotine pouches are significantly lower than those linked to smoking. Encouraging the availability of appropriately regulated nicotine pouches can support smokers in quitting combustible tobacco, ultimately saving lives and reducing healthcare costs.

POSITION ON THE RESTRICTION OF FREE MOVEMENT OF GOODS:

GINN firmly opposes the de facto prohibition of nicotine pouches through an excessively low nicotine limit. Such a prohibition constitutes a restriction on the free movement of goods, contrary to Article 34 of the Treaty on the Functioning of the European Union (TFEU). Article 34 prohibits quantitative restrictions on imports and all measures having equivalent effect between Member States.

Nicotine pouches are lawfully placed on the market across the European Union. Member States such as the Czech Republic, Slovakia, Hungary, Romania, Finland, and others, have adopted regulatory frameworks that permit the sale of nicotine pouches with considerably higher nicotine content than the limit proposed in Spain. No outright prohibition exists elsewhere in the EU.

The Spanish proposal, by effectively banning the product category, would fragment the internal market, undermine legal certainty for manufacturers and consumers, and create unjustified barriers to trade. Such a measure would not be justified under Article 36 TFEU, which allows for restrictions only when duly substantiated on grounds of public health. In this case, the lack of robust scientific evidence provided by Spain and the experience of other Member States shows that appropriate regulation—not prohibition—is the most effective approach for regulating these products.

We therefore urge the Spanish government: To reconsider the proposed measure in light of its obligations under EU law and the broader objectives of maintaining a functioning internal market. To consider seriously an increase in the mg content of nicotine pouches on the basis of the scientific opinions that have been delivered. And finally to aim for harmonising rules with the other Member States of the EU.

We also urge the European Commission: Not to allow de facto bans across the EU and to ensure the protection of the EU single market. To call upon the Spanish Ministry of Health to review the threshold proposed and to propose a higher threshold in line with other EU Member States. To call upon the Spanish Ministry of Health to propose a much more comprehensive and complete impact assessment that can justify such proposal.

CONCLUSIONS:

Based on the evidence presented, GINN:

- Opposes the proposed 0.99 mg nicotine limit.
- Calls for a nicotine limit aligned with scientific recommendations and existing practices in other Member States (up to 16–20 mg per pouch).
- Urges Spain to reconsider the measure to avoid unjustified market fragmentation and negative public health outcomes.
- Advocates for science-based regulation that preserves the internal market and promotes harm reduction.

We respectfully encourage the Spanish authorities to conduct a thorough impact assessment and align national regulation with broader EU public health and internal market objectives. GINN remains fully committed to working with policymakers to establish a responsible regulatory framework that protects consumers, supports public health, and ensures fair market conditions for European manufacturers.