Comments on 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.

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EXECUTIVE SUMMARY

This report endorses Spain's Draft Royal Decree amending RD 579/2017, focusing primarily on two key areas: the regulation of nicotine pouches and the ban on flavors in e-cigarettes.

Documented Harms

The report summarizes significant documented harms associated with these products.

Nicotine: Regardless of the delivery system, nicotine poses well-documented health risks. These include increased heart rate and blood pressure which can contribute to atherosclerosis , and neurotoxic harm to the developing adolescent brain, which can disrupt circuits controlling attention, learning, and mood. Nicotine is also a known reproductive toxicant, harmful to a developing fetus. While not classified as a carcinogen by the IARC , some research suggests it may act as a tumor promoter. Independent studies have also found that some "tobacco-free" pouches contain potent carcinogens like tobacco-specific nitrosamines (TSNAs), formaldehyde, and chromium.

Flavors in E-cigarettes: The heating of flavoring chemicals can create new toxic compounds, including known carcinogens like formaldehyde. Specific flavor chemicals like diacetyl are linked to severe, irreversible lung disease ("popcorn lung") , while others like cinnamaldehyde and menthol can trigger cell damage. For adolescents, flavored e-cigarette use is linked to an increased likelihood of respiratory symptoms , and the presence of flavors is proven to increase the product's attractiveness and intention to use among youth by lowering the perception of harm.

Need for Additional Evidence

The authors acknowledge that a fully sound foundation for regulation is challenged by gaps in evidence. Specifically, there is insufficient long-term epidemiological data on the specific health risks of nicotine pouches, as they are relatively new to the market. Likewise, the long-term toxicological effects of inhaling flavor chemicals—many of which are approved for ingestion but not inhalation—are largely unknown. Furthermore, reviews of existing studies conclude that evidence on how e-cigarette flavors affect adult smoking cessation is inconsistent and inconclusive.

Rationale for Proposed Measures

While this long-term evidence is developed, the authors argue that the proposed measures are both necessary and proportionate to curb the growing popularity of these products, particularly among youth, and to prevent a new wave of nicotine addiction.

The report contends that in the absence of a harmonized, product-specific regulatory framework at the EU level for these products, Member States retain the discretion to legislate nationally to protect public health. The justification for Spain's proposed measures is based on the following rationale:

1. Objective Justification: The measures have plausible mechanisms of action to achieve their public health goals. Capping nicotine content in pouches directly targets the dose and speed of delivery, which are linked to addictive potential. Banning non-tobacco e-cigarette flavors aims to

reduce youth initiation by removing the "beginner-friendly" characteristic that masks nicotine's harshness and lowers harm perception.

2. Benchmarking: The proposed regulations are comparable to or less stringent than measures in other EU Member States. For nicotine pouches, countries like Belgium and the Netherlands have implemented outright bans, while others have set nicotine caps. For e-cigarette flavors, the Netherlands and Denmark have implemented near-total bans.

3. Expert Opinion and Scientific Consensus: The measures align with the advice of a majority of the health community. The World Health Organization (WHO) and the Forum of International Respiratory Societies (FIRS) have urged caution and regulation for new nicotine products to prevent youth uptake. A strong consensus exists among US and Canadian medical organizations for total bans on flavored e-cigarettes , a position shared by European bodies like the European Society of Cardiology.

4. Absence of Less Restrictive Alternatives: The report argues that proposed alternative measures are not equally effective. Public education campaigns struggle against aggressive marketing, and age verification is often circumvented. There is no scientific evidence establishing that any standalone measure is as effective as a flavor ban in reducing youth vaping.

5. Application of the Precautionary Principle: Given the known risks of nicotine addiction versus the unknown long-term health risks of the products, the report asserts that preventive action is ethically required. Waiting for conclusive proof could lead to irreversible harm. The application of this principle entails not just enacting protective measures, but also Commissioning independent, publicly-funded research to resolve evidence gaps; implementing robust post-market surveillance to assess the impact of the approved measures and scheduling a mandatory legislative review so that policy can evolve with the evidence.

6. Finally the authors conclude that the proposed measures are justified as both necessary and proportionate.

- Necessity: The intervention is necessary due to the demonstrable public health threat posed by the increased use of these products, especially among adolescents and young people in Europe.
- Proportionality: The measures are proportionate because they do not constitute a total ban but instead strike a rational balance. They mitigate the unacceptable risk of fueling a new epidemic of youth addiction while respecting adult choice and allowing less toxic alternatives to cigarettes to remain on the market.

The organizations signing below support the Draft Royal Decree amending Royal Decree 579/2017 of 9 June 2017 and would like to contribute with the following comments.

PART A.- ON NICOTINE POUCHES

Introduction

The Ministry of Health of Spain proposes in RD579 /2017 to adopt the following rules with regard to nicotine pouches:

- Quality and Safety Requirements:
  - Capping the maximum amount of nicotine per pouch at 0.99 mg.
  - Outlaw the use of additives that facilitate nicotine absorption.
  - Ban the use of stimulants associated with energy or relaxation, including caffeine, taurine, and CBD.
  - Allow only tobacco aromas or flavors.
  - Require the outside packaging of the product to be child- and tamper-proof.
- Reporting and Market Placement:
  - Require Manufacturers or importers to report information to the Directorate-General for Public Health and Health Equity through the EU-CEG Portal six months before placing the products on the market. Required information includes manufacturer/importer details, product composition, nicotine content per unit, and a list of all ingredients.
  - Submit in advance the design of the labeling and packaging for verification before placing the product on the market.
- Labeling and Packaging:
  - Require packaging to include a list of all ingredients, nicotine content, delivery per dose, a batch number, and a recommendation to keep the product away from children.
  - Require the health warning: "This product contains nicotine, which is a highly addictive substance. It is not recommended for use by non-smokers". Unit packets must also include a leaflet in Spanish with information on instructions for use, contraindications, warnings, possible adverse effects, and manufacturer/importer contact details.
  - Pack the product without elements or designs that are likely to attract the interest of minors.

Several EU member states and stakeholders have raised some objections to the Spanish regulation. In this contribution, the signatory organizations would like to discuss and support Spain's proposal.

To provide context for our comments, we would like to raise two caveats.

First, the regulation of nicotine pouches is not currently subject to a harmonized, product-specific framework at the European Union level. These products fall outside the material scope of the EU's Tobacco Products Directive (2014/40/EU). In the absence of such lex specialis, Member States retain greater competence to legislate nationally.

While the legal test—balancing the free movement of goods against public health protection—is always present, the absence of EU-level harmonization fundamentally alters the context of that test, affording Member States a greater margin of discretion. We contend that in a non-harmonized area like that of nicotine pouches, if the EU has not exercised the primary responsibility for determining the appropriate level of health protection, such responsibility therefore falls to the Member States. The Court of Justice of the European Union has consistently recognized that, in such circumstances, Member States retain the power to decide on the level of protection they wish to afford public health, particularly where scientific uncertainty exists about the risks of a new product. While the resulting national measure must still be proportionate and non-discriminatory, the Member State has more freedom to define the public health objective it is pursuing, giving greater weight to health considerations in its initial balancing of interests.

Second, tobacco and nicotine products are not regular goods. While we respect the principle of adult autonomy, we must challenge the fiction that choosing a highly addictive product is a wholly free act. Nicotine addiction, by its very nature, systematically compromises long-term autonomy for short-term reward. When the tobacco industry demands the 'freedom' to sell pouches with high nicotine concentrations, they are not defending consumer choice; they are defending their business model, which depends on addicting consumers as quickly and durably as possible. For this reason alone, any proportionate public health measure must rightly balance the freedom from addiction and the freedom to make personal choices, even those with associated risks. It's about finding the right balance between preventing nicotine addiction and related health consequences, and respecting individual autonomy and the potential for harm reduction strategies."

What are nicotine pouches?

One key recreational product is the so-called nicotine pouch. The concentration of nicotine in oral pouches available on the world market spans a vast spectrum. Consumers can find products with as little as 1.5 mg of nicotine per pouch, while some brands offer potencies that reach exceptionally high levels (Fig. 1), up to 150 mg per pouch. Its growing popularity, especially among young people and non-smokers, raises significant public health concerns due to nicotine's addictive potential and its adverse health effects.

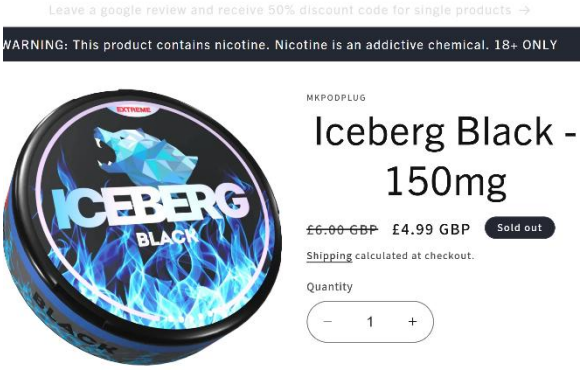

Figure 1. Nicotine pouches with 150 mg of nicotine per pouch sold by internet

Documented Potential Harm from Nicotine Pouches

A review of the potential harms associated with nicotine pouches reveals concerns across several categories, from the systemic effects of nicotine to the risks posed by additives and the inherent potential for addiction.

Systemic Harm and Toxicity from Nicotine Itself

Nicotine is the primary active ingredient and poses significant, well-documented health risks irrespective of its delivery system.

Systemic and Cardiovascular Effects (Short- and Long-Term): It can increase heart rate and blood pressure, contributing to the hardening of arterial walls —a condition known as atherosclerosis, which can lead to heart attacks. The 2010 U.S. Surgeon General's report detailed the biological basis for diseases linked to nicotine's cardiovascular impact.[1] For individuals with pre-existing cardiovascular disease, this can be particularly dangerous. While a direct causal link between nicotine alone and long-term cardiovascular disease is debated, its role in exacerbating existing conditions is clearer. The German Federal Institute for Risk Assessment (BfR) highlights that nicotine has substantial effects on the cardiovascular system, posing high risks for users with cardiovascular conditions.[2]

Neurotoxicity and Developmental Harm: The human brain continues to develop until about age 25. Nicotine exposure during this critical period, as highlighted by the CDC, can disrupt the development of brain circuits that control attention, learning, and mood, and increase susceptibility to future addiction to other substances.[3]

Reproductive Harm: Nicotine is a well-known reproductive toxicant. It is harmful to a developing fetus and poses health dangers for pregnant individuals. Furthermore, nicotine exposure during pregnancy poses significant risks, including preterm delivery, low birth weight, stillbirths, and adverse effects on the brain and lung development of the fetus.[4]

Carcinogenicity of Nicotine: While the combustion of tobacco is the primary source of carcinogens in smoking, the role of nicotine itself is under scrutiny. The International Agency for Research on Cancer (IARC) does not currently classify nicotine as a carcinogen. However, some research suggests it may act as a tumor promoter, potentially contributing to cancer development through various cellular mechanisms, though this is not definitively established.[5]

Despite a significant body of evidence concerning the components of these pouches, their pharmacokinetic profile, and their observed short-term effects, a primary and crucial caveat underscored by virtually all health organizations, including the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC), is that long-term epidemiological data on nicotine pouches is insufficient. As these products are relatively new to the market, definitive conclusions about their long-term disease risks (e.g., cancer, chronic obstructive pulmonary disease) will take many more years to establish. However, the absence of proof of long-term effects is not proof of the lack of such effects.

Localized Toxicity and Oral Harm

The use of nicotine pouches has been associated with mild oral irritation and transient lesions, even at lower doses of 2–4 mg.[6] In laboratory studies, extracts from nicotine pouches with concentrations as low as 0.03 mg/mL have been shown to induce cytotoxicity in human gingival fibroblasts, accompanied by modest increases in inflammatory markers.[7]

In vitro studies and narrative reviews describe increased inflammatory markers (such as interleukin-6, reactive oxygen species, and tumor necrosis factor alpha) and cellular effects that may suggest potential periodontal tissue disruption.[8] One study noted no significant changes in gingival retraction over six weeks, while other reports raise the possibility of gingival recession and alveolar bone loss based on indirect laboratory findings. Variations in product composition—such as differences in nicotine sources, flavorings, and the presence of toxic contaminants like chromium and tobacco-specific nitrosamines—appear to influence these outcomes.[8]

Beyond Nicotine: Harm and Toxicity from Additives and Ingredients

Besides nicotine (either tobacco-derived or synthetic), pouches contain food-grade fillers (e.g., microcrystalline cellulose), humectants (e.g., propylene glycol), pH adjusters (to increase nicotine absorption), and a wide array of additives.

Carcinogens and Toxicants: Independent studies have found that some nicotine pouches contain harmful and potentially harmful constituents, including low levels of tobacco-specific nitrosamines (TSNAs) like NNN and NNK, which are potent carcinogens. Their presence indicates that "tobacco-free" does not mean free of tobacco-related carcinogens. A 2022 study also detected formaldehyde, chromium, and nickel in some products.[9]

Additives that may introduce health risks include:

- Cooling Agents: Synthetic cooling agents, such as WS-3, are used to create an intense cooling sensation with reduced irritation, which may increase the product's appeal and help circumvent flavor restrictions.[10]
- Sweeteners: To mask the bitterness of nicotine, sweeteners such as sucralose, acesulfame-K, aspartame, and xylitol are added. The quantities found in some products raise concerns about potentially exceeding recommended daily intake levels.[11]
- Flavor Modifiers: Flavors ranging from mint and menthol to fruit are used to shape the sensory experience. Some of these have been found to contribute to cytotoxicity and inflammatory responses.[12]
- Nicotine Forms: Nicotine is delivered in various forms, including nicotine salts and synthetic analogs like 6-methyl nicotine, all of which influence the rate of nicotine uptake and potential cardiovascular effects.[13]

Addictiveness and Potential for Dependency

The addictive potential of nicotine pouches is unequivocally high, making them a significant public health concern. This is because nicotine dependency, however it's acquired, keeps individuals vulnerable. It creates fertile ground for dual use with combustible tobacco products, opens the door for new users to become dependent, and always presents a risk of relapse into, or initiation of, combustible tobacco use.

This potential depends on the pharmacokinetics of nicotine in each product, that is, by how quickly and how much nicotine it delivers to the brain. While the initial nicotine "hit" from pouches is slower than from an inhaled cigarette, the absorption through the oral mucosa is efficient, and it can be improved by design. Elements of this design to deliver quicker hits are:

The nicotine dose in pouches. Studies have demonstrated that some high-dose nicotine pouches can lead to maximum plasma nicotine concentrations (Cmax) and overall nicotine exposure (AUC) that are comparable to, or even exceed, that of smoking a cigarette.[14] Research has also demonstrated that 10 mg nicotine pouches could result in greater nicotine absorption (Cmax and AUC) than smoking a standard cigarette.[15] This directly challenges the notion that they are inherently "less addictive."

The use of pH adjusters facilitates the absorption of "free-base" nicotine, enhancing the addictive effect. An increase in the pH of a product leads to a higher concentration of nicotine in its "freebase" form. This form of nicotine is more easily absorbed by cells. This principle of manipulating pH has been a part of cigarette engineering for many years to manage sensory satisfaction. Transbuccal (oral mucosa) permeability can also be enhanced by design with substances, such as menthol and other terpenes, which is a well-studied mechanism in pharmaceutical drug delivery.

In Summary, while nicotine pouches may contain fewer toxicants than combustible cigarettes, they are not harmless, and the notion of being less dangerous than an "atomic bomb"(cigarettes) offers no real comfort. True harm reduction is a population-level concept, not an individual guarantee, meaning any given user could still face significant, unpredictable suffering regardless of overall statistical trends. The net impact of these products poses a grave threat to public health, driven by alarming youth uptake, the prevalence of dual-use with other tobacco products, and clear industry marketing towards non-smokers. Ultimately, we must learn from the past and refuse to allow a new wave of addiction to compromise the health of our communities.

The quest for additional evidence

Despite the documented potential for harm and addiction, we openly acknowledge that the long-term epidemiological evidence on the specific health risks of nicotine pouches is not yet sufficient. These products are relatively new to the market, and the longitudinal studies required to fully understand their impact on cardiovascular health, oral diseases, cancer risk, and metabolic

disorders will take many years to complete. Also, the exact safe dose of nicotine concentration per pouch is yet to be determined. For now, the lowest documented nicotine doses causing physiological changes are 3-4 mg in human adults of average weight (cardiovascular effects)[16] and 0.2 mg/kg in rats (plasma level changes).[17]

However, this absence of long-term proof is not proof of their safety. The presence of nicotine, a well-documented, addictive substance with known acute cardiovascular effects, and other chemical components gives significant cause for concern. To conflate a lack of complete evidence with a confirmation of safety would be a grave and irresponsible error.

Rationale

Due to limited evidence, our rationale is as follows:

1. Objective justification for the public health measures proposed, with plausible mechanisms of action

The primary goal of these measures is to reduce the addictive potential of nicotine pouches, thereby preventing the initiation of nicotine addiction among non-smokers (especially youth) and avoiding the creation of a stronger, more intractable dependency among existing smokers.

Causal Mechanism: The addictive potential of nicotine is directly linked to the dose, speed of delivery, and concentration. High-concentration products deliver a rapid, potent nicotine spike to the brain, which powerfully reinforces the neural pathways of addiction. By capping the nicotine content at 0.99 mg and removing additives that facilitate nicotine absorption and flavorants to increase appeal to adolescents, the measure directly targets this mechanism. The measure aims to make the product less satisfying for new users, slowing or preventing the development of dependency. For existing smokers, it encourages a switch to a less addictive product rather than a transition to a different but equally potent form of nicotine delivery.

The potential capping at 0.99 mg of nicotine per pouch is based on the fact that physiological changes in human adults of average weight (80 kilos) occur at a dose of 3-4 mg per pouch, which is equivalent to 1 mg per pouch for children of approximately 20 kilos in weight.

2. Benchmarking

The proposed regulation in Spain is comparable to, and in some cases even less stringent than, that in some EU Member States. The lack of a harmonized approach to regulating pouches has led to a fragmented regulatory landscape across Europe. It is our understanding that EU Member States' regulatory approaches vary widely:

1. Outright Bans:

Some countries have opted for a complete ban on nicotine pouch sales. Examples include Belgium (banned in 2023), Netherlands (banned since January 1, 2025), and France (notified the European Commission of its intention to ban in February 2025, with a ban expected to be implemented by health ministry decree). Germany also has complex regulations, with some sources suggesting in-person sales are banned, or banned in certain federal states, while online sales from outside the country may remain legal.

2. Nicotine Content Limits:

Several Member States have introduced or are planning to introduce specific limits on nicotine concentration per pouch. These limits vary considerably and are a point of contention:

Denmark is set to implement a limit of 9 mg per pouch starting July 2025, with full enforcement by April 2026. The Czech Republic restricts the nicotine content to 10 mg per pouch. Hungary limits the maximum nicotine concentration to 17 milligrams for all "nicotine-containing smoking substitutes." Romania and Slovakia have adopted cap concentrations of 20 mg/pouch. Finally, Finland is considering capping nicotine levels to 20 mg/pouch (or 20 mg/g).

3. Other Restrictions:

Beyond nicotine caps, Member States are also implementing other measures such as flavor bans. Most countries prohibit sales to minors. Several countries have implemented or are considering restrictions on advertising and promotion, as well as the addition of mandatory health warnings and ingredient lists on packaging. Finally, nicotine pouches are classified differently across countries – some as food products (e.g., Germany), medical items, or tobacco products, which impacts the regulatory framework applied.

In summary, while there is no overarching EU law on nicotine pouch concentration caps, the trend among many Member States is towards increased regulation, often including limits on nicotine content, flavor bans, and marketing restrictions, reflecting a growing concern about public health, particularly youth uptake.

3. Expert Opinion and Scientific Consensus

A third element to consider is whether Spanish legislation deviates from the advice of leading public health bodies.

These, while acknowledging the need for more long-term data, have expressed significant concern about new nicotine products. The World Health Organization (WHO) has repeatedly urged caution, recommending that these products be regulated to curb their appeal and addictiveness, particularly to prevent uptake by young people (https://shorturl.at/b1HaV).[18] The Forum of International Respiratory Societies (FIRS) has warned that new nicotine products are creating a new wave of addiction and that their marketing as "harm reduction" is a tactic borrowed directly from

the old tobacco industry playbook. This expert consensus reinforces the need for proactive regulation rather than a "wait and see" approach.

A range of professional societies and health advocacy organizations have articulated positions on the regulation of nicotine pouches, generally emphasizing the need for public health protection, particularly for youth.

A. Campaign for Tobacco-Free Kids (CTFK)

- Overall Stance: TCTFK advocates for either the strict regulation or outright prohibition of the manufacturing, import, export, and sale of nicotine pouches with the primary goal of preventing the emergence of a new generation of nicotine users.
- Marketing: CTFK highlights the aggressive marketing campaigns launched by tobacco companies for nicotine pouches. These campaigns often include promoting the products for use in smoke-free environments, which can encourage dual-use rather than complete cessation of smoked products. They also point to lifestyle-oriented promotions via social media, involving influencers, music stars, and sporting events, as critical elements of industry marketing aimed at young audiences.
- Flavors: Nicotine pouches are available in numerous flavors, including those described as "candy-like" (e.g., 'Mango Tango,' 'Berry Frost'), which CTFK views as a deliberate tactic by tobacco companies to attract youth and young adults, mirroring strategies previously used for e-cigarettes. While not always explicitly calling for a total ban, CTFK favorably mentions Canada's ministerial order restricting flavors in nicotine pouches to only mint and menthol as a desirable regulatory action.
- Age Limits: Their position strongly implies robust support for prohibiting sales to minors, and they note that some countries have already implemented such measures.
- Taxation: CTFK implicitly supports taxation as an effective regulatory lever for nicotine pouches as well.
- Nicotine Content Caps: CTFK cites the WHO Study Group on Tobacco Product Regulation's finding that these products "contain sufficient nicotine to sustain addiction". Consequently, CTFK supports the regulation of nicotine content in pouches as a measure consistent with WHO FCTC obligations to prevent and reduce nicotine addiction.

B. American Cancer Society (ACS) & ACS Cancer Action Network (ACS CAN)

- Overall Stance: Their fundamental position is that all tobacco products, including novel ones like heated tobacco products (and by extension, nicotine pouches), are unsafe. ACS/ACS CAN does not endorse smokeless tobacco products, including pouches such as Zyn, as safe alternatives to smoking or as effective cessation aids.
- Marketing: ACS CAN actively collaborates with the FDA and other regulatory bodies to ensure the robust regulation of tobacco product marketing, with a particular focus on combating deceptive marketing practices, especially those that target children and young people.

- Flavors: ACS/ACS CAN strongly opposes the use of flavors in tobacco products, viewing them as a key marketing "weapon" that tobacco manufacturers use to target youth and attract them to a lifetime of nicotine addiction
- Age Limits: The consistent emphasis on protecting children and adolescents from tobacco initiation and addiction implies strong support for strict age restrictions on the sale and marketing of all nicotine products, including pouches.
- Taxation: ACS CAN proposes significantly increasing excise taxes on ALL tobacco products. They advocate for tax parity, meaning that when taxes are increased on any single tobacco product, they should be increased at an equivalent rate on all other tobacco products.
- Nicotine Content Caps: While the provided information does not detail an explicit ACS/ACS CAN position on specific nicotine content caps for nicotine pouches, their overarching goals of reducing tobacco-related harm and nicotine addiction would logically align with measures designed to reduce the addictiveness of these products.

C. American Lung Association (ALA)

- Overall Stance: The American Lung Association (ALA) maintains that no tobacco product is safe for consumption.
- Marketing: The ALA notes that while marketing messages for some nicotine pouches claim they are "intended for individuals aged 21+ to help them quit using traditional tobacco products," these products are not FDA-approved smoking cessation medications.
- Flavors: The ALA points to data indicating that among U.S. middle and high school students who currently use nicotine pouches, a very high percentage (85.6% in 2024) reported using flavored products. This highlights the role of flavors in attracting young people.
- Age Limits: The ALA supports laws enacted by certain states and communities that prohibit the sale of some or all flavored tobacco products, which can include flavored nicotine pouches.
- Nicotine Content: The ALA emphasizes that nicotine concentrations can vary significantly across different oral nicotine pouch brands and that nicotine in any form is harmful to young people. They also cite a 2022 study that found cancer-causing chemicals (carcinogens) in 26 out of 44 nicotine pouch products sampled, along with other chemicals like formaldehyde and ammonia.
- Cessation: The ALA strongly encourages individuals to use only FDA-approved medications combined with counseling for tobacco cessation, promoting the message to "quit, don't switch" to other nicotine products.

D. Truth Initiative

- Overall Stance: Truth Initiative seeks to balance the potential for providing adult smokers with access to less harmful alternatives to combustible cigarettes, while rigorously ensuring that public health progress, particularly the recent declines in youth tobacco and nicotine use, is not undermined or reversed.

- Marketing: Truth Initiative asserts that both the FDA and the tobacco industry (including retailers) must be held accountable for ensuring that new nicotine products are marketed and sold legally and responsibly, exclusively to adults aged 21 and older.
- Flavors: They advocate for a permanent ban on flavored tobacco unless a manufacturer can definitively demonstrate to the FDA that: (1) a particular flavor helps current tobacco users to switch entirely to a substantially less hazardous product; (2) the flavor will not lead non-tobacco users, such as youth, to start using the product; and (3) the flavor itself does not increase the risk of harm from using the product.
- Age Limits: Truth Initiative supports the federal minimum age of 21 for the sale of all tobacco products in the U.S.
- Taxation: Truth Initiative advocates for taxing smokeless tobacco products, which would include nicotine pouches, at the highest possible level.
- Nicotine Content Caps: Truth Initiative has expressed strong support for the FDA's proposed rule to make cigarettes and certain other combusted tobacco products minimally or non-addictive by significantly limiting their nicotine levels. While this specific proposal targets combustibles, it demonstrates Truth Initiative's support for the principle of reducing nicotine content to address addiction.

E. European Respiratory Society (ERS) & Forum of International Respiratory Societies (FIRS)

- Overall Stance: Their core message is that all nicotine and tobacco products are highly addictive and harmful, and that quitting smoking and all nicotine use entirely remains the best option for health. ERS is deeply skeptical of "harm reduction" claims made for novel products, viewing such claims as being "simply exploited by the tobacco industry for financial gain" rather than being based on robust, independent evidence. They express concern that novel products may act as gateways to nicotine addiction and could lead to the initiation of smoking, particularly among youth, potentially having a greater adverse effect at the population level.
- Marketing: They advocate for comprehensive bans on all forms of advertising, promotion, and sponsorship of these products to protect public health, especially youth.
- Flavors: These societies advocate for stronger tobacco control policies, explicitly including a ban on flavors that make tobacco and nicotine products more appealing, particularly to young people.
- Age Limits: explicitly calls for a ban on the sale of disposable e-cigarettes to individuals under 18 years of age, indicating a general stance on age restrictions for novel nicotine products. ERS also noted the UK government's measures to tackle underage sales of vapes and nicotine pouches as a positive step.
- Taxation: has called for the introduction of excise taxes on heated tobacco products, e-cigarettes, and nicotine pouches, alongside increases in minimum tax rates for cigarettes and fine-cut tobacco.
- Nicotine Content Caps: The provided information does not specify ERS/FIRS recommendations for particular nicotine content cap levels for pouches.

A common thread running through nearly all these non-industry-affiliated health organizations is a profound concern for youth protection. There is a broad consensus that measures such as restrictions on marketing (especially youth-targeted campaigns), bans or significant limitations on appealing flavors, and robust age verification and sales restrictions are essential to prevent the uptake of nicotine pouches among young people.

These organizations primarily view flavors and marketing not as incidental product characteristics but as key strategic levers used by the industry to attract new, young consumers. However, beyond this consensus on youth protection, there is a spectrum of views regarding the potential role, if any, of nicotine pouches in adult smoking cessation or tobacco harm reduction. This acknowledgment, however, is always coupled with extreme caution and an insistence on stringent safeguards to prevent any reversal of progress in reducing youth nicotine use.

5. Less Restrictive to Trade: Alternative measures

One final question is whether there are reasonably effective, available alternative measures to those proposed by Spain that are less restrictive to trade. We believe that there are none. Some of the proposed alternatives are:

- Education alone is insufficient: While public education campaigns are important, they often struggle to counteract aggressive marketing and the inherent appeal of flavored, high-nicotine products, particularly for youth.
- Age verification challenges: While age restrictions are crucial, they are often circumvented (e.g., through social selling, online loopholes). Restricting product characteristics (flavors, nicotine) tackles the "supply side" and reduces the inherent appeal, making it harder for youth to get addicted even if they acquire the products.
- Targeted enforcement: While robust enforcement of existing regulations is needed, product-level restrictions provide a universal barrier.

6. Application of the Precautionary Principle

When faced with scientific uncertainty about a potential public health threat, several errors should be avoided:

- Dismissing early warnings and waiting for conclusive proof before acting, an approach that may result in "paralysis by analysis." At the same time, do not jump to thoughtless action by
- Misrepresenting the risk by deceptively framing a lack of definitive evidence as "no evidence of risk."
- Interpreting uncertainty as a license to prioritize short-term economic or political interests, particularly when the potential for irreversible harm exists.

Precaution must be the guiding doctrine in the face of scientific uncertainty. Given that the long-term health risks of nicotine pouches are unknown, but the risks of nicotine addiction are

indisputably known, preventive action is not only justified but ethically required. Allowing the market to be flooded with high-dose addictive products while we wait decades for definitive epidemiological data would be a dereliction of our public health duty.

However, the application of the Precautionary Principle goes beyond enacting protective Measures with a priority to prevent irreversible harm. At the same time, more data is gathered, especially concerning the risk of youth addiction. The principle entails:

Commissioning Independent, Publicly-Funded Research To resolve the evidence gap, conducted free from industry influence.

Implementing Robust Post-Market Surveillance to assess the impact of the measures approved, and

Scheduling a Mandatory Legislative Review, Policy should evolve with the evidence.

7. Justification of Necessity and Proportionality

In summary, *the measures proposed by Spain are based on Necessity*: the increased use of nicotine pouches, particularly among adolescents and young people, is a demonstrable public health threat in Europe, establishing the necessity of this intervention.

In Spain, there are no surveys on the use of nicotine pouches. However, it should follow the same trends as seen in other EU members. A European Parliament report states that nicotine pouches were used by 0.3% of the European adult population in 2021, but "their usage could triple by 2025." It further notes that "the use of these products is skyrocketing in Europe, with sharp increases observed in volumes sold in the last fifteen years.[19]

A survey in Great Britain found that 3.3% (95% CI, 2.7-4.0%) of adolescents had ever used nicotine pouches, and 1.2% (95% CI, 0.8-1.6%) reported current use in 2024. [20] In Ireland, 7.6% of students reported having ever used nicotine pouches in 2024.[21] A 2022 Estonian adult population health behavior survey indicated that 20% of men aged 16-24 were regular users of nicotine pouches.[22] Another study empirically demonstrates how brands are using imagery and messaging that appeal to young people and non-smokers.[23]

In Spain, a market research report provides robust empirical data on the growth of the nicotine pouch market. It estimates the market at USD 150.8 million in 2024 and projects growth to USD 774.6 million by 2034, with a compound annual growth rate (CAGR) of 18.2%. Crucially, it highlights that "The expansion of flavor varieties in nicotine pouches has been a significant driver of market growth in Spain... The availability of diverse flavors has also attracted new users who may have been hesitant to try nicotine products with a strong tobacco taste." This directly supports the idea that flavors are attracting new users, often including non-smokers, and the overall market growth indicates an increasing popularity of these products. While it doesn't break down prevalence by age or smoking status directly, the market trajectory is a strong indicator of rising usage. [24]

The *measures proposed by Spain are also proportionate*: The measures proposed by Spain are highly proportional to the nature and growing magnitude of nicotine pouch use. It does not constitute a total ban. It fosters innovation by challenging the industry to find ways to administer nicotine at low doses and without creating dependency. It respects the principle of "harm reduction" by allowing a less harmful alternative to cigarettes to remain on the market. Still, it mitigates the unacceptable risk of fueling a new epidemic of nicotine addiction. It strikes a rational balance between adult consumer choice and the urgent public health imperative to protect our youth.

Conclusion:

From a strict public health advocacy perspective (focused on preventing youth addiction), the measures are deemed both necessary (due to the appeal of flavors and nicotine, and the inadequacy of less restrictive alternatives) and proportionate (given the severe public health risks of youth addiction).

PART B. ON FLAVORS IN ELECTRONIC CIGARETTES

Documented potential harm from flavors in electronic cigarettes

A review of the potential harms associated with flavored electronic cigarettes highlights several areas of concern. These include the toxic effects of certain flavoring substances, the role of flavors in increasing the appeal of e-cigarettes, and their impact on initiation and continued use.

Health Risks for Adolescents

The use of flavored e-cigarettes among adolescents is linked to a range of health risks, from respiratory issues to cognitive problems. The heating of flavoring chemicals can create new, potentially toxic compounds, including known carcinogens such as formaldehyde.

Specific health risks include:

- Respiratory Effects: Studies report a 15–32% increased likelihood of asthma or other respiratory symptoms in adolescent users, [i]ncluding cough and shortness of breath.
- Chemical and Toxin Exposure: E-cigarette flavorings can contain chemicals with significant health risks. For example, diacetyl, a chemical used to create buttery and creamy flavors, is linked to a severe and irreversible lung disease called bronchiolitis obliterans, commonly referred to as "popcorn lung." While this disease is rare in the general population, the relative risk for occupational groups with high exposure to diacetyl has been estimated to be 3 to 11 times higher than that of non-exposed individuals.[25]
  Furthermore, research has identified other potential hazards. Studies have associated sweet-flavored e-cigarette use with higher urinary levels of toxic metals, including lead and uranium, in adolescent users.[26] Additionally, laboratory (in-vitro) studies on human cells show that flavor chemicals like cinnamaldehyde (cinnamon) and menthol (mint) can trigger cell damage and inflammatory responses in respiratory and cardiovascular cells.[27]
- Neurological and Mental Health: The use of flavored, pod-based e-cigarettes is linked to increased reports of attention and learning problems,[28] as well as anxiety and depression.[29] Nicotine, which is highly addictive, is known to harm the developing adolescent brain, impacting learning, mood, and attention.

Influence of Flavors on Attractiveness and Intention to Use in Youth

Non-tobacco flavors, particularly fruit, candy, and mint/menthol, consistently increase the attractiveness and intention to use e-cigarettes among young people . Research shows that these flavors enhance sensory appeal and lower perceptions of harm when compared to tobacco-flavored or unflavored options.

Key findings include:

- **Increased appeal and willingness to try:** Fruit and candy flavors are strongly linked to an increased willingness to try e-cigarettes . Two reviews confirm that the availability and variety of non-tobacco flavors heighten the appeal of vaping for adolescents.[30,31]
- **Perception of reduced harm**: The presence of flavors can lead young people to perceive e-cigarettes as less harmful than they are. Qualitative studies indicate that flavors distort risk perception, leading users to underestimate health risks. Specifically, fruit-flavored e-cigarettes are often perceived as less harmful than tobacco-flavored ones[32].
- **Marketing and packaging:** The appeal of non-tobacco flavors is amplified by marketing tactics, including vibrant packaging and appealing imagery, which increases the intention to use among youth.[33]

Impact on Initiation and Cessation in Youth and Young Adults

Flavored e-liquids play a significant role in both the initiation and continuation of vaping among youth and young adults (ages 18-25), while also complicating efforts to quit.

Key impacts on behavior include:

- **Initiation:** Flavors are a primary reason young people start using e-cigarettes. Over 70% of young adult users reported that their first e-cigarette had a sweet flavor, and 56% cited flavor as the main reason for starting. Two systematic reviews indicated that the availability of flavors may encourage the uptake of e-cigarettes.[7,34]
- **Sustained use and dependence:** Young adults who favor sweet and menthol flavors are linked to increased motivation to vape and higher nicotine dependence. Users who prefer non-tobacco flavors also appear to use e-cigarettes more frequently.[35]
- **Cessation and transition:** The impact of flavors on smoking cessation is inconclusive. While some young adults using non-tobacco flavors made fewer choices to smoke, they also engaged in escalated vaping. Policy evaluations have found that flavor restrictions reduced daily vaping.[36] Furthermore, there is a documented strong association between adolescent e-cigarette use and later starting to smoke combustible cigarettes.[37]

The quest for additional evidence

Despite strong evidence that flavored e-cigarettes are not innocuous, there are three critical areas of uncertainty. Firstly, the long-term toxicological effects of inhaling flavor chemicals, which are approved for ingestion but not for inhalation—are largely unknown. Secondly, the review of existing systematic reviews reveals a lack of consistent, high-quality evidence to definitively conclude how e-cigarette flavors affect overall patterns of cigarette and e-cigarette use. The available studies present conflicting results, leading to the overall assessment that the evidence is inconclusive.

Rationale

Due to limited evidence, our rationale is as follows:

Objective justification for the public health measures proposed, with plausible mechanisms of action

1. Objective justification for the public health measures proposed.

   The Spanish government's proposed measures to ban all e-cigarette flavors except tobacco are primarily justified by the objective of protecting youth. The core argument is that flavors, particularly sweet and fruity ones, make vaping products more attractive and appealing to young people, potentially acting as a gateway to nicotine addiction and traditional smoking. The rising popularity of vaping among teenagers in Spain is a key driver for this public health initiative. The measures aim to make these products less appealing to minors, thereby curbing the growth of a new generation of nicotine users.

2. Plausible mechanisms of action for reducing the appeal of e-cigarettes among youth by banning flavors include:

- **Reducing Palatability:** Non-tobacco flavors mask the harshness of nicotine, making the products easier and more pleasant for non-smokers to try. Removing candy, fruit, and mint flavors eliminates this "beginner-friendly" characteristic.
- **Decreasing Perceived Safety:** Flavored products are often perceived by adolescents as less harmful than tobacco-flavored ones. A ban on these flavors may shift the perception towards seeing the products as more hazardous.
- **Lowering Curiosity and Social Appeal:** The variety and novelty of flavors are a significant draw for young people, fostering experimentation and social sharing. Limiting options to only tobacco flavor diminishes the "fun" and social aspect of vaping.

Benchmarking

The European Union lacks a harmonized approach to regulating e-cigarette flavorants, leading to a patchwork of inconsistent national laws. This fragmentation originates from the 2014 Tobacco Products Directive (TPD), which banned characterizing flavors in traditional tobacco products but omitted any mention of e-cigarettes. This regulatory gap has allowed Member States to develop their own rules based on domestic public health and political concerns, resulting in widely divergent policies across the EU.

- The Netherlands and Denmark have implemented near-total bans on e-cigarette flavors, permitting only tobacco (and in Denmark's case, menthol) flavors. In a recent presentation of the case of the Netherlands in the World Congress on Tobacco Control (Dublin, June 23-25, 2025), presented early results of their evaluation of the flavor ban,

which showed that the Dutch flavor ban motivated EC users to quit vaping while there was no population shift to alternative tobacco and nicotine products. However, the effect of preventing uptake and non-use was not yet determined. [38]

- France has adopted a different strategy, targeting the product format most associated with youth uptake by banning disposable e-cigarettes ("puffs"), while leaving flavored e-liquids for refillable systems on the market.
- Germany adheres closely to the TPD baseline, not banning flavors outright but prohibiting a list of specific harmful or potentially misleading ingredients, representing a "middle-ground" approach.

Expert Opinion and Scientific Consensus

World Health Organization (WHO)

The WHO advocates for an uncompromising regulatory stance, calling on all governments to ban all flavors in e-cigarettes. The organization's primary rationale is that flavors are a key driver for young people to start using nicotine products. It highlights data showing that in all WHO regions, children aged 13–15 use e-cigarettes at higher rates than adults, framing the issue as a "pediatric epidemic" that necessitates a strict, precautionary policy.

USA Governmental Public Health Agencies

U.S. federal agencies, including the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), operate under the premise that the nation faces an "epidemic" of youth vaping. This has led to a stringent premarket authorization process. To date, the FDA has only authorized 34 tobacco- and menthol-flavored e-cigarette products, underscoring its skepticism about other flavors. The CDC recommends that states and localities prohibit the sale of all flavored tobacco products.

USA Professional Organizations

A strong consensus exists among American medical organizations for a total ban on flavored e-cigarettes. The American Medical Association (AMA) has called for a "total ban on all e-cigarette and vaping products from the market" that have not been approved by the FDA as cessation devices, explicitly including mint and menthol. This position is echoed by the American Academy of Pediatrics (AAP), the American Heart Association (AHA), the American Lung Association (ALA), and the American Cancer Society (ACS), all of whom advocate for removing all flavored e-cigarettes to protect youth. This unified stance is more absolute than the FDA's regulatory actions, which are constrained by legal requirements to balance youth risks against potential benefits for adult smokers.

Canada Governmental Public Health Agencies

Health Canada has acknowledged that flavors appeal to youth and, in June 2021, proposed regulations to restrict e-cigarette flavors to tobacco, mint, and menthol. This proposal aimed to make vaping products less appealing to young people while leaving some options for adults seeking to switch from smoking. However, this nationwide flavor ban has not yet been implemented. In the absence of federal action, several provinces, including Quebec, New Brunswick, and Nova Scotia, have enacted their own stricter regulations, banning all e-cigarette flavors except tobacco. Canada's Council of Chief Medical Officers of Health has consistently reiterated its call for a national ban on all flavors to address high rates of youth vaping.

Canadian Professional Organizations

Canadian medical and health organizations strongly support a comprehensive ban on e-cigarette flavors. The Canadian Paediatric Society has called for a ban on all flavored vaping products to protect youth. The Canadian Medical Association also recommends banning all flavors to reduce the attractiveness of vaping to young people. This position is shared by groups like the Canadian Cancer Society and the Canadian Lung Association, who advocate for robust federal action, including a full flavor ban, to curb youth vaping.

UK Governmental Public Health Agencies

The United Kingdom’s public health agencies actively encourage adult smokers to switch to vaping, and flavors are seen as an important part of making that switch successful. The government has backed this with "swap to stop" schemes, providing starter kits with a choice of flavors to one million smokers. The National Health Service (NHS) website also promotes e-cigarettes as an effective cessation tool, implicitly recognizing the role of flavors in this process.

UK Professional Organizations

The UK medical community is divided. The Royal College of Physicians (RCP) explicitly recommends that "a range of flavours should be available to facilitate quitting". While acknowledging rising youth use, the RCP suggests regulating marketing and packaging—such as plain packaging and restricting flavor names like "bubblegum"—rather than banning flavors outright.

Conversely, the British Medical Association (BMA) has adopted a more precautionary stance, expressing alarm over a "growing epidemic of vape use" among youth. The BMA

has called for a ban on all non-tobacco vape flavors, a position that aligns it more with the WHO and U.S. organizations .

European Professional Organizations

European professional organizations, represented by bodies like the European Society of Cardiology (ESC), align with the global precautionary consensus. In a joint statement with the American Heart Association and the World Heart Federation, the ESC called for "greater global action to remove all non-tobacco flavored products from the market".

Other Global or International Organizations

Other major international bodies echo the WHO's position. The World Heart Federation (WHF) calls for the prohibition of all flavoring agents to reduce youth appeal and due to concerns about the unknown health effects of inhaled chemicals. The International Union Against Tuberculosis and Lung Disease (The Union) also recommends prohibiting flavors and is particularly focused on protecting low- and middle-income countries from what it calls "egregious" industry targeting. The Forum of International Respiratory Societies (FIRS) supports the WHO and advocates for a ban on flavors to protect young people from nicotine addiction. This near-unanimous front isolates the UK's harm reduction strategy on the global stage.

Less Restrictive to Trade: Alternative measures

There is no single, standalone measure that has been scientifically established as equally effective as a flavor ban in reducing youth vaping while also being less trade restrictive. By “less trade restrictive” it’s meant that adult smokers willing to quit using flavored ecigarettes have that option. So the question is not if a pack of alternative measures may be equally or even more effective in curbing youth vaping. In fact, it is recommended that flavor bans be accompanied by a multi-pronged approach, incorporating stricter marketing regulations, increased minimum age for purchase, and limits on nicotine concentration. The issue at stake is whether a portion of adult smokers can quit using flavored ecigs while at the same time curving the youth vaping at the same level a flavor ban would do.

Systematic reviews and meta-analyses of randomized controlled trials (RCTs) consistently conclude that the evidence on the role of flavors in smoking cessation is inconclusive.[30,39,40] This includes secondary analyses of the Cochrane review data, which found "no clear association between the use of e-cigarette flavors and smoking cessation or longer-term e-cigarette use".[41]

This reflects a paucity of high-quality data from RCTs designed specifically to answer this question. A 2023 systematic review assigned a very low level of certainty to its findings on quit success precisely because of these issues.[42] The evidence is equally limited when comparing the

effectiveness on curving youth vaping of flavor bans with that of alternative measures. In other words, even if alternative measures were less trade restrictive, there is no evidence that they would as effective in curbing youth vaping.

When he scientific evidence is scarce and will continue to be so for the immediate future, societies may apply two complementary approaches. One refers to let society apply its values towards the life and health of youth versus adults. Societies often value adolescents and adults differently, reflecting a focus on either future potential or present contribution. The health and life of an adolescent are frequently seen as a long-term investment, holding the promise of future innovation and societal continuation. Conversely, an adult's value is often tied to their immediate economic productivity, experience, and established role in maintaining social stability.

The other approach is to apply the precautionary principle.

Application of the Precautionary Principle

In the complex debate over e-cigarette flavors, we are faced with significant scientific uncertainty regarding their long-term effects and impact on smoking cessation. However, the evidence is much clearer on one critical point: the availability of non-tobacco flavors increases the appeal of vaping, especially among adolescents.

Flavor restrictions are proven to be effective at curbing e-cigarette use. However, this has led some to be concerned about a potential "substitution effect," prompting some who quit vaping to start smoking. Modeling studies and systematic reviews that analyze this trade-off have produced conflicting results. Some suggest that youth vaping creates a net public health harm, while others question whether the restrictions themselves are beneficial. Applying the precautionary principle, therefore, requires that the net public health benefit be clearly measured to prevent unintended negative consequences.

This is precisely the scenario where the precautionary principle must be invoked. This principle compels us to take protective measures when an action poses a plausible risk of severe harm, even if conclusive scientific proof is not yet available. The potential for fostering a new generation of nicotine dependence among youth constitutes such a harm.

Waiting for irrefutable, long-term evidence of this harm is a gamble public health cannot afford to take. The burden of proof should fall upon manufacturers to demonstrate that products designed with candy and fruit flavors do not pose an unacceptable risk to young people. In the absence of such proof, applying the precautionary principle through a ban on these appealing flavors is not an overreach, but a responsible and necessary safeguard for the well-being of our youth.

However, as we pointed out when addressing the regulation of nicotine pouches. The application of the Precautionary Principle goes beyond enacting protective measures with a priority to prevent irreversible harm. At the same time, more data is gathered, especially concerning the risk of youth addiction. The principle entails:

- Commissioning Independent, Publicly-Funded Research To resolve the evidence gap, conducted free from industry influence.
- Implementing Robust Post-Market Surveillance to assess the impact of the measures approved, and
- Scheduling a Mandatory Legislative Review, Policy should evolve with the evidence.

justification of Necessity and Proportionality

In the context of public health, Spain's proposed ban on e-cigarette flavors is framed by the principles of necessity and proportionality.

We argue that the ban is a necessity because flavors are identified as a primary driver of e-cigarette appeal and use among youth. Evidence indicates that the availability of non-tobacco flavors increases the appeal of vaping, decreases harm perceptions, and motivates young people to start using e-cigarettes. Less restrictive measures, such as limiting sales, may be insufficient. For instance, one review showed that partial flavor restrictions simply led to increased sales of the remaining unrestricted products, suggesting the core issue of appeal was not resolved.[43] To effectively curb youth initiation, it is therefore necessary to remove the key feature that makes these products attractive to them.

We argue that the measure is also proportional, as the significant benefit of protecting youth from nicotine addiction outweighs the infringement on adult vaper's choice. This is because the evidence supporting the role of flavors in helping adults quit smoking is consistently found to be "inconclusive". The policy curtails access to products with an unproven benefit for adult cessation in order to prevent a documented risk to a vulnerable population. By prioritizing the health of the next generation over access to a feature with ambiguous benefits for adults, the ban strikes a proportional balance between its public health objective and its impact on individual choice.

Conclusion:

From a strict public health advocacy perspective focused on preventing youth addiction, the flavor ban on e-cigarettes is deemed both necessary and proportionate. It is necessary due to overwhelming evidence that non-tobacco flavors increase the appeal of e-cigarettes among youth and the finding that partial restrictions may be inadequate, simply shifting sales to the remaining unrestricted products. The ban is proportionate because the clear and significant public health risk of widespread youth nicotine addiction far outweighs the infringement on adult choice, particularly when systematic reviews consistently conclude that the evidence for flavors as a crucial tool for adult smoking cessation is inconclusive.

PART C. ON OTHER PROVISIONS OF RD579/2017

On Labeling and Packaging Restrictions

The concerns raised by some EU MS about the proposed labeling rules are unconvincing and ignore the well-established "precautionary principle" in EU health law.

Clarity and Purpose of Restrictions: The prohibition on elements that "may attract the attention or special interest of consumers" is not ambiguous; it is a clear effort to denormalize these products and reduce their marketing appeal, similar to plain packaging policies for combustible tobacco products. The purpose is to prevent packaging from functioning as an advertising vehicle, a measure that is crucial for protecting public health. This is not a "de facto ban on trademarks" but a proportionate regulation of their use in the interest of a higher public good.

Regulation of Non-Harmonized Products: For products not fully harmonized by the TPD, such as nicotine-free e-cigarettes and heated herbal products, Member States retain the power to introduce national regulations. The principle of mutual recognition does not prevent a Member State from requiring specific health warnings if it deems them necessary to protect its population.

Application of the Precautionary Principle: Requiring a health warning on nicotine-free products is a prudent application of the precautionary principle. While these products are nicotine-free, the long-term health effects of inhaling the heated aerosols and flavorings they contain remain uncertain. In the face of such uncertainty, a Member State is entitled to take protective measures to inform consumers of potential risks.

On Prior Notification and Reporting Obligations

The objection from an EU MS regarding the technical and legal impossibility of registering non-harmonized products via the EU-CEG portal is a procedural complaint that does not invalidate the substance of the regulation.

Objective of Market Surveillance: The primary goal of extending notification requirements is to establish a comprehensive system for market surveillance of all novel nicotine and inhalation products entering the Spanish market. This is essential for public health authorities to monitor consumption trends, product composition, and potential health impacts.

Sovereign Regulatory Power: The fact that the EU-CEG system is not currently configured for these products does not strip Spain of its authority to require such information. Spain can establish a parallel national system for these specific product categories. The obligation on manufacturers to provide this information is a proportionate measure necessary for the state to carry out its public health mission.

On Disproportionate Restrictions on Heated Herbal Products

An EU MS claim that its legally manufactured products are being unfairly blocked from the Spanish market relies on a flawed application of the mutual recognition principle.

Member State Prerogative: As another EU MS opinion correctly points out, "it is left to Member States to determine the level at which protection is to be ensured". The fact that one EU MS has established its own regulatory framework for these products is not binding on Spain. Spain is entitled to conduct its own risk assessment and determine that a higher level of protection is necessary for its population.

Lack of Harmonization: In the absence of harmonized EU rules for heated herbal products, Member States have wide discretion to regulate or even prohibit them based on public health grounds. The Spanish measures are designed to achieve a specific public health objective, and the restrictions are directly linked to that aim. The burden of proof lies with the objectors to demonstrate that these measures are manifestly inappropriate, a burden they have failed to meet.

In conclusion, the Spanish draft Royal Decree is a coherent, justified, and necessary piece of public health legislation. It is fully compliant with EU law, appropriately prioritizing the health and safety of its citizens over the commercial interests of producers, as permitted under the Treaties.

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