Spain Submission to Draft Royal Decree amending Royal Decree 579/2017

Thank you for the opportunity to comment on the Draft Royal Decree amending Royal Decree 579/2017. Our submission is on behalf of the European Tobacco Harm Reduction Advocates (ETHRA).

ETHRA is the voice of 27 million EU[1] consumers of safer nicotine products (SNPs). The safer nicotine products we use include vapes, nicotine pouches, snus, and heated tobacco products. ETHRA is a consortium of 24 grassroots consumer associations in 17 European countries, supported by experts in tobacco control and nicotine research. We are a voluntary operation with no industry funding or conflicts of interest. Our transparency registration number is 354946837243-73.

We have read with interest the Ministry of Health's consultation document on the Draft Royal Decree amending Royal Decree 579/2017. As people with lived experience of using safer nicotine products to quit smoking and remain smoke free, we have serious concerns that severely restricting flavours in safer nicotine products and the nicotine content of nicotine pouches will be detrimental to public health.

We summarise our response as follows:

- The proposals will trigger a range of harmful unintended consequences, including more smoking, more criminality, risky workarounds and more harm to youth.
- A ban on flavouring (other than the arbitrary choice of tobacco flavour) amounts to a de facto ban on vaping products - all products are artificially flavoured and most adults use fruit flavours. This will promote smoking, generate illicit trade and encourage people to mix their own flavours.
- The way to control flavours is through controls on marketing, branding and packaging, including flavour descriptors and imagery, that appeals to children.
- The packaging restrictions for products that function as alternatives to cigarettes should only be focussed on youth appealing imagery and design, not general appeal as this will discourage adults from switching from cigarettes to safer alternatives.
- The proposed nicotine limit for pouches (0.99mg per pouch) amounts to a de facto ban. We recommend accepting the German BfR proposed threshold of 16.6 mg/pouch.
- There is nothing in the amended decree that would encourage people who smoke to switch to lower risk products. In a population with a daily smoking rate of 25.8%, there should be a major effort to reduce smoking by encouraging people to switch from cigarettes to vapes, pouches and heated tobacco products.

One of the main aims of the proposal is to propose a regulation for the wide range of innovative products (both with and without nicotine) currently lacking the necessary health regulations for the effective protection of the consumer. Regulating these products should not come at the expense of restricting adult access to safer nicotine products or discouraging smokers who could significantly improve their health by switching to a vastly safer product.

The latest data from Spain shows a sharp decline in daily smoking prevalence, falling from 33.1% in 2023 to 25.8%[2], which has coincided with an increase in vaping prevalence. This is further evidence that vaping acts as an exit route away from smoking. A vape flavour ban would undermine efforts to further reduce smoking rates by removing the most popular and effective means of smoking cessation from the market.

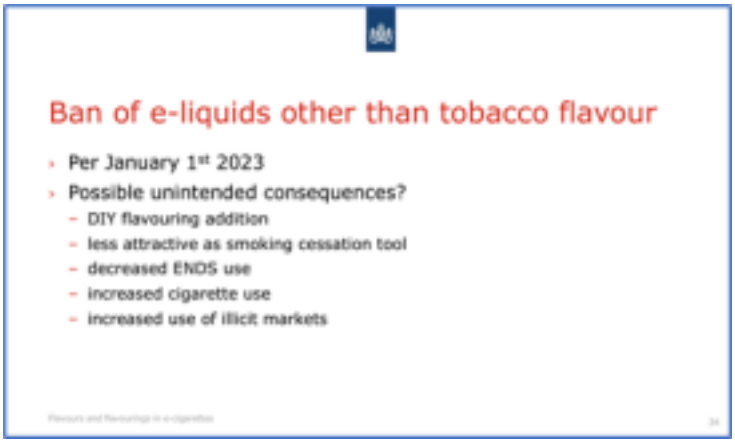
In summary, we should expect such a measure to prompt adverse behavioural responses in both adolescents and adults, protect the cigarette trade, promote black markets and informal trade, and weaken Spain's response to the public health burden of smoking.

Below we briefly summarise our position and share relevant evidence that underpins our position.

- Consumers believe regulation should be risk proportionate and non-discriminatory. While risks arising from combustible products are sufficiently severe to justify many tobacco control measures, no such equivalent risk applies to non-combustible products.
    - Tobacco harm reduction works by encouraging people who smoke to switch their product choice from smoking to much safer, smoke-free products. Smoke-free products must appeal to smokers to compete with cigarettes. One example of this appeal is the wide range of flavourings for safer nicotine products. While banning flavours might reduce the appeal of SNPs to some users, policymakers cannot just assume that users of flavoured SNPs will become abstinent – they may respond in various ways. A ban on flavours makes alternatives to cigarettes less competitive with cigarettes and, in doing so, protects and aids the cigarette trade.
    - Banning flavours. While characterising flavours play some role with combustible products, most of the flavour is imparted by the burning tobacco. For vape products or pouches, added ingredients impart all the flavour. A ban on flavours would be highly prone to unintended consequences. Recent evidence from economic studies in the United States shows that bans on vaping flavours increase cigarette consumption. It should not be surprising that flavour bans favour cigarettes: a flavour ban aims to make an alternative to cigarettes less attractive.
    - Evidence from trials, observational studies, population-level trends, market analysis and user testimony strongly suggest that vaping displaces smoking through quitting or cutting down, including among users who had no intention to quit smoking. Economic data shows that the price of vaping products affects cigarette demand. It is impossible, therefore, to assess vaping or smoking policies in isolation because one affects the other. Given the

respective risks, a ban on flavours will negatively impact health by making vaping less appealing than smoking for those inclined to use nicotine.

- Flavour bans stimulate an increase in adult smoking. December 2023, in a presentation on the Netherlands' approach to banning flavours, the Dutch public health agency RIVM summarised the plausible negative responses to a flavour ban[3].



- The slide represents a good summary of the reasons for scepticism about flavour bans. These unintended consequences are far more significant than the intended purposes of flavours. Yet, the proponents of flavour bans, including RIVM, have no analysis supporting a flavour ban once these effects are included
- A survey of French consumers found that half said they would source flavours illegally, and about one-quarter said they would return to smoking4. Several academic studies have identified risks with flavour bans: Posner et al. (2021)[5] found that one-third of vapers would be likely to switch to cigarettes. Gravely et al. (2021)[6] examined possible responses to flavour restrictions in the United States, Canada, and England, finding that 28.8% would access their preferred flavours via illicit means and 17.1% would stop vaping and smoke instead
- Controls on flavours. Flavours can be conceptualised as either (1) a chemical recipe, (2) a sensory experience (e.g., "apple", "mint"), or (3) a descriptor: the language, trademarks or iconography used to describe a product. Regulation should focus on banning or restricting known toxicants, CMRs, and respiratory sensitisers and ensuring that descriptors are not deliberately appealing to children.
- Regulating nicotine content in pouches. We agree that there should be controls on the amount of nicotine in nicotine pouches. However, we strongly believe that the threshold should be set at the amount of nicotine per sachet not per gram. Nicotine content per sachet increases consumer confidence in the product and the end user knows exactly what they are getting.
- Set the upper limit for pouches relatively high. To be a viable alternative to cigarettes, nicotine pouches must have a nicotine content that is satisfactory for the consumer. The German Federal Institute for Risk Assessment (BfR)[7]

has assessed the health risks from nicotine pouches based on existing studies and data. BfR has calculated that a 16.6 mg dose is estimated to be equivalent to the level in blood after smoking a cigarette. Setting any lower limit increases the risks of adverse consequences (more smoking, illicit trade, workarounds) arising from banning products already used by adult consumers.

- Consumers (smokers, vapers, and other nicotine users) are by far the most significant stakeholders. Economic analyses show that people who smoke bear the overwhelming share of the economic burden through disability and premature death. Consumers have interests that are distinct from economic actors and from professional activists who support the elimination of all nicotine use. We should not be bracketed with either.
- Consumers believe that policymakers should do what they are supposed to do: promote the free movement of goods with a high level of human health and consumer protection while respecting the long-established principles of proportionality and non-discrimination – with a focus on reducing cancer (Europe's Beating Cancer Plan) and reducing the burden of non-communicable disease (Healthier Together). If it did so, it would recognise smoke-free forms of nicotine and tobacco as significant opportunities with minimal and manageable risks, with the potential to expedite the obsolescence of the cigarette through the smooth functioning of a competitive internal market.
- Consumers believe the most important distinction from a policy perspective is between combustible and non-combustible products, not between tobacco and non-tobacco or between traditional and novel products. Smoke inhalation is responsible for the health and other risks of tobacco or nicotine use and should be the basis for defining proportionate regulation and taxation.
- Consumers raise concerns about a range of likely unintended consequences that arise from proposed policies to control products like vapes, heated tobacco, nicotine pouches and snus. There are essentially three forms of risk: (1) reversion to cigarettes or reduced switching or other adverse behavioural response; (2) stimulation of illicit and unregulated trade; (3) potentially risky workarounds by users or suppliers, such as making or adding flavours. In each case of a proposed new regulation, policymakers must recognise and evaluate these effects and be realistic about the damage they could do.
- Consumers believe the concern about youth use is excessive and has become a moral panic aided by tobacco control activists. Most youth use is experimental, infrequent, and likely to be transient. More intensive and frequent use by adolescents is mostly displacing smoking, and hence, beneficial in the longer term. There is no evidence for a gateway effect – all the evidence points the other way: vaping is an exit route from smoking.
- Consumers are not hostile to all regulation but draw a distinction between regulation designed to protect consumers (e.g., from chemical, electrical, or thermal hazards or misleading information) and regulation intended to deter use. The latter diminishes the consumer experience. As a result, it is highly prone to the unintended consequences described above and raises costs to users of finding and maintaining alternatives to smoking.

Further supportive evidence

1. Nicotine regulation must reflect substantial differences in risk between products.

- UK Office for Health Improvement and Disparities (OHID): Nicotine vaping in England: an evidence update including health risks and perceptions[8] (September 2022)

This latest update of the UK-commissioned report on nicotine vaping in England is considered the most comprehensive and rigorous, particularly regarding health risks. It presents strong evidence that nicotine vaping is far less harmful than smoking and that switching away from smoking substantially reduces risk. The report found, among other things, that vaping poses only a small fraction of the risks of smoking, that public perceptions of vaping harm are not in line with the evidence and influence subsequent vaping and smoking behaviours, and that vaping is effective for stopping smoking. It also concluded that non-tobacco flavours, particularly sweet flavours, may play a positive role in helping people switch from smoking to vaping. The report also found that vaping continues to increase and smoking to decrease.

- **Peer-reviewed publication: What are the harms of vaping in young people who have never smoked?[9] (May 2023)**

"Population and modelling studies also suggest that vaping and smoking are substitutes and that vaping displaces smoking at a population level. Studies of the effects of tax increases on vaping products also support a diversion effect. Higher taxes on vapes are associated with increased cigarette smoking, while higher cigarette prices are associated with increased vaping. Bans or purchasing restrictions on the sale of vapes to teens are also associated with increased adolescent smoking."

- **New Zealand Smokefree Environments and Regulated Products (Vaping) Amendment Bill Health Committee Commentary [10]:**

"The bill acknowledges that vaping products and heated tobacco products have lower health risks than smoking and aims to support smokers to switch to these less harmful products."

"The bill also recognises that many smokers need support and advice to successfully move to less harmful alternatives, so the Bill allows for the provision of information and advice for those wishing to switch from smoking to vaping."

- **Cochrane review: Electronic cigarettes for smoking cessation (January 2024)[11]:** "There is high-certainty evidence that ECs with nicotine increase quit rates

compared to NRT and moderate-certainty evidence that they increase quit rates compared to ECs without nicotine… For every 100 people using nicotine e-cigarettes to stop smoking, 8 to 12 might successfully stop, compared with only 6 of 100 people using nicotine- replacement therapy, 7 of 100 using e-cigarettes without nicotine, or 4 of 100 people having no support or behavioural support only."

2. Flavours are important to help adults quit smoking, with studies showing that e-cigarette flavour restrictions increase smoking:

- **Royal College of Physicians UK: E-cigarettes and harm reduction - An evidence review[12] (April 2024)**

"A range of flavours should be available to facilitate quitting among adults who are using e-cigarettes to quit smoking […] Modelling suggests that restricting flavours could disproportionately lead to more people continuing to smoke or relapsing to smoking than preventing uptake of vaping or uptake of smoking". (Executive summary and recommendations, pg 7 & 8)

- **Peer-reviewed publication by authors from Yale, Georgetown University, and University of Missouri : E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales[13] (September 2023)**

"Matching new flavor policy data to retail sales data, we find a trade-off of 15 additional cigarettes for every 1 less 0.7 mL ENDS pod sold due to ENDS flavor restrictions. Further, cigarette sales increase even among brands disproportionately used by underage youth. Thus, any public health benefits of reducing ENDS use via flavor restrictions may be offset by public health costs from increased cigarette sales."

"**Conclusion**: In this study, we find that ENDS flavor policies reduce flavored ENDS sales as intended, but also increase cigarette sales across age groups. As cigarettes are much more lethal than ENDS, the high rate of substitution estimated here suggests that, on net, any population health benefits of ENDS flavor policies are likely small or even negative."

- **ETHRA EU Nicotine Users Survey Report[14] (June 2021)**

This survey assessed potential consumer reaction to flavour bans or the unintended consequences of such an action. The ETHRA Survey, which had over 37000 responses, found that only 5.4% of current vapers used tobacco or unflavoured vapes. ***On potential flavour bans, 28% of vapers said they are likely to restart smoking again, and 71% would consider using the black***

market or other alternative sources. It's important to note that ETHRA and our partners conducted the ETHRA Survey. It is not peer-reviewed, although we did take advice on design from our scientific partners.

- **MERCI LA VAPE survey of consumers of vaping products**[15] **(November 2023)** French association Aiduce, Sovape, La Vape Du Coeur and Fivape launched the MERCI LA VAPE initiative on May 31. At the time of the first summary report the questionnaire received 40,000 responses. ***On potential flavour bans more than 50% of vapers say they would turn to alternative sources of supply (black market, purchases abroad, etc) and 25% say they could start smoking cigarettes again.***

3. Gateway effects

- **Peer-reviewed publication: Dramatic Reductions in Cigarette Smoking Prevalence among High School Youth from 1991 to 2022 Unlikely to Have Been Undermined by E-Cigarettes**[16] **(September 2023)**

"Concerns about a potential rise in adolescent cigarette use following the introduction of e-cigarettes to the US market in the early 2010s are not supported by the data. In fact, the emergence of e-cigarettes has coincided with the most rapid declines in cigarette use over the past thirty years."

- **Peer-reviewed publication: A critique of the Australian National Health and Medical Research Council CEO statement on electronic cigarettes**[17] **(February 2023):**

"There is no convincing evidence that e-cigarette use is a gateway to smoking. […] A more plausible explanation is that young people who engage in one form of risky behaviour, such as vaping, are more likely to engage in other risky behaviours such as smoking, hazardous alcohol consumption and illicit drug use."

- **Invited commentary in JAMA: e-Cigarette and Cigarette Use Among Youth: Gateway or Common Liability?**[18] **(March 2023):**

"At the population level, e-cigarettes do not appear to be a gateway to cigarette smoking... Collectively, concerns about a gateway effect and a potential increase in youth cigarette use following the introduction of e-cigarettes to the US market are not supported by the data."

- **Cancer Research UK: E-cigarette FAQs**[19]**:**

"Regular use of e-cigarettes remains largely confined to current or ex-smokers. Experimentation with e-cigarettes in 'never smokers' remains low and coincides with the continuing decline in youth smoking."

- **Action on Smoking and Health UK[20]: Addressing common myths about vaping (August 2023):**

"If vaping were a gateway into smoking at population level, as vaping increased smoking rates would be expected to show a reduced rate of decline or start to increase. To the contrary between 2010 and 2021, when e-cigarette use grew rapidly from a low base in England, smoking rates among children continued to fall at least as rapidly as previously, which does not support the gateway hypothesis at population level." [...] "Moreover survey data shows that children who tried vaping in the US between 2014 and 2017, compared with matched children who did not try vaping, were equally likely to try a cigarette but less likely to progress to regular smoking."

- **Action on Smoking and Health New Zealand: Harm reduction and vaping [21]:** "Whilst there are concerns about vaping being a gateway into smoking, there is no evidence of this, particularly for youth."

- **Peer-reviewed publication: What are the harms of vaping in young people who have never smoked? [22] (May 2023)**

"It is well established that young people who try vaping are more likely to later try smoking. There is a tendency in policy discussions to assume that this association is causal (the gateway hypothesis). However, it is not the only possible or the most plausible explanation. A more likely explanation is that the association is explained by shared risk factors for vaping and smoking, such as a genetic liability to develop nicotine addiction and environmental, psychological, and social causes e.g., peer group or parental smoking that create a 'common liability' for risk taking. In studies that adjust for these confounders, most of the association between vaping and subsequent smoking has disappeared."

"The gateway hypothesis also predicts that increased vaping will increase cigarette smoking among youth. However, increases in youth vaping have been accompanied by an accelerated decline in smoking since vaping became popular in the US, UK, and New Zealand, suggesting either no overall gateway effect or at most, a small gateway effect that is outweighed by the much larger number moving from smoking to vaping."

4. The primary driver of harm (exposure to toxicants) is smoking, not e-cigarette use:

- **Peer-reviewed publication: Biomarkers of potential harm in people switching from smoking tobacco to exclusive e-cigarette use, dual use or abstinence: secondary analysis of Cochrane systematic review of trials of e-cigarettes for smoking cessation [23] (October 2022)**

The studies analysed in this review showed no evidence that biomarkers of potential harm increased in people who continued to smoke combustible tobacco

while also using EC. In fact, dual use was associated with statistically significant reductions in CO,
nitrosamines (mixed evidence), some metabolites of polyaromatic hydrocarbons and some mercapturic acids."

In conclusion, the evidence presented strongly suggests that a flavour ban on vaping products would be counterproductive to public health goals. Flavours play a crucial role in helping people who smoke transition away from cigarettes, and a ban could lead to increased smoking rates, a rise in the black market, and potentially risky workarounds by users. Furthermore, concerns about youth vaping appear to be overstated, with most use being experimental and displacing smoking in the long run. A focus on harm reduction strategies that acknowledge the significant difference in risk between smoking and vaping is a more effective approach. By regulating vaping products to ensure safety while allowing for a variety of flavours, the government can encourage smokers to switch to a less harmful alternative and ultimately reduce the burden of smoking-related disease.

Sincerely,

Damian Sweeney
On behalf of ETHRA & Partners

A note on ETHRA's preferred terms for products

As people with lived experience of using Safer Nicotine Products (SNPs), we generally choose to use these terms:
- 'vapes', 'vaping products' and 'vaping', rather than 'e-cigarettes' or 'ENDS'. - 'HTPs' to refer to Heated Tobacco Products.
- 'Nicotine pouches' for non-tobacco containing oral sachets.
- 'snus' to refer to the pasteurised Scandinavian oral tobacco product, either in loose or pouch form.

References:

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[13] Friedman, Abigail and Liber, Alex C. and Crippen, Alyssa and Pesko, Michael, E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales. January 29, 2024 [link]

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