

MOHRE SUBMISSION

Introduction

On January 24, 2025, Spain notified the European Commission of a draft Royal Decree amending Royal Decree 579/2017, which regulates the production, presentation, and marketing of tobacco-related products.

Key amendments include a ban on the sale of e-cigarettes, nicotine pouches, and heated herbal products with non-tobacco flavors, as well as a limit of 0.99 mg of nicotine per pouch. These restrictions appear insufficiently supported by scientific evidence.

Scientifically, the proposal raises doubts about the effectiveness of the measures in achieving public health goals. Although aimed at reducing nicotine-related risks, current literature does not clearly link nicotine content or flavors to increased health harm.

2. Ban on Non-Tobacco Flavours

The Spanish government justifies the ban on non-tobacco flavours by citing the need to protect the population, especially youth, from particularly appealing variants, which are deemed to have significant public health implications. However, this position lacks empirical substantiation and is not supported by the available scientific evidence.

Numerous studies have demonstrated that combustion-free products carry significantly lower health risks compared to traditional tobacco, offering smokers viable, less harmful alternatives^{1 2}.

According to various experts, these products represent only a fraction of the risk associated with cigarette smoking. Health authorities in the United Kingdom, for instance, have stated that vaping carries only a small percentage of the health risks of smoking³. Transitioning exclusively to non-combustible products can significantly reduce tobacco-related diseases.

¹ Based on the weight of evidence and assuming a complete switch from cigarette smoking. These products are not risk free and are addictive.

² Without being exhaustive, it is worth mentioning the position of the following health authorities on this issue:

* Public Health England (2015). E-cigarettes: an evidence update A report commissioned by Public Health England.

* Government of Canada: Supporting the Sustained Transition of Smokers of Conventional Cigarettes to Vaping Products - CIHR (cihr-irsc.gc.ca)

* Electronic Nicotine and Non-Nicotine Delivery Systems. A brief. WHO, Regional Office for Europe. May 2020.

* Institut National du Cancer France (2021) : Agir pour sa santé contre les risques de cancer.

* European Parliament (2022): Strengthening Europe in the fight against cancer

* Supporting smokers to switch to significantly less harmful alternatives. 2018. Associate Minister of Health. New Zealand

³ [Nicotine vaping in England: 2022 evidence update summary - GOV.UK](#)

For this reason, public health institutions in countries such as the UK, Canada, New Zealand, and Sweden acknowledge the positive role of these tools in achieving a smoke-free society, in conjunction with traditional tobacco control strategies.

In Spain, 97% of smokers who use e-cigarettes report having reduced or entirely quit smoking. The Cochrane review confirms that individuals using nicotine-containing e-cigarettes are more likely to quit smoking compared to those relying on nicotine replacement therapy⁴.

Secondly, scientific evidence suggests that there is a positive relationship between the use of fruit flavors and other non-tobacco flavors in e-cigarettes and their effectiveness as an alternative to smoking.

The UK *Royal College of Physicians*⁵ has noted that such flavours enhance user satisfaction and help dissociate nicotine consumption from the taste of tobacco, thereby making cessation efforts more effective^{6 7}.

Similarly, the 2020 update from *Public Health England (PHE)* noted that “where flavoured vape products are part of public health measures, there are notable decreases in smoking prevalence rates”⁸. In 2022, the UK's *Office for Health Improvement and Disparities* confirmed that “there is some evidence suggesting that non-tobacco flavors, particularly sweet flavors, may play a positive role in helping people transition from smoking to vaping”⁹.

Similarly, a recent randomized controlled trials by *Nature Medicine* highlighted indicates that individuals assigned to nicotine-containing e-cigarettes exhibit higher smoking cessation rates compared to those using traditional nicotine replacement therapies¹⁰.

Additional research has explored the use of flavours in depth. Data from the U.S. *Population Assessment of Tobacco and Health (PATH)* Survey indicate that individuals who use non-tobacco or menthol-flavoured e-cigarettes are 2.5 to 3 times more likely to quit or reduce smoking than non-users¹¹. Other analyses of *PATH* data show that these flavours do not increase smoking initiation among youth but instead support abstinence in adult populations¹².

A 2019 study by the *Centre for Substance Use Research* in Glasgow, involving over 15,000 U.S. adult smokers, found that those who used exclusively

⁴ Cochrane is a meta-analysis of the available studies and evidence on the effectiveness of vaping as a smoking cessation tool. In 2024 it included a review of 88 studies with over 27,000 participants. Electronic Cigarettes for Smoking Cessation: Cochrane Living Systematic Review - Centre for Evidence-Based Medicine (CEBM), University of Oxford

⁵ Royal College of Physicians (2024): E-cigarettes and harm reduction: An evidence review. Available at

<https://www.rcp.ac.uk/policy-and-campaigns/policy-documents/e-cigarettes-and-harm-reduction-an-evidence-review/>

⁶ How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys, University of Melbourne, 2021.

⁷ The Association of E-cigarette Flavors With Satisfaction, Enjoyment, and Trying to Quit or Stay Abstinent From Smoking Among Regular Adult Vapers From Canada and the United States: Findings From the 2018 ITC Four Country Smoking and Vaping Survey, University of Waterloo, 2020

⁸ McNeill, et al. (2020). Vaping in England: an evidence update including mental health and pregnancy: a report commissioned by Public Health England. London: Public Health England.

⁹ Nicotine vaping in England: 2022 evidence update summary - GOV.UK (www.gov.uk)

¹⁰ Warner, K.E., Benowitz, N.L., McNeill, A. et al. Nicotine e-cigarettes as a tool for smoking cessation. *Nat Med* 29, 520–524 (2023). <https://doi.org/10.1038/s41591-022-02201-7>

¹¹ Chen, J., (2018) Flavored E-cigarette Use and Cigarette Smoking Reduction and Cessation-A Large National Study among Young Adult Smokers. *Substance Use & Misuse*, 53:12, 2017.

¹² Friedman AS, Xu S. Associations of flavored e-cigarette uptake with subsequent smoking initiation and cessation. *JAMA Netw Open* [serial online]. 2020 Jun 5 [cited 2021 Nov 17];3(6): e203826. Available at: <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766787>

characterizing flavours in the 30 days prior had a 38% greater likelihood of being smoke-free after six months compared to users of tobacco flavours alone¹³. Likewise, Li et al. (2021), analyzing cessation rates in Australia, Canada, England, and the U.S., found that users of sweet or fruity-flavoured e-cigarettes were 44% more likely to quit than those using tobacco flavours¹⁴.

Additionally, a 2025 study found that 68% of Canadian smokers who successfully transitioned to vaping used flavoured products, with fruit flavours being the most commonly chosen¹⁵.

Non-tobacco flavours thus appear essential in aiding adult smokers to fully transition to reduced-risk products. As previously noted, these flavours reinforce commitment to vaping and decouple the nicotine experience from the taste of tobacco. Disregarding such evidence leads to an overly restrictive approach that limits access to effective alternatives for adult consumers.

Moreover, flavour bans may result in unintended consequences as it drives former smokers back to cigarette smoking. A study by *Yale School of Public Health* found that for every 0.7 mL of e-liquid not sold due to restrictions, 12 additional cigarettes were sold¹⁶.

According to the *University of Bristol*, a ban would have a net negative impact on public health, particularly among socioeconomically disadvantaged populations who are more vulnerable to tobacco use¹⁷.

3. 0.99 mg Nicotine Limit for Nicotine Pouches

The Spanish government has not provided evidence supporting the public health rationale behind the proposed 0.99 mg nicotine limit per pouch.

Sweden, where smokeless products like snus have been available for over 40 years, demonstrates how such alternatives can reduce smoking prevalence. Between 2008 and today, smoking rates in Sweden dropped from 15% to 5.3%, accompanied by a cancer incidence 41% below the EU average. This trend is largely attributed to the use of less harmful nicotine alternatives¹⁸.

¹³ Gravely S., et al (2020). The Association of E-cigarette Flavors With Satisfaction, Enjoyment, and Trying to Quit or Stay Abstinent From Smoking Among Regular Adult Vapers From Canada and the United States: Findings From the 2018 ITC Four Country Smoking and Vaping Survey. *Nicotine & Tobacco Research* 2020;22:1831-41.

¹⁴ Li. I., et al. (2021). How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys. *Nicotine and Tobacco Research*.

¹⁵ Gravely S, Swenor D, Driezen P, Levy DT, Fong GT, Quah AC, Craig LV, Chung-Hall J, Kaai SC, Cummings KM. Use of nicotine vaping products during an attempt to quit smoking by Canadian adults who smoke or recently quit: findings from the 2022 Canada International Tobacco Control Four Country Smoking and Vaping Survey. *Health Promot Chronic Dis Prev Can*. 2025;45(1):54-60. <https://doi.org/10.24095/hpcdp.45.1.04>.

¹⁶ Friedman, Abigail and Liber, Alex C. and Crippen, Alyssa and Pesko, Michael, E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales (September 26, 2023). Available at SSRN: <https://ssrn.com/abstract=4586701>

¹⁷ Gibson MJ, Munafò MR, Attwood AS, Dockrell MJ, Havill MA, Khouja JN. (2022). A decision aid for policymakers to estimate the impact of e-cigarette flavour restrictions on population smoking and e-cigarette use prevalence among youth versus smoking prevalence among adults. *medRxiv*. 2022:2022-11. DOI: 10.1101/2022.11.14.22282288

¹⁸ Ramström, L. (2020) "Institute for Tobacco Studies. Death rates per 100,000 attributable to tobacco - Sweden and the rest of the EU in 2019. Compiled from The Global Burden of Disease Study", cited in Report The Swedish Experience ES.pdf (smokefreesweden.org)

Moreover, several regulatory bodies have recognized the reduced-risk profile of nicotine pouches. The *German Federal Institute for Risk Assessment (BfR)* concluded that switching from cigarettes to nicotine pouches could reduce health risks¹⁹. The UK government's *Committee on Toxicity (COT)* has stated that nicotine pouches, when used as a substitute for smoking, would likely reduce overall health risks²⁰. Similarly, the *Dutch National Institute for Public Health and the Environment (RIVM)* has stated that nicotine pouches are a less harmful alternative to tobacco products²¹. Despite this, the proposed 0.99 mg nicotine limit is not supported by scientific evidence and is not justified by any identified public health risk. Such a low dosage may fail to provide a satisfying alternative to cigarettes, hindering smokers from transitioning to reduced-risk products. Other Member States, such as Germany and Belgium, recommend significantly higher limits—up to 16,6²² or 20²³ mg per pouch—based on scientific assessments and consumer needs.

A nicotine limit set too low may have counterproductive effects: discouraging smokers from switching, promoting continued use of combustible tobacco, or encouraging use of unregulated, higher-nicotine products. These scenarios would undermine public health efforts.

In conclusion, the proposed 0.99 mg limit appears disproportionate and unsupported by evidence, potentially harming rather than helping public health.

Best regards

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Rome, April 18th 2025

¹⁹ <https://www.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf>

²⁰ <https://cot.food.gov.uk/sites/default/files/2023-04/Publishable%20%20COT%20Oral%20nicotine%20pouches%20-%20final%20v1-0%20Acc%20V.pdf>

²¹ [Nicotineproducten zonder tabak voor recreatief gebruik | RIVM](#)

²² Bundesinstitut für Risikobewertung (2022): Health risk assessment of nicotine pouches. <https://www.bfr.bund.de/cm/349/health-risk-assessment-of-nicotine-pouches.pdf>

²³ FAMHP - Federal Agency for Medicines and Health Products. (2021)

https://www.famhp.be/en/news/nicotine_pouches_are_no_longer_considered_to_be_a_medicinal_product.

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