

Draft Royal Decree amending Royal Decree 579/2017 regulating certain aspects relating to the manufacture, presentation and marketing of tobacco products and related products

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My name is Clive Bates; I am writing as a UK-based expert in tobacco policy and related science with 27 years of experience. I have run the U.K.'s leading anti-smoking advocacy organisation, worked in varied policy environments as a senior civil servant, and now run a sustainability and public health consultancy. I declare no relevant conflicts of interest or issues arising under Article 5.3 of the Framework Convention on Tobacco Control.

I write to follow up on my detailed comments in April 2024 about the proposed amendment to the Royal Decree [[Comments for the consultation on amended Royal Decree 579/2017](#)]. These comments and the multiple concerns raised in that document remain valid and disturbing, given the number of lives at stake and the foreseeable unintended consequences of the proposed regulations. That document also provides an extensive argument for tobacco harm reduction based on [four evidence briefs](#) covering product safety, substitution, youth and policy. I will not repeat these here.

Summary

The public health priority is to reduce very high levels of smoking among everyone in Spain (age 15-64 = 34% in 2024), including young people (age 15-24 = 30%).¹ Yet the proposal restricts valuable options for reducing smoking in adults and displacing smoking in youth. This is the strategic flaw.

The proposals in the draft decree suggest a need for deeper consideration of the likely harmful unintended consequences of applying highly restrictive regulation to far safer alternatives to cigarettes. The vape and pouch flavour ban will not work and do more harm than good. Instead, packaging and marketing regulation should focus on preventing youth-appealing flavour descriptors, packaging and branding. The maximum nicotine level set for nicotine pouches amounts to a *de facto* prohibition on these products and a gift to the cigarette trade. A much higher level should be set and then lowered in future if problems emerge, and unintended consequences are evaluated to be small.

General: recognising unintended consequences

All policies that are designed to place restrictions on safer products that function as alternatives to cigarettes are at risk of four main categories of unintended harmful consequences. These are not speculative; they are very real and likely to substantially outweigh any benefits regulators hope to achieve.

1. **More smoking.** Vapes, pouches, and heated tobacco products function as alternative nicotine delivery systems (ANDS), displacing cigarettes either by helping people quit smoking or diverting them from ever starting. Make them less appealing, less pharmacologically effective, more expensive, harder to access and more confusing, then Spain should expect more smoking, disease and death.

¹ Ministeria de Sanidad, Statistical Portal[Consulta Interactiva del SNS], <https://bit.ly/3DbUKWs> 11 Dec 2024

2. **Illicit trade.** Prohibitions on products (or restrictions that work as *de facto* prohibitions) do not cause the banned products to disappear. Prohibitions cause products to be supplied by opportunists and criminal networks. While this may help to reduce smoking, it is a highly undesirable approach, underpinned by violence, extortion and corruption. It creates a trade in unregulated products that may be dangerous or poor quality, and it brings law-abiding citizens into contact with criminal networks that will supply any illegal products to anyone of any age. It is an abdication of the responsibility of regulators to run a well-regulated market in products adults wish to use.
3. **Workarounds.** Consumers and suppliers are not passive “patients” who can simply be told what to do. If people believe (correctly) that they are taking the initiative at their own expense to protect their own health, they will exercise their autonomy in ways that regulators do not anticipate. Consumers will engage in potentially risky practices like mixing their own flavours or adding their nicotine to products. Innovative suppliers will enter the market with products designed to comply with the letter of the law but to overcome the restriction – such as flavour capsules, menthol inserts, or nicotine analogues.
4. **Harms to youth.** Much of the rhetoric that justifies measures designed to restrict or prohibit ANDS is based on “protecting youth”. But this is based on a naïve understanding of young people and their risk behaviours. Young people can be harmed in at least three ways by these restrictions:
 - a. Some young people take up vaping but would otherwise take up smoking. For these young people, a diversion from smoking to vaping is highly beneficial and may break decades of smoking within their families.
 - b. Young people have an interest in the health of adults in their lives. No child ever wants to say, “My mother has cancer” or “My father can’t breathe”. Nor should they endure the economic, caring and grief burdens arising from smoking-related disease and premature deaths of adults in their lives.
 - c. All illicit trade networks will draw in young people - not only as consumers but also as suppliers in the lowest tier of a criminal supply chain. Illicit trade offers young people an apprenticeship in criminality and exposure to far more harmful trade than vapes.

In my view, there is little sign that such unintended consequences have been seriously considered, yet they are likely to cause harm far exceeding the intended benefits.

Comments on three specific measures

1. A ban on flavours other than tobacco flavour for vapes and pouches

This is implemented in the following draft text:

E-cigarettes. Article 28 [Electronic cigarettes with or without nicotine must meet the following requirements] (h) That only contain flavouring or flavouring ingredients that give the final product aromas and/or flavours of tobacco.²

² *Que solo contengan ingredientes aromatizantes o saborizantes que confieran al producto final aromas y/o sabores a tabaco.*

Pouches. Article 52 (1) [It is prohibited to introduce products containing] (d) flavouring or flavouring ingredients other than those that give the final product aromas and/or flavours of tobacco.³

More smoking. A flavour ban would be a major error and trigger significant negative unintended consequences. There is already considerable evidence that vape flavour bans trigger additional smoking. On the contrary, U.S. quasi-experimental economic research has found the opposite: that flavour bans lead to *increases* in smoking:

We find a trade-off of 12 additional cigarettes for every 1 less 0.7 mL ENDS pod sold due to ENDS flavor restrictions. Friedman et al. (2023)⁴

Statewide comprehensive flavor bans may have generated an unintended consequence by encouraging substitution towards traditional smoking in some populations. Saffer et al. (2024)⁵

We also detect evidence of an unintended effect of ENDS flavor restrictions that is especially clear among 18-20-year-olds: inducing substitution to combustible cigarette smoking. Cotti et al. (2024)⁶

It is unclear why the findings from the United States would not apply to Spain. I know of no analysis or theory that suggests that the findings above would not apply in Spain, where smoking levels are far higher than the U.S.

Illicit trade and workarounds. Illegal trade and workarounds are also highly likely driven by a flavour ban. Because the people affected are not passive, a flavour ban is a route to losing control of the market. Academic research suggests illicit trade will be a significant problem: A survey of 40,000 French consumers found that half said they would source flavours illegally, and about one-quarter said they would return to smoking (SOVAPE, 2023)⁷ Several academic studies have identified risks with flavour bans: Posner et al. (2021)⁸ found that one-third of e-cigarette users would be likely to switch to cigarettes. Gravely *et al.* (2021)⁹ examined possible responses to flavour restrictions in the United States, Canada, and England, finding that 28.8 per cent would access their preferred flavours via illicit means and 17.1 per cent would stop vaping and smoke instead.

Lack of any evidence of success. The experience of vape flavour bans in Europe suggests significant problems with practicality and implementation. Ten European Union member states have flavour restrictions, yet little evaluation has been published. It is likely that the policy has triggered considerable cross-border and internet trade and may have inhibited smoking cessation. For

³ ...ingredientes aromatizantes o saborizantes diferentes a los que confieran al producto final aromas y/o sabores a tabaco.

⁴ Friedman, A. Liber, A. C., Crippen, A., & Pesko, M (2024). *E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales*. [SSRN 45867801](https://ssrn.com/abstract=45867801)

⁵ Saffer, H., Ozdogan, S., Grossman, M., Dench, D. L., & Dave, D. M. (2024). *Comprehensive E-cigarette Flavor Bans and Tobacco Use among Youth and Adults* ([Working Paper 32534](#)). National Bureau of Economic Research.

⁶ Cotti, C. D., Courtemanche, C. J., Liang, Y., Maclean, J. C., Nesson, E. T., & Sabia, J. J. (2024). *The Effect of E-Cigarette Flavor Bans on Tobacco Use* ([Working Paper 32535](#)). National Bureau of Economic Research

⁷ AIDUCE, SOVAPE, La Vape du Coeur and FIVAPE, Communiqué : Première synthèse de l'enquête MERCI LA VAPE – 40000 réponses + 1 alerte sanitaire, 3 November 2023 [[link](#)] Full report (French) [[PDF link](#)]

⁸ Posner H, Romm KF, Henriksen L, Bernat D, Berg CJ. Reactions to Sales Restrictions on Flavored Vape Products or All Vape Products Among Young Adults in the United States. *Nicotine Tob Res.* 2021 <https://bit.ly/30aAdOn>

⁹ Gravely S et al. Responses to potential nicotine vaping product flavor restrictions among regular vapers using non-tobacco flavors: Findings from the 2020 ITC Smoking and Vaping Survey in Canada, England, and the United States. *Addict Behav.* 2021 <https://bit.ly/3oRuSo3>

example, Netherlands-based internet commerce fell following the flavour ban, but Netherlands traffic to international sites increased significantly. Following a flavour ban in Latvia, there was a significant uptick in vape tax revenues in Lithuania.¹⁰ If flavour bans had been a successful policy, we would expect an abundance of evaluations and heavy publicity for the results. The absence of evaluation and publicity should cause concern in Spain and the rest of the European Union.

Deliberately destroying the main competitors to cigarettes. Insisting that legal alternatives to smoking must only have artificial tobacco flavouring is absurd. No one can explain why legislators have chosen artificial tobacco flavour (a mixture of flavouring chemicals like any other) as the only one they have decided to permit. Most users of alternatives are trying to escape from smoking. Why make the products unappealing for the vast majority of consumers who choose flavoured products as their preferred alternatives to cigarettes? One international survey of disposable products across 100 countries found only 1 per cent were tobacco-flavoured, with flavours dominated by fruit flavours.¹¹ For nicotine pouches, it is unusual for the products to be flavoured with tobacco at all: in the U.K., leading flavours are Mint, Berry, Fruit, and Citrus, and tobacco does not even figure in the top ten.¹²

The appropriate way to deal with flavours. For regulatory purposes, flavours can be defined in three ways: first, a recipe of chemical flavour ingredients; second, a sensory character (e.g. apple, mint); and third, a flavour *descriptor* and related branding. For the first of these, it would make sense to limit toxicity and CMR characteristics for consumer protection purposes but not to restrict flavour choices. For the second, there is no case to impose restrictions. The third, descriptors and branding, is a form of marketing and should be subject to control to prevent youth appeal (see below).

2. Packaging restrictions

These are implemented in the following draft text:

E-cigarettes. Article 30: (3) The packaging units, the outer packaging and the device may not include images, with the exception of mandatory pictograms. Likewise, elements and colour combinations that, due to their content or design, are likely to attract the attention or particular interest of consumers, especially minors, may not be used.¹³

Pouches. Article 53: (3) Packaging units and outer packaging may not include elements that, due to their content or design, are likely to attract the particular attention or interest of minors¹⁴

In this case, there is a marked contrast in the language. The language used for packaging restrictions for *pouches* in the draft Article 53(3) is appropriately focussed on minors. This is a better formulation than the language for e-cigarettes, which creates an open-ended definition

¹⁰ Tamarind Intelligence, presentation to the UK E-cigarette Summit 2024, 5 December 2024 [[link](#)]

¹¹ EcigIntelligence Disposables Tracker, December 2024

¹² Haypp Group data portal, Nicotine Pouch Report UK 2024: <https://www.haypp.com/uk/nicotine-report/2024/>

¹³ *Las unidades de envasado, el embalaje exterior y el dispositivo no podrán incluir imágenes, a excepción de los pictogramas obligatorios. Así mismo no se podrán utilizar elementos y combinaciones de colores que por su contenido o diseño sean susceptibles de atraer la atención o interés particular de las personas consumidoras, especialmente menores de edad.*

¹⁴ *Las unidades de envasado y el embalaje exterior no podrán incluir elementos que por su contenido o diseño sean susceptibles de atraer la atención o interés particular de las personas menores de edad.*

and a deliberately self-defeating purpose, which is to make e-cigarettes unappealing to everyone, including adults who smoke.

I recommend that the language of Article 53(3) is also used for Article 33(3) to align the packaging rules for e-cigarettes and pouches with a common goal of blocking product packaging that deliberately appeals to minors.

The appropriate way to address concerns about flavours is through controls *on flavour descriptors and branding*, which this language covers. It is not through a list of permitted flavour ingredients or only allowing one sensory flavour category, like tobacco.

3. Limit on nicotine content and nicotine absorption of pouches

The draft decree text is as follows.

Pouches. Article 52 (1) [It is prohibited to introduce products containing]

(a) more than 0.99 mg of nicotine per sachet¹⁵

(b) additives that facilitate the absorption of nicotine.¹⁶

This language imposes an extreme restriction on the nicotine content of nicotine pouches that amounts to a *de facto* prohibition and a welcome relief for the cigarette trade. Any cursory view of the marketplace will find popular products with far higher nicotine content than this and none with nicotine content as low as this. For example, pouches available and widely used in Norway range from about 5mg to 20mg per pouch.¹⁷ The proposed amended decree would be like insisting that Spanish wine must contain no more than 1 per cent alcohol when the typical range is 8-15 per cent. Such a rule would be a *de facto* wine prohibition.

Repeating the error of the snus ban. No country should permit products that have extreme and threatening levels of nicotine, but equally, it should not deny access to pouch products that are far safer than cigarettes and probably comparable in risk to nicotine replacement therapy. This amounts to an anticompetitive protection of the cigarette trade, a repeat of the grave error of the EU's 1992 snus ban. That ban has denied millions of Spanish and other European smokers a proven safer option for more than three decades. That is a mistake to learn from, not to repeat. I suggest the following approach:

1. **Set the threshold relatively high initially.** The nicotine threshold is set at a relatively high level *initially*; for example, 20 milligrams per serving. The aim would be to eliminate dangerous rogue products with irresponsibly high levels of nicotine without disrupting the mainstream market. A riskier approach would be to set a standard at a lower maximum nicotine content per serving based on a notional toxicity threshold suggested by Germany's Bundesinstitut für Risikobewertung, a standard of 16.6mg nicotine per serving. **Error! Bookmark not defined.** Setting any lower threshold *increases* the risks of adverse

¹⁵ *más de 0,99 mg de nicotina por sobre*

¹⁶ *aditivos que facilitan la absorción de nicotina;*

¹⁷ Vedøy, T. F., & Lund, K. E. (2022). Nicotine Content in Swedish-Type Snus Sold in Norway From 2005 to 2020. *Nicotine & Tobacco Research*, 24(7), 1130–1133. [[link](#)]

consequences (more smoking, illicit trade, workarounds) arising from banning products already used by adult consumers. ***It is not inherently cautious to set a lower threshold.***

2. **Monitor the development of the market and lower thresholds over time if justified.** The impact of the initial threshold should be assessed in a market survey (i.e. what products are available and who is using them), and this would then form the basis for a possible future lowering of the nicotine threshold, providing the Minister is satisfied it will not trigger harmful unintended consequences. Under such a system, the Minister would have powers to set nicotine thresholds through secondary legislation and under conditions specified in the law (e.g. following a market survey).

Such an approach would deal immediately with rogue high-nicotine products with no risk of unintended consequences, provide a basis for a well-managed market meeting adult consumer needs, and support future regulatory development based on evolving learning and insight or responding to innovation.

Banning additives that affect nicotine uptake. There is no case for banning additives, such as acidity regulators that can facilitate nicotine uptake by changing the proportion delivered in protonated and freebase forms. The purpose of nicotine pouches is to provide an alternative to cigarettes that can meet the demand for nicotine at far lower levels of risk. There is no reason to impose limits on the way nicotine is delivered to make these products less effective as alternatives to cigarettes. This is not a case where the restriction protects health: it means more people are likely to smoke cigarettes. I recommend dropping this provision. ***It is not inherently cautious to ban additives that modulate nicotine uptake.***

I hope the comments are helpful as you consider the benefits and risks of this amended decree and determine the appropriate policy response. Please let me know if I may be of further assistance or if I can clarify any aspects of this letter.

Yours sincerely,



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