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4. 2025/0044/ES - X60M - Tobacco

5.

6. Spain thanks the Hungarian authorities for the submission of their comments on the notified draft Royal Decree. In the interest of greater coordination of tobacco control policies within the European Union, and as part of the joint work in the fight against this epidemic together with the other Member States, the Kingdom of Spain provides below more information regarding the origin, motivation and scope of the content of the measures proposed at national level.

The current factual situation in Spain.

At present, the market for tobacco and related products in Spain is expanding rapidly, with a constant evolution of the existing supply and a significant reach to all types of public through extensive communication and marketing campaigns organised by the companies that manufacture these same. Penetration of these products has thus been observed in a wide range of businesses that make up the market at regional and local level in the sales and services sector that is aimed at the end consumer. This means greater accessibility of the population to these products, in premises frequented on a regular basis in both the entertainment and leisure sectors, as well as food, cosmetics and beauty, press kiosks or generalist bazaars. It is worth mentioning the ease of access to tobacco products and related products, due to the wide variety of hospitality and catering premises throughout the national territory.

According to data provided by the National Institute of Statistics (INE) for the year 2024, Spain has a total of 514,441 hotels and restaurants, placing the country at the top of the offer available within the European Union (Premises per Autonomous Community, main activity (CNAE groups 2009). Grossing up sub-headings 56, Food and beverage services, sub-heading 561, Restaurants and food stalls, and sub-heading 563, Beverage establishments

https://www.ine.es/jaxiT3/Tabla.htm?t=294&L=0.

In this regard, according to Eurostat data 2022 for the number of companies dedicated to food and accommodation services (NACE Section I: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Businesses_in_the_accommodation_and_food_services_sector), Spain ranks second with a total of 296.3 compared with 329.1 in Italy or 288.9 in France, which ranks third (figures in thousands).

On the other hand, the legislation currently in force in Spain has significant shortcomings, as there has been no comprehensive update adapted to the national situation for more than 15 years, since the adoption of Law 42/2010 of 30 December and Royal Decree 639/2010 of 14 May. Since then, in the field of tobacco and related products, only Directive 2014/40/EU was transposed in 2017 into Royal Decree 579/2017 of 9 June, which is in the process of being updated. This transposition was carried out in a strictly literal way, adhering exclusively to the content of European legislation, without introducing additional adaptations into the national framework. The same occurred recently, in 2024, with the transposition of Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 into Royal Decree 47/2024 amending Royal Decree 579/2017.

This means that, after more than a decade without revising the regulations, together with the circumstance of the current enormous dynamism of the tobacco and related products market, the national legislation is significantly out of date and urgently needs updating due to its lack of adaptation to the current situation of the tobacco and related products market in Spain.

It should be noted that the lack of adapted regulation of products with mixed characteristics, with or without the presence of tobacco or nicotine, has led to these being placed on the market without being evaluated by the authorities or having the relevant health safeguards in place, which places at risk the health of the consumer, as well as their access to reliable information and a realistic perception of these same. This is also the case for nicotine-free electronic cigarettes, nicotine pouches and heated herbal products. The notified draft Royal Decree aims to resolve the problems arising from this situation by establishing a series of health requirements and obligations that are necessary for the correct control and inspection of these products.

This situation of widespread access, inadequate regulation or deregulatory practice, as the case may be, has resulted in an increase in consumption and thus poses a serious harm to public health and that requires urgent action at national level, especially given the absence at European level of an updated regulatory framework. Likewise, the lack of regulation has given the population a false sense of security and perception of risk of these new products, and has facilitated the access to tobacco and related products by sections of the population that are vulnerable such as children and adolescents.

Data on the prevalence of the consumption of tobacco and related products in Spain is available through the official health surveys:

First of all, there are several updated studies in Spain concerning the starting age of consumption.

According to the survey on drug use in secondary education in Spain (ESTUDES) of 2023 (https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/ESTUDES_2023_Informe.pdf), carried out on students between 14 and 18 years, the starting age in tobacco use is 14.1 years (14.1 for girls and 14.1 for boys). Whereas the starting age of daily tobacco use is 14.6 years (14.6 in girls and 14.7 in boys). However, on expanding the target population of the survey, as was done in the pilot survey on the use of drugs and addictions in secondary school students aged 12 and 13 years old in Year 1 and 2 of ESO (Secondary Education) in Spain (pilot study ESTUDES 2023, https://pnsd.sanidad.gob.es/profesionales/publicaciones/catalogo/catalogoPNSD/publicaciones/pdf/2023_OEDA_InformePilotoESTUDES_1y2_ESO.pdf), we see that the starting age falls to 11.8 for boys and 11.9 for girls, while daily consumption starts at 11.5 for boys and 12.2 for girls on average. That is, the average starting age of consumption goes down when

we lower the age cut of the population group surveyed. If we were to further lower the age range of respondents, there is the possibility that this figure would go down even further. In the case of ESTUDES, the trend in the starting age of consumption remains stagnant. Since records were started in 1996, the starting age of consumption has risen from 13.9 to 14.1 years in 2023 and the starting age of daily consumption remains constant between the two records at around 14.6 years.

On the other hand, in the study Health Behaviour in School-aged Children-Spain (HBSC) of 2022 carried out on more than 30,000 secondary school students between the ages of 11 and 18, an early onset in tobacco use (13 years or earlier) was observed at around 11% in 2018 and 2022, thus breaking the downward trend begun in 2002 (https://www.sanidad.gob.es/areas/promocionPrevencion/entornosSaludables/escuela/estudioHBSC/2022/home.htm).
If we look at the data collected in the survey on alcohol and other drugs in Spain (EDADES) 2024 (https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/2024_Informe_EDADES.pdf), whose age range in the participants includes persons aged between 15 and 64, we see that the starting age in tobacco consumption identified in this study is 16.6 years and for daily consumption it is 18.5 years. The trend of the study has remained constant over the last decades, since in 1997 the starting age of consumption (sporadic and daily) stood at 16.5 years and in 2011 the data stood at 18.5 years.

In relation to the prevalence of tobacco use in the general population, looking at historical data from the National Health Survey in Spain of 2017 (ENSE, https://www.sanidad.gob.es/estadEstudios/estadisticas/encuestaNacional/encuestaNac2017/ENSE17_pres_web.pdf) and the European Health Survey in Spain 2020 (EESE, https://www.sanidad.gob.es/estadEstudios/estadisticas/EncuestaEuropea/Enc_Eur_Salud_en_Esp_2020_datos.htm), both surveys in a population aged between 15 and 99 years, we see that there is a gradual decrease, going from 38.35% in 1987 (55.2% men and 22.93% in women), to 25.35% in 2014 (30.43% in men and 20.50% in women). It is observed that this decrease is more pronounced in men than it is in women, although men started from a situation of greater prevalence. But from 2014 it enters a period of stabilisation where the decline stagnates, with a fall of just 5% in a decade.

According to the EDADES 2024 survey, a similar pattern exists in the decline in tobacco consumption. Going down from a 46.8 % prevalence of tobacco use in persons aged 15 to 64 in 1997 (55.0 % for men and 38.7 % for women) to 40 % in 2011 (44.8 % for men and 37.0 % for women). Thereafter, the decline stagnated at 39.0 % in 2022. That being said, the last study in 2024 showed a significant decrease and placed the prevalence of current consumption at 36.8% (40.9% men and 32.7% women).
In both cases, it is noted that comprehensive regulatory amendments are necessary in order to protect the younger population group that still maintains consumption in the current context.

Focusing on the prevalence of tobacco use in the earliest age segments, the ESTUDES 1994 starting with a survey that detected an alarming level of 60.6 % in secondary school students aged 14 to 18 (56.6 % for boys and 65.1 % for girls), while in the ESTUDES 2023 it was 33.4 % (30.0 % for boys and 36.8 % for girls). In this case, there has therefore been a gradual and continuous decline in consumption of 27 percentage points in 30 years. As we will see below, the reason why the decline in prevalence in this age group has not stagnated in recent years is due to the fact that they have moved onto emerging forms of consumption, such as electronic cigarettes.

On the other hand, the 2022 HBSC Study (https://www.sanidad.gob.es/areas/promocionPrevencion/entornosSaludables/escuela/estudioHBSC/2022/home.htm) found that 4.8 % of adolescents aged 11-18 in Spain smoke cigarettes on a daily basis, with 13.3 % already smoking cigarettes at 17-18 years (14 % girls and 12.2 % boys), indicating a necessity to improve public health interventions to protect this population group. In fact, although daily tobacco consumption decreased by one third from 2002 (14.7%) to 2022 (4.8%), a stabilisation has been detected in recent years both in the sample overall and in the specific groups differentiated by sex, age and family purchasing capacity. It is also of concern that in recent years there has been an increase in consumption in girls (5.3% in 2022 compared to 4.1% in 2018) and in the 17-18 year-old group (13.3% in 2022 compared to 11.1% in 2018).

It is also interesting to note that, as these data show, the prevalence of tobacco use in adolescents is higher in girls than in boys. This is related to the later incorporation of women into tobacco consumption, which meant that women were located in the third phase of the epidemiological smoking model, as well as specific marketing strategies that were aimed at the female gender.
Likewise, we continue to detect a social gradient in tobacco consumption in adolescents, such that the prevalence of daily tobacco consumption is 6.4% in families with a low level of purchasing power compared to 3.9% in adolescents who have families with a high level of purchasing power.

The design of policies with structural and regulatory measures will therefore also be beneficial for reducing health inequalities and for minimising the gender impact on the smoking epidemic, which, as indicated in previous consumption prevalence data, should be particularly addressed in the young and female population groups using measures that aim to reduce the attractiveness of these new devices and products, given that the vast majority of these same have been designed with colours, forms, and specially designed aromas and flavours, which are aimed at attracting these population groups.

As for electronic cigarettes, we see that in recent years the consumption of these products among younger people is on the rise. The ESTUDES 2023 survey found that 55% of secondary school students had at some point tried electronic cigarettes. Among these, the majority said they had used them with nicotine-free cartridges (60.7 %), 14.9 % had done so with nicotine and the remaining 24.4 % had used cartridges or liquids of the two types. However, a slight decrease in the trend was observed in the 2021 survey (https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/ESTUDES_2022_Informe.pdf) probably due to the epidemiological situation arising from COVID-19, which lead to a bias in the data. In the update of the 2023 survey, following the end of the COVID-19 pandemic, a strong rebound was observed in all consumption patterns. Meanwhile, among the general population more than 10% say that they have used them at some point in their life, which is a much lower percentage than secondary school students. The problem is that, following the historical series of the ESTUDES survey, it is observed that the consumption of these products doubled between 2015 and 2022, rising from 20.1% to 54.6% in secondary school students who had consumed electronic cigarettes at least once in their lives.

Tobacco-related products such as electronic cigarettes or nicotine pouches are regarded to be a point of entry to the consumption of other tobacco products. As scientific evidence has shown on numerous occasions, this implies a serious public health problem that requires particular attention at the moment of improving the current regulation of these devices. Camouflaged under the appearance of harmless and attractive colours and shapes, they contribute to normalising and initiating young people into nicotine consumption, thereby elevating the risk of long-term addiction (Adermark, L., Galanti, M.R., Ryk, Ch., Gilljam, H., Hedman, L., (2020) Prospective association between use of electronic cigarettes and use of conventional cigarettes: a systematic review and meta-analysis. ERJ Open Research 2021 7 (3): 00976-2020; DOI: https://doi.org/10.1183/23120541.00976-2020 ; Plurphanswat, N., Hughes, J. R., Fagerström, K., & Rodu, B. (2020). Initial Information on a Novel Nicotine Product. The American journal on addictions, 29(4), 279–286. https://doi.org/10.1111/ajad.13020).

In addition, electronic cigarettes may contain chemical substances that are hazardous to health, as well as heavy metals issuing from resistances and batteries. An illness associated with the use of electronic cigarettes, EVALI (E-cigarette, or Vaping, product use Associated Lung Injury), has also been described, which causes acute lung damage and may be related to multiple causes. All this supports the fact that regulating tobacco-related products facilitates the monitoring of risks associated with their consumption.
For the most novel products (nicotine pouches, heated herbs, etc.) that have recently been launched on the market, consumption data from population surveys in Spain or in Europe or historical data are not yet available due to the fact that they are new products. The evidence of its increase is based, inter alia, on studies such as those from the United States that show alarming data on the dual use of tobacco and other products, as well as other national and international studies that show the increase in problems due to the dual use of tobacco and electronic cigarettes. (Adriaens, K., Van Gucht, D. y Baeyens, F. (2017). Differences between dual users and switchers center around vaping behavior and its experiences rather than beliefs and attitudes. International Journal of Environmental Research and Public Health, 15(1). https://doi.org/10.3390/ijerph15010012 ; Coleman, S. R. M., Piper, M. E., Byron, M. J. y Bold, K. W. (2022). Dual use of

combustible cigarettes and e-cigarettes: A narrative review of current evidence. Current Addiction Reports, 9(4), 353–362. https://doi.org/10.1007/s40429-022-00448-1 ; Ayesta, J., Peruga, A., Rebollar,et al (2024). What does Harm Reduction in Tobacco Use means to Public Health. Spanish Journal of Public Health, 98, e202405037)

Likewise, it is observed that there has been a considerable increase in the points of sale where these products are sold, which have gone from zero to thousands (government approved tobacco shops stores, petrol stations, specialised shops, among others), as well as the promotion and advertising of these products across all possible media such as social networks, public events, etc. In terms of consumption patterns it has also been observed that these products are consumed in smoke-free places where tobacco is no longer consumed, and so now all of these new alternatives are being consumed in contravention of the regulations regarding the areas where smoking is prohibited. Likewise, the market studies carried out by the industry itself show alarming forecasts in growth, and even more so in the absence of clear regulation of new nicotine products (Spanish market for nicotine pouches: by type, by nicotine content, by category, by consumer group, by distribution channel - Forecast, 2025-2034 https://www.gminsights.com/es/industry-analysis/spain-nicotine-pouches-market).
Likewise, the 2022 HBSC study detected that 12.1% of adolescents between 11-18 years of age have consumed electronic cigarettes at some point in their lives, and that this consumption increases with age, reaching 18.8% in the 17-18 age group (20.6% in girls, and 18.9% in boys).
In response to these data, especially among the population sectors of minors and young people, Spain is working on the control and prevention of consumption not only of tobacco products, but also of new related products.
Thus, in April 2024, the Comprehensive Plan for the Prevention and Control of Tobacco 2024-2027 was approved, which establishes the strategic lines, objectives and goals to be carried out during the coming years.
Specifically, the measure presented as a legislative amendment is part of the development of 1 of its 5 targets, namely ‘Target 1. Prevent the start of tobacco and related product consumption”. Thus, as part of that target and the Legislative Strategy agreed upon in this regard with all related sectors at national level, the Plan specifically sets out the following:
• Regulate the sale and consumption of tobacco-related products.
• Prohibition of additives conferring flavourings in tobacco and related products.
The Member States that wish to analyse and study further the content of the approved Comprehensive Plan can do so through the link published in the corresponding section of the website of the Spanish Ministry of Health (https://www.sanidad.gob.es/areas/promocionPrevencion/tabaco/legislacionAcuerdosDenuncia/docs/planIntegralPrevencionyControlTabaquismo(PIT)2024_2027.pdf)
It should be noted that the Plan has been agreed between various social, administrative, and scientific sectors and, in line with what was expressed in this response, entails the need to introduce various improvements that are not yet contemplated in the harmonised regulations of the Union, due to the significant changes experienced both at epidemiological level and in consumption patterns, as well as in the current configuration of the market for tobacco products and related products in our country.

Justification of the need to update the standard.
In conclusion, justification for the need to update Royal Decree 579/2017, as part of the fight against smoking in Spain, is based on the evolution of tobacco products and related products and the need to strengthen measures for protecting public health, especially that of young people.

The protection of public health constitutes one of the priority general interests within the legal order of the European Union. In particular, Article 168 TFEU gives Member States the power to adopt national measures in this area, provided that they are proportionate, non-discriminatory and duly justified.

The measures introduced in the update of the Spanish regulation comply with the justification criteria imposed by EU legislation (Articles 36 and 168 of the Treaty on the Functioning of the European Union (TFEU)) that permits derogations from Articles 34 and 35 TFEU and permits, on the grounds of public health, national measures that are proportionate, non-discriminatory and justified.

Likewise, the proposal for a Royal Decree is aligned with the European directives and does not contradict them, but

complements them and in some cases is more restrictive, something that is permitted. Its primary objective is the protection of public health and the measures are considered proportionate to the goal pursued, since they seek to restrict the consumption of tobacco and related products, prevent their initiation, especially in vulnerable groups such as in minors and young people, and improve availability of information for consumers, especially regarding those novel products that have a growing presence on the market and that lack any harmonised regulatory framework at European level. All this with the ultimate aim of protecting public health, and the appearance of illnesses associated with the use and abuse of these products. In order to clarify the proportionality of the project, it should be noted that, as a result of the process of drafting the Comprehensive Plan mentioned above, the measures proposed result from the arduous work of evaluation, analysis and study carried out during the drafting of this Plan. This work involved the technical participation of the Group of Experts on Smoking in coordination between the Autonomous Communities and the Ministry of Health. In addition, the measures included in the Plan have been scientifically endorsed by the various health societies and related entities at national level, which have participated in drawing up the Plan together with all the ministerial departments related to the matter. Thus, in the various technical meetings held in advance, and in the drafting of the multiple drafts of the Plan, the measures necessary to combat the tobacco epidemic in Spain were identified, together with the different alternatives available ranging from the least restrictive to the most far-reaching. Finally, it is worth mentioning that the final text, published in the link provided in this reply, had the analysis and assessment of proportionality carried out by the technical services of the Council of Ministers, the first-level institutional body in the Government of the Kingdom of Spain, which proceeded with its approval, on the joint proposal of the Minister of Health and the Minister of Finance at the meeting of 30 April 2024.

In addition, at international level, the health sector points out the necessity to make advances in the regulatory regulation of tobacco and related products in order to adapt it to the evolution of the market and protect the health of the population, both for the health of children and adolescents and to be an essential line of action in the prevention of non-communicable illnesses.
In this regard, ahead of the Summit of the Parties to the Framework Convention on Tobacco Control COP 10 held in Panama in February 2024, the EU Member States prepared a common position paper to bring to COP10, during Spain's Presidency of the Council of the EU, in which it was agreed as a common position, a number of points regarding the necessary rigorous regulation of all novel tobacco-related products, disposable electronic cigarettes with and without nicotine, as well as nicotine sachets and other non-tobacco nicotine products, which could also include their prohibition, especially in the interest of protecting children and adolescents, in addition to their regular monitoring in the future. It also includes the necessary review and regulation of the sweeteners, additives and flavourings that make these products attractive and thus increase their addictiveness. It is considered important to rigorously regulate and continuously monitor the consumption of new and emerging tobacco products, including the novel and emerging tobacco products, especially by young people, given the worrying trends in popularity in this age group and among non-smokers. This document (Interinstitutional File: 2023/0313(NLE)), was classified as LIMITE and is therefore not available to the general public, but this document is available to Member States for consultation. (WHO Framework Convention on Tobacco Control (FCTC) – Tenth session of the Conference of parties (COP10) a) Council Decision on the positions to be taken on behalf of the European Union at the tenth session of the Conference of the Parties to the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) - Adoption b) Union positions and common positions – Approval. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=consil:ST_14761_2023_REV_1)

Finally, at the COP10 Summit of the Parties (https://fctc.who.int/resources/publications/i/item/fctc-cop10(26)-report-of-the-tenth-session-of-the-conference-of-the-parties-to-the-who-framework-convention-on-tobacco-control), the signatories agreed, through the common position advocated by the EU, by means of the above-mentioned document, to apply to novel products (ENDS (electronic cigarettes), HTP (Heated Tobacco Products) and nicotine pouches) the same regulatory framework that already covers traditional cigarettes. This includes all the provisions of the FCTC convention, such as labelling with health warnings, taxes, advertising restrictions or prohibition of their use in public spaces. It was suggested that the countries consider the total or restrictive prohibition of these products, the prohibition of flavours that attract young people, the restriction or prohibition of commercial marketing, as well as the strict control or prohibition of disposable devices (D ENDS) and nicotine pouches, with emphasis on their environmental impact and use by adolescents.
Spain participates actively in various Joint Actions, including the one on tobacco control, which establishes spaces for

collaboration and exchange of information between participating Member States on the regulation of devices not covered by the Tobacco Products Directive (TPD) (Directive 2014/40/EU). Based on this cooperation, various progress reports have been drawn up that analyse the evolution and characteristics of the new related products that have been emerging on the market.

In addition, Spain is part of the JA Prevent Non-Communicable Diseases and Cancer, where various activities are developed, such as Work Package 5 (WP5) that is focused on strengthening fiscal and regulatory policies against the main risk factors of non-communicable diseases. In the field of tobacco and related products, this joint action contributes to the comparative analysis of legislative frameworks, the development of fiscal measures that promote healthier behaviours, and supports the implementation of policies to reduce the impact of harmful marketing. This participation makes it possible to share good practices at European level and strengthen national tobacco control strategies not only for conventional products, but for all those new products that may pose a risk to health and nicotine addiction (Report-on-regulation-of-novel-tobacco-products-and-e-cigarettes-in-different-EU-Member-States.pdf https://jaotc.eu/wp-content/uploads/2023/10/D7.1 ; JA Prevent NCD. Work Package 05: Fiscal and regulatory policies. https://preventncd.eu/work-packages/wp-05/).

1. Regarding the violation of the principle of free movement of goods and the situation of nicotine pouches in other Member States

Regulation of the limit of nicotine content in nicotine pouches is a health measure that has taken account of the potential toxic and addictive effects on people that this substance exerts and of which there is ample scientific evidence in this regard. This toxic and addictive potential is why the limitation of this substance for the protection of public health underpins the application of Article 36 TFEU “The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or transit that are justified on the grounds of public policy, public morality and public security, the protection of health and life of humans and animals, the preservation of plants, the protection of national artistic, historical or archaeological heritage or the protection of industrial and commercial property”. The application of the limits included in the proposal, which will be evidenced below, is therefore justified.

Regardless of the system of administration, nicotine has impacts on health that are well-documented. They include increased heart rate and blood pressure, which can contribute to atherosclerosis, and to neurotoxic damage to the developing adolescent brain that can alter the circuits that control attention, learning, and mood. Nicotine is also a well-known reproductive toxicant that is harmful to the developing foetus. While not classified as a carcinogen by the International Agency for Research on Cancer (IARC), some research suggests it may act as a tumour promoter.
The Spanish authorities, in the exercise of their powers in the field of public health protection, have considered it appropriate to establish a maximum limit of 0.99 mg of nicotine per pouch. This decision has been based on technical, scientific and regulatory criteria, in application of the precautionary principle (Article 191 TFEU) and in line with existing health legislation.

Spain recognises the need to act with caution, in the face of a product that has appeared recently, where the scientific evidence is limited and where there is no history of use that allows its effects over the medium and long term to be evaluated. Notwithstanding, various studies have shown the significant risks of toxicity and addiction associated with the use of nicotine pouches. In turn, European entities such as the European Chemicals Agency and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on the classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, classify nicotine as acutely toxic at inhalation, oral and dermal level (H330, H310 and H300).

The toxicity and addiction generated by nicotine has been documented in various scientific studies. Research such as that of Lunell et al. (2020) has shown that the use of pouches with 6 mg of nicotine leads to significant increases in heart rate (up to 10.5 beats per minute) and plasma nicotine levels similar to those of snus, which evidences its immediate physiological impact (Lunell E, Fagerström K, Hughes J, Pendill R. Pharmacokinetic Comparison of a Novel Non-tobacco-Based Nicotine Pouch (ZYN) With Conventional, Tobacco-Based Swedish Snus and American Moist Snuff. Nicotine Tob

Res. 2020 Oct 8;22(10):1757-1763https://doi.org/10.1093/ntr/ntaa068).
For their part, McEwan et al. (2022) observed that with concentrations of 6 to 10 mg, plasma peaks similar to those recorded after the consumption of a traditional cigarette were reached, reinforcing its ability to generate dependence (McEwan, M., Azzopardi, D., Gale, N., Camacho, O. M., Hardie, G., Fearon, I. M., & Murphy, J. (2022). A Randomised Study to Investigate the Nicotine Pharmacokinetics of Oral Nicotine Pouches and a Combustible Cigarette. European journal of drug metabolism and pharmacokinetics, 47(2), 211–221. https://doi.org/10.1007/s13318-021-00742-9).
However, even products with lower doses have shown that these products are not risk-free, since nicotine elevates cardiovascular risk, particularly in young people and in people with genetic predisposition (Benowitz, N. L., & Burbank, A. D. (2016). Cardiovascular toxicity of nicotine: Implications for electronic cigarette use. Trends in cardiovascular medicine, 26(6), 515–523. https://doi.org/10.1016/j.tcm.2016.03.001).
In addition, clinical cases of acute toxicity have been described, such as that of a 21-year-old non-smoker who required hospital admission for consuming 15 nicotine pouches of 10.9 mg per pouch in a 12-hour period as a study tool for preparing for an examination the following day (Kent, J. T., Mok, G., & Austin, E. (2025)). Nicotine Toxicity From Repeat Use of Nicotine Pouches. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco, 27(4), 767–768. https://doi.org/10.1093/ntr/ntae111).
From a public health perspective, the use of these products among adolescents and young people is an increasing cause for concern, due to their high content in free nicotine and their attractive presentation (Stanfill, S., Tran, H., Tyx, R., et al (2021). Characterization of Total and Unprotonated (Free) Nicotine Content of Nicotine Pouch Products. Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco, 23(9), 1590–1596. https://doi.org/10.1093/ntr/ntab030).
Various studies have indicated that these products are particularly attractive to young people and dual users, and can favour an escalation in consumption and initiation in non-smokers (Plurphanswat, N., Hughes, J. R., Fagerström, K., & Rodu, B. (2020). Initial Information on a Novel Nicotine Product. The American journal on addictions, 29(4), 279–286. https://doi.org/10.1111/ajad.13020).
Although they are marketed as ‘lower risk’ alternatives to conventional tobacco, recent analyses have detected in some of these nicotine pouches the presence of potentially toxic compounds, including Tobacco-Specific NitrosAmines (TSNA), which are known for their carcinogenicity (Mallock N, Schulz T, Malke S, et al. Levels of nicotine and tobacco-specific nitrosamines in oral nicotine pouches). Tobacco Control 2024;33:193-199. https://tobaccocontrol.bmj.com/content/tobaccocontrol/33/2/193.full.pdf).

Overall, current scientific evidence leads to the conclusion that nicotine pouches, especially in the absence of regulation, present a real risk of acute toxicity, exposure to carcinogenic compounds and a high addictive potential. These findings fully justify the need to set strict limits on their composition, dosing and marketing.

Spain is not the only Member State to advocate limitation of these products that are currently on the market without any kind of health regulation. In this context, we consider it important to also look at the experience of countries such as France, the Netherlands, Belgium, Germany, Denmark, Lithuania, Latvia and Norway, which have adopted restrictive or directly prohibitive approaches on these products.

France, like Spain, is in the comments phase of the TRIS procedure of its Regulatory Decree submitted on 24 February 2025 (TRIS/(2025)0538). This decree proposal provides for: “a ban on products for oral use containing nicotine, particularly in the form of sachet portions or porous sachets, paste, pellets, liquids, chewing gum, lozenges, strips or any combination of these forms”. In addition to that, the following is noted: “The draft decree defines products for oral use containing nicotine that are intended for human consumption by ingestion or absorption, in particular in the form of sachet portions or porous sachets, paste, sweets, pellets, liquids, chewing gum, lozenges, strips or any combination of these forms. It specifies that these products are subject to a prohibition throughout the national territory, insofar as they are intended for the French market in the relevant metropolitan and overseas territories, with regard to their production, manufacture, transport, import, export, possession, offer, transfer or acquisition, as well as their distribution and use”. The text provides for an exception to this prohibition for medicinal products and raw materials for pharmaceutical use.
In the Netherlands (Rijksinstituut voor Volksgezondheid en Milieu/Ministerie van Volksgezondheid, Welzijn en Sport), since 1st January 2025 these products have been included within the scope of the Tobacco and Tobacco Products Act by establishing their complete prohibition from that date. Previously, the nicotine limit content per pouch had been set at a

maximum of 0.035 mg. In addition, the Netherlands has even limited the places where these products can be consumed, due to the harm they can cause.
Belgium, which is at the forefront of the regulation of these products, was the first country to ban nicotine pouches. This measure was approved in October 2023, this prohibiton being justified not only due to the toxicity of these products, but also due to the fact that they represent a point of entry into the consumption of tobacco and other related products.
Germany has regulations that take a different line than the rest of the Member States with regard to the classification of this type of product, since it considers them to be food products (novel food). Although it does not set a specific limit at regulatory level for nicotine content, the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung - BfR) prepared a report in 2022 on the risk assessment of nicotine pouches (described below) (Bundesinstitut für Risikobewertung. (2022). Health Risk Assessment of Nicotine Pouches: Updated BfR Opinion No. 023/2022 of 7 October 2022. In BfR-Stellungnahmen (Vol. 2022, Issue 23). Bundesinst. für Risikobewertung. https://doi.org/10.17590/20220204-105615).
Among the Nordic countries, Denmark for its part notified the rest of the Member States through the Ministry of the Interior and Health of the entry into force on 1st April 2025 of the limitation of the nicotine concentration in nicotine pouches to 9.0 mg. The full application of this threshold is forecast for the year 2026. Regarding Norway, although it does not allow the sale of these products, it has no specific limitation in place.

In the Baltic countries, Lithuania has banned Nicotine Pouches since 2024 and the limit of 4 mg of maximum nicotine content has been established in Latvia since January 2025.
It is worth mentioning that many EU/EEA Member States have adopted not only strict tax measures to discourage the consumption of these products, but also health warnings to inform about the danger of consuming these products.
From Spain´s perspective, and with full respect for the diversity of regulatory approaches within the European Union, we wish to reiterate our willingness to cooperate and engage in dialogue in the search for common regulatory frameworks that guarantee the protection of health, especially of minors, non-smokers or those with cardiovascular diseases.
In the absence of a harmonised framework in the EU for these devices, numerous proposals for their national regulation have been examine based on studies, contributions from civil society, scientific and patient societies, entities of health professionals, etc. that were collected following the periods of consultation, hearing and public information of national procedures. After a long debate, it was determined that, given the characteristics of these products, the intended use and the potential risk to human health, these products should be regulated and limited. The setting of the limit of 0.99 mg/pouch in Spain is based on a technical criterion, consistent with the existing health regulations.
The limit proposed by Spain takes as a reference the existence of nicotine release presentations covered by what is known as ‘Nicotine Replacement Therapy (NRT)’ and that is authorised as medicinal products by national procedure. These products, most with nicotine in the form of nicotine bitartrate dihydrate, have been authorised for placement on the market after receiving a favourable opinion from the relevant expert committees regarding their risk and benefit following submission of data on efficacy, safety and quality. In addition, as indicated in their technical data sheets, they are authorised for the following indication: “Treatment for tobacco dependence by providing relief from nicotine withdrawal symptoms, including anxiety in nicotine dependence as an aid to quitting smoking or achieving a progressive reduction in tobacco use in smokers who are motivated to quit smoking. The permanent abandonment of smoking is the ultimate goal.” Among the medications authorised in Spain as oral NRT are 1 mg, 2 mg, and 4 mg lozenges, 2 mg and 4 mg chewing gum, and 1 mg oral spray. Technical sheet Nicotinell Mint 1 mg lozenges. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/63795/FT_63795.html ; Technical sheet Nicotinell Mint 2 mg lozenges. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/65407/FT_65407.html ; Technical sheet NiQuitin 4 mg lozenges. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/70554/FT_70554.html ; Technical Sheet Nicotinell Fruit 2 mg medicated chewing gum. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/65587/FT_65587.html ; Technical Sheet Nicotinell Fruit 4 mg chewing gum. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/65586/FT_65586.html ; Technical sheet Nicorette BuComist 1 mg/pulsed oral spray solution. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/76185/FT_76185.html ; Royal Legislative Decree 1/2015 of 24 July approving the consolidated text of the Law on guarantees and rational use of medicines and medical devices. (2015). ‘BOE’ (Official State Gazette) No 177 of 25 July 2015. Available at: https://www.boe.es/buscar/pdf/2015/BOE-A-2015-8343-consolidado.pdf).

Given that nicotine pouches are, according to their definition proposed in the draft Royal Decree, “a product for oral use

without tobacco, composed wholly or partly of synthetic or natural nicotine, mixed with vegetable fibres or an equivalent substrate, and presented in the form of powder, fibres, particles or paste, or a combination of these forms, in single-dose sachets, porous envelopes, tablets or in equivalent form, without being intended for smoking", and considering the possible similarity in terms of route of administration and nicotine content, their recreational use should in no case exceed the amounts of nicotine present in the authorised medicinal products mentioned above.
The non-regulation and control of these products poses a public health risk since, in the Technical Sheet of these medicinal products used for NRT, not only are there laid down a series of precautionary measures to be taken into account, but warning is given on the risks of misuse or overdose of the same. This control in NRT can be carried out since they are medicinal products that are sold in pharmacies with the corresponding control by pharmaceutical staff, where the risks of consumption are warned about, and where the guidelines for use prescribed by optional staff are established. Since, in the case of nicotine pouches, this pharmaceutical control is not going to be carried out, it is urgent to establish a limit that is lower than in NRT, in particular for the authorised product with the lowest dose that corresponds to 1 mg lozenges.
Since nicotine pouches are small in size, it is also necessary to establish a low nicotine limit (in our case 0.99 mg) since overdose can, in the case of young children, be fatal. According to the Technical Sheet of the medicines authorised for TSN themselves, in the case of adults as well as heart conditions that may be severe or very serious in people with pathologies, there may be effects of weakness, sweating, pallidity, hyperhydrosis, salivation, burning in the throat, nausea, vomiting, diarrhoea, abdominal pain, impaired sight and ears, headache, tachycardia, cardiac arrhythmia, dyspnoea, dizziness, temblours, confusion and asthenia. In addition, in severe conditions hypotension, circulatory collapse, coma, respiratory failure and terminal seizures may occur.

Among other less restrictive measures envisaged, the following scenarios were considered, which were rejected for the reasons below:
• Establish a nicotine dose limit of 20 mg/bag to match electronic cigarettes: from Spain it was considered that nicotine doses cannot be comparable between nicotine bags and electronic cigarettes (limits set by the TPD of 20 mg/ml) for various reasons. The forms of presentation are not similar. While nicotine pouches are solid forms whose main absorption of nicotine is oral and sublingual and where in addition a sustained release has not been demonstrated, in electronic cigarettes with a concentration of 20 mg/ml (40 mg content in the total of 2 ml) in the approximately 600-800 puffs around 0.05 and 0.07 mg are released in each inhalation (inhalation route). Therefore, at the same dose, the release of nicotine in nicotine pouches is acute, with a higher risk of toxicity, compared to the same dose of nicotine in electronic cigarettes, where the release is lower, fractionated, and part is exhaled. This dose limit was therefore discarded.

• Set nicotine dose limit of 16.6 mg/pouch, as suggested by the German Federal Institute for Risk Assessment (BfR), since that dose of 16.6 mg of nicotine per pouch could resemble the average nicotine exposure when smoking a tobacco cigarette. However, this same report recognises that at least 50 % of the nicotine in the pouch is rapidly absorbed by the oral mucosa, generating plasma concentrations that in some cases exceed those of cigarette consumption, especially in nicotine pouches with higher doses (Bundesinstitut für Risikobewertung. (2022). Health Risk Assessment of Nicotine Pouches: Updated BfR Opinion No. 023/2022 of 7 October 2022. In BfR-Stellungnahmen (Vol. 2022, Issue 23). Bundesinst. für Risikobewertung. https://doi.org/10.17590/20220204-105615). The rate of absorption and the consequent rapid increase in blood nicotine levels are key factors in the addictive potential of these presentations, a risk that is particularly concerning when the products are designed with attractive flavours and are aimed at a young public.

Additionally, this study is based on a theoretical calculation extrapolated from a 30 mg product, assuming a similar absorption, which we believe would not accurately represent the variability between products and users. In addition, it focuses exclusively on the acute toxicity of nicotine, without taking into account the effects of prolonged use or individual differences in sensitivity and metabolisation of the substance.

Finally, a particularly relevant fact from the BfR report is that more than half of the pouches analysed contained tobacco-specific nitrosamines, which are genotoxic carcinogens recognised by the International Agency for Research on Cancer (IARC) and in the database of the European Chemicals Agency (ECHA) where they are proposed as Carcinogenic 1B H350. The presence of these substances in products not containing tobacco directly demonstrates a lack of control in the purity and quality in recreational products that have not been subjected to pharmaceutical requirements.

• Set a nicotine dose limit of 4 mg/bag, coinciding with the maximum authorised dose for nicotine gums used as nicotine replacement therapy medicinal products and with the threshold adopted by countries such as Latvia. However, it should be noted that the effective release of nicotine in chewing gum is considerably lower than in nicotine pouches, due to differences in formulation and absorption kinetics. (Azzopardi, D., Ebajemito, J., McEwan, M., et al (2022). A randomised study to assess the nicotine pharmacokinetics of an oral nicotine pouch and two nicotine replacement therapy products. Scientific reports, 12 (1), 6949. https://doi.org/10.1038/s41598-022-10544-x). Therefore, this option also does not provide objective certainty against the threshold finally proposed.
In parallel, more restrictive measures, including a total ban, were also assessed, as already implemented by countries such as France, Belgium, the Netherlands and Norway. However, the measure considered to be the most proportionate and justified was established on the basis of the Spanish and European legal and health framework, and the known risks.

In short, while Article 34 TFEU prohibits restrictions on the free movement of goods within the internal market, Article 36 permits exceptions where they are based on the protection of public health. The provisions of the draft Royal Decree respond to this exception: they are based on legitimate reasons, are adequate to prevent initiation of consumption and nicotine dependence among vulnerable groups, and do not introduce covert discrimination or disproportionate restrictions on trade.

2. Failure to comply with the proportionality criterion and the criteria for justified public interest objectives, as well as the use of less restrictive measures

The proposed regulatory framework pursues a legitimate objective of protecting public health in line with Article 168 TFEU and the proposed measures are considered proportionate, non-discriminatory and justified. In the absence of European-level harmonisation for this product category, it is up to Member States to adopt appropriate measures in this area, in line with the jurisprudence of the Court of Justice of the European Union.
The proposed provisions, including requirements for notification, labelling, packaging, limits on certain substances, and quality control, respond to the precautionary principle and seek to provide consumers with clear, truthful, and consistent information about products that may have health implications, especially among young people and non-smokers.

The proposed regulations have been designed in a proportionate manner, following a regulatory impact analysis and under consideration of alternative measures. The obligations imposed are comparable to those already in force for products with a similar profile (such as electronic cigarettes or heated tobacco products, or new ones such as nicotine pouches), and do not constitute a marketing ban, but rather a reasonable regulation aimed at ensuring safe and fair market conditions.

Regardless of the system of administration, nicotine has impacts on health that are well-documented. They include increased heart rate and blood pressure, which can contribute to atherosclerosis and neurotoxic damage to the developing adolescent brain, which can alter the circuits that control attention, learning, and mood.
Nicotine is also a well-known reproductive toxicant that is harmful to the developing foetus. Although it is not classified as a carcinogen by the IARC, some research suggests that it may act as a tumour promoter.

Furthermore, scientific evidence points to the danger of new forms of consumption. All of these studies reflect the health risks of these devices, especially at the pulmonary and cardiovascular levels, even over short-term use, to which EVALI is added.

From a strict public health advocacy perspective, focused on preventing youth addiction, banning electronic cigarette flavours is necessary due to the overwhelming evidence that non-tobacco flavours increase the appeal of electronic cigarettes among young people and the finding that partial restrictions may be insufficient, since they simply divert sales to the products that remain without restriction. The clear and significant public health risk posed by widespread juvenile nicotine addiction far outweighs the violation of freedom of choice for adult, especially given that systematic reviews reveal that the evidence that flavours are a crucial tool for smoking cessation in adults is inconclusive.

Regarding nicotine pouches, we can highlight that, due to the considerable amount of evidence on the components of

these pouches, their pharmacokinetic profile and their observed short-term effects, fundamental health warnings regarding the same have been issued by virtually all health organisations, including the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) of the United States. In the U.S., there are insufficient long-term epidemiological data on nicotine pouches.
On the other hand, independent studies have also found that some "tobacco-free" pouches contain potent carcinogens such as tobacco-specific nitrosamines (TSNAs), formaldehyde, and chromium.

Because 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 years to establish. However, absence of evidence of long-term effects does not prove absence of such effects.

Other alternatives evaluated are:

• Education alone is insufficient: While public education campaigns are important, they often struggle to counter the aggressive marketing and inherent appeal of flavoured, high-nicotine products, especially for young people.
• Challenges regarding age verification: While age restrictions are crucial, they are often circumvented (for example, through social selling or online loopholes). Restricting product features (flavours, nicotine) limits supply and reduces their intrinsic appeal, making it harder for young people to become addicted, even if they do buy the products.
• Selective application: While rigorous enforcement of existing regulations is necessary, product-level restrictions constitute a universal barrier.
In other words, even if the alternative measures were less trade-restrictive, there is no evidence that they were as effective in curbing vaping among young people.
For further information and references to the evidence, see Section 1 (Regarding the violation of the principle of free movement of goods and the situation of nicotine pouches in other Member States).

3. Violation of the prohibition of discrimination

Regarding a less regulation of nicotine pouches that is less favourable than the existing one for more harmful products such as conventional tobacco, it is worth mentioning that there is a profound difference between the regulatory regime established for both types of products, as well as a clear difference in the scope of action available to Member States.

Regarding conventional tobacco, there is thus an abundant body of regulations, the fruit of a long historical tradition in terms of regulation, at national, regional European, and international levels. This is completely at odds with the current regulation of nicotine pouches, which lacks a harmonised European standard, and instead features highly dispersed, limited, and even contradictory regulations, given the significant differences between national markets.
Regarding the greater or lesser risk attributable to nicotine pouches compared to other products, the information provided by Eurostat and the OECD only includes data relating to tobacco consumption, and thus cannot perform a comparison with the risk attributable to other products (see section on the current situation in Spain). In this regard, the WHO establishes that nicotine alone is a risk factor, especially for cardiovascular diseases, although not exclusively (https://www.who.int/es/news-room/fact-sheets/detail/tobacco). Furthermore, it is a known toxic substance registered under the European Union's REACH regulations. It is classified as acutely toxic (category 2) after oral, dermal or inhalation exposure and is subject to hazard statements such as “H300: fatal if swallowed”, “H310: fatal in contact with skin” and “H330: fatal if inhaled”, as already explained in Section 1: Regarding the violation of the principle of free movement of goods and the situation of nicotine pouches in other Member States

For all these reasons, and those explained throughout the document, the measures included in the proposed Royal Decree are considered proportional, non-discriminatory and justified for reasons of public health as established in Article 168 of the TFEU and which allow, according to Article 36 of the TFEU, exceptions to the articles

4. Misdefinition of the proposed nicotine limit

The protection of public health is constituted by a fundamental priority of general reconfirmation in EU law. Thus, Article

168 TFEU allows Member States to adopt national measures in this area, provided that such measures are proportionate, non-discriminatory, and duly justified.
In this context, the establishment of a maximum limit of 0.99 mg of nicotine per pouch, as explained in reference to Section 1 (Regarding the violation of the principle of free movement of goods and the situation of nicotine pouches in other Member States), as well as the labelling requirements applicable to new products containing nicotine, fall within this competence.
Its purpose is clear: to effectively protect consumers, especially minors, young people, and non-smokers, from the increasing commercialisation of these products, without specific regulation at the European level.

5. Postponement of the adoption of the draft regulation for 12 months under pending European Union legislation

Unlike other traditional products that are properly regulated and authorised, nicotine pouches are available on the Spanish market without such health regulations. For this reason, it was considered unnecessary to establish a transitional period for its adaptation.

However, in view of the arguments put forward by Hungary and its reasoning in relation to the case-law of the Court of Justice of the European Union, it is considered necessary to recognise the same transitional period laid down for the other products and it will be amended accordingly in the final text of the Royal Decree.

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