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4. 2025/0044/ES - X60M - Tobacco

5.

6. Spain thanks the Croatian 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 proceeds to provide more information regarding the origin, motivation and scope of the content of the measures proposed at national level.

The current factual situation in Spain.

Currently, the market for tobacco and related products in Spain is expanding rapidly, with a constant evolution of the existing supply and significant access to all types of consumers through extensive communication and marketing campaigns organised by the manufacturing companies. Thus, the penetration of these products has been observed in a wide range of businesses that make up the market at regional and local level within the sales and services sector to the final consumer. This means that these products are more accessible to the general public, as they are sold in places that people visit regularly, such as entertainment and leisure venues, food shops, cosmetics and beauty stores, newsagents, and general stores. 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 Statistics Institute (INE) for 2024, Spain has a total of 514,441 hospitality and catering premises, placing the country at the forefront of available supply within the European Union (ref: premises by Autonomous Communities, main activity (CNAE groups 2009). Combined headings 56, Food and beverage services,

heading 561, Restaurants and food stalls, and heading 563, Beverage establishments). https://www.ine.es/jaxiT3/Tabla.htm?t=294&L=0).

In this regard, and according to Eurostat 2022 data on the number of companies engaged in 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, Directive 2014/40/EU was only 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 manner, adhering exclusively to the content of the European regulations, without introducing any additional adaptations to 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.

Therefore, after more than a decade without revising the regulations, together with the circumstance of the current enormous dynamism of the market for tobacco and related products, the national regulations are now greatly outdated and urgently need to be updated due to their failure to adapt to the current situation of the tobacco and related products market in Spain.

It should be noted that the lack of appropriate regulation of products with mixed characteristics, with or without the presence of tobacco or nicotine, has meant that they have been placed on the market without evaluation by the authorities or the relevant health safeguards, putting consumer health at risk, as well as their information and perception in this regard. 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-related requirements and obligations that are necessary for the proper control and inspection of these devices.

This situation of widespread access, inadequate regulation or deregulatory practice, as the case may be, has resulted in an increase in consumption and therefore in serious harm to public health that requires urgent action at national level, in the absence, in addition, of an updated regulatory framework at European level. Likewise, the lack of regulation has facilitated a false sense of security and perception of risk on the part of the population with regard to new products, which in turn has facilitated access to tobacco and related products for vulnerable populations such as children and adolescents.
Prevalence data on the consumption of tobacco and related products in Spain available through official health surveys are provided below:
Firstly, in relation to the starting age of consumption, we have several updated studies in Spain.

According to the survey on drug use in secondary education in Spain (ESTUDES) of 2023 carried out on students between 14 and 18 years old, the age of onset in tobacco use is 14.1 years (14.1 for girls and 14.1 for boys). Meanwhile, the onset of daily tobacco use is 14.6 years (14.6 in girls and 14.7 in boys) (ESTUDES 2023: https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/ESTUDES_2023_Informe.pdf). Furthermore, by expanding the target population of the survey, as done in the pilot survey on drug use and addiction among 12- and 13-year-old secondary school students in the 1st and 2nd years of ESO Compulsory Secondary Education in Spain, (ESTUDES 2023 pilot study: https://pnsd.sanidad.gob.es/profesionales/publicaciones/catalogo/catalogoPNSD/publicaciones/pdf/2023_OEDA_InformePilotoESTUDES_1y2_ESO.pdf), we see that the age of onset decreases to 11.8 years for boys and 11.9 for girls, while daily consumption begins at 11.5 years for boys and 12.2 for girls on average. In other words, the average age of onset in consumption decreases if we lower the age cut-off for the population group surveyed. If we further decrease the age range of respondents, there is the possibility that this figure will decrease even further. In the case of ESTUDES, the trend in the age of onset in consumption is stagnant. Since records began in 1996, the age of onset in consumption has risen

from 13.9 to 14.1 years in 2023 and the age of onset in 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 school-aged adolescents 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, breaking the downward trend started in 2002 (HBSC Study 2022 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 of participants includes people between 15 and 64 years, we see that the age of onset in tobacco use identified in this study is 16.6 years, with daily consumption at 18.5 years. The trend of the study has been maintained for the last few decades as in 1997 the age at which consumption (sporadic and daily) began was 16.5 years, and in 2011 the figure 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 in a population 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 in women, although they also started from a position of higher prevalence. However, from 2014 onwards, the decline stabilised, falling by just 5% over a decade.
According to the EDADES 2024 survey, there is a similar pattern in the decline in tobacco consumption. From 46.8% prevalence of tobacco use in people 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 to 39.0% in 2022. Although it is true that, in the latest study in 2024, there was a significant decrease, placing 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 reach 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 survey started with an alarming 60.6% in secondary school students aged 14 to 18 in 1994 (56.6% for boys and 65.1% for girls), with 33.4% detected in the ESTUDES 2023 (30.0% for boys and 36.8% for girls). In this case, the decline in consumption has been gradual and continuous, decreasing 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 because they have moved to emerging forms of consumption, such as electronic cigarettes.

On the other hand, the HBSC Study of 2022 (https://www.sanidad.gob.es/areas/promocionPrevencion/entornosSaludables/escuela/estudioHBSC/2022/home.htm) finds that 4.8% of adolescents aged 11-18 years in Spain smoke cigarettes daily, with 13.3% smoking cigarettes already at 17-18 (14% girls and 12.2% boys), so there is still a need to improve public health interventions in order to reach this population group. In fact, although daily tobacco consumption fell by a third between 2002 (14.7%) and 2022 (4.8%), in recent years there has been a stabilisation both in the overall sample and in the different specific groups by gender, age and family purchasing power. Furthermore, it is worrying that in recent years there has been an increase in girls (5.3% in 2022 compared to 4.1% in 2018) and in the 17-18 age 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 women taking up smoking later in life, with women currently in the third phase of the epidemiological model of smoking, as well as specific marketing strategies aimed at women.
Likewise, we continue to detect a social gradient in tobacco consumption in adolescents, so that the prevalence of daily tobacco consumption is 6.4% in families with low purchasing power compared to 3.9% in adolescents with families with high purchasing power.
Therefore, the design of policies with structural and regulatory measures will also be beneficial for the reduction of health

inequalities and for minimising the gender impact on the smoking epidemic, which, as indicated in previous consumption prevalence data, should be addressed with particular interest in young and female population groups, through measures that aim to reduce the attractiveness of these new devices and products, as the vast majority of them have been designed, using colours, forms, aromas and flavours specially designed and aimed at attracting these population groups.

As for electronic cigarettes, we see that in recent years the consumption of these products among younger people has increased. The ESTUDES 2023 survey found that 55% of secondary school students have tried electronic cigarettes. Of these, the majority said they had used it with nicotine-free cartridges (60.7%), 14.9% had done so with nicotine and the remaining 24.4% had used cartridges or liquids of both types. However, a slight downward trend was observed in the 2021 survey (https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/ESTUDES_2022_Informe.pdf), likely due to the fact that the epidemiological situation caused by COVID-19 introduced 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. In contrast, more than 10% of the general population say they have used them at some point in their lives, a much lower percentage than students. The problem is that, according to the official records of the ESTUDES survey, it is observed that the use of these products doubled between 2015 and 2022 from 20.1% to 54.6% of students who have used electronic cigarettes at least once in their lives.
Tobacco-related products such as electronic cigarettes or nicotine pouches have been found to be a gateway to the consumption of other tobacco products. As scientific evidence has shown on numerous occasions, this implies a serious public health problem that requires special attention when improving the current regulation of these devices which, camouflaged to appear harmless with attractive colours and shapes, contribute to the normalisation and the initiation of nicotine use among young people, increasing the risk of long-term addiction (ref: 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 and 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. DOI: 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 from coils and batteries. A disease 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 of this supports the fact that regulating tobacco-related products facilitates the monitoring of risks associated with their consumption.
For the newest products (nicotine pouches, heated herbs, etc.) with little time on the market, neither consumption data from population surveys in Spain or in Europe nor historical data are available yet because they are new products. The evidence of its increase is based, among other aspects, on studies such as those from the United States that show alarming data on dual use between 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. (Ref: Han D, Harlow AF, Miech RA, et al. Nicotine Pouch and E-Cigarette Use and Co-Use Among US Youths in 2023 and 2024. JAMA Netw Open. 2025;8(4): e256739. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2833331; Cornelius, M. E., Loretan, C. G., Wang, T. W., Jamal, A. and Homa, D. M. (2022). Tobacco Product Use Among Adults – United States, 2020. MMWR Recommendations and Reports, 71 (11), 397 – 405. https://doi.org/10.15585/mmwr.mm7111a1; Adriaens, K., Van Gucht, D. and 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. and 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. doi:10.1007/s40429-022-00448-1; Ayesta, J., Peruga, A., Rebollar, A., Rey, N., Zamorano, A., Verdejo, S., Panero, J., Doncel, J. C., Martín, A., & Pérez-Sacristán, E. M. (2024). What does Harm Reduction in Tobacco Use means to Public Health. Revista Española de Salud Pública, 98, e202405037.)

Likewise, there has been a considerable increase in the points of sale where these products are marketed that have gone from zero to thousands, (state-owned stores, petrol stations, specialist shops, among others), as well as the promotion and advertising of these products in all possible media such as social networks, public events, etc. It is also evidenced in

the observation of consumption patterns, returning to consume these products in smoke-free places where tobacco was no longer consumed and now all these new alternatives are consumed bypassing the regulations of areas where smoking is prohibited. Also, the market studies carried out by the industry itself show alarming growth forecasts, and more especially in the absence of clear regulation of new nicotine products. (Ref: 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)
Similarly, the 2022 HBSC study detects that 12.1% of adolescents between 11-18 years of age have consumed e-cigarettes at some point, and that this consumption is increasing with age, reaching 18.8% at 17-18 years of age (20.6% in girls, and 18.9% in boys).
In response to these data, especially among the sector of the minor and young population, Spain is working on the control and prevention of the consumption not only of tobacco products, but of new related products.

Therefore, 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 goals, namely 'Goal 1. Prevent the onset of tobacco and related product use'. Thus, within that goal 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.
• Ban additives imparting aromas in tobacco and related products.
Member States wishing 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 upon by different social sectors, the administration and scientists and, in line with what has been stated in this response, entails the need to introduce various improvements not yet covered by harmonised EU regulations as a result of the significant changes that have taken place, both in terms of epidemiology and consumption patterns, and in the current configuration of the market for tobacco products and related products in our country.

Justification of the need to update the regulation.
In conclusion, the justification for the need to update Royal Decree 579/2017, in the context 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 the protection of public health, especially among young people.

The protection of public health constitutes one of the priority general interests within the European Union legal order. 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)) which allows for exceptions from Articles 34 and 35 TFEU and allows proportionate, non-discriminatory and justified national measures on public health grounds.

Likewise, the proposal for a Royal Decree is aligned with the European directives and does not contradict them; it complements them and in some cases is more restrictive, an issue that is admitted. Its primary objective is the protection of public health and the measures are considered proportionate to the aim pursued, since they seek to restrict the consumption of tobacco and related products, prevent their initiation, especially in vulnerable groups such as minors and young people, and improve information for consumers, especially of those novel products with a growing presence on the market and without a harmonised regulatory framework at European level. All of this has the ultimate aim of protecting public health and the appearance of diseases 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 are the result of the hard work of evaluation, analysis and study carried out during the drafting of this Plan. This work has 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 the scientific endorsement of the different health societies and related entities at national level that have participated in the preparation of 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 necessary measures to combat the tobacco epidemic in Spain were identified, along with the different alternatives existing 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 to 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 the international level, the health sector points out the need to advance in the regulatory regulation of tobacco and related products, to adapt to the evolution of the market and protect the health of the population, both for the health of children and adolescents and for being an essential line of action in the prevention of non-communicable diseases.
In this regard, ahead of the COP 10 Summit of the parties to the Framework Convention on Tobacco Control held in Panama in February 2024, EU Member States prepared a common position paper to bring to COP 10, 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 regulation of all novel tobacco-related products, in which disposable electronic cigarettes with and without nicotine, as well as nicotine pouches and other non-tobacco nicotine products, are rigorously regulated, which could include their prohibition to protect in particular children and adolescents, and in which they are regularly monitored in the future. It also includes the necessary review and regulation of sweeteners, additives, flavourings that make these products attractive by increasing their addictiveness. It considers it important to rigorously regulate and continuously monitor the use of tobacco, including new and emerging tobacco products, especially among young people, given the concerning trends in popularity within this age group and among non-smokers. This document (Interinstitutional File: 2023/0313(NLE)), was classified as LIMITE, so it is not available to the general public, but the Member States have this document available for consultation (ref: 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, the signatory parties, through the common position defended by the EU in the aforementioned document, agreed to apply the same regulatory framework that already covers traditional cigarettes to novel products (ENDS (electronic cigarettes), HTP (heated tobacco products) and nicotine pouches. 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. Countries were encouraged to consider a total or restrictive ban on these products, a ban on flavours that appeal to young people, restrictions or a ban on commercial marketing, as well as strict control or a ban on disposable devices (D ENDS) and nicotine pouches, with an emphasis on their environmental impact and use by adolescents.
(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)
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 prepared analysing the evolution and characteristics of the new related products that have been emerging on the market.

In addition, Spain is part of the Joint Action to Prevent Non-Communicable Diseases and Cancer, where different activities are developed such as Work Package 5 (WP5), focused on strengthening fiscal and regulatory policies against the main risk factors of non-communicable diseases. In the field of tobacco and related products, it contributes to the comparative

analysis of legislative frameworks, the development of fiscal measures that promote healthier behaviours and support in the implementation of policies to reduce the impact of harmful marketing. This participation makes it possible to share good practices at European level and to strengthen national smoking control strategies not only for conventional products, but for all new products that may pose a risk to health and nicotine addiction. (Ref: 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/).

In short, the draft Royal Decree establishes new regulations applicable to novel products without prior harmonised regulation. These measures aim to ensure a clear and coherent regulatory framework, aligning these new products with the regime applicable to other tobacco products already regulated.
The new regulations have been designed taking into account the principles of proportionality and necessity, in accordance with national and Community legislation. The main objective is to protect public health, ensure consumer safety and facilitate the correct marketing of these products. It is not an arbitrary restriction that is sought, but a regulation necessary to avoid legal loopholes that could compromise these objectives.

Given that many novel products lack specific regulation, the implementation of an appropriate regulatory regime is considered indispensable to achieve the objectives pursued. Appropriate and proportionate measures have been considered to ensure effective control over these products and, consequently, to ensure consumer protection and public health.

The regulation of nicotine content limits in nicotine pouches is a health measure that has been taken in consideration of the potential toxic and addictive effects this substance has on people, with ample scientific evidence to support this. 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 justified on 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'. Therefore, the application of the limits included in the proposal, which will be explained below, is justified.

Regardless of the administration system, nicotine has well-documented health impacts. These 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, 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 proceed with caution when dealing with a recently introduced product with limited scientific evidence and no history of use that would allow its medium- and long-term effects to be assessed. However, 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 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 for acute inhalation, oral and dermal toxicity (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 causes 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 plasma peaks similar to those recorded after the consumption of a traditional cigarette were reached with concentrations of 6 to 10 mg, reinforcing their capacity 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 without risk, since nicotine increases cardiovascular risk, particularly in young people and 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 requiring hospital admission for consuming 15 nicotine pouches of 10.9 mg per pouch in a 12-hour period as a study tool in preparation 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 generates increasing concern, due to their high free nicotine content and attractive presentation (Stanfill, S., Tran, H., Tyx, R., Fernandez, C., Zhu, W., Marynak, K., King, B., Valentín-Blasini, L., Blunt, B. C., & Watson, C. (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 generate particular interest among young people and dual users, potentially favouring both 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), 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 when unregulated, present a real risk of acute toxicity, exposure to carcinogenic compounds and high addictive potential. These findings fully justify the need to set strict limits on their composition, dose and marketing.
Spain is not the only Member State to advocate limiting 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, in particular on 24 February 2025 (TRIS/(2025)0538). This proposed decree establishes the following: ‘a ban on oral-use nicotine products, particularly in the form of portioned sachets or porous sachets, paste, pellets, chewing gum, lozenges, strips, or any combination of these forms.'. The following is also added: 'The draft Decree defines oral-use nicotine products intended for human consumption by ingestion or absorption, particularly in the form of portioned sachets or porous sachets, paste, candies, pellets, liquids, chewing gum, lozenges, strips, or any combination of these forms. It specifies that these products are subject to a ban 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, supply, 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), from 1 January 2025 these products were 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, at the forefront of the regulation of these products, was the first country to ban nicotine pouches. This measure was approved in October 2023 justifying this prohibition not only because of the toxicity of these products, but because they represent a route of entry for the consumption of tobacco and other related products.
Germany has regulations along different lines than the rest of the Member States with regard to the classification of this type of product, as 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) drew up 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 1 April 2025 of the limitation of the nicotine concentration in nicotine pouches of 9.0 mg. It foresees the full implementation of this restriction by 2026. Norway for its part does not allow the sale of these products, but it does not have a 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 set 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 informing about the danger of the consumption of these products.
In Spain, 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 products, numerous proposals for their national regulation have been studied based on studies, contributions from civil society, scientific and patient societies, entities of health professionals, etc., which they collected after the periods of consultation, hearing and public information of national procedures. After a long discussion, 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. Setting 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 authorised as medicinal products by national procedure. These products, most with nicotine in the form of nicotine bitartrate dihydrate, have been authorised for marketing after receiving a favourable opinion from the relevant expert committees as to their risk and benefit following the submission of efficacy, safety and quality data. 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 motivated to quit smoking. The permanent abandonment of smoking is the ultimate goal.' Among the medicines 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 Data Sheet: Nicotinell Mint 1mg lozenges. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/63795/FT_63795.html Technical Data Sheet: Nicotinell Mint 2 mg lozenges. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/65407/FT_65407.html; Technical Data Sheet: NiQuitin 4 mg lozenges. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/70554/FT_70554.html Technical Data Sheet Nicotinell Fruit 2 mg medicated chewing gum. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/65587/FT_65587.html Technical Data Sheet Nicotinell Fruit 4 mg medicated chewing gum. CIMA database (AEMPS): https://cima.aemps.es/cima/dochtml/ft/65586/FT_65586.html Technical Data Sheet: Nicorette BuComist 1 mg/pulsation mouth 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 revised text of the Law on Guarantees and Rational Use of Medicinal Products 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, by definition as 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 sachets, 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 as in the authorised medicinal products mentioned above.

The lack of regulation and control of these products poses a public health risk, as the Technical Data Sheet for these medications used in NRT not only sets out a series of precautionary measures to be taken into account, but also warns of the risks associated with misuse or overdose. This control in the NRT can be carried out as 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 medical staff are established. In the case of nicotine pouches, this pharmaceutical control is not going to be carried out, so it is urgent to establish a lower limit than the NRT, in particular 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, become fatal. According to the Technical Data Sheet of the medicines authorised for NRT themselves, in the case of adults in addition to heart conditions that may be severe or very severe in people with pathologies, there may be effects of weakness, sweating, pallidity, hyperhidrosis, salivation, burning in the throat, nausea, vomiting, diarrhoea, abdominal pain, impaired sight and hearing, headache, tachycardia, cardiac arrhythmia, dyspnoea, dizziness, tremors, confusion and asthenia. In addition, hypotension, circulatory collapse, coma, respiratory failure and terminal seizures may occur in severe conditions.
Among other less restrictive measures envisaged, the following scenarios were considered, which were rejected for the following reasons:

• Set a nicotine dose limit of 20 mg/pouch to match electronic cigarettes: in Spain it was considered that nicotine doses cannot be comparable between nicotine pouches and electronic cigarettes (limits set by the NRT of 20 mg/ml) for various reasons. The presentation formats are not similar. While nicotine pouches are solid forms whose main nicotine absorption is oral and sublingual and where sustained release has not been demonstrated, electronic cigarettes with a concentration of 20 mg/ml (40 mg content in the total 2 ml) release around 0.05 and 0.07 mg per inhalation (inhalation route) in approximately 600-800 puffs. Therefore, at the same dose, the release of nicotine in nicotine pouches is acute, with a higher risk of toxicity, compared to that same dose of nicotine in e-cigarettes, where the release is lower, fractionated, and part is exhaled. Therefore, this dose limit was 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 particularly worrying risk when the products are designed with attractive flavours and aimed at a young audience.
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. Also, it focuses exclusively on the acute toxicity of nicotine, without taking into account the effects of prolonged use or individual differences in the 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) as proposed as Carcinogenic 1B H350. The presence of these substances in products not containing tobacco directly demonstrates a lack of purity and quality control in recreational products that have not been subjected to pharmaceutical requirements.

• Set a nicotine dose limit of 4 mg/pouch, 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 has been 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 disguised discrimination or disproportionate restrictions on trade.
Therefore, the proposed regulations are in line with Directive 2014/40/EU and other Community provisions, seeking a balance between innovation in the market and the protection of consumer rights and health.

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