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2. Spain

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4. 2025/0044/ES - X60M - Tobacco

5.

6. Spain thanks the Greek authorities for submitting their opinions 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 effort to combat this epidemic together with the other Member States, the Kingdom of Spain moves to provide more information regarding the origin, motivation and scope of the content of the measures proposed at national level.

The current 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 significant access to all types of public through extensive communication and marketing campaigns organised by the same companies that manufacture them. 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 all the way along to the final consumer. This fact leads to 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 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 the year 2024, Spain has a total of 514,441 hotels and restaurants, placing the country at the top of the offering available within the European Union (Premises per Autonomous Community, main activity (CNAE 2009 groups)). Add sub-heading 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 sense, and according to Eurostat 2022 data regarding 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 to 329.1 in Italy or 288.9 in France, which ranks third (figures in thousands).

On the other hand, the regulations currently in force in Spain have significant shortcomings, as there has been no comprehensive update adapted to the national situation for more than 15 years, since the passing 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 has only been transposed in 2017 into Royal Decree 579/2017, of 9 June, which is in the process of being updated. This transposition was carried out strictly literally, adhering exclusively to the content of the European regulations, without introducing 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, the passing of more than a decade without revising the regulations, combined with the tremendous growth of the tobacco and related products market, means that the national regulations are significantly outdated and urgently need to be updated due to their lack of adaptation 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 led to their placing on the market without evaluation by the authorities or the relevant health safeguards, putting at risk the health of the consumer, as well as their information and perceptions 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 requirements and obligations that are necessary for the proper 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 therefore in serious harm to public health that requires urgent action at national level, in the absence, moreover, of an updated regulatory framework at European level. Likewise, the lack of regulation has fostered 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:

Firstly, in relation to the age of onset of consumption, we have several updated studies in Spain.

According to the 2023 Survey on Drug Use in Secondary Education in Spain (ESTUDES) (https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/ESTUDES_2023_Informe.pdf), carried out on pupils and students between 14 and 18 years of age, the age of onset for tobacco use is 14.1 years (14.1 for girls and 14.1 for boys). Whereas the age of onset of daily tobacco use is 14.6 years (14.6 in girls and 14.7 in boys). However, in addition, by expanding the target population of the survey, as was done in the pilot survey on the use of drugs and addictions among 1st and 2nd year secondary school students aged 12 and 13 years old in Spain (ESTUDES pilot study 2023: https://pnsd.sanidad.gob.es/profesionales/publicaciones/catalogo/catalogoPNSD/publicaciones/pdf/2023_OEDA_InformePilotoESTUDES_1y2_ESO.pdf), we see that the onset age decreases to 11.8 years for boys and 11.9 years for girls, while daily consumption starts at 11.5 years for boys and 12.2 years for girls on average. That is to say, the average onset age

of consumption decreases if we lower the age cut-off of the population group surveyed. If we further decrease the age range of persons surveyed, there is the possibility that this figure will decrease even further. In the case of ESTUDES, the trend in the onset age of consumption is stagnant. Since records began in 1996, the age of onset of consumption has risen from 13.9 to 14.1 years in 2023 and the age of onset of daily consumption remains constant between the two records at around 14.6 years.

On the other hand, in the 2022 study Health Behaviour in School-aged Children-Spain (HBSC) carried out on more than 30,000 school-aged adolescents between the ages of 11 and 18, early onset tobacco use (13 years or earlier) was observed at around 11% in 2018 and 2022, breaking the downward trend started 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 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 and daily consumption at 18.5 years. The trend of the study has been maintained for the last few decades since in 1997 the onset of consumption (sporadic and daily) was 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 for 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 in women, although they also started from a situation of greater prevalence. But from 2014 it enters a stabilisation phase where the decline stagnates, falling just 5% in a decade.

According to the EDADES 2024 survey, there is a similar pattern in the decline in tobacco consumption, which dropped 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 stagnates, reaching 39.0% in 2022. While it is also true that, in the last 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% consumption rate among secondary school students aged 14 to 18 in 1994 (56.6% for boys and 65.1% for girls), with 33.4% detected in 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 among 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 2022 HBSC Study (https://www.sanidad.gob.es/areas/promocionPrevencion/entornosSaludables/escuela/estudioHBSC/2022/home.htm) finds that 4.8% of adolescents aged 11-18 in Spain smoke cigarettes daily, reaching 13.3% 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 has decreased by one third from 2002 (14.7%) to 2022 (4.8%), in recent years a stabilisation has been detected both in the sample overall and in the different specific groups by sex, age and family purchasing power. Moreover, it is of concern that in recent years there has been an increase in girls (5.3% in 2022 compared to 4.1% in 2018) and in the group aged 17-18 years (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 adoption of tobacco use by women, as women are in the third phase of the epidemiological model of smoking, as well as to specific marketing strategies aimed at the female gender.

Likewise, we continue to detect a social gradient in tobacco consumption in adolescents, with the prevalence of daily tobacco consumption being 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, shapes, 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 at some point. Of 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 both types of cartridges or liquids. 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 a bias in the data caused by the epidemiological situation generated by COVID-19. In the update of the 2023 survey, following the end of the COVID-19 pandemic, a strong rebound was observed across all modes of consumption. On the other hand, more than 10% of the general population report having 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 has been observed that the consumption of these products has doubled between 2015 and 2022 from 20.1% to 54.6% of students who have consumed 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 particular attention in improving the current regulation of these devices, which, camouflaged under the appearance of harmless and attractive colours and shapes, contribute to the normalisation and onset of young peoples' nicotine consumption, increasing 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 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 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.) with little time on the market, there is no consumption data from population-level surveys in Spain or Europe, nor historical data, as these are new products. The evidence of its increase is based, among other things, 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. (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 behaviour 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., et al. (2024). What does Harm Reduction in Tobacco Use means to Public Health. Spanish Journal of Public Health, 98, e202405037)

It is also observed in the considerable increase in the points of sale where these products are marketed, which have gone from zero to thousands, (state-owned retailers, gas stations, speciality stores, among others), as well as the promotion and advertising of these products across all possible media such as social networks, public events, etc. It is also evidenced in the observation of consumption patterns, with these products once again being consumed in smoke-free places where tobacco was no longer consumed, and now all these new alternatives are consumed circumventing the regulations in areas where smoking is prohibited. Likewise, 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 (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 detects that 12.1% of adolescents between 11-18 years of age have used electronic 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 minor and young population sector, 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, establishing the strategic lines, objectives and goals to be carried out over 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.
• Prohibition of flavouring additives in tobacco and related products.
Member States wishing to further analyse and study the content of the approved Comprehensive Plan can do so through the link published in the corresponding section of the Spanish Ministry of Health’s website (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 the different social, governmental, and scientific sectors, and in line with what was expressed in this response, has identified the need to introduce various improvements not yet contemplated in the harmonised regulation of the Union, as a result of 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, 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 public health protection measures, especially among young people.

The protection of public health constitutes one of the priority general interests within the European Union’s 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 derogations from Articles 34 and 35 TFEU and allows proportionate, non-discriminatory and justified national measures on the grounds of public health.

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, a point that is accepted. 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 on those novel products with a growing presence on the market and without a harmonised regulatory framework at European level. All this with the ultimate aim of protecting public health, and preventing the emergence of diseases associated with the use and abuse of these products. In order to better clarify the proportionality of the project, it should be noted that, as a result of the drafting process of the Comprehensive Plan mentioned above, the measures proposed are the result of the arduous 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 with 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 relevant ministerial departments. 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 from the least restrictive to the most far-reaching. Finally, it is worth mentioning that the analysis and assessment of proportionality of the final text, published in the link provided in this response, was 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 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 as 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, the 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 a common position was reached, a series of points regarding the necessary 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, are rigorously regulated, which could include their prohibition to protect children and adolescents in particular, and be regularly monitored in the future. It also includes the necessary review and regulation of the sweeteners, additives and flavourings that make these products attractive by increasing their addictiveness. It considers it important to rigorously regulate and continually monitor the consumption of new and emerging tobacco products, including novel and emerging tobacco products, especially by young people, given the worrying popularity trends in 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 Member States have this document available for consultation (WHO Framework Convention on Tobacco Control (FCTC) – Tenth session of the Conference of the Parties (COP 10) 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 COP 10 Summit of the Partieshttps://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 restrictions or prohibition of commercial marketing, as well as the strict control or prohibition of disposable devices (D ENDS) and nicotine pouches, with an emphasis on their environmental impact and their use by adolescents.

Spain actively participates 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 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 labelling of heated tobacco products not intended for smoking and the amendments brought about for the labelling of regulated and non-regulated products by Directive 2014/40/EU and the proportionality of the measures.

The proposed standard introduces two amendments regarding the labelling and presentation of related products. On the one hand, it includes labelling obligations and health warnings for products not regulated by Directive 2014/40/EU, namely nicotine-free electronic cigarettes and their refill containers, nicotine pouches and heated herbal products. In all cases these obligations are comparable to those of the products regulated in the Directive, with the idea of making all types of products equal.

The second amendment is the extension of some restrictions on the packaging of electronic cigarettes with and without nicotine. These prohibit the inclusion of images, except for the mandatory safety pictograms, as well as combinations of colours that, due to their content or design, are likely to attract the particular attention or interest of consumers, in particular minors.

Spain believes that products aimed at the adult population and expressly prohibited from being sold to minors, have no reason to carry packaging designs focused on these age groups. This measure aims to reduce the appeal of these products to the most vulnerable age groups.

Furthermore, this draft Royal Decree does not include amendments to the measures provided for in Delegated Directive (EU) 2022/2100 on the labelling of heated tobacco products.

Finally, the draft includes the following restriction on nicotine pouches and heated herbal products: ‘Packaging units and outer wrapping may not include elements which, because of their content or design, are likely to attract the particular attention or interest of minors’ (Article 53(3) of the proposed Royal Decree). Again, as in the previous case, Spain considers that there is no place for marketing designs aimed at minors and children in products whose sale is prohibited.

This extension to packaging restrictions is due to the great boom of products on the market bearing children's themes or

aimed at children. A measure that prevents the inclusion of marketing elements focused on arousing the interest of children and adolescents seems totally proportionate, based on the protection of the general public health, and specifically that of minors. This is a matter of great concern for Spain and the rest of the Member States. Therefore, a measure that prevents this type of design is considered necessary and proportionate, based on the protection of public health and minors.

In addition, it has been observed that tobacco-related products, such as electronic cigarettes or nicotine pouches, can act as a gateway to the consumption of conventional tobacco products, especially among adolescents, promoting the normalisation of nicotine consumption and increasing 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)

2. Regarding the nicotine limit in nicotine pouches and the proportionality of the measures. Situation in other Member States.

The regulation of the limit of nicotine content in nicotine pouches is a health measure that has taken into account the potential toxic and addictive effects on people that this substance exerts, there being 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 be an obstacle to prohibitions or restrictions on imports, exports or transit 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'. Therefore, the application of the limits included in the proposal, which will be justified below, is justified.

Regardless of the system of administration, nicotine has well-documented impacts on health. 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 act with caution, in the face of a recently introduced product, with still limited scientific evidence and without a history of use that allows the evaluation of its effects in the medium and long term. 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 have 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 shows its immediate physiological impact (Lunell E, Fagerström K, Hughes J, Pendrill 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., et al. (2022). A Randomized 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 their risks, since nicotine increases cardiovascular risk, particularly in young people and people with a 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 gives rise to increasing concern, due to their high levels of free nicotine and 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 generate a particular interest among young people and dual users, potentially favouring both escalation in consumption and onset 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 to be carcinogenic (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, the 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 a high addictive potential. These findings fully justify the need to set strict limits on their composition, dosage and marketing.

Spain is not the only Member State that is committed to limiting these products that are currently available on the market without any type of health regulation. With that in mind, we also consider it relevant to look at the experience of countries such as France, the Netherlands, Belgium, Germany, Denmark, Lithuania, Latvia and Norway, which have adopted restrictive or outright prohibitive approaches to these products.

Like Spain, France is in the comments phase of the TRIS procedure for its Regulatory Decree presented specifically 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 portioned sachets or porous sachets, paste, pellets, 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, intended for human consumption by ingestion or absorption, in particular 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 prohibition throughout the national territory, in so far 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), 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 content limit 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 gateway for the consumption of tobacco and other related products.

Germany has regulations along different lines from 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) 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 1 April 2025 of the limitation of the nicotine concentration in nicotine pouches of 9.0 mg. It anticipates the complete application of this limit for the year 2026. Norway for its part does not allow the sale of these products, however, it does not have a specific limitation in place.

Among the Baltic countries, Lithuania has banned nicotine pouches since 2024, and Latvia has set a maximum nicotine content limit of 4 mg 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 that provide information about the danger of consuming these products.

From 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 for minors, non-smokers and those with cardiovascular diseases.

In the absence of a harmonised framework in the EU for these products, numerous proposals have been studied for their national regulation, based on studies, contributions from civil society, scientific and patient societies, entities of health professionals, etc., which were collected after the periods of consultation, hearing and public information of the national procedures. After a long discussion, it was determined that, given the characteristics of these products, their intended use and their 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 formulations encompassed in 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 consumption in smokers motivated to quit smoking. Permanent cessation of smoking is the ultimate goal.' Medicinal products authorised in Spain as NRT for oral use include formulations of 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 1 mg 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 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, by 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 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 to that of the authorised medicinal products mentioned above.

The non-regulation and control of these products poses a public health risk since the Technical Data Sheet of these medicinal products used for NRT establishes not only a series of precautionary measures to be taken into account, but also warns of the risks posed by their 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, and where the guidelines for use prescribed by the 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 that of 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, be fatal. According to the Technical Data Sheet of the medicines authorised for NRT, in the case of adults, in addition to cardiac conditions, which in people with pathologies can be serious or very serious, the following effects may occur: weakness, sweating, pallidity, hyperhydrosis, 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 contemplated, the following scenarios were considered and were rejected for the following reasons:

• Establish a nicotine dose limit of 20 mg/pouch to match electronic cigarettes: from Spain it was considered that the nicotine doses of nicotine bags and electronic cigarettes (limits of 20 mg/ml set by the TPD) cannot be comparable for various reasons. The forms of presentation are not similar. While nicotine pouches are solid forms whose main absorption of nicotine is buccal and sublingual and where, in addition, sustained release has not been demonstrated, in e-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 by 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 that same dose of nicotine in electronic 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), because 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 speed of absorption and the consequent rapid increase in blood nicotine levels are key factors in the addictive potential of these formulations,

a risk that is particularly worrying 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. Furthermore, 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) under the category Carcinogen 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 chewing 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 compared to the threshold finally proposed.

At the same time, more restrictive measures, including a total ban, were also considered, 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.

To sum up, while Article 34 TFEU prohibits restrictions on the free movement of goods within the internal market, Article 36 permits exceptions when 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.

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