Message 201

Communication from the Commission - TRIS/(2025) 1968

Directive (EU) 2015/1535

Notification: 2025/0044/ES

Forwarding of the response of the Member State notifying a draft (Spain) to comments (5.2) of European Commission.

MSG: 20251968.EN

1. MSG 201 IND 2025 0044 ES EN 28-07-2025 22-07-2025 ES ANSWER 28-07-2025

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4. 2025/0044/ES - X60M - Tobacco

5.

6. Spain thanks the European Commission for submitting its comments on the notified draft Royal Decree. In the interest of enhanced coordination of control policies for tobacco use within the European Union, and as part of the joint efforts to combat this epidemic together with other Member States, the Kingdom of Spain would like to provide clarification and further information on the issues raised.

Current situation in Spain.

Currently, the market for tobacco and related products in Spain is experiencing significant growth, marked by a continual evolution of available products and widespread access across all demographic groups through extensive communication and marketing campaigns organised by manufacturers. There has been a notable proliferation of these products in a broad range of retail and service establishments at both regional and local levels, resulting in increased accessibility to the final consumer. This means that these products are more accessible to the general public, as they are available in places that are frequently visited, such as entertainment and leisure venues, food outlets, cosmetics and beauty stores, newsagents, and general stores. It is also important to note the ease of access to tobacco and related products due to the wide range of hospitality and catering establishments across the national territory.

According to data provided by the National Institute of Statistics (Instituto Nacional de Estadística - INE) for the year 2024, Spain has a total of 514,441 hospitality and catering establishments, positioning the country at the forefront of available venues within the European Union (Establishments by Autonomous Community, main activity (CNAE 2009

groupings). Code 56, Food and beverage services, code 561, Restaurants and food stalls, and code 563, Beverage establishments.

https://www.ine.es/jaxiT3/Tabla.htm?t=294&L=0).
Similarly, according to Eurostat 2022 data on the number of enterprises 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 and 288.9 in France (figures in thousands).
On the other hand, the legislation currently in force in Spain has significant shortcomings, as no comprehensive national update has taken place for over 15 years, since the adoption of Law 42/2010 of 30 December 2010 and Royal Decree 639/2010 of 14 May 2010. Since then, the only developments in tobacco-related legislation have been limited to the transposition of Directive 2014/40/EU via Royal Decree 579/2017 of 9 June 2017, which is currently being updated. This transposition strictly adhered to the content of the European Directive, without introducing any additional provisions adapted to the national context. 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, which amended Royal Decree 579/2017.

Therefore, after more than a decade without regulatory revision, combined with the dynamic and rapidly evolving nature of the tobacco and related product market, the national regulations are now seriously outdated and urgently need to be updated due to their failure to adapt to the current situation of the market for tobacco and related products in Spain.

It should be noted that the lack of appropriate regulation of products with mixed characteristics, whether or not they contain tobacco or nicotine, has led to their being placed on the market without evaluation by the authorities or the relevant health safeguards, risking consumer health, as well as hindering their capacity to carry-out informed decision-making. This is also the case for nicotine-free electronic cigarettes, nicotine pouches and heated herbal products. The draft royal decree aims to resolve the problems arising from this situation by establishing a set of essential health-related requirements and obligations to ensure adequate oversight and control of such products.

This situation of widespread access, lack of effective regulation, or in some cases, deregulation, has led to increased consumption and therefore serious harm to public health, requiring urgent action at the national level, especially in the absence of an updated regulatory framework at the European level. The regulatory void has also fostered a false sense of safety and underestimation of risk among the public concerning new tobacco-related products, thereby facilitating access among vulnerable sections of the population, such as children and adolescents.

The following data on the prevalence of tobacco and related product consumption in Spain are available from official health surveys:
Firstly, with regard to the age of initial consumption, we have various up-to-date 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 students aged between 14 and 18 years of age, the age of initial consumption of tobacco is 14.1 years (14.1 for girls and 14.1 for boys). Meanwhile, daily tobacco consumption begins at 14.6 years (14.6 for girls and 14.7 for boys). However, in addition, by expanding the target population of the survey, as is the case in the Pilot Survey on Drug Use and Addiction among Secondary School Students Aged 12 and 13 in the 1st and 2nd Years of ESO 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 starting age decreases to 11.8 years in boys and 11.9 in girls, while daily consumption begins at 11.5 years in boys and 12.2 in girls on average. In other words, the average age of initial consumption decreases if we lower the age cut-off of the population group surveyed. If we narrow down the age range of respondents even further, it is possible that this figure could fall even lower. In the case of ESTUDES, the trend in the age of initial consumption appears to have stabilised. Since data collection began in 1996, the average age of initial consumption has risen slightly from 13.9 years to 14.1 in 2023, while the age of daily consumption has remained constant at approximately 14.6 years.

On the other hand, in the 2022 Health Behaviour in School-aged Children-Spain (HBSC) study conducted on more than 30,000 school-aged adolescents between the ages of 11 and 18, an early onset of tobacco consumption (13 years or earlier) was observed in around 11% in 2018 and 2022, breaking the downward trend that began in 2002 (https://www.sanidad.gob.es/areas/promocionPrevencion/entornosSaludables/escuela/estudioHBSC/2022/home.htm).

If we look at the data collected in the 2024 survey on alcohol and other drugs in Spain (EDADES) (https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/2024_Informe_EDADES.pdf), which includes participants aged between 15 and 64, we see that the age of initial consumption of tobacco identified in this study is 16.6 years and for daily consumption, it stands at 18.5 years. The trend observed in the study has remained stable over recent decades, with the age of initial consumption (sporadic and daily) standing at 16.5 years in 1997 and 18.5 years in 2011.
With regard to the prevalence of tobacco consumption in the general population, looking at historical data from the 2017 Spanish National Health Survey (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, we see a gradual decline, from 38.35% in 1987 (55.2% in men and 22.93% in women) to 25.35% in 2014 (30.43% in men and 20.50% in women). This decline has been more marked among men, who initially had higher prevalence rates. However, since 2014, the trend has plateaued, with only a 5% reduction observed over the past decade.

According to the EDADES 2024 survey, there is a similar pattern in the decline in tobacco consumption. From a 46.8% prevalence of tobacco consumption in people aged 15 to 64 in 1997 (55.0% in men and 38.7% in women) to 40% in 2011 (44.8% in men and 37.0% in women). From that point onward, the decline stalled, to 39.0% by 2022. Notably, in the latest study, in 2024, there was a significant decline, placing the prevalence of current consumption at 36.8% (40.9% men and 32.7% women).
In both cases, comprehensive regulatory changes are needed to reach the younger population group that still consumes tobacco in the current context.

Focusing on the prevalence of tobacco consumption in the earliest age groups, the ESTUDES survey found an alarming consumption rate of 60.6% of secondary school students aged 14 to 18 in 1994 (56.6% of boys and 65.1% of girls), while the 2023 ESTUDES survey found 33.4% (30.0% of boys and 36.8% of 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 2022 HBSC Study (https://www.sanidad.gob.es/areas/promocionPrevencion/entornosSaludables/escuela/estudioHBSC/2022/home.htm) reports that 4.8% of adolescents aged between 11-18 in Spain smoke cigarettes daily, reaching 13.3% by the age of 17-18 (14% girls and 12.2% boys), which means that public health interventions need to be improved to reach this population group. In fact, although daily tobacco consumption has fallen by a third between 2002 (14.7%) and 2022 (4.8%), in recent years there has been a stabilisation in both the overall sample and in the different specific groups by sex, 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 consumption among adolescents is higher among girls than among boys. This is related to women consuming tobacco later in life, with women now in the third phase of the epidemiological model of tobacco use, as well as specific marketing strategies aimed at women.

Likewise, we continue to detect a social gradient in tobacco consumption among adolescents, with a prevalence of daily tobacco consumption of 6.4% in families with low purchasing power, compared to 3.9% in adolescents from families with high purchasing power.

Therefore, the design of policies with structural and regulatory measures will also be beneficial for reducing health inequalities and minimising the gender impact of the tobacco use epidemic, which, as indicated in the previous consumption prevalence data, must be addressed with particular attention to young and female population groups, through measures aimed at reducing the appeal of these new devices and products, since the vast majority of them have been designed using colours, shapes, aromas, and flavours specifically designed and targeted to attract these population groups.

As for electronic cigarettes, we have seen an increase in the consumption of these products among young people in recent years. The 2023 ESTUDES survey found that 55% of secondary school students have tried electronic cigarettes at some point. Of these, most said they had used them with nicotine-free cartridges (60.7%), 14.9% had used them with nicotine, and the remaining 24.4% had used cartridges or liquids of both types. However, the 2021 survey (https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/ESTUDES_2022_Informe.pdf) showed a slight decline in the trend, probably due to the COVID-19 pandemic skewing the data. In the 2023 survey update, following the end of the COVID-19 pandemic, a strong rebound was observed across all consumption categories. In contrast, in the general population, more than 10% report having used them at some point in their lives, a much lower percentage than students. The problem is that, according to the historical data from the ESTUDES survey, consumption of these products doubled between 2015 and 2022, with the percentage of students who have used electronic cigarettes at least once in their lives rising from 20.1% to 54.6%.
It has been observed that tobacco-related products, such as electronic cigarettes and nicotine pouches, are a gateway to the consumption of other tobacco products. As scientific evidence has demonstrated on numerous occasions, this poses a serious public health problem that requires special attention when improving the current regulation for these devices, which, disguised under the appearance of harmless and attractive colours and shapes, contribute to the normalisation and initiation of nicotine consumption among young people, 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)

Furthermore, electronic cigarettes may contain chemicals that are hazardous to health, as well as heavy metals from heating elements and batteries. A disease associated with the use of electronic cigarettes has also been identified, EVALI (E-cigarette, or Vaping, product use Associated Lung Injury), which causes acute lung damage and may be related to multiple factors. All of this supports the fact that regulating tobacco-related products facilitates the monitoring of risks associated with their consumption.
For the most innovative products (nicotine pouches, heated herbs, etc.) that have only been on the market for a short time, there are no consumption data available from population-based surveys in Spain or Europe, nor are there any historical data available, given the novelty of these products. Evidence of this increase is based, among other things, on studies such as those conducted in the United States, which show alarming data on dual use of tobacco and other products, as well as other national and international studies that show an 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. & 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. & 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. & 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)
Likewise, there has been a considerable increase in the number of outlets where these products are sold, which have gone from zero to thousands (state-owned shops, petrol stations, specialised shops, among others), as well as the

promotion and advertising of these products in all possible media, such as social networks, public events, etc. Patterns of consumption also reveal that these products are increasingly being used in smoke-free environments where tobacco consumption had previously been eradicated, thus circumventing existing regulations prohibiting smoking in such places. Similarly, market studies carried out by the industry itself show alarming growth forecasts, particularly in the absence of clear regulation on new nicotine products (Spanish nicotine pouch market: by type, nicotine content, category, consumer group, distribution channel - Forecast, 2025-2034)
https://www.gminsights.com/es/industry-analysis/spain-nicotine-pouches-market).

Similarly, the 2022 HBSC study found that 12.1% of adolescents aged 11-18 have used electronic cigarettes at some point, and that this consumption increases with age, reaching 18.8% among 17-18 year-olds (20.6% among girls and 18.9% among boys).
In response to these figures, particularly among the younger population, Spain is working to control and prevent the consumption not only of tobacco products, but also of new related products.

Therefore, in April 2024, the Comprehensive Plan for the Prevention and Control of Tobacco Use 2024-2027 (Plan Integral de Prevención y Control del Tabaquismo 2024-2027) was approved, establishing the strategic lines, objectives, and goals to be achieved over the next few years.
Specifically, the legislative amendment presented is part of the implementation of one of its five goals, namely 'Goal 1. Prevent the onset of tobacco and related product use'. Thus, within that goal and the legislative strategy agreed upon with all relevant national stakeholders, the Plan specifically establishes the following:

• Regulate the sale and consumption of tobacco-related products.
• Prohibition of additives that produce aromas in tobacco and related products.

Member States wishing to analyse and study the content of the approved Comprehensive Plan in greater depth may do so via the link provided in the relevant section of the Spanish Ministry of Health 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 different social, governmental, and scientific sectors and, in line with this response, identifies 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 for the need to update the regulation.
In conclusion, the justification for updating Royal Decree 579/2017, in the context of the fight against tobacco use 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 legal order. In particular, Article 168 of the TFEU (Treaty establishing the European Economic Community) recognises the power of Member States to adopt national measures in this area, provided that they are proportionate, non-discriminatory and duly justified.

The measures introduced in the update to the Spanish regulation comply with the justification criteria imposed by EU legislation (articles 36 and 168 of the TFEU), which allows for exceptions to articles 34 and 35 of the TFEU and permits, on grounds of public health, national measures that are proportionate, non-discriminatory and justified.

Furthermore, the proposed royal decree is aligned with European directives and does not contradict the same; it complements these and, in some cases, is more restrictive, which is permitted. Its primary objective is to protect public health, and the measures are considered proportionate to the aim pursued, as they seek to restrict the consumption of tobacco and related products, prevent people from taking them up, especially among vulnerable groups such as minors and young people, and improve information for consumers, particularly regarding new products with a growing presence

on the market and without a harmonised regulatory framework at European level. All of this with the ultimate aim of protecting public health and preventing the emergence of diseases associated with the consumption and abuse of these products. For greater clarity regarding the proportionality of the draft legislation, it should be noted that, as a result of the process of drawing up the aforementioned Comprehensive Plan, the measures proposed are the result of the hard work of evaluation, analysis and study carried out during the creation of this Plan. This work has benefited from the technical participation of the Expert Group on tobacco use coordinating the work of the Autonomous Communities and the Ministry of Health. Furthermore, the measures included in the Plan have the scientific backing of various health societies and related national entities that participated in its development alongside all the relevant ministerial departments. Therefore, in the various technical meetings held beforehand and in the drafting of the multiple versions of the Plan, the measures necessary to combat the tobacco use epidemic in Spain, along with the various alternatives available, were identified, from the least restrictive to the most far-reaching. Finally, it should be noted that the final text, published at the link provided in this response, was analysed and assessed for proportionality by the technical services of the Council of Ministers, a top-level institutional body of the Government of the Kingdom of Spain, which approved the same on the joint proposal of the Minister of Health and the Minister of Finance at their meeting on 30 April 2024.

Furthermore, at the international level, the health sector has highlighted the need to advance regulatory measures on tobacco and related products in order to adapt to market developments and protect public health, both for the sake 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 be taken to COP10, under the Spanish Presidency of the Council of the EU, in which a series of points were agreed as a common position regarding the necessary regulation of all novel tobacco-related products, disposable electronic cigarettes, with and without nicotine, as well as nicotine pouches and other tobacco-free nicotine products, to be strictly regulated, which could include their prohibition to protect children and adolescents in particular, and for their ongoing monitoring. This also includes the necessary review and regulation of sweeteners, additives and flavourings that may make these products attractive and increase their addictiveness. It further emphasised the importance of rigorous regulation and continuous monitoring of the use of novel and emerging tobacco products, especially among young people, given the concerning trends in popularity among this age group and among non-smokers. This document (Interinstitutional File: 2023/0313(NLE)), has been classified as LIMITED (LIMITE), and is therefore not publicly accessible, although it is available to Member States for reference (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
(https://fctc.who.int/resources/publications/i/item/fctc-cop10(26)-report-of-the-tenth-session-of-the-conference-of-the-parties-to-the-who-framework-convention-on-tobacco-control), the 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 relevant FCTC provisions, such as health warnings on packaging, taxation, advertising restrictions, and bans on use in public spaces. Parties were advised to consider total or partial bans on these products, to prohibit flavours appealing to young people, to restrict or prohibit commercial marketing, and to impose strict control or prohibition of disposable devices (D ENDS) and nicotine pouches, particularly due to their environmental impact and use among adolescents.
Spain actively participates in various Joint Actions, including those relating to tobacco control, which establish spaces for collaboration and information exchange between participating Member States on the regulation of devices not covered by the Tobacco Products Directive (TPD) (Directive 2014/40/EU). This cooperation has resulted in a series of situation reports analysing the development and characteristics of emerging market products.

Spain is also part of the Joint Action on Preventing Non-Communicable Diseases and Cancer, which carries out various activities such as Work Package 5 (WP5), focused on strengthening fiscal and regulatory policies to address the main risk

factors for non-communicable diseases. In the context of tobacco and related products, Spain contributes to the comparative analysis of legislative frameworks, the development of fiscal measures to promote healthier behaviours, and the implementation of policies to mitigate harmful marketing. This engagement supports the sharing of good practices across Europe and reinforces national tobacco use control strategies not only for conventional products but also for novel products that pose potential health risks and that may foster 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/)

The definition of disposable electronic cigarettes

The notified draft makes several changes to the article on definitions relating to different types of electronic cigarettes, with or without nicotine, as well as those that are disposable or single-use.
The regulation of the only category contained in Directive 2014/40/EU is that contained in Article 3(m), which maintains the exact and literal content of the Directive, in force in Spain since its transposition in 2017 by Royal Decree 579/2017.
The sole amendment to Article 3(m) aims to reinforce alignment between national legislation and EU law by adopting the exact terminology used in the Directive. Thus, the change replaces the term ‘device capable of delivering nicotine’, currently used in Spanish legislation, with ‘electronic cigarette’, which is the term used in European Directive 2014/40/EU.

In addition to the above, the notified draft adds the definition of two new categories of products that are not currently defined in Directive 2014/40/EU and that are defined below:

• nicotine-free electronic cigarettes, the definition of which is added to Article 3(ap) as follows:
‘ap) “Nicotine-free electronic cigarette” means a product, or any component thereof, including a cartridge, a tank and the device without cartridge or tank, which can be used for vapour consumption via a mouth piece. Nicotine-free electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges’.
• disposable electronic cigarettes, the definition of which is added to Article 3(aq) as follows:
‘aq) “Disposable or single-use electronic cigarette or nicotine-free electronic cigarette”: a device containing a liquid with or without nicotine, ready for consumption and intended to be discarded after use’.
The draft therefore complements the provisions of the Directive, maintaining its general definition of electronic cigarettes (Article 3(m)) and adding additional definitions: firstly, that of nicotine-free electronic cigarettes, which are excluded from the scope of the Directive; secondly, disposable nicotine-containing electronic cigarettes, which are mentioned but not defined in the Directive; and thirdly, disposable nicotine-free electronic cigarettes, which are outside the scope of the Directive.

As the Commission rightly points out, the innovative definitions proposed by the draft ‘reflect Article 2(16) of Directive 2014/40/EU’, which demonstrates the Kingdom of Spain's intention to align them as closely as possible with the wording of the European legislation and in the interests of regulatory consistency, even where the latter lacks definitions for products currently present on both the Spanish and European markets.

These definitions contribute to improving the classification of the various types of electronic cigarettes currently available on the market, which differ substantially from those available at the time the Directive was drafted and adopted in 2014. At that time, the consumption of electronic cigarettes was much more limited and the formats available differed significantly from those available today. Market trends have shown a growing prevalence of disposable or single-use devices, which raise significant public health concerns, especially among young people, as well as having negative environmental implications. The clear and precise definition of these disposable devices makes it possible to differentiate them from traditional rechargeable devices, thus facilitating appropriate and specific regulation for each type of product.

Finally, it should be noted that during the prior public consultation and the public hearing and information process, approximately 4,000 and 2,000 contributions were received respectively, with significant participation from the Spanish electronic cigarette sector, which made more than 100 contributions during the public hearing and information phase. Among the contributions, entities such as the Union of Vaping Promoters and Entrepreneurs (Unión de Promotores y

Empresarios del Vapeo - UPEV,https://upev.org/), stand out, with whom technical meetings have been held on two occasions, as well as the Spanish Association of Personal Vaporiser Users (Asociación Española de usuarios de Vaporizadores Personales - ANESVAP,https://www.anesvap.es/), two of the main entities in the electronic cigarette sector in Spain and representatives of the sector, as well as large tobacco companies (PMI, BAT, etc. active in the electronic cigarette market). It should be noted that none of the comments received from the industry or these organisations mentioned the possible confusion referred to by the Commission in relation to the new definitions of electronic cigarettes.

Based on the above, it follows that, in the opinion of the Kingdom of Spain, there is no risk of confusion between the different categories of products, nor any threat to the correct application of the Directive's provisions to those products that fall within its scope.

The definition of related products

As noted by the Commission in its observations, although Directive 2014/40/EU mentions related products, there is a significant shortcoming in that it does not include a definition of what it considers to be 'related products'.

This draft aims to fill this gap in European legislation by introducing a broad concept that responds to the vast development experienced in the national and European market through the marketing of a wide variety of differentiated products. This concept is also included in the document 'Comprehensive Plan for the Prevention and Control of Tobacco Use 2024-2027', which has been approved with the consensus of the different sectors involved in the prevention and control of tobacco use in Spain, with technical participation from different regional administrations, scientific societies, and civil society organisations.

It should be noted, in response to the Commission's concerns regarding possible confusion about the applicable requirements under the Directive, that the existence of this 'umbrella' concept does not interfere with the recognition of different health requirements for each of them. Thus, it can be seen throughout the text of the draft that it includes specific articles, chapters and sections on the requirements applicable to different products based on their characteristics.

Furthermore, it should be noted that the regulation of health requirements established for product categories not included in the Directive is similar to that already existing and recognised in the Directive, demonstrating the Kingdom of Spain's desire to align it as closely as possible with the letter of the requirements laid down in European legislation and in the interests of regulatory consistency with the latter.

Finally, as mentioned in the previous section, during the public hearing and information process, which saw extensive participation from the Spanish electronic cigarette sector, none of the comments received mentioned the potential confusion referred to by the Commission.

The definition of ingredients harmful to human health

The inclusion of a more specific definition of 'ingredients harmful to human health' in Article 3(ar) in no way seeks to contradict or limit the provisions of Directive 2014/40/EU, but rather complements them and aims to provide tools at national level to control certain substances with a harmonised classification established by the Commission itself on the basis of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. At present, Spain is registering a number of such substances in a national internal database. However, the definition set out in the current legislation has led to difficulties in the conformity verification process. As of 1 July 2025, approximately 80 substances (ingredients) have been notified to the EU-CEG Portal that have a harmonised classification (human health) and are included in the database of the European Chemicals Agency (ECHA, Information on chemicals). Available at: https://echa.europa.eu/es/information-on-chemicals). This list includes substances such as D-limonene/(R)-p-mentha-1,8-diene (CAS 5989-27-5) classified as Toxic by inhalation category 1 (H304), Geraniol (CAS 106-24-1) classified as Skin sensitiser category 1B (H317), and Butyl Acetate (CAS 123-86-4) classified as Toxic to specific organs through repeated exposure (STOT SE 3 H336).

That is why Spain wishes to provide legal certainty within the discretionary powers granted to Member States in the interests of protecting public health through the analysis of risk assessments.
It should be noted that, with regard to this matter of significant concern, the Commission was asked for its opinion following the meeting of the 'Expert Group on Tobacco Policy' held in Luxembourg on 8 October 2024. In addition, a formal inquiry was also submitted on 22 October 2024 via the Directorate-General for Health and Food Safety (Unit B4 – Disease Prevention and Health Promotion) regarding these issues.

The definition of nicotine

The proposed amendment responds to the need to avoid certain legal loopholes that have been exploited by various economic operators to try to market substances with pharmacological effects similar to those of traditional nicotine (such as 6-methylnicotine or metatine), arguing that, as they are not technically and strictly 'nicotine alkaloids', their products do not fall within the scope of Royal Decree 579/2017 and are therefore considered 'nicotine-free' products, thus escaping health regulation. This situation undermines the effectiveness of the regulatory framework and the protection of public health.

Directive 2014/40/EU defines 'nicotine' as 'nicotinic alkaloids' without distinguishing between natural and synthetic origin. However, this definition — as the Commission rightly points out — may give rise to different interpretations as to whether certain synthetic compounds not found in nature, such as 6-methylnicotine, are included. Therefore, the wording proposed in the Spanish draft does not seek to contradict the Directive but to extend its coverage, closing off regulatory loopholes exploited by some manufacturers and importers.

According to the IUPAC (International Union of Pure and Applied Chemistry), alkaloids are defined as 'organic nitrogenous compounds, of a basic nature, produced naturally, mainly in plants' (International Union of Pure and Applied Chemistry. (2006). Alkaloids (A00220). In Compendium of Chemical Terminology (Gold Book). Available at: https://goldbook.iupac.org/terms/view/A00220). This definition, widely accepted in the scientific community, establishes as a fundamental criterion the natural biosynthetic origin of the compound (Rodger, M. F., & Wink, M. (1998). Alkaloids Biochemistry, ecology and medicine applications; Semwal, D. K., (2023). The Essential Guide to Alkaloids. Nova Science Publishers, Inc.).

Consequently, substances such as 6-methylnicotine or metatine, which are synthesised exclusively in the laboratory and have not been detected in tobacco leaves or other organisms, should not be classified as alkaloids, despite their structural similarity to nicotine. Spain therefore considers it necessary to include this technical specification, which, not only does not contradict the Directive but enhances technical control at the national level, thereby strengthening regulatory oversight and public health protection.
The Spanish authorities reiterate their commitment to maintaining full compliance with Directive 2014/40/EU, while emphasising the importance of adapting the national regulatory framework at a technical level to market developments, where new compounds with addictive potential are being introduced in order to circumvent the legislation in force.

The use of the EUCEG portal

Spain considers that, by equating these new forms of consumption with the products covered by Directive 2014/40 EU, it is logical to request the communication of the same information regarding both commercial aspects and composition and safety and quality requirements. Accordingly, and in the interest of maintaining such equivalence, the use of the EU-CEG portal is deemed the optimal mechanism for ensuring uniform information across all products. Furthermore, using the same platform makes the process more accessible and convenient for importers and manufacturers, who are already familiar with this portal.
We are aware of the categories divisions currently established by the EU-CEG European portal. It also takes into account Decision (EU) 2015/2186 and Decision (EU) 2015/2183 on product notification formats on that portal.
The purpose of including notification of these products through this European portal is twofold:
- To obtain the information required for the monitoring of newly regulated products at national level
- To align these new products with those already covered under Directive 2014/40/EU

The inclusion of these new products in the EU-CEG portal database does not hinder the proper functioning of the database or the activities already carried out with products regulated by the Directive.

As for the issue of new categories, we believe that the portal is sufficiently flexible in terms of categories that this should not pose a problem. For example, under the current EU-CEG portal system, herbal products for smoking are included under the 'tobacco products' category, showing that the classification system allows for a degree of flexibility. Another example is that there is no category for heated tobacco, as these types of products did not exist when the Directive was drafted, but they are included in the section on 'novel tobacco products'.

Furthermore, there are open subcategories that may be used for products that do not fit into any of the other subcategories. For example, in the electronic cigarettes section, there is a subcategory called 'others', which is flexible in terms of content.
The only challenge would be the increase in the volume of communications and workload, however Spain has acknowledged this issue. Furthermore, the restriction on products with flavours other than tobacco, which is another measure included in this regulatory reform, would lead to a decrease in the volume of communications, thereby aligning the situation with current levels.
Therefore, it is not considered that the EU-CEG European portal poses technical limitations to the inclusion of these new and emerging products. In any case, the option of developing a complementary national database to support the portal, using the information it provides, remains under consideration. The remarks made by the Commission in this regard have been duly noted.

The labelling of electronic cigarettes

Spain is aware of the obligations regarding products containing nicotine regulated by Directive 2014/40 EU. The amendment to national regulations seeks to extend these same obligations to nicotine-free products, thereby ensuring consistency with European regulations.
Firstly, products containing a nicotine-free liquid but which can subsequently be used with a nicotine-containing liquid are subject to the same obligations as nicotine-containing products.
The labelling of nicotine-free products shall be aligned, wherever possible, with the obligations set out in the Directive, except for the health warning provided for in Article 20(4)(b)(iii). In this case, it has been adapted so as to avoid reference to nicotine content, seeking also to be as consistent as possible with existing European regulations. The health warning text specified by the Directive for herbal products for smoking is used.

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