

**REGULATORY IMPACT ANALYSIS REPORT ON THE PRELIMINARY DRAFT
LAW AMENDING LAW 28/2005 OF 26 DECEMBER ON HEALTH MEASURES
AGAINST SMOKING AND REGULATING THE SALE, SUPPLY, CONSUMPTION
AND ADVERTISING OF TOBACCO PRODUCTS**

EXECUTIVE SUMMARY

Proposing Ministries/Bodies	Ministry of Health	Date	13/10/2025
Title of the regulation	PRELIMINARY DRAFT LAW AMENDING LAW 28/2005 OF 26 DECEMBER ON HEALTH MEASURES AGAINST SMOKING AND REGULATING THE SALE, SUPPLY, CONSUMPTION AND ADVERTISING OF TOBACCO PRODUCTS		
Type of report	Normal <input checked="" type="checkbox"/> Abbreviated <input type="checkbox"/>		
TIMELINESS OF THE PROPOSAL			
Situation Covered by the Regulation	<p>The aspects regulated by the preliminary draft law involve the effective implementation of one of the main measures envisaged in the Comprehensive Plan for the Prevention and Control of Tobacco 2024-2027, and relate to the updating of health regulations on tobacco products and related products, in aspects such as their sale, supply, consumption, advertising, promotion and sponsorship, health prevention and promotion measures and cessation. Thus, it should be emphasised as regards the factual situation currently existing in our country that there is a variety of products with different characteristics, with or without tobacco, with or without nicotine, with or without electronic components, and even with hybrid aspects of complex cataloguing, that pose a challenge with respect to the epidemiological situation in our country and that constitute a highly dynamic factual situation lacking adequate and adapted regulations given that 15 years have passed since the last comprehensive amendment of the regulation in 2010.</p> <p>It is emphasised that the preliminary draft law has a significantly innovative character since it regulates several categories of complex products for the first time.</p>		
Objectives pursued	<p>The objectives that aim to be achieved are, on the one hand, the improvement in the health of smokers and non-smokers, the promotion of healthy spaces with greater protection for different social groups and, on the other hand, an improvement in the regulations applicable to tobacco products and related products. Furthermore, the aim is to adopt all necessary measures to develop what is established in the Basic Axis of Regulatory Action contemplated in the aforementioned Plan. The plan has thus identified the need to make decisive progress on public health objectives to reduce the tobacco epidemic, as well as</p>		

	to introduce various improvements that are not yet envisaged in the harmonised regulation of the European Union due to the significant changes experienced at the 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.
Main alternatives considered	The possibility of not taking any measures has been considered, pending an update of the European regulations. However, there are currently no proposals or intentions to do so in this area. No alternative can therefore be considered with regard to the promotion of new healthy spaces or the regulation of new products that are currently on the market and that lack properly adapted regulation, since there are significant shortcomings in this regard, whether in terms of their sale, consumption, or advertising. The proposal made in Spain is in line with those also made by neighbouring Member States. Regarding the regulation of other tobacco products and related products, contradictory alternatives were raised in the public consultation process prior to the preparation of this draft, and those that provide a greater guarantee of public health protection were chosen.
CONTENT AND LEGAL ANALYSIS	
Type of Regulation	Act
Structure of the Regulation	<p>The preliminary draft law consists of an expository part, a sole article with twenty-five paragraphs, a sole transitional provision and a sole final provision.</p> <p>The sole article therefore contains the following sections:</p> <ul style="list-style-type: none"> • Paragraph 1 extends the scope of the regulation to related products and devices for tobacco consumption. • Paragraph 2 adds new definitions. • Paragraph 3 introduces the ban on the consumption of tobacco products by minors. • Paragraph 4 expands the possible spaces where smoking is prohibited. • Paragraph 5 amends the advertising, promotion and sponsorship regime, extending it to devices for tobacco consumption. • Paragraph 6 extends the application of the rules on common names to devices for tobacco consumption. • Paragraphs 7 and 8 introduce specific regulations for new categories of related products into our legal system; adding, respectively, a new Chapter IIIa, which sets out the limitations on the sale, supply and consumption of related products in order to update the regulation of these products in the interests of the protection of public health; and a new Chapter IIIb, which establishes the regulation of advertising,

	<p>promotion and sponsorship of related products. Among other provisions, the new measure includes a ban on the sale and supply of single-use electronic cigarettes.</p> <ul style="list-style-type: none"> • Paragraph 9 amends the title of Chapter IV, which is now entitled 'Measures to prevent smoking, promote health and facilitate smoking cessation'. • Paragraphs 10 and 12 replace references to 'tobacco withdrawal' with 'tobacco cessation'. • Section 11 introduces the creation of the Observatory for the Prevention of Smoking. • Paragraphs 13 to 18 modify the system of penalties, the infringements, the amount of the penalties and the persons responsible. • Paragraph 19 extends the scope of the signage obligation in centres or premises where there is a ban on consumption by extending it to tobacco products and related products. • Paragraphs 20, 21 and 23 set out the consumption requirements in prisons and psychiatric centres and residential centres for the elderly or persons with disabilities. • Paragraph 22 removes the ninth additional provision, concerning the special exemption for private smoking clubs. • Paragraph 24 adds the additional provision on signage obligations. • Paragraph 25 deletes the twelfth additional provision, on the consumption and sale to minors of devices susceptible to nicotine release and similar products, and the thirteenth additional provision, on restrictions on the advertising, promotion and sponsorship of devices susceptible to nicotine release and refill containers. <p>The sole transitional provision recognises a transitional period through the marketing extension, which responds to the need to allow manufacturers and marketers to adapt the affected products to the new requirements established, as well as to exhaust the available stocks. In this regard, a period of 12 months is recognised for carrying out this adaptation. It also provides for a period of 12 months during which single-use electronic cigarettes may continue to be placed on the market.</p> <p>The single final provision establishes the entry into force.</p>
<p>Reports collected</p>	<p>The following reports are expected to be collected:</p> <ul style="list-style-type: none"> ➤ <u>Department reports:</u> <ul style="list-style-type: none"> • Report from the Technical General Secretariat of the Ministry of Health, in accordance with the provisions of Article 26(5), fourth paragraph, of Law 50/1997 of 27 November, of the Government. ➤ <u>Reports from other departments:</u> <ul style="list-style-type: none"> • In accordance with the provisions of Article 26(5), first paragraph, of

Law 50/1997 of 27 November:

- Ministry of Finance and the State Agency for Tax Administration
 - Ministry of Social Rights, Consumer Affairs and 2030 Agenda
 - Ministry of Agriculture, Fisheries and Food
 - Ministry of Economy, Trade and Business
 - Ministry of Industry and Tourism
 - Ministry of the Interior
 - Ministry of Defence
 - Ministry of Transport and Sustainable Mobility
 - Ministry of Work and Social Economy
 - Ministry of Youth and Children
 - Ministry of the Presidency, Justice and Relations with the Courts and the National Institute of Toxicology and Forensic Sciences
 - Ministry of Education, Vocational Training and Sports
 - Ministry of Science, Innovation and Universities
 - Ministry of Housing and Urban Agenda
 - Ministry of Culture
 - Ministry of Equality
 - Ministry of Digital Transformation and Civil Service
- Report from the Ministry of Territorial Policy and Democratic Memory, in accordance with the provisions of Article 26(5), paragraph six, of Law 50/1997 of 27 November.
 - Report of the Office of Coordination and Regulatory Quality of the Ministry of the Presidency, Justice and Relations with the Courts, in accordance with Article 26(9) of Law 50/1997, of 27 November.
- **Reports from the autonomous communities and local authorities:**
- Report of the autonomous communities and the cities of Ceuta and Melilla through the Technical Secretariat of the Interterritorial Council of the National Health System and the Spanish Federation of Municipalities and Provinces (FEMP).
 - Advisory Committee and Interterritorial Council of the National Health System.
- **Other reports:**
- Report of the Autonomous Body Commissioner for the Tobacco Market and Advisory Committee, in accordance with Articles 4 and 8(2)(a) of Royal Decree 2668/1998 of 11 December approving the by-laws of the Autonomous Body Commissioner for the Tobacco Market.
 - Report of the Spanish Data Protection Agency, in accordance with Article 47 of Organic Law 3/2018, of 5 December, on the protection of personal data and guarantee of digital rights, and Article 5(3)(b) of the Statute of the Agency, approved by Royal Decree 389/2021, of 1 June.
 - Report of the National Disability Council, in accordance with Article 2(1) (d) of Royal Decree 1855/2009, of 4 December, regulating the National Disability Council.

	<ul style="list-style-type: none"> Notification Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services. <ul style="list-style-type: none"> ➤ <u>Government Delegated Committee for Economic Affairs.</u> ➤ <u>Opinion of the Economic and Social Council</u>, in accordance with the provisions of Article 7(1)(1)(a) of Law 21/1991, of 17 June, establishing the Economic and Social Council. ➤ <u>Opinion of the Council of State</u>, in accordance with the provisions of Article 22(2) of Organic Law 3/1980, of 22 April, of the Council of State. 	
<p>Public consultation process</p>	<p>The public consultation process took place from 19 August to 10 September 2024.</p>	
<p>Public information process</p>	<p>The public information process took place from 10 September to 30 September 2025.</p>	
<p>IMPACT ANALYSIS</p>		
<p>COMPLIANCE WITH THE DISTRIBUTION OF POWERS</p>	<p>This preliminary draft law has the character of primary legislation on the protection of the right to health and is issued under Article 149(1)(16) of the Spanish Constitution, which grants the State jurisdiction over the foundations and general coordination of healthcare.</p> <p>It is also based on other powers recognised in Article 149(1) of the Constitution, specifically paragraphs 1, 9, 18 and 27.</p>	
<p>ECONOMIC AND BUDGETARY IMPACT</p>	<p>General impact on the economy</p>	<p>It has an impact on the sector of tobacco products and related products.</p>
	<p>With regard to competition</p>	<p><input checked="" type="checkbox"/> The regulation has no significant impact on competition.</p> <p><input type="checkbox"/> The regulation has positive effects on competition.</p> <p><input type="checkbox"/> The regulation has negative effects on</p>

		competition.
	With regard to administrative burdens	<input type="checkbox"/> It entails a reduction in administrative burdens. Estimated quantification € _____ <input type="checkbox"/> It incorporates new administrative burdens. Estimated quantification € _____ <input checked="" type="checkbox"/> It does not affect the administrative burdens
	With respect to budgets, the regulation: <input type="checkbox"/> Affects the budgets of the General State Administration. <input type="checkbox"/> Affects the budgets of other Regional Administrations	<input type="checkbox"/> Involves an expense: € _____. <input type="checkbox"/> Involves a revenue.
GENDER IMPACT	The regulation has the following gender impact	Negative <input type="checkbox"/> None Positive X
IMPACT DUE TO CLIMATE CHANGE AND THE ENVIRONMENT	Positive, since the reduction in smoking prevalence leads to a reduction in the emission of smoke and aerosols, as well as a reduction in waste, both through a reduction in consumption and a ban on single-use tobacco-related devices.	
OTHER IMPACTS CONSIDERED	<ul style="list-style-type: none"> - Impact on health (POSITIVE) - Impact on childhood and adolescence (POSITIVE) - Impact on the family (POSITIVE) - Impact on equal opportunities, non-discrimination and universal accessibility for persons with disabilities. NONE) - Impact on LGBTI+ people (POSITIVE) 	
EX POST EVALUATION	Not applicable	

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I.- JUSTIFICATION OF THE REPORT

The purpose of the preliminary draft law is to implement the provisions of the Comprehensive Plan for the Prevention and Control of Tobacco 2024-2027, specifically that which is established in the Basic Axis of Regulatory Action. The autonomous communities, as well as other social and economic agents, together with non-governmental organisations and scientific societies, have duly participated in the preparation of the plan, thus achieving a remarkable consensus regarding the measures envisaged in the plan.

The economic impact of the envisaged measures is limited, given that the continued marketing of most tobacco products and related products is allowed.

On the other hand, neighbouring countries have established or proposed the prohibition of single-use electronic cigarettes, a measure that is fully justified given their high impact on waste generation due to highly toxic electronic components that are difficult or impossible to recycle. In addition, from a health point of view, their low price facilitates greater accessibility for young people, with profound implications for the epidemiological situation in terms of their consumption and their impact on health.

The measures included in the draft legislation affect competition at the manufacturing level, by prohibiting that specific product category.

The measures envisaged correspond to the forecasts included in the Comprehensive Plan for Tobacco Prevention and Control 2024-2027, approved by the Council of Ministers on 30 April 2024, with the participation of the technical working group of tobacco officials from the autonomous communities, the Spanish Federation of Municipalities and Provinces, as well as scientific societies and bodies involved in the fight against smoking, and appear appropriate from the point of view of the principles of good regulation to protect health and prevent smoking.

In this sense, the changes proposed in the manufacture, presentation, and marketing of tobacco products and related products can be assumed by manufacturers and related sectors, and the observations presented during the prior public consultation process have been taken into account.

Finally, the application of the regulation is expected to result in positive health impacts, although these cannot be considered appreciable or significant at present since they could only be measured, where applicable, in the medium to long term, and possibly focused on the population sector of adolescent and young women.

II.- TIMELINESS OF THE PROPOSAL

1. Rationale.

The purpose of the preliminary draft law is to implement the provisions of the Comprehensive Plan for the Prevention and Control of Tobacco 2024-2027, specifically what is established in Goals 1 and 3 of the Basic Axis of Regulatory Action. Within the first goal, “Prevent the onset of tobacco and related product use”, and more specifically with regard to Objective 1.3 *“Denormalise the use of tobacco and related products in public spaces and in the private sphere”* and Objective 1.5 *“Strengthen compliance with and monitoring of existing legislation”*. Thus, as a development of this Goal and its Objectives, the plan envisages the following lines of action regarding the legislative strategy for that Goal:

“■ Progress towards the legal harmonisation of advertising, promotion and sponsorship of related products and new products with that which exists for tobacco products.

■ Regulate the sale and consumption of tobacco-related products (with and without nicotine), advancing the harmonisation of legislation for tobacco products.

■ Review the penalty amounts.”

For its part, in relation to Goal 3, *“Reduce environmental exposure to emissions of tobacco and related products in public and private spaces and reduce the ecological footprint”*, and its Objective 3.1 – *“Promote the amendment and enforcement of the law in smoke-free spaces with proper signage of these spaces”*, the Plan sets out the following course of action as regards the legislative strategy for this Goal:

“■ Legislative expansion of smoke-free areas and areas free of aerosols from electronic cigarettes and related products in certain public or collective spaces, especially those where minors are present. Prohibition of tobacco-related single-use devices”.

Furthermore, the proposal is in line with the Sustainable Development Goals (SDGs), especially Target 3.4, to reduce by one third premature mortality from non-communicable diseases by 2030. In addition, it takes into account the recommendations established by the fourth edition of the European

Code Against Cancer¹, in relation to avoiding the consumption of tobacco and related products, the maintenance of a home and workplace free of environmental tobacco smoke, as well as the objectives set by Europe's Beating Cancer Plan², submitted by the European Commission to the European Parliament and Council. This plan sets the goal that, by 2040, less than 5% of the population will consume tobacco, compared to the current average of 25% in Europe.

The plan also involves advancing the actions already undertaken in response to the challenge of emerging products that have appeared on the market and which, due to their attractiveness to young people, serve as a gateway to tobacco use. In this regard, reference should be made to the agreement adopted by the Interterritorial Council of the National Health System entitled '*Tobacco products and related products: the implication of their consumption on Public Health*'³.

Thus, the current situation of the market for tobacco products and related products requires an urgent update, as there is a variety of products with differentiated characteristics, with or without tobacco, with or without nicotine, with or without electronic components, and even with hybrid aspects that are complex to classify, that pose a challenge and for which it is necessary to provide the appropriate technical response in order to guarantee proper protection of people who consume these new unconventional products.

The proposal arises from and is a consequence of this factual situation and represents a response to it by updating the regulation, which has become obsolete following the gradual introduction of new tobacco products and related products to the market over the last decade.

These measures are in line with recent statements by the European Commissioner for Health during the presentation of the EU budget, who recognised for the first time the health risk of new tobacco and nicotine products, stating that it is comparable to other traditional tobacco products and calling for a reduction in consumption rates for these products together with the need to protect future generations.⁴

¹ European Code against Cancer

https://www.sanidad.gob.es/ciudadanos/enfLesiones/enfNoTransmisibles/docs/Codigo_Cancer.pdf

² Communication from the Commission to the European Parliament and the Council. Europe's Beating Cancer Plan.

https://ec.europa.eu/health/sites/health/files/non_communicable_diseases/docs/eu_cancer-Plan_es.pdf

³ Tobacco and related products: Implication of its consumption on public health

https://www.sanidad.gob.es/areas/promocionPrevencion/tabaco/legislacionAcuerdosDenuncia/docs/Acuerdo_Productos_Tabaco.pdf

⁴ *An ambitious budget for a stronger Europe: 2028-2034*

https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1847

Due to this highly changing situation, at national and European level, the amendment could not be included in the 2025 Annual Regulatory Plan. It should be noted that it was included in previous regulatory plans in earlier years, but could not be implemented due to political developments at both the national and European levels.

2. Objectives.

The main objective of the proposal is to provide a health-based response to the changes experienced, both at the 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. The aim is to offer greater protection for citizens by promoting healthy and smoke-free spaces in community and social environments. Finally, the draft law aims to offer greater clarity, uniformity and legal certainty at national level with regard to emerging products that have clear public health implications in terms of their consumption, particularly among young people. With regard to this sector of the population, the proposal aims to put an end to a situation that is contrary to the regulation but that has been repeated over time, namely tobacco consumption by minors, by introducing for the first time a ban on such consumption and recognising penalties in this regard. It should be noted that up until now, only the sale or delivery to minors has been prosecuted, which has proven unsatisfactory given the actual situation experienced and that is reflected in the start-up age rates set out in the national surveys. The draft law therefore aims to address this issue by providing stricter regulation in the interests of adequate protection for children.

3. Alternatives.

The possibility of not taking any measures has been considered, pending an update of the European regulations. However, there are currently no proposals or intentions to do so in this area. Therefore, no alternative can be considered with regard to the promotion of new healthy spaces or the regulation of new products that are currently on the market and that lack properly adapted regulation, the latter having significant shortcomings in this regard, whether in terms of their sale, consumption, and advertising. The proposal made in Spain is in line with those also made by neighbouring Member States. Regarding the regulation of other tobacco products and related products, contradictory alternatives were raised in the public consultation process prior to the preparation of this draft, and those that provide a greater guarantee of public health protection were chosen. These contradictory alternatives range from the promotion of related products as healthy options within the so-called 'harm reduction' policy, to a total ban on these products.

4. Compliance with the principles of good regulation

The proposed law is in line with the principles of good regulation of Article 129 of Law 39/2015 of 1 October on the Common Administrative Procedure for Public Administrations, and in particular those of necessity, effectiveness, proportionality, legal certainty, transparency and efficiency.

From the point of view of necessity and effectiveness, this regulation is the most appropriate instrument for comprehensively addressing the regulation of tobacco control and prevention. Aspects such as the sale, supply, advertising, promotion, sponsorship and consumption of tobacco products and related products are regulated in a uniform manner. This decision was adopted after analysing various regulatory alternatives, and aims to avoid regulatory dispersion and ensure greater coherence and clarity of the regulation, contributing to administrative and regulatory simplification.

As regards the principle of proportionality, the law contains the provisions strictly necessary for meeting the public health protection objectives that motivate the same. It also reinforces the principle of legal certainty by consolidating a clear, stable and predictable regulatory framework, which originated in the law adopted in 2005, the purpose of which was to overcome the fragmented and unsystematic nature of the previous legislation. This framework has been subject to subsequent amendments, including the 2017 reform, which incorporated devices susceptible to nicotine release. This law updates and expands that regulatory framework by expressly including related products, in response to market and consumer trends.

In order to strengthen both legal certainty and consistency with European Union law, the terminology used is adapted to that used in Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014. In particular, the expression “devices susceptible to nicotine release” is replaced by the expression “electronic cigarette”, and the concept of “related products” is introduced; both terms are referred to in the aforementioned directive, but hitherto absent in national legislation. In addition, the reference to devices used in the consumption of heated tobacco products is incorporated, with the aim of clarifying their legal situation and resolving the uncertainty generated by the existence of contradictory judicial pronouncements on their legal nature.

Pursuant to the principle of transparency and in compliance with Law 50/1997, of 27 November, of the Government, the preliminary public consultation procedures have been carried out, as well as the public hearing and information procedure. Both processes have been developed through the publication of the draft preliminary law on the website of the Ministry of Health, thus ensuring the participation of citizens and the sectors concerned.

Finally, the law observes the principle of efficiency by not imposing additional administrative burdens that are not strictly necessary to ensure that all tobacco products and related products on the market, as well as the operators involved in their marketing, comply with the established health requirements.

5. Annual Regulatory Plan

Although the 2025 Annual Regulatory Plan did not include the amendment to the law, it does mention its planned revision in relation to the inclusion of the amendment to Royal Decree 579/2017, of 9 June, regulating certain aspects relating to the manufacture, presentation and marketing of tobacco products and related products.

III.- CONTENT

1. Structure

The preliminary draft law consists of an expository part, a sole article with twenty-five paragraphs, a sole transitional provision and a sole final provision.

2. Content

The sole article amends Law 28/2005 of 26 December on health measures against smoking and regulating the sale, supply, consumption and advertising of tobacco products, as follows:

- Article 1 is amended, extending the subject matter of the regulation to related products and devices for tobacco consumption. The regulatory harmonisation of tobacco with other related products is carried out due to its direct effects on the health of consumers and passive smokers, as well as the visibility of consumption.
- Article 2 is amended to include new definitions.
- Article 6 is amended to prohibit the consumption of tobacco products by minors.
- Article 7 is amended to extend smoke-free areas to vehicles used by persons in the course of or as a result of their employment, except when used exclusively for personal purposes; university centres and adult education centres; the interior and exterior of swimming pools for collective use; the exterior of sports facilities and venues where public shows are held; outdoor areas of nightclubs, gambling establishments or establishments for general public use; outdoor bus

stations; transport vehicles with drivers; suburban transport spaces that are completely outdoors; exteriors of bars, restaurants and other commercial establishments; concerts; theatres, cinemas and other public shows held in open spaces; as well as enhanced protection in healthcare, cultural, educational, sports and social environments, and parks or children's playgrounds. Also included in the extension of smoke-free spaces are those with an important environmental component, i.e. beaches and National Parks, and which have been the subject of different protection initiatives, both voluntary and regulatory, both at regional level, through the different Smoke-Free Beach Networks, and the prohibitions on consumption on beaches in different localities, using in this regard the regulatory authorisation approved by Article 18 of Law 7/2022 of 8 April, on waste and contaminated soils for a circular economy, which provides for this prohibition among its prevention measures to curb the generation of litter in the marine environment and as a contribution to the United Nations sustainable development objective. The smoking ban in National Parks also contributes to these objectives by way of example and as a fire protection measure in these spaces that are specially protected due to their unique biodiversity and ecological characteristics. In this regard, National Parks already have significant restrictions on activities such as lighting fires, camping, land-use, and resource collection. Tobacco smoke unintentionally exposes visitors and workers, including children, the elderly and people with respiratory diseases and represents a direct cause of forest fires (approximately 3% of fires according to some estimates), with serious consequences for biodiversity, natural heritage and human safety. Furthermore, there is clear public support for this measure: the petition by Nofumadores.org (Non-Smokers.org) "*No more tobacco smoke and cigarette butts in Spain's National Parks! STOP*" has collected nearly 80,000 signatures. This level of support demonstrates that the regulation has social legitimacy. Finally, mention should be made of the amendments in the field of transport in response to the requests from various scientific societies based on the mandatory presence in these spaces as part of the right to mobility of citizens. This must be carried out without undermining their right to health, and avoiding exposure to the polluting particles present in these spaces where people congregate and gather.

- Article 9 is amended to extend the regime governing advertising, promotion and sponsorship of tobacco products to devices for tobacco consumption. In addition, regarding the exception for presentations of products to professionals in the sector, a clarification has been added regarding the value or price of the goods or services referred to, due to the fact that numerous violations have been regarding tobacco product promotions. It was considered from the outset that the amount of the promotions could in no case exceed 5% of the price of the individual products; however, this requirement has often been ignored, with an interpretation that it

referred to 5% of the total of the campaign. For this reason, it has been considered appropriate to specify this requirement.

- Article 10 is amended to extend the application of the rules on common names to tobacco consumption devices.
- Specific regulation is being introduced for new categories of related products in our legal system. To this end, a new Chapter IIIa is incorporated, which sets out the limitations on the sale, supply and consumption of related products in order to update the regulation of these products in the interests of the protection of public health, and a new Chapter IIIb is being incorporated, which establishes the regulation of advertising, promotion and sponsorship of related products, thus adapting it to the current situation.

Among other provisions, the prohibition on the sale and supply of single-use electronic cigarettes stands out as a new feature.

- In Chapter IV, the title is amended to “Measures for the prevention of smoking, promotion of health and facilitation of tobacco cessation”, and references to “tobacco withdrawal” are replaced by “tobacco cessation”.
- The creation of the Observatory for the Prevention of Smoking is introduced as a sector-wide coordination body.
- Modifications are also made to the penalty system, the violations, the penalty amounts and the responsible persons set out in Chapter V.
- In addition, three additional provisions are deleted, one of which removes the special exemption enjoyed by private smoking clubs, and amendments are made to others, which include expanding the scope of the signage requirement in centres or premises where smoking is prohibited, and extending it to include tobacco products and related products; and establishing requirements for consumption in prisons, psychiatric centres and residential centres for the elderly or persons with disabilities. An additional provision is added with regard to signage obligations.

The single transitional provision recognises a transitional period through the marketing extension, which responds to the need to allow manufacturers and marketers to adapt the affected products to the new requirements established, as well as to exhaust available stocks. A period of 12 months is recognised. It also provides that single use electronic cigarettes may continue to be marketed for 12 months after the law comes into force.

The sole final provision indicates the entry into force.

3. Main new features.

Expand smoke-free spaces, especially outdoors. Prohibit disposable electronic cigarettes. Introduce specific regulations for new categories of related products in our legal system, in particular nicotine pouches and heated herbal products. Prohibit the consumption of tobacco products by minors.

IV.- LEGAL ANALYSIS

1. Legal basis and regulatory status.

The legal basis of the draft is initially grounded in the General Health Act 14/1986, of 25 April, which established the obligation of public health administrations to direct their actions primarily towards the promotion of health and the prevention of diseases, to avoid activities and products that, directly or indirectly, may have negative consequences for health, and to regulate their advertising and commercial marketing.

It is therefore a proposal with the force of law, since it is intended to amend a regulation of equal status.

2. Link between the Regulation and European Union Law.

The regulation is fully consistent with relevant European Union law, in particular Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, which was incorporated into national law by Royal Decree-Law 17/2017, of 17 November, amending Law 28/2005, of 26 December, on health measures against smoking and regulating the sale, supply, consumption and advertising of tobacco products, to transpose Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014.

This Directive was amended by Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products, which is limited in scope due to its delegated status and was made pursuant to the authorisation contained in Articles 7(12) and 11(6) of Directive 2014/40/EU of 3 April 2014, in the event of a substantial change of circumstances. For this reason, it recently became necessary to carry out a limited and specific amendment to Royal Decree 579/2017 of 9 June, insofar as it affects the withdrawal of said exemptions in respect of heated tobacco products. Thus, by means of Royal Decree 47/2024, of 16 January, amending Royal Decree 579/2017, of 9 June, regulating certain aspects relating to the manufacture, presentation and marketing of tobacco products and related products, improvements were introduced with regard to the regulation of heated tobacco products in accordance with the changes experienced in the market for these products and their notable increases in sales.

These changes in the market for tobacco products and related products, together with the deficiencies that currently exist in European regulations, such as the lack of regulation of products like nicotine pouches and heated herbal products, are the reason for the presentation of this preliminary draft, the contents of which are consistent with what has already been put forward by other Member States and with the orientation foreseen by the current process of revision of European regulations related to these products.

3. Repeal of regulations.

There is no necessity to repeal any regulation.

4. Entry into force and validity.

This regulation shall have indefinite validity. The sole final provision establishes that the regulation will enter into force on the twentieth day following that of its publication in the Official State Gazette.

However, a transitional period is recognised through the extension of marketing, which responds to the need to allow manufacturers and marketers to adapt the products concerned to the new established requirements, as well as to allow the exhaustion of the available stocks. Depending on the various changes made to the draft law, a period of 12 months is recognised, which is considered sufficiently long to allow the sector to adapt without putting public health at risk. This period is therefore similar to or even longer than that recognised in previous amendments to the rules on the

prevention and control of smoking. In the case of Royal Decree 579/2017, of 9 June, regulating certain aspects relating to the manufacture, presentation and marketing of tobacco products and related products, transitional periods of between 3 and 10 months were recognised, depending on the case. For its part, the latest amendment to this regulation, approved by Royal Decree 47/2024, of 16 January, recognised a short adaptation period of 3 months. In this regard, following a technical assessment, the longer transitional period has been chosen.

V.- ADAPTATION OF THE REGULATION TO THE ORDER OF DISTRIBUTION OF POWERS

This preliminary draft has the character of basic legislation and conforms to the constitutional order of distribution of competences, being issued in accordance with the provisions of Article 149(1) (16) of the Spanish Constitution, which confers on the State competence over the basic conditions and general coordination of health matters, without prejudice to the autonomous communities establishing additional standards of protection.

It is also based on other powers recognised in Article 149(1) of the Constitution, specifically paragraphs 1, 9, 18 and 27.

VI.- DESCRIPTION OF THE PROCESS

Article 133 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, concerning citizen participation in the procedure for drawing up laws and regulations, with the aim of improving citizen participation in the procedure for drawing up draft or preliminary draft laws or regulations, and Article 26(2) of Law 50/1997, of 27 November, of the Government, concerning the procedure for drawing up laws and regulations, establish that prior to the drafting of the text, a public consultation must be conducted through the Ministry of Health's website, in which the opinions of the most representative individuals and organisations potentially affected by the future regulation will be gathered. This has been substantiated on the website of the Ministry of Health, with a period open from 19 August to 10 September 2024 for sending by e-mail any comments or observations deemed appropriate, contributions having been received in this process from various distributing companies of Devices Susceptible to Nicotine Release, scientific societies such as the General Council of Official Associations of Pharmacy, the Spanish Society of Medical Oncology, the General Council of Official Nursing Associations, the Spanish Society of Pneumology and Thoracic Surgery, civic entities such as Nofumadores.org and AECC or

Autonomous Communities such as the Department of Health of Galicia and the Public Health Agency of Barcelona and business entities from different sectors.

There are also numerous personal experiences shared by consumers of tobacco products and other related products who mention the "*benefits*" of consuming, above all, electronic cigarettes. As regards those presented as tobacco consumers, the main claims are related to the 'freedom' of smoking in spaces such as terraces, parks or open-air areas and complaints related to tobacco-related taxes.

Of special relevance was a proposal submitted by the State Confederation of Deaf People to include health warnings related to tobacco in sign language in smoking prevention programmes and campaigns.

With regard to the expansion of smoke-free spaces, there is support for smoking on terraces, bus stops, sports facilities, beaches, parks, etc., although less support is seen with regard to equalising related products. On the part of the industry, it is mentioned that this could involve "*disorderly leisure time*", as well as job losses due to decreased consumption.

The following reports and opinions are expected to be collected:

➤ **Department reports:**

- Report from the Technical General Secretariat of the Ministry of Health, in accordance with the provisions of Article 26(5), fourth paragraph, of Law 50/1997 of 27 November, of the Government.

➤ **Reports from other departments:**

- In accordance with the provisions of Article 26(5), first paragraph, of Law 50/1997 of 27 November:
 - Ministry of Finance and the State Agency for Tax Administration
 - Ministry of Social Rights, Consumer Affairs and 2030 Agenda
 - Ministry of Agriculture, Fisheries and Food
 - Ministry of Economy, Trade and Business
 - Ministry of Industry and Tourism
 - Ministry of the Interior
 - Ministry of Defence
 - Ministry of Transport and Sustainable Mobility
 - Ministry of Work and Social Economy
 - Ministry of Youth and Children

- Ministry of the Presidency, Justice and Relations with the Courts and the National Institute of Toxicology and Forensic Sciences
- Ministry of Education, Vocational Training and Sports
- Ministry of Science, Innovation and Universities
- Ministry of Housing and Urban Agenda
- Ministry of Culture
- Ministry of Equality
- Ministry of Digital Transformation and Civil Service
- Report from the Ministry of Territorial Policy and Democratic Memory, in accordance with the provisions of Article 26(5), paragraph six, of Law 50/1997 of 27 November.
- Report of the Office of Coordination and Regulatory Quality of the Ministry of the Presidency, Justice and Relations with the Courts, in accordance with Article 26(9) of Law 50/1997, of 27 November.
- **Reports from the autonomous communities and local authorities:**
 - Report from the Autonomous Communities through the Technical Secretariat of the Interterritorial Council of the National Health System and the Spanish Federation of Municipalities and Provinces (FEMP).
 - Advisory Committee and Interterritorial Council of the National Health System.
- **Other reports:**
 - Report of the Autonomous Body Commissioner for the Tobacco Market and Advisory Committee, in accordance with Articles 4 and 8(2)(a) of Royal Decree 2668/1998 of 11 December approving the by-laws of the Autonomous Body Commissioner for the Tobacco Market.
 - Report of the Spanish Data Protection Agency, in accordance with Article 47 of Organic Law 3/2018, of 5 December, on the protection of personal data and guarantee of digital rights, and Article 5(3)(b) of the Statute of the Agency, approved by Royal Decree 389/2021, of 1 June.
 - Report of the National Disability Council, in accordance with Article 2(1)(d) of Royal Decree 1855/2009, of 4 December, regulating the National Disability Council.
 - Notification Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.
- **Government Delegated Committee for Economic Affairs.**
- **Opinion of the Economic and Social Council**, in accordance with the provisions of Article 7(1)(1)(a) of Law 21/1991, of 17 June, establishing the Economic and Social Council.
- **Opinion of the Council of State**, in accordance with the provisions of Article 22(2) of Organic Law 3/1980, of 22 April, of the Council of State.

In accordance with the provisions of Article 105(a) of the Spanish Constitution and Article 26(6) of Law 50/1997, of 27 November, the mandatory public information process for the preliminary draft will be carried out by means of its publication on the Ministry of Health's website, during the period from

19 August to 10 September 2024. For its part, the public hearing was held from 10 September to 30 September 2025.

Once all the procedures had been completed, the preliminary draft was submitted to the General Commission of State Secretaries and Deputy Secretaries on 24 July 2025, prior to its submission to the Council of Ministers for approval as a draft law on 9 September 2025.

Finally, prior evaluation and comments have been submitted in relation to the procedure under Directive (EU) 2015/1535 in the field of technical regulations (TRIS Procedure), including those carried out by the Ministry of Finance.

VII.- IMPACT ANALYSIS

1. Economic and budgetary impact

General Impact on the Economy:

Impact on economic activities and sectors

The draft legislation directly affects the tobacco sector, including the cultivation, manufacture and distribution of tobacco products and their marketing. This impact also extends to related products, such as electronic cigarettes, insofar as the draft law extends to these products the regulations contained in Law 28/2005, of 26 December, applicable to conventional tobacco.

In particular, the following measures introduced by the draft law have specific impacts:

- Ban on the sale of single-use electronic cigarettes: affects the manufacturers, distributors and marketers of these products.
- Regulatory harmonisation of advertising for electronic cigarettes and conventional tobacco-related products: affects the manufacturers, distributors and marketers of these products.
- Extension of smoke-free spaces: can indirectly impact the hospitality and event planning sector, such as terraces and music festivals. However, none of these sectors require adaptations to continue their usual activity.

In general terms, and not for each specific measure, the reduction in tobacco consumption could affect the tobacco growing sector in Spain.

However, the sector that will be most affected in the medium term is the healthcare system, since reducing the prevalence of smoking or exposure to environmental tobacco smoke reduces healthcare expenditure by lowering the costs associated with tobacco-related diseases.

General economic impact as a result of the impact on the economic sectors

In the short term, a possible decline in sales of tobacco and related products is to be expected, due to the deterrent effect of the measures adopted. This decrease could result in a reduced revenue for manufacturers, distributors and points of sale, as well as a potential market restructuring.

For its part, and specifically for the tobacco-growing sector, purchases of tobacco grown in Spain could be affected in proportion to the aforementioned decline in sales. The heavy influence of the sector can be recognised in agricultural areas and specific districts of the province of Cáceres, where agricultural activity related to tobacco cultivation is significant. However, the decline in sales may be offset by manufacturers, distributors and importers, due to Spanish agricultural production being diverted to other international markets. This is facilitated by the multinational nature of the main operators in the market, which is mostly dominated by companies with a significant global presence.

On the other hand, and regarding the need to implement restructuring plans, it should be noted that this is already provided for in the WHO Framework Convention on Tobacco Control, which establishes the following:

“Article 17

Support for economically viable alternative activities

The parties, in cooperation with each other and with relevant international and regional intergovernmental organisations, shall promote, as appropriate, economically viable alternatives for tobacco workers, growers and, where applicable, small tobacco sellers.

In addition, guidance on the application of this article is available in the document "Policy options and recommendations on economically viable alternatives to tobacco cultivation (in relation to Articles 17 and 18 of the FCTC of the WHO)".

Notwithstanding all of the above, the evidence available at international level suggests that the effects in these sectors are proportional to the economic benefits in the health sector detailed in this report.

In relation to other measures in this draft law, smoke-free spaces must be taken into consideration. The extension of smoke-free spaces can indirectly impact the hospitality and event planning sector,

such as terraces and music festivals. However, none of these sectors require adaptations in order to continue their usual activity, as was required in previous legislative reforms. In fact, evaluations of past legislation in Spain showed that the legislative changes were not associated with a reduction in the activity of bars and restaurants in Spain¹ other than the general context of the reduction in economic activity due to the economic crisis of 2008. It is therefore estimated that the changes in this draft do not have a significant economic impact on the activity of catering premises. As was the case with the past legislation on smoke-free spaces, evaluated by the Spanish Society of Epidemiology² and the report of the Directorate-General for Public Health to the Parliament³ assessing the impact on public health of Law 42/2010, of 30 December, the reduction of smoke exposure is directly related to a reduction in the incidence of diseases associated with tobacco smoke⁴, which impacts health expenditure and the costs associated with smoking in Spain.

The overall economic impact is therefore considered to be low in the short term on some specific sub-sectors, and positive in the medium and long term from a perspective of economic efficiency and sustainability, whether health, environmental⁵ or economic.

Effects on the competitiveness of Spanish exports

No significant effects on the international competitiveness of Spanish exports are expected. The measures contemplated in the draft law are aimed at the domestic market and do not alter the conditions of production and export of products manufactured in Spain and destined for foreign markets.

Consequently, it is concluded that this draft legislation will not have any significant adverse effects on external competitiveness.

Effects on competition and market unity:

Effects on competition

The draft law introduces regulatory measures that affect economic operators in the tobacco and related products sector in a differentiated manner (especially electronic cigarettes and other related products described in the draft law), however it is considered that it **does not introduce unjustified barriers to competition**, but rather responds to legitimate public health objectives, in accordance with the principles of necessity, proportionality and non-discrimination.

In view of the above, the draft law **does not unjustifiably restrict competition** and is considered aligned with the principles set out in Law 15/2007, of 3 July, on the Defence of Competition.

Effects on market unity

From the point of view of market unity, the draft law establishes general and uniform requirements applicable throughout the national territory, without introducing distinctions between operators based on their geographical location or establishing different requirements for access or exercise of activity between autonomous communities.

It also ensures that the principle of non-discrimination on the basis of geographical origin is respected and does not prevent or hinder the access of operators established in other autonomous communities or EU Member States to the national market.

The proposed measures fall within the competence of the State in matters of health and basic conditions that guarantee the equality of all citizens in the exercise of their rights (Article 149(1)(1) and (16) EC), and comply with the principles of necessity and proportionality required by Law 20/2013, of 9 December, on the guarantee of market unity. They also rely on the exclusive powers of the State set out in Articles 149(1)(.), (18) and (27).

Consequently, it is concluded that **the draft legislation does not create undue restrictions on market unity** and is in accordance with the current legislation in this area.

Effects on SMEs:

Import and distribution

Companies engaged in the manufacture or distribution of electronic cigarettes or vaping accessories, many of which are newly established SMEs, could experience negative economic impacts in the short term, especially if their business model depends on non-specialised retail channels. However, these companies maintain their ability to compete within the new regulatory framework, which contributes to providing the sector with greater legal certainty and regulatory homogeneity.

Advertising and graphic design

No impact on SMEs in the communications, marketing and graphic design sector.

Mitigation measures

No specific administrative burdens or additional information requirements are foreseen for SMEs, beyond the adaptation to the new sectoral regulation, so **it is not considered necessary to apply differentiated exemptions and treatments**. The proposed measures are in line with the principle of proportionality and have been designed to minimise unnecessary burdens.

Overall, it is estimated that the impact on SMEs is **moderate and transitional**, limited to certain subsectors, and is **proportional to the general interest objective of protecting public health** pursued by the draft regulation.

Budgetary Impact

The draft legislation does not generate significant additional costs for the General State Administration, nor does it entail the creation of new administrative structures or the allocation of extraordinary resources. Neither does it entail any tax changes or substantially affect the collection of taxes. In relation to the General State Budgets, with respect to the Ministry of Health, for those activities that fall within the remit of the Directorate-General for Public Health and Health Equity, there are no direct or indirect associated costs, so any impact on public revenue or expenditure budgets is not foreseeable. With regard to the regional budgetary impact, there are no associated costs on the part of the competent authorities in the field of public health, so it is not foreseeable that there will be extraordinary repercussions on public revenue or expenditure budgets.

On the other hand, with regard to the impact on revenue from Excise Duties, and according to the latest Annual Tax Collection Report⁵ these increased by 6.6% in 2024, reaching a collection of 22,128 million euro and recording significant increases in the Tax on Tobacco Products, located in this case by 3.2% due to the increase in prices and consumption. The collection thus reached 6,927 billion euro, the highest figure since 2012. In terms of accrued tax, the increase was even greater, at 6%. The growth in tax revenue was higher for other tobacco products (8.3%) than for cigarettes (5.7%), which can be explained by two factors: on the one hand, the increase in the average pre-tax price (7.1% overall, 6.6% for packets and 11.3% for other products) and, on the other hand, the evolution of consumption (2.2% overall, 2.6% for packets and 1.1% for other tobacco

⁵Annual Tax Collection Report 2024

<https://sede.agenciatributaria.gob.es/Sede/estadisticas/recaudacion-tributaria/informe-anual/ejercicio-2024/5-impuestos-especiales.html>

products). It should be noted that up to September consumption had been reduced by 0.8%, with all the increase being concentrated in the last quarter due to the process of prior hoarding that usually accompanies interest rate hikes.

We therefore see that variations in consumption close to around 1%, the reduction figure envisaged with the measures included in the preliminary draft law, are part of the usual fluctuations in the market, without the application of definitive measures such as the adoption of a fiscal policy with priority health content, in line with international recommendations. Thus, as shown by the available scientific evidence and the recommendations of the World Health Organisation⁶, the increase in the tax burden and tobacco prices is the single most effective measure in terms of reducing consumption. This measure is not included in this preliminary draft law as it does not fall within the competence of the proposing department. In this regard, the historical revenue figures since 2012 mentioned in the National Tax Collection Agency's report are consistent with the absence of such a health tax policy over the last decade, a measure demanded by scientific societies as a way of advancing the goal of achieving significant reductions in consumption in Spain. Finally, it should be added that the impact on tax collection resulting from the approved health measures can be offset by the instruments available to the tax authorities. Thus, as could already be observed with the approval of Law 42/2010, by adopting an appropriate tax increase that entails a positive impact on revenue it is possible to compensate, at least in part, for the decreases in consumption resulting from the new health measures.

Direct costs

The main potential costs arise from monitoring compliance with the new provisions (verification of authorised points of sale, inspection of smoke-free spaces), which will be assumed within the ordinary competences of both state and regional health authorities.

The regulatory harmonisation of electronic cigarettes does not require public investment.

The creation of the Tobacco Prevention Observatory does not entail any additional costs to the administration since this coordination work is already being carried out with its own resources. The

⁶ Raising taxes on tobacco
<https://www.who.int/activities/raising-taxes-on-tobacco>

creation of the Observatory facilitates greater regulatory anchoring and guarantees such coordination, but does not entail additional costs.

It is therefore estimated that **the direct budgetary costs are minimal** and fall within the scope of the human and material resources already available in the competent units.

Expected Savings

Scientific literature and the experience of other countries show that tobacco control policies such as those envisaged here—when they are consistent, sustained, and integrated—generate significant reductions in smoking prevalence, which means significant savings in healthcare expenditure and an improved productivity.

- An **estimated saving in annual public healthcare expenditure** of between **100 and 200 million euro per year** in the medium term (derived from the reduction in tobacco-related diseases such as cancer, COPD and cardiovascular diseases).
- A **reduction of indirect costs** for labour productivity losses, absences and premature mortality, with a potential value greater than **2 billion euro per year** after 10 years of application.

Final assessment

Consequently, the budgetary impact of the draft regulation is assessed as **positive in the medium and long term**, since it contributes to the sustainability of the health system and a greater efficiency in the use of public resources. In the short term, the impact is **neutral or very limited** in terms of cost to the administration.

Analysis of administrative burdens

Identification of possible burdens

The draft law does not establish new complex administrative procedures and does not impose an obligation on operators to submit authorisations, self-declarations or notifications in addition to those that are already in place. No registers or licences will be created, nor will the requirements for accessing or exercising economic activities be substantially modified. In the case of nicotine-free electronic cigarettes and new related products, new administrative burdens are incorporated as a result of marketing communications, which, once formalised, are considered low and acceptable

given their impact on health. Thus, the mandatory payment of fees introduced by this draft is covered by the applicable European regulations and is common practice in different Member States. In this regard, Article 20(1) of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States regarding the manufacture, presentation and sale of tobacco products and related products establishes the following:

“Member States may impose proportionate fees on manufacturers and importers for the reception, storage, processing and analysis of the information submitted to them.”

The main implication from an administrative point of view is **that the health administrations** will assume the monitoring and supervision of the new obligations within the framework of their ordinary powers, without requiring new documentary or procedural burdens for operators or citizens.

Impact analysis

The **draft law does not introduce significant administrative burdens** for citizens or businesses. The regulatory amendments mainly involve **material compliance obligations**, but not additional information, authorisation or notification procedures. In addition, no additional forms, declarations or electronic procedures are required.

Consideration of the elimination or reduction of existing burdens

The draft law does not eliminate pre-existing administrative burdens, but it does **streamline and unify the regulatory treatment** of tobacco-related products (such as electronic cigarettes), which may facilitate inspection work and improve regulatory clarity and predictability for operators.

2. Gender impact

The consumption of tobacco and related products goes far beyond an individual decision, as it is influenced by numerous factors within the framework of the social determinants for health. Scientific evidence^{6 7} indicates that smoking and the consumption of related products have gender-specific determinants that influence both initiation and cessation, as well as the effects on health and the associated behaviour.

In the general population, the prevalence of tobacco use remains higher in men (20.2% in 2023)⁸ than in women (13.3% in 2023). However, although a decreasing trend is observed in both cases, the rate of decrease differs between the sexes, such a reduction being greater in men: between 1993 and 2023, the proportion of men who smoke daily decreased by 24 percentage points, while in women the decrease was only 7 points. In contrast, the prevalence of electronic cigarette use for the lifetime timeframe has increased by almost 7 percentage points compared to 2022⁹, among both men and women. However, among students aged 14 to 18, there is a greater increase among female students than among male students compared to 2021 (15.1 percentage points and 5.6 percentage points, respectively)²¹, this being the first time that higher consumption has been recorded among females. In addition, the adolescent girl group stands out for its greater use of nicotine devices, which creates a particularly worrying risk profile due to its medium- and long-term health implications.

The gender dimension also manifests itself in the attractiveness and advertising of these products. Various international studies and recommendations^{10 11}, such as those issued by the US Centres for Disease Control and Prevention (CDC), indicate that the characteristic flavours and aromas are particularly appealing to women, and thus encourage them to start smoking and make it difficult for them to quit. In addition, gender differences have been identified in terms of risk factors, consumption motivations, behaviour and health effects. In women, consumption is more influenced by emotional, social and cultural factors, such as low self-esteem, body image pressure, stress or the association of consumption with independence, social acceptance and slimness. In addition, it has been observed that the female sex is more likely to experience negative effects on the cardiopulmonary, immunological and nervous system.¹²

In this context, the envisaged measures not only have a positive overall impact on public health, but also represent significant progress in the area of gender equality. By reducing the accessibility, visibility and appeal of these products and with the objective of denormalising their consumption, the regulation helps to curb a growing trend in this group and prevents the consolidation of smoking and the consumption of related products as a problem with marked gender implications. It also contributes to the fulfilment of the Third Strategic Plan for the Effective Equality of Women and Men (III PEIEMH 2022-2025) by deepening the understanding of gender inequalities and the social, labour and environmental conditions that affect women's health".

In short, and taking into account the provisions of Article 26(3)(f) of Law 50/1997 of 27 November of the Government, it is considered that the proposed Regulation has a foreseeable positive gender

impact, and thus contributes to reducing health inequalities between women and men and aligning with the established objectives of the public equality policies.

3. Impact on children and adolescents

According to the 2023 ESTUDES survey,¹³ more than half of students aged 14-18 acknowledge having consumed electronic cigarettes (54.6%), tobacco (33.4%), and water pipes (40.5%) at some point in their life. This represents an increase of 10.3 percentage points compared to the previous survey in 2021 in the consumption of electronic cigarettes and an increase of 12.8 points in the consumption of water pipes, placing the use of these forms of consumption at the highest point in the historical series. By sex, a greater increase in the prevalence of this substance is observed among female students (15.1 percentage points compared to 2021) than among male students (5.6 percentage points compared to 2021), this being the first time since this substance has been analysed that higher consumption has been recorded among girls than boys. With regard to the use of water pipes, a similar prevalence is observed in both sexes. Finally, it is worth mentioning the low age of onset of consumption reported in the survey: 14.1 years for both sexes.

According to sex and age, it is observed that, in both groups, the prevalence of consumption increases with age, thus recording the highest proportion among those aged 18 (65.8% in boys and 66.3% in girls). The use of water pipes concerns a higher proportion of boys than girls from the age of 16 onwards.

Regarding the content of e-cigarettes, more than half of those who have used these products have done so without nicotine. It is also observed that women consume more electronic cigarettes with nicotine than men do.

With regard to disposable devices, they have a higher prevalence among adolescents and young people, and are especially attractive for these age groups, thus encouraging the consumption of nicotine, which is a highly addictive substance that generates short-term dependence.^{14 15 16 17 18 19 20}. Numerous studies^{21 22 23 24 25 26 27 28 29} point to the appeal of these products among younger age groups, particularly because of their flavours. Studies indicate that these types of devices constitute a significant gateway to consumption among young people, even those who have never used any other forms of nicotine. Finally, scientific evidence indicates the importance of the regulation or prohibition of this type of device, a recommendation also made by the WHO³⁰.

4. Impact on the family

This regulation is expected to have a positive impact on family health due to its effect on preventing the onset of smoking and nicotine addiction, preferably among the youngest family members. In addition, as a consequence and indirectly, it would prevent loss in the family's purchasing power by reducing the consumption of tobacco products and related products. There is also a positive impact on the protection of families attending public events, in both open and closed spaces, especially on terraces, for elderly persons and children who are affected by tobacco smoke in these outdoor spaces.

With regard to the subsidiary responsibility of parents, guardians or carers as regards the prohibition of consumption by minors, the need for which has been justified in the previous section, it is worth adding a mention of the proportionality of the measure in terms of its recognition in our legal system within the provisions of other regulations. Thus, Article 28.4 of Law 40/2015, of 1 October, on the Legal Regime of the Public Sector, provides for the possibility that sectoral penalty laws may establish that certain persons are liable to the payment of the financial penalties that are imposed on those who depend on them or are linked to them:

4. The laws regulating the various penalty regimes may classify as an infringement the failure to comply with the obligation to prevent the commission of administrative violations by those who are subject to a relationship of dependency or connection. They may also provide for the circumstances in which certain persons will be liable for the payment of the financial penalties that are imposed on those who depend on them or are linked to them.

By way of example, this occurs in the case of traffic offences and penalties, regulated by Royal Legislative Decree 6/2015, of 30 October, approving the consolidated text of the Law on Traffic, Motor Vehicle Circulation, and Road Safety. Furthermore, with regard to the long tradition of recognising similar responsibilities in our legal system, it is worth mentioning the provisions of Article 1903 of the Civil Code, which recognises the obligation of those who exercise guardianship over minors to prevent the damage these devices may cause, responding civilly in case of failure to perform due diligence.

5. Impact in terms of climate change and the energy transition

This regulation has a positive impact on climate change, since the expected decrease in the prevalence of people who consume tobacco or related products on a daily basis, as well as the expected decrease in consumption intensity, leads to a decrease in the emission of smoke and

aerosols, which benefit ambient air quality. In addition, both the decrease in consumption and the ban on single-use electronic cigarettes are associated with a reduction in waste.

In 2022, the World Health Organisation published the report "Tobacco: Poisoning our planet" which reports that every year the tobacco industry costs the world 600 million trees, with 200,000 hectares of land used, competes with other crops in countries with food shortages, consumes 22 billion tonnes of water, and emits 84 million tonnes of CO₂ into the environment. In addition, it is estimated that around 4.5 trillion cigarette butts are discarded each year, many of them containing microplastics and heavy metals that contaminate oceans, rivers and soil.

Similarly, the STOP (Stopping Tobacco Organisations and Products) initiative published a report entitled "The tobacco industry and the environment", which highlighted data such as that tobacco cultivation is responsible for 5% of global deforestation, the intensive use of pesticides and fertilisers, and that poorly extinguished cigarettes are a frequent cause of fires.

It should also be borne in mind that electronic cigarettes include not only nicotine waste but also plastic and electronic waste (lithium batteries and other components). In addition, disposables increase the generation of non-recyclable waste.

In fact, the report "Tobacco: Poisoning our planet", and the Global Youth Tobacco Survey conducted by the WHO and the CDC, all find that for adolescents and young people, the environmental impact of tobacco constitutes an increasing reason not to smoke or to quit. It is not considered to have an impact due to climate change.

6. Impact on health

This regulation regulates both consumer products that have an impact on health and their sale, advertising and promotion. In addition, the spaces where these products are consumed are regulated, as this may affect the health of third parties. It is therefore considered that this regulation has a positive impact on health.

Furthermore, scientific evidence points to the danger of new forms of consumption. For example, electronic cigarettes contain a large amount of chemicals hazardous to health as^{31 32 33 34 35 36 37} well as heavy metals from coils and batteries.³⁸ All of these studies reflect the health risks of these devices, especially in terms of pulmonary and cardiovascular issues,^{39 40 41} even during short periods of use. In addition, a disease specific to the consumption of these devices, EVALI⁴² (Electronic

cigarette, or Vaping, product use Associated Lung Injury), is described, which causes acute lung damage.

On the other hand, several studies highlight the consumption situation in Spain^{43 44} and recommend the strict regulation of this type of device, especially disposable devices.

The focus now on the expansion of spaces that are smoke-free and free from other devices (such as electronic cigarettes and heated tobacco products) to new spaces such as hospitality, leisure areas, shelters and outdoor sports centres, among others, has a significant positive impact on public health. Among the benefits of this expansion of smoke-free spaces is a significant reduction in exposure to second-hand smoke by people who do not consume these products, thus reducing their exposure to more than 7,000 chemicals emitted by these products, many of which are carcinogenic. Passive exposure is associated with cardiovascular and respiratory diseases, asthma, lung cancer, and other illnesses. It also significantly reduces exposure to third-hand smoke, which consists of residues left on surfaces, clothing or furniture. These residues are also toxic and especially dangerous for children and people with respiratory problems.

This measure is particularly important due to its positive impact on the health and protection of vulnerable groups (children, the elderly, pregnant women, people with chronic diseases), who are the main beneficiaries of this measure since, on busy terraces and open spaces, the distance is no guarantee that there will be no exposure to smoke.

Scientific evidence shows that the expansion of smoke-free environments reduces the incidence of cardiovascular diseases, tobacco-related cancers, respiratory infections and asthma attacks, among other health benefits.

The entry into force of these measures also benefits smokers or consumers of related products themselves as it promotes the reduction in consumption and encourages people to quit smoking. This denormalises the habit of smoking and thus can motivate smokers to reduce their consumption or to immediately stop smoking, since they will have fewer opportunities to smoke. This, together with reducing the visibility of consumption in social or leisure spaces, denormalises the habit of smoking, especially among adolescents, allowing social perceptions to change and thus contributing to fewer people smoking or starting to consume other related products.

There are numerous studies and scientific evidence on the benefits of smoke-free spaces. These studies provide a solid basis for the implementation of laws that expand smoke-free spaces, since they demonstrate tangible benefits for public health and the well-being of the population.

Numerous studies show a significant improvement in air quality in outdoor spaces in the hospitality industry, while on covered or poorly ventilated terraces, the air can accumulate harmful particles at levels similar to those found in interior spaces where people smoke. The ban on consumption substantially improves air quality in these spaces, thus benefiting workers and customers.

A revised study in BMC Public Health analysed air quality in partially closed hospitality terraces and found that the concentration of fine particulate matter (PM 2.5) was considerably higher in areas where smoking was permitted, and exceeded the WHO air quality guidelines. This indicates that, even in outdoor spaces, exposure to smoke can be harmful to the health of customers and workers⁴⁵.

In addition, there are international recommendations, such as the WHO⁴⁶, the CDC⁴⁷ or the European Commission⁴⁸, on the importance of the implementation of these smoke-free spaces. As well as certain Scientific Societies at the national level.^{49 50}. The most recent, but important development within European regulations is the **Council Recommendation** on smoke-free environments of December 2024. It stresses that the restriction of the consumption of these products has the purpose of protecting people, especially children, not only from tobacco environmental smoke, but also from aerosols. Furthermore, it aims to denormalise and discourage the consumption of tobacco and emerging products, especially among young people, and to combat nicotine addiction.

The WHO already in 2014 recommended the prohibition of the use of electronic cigarettes in closed spaces to prevent pollution from passive smokers, which was addressed under the [WHO Framework Convention on Tobacco Control](#).

This and other measures are supported by various studies such as 'The Impact of Secondhand Vape Exposure on Adolescents' Willingness to Try E-Cigarettes', 'Exposure to secondhand aerosol from electronic cigarettes at homes: A real-life study in four European countries.' O "Characteristics of second-hand exposure to aerosols from e-cigarettes: A literature review since 2010", which states that the risks of environmental smoke are not only present indoors, but also in public spaces. These reviews determine how the presence of aerosols from potentially toxic substances, such as nicotine itself, can be harmful. This has been determined by measuring biomarkers in saliva and urine of electronic cigarette components in people who do not consume these products but have been exposed to aerosols generated by people who have used these products in the same space.

As regards studies on the impact on cardiovascular and respiratory health, Spain already saw benefits with Law 42/2010 of 30 December (which eliminated consumption in indoor hospitality spaces), and several studies after its implementation showed a decrease in hospital admissions due to myocardial infarction and asthma attacks.. The referenced report noted a significant reduction of

9.7% in hospitalisations for myocardial infarction in the months following the implementation of the law prohibiting smoking in closed spaces (including in hospitality). Another study found a significant decrease in childhood asthma hospitalisations after the implementation of Law 42/2010 of 30 December, which attributed this to the reduction of exposure to environmental smoke. The significant drop in exposure to tobacco smoke in the home and in public places after the law came into effect is also documented, leading to an improvement in the respiratory health of the population.⁵¹ A systematic review concluded that the implementation of smoke-free laws is associated with a significant reduction in the rate of hospitalisations for myocardial infarction, with a decrease of 17% in the 12 months following the application of the law. In addition, there was a decrease in the prevalence of tobacco consumption and in the number of cigarettes consumed per smoker.⁵²

A systematic analysis published in eClinicalMedicine highlighted that smoke-free policies in outdoor areas and private locations have a positive impact on reducing exposure to tobacco smoke in children, improving their respiratory health and reducing the prevalence of asthma.⁵³

A systematic review published in eClinicalMedicine revealed that more than 70% of the population supports smoke-free space policies in outdoor and private places. This support is particularly high in areas where children are commonly exposed to tobacco smoke. This public support is crucial for the implementation and success of such policies.⁵⁴

Finally, the ban on consuming tobacco products and related products within a perimeter of 15 linear metres from the entrances to reinforced protection areas is intended to ensure that smoke and aerosols do not accumulate and that exposure to second-hand smoke and aerosols is reduced at the entrances to public buildings and those frequented by children and adolescents, sick people or the most vulnerable members of the population, and an exemplary purpose is achieved. The 15-metre limit has been added to establish an objective definition to facilitate compliance, taking into account both the range of smoke and aerosols and the exemplary purpose of the regulation.

7. Impact on LGBTI+ people

Various studies^{55 56 57 58} indicate that the prevalence of tobacco and related product use is higher in the LGBTI+ community compared to the general population. These differences are more pronounced in the younger and adolescent age brackets⁵⁹.

Some studies also suggest that the LGBTI+ community is more exposed to the impact of advertising received on social media⁶⁰. As social media are precisely the main channels for advertising related products, this would suppose greater vulnerability for this group.

In addition, scientific evidence shows that there are differences in consumption patterns according to gender and sexual orientation,⁶¹ potentially influenced by advertising specifically targeted at the different groups.

8. Impact on equal opportunities, non-discrimination and universal accessibility for persons with disabilities.

None of the measures included in this Draft Law have any impact on this matter.

VIII.- EX POST EVALUATION

Due to the impact assessment carried out, no ex-post evaluation is considered necessary.

BIBLIOGRAPHY

- ¹ Anna García-Altés, Jaime Pinilla, Marc Marí-Dell'Olmo, Esteve Fernández, Maria José López, Economic Impact of Smoke-Free Legislation: Did the Spanish Tobacco Control Law Affect the Economic Activity of Bars and Restaurants?, *Nicotine & Tobacco Research*, Volume 17, Issue 11, November 2015
<https://academic.oup.com/ntr/article-abstract/17/11/1397/1070887?redirectedFrom=fulltext&login=true>
- ² Evaluation of tobacco control policies in Spain (Laws 28/2005 and 42/2010) Review of the evidence
<https://www.seepidemiologia.es/documents/dummy/V9.0%20-%20Libro%20Tabaquismo%202017%20-%20Abierto%20Final.pdf>
- ³ Report to the Parliament on the assessment of the impact on public health of Law 42/2010
https://www.sanidad.gob.es/areas/promocionPrevencion/tabaco/profesionales/docs/Informe_Impacto_Salud_Ley_Tabaco.pdf
- ⁴ de Bobadilla, J. F., Dalmau, R., & Galve, E. (2014). Impact of legislation prohibiting smoking in public places on reducing the incidence of acute coronary syndrome in Spain. *Rev Esp Cardiol*, 67(5), 349–352.
- ⁵ The WHO warns about the environmental impact of the tobacco industry. <https://www.who.int/es/news/item/31-05-2022-who-raises-alarm-on-tobacco-industry-environmental-impact>
- ⁶ Ozbay, N., Shevorykin, A., Smith, P. H., & Sheffer, C. E. (2020). The association between gender roles and smoking initiation among women and adolescent girls. *Journal of gender studies*, 29(6), 664–684.
<https://www.tandfonline.com/doi/abs/10.1080/09589236.2019.1693985>
- ⁷ Alam, F., & Silveyra, P. (2023). Sex differences in e-cigarette use and related health effects. *International Journal of Environmental Research and Public Health*, 20(22), 7079. <https://www.mdpi.com/1660-4601/20/22/7079>
- ⁸ 2023 Spain Health Survey
https://www.sanidad.gob.es/estadEstudios/estadisticas/encuestaSaludEspana/ESdE2023/ESdE2023_notatecnica.pdf
- ⁹ Survey on alcohol and other drugs in Spain EDADES 2024
https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/pdf/2024_Informe_EDADES.pdf
- ¹⁰ Gilbert, E., & Ewald, A. (2021). Fresher with flavour: young women smokers' constructions and experiences of menthol capsule cigarettes and regular cigarettes. *BMC Women's Health*, 21, 1–8.
<https://link.springer.com/article/10.1186/s12905-021-01297-2>
- ¹¹ Feeny, E., Dain, K., Varghese, C., Atim, G. A., Rekke, D., & Gouda, H. N. (2021). Protecting women and girls from tobacco and alcohol promotion. *bmj*, 374. <https://www.bmj.com/content/374/bmj.n1516.short>
- ¹² Alam, F., & Silveyra, P. (2023). Sex differences in e-cigarette use and related health effects. *International Journal of Environmental Research and Public Health*, 20(22), 7079. <https://www.mdpi.com/1660-4601/20/22/7079>
- ¹³ Survey on the use of drugs in Secondary Schools in Spain, ESTUDES
https://pnsd.sanidad.gob.es/profesionales/sistemasInformacion/sistemaInformacion/encuestas_ESTUDES.htm
- ¹⁴ Williams, Rebecca. "The rise of disposable JUUL-type e-cigarette devices." *Tobacco Control* 29.e1 (2020): e134–e135.
<https://onlinelibrary.wiley.com/doi/full/10.1111/add.16675>
Ran, Shuyao, et al. "Health Risks Associated with Adopting New-Generation Disposable Products Among Young Adults Who Use E-Cigarettes." *International Journal of Environmental Research and Public Health* 21.10 (2024): 1375.
<https://www.mdpi.com/1660-4601/21/10/1375>
- ¹⁵ Williams, Monique, Sanjay Ghai, and Prue Talbot. "Disposable electronic cigarettes and electronic hookahs: evaluation of performance." *Nicotine & Tobacco Research* 17.2 (2015): 201–208.
<https://academic.oup.com/ntr/article-abstract/17/2/201/1259154>

Hammond, David. "The rise of disposable e-cigarettes in England and implications for public health." *bmj* 386 (2024). <https://www.bmj.com/content/386/bmj.q1508>

¹⁶ Falarowski, Christin, et al. "Disposable e-cigarettes and their nicotine delivery, usage pattern, and subjective effects in occasionally smoking adults." *Scientific Reports* 15.1 (2025): 1-10. <https://www.nature.com/articles/s41598-025-97491-5>
Tattan-Birch, Harry, et al. "Trends in vaping and smoking following the rise of disposable e-cigarettes: a repeat cross-sectional study in England between 2016 and 2023." *The Lancet Regional Health–Europe* 42

¹⁷ Tattan-Birch, Harry, et al. "Trends in vaping and smoking following the rise of disposable e-cigarettes: a repeat cross-sectional study in England between 2016 and 2023." *The Lancet Regional Health–Europe* 42 (2024). [https://www.thelancet.com/journals/lanep/article/PIIS2666-7762\(24\)00091-7/fulltext](https://www.thelancet.com/journals/lanep/article/PIIS2666-7762(24)00091-7/fulltext)

¹⁸ Delnevo, Cristine, Daniel P. Giovenco, and Mary Hrywna. "Rapid proliferation of illegal pod-mod disposable e-cigarettes." *Tobacco control* 29.e1 (2020): e150-e151. <https://pubmed.ncbi.nlm.nih.gov/32001606/>

¹⁹ Quackenbush, Cameron S. "E-Cigarettes as Waste and the Need to Regulate" Disposable" Products." *Env't L. Rep.* 55 (2025): 10219. <https://heinonline.org/HOL/LandingPage?handle=hein.journals/elrna55&div=25&id=&page=>
Ma, Shaoying, et al. "Features of disposable e-cigarettes and their association with pricing and consumer preference: Evidence from web data of US online stores." *Addiction* 120.3 (2025): 514-523. <https://onlinelibrary.wiley.com/doi/full/10.1111/add.16719>

²⁰ Ma, Shaoying, et al. "Features of disposable e-cigarettes and their association with pricing and consumer preference: Evidence from web data of US online stores." *Addiction* 120.3 (2025): 514-523. <https://onlinelibrary.wiley.com/doi/full/10.1111/add.16719>

Scala, Marco, et al. "The newest vape devices: disposable electronic cigarettes spread in Italy." *Tabaccologia* 21.2 (2023): 6-11. <https://www.tabaccologiaonline.it/article/view/86>

²¹ Ran, Shuyao, et al. "Health Risks Associated with Adopting New-Generation Disposable Products Among Young Adults Who Use E-Cigarettes." *International Journal of Environmental Research and Public Health* 21.10 (2024): 1375. <https://www.mdpi.com/1660-4601/21/10/1375>

²² Donovan, Emily M., et al. "Not-so-disposable e-cigarettes: methods young people use to discard single-use e-cigarettes." *Addiction* 120.3 (2025): 452-457. <https://onlinelibrary.wiley.com/doi/abs/10.1111/add.16538>

Smith, Marissa J., et al. "Youth's engagement and perceptions of disposable e-cigarettes: a UK focus group study." *BMJ open* 13.3 (2023): e068466. <https://bmjopen.bmj.com/content/13/3/e068466.abstract>

²³ Smith, Marissa J., et al. "Youth's engagement and perceptions of disposable e-cigarettes: a UK focus group study." *BMJ open* 13.3 (2023): e068466. <https://bmjopen.bmj.com/content/13/3/e068466.abstract>

²⁴ Leventhal, Adam M., et al. "Disposable e-cigarette use prevalence, correlates, and associations with previous tobacco product use in young adults." *Nicotine and Tobacco Research* 24.3 (2022): 372-379. <https://academic.oup.com/ntr/article/24/3/372/6348227>

²⁵ Han, Dae-Hee, et al. "Disposable e-cigarette use and subsequent use patterns in adolescents and young adults." *Pediatrics* 153.4 (2024): e2023063430. <https://pubmed.ncbi.nlm.nih.gov/38463010/>

²⁶ Hammond, David, et al. "Use of disposable e-cigarettes among youth who vape in Canada, England and the United States: Repeat cross-sectional surveys, 2017–2023." *Addiction* 120.3 (2025): 405-413. <https://onlinelibrary.wiley.com/doi/full/10.1111/add.16596>

²⁷ Azagba, Sunday, Todd Ebling, and Alperen Korkmaz. "Disposable e-cigarette use: Factors, frequency and cigarette smoking among United States high school students." *Addiction* 120.3 (2025): 423-431. <https://onlinelibrary.wiley.com/doi/full/10.1111/add.16612>

- ²⁸ Chok, Lorraine, et al. "What are the characteristics of disposable electronic cigarettes users in Switzerland? A quantitative study among 14–25 year olds." *BMJ Public Health* 2.1 (2024). <https://bmjpublichealth.bmj.com/content/2/1/e000763>
- ²⁹ Kopa-Stojak, Paulina Natalia, and Rafal Pawliczak. "The role of sweet/fruit-flavored disposable electronic cigarettes on early nicotine initiation-a systematic review." *BMC Public Health* 25.1 (2025): 643. <https://link.springer.com/article/10.1186/s12889-025-21897-z>
- ³⁰ <https://www.who.int/publications/i/item/WPR-2024-DHP-001>
- ³¹ Kopa-Stojak, Paulina Natalia, and Rafal Pawliczak. "Disposable electronic cigarettes–Chemical composition and health effects of their use. A systematic review." *Toxicology Mechanisms and Methods* 35.3 (2025): 250-261. <https://www.tandfonline.com/doi/ref/10.1080/15376516.2024.2423927>
- ³² Lin, Hsien-Chang, Anne Buu, and Wei-Chung Su. "Disposable E-cigarettes and associated health risks: an experimental study." *International journal of environmental research and public health* 19.17 (2022): 10633. <https://www.mdpi.com/1660-4601/19/17/10633>
- ³³ Talih, Soha, et al. "Electrical features, liquid composition and toxicant emissions from 'pod-mod'-like disposable electronic cigarettes." *Tobacco control* 31.5 (2022): 667-670. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8586044/>
- ³⁴ Pagano, Todd, et al. "Determination of nicotine content and delivery in disposable electronic cigarettes available in the United States by gas chromatography-mass spectrometry." *Nicotine & Tobacco Research* 18.5 (2016): 700-707. <https://academic.oup.com/ntr/article/18/5/700/2509845>
- ³⁵ Williams, Monique, et al. "Elements including metals in the atomizer and aerosol of disposable electronic cigarettes and electronic hookahs." *PloS one* 12.4 (2017): e0175430. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0175430>
- ³⁶ Jabba, Sairam V., et al. "Synthetic cooling agents in US-marketed e-cigarette refill liquids and popular disposable e-cigarettes: chemical analysis and risk assessment." *Nicotine and Tobacco Research* 24.7 (2022): 1037-1046. <https://academic.oup.com/ntr/article/24/7/1037/6528985>
- ³⁷ Ramamurthi, Divya, et al. "Flavour spectrum of the puff family of disposable e-cigarettes." *Tobacco Control* 32.e1 (2023): e71-e77. <https://tobaccocontrol.bmj.com/content/32/e1/e71>
- ³⁸ Reid, Hamish T., et al. "Up in smoke: Considerations for lithium-ion batteries in disposable e-cigarettes." *Joule* 7.12 (2023): 2749-2759. [https://www.cell.com/joule/fulltext/S2542-4351\(23\)00482-8?uuiid=uiid%3A5920cece-c780-459f-9882-51aae55eb11b](https://www.cell.com/joule/fulltext/S2542-4351(23)00482-8?uuiid=uiid%3A5920cece-c780-459f-9882-51aae55eb11b)
- ³⁹ Abelia, X. A., Lesmana, R., Goenawan, H., Abdulah, R., & Barliana, M. I. (2023). Comparison impact of cigarettes and e-cigs as lung cancer risk inductor: a narrative review. *European Review for Medical & Pharmacological Sciences*, 27(13). <https://www.europeanreview.org/wp/wp-content/uploads/6301-6318.pdf>
- ⁴⁰ Gugala, E., Okoh, C. M., Ghosh, S., & Moczygemba, L. R. (2022). Pulmonary health effects of electronic cigarettes: a scoping review. *Health promotion practice*, 23(3), 388-396. <https://journals.sagepub.com/doi/full/10.1177/1524839920985506>
- ⁴¹ Itoh, M., Aoshiba, K., Herai, Y., Nakamura, H., & Takemura, T. (2018). Lung injury associated with electronic cigarettes inhalation diagnosed by transbronchial lung biopsy. *Respirology case reports*, 6(1), e00282. <https://onlinelibrary.wiley.com/doi/full/10.1002/rcr2.282>
- ⁴² Winnicka, L., & Shenoy, M. A. (2020). EVALI and the pulmonary toxicity of electronic cigarettes: a review. *Journal of general internal medicine*, 35, 2130-2135. <https://link.springer.com/article/10.1007/s11606-020-05813-2>

- ⁴³ Jovell, Laura, et al. "Compliance Surveillance of the Tobacco Control Legislation in a Spanish Region and Characterization of Passive Exposure to Tobacco Smoke and E-Cig in Children in Outdoor Spaces." *Healthcare*. Vol. 10. No. 4. MDPI, 2022. <https://www.mdpi.com/2227-9032/10/4/717>
- ⁴⁴ Fernández, Esteve, et al. "Tackling second-hand exposure to tobacco smoke and aerosols of electronic cigarettes: the TackSHS project protocol." *Gaceta sanitaria* 34 (2020): 77-82. <https://www.scielosp.org/article/ga/2020.v34n1/77-82/>
- ⁴⁵ Tong, M., Goodman, N., & Vardoulakis, S. (2024). Impact of second-hand smoke on air quality in partially enclosed outdoor hospitality venues: a review. *BMC Public Health*, 24(1), 1872. <https://link.springer.com/article/10.1186/s12889-024-19394-w>
- ⁴⁶ WHO Protection from Exposure to Second-Hand Tobacco Smoke. Policy recommendations https://apps.who.int/iris/bitstream/handle/10665/43677/9789241563413_eng.pdf?sequence=1
- ⁴⁷ CDC Ventilation Does Not Effectively Protect People Who Don't Smoke from Second-hand Smoke <https://www.cdc.gov/tobacco/secondhand-smoke/protection/ventilation.htm>
- ⁴⁸ Commission welcomes Council Recommendation on stronger measures on smoke-free environments https://ec.europa.eu/commission/presscorner/detail/en/ip_24_6185
- ⁴⁹ Smoke-free spaces in Spain: Where are we now? Where do we want to be? Spanish Association Against Cancer (AECC) https://observatorio.contraelcancer.es/sites/default/files/informes/Espacios_sin_humo_Espa%C3%B1a.pdf
- ⁵⁰ Expansion of smoke-free spaces. Spanish Society of Epidemiology (SEE) <https://seepidemiologia.es/download/43/documentos-revisar/2951/policy-brief-ampliacion-de-espacios-libres-de-humo.pdf>
- ⁵¹ Cordoba Rodrigo et al. Impact of the new legislation on smoking (Law 42/2010) on environmental tobacco smoke levels in hospitality premises. *GAC Sanit* [online]. 2013, vol. 27, no. 2 [cited 13 June 2025], pp. 161–163. https://scielo.isciii.es/scielo.php?script=sci_arttext&pid=S0213-91112013000200011
- ⁵² Lorenzo, C. M., Espinosa, E. O., & Sánchez-Rodrigo, J. V. (2010). ¿Por qué debemos apoyar las leyes de espacios sin humo? (Why should we support laws for smoke-free spaces?) *Atención primaria (Primary healthcare)*, 42(5), 251. <https://pmc.ncbi.nlm.nih.gov/articles/PMC7024478/>
- ⁵³ Radó, M. K., Möhlenberg, F. J., Westenberg, L. E., Sheikh, A., Millett, C., Burdorf, A., ... & Been, J. V. (2021). Effect of smoke-free policies in outdoor areas and private places on children's tobacco smoke exposure and respiratory health: a systematic review and meta-analysis. *The Lancet Public Health*, 6(8), e566-e578. [https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667\(21\)00097-9/fulltext](https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(21)00097-9/fulltext)
- ⁵⁴ Boderie, N. W., Sheikh, A., Lo, E., Sheikh, A., Burdorf, A., van Lenthe, F. J., ... & Been, J. V. (2023). Public support for smoke-free policies in outdoor areas and (semi-) private places: a systematic review and meta-analysis. *EClinicalMedicine*, 59. [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(23\)00159-1/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(23)00159-1/fulltext)
- ⁵⁵ Kann L, McManus T, Harris WA, et al. Youth Risk Behavior Surveillance — United States. (2017). *MMWR Surveill Summ* 2018;67(No. SS-8):1–114. DOI: <http://dx.doi.org/10.15585/mmwr.ss6708a1External>.
- ⁵⁶ Soneji, S., Barrington-Trimis, J. L., Wills, T. A., Leventhal, A. M., Unger, J. B., Gibson, L. A., ... Sargent, J. D. (2017). Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis. *JAMA Pediatrics*, 171(8), 788–797. <https://doi.org/10.1001/jamapediatrics.2017.1488>
- ⁵⁷ Emory, K. T., Scout, Kim, Y., Fagan, P., Vera, L. E., & Emery, S. (2017). Transgender Use of Cigarettes, Cigars, and E-Cigarettes in a National Study. *American Journal of Preventive Medicine*, 53(1), e1–e7. <https://doi.org/10.1016/j.amepre.2016.11.022>

⁵⁸ Salloum, R. G., Thrasher, J. F., Kates, F. R., & Maziak, W. (2015). Water pipe tobacco smoking in the United States: Findings from the National Adult Tobacco Survey. *Preventive Medicine*, 71, 88–93.
<https://doi.org/10.1016/j.ypmed.2014.12.012>

⁵⁹ https://www.cdc.gov/tobacco/basic_information/menthol/spanish/index.html

⁶⁰ Emory, K., Buchting, F. O., Trinidad, D. R., Vera, L., & Emery, S. L. (2018). Lesbian, Gay, Bisexual, and Transgender (LGBT) View it Differently Than Non-LGBT: Exposure to Tobacco-related Couponing, E-cigarette Advertisements, and Anti-tobacco Messages on Social and Traditional Media. *Nicotine & Tobacco Research*, 21(4), 513–522.

⁶¹ Budenz A, Grana R. Cigarette Brand Use and Sexual Orientation: Intersections With Gender and Race or Ethnicity. *Prev Chronic Dis*. 2021 Oct 28;18:E94. doi: 10.5888/pcd18.210160. PMID: 34710347; PMCID: PMC8588870