



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

EXPLANATORY NOTE

I

Tobacco use continues to be one of the main threats to public health worldwide. According to the World Health Organization (WHO), tobacco is estimated to kill more than 8 million people each year, of whom approximately 1.3 million are non-smokers exposed to second-hand smoke.

In Spain, more than a decade has passed since the last substantial amendment to Law 28/2005, of 26 December, on health measures against smoking and regulating the sale, supply, consumption and advertising of tobacco products. During this period, significant changes have occurred, both epidemiologically and in consumption patterns, as well as in the current configuration of the tobacco and related products market.

Since the approval of Law 28/2005, of 26 December, most indicators of regular or recent tobacco consumption have decreased. For example, according to the EDADES 2024 survey, the proportion of people aged 15 to 64 who have consumed tobacco in the past year has gone from 42.4% in 2005 to 36.8% in 2024, while the percentage of people who consume tobacco on a daily basis has decreased from 32.8% in 2005 to 25.8% in 2024. This reflects the effectiveness of the anti-smoking measures implemented in Spain, both in 2005 and in the 2010 law reform. However, preventing tobacco use among minors remains a challenge. According to data from the 2022 HBSC Study, 4.8% of adolescents smoke cigarettes daily, with a slight increase compared to 2018, especially among girls, reaching 13.3% of adolescents aged 17-18 (14% girls and 12.2% boys). Despite improvements in recent years, the prevalence of smoking in Spain remains high.

In recent years, new tobacco-related products have emerged, including electronic cigarettes. Although their consumption has increased in recent years, this is especially noticeable among people between 14 and 18 years old. According to the ESTUDES 2023 survey, 54.6% of adolescents had at some point tried these types of products. Electronic cigarette use among 14- to 18-year-olds has increased from 14.9% in 2019 to 26.3% in 2023, while the prevalence among 15- to 64-year-olds is slightly lower than 5%. It is therefore important that public health measures against smoking take account of the changes in consumption patterns of both tobacco and emerging products and how these may differ by age. Likewise, in the design and development of these measures, social inequalities must be taken into consideration and a gender perspective incorporated.



In this context, it is imperative to update national legislation to address emerging challenges related to the use of tobacco, nicotine products and related products. This includes regulating new devices, protecting minors from targeted marketing strategies and expanding smoke-free spaces. In addition, prevention and cessation programmes based on scientific evidence must be implemented.

This law is in line with the “Comprehensive Plan for Tobacco Prevention and Control 2024-2027” document, approved by the Council of Ministers on 30 April 2024, and represents the effective implementation of one of its main measures, in line with its general objective and within the basic axis of action at the regulatory level. The plan has thus identified the need to introduce various improvements not yet contemplated in the European Union’s harmonised regulations.

Furthermore, this amendment seeks to respond to the demands expressed by both scientific societies and civil society organisations involved in the subject, in order to contribute to improving the health of citizens and preventing the onset of tobacco and related product use, especially among young people, in line with the “Tobacco-Free Generations” strategies currently being proposed internationally.

The Spanish Constitution recognises the right to health protection in Article 43, and in Section 2 a mandates the public authorities to organise and protect public health through preventive measures. To contribute to the effectiveness of this right, the Law 14/1986, of 25 April, on General Health, established the obligation of public health administrations to focus their actions primarily on health promotion and disease prevention, avoid activities and products that, directly or indirectly, may have negative consequences for health, and regulate their advertising and commercial promotion.

The above considerations make it necessary to adopt new innovative measures adapted to the profound changes experienced in recent years. On the one hand, it is necessary to impact consumption and sales, by increasing the number of smoke-free outdoor spaces, creating the concept of enhanced protection spaces in special environments, in which society demands greater awareness and exemplary behaviour due to the characteristics of these spaces. This recognises that the right of non-smokers to breathe air uncontaminated by tobacco smoke prevails over the right of smokers to smoke, and that, together, this contributes to the denormalisation of consumption. While establishing smoke-free spaces is a priority health protection measure for the general population, it is even more so for minors. It is important to highlight the exemplary role of teaching and healthcare professionals in their work to educate, raise awareness and prevent tobacco use, promoting tobacco-free lifestyles. In line with this, the debate currently underway in the parliament within the Joint Committee for the Study of Addiction Problems regarding the establishment of smoke-free perimeter zones in certain areas has been taken into account.

On the other hand, restrictions on the availability and accessibility of tobacco and related products should be expanded, especially for young people. It is therefore timely and necessary to introduce new measures to address the limitations and shortcomings of existing legislation that have been revealed by the passage of time, the progressive increase in scientific evidence, the greater social awareness and consciousness, as well as the proliferation and diversification of sales and promotion strategies for tobacco and related products. In this sense, products with a high content of toxic substances must be subject to a greater level of control and oversight than provided for by the current significantly inadequate provisions.



Likewise, measures relating to the advertising and promotion of tobacco and related products, whether direct or indirect, and the sponsorship of various activities, have a proven influence on personal behaviour and social habits, and are a clear factor in inducing and encouraging consumption, especially among children and young people. It is therefore necessary to restrict all types and media of advertising, whether print, radio, television, electronic, or cinematographic.

With the same objective, the prohibition of direct and indirect advertising and sponsorship of tobacco and related products represents one of the main protection measures aimed at children and young people, and highlights the responsibility of public authorities in limiting access and availability of a product that causes addiction, disability, illness and death.

For all the above reasons, and taking into account the regulation and the normative scope of the provisions cited, it is advisable to enact a general rule that systematises the regulation and whose scope is appropriate for the intended purpose, for which the form of a law has been chosen.

II

The law consists of a sole article amending Law 28/2005, of 26 December, on health measures against smoking and regulating the sale, supply, consumption and advertising of tobacco products, a sole transitional provision, and two final provisions.

Article 1 is amended by extending the scope of the regulation to related products and devices for tobacco consumption or for the consumption of related products.

Article 2 is amended to include new definitions.

Article 6 is amended to include a ban on the use of tobacco products by minors in order to strengthen the health protection of children and adolescents.

Article 7 is amended by extending smoke-free spaces to vehicles used by individuals for or as a result of their employed work, except for their exclusively personal use; 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 performances are held; open-air spaces in nightclubs, gambling establishments, or venues for general public use; open-air bus stations; chauffeur-driven transport vehicles; completely open-air suburban transport spaces; the exterior of bars, restaurants, and other commercial establishments; concerts; theatres, cinema, and other public performance venues held in open spaces; as well as enhanced protection in healthcare, cultural, educational, sports, social, and children's parks and venues.

Article 9 is amended to extend the advertising, promotion, and sponsorship regime for tobacco products to tobacco consumption devices.

Article 10 is amended to extend the application of the common naming rules to tobacco smoking devices.

Specific regulations for new categories of related products are being introduced into our legal system. To this end, a new Chapter III bis is being incorporated, which sets out limitations on the sale, supply and consumption of related products in order to update the regulation of these products for the protection of public health. A new Chapter III bis is being incorporated, which



establishes the regulation of advertising, promotion and sponsorship of related products, adapting it to the current situation.

Among other new provisions, the ban on the sale and supply of single-use electronic cigarettes stands out.

In Chapter IV, the title is amended to read “Measures for the prevention of smoking, health promotion and facilitation of smoking cessation”, and references to “smoking withdrawal” are replaced with “smoking cessation”.

The creation of the Observatory for the Prevention of Smoking is planned, in accordance with the provisions of Article 22 of Law 40/2015, of 1 October, on the Legal Regime of the Public Sector, as a fundamental body for specific coordination in matters of prevention and control for better compliance with the law. This observatory, which was abolished by Law 15/2014, of 16 September, on the rationalisation of the Public Sector and other administrative reform measures, will be created with a new composition, allowing for the necessary coordination and collaboration in this area.

Changes have also been made to the sanctioning regime, the violations, the amounts of the penalties, and the responsible persons listed in Chapter V.

In addition, amendments are being made to additional provisions of Law 28/2005, of 26 December, expanding the scope of the signage requirement in centres or facilities where consumption is prohibited, extending it to tobacco and related products; and establishing consumption requirements in penitentiary establishments, psychiatric centres and residential centres for the elderly or people with disabilities.

Finally, the sole transitional provision establishes an adaptation period intended to enable manufacturers and marketers to adapt affected products to the new requirements, the marketing of single-use electronic cigarettes, and the labelling of nicotine products to the new requirements. For their part, the first and second final provisions specify, respectively, the jurisdictional titles under which this law is issued and determine the time of its entry into force.

III

This law responds to the principles of good regulation established in Article 129 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, specifically those of necessity, effectiveness, proportionality, legal certainty, transparency, and efficiency.

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



Regarding the principle of proportionality, the law contains the provisions strictly necessary to satisfy the public health protection objectives that motivate it. Furthermore, the principle of legal certainty is reinforced by consolidating a clear, stable and predictable regulatory framework, which originated in the law passed in 2005, the purpose of which was to overcome the fragmented and unsystematic nature of the previous regulations. This framework has been subject to subsequent modifications, most notably the 2017 reform, which incorporated nicotine-releasing devices. This law updates and expands this regulatory framework, expressly including related products, in response to market and consumer developments. Specifically, progress is being made toward aligning tobacco regulations with other related products due to its direct health effects on consumers and passive smokers, as well as the visibility of consumption.

In order to strengthen both legal certainty and consistency with European Union law, the terminology used is aligned with that used in 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 Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC. In particular, the term “nicotine-releasing devices” is replaced by “electronic cigarettes”, and the concept of “related products” is introduced. Both terms are included in the aforementioned directive but have not been included in national legislation until now. Furthermore, a reference is added to devices used for the consumption of heated tobacco products, with the aim of clarifying their legal status and addressing the uncertainty generated by the existence of conflicting judicial rulings regarding their legal nature.

Pursuant to the principle of transparency and in accordance with Government Law 50/1997 of 27 November, the prior public consultation procedures, as well as the public hearing and information procedure, have been carried out. Both processes have been carried out by the publishing of the draft law on the Ministry of Health’s website, thus ensuring the participation of citizens and the affected sectors. During the public hearing and information process, reports were collected from the autonomous communities and cities of Ceuta and Melilla, and business organisations, scientific societies, and social entities participated. Likewise, the regulations have been notified to EU Member States based on 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 rules on information society services.

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

This regulation constitutes basic legislation regarding the protection of the right to health and is enacted under Article 149.1.16 of the Spanish Constitution, which grants the State jurisdiction over the foundations and general coordination of healthcare. It is also based on other powers recognised in Article 149.1 of the Constitution, specifically in its Sections 1, 9, 18, and 27.

Sole article. Amendment to Law 28/2005, of 26 December, on health measures against smoking and regulating the sale, supply, consumption and advertising of tobacco products.



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

One. Article 1, letter a) is amended as follows:

“a) Establish, as a basic rule, the limitations, provided that these are retail operations, on the sale, supply and consumption of tobacco products and related products, as well as devices for their consumption, in addition to regulating the advertising, promotion and sponsorship of said products, to protect the health of the population”.

Two. Letter f) of Article 2 is amended and new letters h) (bis), k, l, m, n, ñ, o, p are added, which are worded as follows:

“f) Electronic cigarette: any product capable of delivering nicotine, or any of its components, including a cartridge, a tank and the device without a cartridge or tank, that can be used for the consumption of vapour containing nicotine through a mouthpiece. E-cigarettes can be disposable or refillable using a refill container and a tank, or refillable with single-use cartridges.

“h) Refill container: a receptacle of liquid containing nicotine, which can be used to refill an electronic cigarette.

“h) (bis) Nicotine-free refill container: a receptacle of liquid that does not contain nicotine, which can be used to refill an electronic cigarette without nicotine.

“k) Related product: Product related to tobacco products, without containing it, and which may include, but is not limited to, electronic cigarettes with and without nicotine, herbal smoking/shisha products, nicotine pouches and any other product with nicotine, whether natural or synthetic, or without it, used for recreational purposes and/or that imitates the act of smoking, induces it or is related to its traditional and/or social consumption.

l) Nicotine pouch: a non-tobacco product for oral use, composed wholly or partly of synthetic or natural nicotine, mixed with vegetable fibres or an equivalent substrate, and presented in the form of powder, fibres, particles or paste, or a combination of these forms, in single-dose sachets, porous sachets, tablets or in equivalent form, not intended to be smoked.

m) Non-nicotine e-cigarette: a product, or any of its components, including a cartridge, a tank, and the device without a cartridge or tank, that can be used for the consumption of vapour through a mouthpiece. Nicotine-free electronic cigarettes can be disposable or refillable using a refill container and a tank, or refillable with single-use cartridges.

n) Disposable or single-use electronic cigarette or nicotine-free electronic cigarette: a device provided with a liquid with or without nicotine, ready for consumption and intended to be discarded after use.

ñ) Heated herbal product: a non-tobacco product, with or without nicotine, used for the inhalation of an aerosol, consisting of an electronic device and a refill in a stick, cigarette, capsule or other format containing a substrate based on herbs or other plant fibres in a dry state or with very low humidity, which may or may not contain artificially added nicotine.



o) Device for consumption of tobacco or related products: a system intended exclusively or preferentially for the consumption of tobacco products or related products, such that said products could not be consumed without the device. In particular, systems used for the consumption of tobacco or herbs through a heating or combustion process are considered to be devices.

Three. Article 6 is amended as follows:

“Article 6. Limitations on the consumption of tobacco products.

1. The consumption of tobacco products by persons under eighteen years of age is prohibited.
2. The consumption of tobacco products should be carried out exclusively in places or spaces where it is not prohibited”.

Four. Article 7 is amended as follows:

“Article 7. Smoking ban.

1. Smoking, as well as the consumption of tobacco and the use of tobacco devices, is prohibited, except in those places or spaces defined in the regulations of the Autonomous Communities, in:

- a) Public and private workplaces, except in open-air spaces, and in vehicles used by individuals on the occasion of or as a result of their work for others, except for their exclusively personal use.
- b) Centres and offices of public administrations and public law entities.
- c) Health centres, services or establishments, as well as in open-air or covered spaces within their premises.
- d) Educational and training centres, university centres, research centres and adult training centres.
- e) Sports facilities, swimming pools for collective use and venues where public shows are held, both indoors and outdoors.
- f) Areas intended for direct attention to the public.
- g) Shopping centres, including large stores and galleries, except in open-air spaces.
- h) Social care centres.
- i) Leisure or recreation centres, except in open-air spaces.
- j) Cultural centres, reading rooms, exhibitions, libraries, conferences and museums.
- k) Event rooms, gambling establishments or those for general public use.



- l) Areas or establishments where food is produced, transformed, prepared, tasted or sold.
 - m) Elevators and lifts.
 - n) Telephone booths, ATM enclosures and other small enclosed public spaces. A small public space is defined as one that does not occupy an area greater than five square metres.
 - ñ) Bus stations, platforms and shelters, urban and interurban public transport vehicles or means, company transport vehicles, taxis, transport vehicles with drivers, ambulances, funiculars and cable cars.
 - o) All spaces of suburban transport (wagons, platforms, corridors, stairs, stations, etc.).
 - p) Stations and means of railway transport.
 - q) Ports, maritime transport and airports, except in open-air spaces, and in aircraft operating in Spanish sovereign airspace, as well as in aircraft with Spanish registration in international airspace or airspace subject to the sovereignty of other States”.
 - r) Service stations and similar.
 - s) Any other place where, by mandate of this law or another regulation or by decision of its owner, smoking is prohibited.
 - t) Hotels, hostels and similar establishments, except in open-air spaces other than those contemplated in letter u) of this Article. However, permanent smoking rooms may be provided, insofar as they meet the requirements set forth in Article 8.
 - u) Bars, restaurants and other commercial catering establishments, both indoors and outdoors.
 - v) Theatres, cinemas, concert halls and other public shows.
 - w) Children’s playground areas and play areas or zones for children, understood as the enclosed open-air spaces that contain equipment or facilities specifically intended for the play and recreation of minors.
 - x) On all sea and river beaches and National Parks.
 - y) In all other closed spaces for public or collective use.
2. Likewise, as these are enhanced protection environments, the consumption of tobacco products will be prohibited within a perimeter less than 15 linear metres from the entrances to public buildings, public and private healthcare centres, public and private social centres, educational centres, universities, research centres, museums, libraries, and other public or private teaching or cultural centres, public or private sports centres, and parks or children’s playgrounds.
- ”



Five. Article 9 is amended as follows:

“Article 9. Limitations on the advertising, promotion and sponsorship of tobacco products.

1. The sponsorship of tobacco products and devices for their consumption, as well as all types of advertising and promotion of said products in all media and formats, including vending machines and information society services, is prohibited, with the following exceptions:

a) Publications intended exclusively for professionals involved in the tobacco trade.

b) Presentations of tobacco products to professionals in the sector within the framework of Law 13/1998, of 4 May, on the regulation of the tobacco market and tax regulations, as well as the promotion of said products in state-owned tobacco and stamp retailers, provided that they are not intended for minors and do not involve the free distribution of tobacco or goods and services related exclusively to tobacco products or the habit of smoking or that carry names, trademarks, symbols or any other distinctive signs that are used for tobacco products. In any case, the value or price of the goods or services mentioned may not exceed five percent of the retail price of the unit of packaging for the tobacco products being promoted.

Under no circumstances may such activities be carried out in shop windows or extend outside the establishments, nor may signage be used that, due to its characteristics and location, is visible or perceivable from outside the tobacco shops, or directed toward the outside.

c) Publications containing advertising for tobacco products and devices for their consumption, published or printed in countries that are not part of the European Union, provided that such publications are not primarily intended for the Community market, unless they are primarily aimed at minors.

2. Outside the network of state-owned tobacco and stamp retailers, the free or promotional distribution of products, goods, or services, or any other action whose direct or indirect, primary or secondary objective or effect is the promotion of a tobacco product, is prohibited.

3. The broadcasting of programmes, videos or images in which presenters, collaborators or guests are prohibited in all media, including information society services:

a) Appear smoking, consuming or displaying tobacco products or devices for their consumption.

b) Mention or display, directly or indirectly, trademarks, trade names, logos or other identifying or associated signs with tobacco products or devices for their consumption”.

Six. Article 10 is amended and reads as follows:

“Article 10. Rules applicable to common names.

The use of names, trademarks, symbols, or any other distinctive signs to identify tobacco products and their devices in traffic, and simultaneously other goods or services marketed or offered by the same company or group of companies, is prohibited.



For this purpose, companies that constitute a decision-making unit will be considered to belong to the same group because one of them exercises or may exercise, directly or indirectly, control over the others, or because such control corresponds to one or more natural persons who systematically act in concert. It shall be presumed that there is unity of decision in any case when any of the situations provided for in Section 1 of Article 42 of the Commercial Code and in Article 4 of Law 24/1988, of 28 July, on the Securities Market, occur”.

Seven. A new Chapter III bis is incorporated, with the following heading and content:

“CHAPTER III bis

Limitations on the sale, supply and consumption of related products

Article 10 bis. Single-use electronic cigarettes.

The sale and supply of single-use electronic cigarettes is prohibited.

Article 10 bis. Limitations on the consumption of related products.

The consumption of related products, with the exception of nicotine pouches, is subject to the same provisions established for tobacco consumption as set out in Articles 6, 7, and 8. The provisions of Article 6.1 shall apply to nicotine pouches”.

Eight. A new Chapter III bis is incorporated, with the following heading and content:

“CHAPTER III bis

Regulation of advertising, promotion and sponsorship of related products

Article 10 quater. Limitations on the advertising, promotion and sponsorship of related products

1. The sponsorship of related products and devices for their consumption, as well as all types of advertising and promotion of the aforementioned products in all media and supports, including vending machines and information society services, is prohibited, with the following exceptions:

a) Publications intended exclusively for professionals involved in the trade of related products and devices for their consumption.

b) Presentations of products related to professionals in the sector, as well as the promotion of said products in state-owned tobacco and stamp retailers, provided that they are not intended for minors and do not involve the free distribution of these products or of goods and services related exclusively to these products or their consumption or that carry names, trademarks, symbols or any other distinctive signs that are used for tobacco products and related products. In any case, the value or price of the goods or services mentioned may not exceed five percent of the retail price of the packaging unit of the products being promoted.



Under no circumstances may these activities be carried out in shop windows or extend outside the establishments, nor may signage be used that, due to its characteristics and location, is visible or perceivable from outside the tobacco shops.

c) Publications containing advertising for related products and devices for their consumption, published or printed in countries outside the European Union, provided that such publications are not primarily intended for the Community market, unless they are primarily aimed at minors.

2. Outside the network of state-owned tobacco and stamp retailers, the free or promotional distribution of products, goods, or services or any other action whose direct or indirect, primary or secondary objective or effect is the promotion of related products or devices for their consumption, is prohibited.

3. The broadcasting of programmes, videos or images in which presenters, collaborators or guests are prohibited in all media, including information society services:

a) Appear consuming or showing related products or their devices for consumption.

b) Mention or display, directly or indirectly, trademarks, trade names, logos or other identifying or associated signs of related products or devices for their consumption.

Article 10 quinquies. Rules applicable to common names.

The use of names, trademarks, symbols, or any other distinctive signs to identify related products, as well as their devices, and simultaneously other goods or services marketed or offered by the same company or group of companies is prohibited.

For this purpose, companies that constitute a decision-making unit will be considered to belong to the same group because one of them exercises or may exercise, directly or indirectly, control over the others, or because such control corresponds to one or more natural persons who systematically act in concert. It shall be presumed that there is unity of decision in any case when any of the situations provided for in Section 1 of Article 42 of the Commercial Code and in Article 4 of Law 24/1988, of 28 July, on the Securities Market, occur”.

Nine. The title of Chapter IV is modified and reads as follows:

“CHAPTER IV

Measures to prevent smoking, promote health and facilitate smoking cessation”.

Ten. Article 12 is amended as follows:

“Article 12. Concerning smoking cessation programmes.

The competent public authorities will promote the development of health programmes for smoking cessation within the healthcare network, especially in primary care. Likewise, tobacco cessation



programmes will be promoted in schools, educational institutions, healthcare centres, workplaces, and sports and leisure settings. The creation of smoking cessation units will be fostered and promoted within the Interterritorial Council of the National Health System, which will also identify the most vulnerable priority groups.

Access to smoking cessation treatments, whose efficacy and cost-effectiveness have been supported by scientific evidence, will be fostered and promoted within the Interterritorial Council of the National Health System, assessing, where appropriate, their incorporation into the National Health System's portfolio of services".

Eleven. Article 16 is amended as follows:

"Article 16. From the Observatory for the Prevention of Smoking.

The Tobacco Prevention Observatory will be created as an intersectoral coordination body, with the participation of the General Directorate of Public Health and Health Equity of the Ministry of Health, the Tobacco Market Commissioner of the Ministry of Finance, the Ministry of Agriculture, Fisheries and Food, the Research and Quality Control Centre of the Ministry of Social Rights, Consumption and the 2030 Agenda, the Carlos III Health Institute, the Autonomous Communities, scientific societies, consumer associations and non-governmental organisations.

Its functions, among others, will be:

- a) Proposing initiatives, programmes and activities to be carried out to achieve the objectives of the law.
- b) Establishing targets for reducing smoking prevalence.
- c) Preparing a biennial report on the status, application, results and compliance with this law.
- d) Coordinating and collaborating between the competent authorities regarding health, marketing and consumption records".

In the development of these functions, the gender variable will be taken into account, incorporating information disaggregated by gender".

Twelve. Article 17 is amended as follows:

"Article 17. On the destination of the sanctions imposed.

The competent authorities may allocate the amounts collected from sanctions, imposed in accordance with the provisions of this law, to the development of research, education, prevention, tobacco control and smoking cessation programmes".

Thirteen. Section 1 and the first paragraph of Section 2 of Article 18 are amended as follows:

"1. The sanctioning power regulated by this law shall be exercised, in all matters not provided for herein, in accordance with the provisions of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, and the Law 14/1986, of 25 April, on General Health, all without prejudice to any civil, criminal or other liability that may arise.



2. In sanctioning procedures for serious or very serious violations, in accordance with Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, and its implementing regulations, and without prejudice to those that may be established by the regulations of the Autonomous Communities, provisional measures provided for in said regulations that are deemed necessary to ensure the effectiveness of the final resolution issued, ensure the successful completion of the procedure, avoid the continuation of the effects of the violation, and respond to the requirements of collective well-being, may be adopted. In particular, the following may be agreed:”

Fourteen. Article 19 is amended as follows:

“Article 19. Violations.

1. The violations for non-compliance with the provisions of this law are classified as minor, serious and very serious.

2. The following will be considered minor violations:

a) Smoking or consuming related products, excluding nicotine pouches, in places where there is a ban or outside designated areas.

b) Not possessing or not displaying in a visible place in establishments where the sale of tobacco and related products is authorised, signs informing of the prohibition of the sale of tobacco and related products to persons under eighteen years of age and warning of the health risks derived from the use of tobacco and related products.

c) Vending machines not displaying the required health warning or not complying with the legally required characteristics.

d) Failure to inform at the entrance of establishments of the prohibition on smoking or consuming related products, excluding nicotine pouches, or failure to comply with the other formal obligations referred to in this law.

e) The sale or marketing of tobacco products and related products by minors.

f) The consumption of tobacco and related products by minors.

3. The following will be considered serious violations:

a) Enabling areas for smoking or consuming related products in establishments and places where their use is not permitted.

b) Allowing smoking or consumption of related products in places where it is prohibited.

c) The accumulation of three of the violations provided for in Section 2.a) of this Article.



- d) The marketing, sale and supply of cigarettes and small cigars not provided with a natural wrapper in sales packaging units of less than 20 units, as well as individual units.
- e) The sale and supply of cigars and small cigars with a natural wrapper by units in those places where this is not permitted.
- f) The delivery or distribution of samples of any tobacco product or related products, whether or not free of charge.
- g) The installation or placement of vending machines for tobacco products in expressly prohibited places.
- h) The supply or dispensing of products other than tobacco through tobacco vending machines.
- i) The sale and supply of tobacco products through distance selling or similar procedures, except sales through vending machines.
- j) The free or promotional distribution, outside the network of state-owned tobacco and stamp retailers, of products, goods or services with the purpose or direct or indirect effect of promoting a tobacco product.
- k) The sale of tobacco products and related products at a discount.
- l) The sale or delivery to persons under eighteen years of age of tobacco products and related products, as well as their devices, or products that imitate tobacco products and induce smoking or consumption of related products, as well as sweets, snacks, toys and other objects that are shaped like tobacco products or related products and that may be attractive to minors.
- m) Allowing persons under eighteen years of age to use vending machines for tobacco or related products.
- n) Vending machines not having the appropriate activation or start-up mechanism by the owner of the establishment.
- ñ) The free or promotional distribution of products, goods or services with the purpose or direct or indirect effect of promoting a tobacco product or related products to persons under eighteen years of age.
- o) The marketing of goods or services using names, trademarks, symbols or other distinctive signs already used for a tobacco product and related products under conditions other than those permitted in Article 10 and the second transitional provision.
- p) The marketing of tobacco products or related products using the name, trademark, symbol or any other distinctive sign of any other good or service under conditions other than those permitted by this law.
- q) The sale, transfer or supply of tobacco products and related products in violation of the other prohibitions or limitations established in this law.



r) The free distribution in state-owned tobacco and stamp retailers of goods and services related exclusively to tobacco products or to the habit of smoking or consuming related products or that carry names, trademarks, symbols or any other distinctive signs that are used for tobacco products or related products.

s) The marketing of tobacco for oral use.

t) Failure to comply with the regulatory requirements regarding the communication of information by manufacturers and importers of tobacco products, electronic cigarettes and refill containers, and herbal smoking products, heated herbs, and nicotine pouches.

u) Failure to comply with the regulatory requirements regarding registration of manufacturers, importers and distributors of electronic cigarettes and refill containers, and herbal smoking products, heated herbal products and nicotine pouches.

v) Failure to comply with the regulatory requirements regarding presentation and marketing by manufacturers and importers of herbal smoking products.

w) Failure to comply with the regulatory requirements regarding the manufacture, presentation, marketing, quality and safety of tobacco products and electronic cigarettes, refill containers, heated herbs and nicotine pouches.

x) The cross-border distance selling of related products.

y) The marketing of single-use electronic cigarettes.

4. The advertising, promotion and sponsorship of tobacco products or related products, as well as the devices necessary for their consumption, in all media, including information society services, are considered very serious violations, except in the cases provided for in Article 9.1”.

Fifteen. Section 1 of Article 20 is amended as follows:

“1. Minor violations shall be sanctionable by a fine of 200 to 600 euro, except for smoking in prohibited areas other than air, sea, or land transport within a supra-regional or international scope, as provided for in Article 19.2.a), which shall be sanctionable by a fine of up to 200 euro if the violation is committed in isolation; serious violations shall be sanctionable by a fine of 601 to 10,000 euro; and very serious violations shall be sanctionable by a fine of 10,001 to 600,000 euro”.

Sixteen. Sections 2, 3 and 6 of Article 21 are amended as follows:

“2. In the case of the violations described in Article 19.2.b), d) and e) and 19.3.a), the owners of the establishments in which the violation is committed shall be responsible.

3. The manufacturer, the importer, where applicable, the distributor and the operator of the machine shall be jointly and severally liable for the violations described in Article 19.2.c) and



19.3.n). Parents, guardians or custodians shall be subsidiarily liable for the violation described in Article 19.2. f). Subsidiary liability consists of covering the monetary amount of the fine imposed”.

“6. In the case of the violation described in Article 19.3.l) of supplying tobacco products and related products to persons under eighteen years of age, the person who supplied the product to the minor shall be liable”.

Seventeen. Sections 1, 3 and 5 of Article 22 are amended as follows:

“1. The General State Administration shall exercise the functions of inspection and control, ex officio or at the request of a party, as well as the instruction of sanctioning files and the imposition of sanctions, in the field of air, sea or land transport, when these are carried out within the supra-autonomous or international framework, as well as in all those enclosures, spaces or environments that, due to their characteristics, exceed the scope of competence of the Autonomous Communities and Cities with Statute of Autonomy, as well as in cases where operators based in different Autonomous Communities or Cities with Statute of Autonomy, in other Member States of the European Union or in third countries or territories intervene.

3. The sanctioning powers of the bodies referred to in this Article are understood to be without prejudice to those corresponding to the Tobacco Market Commissioner in accordance with Law 13/1998, of 4 May, on the Regulation of the Tobacco Market and Tax Regulations and other applicable provisions.

Among other things, the Tobacco Market Commissioner is responsible for the control, inspection, and sanctioning of emissions, ingredients, additives, labelling, packaging, presentation, traceability and safety measures for tobacco products, as well as novel tobacco products and tobacco for oral use. This is without prejudice to the sanctioning powers of the State Tax Administration Agency for non-compliance with the regulations on tax trademarks on which these security measures are incorporated.

5. Violations committed through information society services or devices will be sanctioned by the corresponding body of the Ministry of Health, without prejudice to those of the Tobacco Market Commissioner”.

Eighteen. Section 2 of Article 23 is amended as follows:

“2. In terms of advertising, any natural or legal person who is affected and, in general, those who hold a subjective right or a legitimate interest may request the cessation of advertising contrary to this law, under the terms provided, as appropriate, in the General Law 13/2022, of 7 July, on Audiovisual Communication, and Law 34/2002, of 11 July, on Information Society Services and Electronic Commerce”.

Nineteen. The third additional provision is amended and reads as follows:

“Third additional provision. Signage for centres or spaces where the consumption of tobacco and related products is prohibited, as well as designated areas for the consumption of such products.



In centres or spaces where the use of tobacco and related products is legally prohibited, signs announcing the prohibition on the use of tobacco and related products and the locations, where applicable, of designated areas for their use must be posted in a visible location at the entrance. These signs will be written in Spanish and the co-official language, complying with the requirements established by the corresponding regional regulations".

Twenty. The sixth additional provision is modified and reads as follows:

"Sixth additional provision. Special regime of penitentiary establishments.

The provisions of Article 5.a) are exempt from the tobacco and stamp retailers referred to in the seventh additional provision of Law 13/1998, of 4 May, on the Regulation of the Tobacco Market and Tax Regulations.

In penitentiary establishments, prisoners are permitted to smoke in outdoor areas of their buildings or in closed rooms designated for this purpose. These rooms must be properly and visibly marked and have independent ventilation or other devices for smoke removal".

Twenty-one. The eighth additional provision is modified and reads as follows:

"Eighth additional provision. Psychiatric centres or facilities.

In medium- and long-stay psychiatric facilities, patients are permitted to consume tobacco products and related products in outdoor areas of their buildings, or in a designated closed room. This room must be properly and visibly signposted and have independent ventilation or other smoke removal devices".

Twenty-two. The ninth additional provision is deleted.

Twenty-three. The tenth additional provision is modified and becomes the ninth additional provision and is worded as follows:

"Ninth additional provision. Residential centres for the elderly or people with disabilities.

In residential centres for the elderly or people with disabilities, a specific area may be set up for consumers of tobacco and related products. This area will be exclusively for residents and must be properly and visibly marked and have independent ventilation or other devices for smoke removal. The smoking permit may not extend to bedrooms or other common areas in said centres".

Twenty-four. The tenth additional provision is added.

"Tenth additional provision. Signage obligations.



A two-month period is established for compliance with the signage obligations provided for in this standard”.

Twenty-five. The twelfth and thirteenth additional provisions are deleted.

Sole transitional provision. *Marketing*

A 12-month transitional period for marketing extension is granted to allow manufacturers and marketers to adapt the affected products to the new requirements.

Single-use electronic cigarettes may continue to be sold for up to 12 months after the entry into force of this law.

Changes in the labelling of nicotine products must be adapted within a maximum period of 12 months from the entry into force of this law.

Sole final provision. *Entry into force.*

This law shall enter into force twenty days after its publication in the “Official State Gazette”.

TO BE SUBMITTED TO THE COUNCIL OF MINISTERS

Madrid, of of 2025

THE MINISTER OF HEALTH

Mónica García Gómez