I. GENERAL PROVISIONS

MINISTRY OF THE PRESIDENCY AND REGIONAL GOVERNMENTS

6585 *Royal Decree 579/2017, of 9 June, regulating certain aspects related to the manufacturing, presentation and marketing of tobacco and related products.*

I

In its article 43, the Spanish Constitution recognizes the right to health protection and it entrusts the public administrations with the organization and protection of public health through the adoption of preventive measures as considered necessary.

Law 14/1986, of 25 April, the General Health Law, established the obligation of the public healthcare administrations to orient their actions mainly towards the promotion of health and the prevention of illnesses, to prevent those activities and products that, directly or indirectly may have negative health consequences and to regulate their advertising and commercial advertising.

Tobacco consumption is considered to be the principal risk factor for illness and mortality in developed countries. Therefore, its regulation and consumption control should be a public health priority. The current regulation of tobacco products, from a healthcare point of view, is primarily included in two regulations.

On the one hand, there is Law 28/2005, of 26 December, on healthcare measures against tobacco consumption and sales regulation, the supply, consumption and advertising of tobacco products, making up the basic general regulation of the State with regards to tobacco, from a public health perspective.

On the other hand, Royal Decree 1079/2002, of 18 October, regulating the maximum content of nicotine, tar and carbon monoxide in cigarettes, tobacco product labelling, and measures regarding ingredients and names of tobacco products, including the content of Directive 2001/37/EC, from 5 June 2001, on the approximation of laws, regulations and administrative provisions of member states with regards to tobacco product manufacturing, presentation and sale, in our legal system. With Royal Decree 639/2010, of 14 May, Royal Decree 1079/2002, of 18 October was modified so as to adapt its content to that included in Law 28/2005, of 26 December.

Subsequently, diverse community norms have been approved which have led to a new legal framework of tobacco on a European level, thus requiring the adaptation of our legal system to the same.

First, Directive 2014/40/EU of the European Parliament and of the Council, from 3 April 2014, on the approximation of the laws, regulations and administrative provisions of the member states with regards to the manufacturing, presentation and sale of tobacco and related products, and leading to the repeal of Directive 2001/37/EC, approved with the purpose of facilitating the proper functioning of the internal market for tobacco and related products in the European Union, based on a high level of human health protection and to comply with the obligations established in the WHO Framework Convention on Tobacco Control.

Second, the Commission Delegated Directive 2014/109/EU, of 10 October 2014, modifying annex II of Directive 2014/40/EU, establishing a picture library of warnings that are to be used with tobacco products, as well as diverse implementation decisions that follow up on different aspects of its content and that may be grouped together in three blocks.

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On the one hand, the decisions related to the placement of the health warnings, such as the Commission Implementing Decision (EU) 2015/1735, of 24 September 2015, on the precise position of the general warning and the informative message on roll-your-own tobacco in pouches, and the Commission Implementing Decision (EU) 2015/1842, of 9 October 2015, regarding the technical specifications on the presentation, design and form of the combined health warnings on the tobacco smoking products.

On the other hand, the decisions related to the common electronic format for notifications such as the Commission Implementing Decision (EU) 2015/2183, of 24 November 2015, establishing a common format for the notification of electronic cigarettes and charging packs, Commission Implementing Decision (EU) 2015/2186, of 25 November 2015, establishing a format for the presentation and provision of information regarding the tobacco products, and the Commission Implementing Decision (EU) 2016/586, of 14 April 2016, on the technical regulations for the charging mechanism for electronic cigarettes.

Finally, decisions and implementing regulations related to ingredients, such as the Commission Implementing Decision (EU) 2016/787, of 18 May 2016, establishing a prioritized list of the additives contained in cigarettes and roll-your-own tobacco that are subject to reinforced notification obligations, the Commission Implementing Regulation (EU) 2016/779, of 18 May 2016, adopting uniform regulations regarding the procedures to determine whether or not a tobacco product contains a characteristic scent, and Commission Implementing Decision (EU) 2016/786, of 18 May 2016, adopting the procedure regarding the creation and functioning of an independent consulting group that turns to the member states and the commission upon determining whether or not the tobacco products have a characteristic scent.

Third and finally, it is also necessary to consider Regulation (EC) no. 1272/2008 of the European Parliament and of the Council, of 16 December 2008, on the classification, labelling and packaging of substances and mixtures, and which modified and repealed Directives 67/548/EEC and 1999/45/EC and modified Regulation (EC) no. 1907/2006.

II

The objective of this royal decree is the partial transposition of Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, in aspects related to the manufacturing, presentation and marketing of tobacco and related products, including the traceability and safety measures for tobacco products, substituting the regulations included in Royal Decree 1079/2002, of 18 October, which has been repealed.

The royal decree regulates certain aspects related to the manufacturing and marketing of tobacco products, novel products, nicotine release devices, recharging packages and herbal products for smoking. It should be noted that for the first time from a public health perspective, novel tobacco products and herbal products for smoking are being regulated.

Also included are the provisions of the cited directive regarding labelling and packaging of tobacco products, as well as the obligation of including specific health warnings in all packaging units, as well as in all outside packaging. Furthermore, the law furthers the qualification included in article 3.7 of Law 28/2005, of 26 December, and regulates the contents and components of the tobacco products.

The law also includes the regulation of verification laboratories, as well as the procedures for their authorization.

Finally, the law creates three new registries, including that of the manufacturers, importers and distributors of nicotine release devices and recharging packages, that of manufacturers, importers and distributors of herbal products for smoking and that of the verification laboratories.

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III

The royal decree is structured in five titles, two additional provisions, three transition provisions, one derogatory provision, five final provisions and two annexes.

The preliminary title, «General provisions», establishes the objective of the royal decree, its scope of application and the definitions of the terms included throughout the same.

Title I, «Tobacco products», includes three chapters. Chapter I, devoted to «Ingredients and emissions», establishes the maximum levels of emissions for cigarettes that are marketed or manufactured in Spain, as well as the methods of measurement and the ingredients of the tobacco products.

Chapter II, dedicated to «Labelling and packaging», includes the novelties introduced by the directive in the area of labelling and packaging of tobacco products. Requirements for labelling and packaging of tobacco products have been updated with the obligation to include combined health warnings in all packaging units, as well as in all outside packaging, of tobacco smoking products, as well as other text warnings and informative messages. These measures are in line with the WHO Framework Convention on Tobacco Control, ratified by Spain on the 30th of December of 2004, including in its article 11 that health warnings in the tobacco product labelling, in the form of images or pictograms, is an appropriate instrument for the reduction of tobacco demand. Furthermore, it anticipates that the packaging units for the tobacco products are to be labelled in a unique and safe manner, and their movements shall be registered so as to facilitate the follow-up and tracking of these products in the Union. The introduction of safety measures is also anticipated so as to facilitate the verification of the authenticity of the tobacco products, however, in principle, only cigarettes and roll-your-own tobacco shall be subject to the follow-up and tracking systems and safety measures.

Chapter III, devoted to «Novel tobacco products and tobacco for oral use», regulates the notification obligations prior to the marketing of the former, which should include the available scientific and market research studies and which continues to prohibit the marketing of oral tobacco in Spain, as previously done in Royal Decree 1079/2002, of 18 October, which has now been repealed.

Title II, «Electronic cigarettes and refill containers», is divided into three chapters. Chapter I contains “Provisions regarding the marketing” of these products. Their regulation, in addition to the inclusion of the community law, is a result of their increasing importance, due to recent market development on a European level, which has led to the need for their inclusion as tobacco-related products. The notifications obligations regarding these products, trials and requirements of control and verification are also regulated.

Chapter II creates and regulates the Registry of Manufacturers, Importers and Distributors of these products and their functioning.

Chapter III is dedicated to the adverse effects that may be produced by these products, to the actions that should be carried out and to their monitoring.

In title III, under the section «Herbal products for smoking», the requirements of these products are regulated, including the notification obligations or their labelling. Furthermore, the Registry of Manufacturers, Importers and Distributors of these products and their functioning are also regulated.

Title IV is devoted to the «Verification and control» and regulates the annual plan of verification, the procedure to authorize the verification laboratories and creates a registry in order to collect and order the information regarding these.

The regulation concludes with two additional provisions, three transition provisions, one derogatory provision, five final provisions and two annexes.

The final second provision modifies Decree 2484/1967, of 21 September, which approved the text of the Spanish Food Code, suppresses section 3.25.80 of the 8th section of Chapter XXV of the Third Part of the Spanish Food Code, thereby complementing specific requirements for components of the smoking paper, imposed on a European level.

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IV

During the creation of this royal decree, reports from the autonomous communities and the cities of Ceuta and Melilla were obtained and the participation of business and trade union organizations, scientific societies and business entities which were consulted in hearings has been provided.

In addition, the Spanish Agency of Data Protection and Economic and Social Council have issued their mandatory reports.

This royal decree has the nature of a basic law and has been issued within the scope of article 149.1.16. ª of the Spanish Constitution and in the development of articles 24, 25.3 and 40, sections 5 and 6, of Law 14/1986, of 25 April.

By virtue of this, in a collective proposal by the Ministry of Health, Social Services and Equality and the Ministry of Finance and Public Function, in accordance with the State Council and following deliberation of the Council of Ministers in its meeting on the 9th of June of 2017,

I STIPULATE:

PRELIMINARY TITLE

General provisions

Article 1. *Objective.*

This royal decree aims to regulate the following:

a) The ingredients and emissions of tobacco products.
b) The labelling and packaging of tobacco products.
c) The traceability and safety measures of tobacco products.
d) Novel tobacco products.
e) The marketing and labelling of specific products related to tobacco products, specifically electronic cigarettes and recharging packages and herbal products for smoking.
f) The Registry of Manufacturers, Importers and Distributors of electronic cigarettes and recharging packages, the Registry of Manufacturers, Importers and Distributors of herbal products for smoking, and the Registry of Verification Laboratories.
g) The verification and control procedure for tobacco products, electronic cigarettes and herbal products for smoking, as well as the functions and the procedure for the authorization of verification laboratories.

Article 2. *Scope of application.*

1. This royal decree shall be applicable to tobacco products and related products that are specified in article 1.d) that are manufactured or marketed in Spain.
2. This royal decree shall not apply to::

a) Products included in the definition of medicines or healthcare products that are included in the re-drafted text of the law of guarantees and rational use of medicines and healthcare products, approved by Legislative Royal Decree 1/2015, of 24 July.
b) Electronic cigarettes and refill containers that are subject to authorization based on that anticipated in Royal Decree1345/2007, of 11 October, regulating the procedure for the authorization, registration and dispensing conditions for medicines for human use, manufactured industrially or in Royal Decree 1591/2009, of 16 October, regulating health products.

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Article 3. *Definitions*.

For the purpose of this royal decree, the following definitions are used:

a) “Additive”: a substance that is distinct from tobacco leaves, added to a tobacco product, its packaging unit or any exterior packaging.

b) “Health warning”: a warning related to the adverse effects to human health of the products, or other undesired consequences resulted from its consumption, including the text warnings, combined health warnings, general warnings and informative messages.

c) “Combined health warning “: health warning established in this royal decree, combining a text warning with the corresponding photograph or illustration.

d) “Tar”: raw anhydrous nicotine-free condensate of smoke.

e) “Characterising flavour”: a distinct scent or flavour of tobacco that is clearly perceptible, due to an additive or combination of additives, including fruit, spices, herbs, alcohol, caramel, mint or vanilla, among others, which is noticeable prior to or during the consumption of the tobacco product.

f) “Flavouring”: an additive that offers scent and/or taste.

g) “Substantial change of circumstances “: an increase of the sales volume by product category by at least 10% in at least five Member States, based on sales data transmitted in accordance with article 11.1 or an increase in the level of prevalence of use in the under 25 years of age consumer group, by at least five percentage points in at least five Member States, for the affected product category. A substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at a retail level does not exceed 2.5 % of the total sales of tobacco products at Union level.

h) “Cigarette”: a roll of tobacco that may be consumed through a combustion process, whose detailed definition is included in sections 3 and 6 of article 59 of Law 38/1992, of 28 of December, on Special Taxes.

i) “Cigarillo”: a small type of cigar whose detailed definition is included in sections 1 and 2 of article 59 of Law 38/1992, of 28 of December.

j) “Cigar”: a roll of tobacco that may be consumed through a combustion process whose detailed definition is included in sections 1 and 2 of article 59 of Law 38/1992, of 28 of December.

k) “Market”: an activity consisting of placing products, regardless of their place of manufacturing, at the disposal of consumers, through the payment or not of said products, including through distance sales.

l) “Consumer”: all natural persons acting for purposes which are outside of his trade, business, craft or profession.

m) “Electronic cigarette”: a product or any of its components, including a cartridge, a deposit and a device without cartridge or deposit, that may be used for the consumption of steam containing nicotine through a nozzle. Electronic cigarettes may be disposable or rechargeable through a recharging package and a deposit, or rechargeable through single-use cartridges.

n) “Distribute”: an activity making up part of the supply chain of a product and consisting of its marketing from the manufacturer or importer to the retail outlet.

ñ) “Outside packaging”: all packaging used to market the tobacco or related products and that include a packaging unit or set of packaging units. Transparent wrappings are not considered to be outside packaging.

o) “Emissions”: all substances released from the tobacco product or related to its intended use, such as, for example, the substances present in the smoke or the substances released during the consumption of smokeless tobacco products.

p) “Refill container”: a receptacle containing nicotine-containing liquid which may be used to recharge an electronic cigarette.

q) “Retail outlet”: all outlets where tobacco products are placed on the market, even by a physical individual.

r) “Manufacturer”: any legal or natural individual who manufactures a product or has a product designed or manufactured and markets it under their name or trademark.

s) “Importation of tobacco or related products “: the entry into European Union territory of such products, unless these, at the time of their entry to the Union, are included in a suspension customs procedure or arrangement, as well as their release for consumption from a suspension customs procedure or arrangement.

t) “Importer of tobacco or related products”: the owner or individual having the right of disposal of tobacco and related products that have been introduced into European Union territory.

u) “Ingredient”: tobacco, an additive, as well as all substances or elements present in the completed product, including paper, filter, ink, capsules and adhesives.

v) “Nicotine”: nicotinic alkaloids.

w) “Maximum level” or “maximum emissions level “: the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams.

x) “Pouch”: a unit packet of roll-your-own tobacco, either in the form of a rectangular pocket with a flap that covers the opening or in the form of a standing pouch.

y) “Roll-your-own tobacco”: tobacco product for smoking that complies with the requirements established in article 59.5 of Law 38/1992, of 28 of December.

z) “Addictive power”: the pharmacological power of a substance to cause addiction, a state that affects the capacity of the individual to control their behaviour, generally offering some compensation or relief of abstinence symptoms, or both.

aa) “EU-CEG Portal”: common electronic portal of entry for all member countries of the European Union in which notifications are made regarding tobacco and related products by manufacturers and importers.

ab) “Herbal product for smoking “: product based on plants, herbs or fruit that does not contain tobacco and that may be consumed via a combustion process.

ac) “Tobacco products”: products that can be consumed and that consist, totally or in part, of tobacco, genetically modified or not.

ad) “Novel tobacco product”: a tobacco product that:

1st. It does not include any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or oral use tobacco; and

2nd. It has been marketed after the 19th of May of 2014.

ae) “Smoking tobacco products”: tobacco products distinct from non-smoking tobacco products.

af) “Smokeless tobacco products”: a tobacco product that does not involve a combustion process, including chewing tobacco, nasal tobacco and oral use tobacco.

ag) “Tobacco”: refers to plants and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco.

ah) “Chewing tobacco”: non-smoking tobacco product, exclusively for chewing.

ai) “Pipe tobacco”: tobacco that may be consumed through a combustion process and that is exclusively intended for use in a pipe.

aj) “Nasal tobacco”: non-smoking tobacco product, that may be administered through the nose.

ak) “Tobacco for oral use”: all tobacco products that are intended for oral use, with the exception of products intended to be inhaled or chewed, made wholly or partly of tobacco in the form of powder or particulate form or any combination of those forms, especially those present in sachet portions or in porous sachets.

al) “Waterpipe tobacco”: a tobacco product that may be consumed with a waterpipe. For the purposes of this royal decree, waterpipe tobacco is considered to be a tobacco product for smoking. In the case of a product that may be used both as waterpipe tobacco as well as roll-your-own tobacco, it is considered roll-your-own tobacco.

am) “Toxicity”: the degree to which a substance may cause harmful effects to the human organism, including long term effects, generally caused from continued consumption or exposure.

an) “Packaging unit”: the smallest individual package of a marketed tobacco or related product.

TITLE I

Tobacco products

CHAPTER I

Ingredients and emissions

Article 4. *Emissions scheme.*

1. Cigarettes that are marketed or manufactured in Spain may not have emissions levels that exceed the following:

a) 10 mg of tar per cigarette.
b) 1 mg of nicotine per cigarette.
c) 10 mg of carbon monoxide per cigarette.

2. Emissions of tar, nicotine and carbon monoxide as referred to in the previous section shall be measured according to ISO standards 4387, 10315 and 8454, respectively. The precision of the measurement shall be verified according to that included in ISO standard 8243.

Article 5. *Ingredients and additives regime.*

1. Tobacco products that are marketed in Spain may not:

a) Have a characterizing flavour.
b) Contain flavouring substances in their components, such as filters, rolling papers, packages, capsules or any other characteristic technique that permits modification of the scent or the flavour of the tobacco products, or intensify the smoke. Filters, papers and capsules may not contain tobacco or nicotine.
c) Contain any of the following additives:

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1.º Vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks.

2.º Caffeine, taurine or other additives and stimulant compounds associated with energy and vitality.

3.º Additives having colouring properties while smoking.

4.º Additives that facilitate the inhalation or nicotine uptake, for tobacco products for smoking.

5.º Additives having carcinogenic, mutagenic or nephrotoxic properties, hereinafter CMR, in unburnt form.

d) Contain additives in quantities that, according to scientific data, significantly and measurably increase during its consumption, the toxic or addictive effect or the CMR properties of the tobacco.

2. As an exception to that established in the paragraph a) from the previous section, the essential additives required for the manufacturing of tobacco products, such as sugar added to substitute for sugar that is lost during the curing process, always when these additives do not give the product a unique scent and do not significantly and measurably increase the addictive power, toxicity or CMR properties of the product.

3. That established in paragraphs a) and b) of the first section do not apply to tobacco products distinct from cigarettes and roll-your-own tobacco.

4. The procedure applicable for the determination of the unique scents referred to in section 1.a) shall be included in the Commission Implementing Regulation (EU) 2016/779, of 18 May 2016, adopting the uniform laws regarding the procedures to determine whether or not a tobacco product has a unique scent and in Commission Implementing Decision (EU) 2016/786, of 18 May of 2016, adopting the procedure regarding the creation and functioning of an independent consulting group that assists the member countries and the Commission to determine if the tobacco products have a unique scent.

5. In the case of tobacco products with a unique scent whose sales on a European Union scale represent 3 % or more of a specific product category, the provisions of this article shall be applied as of the 20th of May of 2020.

6. The General Management of Public Health, Quality and Innovation shall communicate the measures adopted to comply with that established in this article to the European Commission.

Article 6. *Notification obligations regarding ingredients and emissions.*

1. Manufacturers or importers of tobacco products should present the following information (detailed by brands and individual product types) to the General Management of Public Health, Quality and Innovation within the period mentioned in article 7:

a) The list of ingredients and their quantities, used in the manufacturing of the tobacco products, ordered in decreasing order of weight, as well as their placement. It should be specified if the ingredients have been registered in accordance with Regulation (EC) no. 1907/2006 of the European Parliament and of the Council, de 18 of December of 2006, and their classification in accordance with Royal Decree 255/2003, of 28 February, approving the Regulation on classification, packaging and labelling of dangerous preparations and with Regulation (EC) no. 1272/2008 of the European Parliament and of the Council, of 16 of December of 2008, on classification, labelling and packaging of substances and mixtures and which modifies and repeals Directives 67/548/EEC and 1999/45/EC and modifies Regulation (EC) no. 1907/2006.

b) A declaration intended for the inclusion of the ingredients in the relevant tobacco product.

c) Toxicological data on the ingredients, with or without combustion, and specific information regarding their effects on consumer health and possible addictive effects.

d) In the case of cigarettes and roll-your-own tobacco, a technical document in which a general description of the additives used and their properties appears.
e) Emissions levels as specified in article 4.
f) Information available on other emissions, their levels and measurement methods.

2. Manufacturers or importers are also obliged to notify the modifications that affect the information referred to in the previous section, once they have been made.
3. The General Management of Public Health, Quality and Innovation shall verify that the documentation provided is in line with that which has been established in the previous sections, possibly requiring the sending of unavailable data until the documentation is considered complete.
4. The notifications anticipated in this article are to be carried out via the EU-CEG Portal, according to that anticipated in the Commission Implementing Decision (EU) 2015/2186, of 25 November of 2015, which establishes a format for the presentation and distribution of information on tobacco products.

Article 7. *Notification period.*

1. The notification referred to in the previous article is to be made six months prior to the date of marketing, when dealing with novel tobacco products or those that have been modified.
2. For tobacco products marketed at the time of enforceability of this royal decree, this notification shall be made within a period of six months as of the date of enforceability of the same, except when this notification has already been previously made, notwithstanding that the same may be completed under the terms described in the previous article, or are modified, in both cases, requiring notification via the EU_CEG Portal.

Article 8. *Additional studies on additives.*

1. Manufacturers or importers of cigarettes and roll-your-own tobacco that contain an additive included in Commission Implementing Decision (EU) 2016/787, of 18 May of 2016, which establishes a priority list of additives contained in the cigarettes and roll-your-own tobacco that are subject to reinforced notification obligations, should conduct exhaustive studies in which, for each additive, the following is examined:
a) Contribution to the toxicity or addictive power of the relevant products, and whether they result in a significant or measurable increase in toxicity or addictiveness of any of the products in question.
b) Generate a unique scent.
c) Facilitate the inhalation or ingestion of nicotine.
d) Lead to the formation of substances having CMR properties and in what quantities, and if they result in the significant or measurable increase in the CMR properties in any of the relevant products.

2. The studies shall consider the anticipated use of the products, and shall also assess the following:

a) Emissions resulting from the combustion process in which the relevant additive intervenes.
b) The interaction with other ingredients contained in the products at hand.

3. Manufacturers or importers who use the same additive in their tobacco products may carry out a collective study when using said additive in the composition of comparable products.
4. The obligations established in these articles shall not refer to small and medium companies as defined in the Commission Recommendation 2003/361/EC, of 6 of May of 2003, when another manufacturer or importer has created a report on the relevant additive

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Article 9. *Report on the studies on additives.*

1. Annually, the manufacturers and importers of cigarettes and roll-your-own tobacco shall create a report including the results of studies referred to in the previous article which shall have the following content:

a) A summary of the studies conducted.
b) A detailed presentation listing the scientific bibliography available in regards to each additive and a summary of the internal data on their effects.

2. This report shall be sent to the General Management of Public Health, Quality and Innovation and the European Commission within the period indicated in Commission Implementing Decision (EU) 2016/787, of 18 May of 2016.
3. The General Management of Public Health, Quality and Innovation shall verify the data from these reports, requesting additional information from the manufacturer or importer regarding the additive in question, to be included in the same report.
4. If there are reasonable doubts regarding the studies or results provided in the reports, the General Management of Public Health, Quality and Innovation , the European Commission or any member country may demand that these be subject to *inter pares* revision by an independent scientific organism, specifically with respect to its thoroughness, methodology and conclusions, in accordance with Commission Implementing Decision (EU) 2016/787, of 18 May of 2016.
5. The obligations established in this article are not required of the small and medium companies defined in the Commission Recommendation 2003/361/EC, of 6 May of 2003, when another manufacturer or importer has created a report on said additive.

Article 10. *Information available to the public.*

1. The information presented in compliance with sections 1 and 2 of article 6 and in sections 1 and 2 of article 8, shall be available on the website of the Ministry of Health, Social Services and Equality with the limitations indicated by current law.
2. Of the information referred to in the previous section, the manufacturers or importers shall be obligated to specify whatever they consider to be subject to confidentiality, so as to take the necessary measures for its protection.

Article 11. *Obligations for the presentation of market studies.*

1. Manufacturers or importers of the tobacco products that are marketed in Spain should present:

a) The internal and external studies that they have regarding market studies and preferences of different consumer groups, including youth and current smokers, with regards to ingredients and emissions.
b) The operational summaries of any market study that is carried out for the launching of new products.
c) Information on sales volumes, specified by individual brands and types, in tobacco units in rolls or in kilos, on an annual basis.

2. This information shall be communicated to the General Management of Public Health, Quality and Innovation, following the format established in Commission Implementing Decision (EU) 2015/2186, of 25 November of 2015. The first notification shall be made within the six months following the entry in to enforceability of this royal decree and subsequently, it shall be presented on an annual basis within the first quarter of each year.

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CHAPTER II

Labelling and packaging

Article 12. *General provisions on health warnings.*

1. Each unit of packaging and outside packaging of the tobacco products shall include the health warnings in Spanish, as referred to in this chapter.
2. The health warnings shall be surrounded by a black border of 1 mm thickness inside the surface reserved for the same, except in the case of health warnings as referred to in article 17.
3. The images of the packaging unit and outside packaging should be adjusted in accordance with that described in this chapter.
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Article 13. *Calculation of health warning dimensions.*

1. The dimensions for the health warnings referred to in this chapter are to be calculated in relation to the overall surface area of the closed package.
2. The health warnings shall occupy the entirety of the surface area of the packaging unit or of the packaging that has been reserved for the same, and should not be subject to any commentary, paraphrasing or other type of reference.
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Article 14. *Characteristics of the health warning impression.*

1. The health warnings of the packaging unit and the outside packaging are to be printed in an immovable and undeletable manner and shall be completely visible. They should not be partially or fully concealed or separated by tax stamps, security features, wrappings, bags, boxes or any other object, mark or legend that should also appear.
2. The health warnings should not be separated upon opening the packaging unit, except in the case of packages having a foldable lock in which case, the graphic integrity, visibility of the text, photographs and information regarding smoking cessation shall be ensured.
3. The health warnings should in no case conceal or hide tax stamps, tracking or tracing marks or security features on the packaging units.
4. The health warnings of the packaging units of the tobacco products other than cigarettes and roll-your-own tobacco in pouches may be attached via adhesives, as long as these may not be removed.

Article 15. *General warning and informative message on tobacco products for smoking.*

1. The units of packaging and outside packaging of the tobacco products for smoking shall include the general warning “Smoking kills”.
2. Furthermore, the packaging units and outside packaging of the tobacco products for smoking shall include the informative message “Tobacco smoke contains over 70 carcinogenic substances”.
3. As for their placement, the following shall be considered:

a) In packages of cigarettes and roll-your-own tobacco in a parallel-piped shape, the general warning shall be printed in the lower part of the lateral surface of the packaging unit and the informative message shall be printed in the lower part of the other lateral surface. These warnings shall be a minimum of 20 mm in width.

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b) In packages having a pack shape with a hinged upper part in which the lateral surface is divided into two parts when opening the package, the general warning and the informative message shall be printed completely on the largest part of these two surfaces. The general warning shall also appear in the interior surface of the cover that is visible when opening the pack. The lateral side of this type of pack shall have a minimum height of 16 millimetres.

c) In roll-your-own tobacco in a pouch, the health warning and informative message shall be printed on the surfaces so as to permit their complete visibility.

d) In packages of roll-your-own tobacco that have a cylindrical shape, the general warning shall be printed on the external surface of the cover and the informative message shall be on the internal surface of the cover.

4. The general warning and informative message shall:

a) Cover 50 % of the surface area on which they are printed.

b) Be printed in black in Helvetica font, black on a white background, with a font size that permits their filling of as much space as possible in the area reserved for said purposes.

c) Be centred in the space reserved for their printing. In packages having a parallel piped shape, and in all outside packaging, they shall be parallel to the lateral border of the packaging unit.

5. The following are exceptions from the requirements of the previous section: roll-your-own tobacco in pouch, with the European Commission establishing the exact position of the general warning and informative message in this case.

Article 16. *Combined health warnings of tobacco products for smoking.*

1. Each unit of packaging and outside packaging of the tobacco products for smoking shall include combined health warnings.

2. The combined health warnings:

a) Shall include one of the text warnings described in annex I and the corresponding colour photograph as specified in the picture library of annex II.

b) Shall include information regarding smoking cessation, such as telephone numbers, email addresses or Internet sites having the goal of informing consumers regarding smoking cessation programs.

c) Shall cover 65 % of the external side of the front and back cover of the packaging unit, as well as all of the outside packaging. Packages having a cylindrical shape shall have two combined health warnings situated an equal distance from each other and covering 65 % of its respective half of the curved surface.

d) Shall reveal identical text warnings and corresponding colour photographs on both sides of the packaging units and on all of the outside packaging.

e) Are located in the upper border of the packaging unit or on the entire outside packaging and appear in the same direction as the other information appearing on said packaging surface.

f) Shall be reproduced in accordance with the format, presentation, design and proportions specified by the Commission, which are detailed in the Commission Implementing Decision (EU) 2015/1735, of 24 September 2015, on the precise position of the general warning and the informative message in the roll-your-own tobacco in a pouch, and in Commission Implementing Decision (EU) 2015/1842, of 9 October 2015, regarding the technical specifications on the presentation, design and shape of the combined health warnings of tobacco products for smoking.

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g) Shall respect, in the cigarette packaging units, the following dimensions:

1st Height: no less than 44 mm.
2nd Width: no less than 52 mm.

3. The combined health warnings shall be grouped in three sets, in the manner that was established in annex II. Each set may be used throughout one calendar year, beginning as of the entry into effectiveness of this royal decree and they shall be alternated so as to ensure the regular appearance of each warning in an equal quantity of packaging units for each brand.

Article 17. *Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco.*

1. Tobacco products distinct from smoking: cigarettes, roll-your-own tobacco and waterpipe tobacco may be exempt from the obligation of including the informative message described in article 15.2 and the colour photographs specified in in the picture library of annex II, which form a part of the combined health warnings discussed in article 16.

2. Each packaging unit and the outside packaging of these products should include the general warning specified in article 15.1, which complies with the following requirements:

a) Include a reference to the services for smoking cessation as found in article 16.2.b).

b) Shall appear in the more visible side of the packaging unit as well as the entire outside packaging, and should cover 30 % of the external side of the surface corresponding to the packaging unit and all of the outside packaging. In the case in which it should appear on a surface exceeding 150 cm², the warning shall cover an area of 45 cm².

c) Comply with the requirements specified in paragraphs b) and c) of article 15.4.

d) The text should be parallel to the main text that appears on the surface that is reserved for these warnings.

e) The general warning shall be surrounded by a black border of no less than 3 mm and no more than 4 mm width. This border shall appear outside of the surface that is reserved for the general warning.

3. Furthermore, each unit of packaging and outside packaging of these products should include one of the text warnings found in annex I, that:

a) Shall be printed on the next most visible surface of the packaging unit, as well as on the entire outside packaging.

In the packaging units with hinged lids, the next most visible surface is the one that shall become visible when the pack is open.

b) Shall cover 40 % of the outside of the surface corresponding to the packaging unit and all of the outside packaging. In the case in which it should appear on a surface that exceeds 150 cm², the warning shall cover an area of 45 cm².

c) Shall be surrounded by a black border of a width of no less than 3 mm and no more than 4 mm. This border shall appear outside of the surface reserved for the health warnings.

The text warnings mentioned in this section shall be alternated so as to ensure the regular appearance of each warning in an equal quantity of packaging units for each brand.

Article 18. *Labelling of non-smoking tobacco products.*

1. In the packaging units and the outside packaging of the non-smoking tobacco products, the following health warning shall appear: “this tobacco product is harmful to your health and is addictive”.

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2. This health warning:

a) Complies with the requirements specified in paragraphs b) and c) of article 15.4.
b) The text should be parallel to the main text on the area reserved for these warnings.
c) It shall appear on the two largest surfaces of the packaging unit, as well as on all of the outside packaging.
d) It shall cover 30% of the outside of the corresponding surface of the packaging unit and on all of the outside packaging.

Article 19. *Presentation of the tobacco products.*

1. The labelling of each package unit, of the outside packaging and of the tobacco product itself shall appear in the Spanish language. No elements or characteristic should appear which:

a) Promote a tobacco product or support its consumption, offering a misleading impression regarding its characteristics, health effects dangers or emissions. They should not include any information regarding the content of nicotine, tar or carbon monoxide.
b) Suggest that a specific tobacco product is less harmful or that it has the objective of reducing the effect of certain harmful smoke components, or that it has revitalizing, energizing, curative, rejuvenating, natural, ecological or other positive effects on the health or lifestyle.
c) Refer to tastes, scents, flavours or other additives or the absence of the same.
d) Appear to be a food or cosmetic product.
e) Suggest that said tobacco product has improved in terms of bio-degradability or other environmental advantages.

2. The packaging unit or outside packaging should not include indications suggesting any economic advantage based on the inclusion of printed sales vouchers, discount offers, free distribution or two-for-one offers or the like.
3. The packaging unit or outside packaging should not contain prohibited elements of characteristics in accordance with the prior sections, such as texts, symbols, names, trademarks, figurative signs, drawings, photographs or other similar elements.

Article 20. *Appearance and content of the packaging units.*

1. The cigarette packaging units shall have a parallel piped shape. Packaging units of roll-your-own tobacco should have a parallel piped or cylindrical shape or should be in the form of a pouch. One cigarette pack shall include, at least, twenty cigarettes. One packaging unit of roll-your-own tobacco should have a minimum weight of 30 g.
2. Cigarette packaging units may be made of cardboard or another soft material and should not have any opening that may be re-closed or re-sealed after being opened, other than the flip top lid and the shoulder box with a hinged lid. For packets with a flip top lid and hinged lid, the lid shall only be hinged at the back of the unit packet.

Article 21. *Traceability of tobacco products.*

1. All unit packets of tobacco products are to be marked with a unique identifier. In order to ensure the integrity of the unique identifier, it shall be irremovably printed or affixed, indelible and not hidden or interrupted in any way, even with tax stamps or price marks, or by the opening of the unit packet. In the case of tobacco products that are manufactured outside of the European Union, the obligations laid down in this article are only applicable to those that are destined for, or marketed in the European Union market.

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2. The unique identifier shall allow for the determination of the following:

a) the date and place of manufacturing.
b) manufacturing facilities.
c) the machine used to manufacture the tobacco products.
d) the production shift or time of manufacture.
e) the product description.
f) the intended market or establishment of retail sale.
g) the intended shipment route.
h) where applicable, the importer into the Union.
i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure and consignee.
j) the identity of all purchasers from manufacturing to the first retail outlet.
k) the invoices, order numbers and payment records for all purchases from manufacturing until the first retail outlet.

3. Information referred to in paragraphs a), b), c), d), e), f), g) and, when relevant, h) of the previous section shall form part of the unique identifier.

4. The information mentioned in paragraphs i), j) and k) of section 2 should be accessible electronically by means of a link to the unique identifier.

5. All economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, shall record the entry of all unit packets in their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all packets remains possible.

6. All natural and legal persons engaged in the supply chain of tobacco products shall maintain complete and accurate records of all relevant transactions referred to in this article.

7. Manufacturers of tobacco products should provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transport companies, with the necessary equipment to record the tobacco products acquired, sold, stored, transported or otherwise handled in any manner. That equipment should be able to read and transmit the recorded data electronically to a data storage facility pursuant to section 8.

8. The manufacturers and importers of tobacco products should enter into data storage contracts with an independent third party, for the purposes of hosting the storage facility for all relevant data. The facility for the data storage should be physically located in the European Union territory. The European Commission shall approve the suitability of the third party, especially, its independence and technical capacities. They shall also approve the contract.

The third party's activities shall be monitored by an external auditor who is proposed and paid by the tobacco manufacturer and approved by the European Commission. The external auditor shall present an annual report to the relevant authorities designated by the Ministry of Finance and Public Function and the European Commission, in which any irregularities related to access shall be assessed.

The data storage facilities shall be completely accessible for the competent authorities of the Member States, the European Commission and the external expert. In duly justified cases, the manufacturers or importers shall be granted access to the stored data, provided that commercially sensitive information remains appropriately protected, in conformity with the relevant Union and Spanish law

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9. No economic operator participating in the tobacco product commerce may modify or delete the recorded data.

10. The Ministry of Finance and Public Function shall be responsible for the traceability of the tobacco products, with the implementing and development provisions to ensure its compliance being regulated by ministerial decree.

11. Personal information shall only be used in compliance with the laws and safeguards established in Organic Law 15/1999, of 13 December, on Personal Data Protection.

12. The previous sections apply to cigarettes and roll-your-own tobacco as of the 20th of May of 2019 and to other tobacco products distinct from cigarettes and roll-your-own tobacco as of the 20th of May 2024.

13. The Ministry of Finance and Public Function shall dictate the technical regulations of development and implementation regarding the traceability of the tobacco products.

Article 22. *Security features of the tobacco products.*

1. In addition to the unique identifier referred to in article 21, the packaging units of the tobacco products that are marketed in Spain shall include a tamper-proof security feature, composed of visible and invisible elements. The security feature shall be irremovably printed or affixed, indelible and not hidden or concealed in any manner, including with tax stamps and price marks or other elements imposed by the law.

Tax marks regulated in the tax regulation for special taxes as a security feature may be used according to the conditions determined by the regulation.

2. The Ministry of Finance and Public Function shall be responsible for dictating the technical regulations of development and execution regarding the security feature.

3. Section 1 shall apply to cigarettes and roll-your-own tobacco from 20 May of 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May of 2024.

CHAPTER III

Novel tobacco products and tobacco for oral use

Article 23. *Notification of novel tobacco products.*

1. Manufacturers or importers who intend to market a novel tobacco product should notify the General Management of Public Health, Quality and Innovation of the following information, through the EU-CEG Portal, and following the format established in Commission Implementing Decision (EU) 2015/2186, of 25 November 2015:

a) A detailed description of the relevant novel tobacco product.
b) A description of usage instructions.
c) Information on ingredients and emissions as described in article 6.

2. The following documentation should be attached to the previous notification:

a) available scientific studies on toxicity, addictiveness and attractiveness of the tobacco product, in particular as regards its ingredients and emissions.

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b) available studies, executive summaries thereof and market research on the preferences of various consumer groups, including youth.

c) other available and relevant information including a risk/benefit analysis of the product, its anticipated effects on cessation of tobacco consumption and its anticipated effects on initiation of tobacco consumption, and effects on predicted consumer perception.

3. The notification referred to in the previous sections shall be made within six months as of the anticipated date of marketing of the product.

4. Similarly, any modification of the information referred to in the previous sections shall be notified.

5. The General Management of Public Health, Quality and Innovation shall verify that the documentation provided is in line with that established in sections 1 and 2, possibly requiring the remission of data that was not provided, until the document is complete. It may also request, with justification, that manufacturers or importers conduct additional trials or present complementary information.

Article 24. *Regime applicable to novel tobacco products.*

1. Regarding the novel tobacco products that are included in the definition of smokeless tobacco products, as described in article 3.af), that established in this royal decree shall be applicable to this type of products.

2. Regarding the novel tobacco products that are included in the definition of smoking tobacco products as described in article 3.ae), that established in this royal decree shall be applicable to this type of products.

Article 25. *Tobacco for oral use.*

The marketing of tobacco for oral use is prohibited.

TITLE II

Electronic cigarettes and refill containers

CHAPTER I

Provisions regarding marketing

Article 26. *Notification obligations regarding marketing.*

1. Manufacturers or importers who intend to market electronic cigarettes or refill containers should notify the General Management of Public Health, Quality and Innovation of the following information through the EU-CEG Portal and in accordance with the format established in the Commission Implementing Decision (EU) 2015/2183, of 24 November 2015, establishing a common format for the notification of electronic cigarettes and refill containers:

a) the name and contact details of the manufacturer and , when relevant, the importer into the European Union.

b) a description of the product composition, including, when relevant, the opening and refill mechanism of the device or of the refill devices.

c) a list of all ingredients of the electronic cigarette and the emissions generated from the use of the same, specified by brands and types, including the quantities of said ingredients.

d) toxicological data regarding the product ingredients and emissions, including when heated, referring in particular to their effects on the health of the consumers when inhaled and taking into account, among others, any addictive effect.

e) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions.

f) description of the production process, including series production and a declaration that the production ensured conformity with the requirements of this article.

g) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, once placed on the market and used under normally foreseeable conditions.

This notification should also be made in the case of any substantial modification to the electronic cigarettes and refill containers that are marketed.

2. Furthermore, manufacturers and importers of electronic cigarettes and refill containers should present the design of the labelling, packaging and informative leaflet of each brand and type of product to the General Management of Public Health, Quality and Innovation so as to verify that they comply with the requirements established in article 30.

3. The General Management of Public Health, Quality and Innovation shall verify that the documentation provided complies with that established in sections 1 and 2, possibly requiring the remission of other data in order to complete this documentation.

4. The notifications referred to in sections 1 and 2 shall be made:

a) For new devices or those that have been modified, six months prior to the date of their marketing.

b) For electronic cigarettes and refill containers marketed prior to the entry into effect of this royal decree, the notification should be presented within a period of six months as of the entry into effect of the same, except in the case in which this information has already been communicated previously, notwithstanding that the same should be carried out according to the terms described in sections 1 and 2, or in the case in which they have been modified, in both cases requiring notification via the EU-CEG Portal.

Article 27. *Other notification obligations.*

1. Manufacturers and importers of electronic cigarettes and refill containers should present the following information, on an annual basis and within the first quarter of each year, to the General Management of Public Health, Quality and Innovation:

a) General details on sales volume, by product brand and type.

b) Information on the preferences of diverse consumer groups, including young smokers, non-smokers and the main types of current users.

c) The product sales mode.

d) Summaries of any market studies that are carried out with respect to the previous, in Spanish or English.

2. The General Management of Public Health, Quality and Innovation shall be responsible for the assessment of the evolution of the electronic cigarette and refill container markets, and their potential to lead to nicotine addiction or to the traditional consumption of tobacco, especially in youth and non-smokers.

Article 28. *Quality and security requirements.*

1. Electronic cigarettes and refill containers should comply with the following requirements:

a) Nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges or tanks that do not exceed a volume of 2 ml.

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b) That the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.
c) That the nicotine-containing liquid does not contain additives listed in article 5.1.c).
d) Only ingredients of high purity are to be used in the manufacturing of nicotine-containing liquid, according to those quality standards established in the European pharmacopeia or similar documents. Substances other than the ingredients referred to in article 26.1.c) are to be present only in trace amounts and are technically unavoidable during manufacture.
e) Except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in their heated and unheated forms, and whose quality standards comply with that described in paragraph d) of this section.
f) That they administer nicotine doses in a constant form under normal usage conditions.
g) That they are safe for children and impossible to handle, are protected from breakage and leaks and have a mechanism permitting their leak-proof refilling.

2. Furthermore, the electronic cigarettes should administer the dosage of nicotine in a constant manner under normal usage conditions.

Article 29. *Obligations regarding trials.*

1. Manufacturers or importers of electronic cigarettes and refill containers, as the parties responsible for ensuring the quality and safety requirements of their products, shall present, on an annual basis, a report containing the following information:
a) The qualitative and quantitative results of the ingredients in these products.
b) Sample size in relation to the production batch size.
c) Analytical procedures used, as well as the validation of the same.

2. This report should be notified to the General Management of Public Health, Quality and Innovation during the first quarter of the year following its completion.

Article 30. *Labelling and packaging.*

1. The packaging units and outside packaging of the electronic cigarettes and refill containers should comply with the following requirements:
a) Include a list of all ingredients that the product contains in descending order and an indication of the nicotine content and its administration per dose, the manufacture batch number and a recommendation that it be kept outside of the reach of children.
b) Not include elements or characteristics mentioned in article 19.1, except for those described in its paragraphs b) and d) referring to information on the content of nicotine and its aromas.
c) Contain the following health warning: “This product contains nicotine, a very addictive substance. It is not recommended for consumption by non-smokers”. This warning should comply with the requirements specified in article 18.2..

2. In addition, the packaging units and outside packaging of the electronic cigarettes and refill containers should include a leaflet, written in Spanish, containing information on:

a) Use and storage, including the warning that the product is not recommended for consumption by youth and non-smokers.
b) Contraindications.
c) Warnings to specific risk groups.
d) Potential adverse effects.
e) Addiction and toxicity.
f) Manufacturer or importer contact information and details on a physical or legal entity in the European Union.

Article 31. *Information available to the public.*

1. The information presented in compliance with that included in article 26.1 shall be available on the website of the Ministry of Health, Social Services and Equality, with the exceptions that have been anticipated by the law.

2. Of the information referred to in the previous section, manufacturers or importers shall be obligated to specify that which they consider to be subject to trade secrecy, in order to adopt the measures required for its protection.

CHAPTER II

Registry of Manufacturers, Importers and Distributors of electronic cigarettes and refill containers

Article 32. *Registry creation.*

1. The Registry of Manufacturers, Importers and Distributors of electronic cigarettes and refill containers shall be created with the goal of collecting and ordering the information on these and to facilitate the exercising of administrative actions related to their potential adverse effects.
2. The registry shall be of an administrative nature and shall be part of the General Management of Public Health, Quality and Innovation which shall be the organism responsible for the same.
3. The characteristics and content of the registry shall be determined by order of the head of the Ministry of Health, Social Services and Equality.

Article 33. *Functioning of the registry.*

1. The registry shall include the following information regarding manufacturers, importers and distributors of electronic cigarettes and refill containers having their corporate headquarters in Spain:
a) Name and contact details of the manufacturer, importer and distributor in Spain.
b) Name and contact details of the legal representative.
c) Types, brands and models of products marketed with indications of the product reference identification, “ID”, assigned by the EU-CEG Portal.

2. In the case of manufacturers and importers, the inclusion of this information in the registry shall be carried out by the General Management of Public Health, Quality and Innovation, based on data provided to the EU-CEG Portal under the context of the notification obligations referred to in article 26. In the case of distributors, they should notify the information to the General Management of Public Health, Quality and Innovation, to be included in the registry.
3. Modification and cancelation of the information contained in the registry shall be carried out by the General Management of Public Health, Quality and Innovation in accordance with that determined by the regulations governing the registry.

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CHAPTER III

Adverse effects

Article 34. *Information collection system.*

1. The manufacturers, importers and distributors of electronic cigarettes and refill containers should have an information collection system for the potential adverse effects of the products that they manufacture, import or market, including the following minimum content:

a) Information on potential adverse effects.
b) Information on security and dangers of their products.
c) Information on the quality of their products.

2. This information shall be available to the General Management of Public Health, Quality and Innovation and competent health authorities for their consultation.

Article 35. *Obligations related to the adverse effects.*

1. The manufacturers, importers and distributors of electronic cigarettes and refill containers shall be obligated to immediately adopt the necessary corrective measure, including the temporary or permanent removal of the products from the market, when there is evidence of any of the following circumstances:

a) That the products are dangerous or unsafe
b) That they fail to comply with the quality regulations regarding ingredients and emissions as established in this royal decree.
c) That they fail to comply with any other obligations established for these products in this royal decree.

2. In the cases described in the previous section, the manufacturers, importers and distributors of electronic cigarettes and refill containers shall be obligated to remit the following information to the General Management of Public Health, Quality and Innovation, in a detailed manner within 24 hours of having adopted the measure:

a) Risk to health and safety.
b) Corrective measures adopted.

The General Management of Public Health, Quality and Innovation shall send this information to the autonomous communities and to the cities of Ceuta and Melilla.

3. Furthermore, the manufacturers, importers and distributors of electronic cigarettes and refill containers shall be obligated to send the information referred to in the previous section to the Member States as soon as the product is or shall be available.

Article 36. *Oversight and adoption of measures.*

1. According to that included in Chapter I of Title II of Law 33/2011, of 4 October, the Ministry of Health, Social Services and Equality, autonomous communities and cities of Ceuta and Melilla shall be responsible for the organization and management of the oversight of public health, the functions of oversight of the risks to human health that may be caused by electronic cigarettes and refill containers, potentially adopting some of the measures described in article 54 of Law 33/2011, of 4 October and in article 26 of Law 14/1986, of 25 April.

2. The adopted measures and the supporting data shall be communicated to the European Commission and to the competent authorities of the other Member States.

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TITLE III

Herbal products for smoking

Article 37. *Notification of obligations.*

1. Manufacturers or importers of herbal products for smoking are obligated to notify the General Management of Public Health, Quality and Innovation of the following information through the EU-CEG Portal, and according to the format established in Commission Implementing Decision (EU) 2015/2186, of 25 November of 2015:

a) The list of all ingredients used in the manufacturing of the products, specified by brands and types.
b) The quantities of said ingredients.

2. In addition, prior to their marketing, manufacturers or importers of herbal products for smoking should present the General Management of Public Health, Quality and Innovation, with the design of labelling and packaging for each brand and type of product, in order to verify that they comply with the requirements established in article 39.
3. The General Management of Public Health, Quality and Innovation shall verify that the documentation provided complies with that established in the previous sections, potentially requiring the remission of data that has not been provided, so as to complete the documentation.
4. The communications referred to in sections 1 and 2 of this article shall be made:

a) For the new herbal products for smoking or those that have been modified, six months prior to the date of their placement on the market.
b) For the herbal products for smoking that have already been marketed prior to the entry into effectiveness of this royal decree, the notification shall be presented within a period of six months as of the date of entry into force of the same, except in the case in which this information has already been communicated through the EU-CEG Portal.

Article 38. *Information available to the public.*

1. The information presented in compliance with that included in article 37.1 shall be available on the website of the Ministry of Health, Social Services and Equality, with any exceptions mentioned in the current legislation.
2. Of the information referred to in the previous section, the manufacturers or importers shall be obliged to specify that which they consider to be subject to trade secrecy, in order to adopt the necessary measures so as to protect the same.

Article 39. *Labelling and packaging.*

1. Each unit of packaging and outside packaging of the herbal products for smoking should include the following general warning: “Smoking this product is harmful to your health”.
2. The health warning shall be printed on the front and back external surface of the packaging and outside packaging.
3. The health warning shall cover 30% of the area of the external surface of each packet unit and all of the outside packaging, and should:

a) Be printed in bold, in black Helvetica font on a black background, with a type size such that it fills up the maximum space possible in the area reserved for this purpose.
b) Be centred in the space reserved for its printing and in the parallel piped packs and in all outside packaging, parallel to the lateral border of the unit pack.

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4. The unit packs and outside packaging of the herbal products for smoking shall not include any element or characteristic that:

a) Promote the product or its consumption by offering a misleading impression regarding its characteristics, its effects on health, its dangers or its emissions.
b) Suggest that the specific product is less harmful than others or that it has the objective of reducing the effect of some harmful smoke components, or that it has revitalizing, energetic, curative, rejuvenating, natural, ecological or other positive effects on the health or lifestyle.
c) Appear to be a food or cosmetic product.
d) Indicate that the product does not contain additives or flavouring substances.

Article 40. *Registry of manufacturers, importers and distributors of herbal products for smoking.*

1. A Registry of manufacturers, importers and distributors of herbal products for smoking shall be created with the purpose of collecting and ordering the information regarding the same.
2. The registry is administrative in nature and shall be part of the General Management of Public Health, Quality and Innovation which shall be the organism that oversees the same.
3. The characteristics and content of the registry shall be determined by order of the head of the Ministry of Health, Social Services and Equality.

Article 41. *Functioning of the registry.*

1. The registry shall include the following information regarding manufacturers, importers and distributors of herbal products for smoking that have their corporate headquarters in Spain:
a) Name and contact details of the manufacturer, importer and distributor in Spain.
b) Name and contact details of the legal representative.
c) Types, brands and models of products marketed with indications of the product reference identification, “ID”, assigned by the EU-CEG Portal.

2. In the case of manufacturers and importers, the inclusion of this information in the registry shall be carried out by the General Management of Public Health, Quality and Innovation, based on the data provided to the EU-CEG Portal in the context of the notification obligations referred to in article 37. In the case of distributors, they shall notify the General Management of Public Health, Quality and Innovation of this information that shall be included in the registry.
3. Modification and cancelation of the information contained in the registry shall be carried out by the General Management of Public Health, Quality and Innovation in accordance with that determined by the regulations governing the registry.

TITLE IV

Verification and control

Article 42. *Annual verification plan.*

1. The General Management of Public Health, Quality and Innovation shall approve an Annual verification plan regarding tobacco products, electronic cigarettes and refill containers and herbal products for smoking that are on the market, with the goal of controlling compliance with the requirements regarding ingredients, emissions, quality and security as established by current regulations.

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2. This plan shall include the brands and types of products that should be analysed, the number of samples to be taken and the verification laboratories as referred to in article 44, which shall participate in the trials.

3. The control and supervision laboratory referred to in article 43 shall participate in the creation of this plan.

Article 43. *Control and supervision laboratory.*

1. The Research and Quality Control Centre that is headed by the Spanish Agency of Consumption, Food Safety and Nutrition, shall be considered a control and supervision laboratory, for the purposes established in this royal decree.

2. The control and supervision laboratory shall collaborate with the General Management of Public Health, Quality and Innovation in the authorization procedure of the verification laboratories foreseen in this title and shall inspect their functioning.

3. The control and supervision laboratory shall create, on an annual basis, a report on compliance with the Annual verification plan that shall be sent to the General Management of Public Health, Quality and Innovation.

Article 44. *Verification laboratories.*

1. The verification laboratories shall verify some of the following aspects:

a) Ingredients referred to in article 6.1.a)

b) Emissions levels referred to in article 6.1.e).

c) Emissions levels and ingredients referred to in paragraphs b), c) and d) of article 26.1 and article 29.

d) Quality and safety requirements established in article 28.

e) Ingredients referred to in article 37.1.

To do so, analyses and trials may be conducted on the tobacco products, electronic cigarettes and refill containers and herbal smoking products, in accordance with that which has established its authorization and Annual verification plan.

2. The verification laboratories shall be authorized by the General Management of Public Health, Quality and Innovation always in the case that they comply with the requirements referred to in article 45. In the authorization, their scope of action is to be established with regards to tobacco products, electronic cigarettes and refill containers and herbal products for smoking that have been placed on the market.

Article 45. *Requirements of the verification laboratories.*

The verification laboratories should comply with the following requirements:

a) Be independent of the entities related with the sector that is subject to the verification and not belong to or be controlled directly or indirectly by them.

b) Have the adequate financial, technological, human and organizational resources to carry out the necessary verifications.

c) To create activities in the scope of European and international cooperation regarding tobacco products, electronic cigarettes and refill containers or herbal smoking products.

d) Have a quality control system implemented that justifies and determines its technical competence to carry out the opportune measurements on the tobacco products, electronic cigarettes and refill containers or herbal smoking products.

e) Ensure the confidentiality of its actions.

Article 46. *Onset of the authorization procedure.*

1. The entities interested in obtaining authorization as a verification laboratory should make their request to the General Management of Public Health, Quality and Innovation, attaching the documentation that justifies compliance with the requirements detailed in article 45.

2. Furthermore, the following documentation should be provided:

a) Name and contact details of the laboratory and legal representative.
b) Description of the scope of action for which the authorization has been requested.
c) Plan of the facilities and description of equipment.
d) Information available regarding the quality assurance of the analytical trials undertaken for the control of emissions and components of the tobacco products, of the electronic cigarettes and refill containers or herbal smoking products.

Article 47. *Procedural instruction.*

1. The Sub-directorate General of Health Promotion and Epidemiology shall be entrusted with the procedural instruction, with the collaboration of the control and supervision laboratory referred to in article 43.

2. The control and supervision laboratory shall issue a report on the compliance with the requirements detailed in article 45 based on a verification visit to the applicant entity.

Article 48. *Proceedings outcome.*

1. The General Management of Public Health, Quality and Innovation, in a period of six months as of the presentation of the request, shall dictate and notify the outcome, granting or denying the authorization to the applicant entity.

Once this period has ended, without dictating or notification as to the corresponding outcome, the request shall be considered to be considered approved.

2. The authorization shall define the scope of action of the laboratory with regards to the tobacco products, electronic cigarettes and refill containers or herbal smoking products.

3. An appeal may be filed against the outcome of the General Management of Public Health, Quality and Innovation within a period of one month, before the General Secretariat of Health and Consumers, in compliance with that included in articles 121 and 122 of Law 39/2015, of 1 October, on Common Administrative Procedures of the Public Administrations.

4. The General Management of Public Health, Quality and Innovation shall register the content of the authorization in the Registry of Verification Laboratories, referred to in article 50, and shall notify this to the European Commission, detailing the criteria used for its authorization as well as the applicable supervision measures.

Article 49. *Control, revocation and termination.*

1. The General Management of Public Health, Quality and Innovation shall verify compliance with the authorization requirements. For this, it may require the collaboration of the control and supervision laboratory.

2. In the case of a breach of the authorization or of the requirements detailed in article 45, the General Management of Public Health, Quality and Innovation may revoke the granted authorization, following a hearing with the interested party.

3. In the case of the termination of activity of the laboratory, of its own accord, this should be notified to the General Management of Public Health, Quality and Innovation, who shall proceed to remove it from the registry and shall communicate this to the European Commission.

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Article 50. *Registry of Verification Laboratories.*

1. The Registry of Verification Laboratories shall be created with the purpose of collecting and ordering the information on the authorized verification laboratories.
2. The registry shall be administrative in nature and shall be a part of the General Management of Public Health, Quality and Innovation, which shall be the organism responsible for the same.
3. By order of the head of the Ministry of Health, Social Services and Equality, the characteristics and content of the registry shall be determined.

First additional provision. *No increase in public spending.*

The contents of this royal decree shall not result in an increase in the allocations, payments or other expenses in the area of personnel. Similarly, the implementation and maintenance of the registries that are created based on this royal decree shall be made with the personnel means that currently exist in the affiliated organism, without increasing the budget appropriations or other personnel spending.

Second additional provision. *Competencies in the area of control and inspection.*

According to that detailed in article 5 of Law 13/1998, of 4 May, on Organization of the Tobacco Market and Tax Regulations, the Tobacco Market Commission shall be responsible for the functions of inspection and control as established in articles 4, 5 and 7 and in chapters II and III of title I of this royal decree.

First transitory provision. *Extensions in manufacturing and marketing.*

1. Notwithstanding that established in the sole repeal provision, it shall be possible to continue manufacturing or freely circulate the following up to three months following the entry into effect of this royal decree:

a) Tobacco products labelled in compliance with that included in Royal Decree1079/2002, of 18 October.
b) Electronic cigarettes and refill containers and herbal smoking products, packaged and labelled in compliance with the previously mentioned regulations.

2. Products referred to in the previous section may continue to be marketed up to ten months following the entry into effect of this royal decree.
3. Roll-your-own tobacco in pouches that are labelled with a general warning and an informative message in compliance with that contained in Commission Implementing Decision (EU) 2015/1735, may continue to be manufactured or freely distributed until the 20th of May of 2018 and may continue to be placed on the market until the 20th of May of 2019.

Second transitory provision. *Transitional regime regarding the position of the combined health warnings.*

In cigarette packaging units that are to contain a circulation seal or tax mark, which are in force until the 20th of May of 2019, the position of the combined health warnings shall be governed by the following rules:

a) If the tax marks are placed on the upper border of a packaging unit made of cardboard, the combined health warnings that appear on the back side should be placed directly below the tax mark.
b) In the case of a packaging unit made of a soft material, a rectangular area shall be reserved for the tax marks, having a height that cannot exceed 13 mm between the upper border of the pack and the upper border of the health warnings.
c) The marks and logotypes cannot be situated above the health warning.

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Third transitory provision. *Verification laboratories existing upon entry into effect of this royal decree.*

Laboratories which, upon entry into effect of this royal decree, are carrying out some of the functions detailed in article 44 may continue to carry them out for a maximum period of one year as of its entry into effect, even though they do not have the authorization described in title IV of this royal decree.

Sole repeal provision. *Repeal regulation.*

Royal Decree1079/2002, of 18 October, regulating the maximum content of nicotine, tar and carbon monoxide of cigarettes, the labelling of tobacco products as well as measures regarding ingredients and names of tobacco products has been repealed as well as all provisions of equal or lower ranking that refute that which is laid out in this royal decree.

First final provision. *Jurisdictional authority.*

This royal decree has the nature of a basic regulation, dictated in the scope of article 149.1.16ª of the Constitution which attributes the state with the competency over the general bases and coordination of health.

Second final provision. *Modification of Decree 2484/1967, of 21 September, approving the text of the Spanish Food Code.*

Section 3.25.80 of the 8th section of Chapter XXV of the Third Part of the Spanish Food Code, approved via Decree 2484/1967, of 21 September, approving the text of the Spanish Food Code, has been suppressed.

Final provision three. *Incorporation of European Union law.*

1. Through this royal decree, Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, regarding the approximation of legal, regulative and administrative provisions of Member States in the area of manufacturing, presentation and sale of tobacco products and related products and which repealed Directive 2001/37/EC was partially incorporated into Spanish law.

Similarly, Commission Delegated Directive 2014/109/EU, of 10 October 2014, modifying annex II of Directive 2014/40/EU of the European Parliament and of the Council establishing the library of picture warnings that is to be used in tobacco products, shall be included in Spanish law.

2. References made in current legislation to Directive 2001/37/EC of the European Parliament and of the Council, of 5 of June 2001, on the approximation of the legal, regulatory and administrative provisions of the Member States in the area of manufacturing, presentation and sale of tobacco products, shall be understood to be made to Directive 2014/40/EU of the European Parliament and of the Council, of 3 of April 2014, regarding the approximation of the legal, regulatory and administrative provisions of the Member States in the area of manufacturing, presentation and sale of tobacco and related products and which repealed Directive 2001/37/EC.

Final provision four. *Regulative powers.*

1. The head of the Ministry of Health, Social Services and Equality shall be empowered to dictate any provisions that may be considered necessary for the development of that established in this royal decree, with the exception of that detailed in articles 21 and 22, in which the dictating of technical developmental and execution regulations on the traceability of tobacco products and security measures, corresponds to the head of the Ministry of Finance and Public Function.

2. Via order of the head of the Ministry of Health, Social Services and Equality, it is possible to do the following:

a) To establish the maximum emissions levels for cigarettes with reference to substances distinct from those detailed in article 4.

b) To establish the maximum levels of the substances released from other tobacco products distinct from cigarettes.

c) To establish the emissions measurement methods referred to in the previous sections.

The General Management of Public Health, Quality and Innovation shall notify the European Commission regarding the maximum levels and measurement methods that are established in regards to this section.

Final provision five. *Entry into force.*

This Royal Decree shall go into effect on the day following its publication in the “Official State Bulletin”.

In the Spanish Embassy of Astana, on 9 June of 2017.

FELIPE R.

The Vice-President of the Government and Minister of the Presidency and for the Regional Governments,

SORAYA SÁENZ DE SANTAMARÍA ANTÓN

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ANNEX I

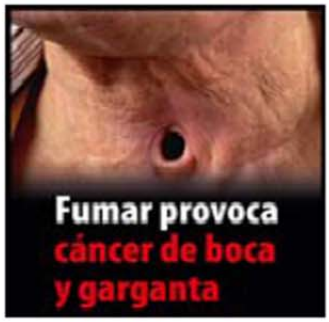
List of text warnings

(1) Smoking causes 9 out of 10 lung cancers
(2) Smoking causes mouth and throat cancer
(3) Smoking damages your lungs
(4) Smoking causes heart attacks
(5) Smoking causes strokes and disability
(6) Smoking clogs your arteries
(7) Smoking increases the risk of blindness
(8) Smoking damages your teeth and gums
(9) Smoking can kill your unborn child
(10) Your smoke harms your children, family and friends
(11) Smokers' children are more likely to start smoking
(12) Quit smoking -- stay alive for those close to you
(13) Smoking reduces fertility
(14) Smoking increases the risk of impotence.

ANEXO II

Picture Library

Juego 1



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Juego 2

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Juego 3

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