MINISTRY
OF HEALTH

Draft Royal Decree XXXX/XXXX of XX XXXXX amending Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and placing on the market of tobacco products and related products.

I

Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC was adopted with the aim of facilitating the smooth functioning of the internal market for tobacco and related products in the European Union, based on a high level of protection of human health, as well as to fulfil the obligations under the World Health Organisation Framework Convention on Tobacco Control (FCTC), signed in Geneva on 21 May 2003.

This Directive was amended by Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products. Several implementing decisions were subsequently adopted, which developed different aspects of their content.

The Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and placing on the market of tobacco products and related products, transposed into the Spanish legal system the content of the aforementioned Directive, as well as its amendment.

On 3 November 2022 the Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products, was published.

This Delegated Directive was recently transposed into Spanish law by Royal Decree 47/2024 of 16 January 2024 amending Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and placing on the market of tobacco products and related products.

After this date, on 30 April 2024, the Council of Ministers approved the Comprehensive Plan for the Prevention and Control of Tobacco 2024-2027, which includes an

extensive package of measures aimed at reducing the consumption of tobacco products and related products, and with the objective of achieving a tobacco-free generation in Spain.

II

The purpose of this Royal Decree is, therefore, the effective implementation of one of the main measures contemplated in the Comprehensive Plan, within the key action elements at normative level. The Plan has, thus, identified the need to introduce various improvements, not yet contemplated in the harmonized legislation of the European Union, as a result of the significant changes experienced, both at epidemiological level and in consumption patterns, as well as in the current configuration of the market for tobacco products and related products in Spain.

In this sense, there is currently a variety of products with differentiated characteristics, with or without tobacco, with or without nicotine, with or without electronic components, and even with hybrid aspects of complex classification. These developments pose a challenge, making it necessary to provide an appropriate technical response to ensure the adequate protection of individuals who consume these new unconventional products.

Consequently, this Royal Decree amends Royal Decree 579/2017 of 9 June 2017 in order to, on the one hand, improve the regulations applicable to tobacco products, and, on the other, offer an innovative body of regulations to the wide range of related products currently devoid of proper health regulations in the interest of effective consumer protection.

The Royal Decree, thus, regulates certain aspects related to the manufacture and placing on the market of tobacco products and related products. The latter include, as they are regulated for the first time from a public health perspective, nicotine pouches and heated herbal products.

Finally, with regard to electronic cigarettes, two new aspects should be highlighted, firstly, the replacement of the term ‘Nicotine Susceptible Release Device’ with that of ‘electronic cigarette’. This term is used in EU legislation, both being equivalent and in line with Article 2(1)(f) of Law 28/2005 of 26 December 2005 on sanitary measures against smoking, and on regulating the sale, supply, consumption and advertising of tobacco products. On the other hand, the regulation of these products without

nicotine, not included in the scope of EU legislation, along with measures to restrict flavours and disposable products in the interests of proper protection of children and adolescents, as well as the protection of the environment and the reduction of waste, is also new.

III

The Royal Decree is structured in a single article with sixteen paragraphs, one additional provision, one transitional provision, and one final provision.

Paragraph 1 amends the purpose of the standard to include nicotine-free electronic cigarettes.

Paragraph 2 amends and introduces definitions of the terms expressed throughout the standard.

Paragraph 3 amends the rules for ingredients and additives to include heated products.

Sections 4 to 15 regulate, along with electronic cigarettes, nicotine-free electronic cigarettes. The regulation of these is due to their growing importance, especially among the young population, and due to recent market developments at European level that have made it necessary to include them as tobacco-related products. They regulate reporting obligations in relation to these products, testing, as well as control and verification requirements. It also amends certain quality and safety requirements for electronic cigarettes.

Paragraph 16 introduces a new title to regulate related products other than electronic cigarettes, nicotine-free electronic cigarettes and herbs for smoking. Two new product categories are introduced into the Spanish legal system: nicotine pouches and heated herbal products.

The single additional provision defines competences in the classification of new products.

The single transitional provision establishes an extension for manufacturing and placing on the market.

The single final provision provides for its entry into force on the day following that of its publication in Spain’s Official State Gazette.

This rule is in line with the principles of sound regulation set out in Article 129(1) of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations. In particular, as regards the principles of necessity and effectiveness, this rule is justified by a reason of general interest, such as the protection of the health of the population, through the implementation of measures aimed at preventing and protecting against exposure of the population. In addition, this Royal Decree arises from the need to introduce various improvements identified during this period in which significant changes have occurred, both at epidemiological level and in consumption patterns, as well as in the current configuration of the market for tobacco products and related products. The rule complies with the principle of proportionality, by including the regulations that are essential to address the aforementioned needs it aims to meet. It also complies with the principle of legal certainty, as it is fully consistent with the rest of the legal order. Likewise, during the procedure for drafting the rule, the procedures for public consultation and public information established by law, in compliance with the principle of transparency, have been formalised, with broad participation from the different sectors affected, not only in the business and health fields but also among consumers, in addition to clearly describing the objectives of the rule. Finally, the Royal Decree complies with the principle of efficiency, as the approval of the regulation will not generate new administrative burdens.

IV

In the process of preparing this Royal Decree, reports from the Autonomous Communities, and the cities of Ceuta and Melilla have been collected, and business organisations, scientific societies, and social entities were involved in both the prior consultation and the public hearing and information.

This Royal Decree has the character of a basic norm and is issued under the provisions of Article 149(1)(16) of the Spanish Constitution, which attributes to the State the competence over the bases and general coordination of health.

Accordingly, on a proposal from the Minister for Health and the First Deputy Prime Minister and Minister for Finance, with the prior approval of the Minister for Digital Transformation and the Civil Service, in agreement with the Council of State, and after deliberation by the Council of Ministers at its meeting on XXX XXXX 202X,

THE FOLLOWING IS DECREED:

Single Article. *Amendment of Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and placing on the market of tobacco products and related products*.

Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and placing on the market of tobacco products and related products is hereby amended as follows:

One. Subparagraphs (e), (f) and (g) of Article 1 are amended to read as follows:

'e) The placing on the market, composition and labelling of certain products related to tobacco products, namely electronic cigarettes, nicotine-free electronic cigarettes and refill containers with or without nicotine, and herbal products for smoking, as well as other products containing natural or synthetic nicotine and derivatives.

f) The Register of Manufacturers, Importers and Distributors of electronic cigarettes and electronic cigarettes without nicotine, and refill containers with and without nicotine, the Register of Manufacturers, Importers and Distributors of herbal products for smoking, and the Register of Verification Laboratories.

g) The verification and control procedure for tobacco products, electronic cigarettes, nicotine-free electronic cigarettes, and herbal products for smoking, as well as the functions and the authorisation procedure of the verification laboratories.'

Two. Subparagraphs (a), (m), (p) and (v) are amended and subparagraphs (p)bis, (añ), (ao), (ap), (aq), (ar), and (as) of Article 3 are added as follows:

'a) "additive" means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging;'.

'm) "electronic cigarette" means, in accordance with Article 2(1)(f) of Law 28/2005 of 26 December 2005 on health measures against smoking and on regulating the sale, supply, consumption, and advertising of tobacco products, any product capable of releasing nicotine, or any of its components, including a cartridge, a tank, and the device without cartridge or tank, which can be used for consumption of nicotine-containing vapour via a mouth piece. Electronic cigarettes can be disposable or

refillable by means of a refill container and a tank, or rechargeable with single use cartridges;'.

'p) "refill container" means, in accordance with Article 2(1)(h) of Law 28/2005 of 26 December 2005 on health measures against smoking and on regulating the sale, supply, consumption, and advertising of tobacco products, a receptacle that contains a nicotine containing liquid, which can be used to refill an electronic cigarette;

(p)bis "nicotine-free refill container" means a receptacle that contains a nicotine-free liquid, which can be used to refill an electronic cigarette.'

'v) "nicotine" means nicotinic alkaloids, and any nicotine derivatives.'

'añ) "related product" means tobacco-free product related to tobacco products, including, but not limited to, electronic cigarettes, with and without nicotine, herbal products for smoking/shisha, nicotine pouches, and any other product containing nicotine, whether natural or synthetic, or without nicotine, used for recreational purposes and/or imitating the act of smoking, inducing it, or relating to its traditional and/or social consumption.'

'ao) "nicotine pouch": a tobacco-free product for oral use, consisting 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 pouches, in porous sachets, tablets, or in an equivalent form, not intended for smoking.'

'ap) "nicotine-free electronic cigarette" means a product, or any component thereof, including a cartridge, a tank and the device without cartridge or tank, which can be used for vapour consumption via a mouth piece. Nicotine-free electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.'

'aq) "disposable or single-use electronic cigarette or nicotine-free electronic cigarette": a device containing a liquid with or without nicotine, ready for consumption and intended to be discarded after use.'

'ar) "ingredients hazardous to human health": substances meeting the criteria for classification as hazardous to human health as laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and

repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.'

'as) "heated herbal product" means a tobacco-free product, with or without nicotine, used for inhalation of an aerosol, consisting of an electronic device and a refill in stick, cigar, capsule or other format containing a substrate of herbs or other vegetable fibres, either dry or with very low humidity, whether or not containing artificially added nicotine.'

Three. Paragraph 5 of Article 5(1)(c) is amended to read as follows:

'5. Additives having carcinogenic, mutagenic or reprotoxic properties, hereinafter CMR, without combustion or heating.

Four. The heading of Title II is amended to read as follows:

'TITLE II

Electronic cigarettes and nicotine-free electronic cigarettes and refill containers with and without nicotine'

Five. Article 26 is amended to read as follows:

'Article 26. *Reporting obligations relating to placing on the market*.

1. Manufacturers or importers intending to place on the market electronic cigarettes, nicotine-free electronic cigarettes or refill containers with or without nicotine shall, to the Directorate-General for Public Health and Health Equity, through the EU-CEG Portal, and following the format set out in Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers, report the following information:

a) Name and contact details of the manufacturer and, where applicable, the importer in the European Union.

b) A description of the composition of the product, including, where applicable, the mechanism for opening and refilling the device or refill containers.

c) The list of all ingredients of the electronic cigarette or nicotine-free electronic cigarette, the ingredients of the refill container with or without nicotine, and the emissions generated by its use, specified by brand and type, including the quantities of those ingredients.

d) Toxicological data on the ingredients and emissions of the product, including those subject to heating, mentioning in particular their effects on the health of consumers and taking into account, inter alia, their potential addictive effect.

e) Information on dosage and intake, if any, of nicotine under normal or reasonably foreseeable conditions of consumption.

f) Description of the production process, including series production, and a declaration that the production process ensures compliance with the requirements of this Article.

g) Declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

This communication must also be submitted whenever there is any substantial modification of the products placed on the market, and, in any case, ten years after the first communication.

2. In addition, prior to placing on the market, manufacturers and importers of electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with or without nicotine shall submit to the Directorate-General for Public Health and Health Equity, the design of the labelling, packaging, and information leaflet for each brand and type of product, in order to verify its compliance with the requirements laid down in Article 30.

3. The Directorate-General for Public Health and Health Equity will verify that the documentation provided complies with the provisions of Paragraphs 1 and 2, and may require the submission of other data to complete this documentation.

4. The communications referred to in Paragraphs 1 and 2 shall be made:

a) For new or modified devices, six months before the date of their placing on the market.

b) For electronic cigarettes and refill containers placed on the market before the entry into force of this Royal Decree, the notification shall be submitted within six

months from the entry into force of this Royal Decree, unless this communication has already been made previously, without prejudice to the fact that it must be completed in the terms indicated in Paragraphs 1 and 2, or that it is modified, and must, in both cases, be notified through the EU-CEG Portal.

c) For nicotine-free electronic cigarettes and nicotine-free refill containers marketed prior to the entry into force of Royal Decree ---/---- of ---- amending Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and placing on the market of tobacco products and related products, the notification shall be submitted within six months from the entry into force of this Royal Decree, unless this communication has already been made previously, without prejudice to the fact that it must be completed in the terms indicated in Paragraphs 1 and 2, or that it is modified, and must, in both cases, be notified through the EU-CEG Portal.'

Six. Article 27 is amended to read as follows:

'Article 27. *Other reporting obligations*.

1. Manufacturers and importers of electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with or without nicotine shall submit the following information annually within the first quarter of each year to the Directorate-General for Public Health and Health Equity:

a) comprehensive data on sales volumes, by brand name and type of the product;

b) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;

c) the mode of sale of the products;

d) executive summaries of any market surveys carried out in respect of the above, in Spanish or English.

2. The Directorate-General for Public Health and Health Equity is responsible for assessing the evolution of the market for electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with or without nicotine, and their possible use as a gateway to nicotine addiction or traditional tobacco consumption, especially among young people and non-smokers.

Seven. Article 28 is amended to read as follows:

‘Article 28. *Quality and safety requirements*.

Electronic cigarettes and nicotine-free electronic cigarettes and refill containers with or without nicotine shall comply with the following requirements:

a) That the liquid shall be marketed in refill containers not exceeding a volume of 10 ml. In refillable, disposable or single-use electronic cigarettes and nicotine-free electronic cigarettes, that the cartridge or the tank do not exceed 2 ml. Electronic cigarettes and nicotine-free electronic cigarettes shall not contain more than one cartridge or tank;

b) That for electronic cigarettes, the nicotine-containing liquid shall not contain nicotine in excess of 15 mg/ml;

c) That the liquid does not contain any of the non-permitted additives referred to in Article 5(1)(c);

d) That only ingredients of high purity, the quality standards of which have been defined by the European Pharmacopoeia or similar, are used in the manufacture of the nicotine-containing liquid, and substances other than the ingredients referred to in Article 26(1)(c) are only present in trace levels, if such traces are technically unavoidable during manufacture;

e) That, except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health, in accordance with Article 3(ar), in heated or unheated form, and the quality standards of which comply with the provisions of Subparagraph (d) of this Paragraph.

f) That for electronic cigarettes, that they deliver the nicotine doses at consistent levels under normal conditions of use;

g) That the products are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage;

h) That they containing only flavouring ingredients that impart tobacco aromas and/or flavours to the final product.’

Eight. Article 29 is amended to read as follows:

‘Article 29. *Obligations relating to testing*.

1. As those responsible for ensuring the quality and safety requirements of their products, manufacturers or importers of electronic cigarettes or nicotine-free electronic cigarettes and refill containers with or without nicotine, shall annually submit a report with the following information:

a) The qualitative-quantitative results of the ingredients of these products.

b) The size of the sample in relation to the size of the production batch.

c) The analytical procedures employed, as well as their validation.

2. This report must be communicated to the Directorate-General for Public Health and Health Equity during the first quarter of the year following its completion.

Nine. Article 30 is amended to read as follows:

'Article 30. *Labelling, packaging and product design*.

1. Unit packets, outside packaging of electronic cigarettes, nicotine-free electronic cigarettes and refill containers with or without nicotine shall comply with the following requirements:

a) Include a list of all ingredients contained in the product in descending order, and an indication, where appropriate, of the nicotine content, in millilitres, of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children;

b) Not include elements or features referred to in Article 19(1), except as provided for in Subparagraphs (a) and (c) thereof concerning information, where appropriate, on the nicotine content and on flavourings;

c) For electronic cigarettes, carry the following health warning: "This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers". This warning shall comply with the requirements specified in Article 18(2).

d) For nicotine-free electronic cigarettes, carry the following health warning: "Smoking this product damages your health". This warning shall comply with the requirements specified in Article 18(2).

2. In addition, the unit packets and outside packaging of electronic cigarettes and nicotine-free electronic cigarettes and refill containers with or without nicotine must include a leaflet, written at least in Spanish, with information on:

a) Instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;

b) Contra-indications;

c) Warnings for specific risk groups;

d) Possible adverse effects.

e) Addictiveness and toxicity;

f) Contact details of the manufacturer or importer and a legal or natural contact person within the Union.

3. The unit packet, the outside packaging, and the device may not include images, with the exception of the mandatory pictograms. Likewise, elements and combinations of colours that, due to their content or design, are likely to attract the attention or particular interest of consumers, especially minors, may not be used.

Ten. The heading of Chapter II is amended to read as follows:

'CHAPTER II

Register of Manufacturers, Importers and Distributors of electronic cigarettes and nicotine-free electronic cigarettes, and refill containers with or without nicotine'

Eleven. Article 32 is amended to read as follows:

'Article 32. *Creation of the register*.

1. The Register of Manufacturers, Importers and Distributors of electronic cigarettes and nicotine-free electronic cigarettes, and refill containers with or without nicotine is established, with the purpose of collecting and organising the information on them and of facilitating the exercise of administrative actions related to their possible adverse effects.

2. The register shall be administrative in nature and shall be managed by the Directorate-General for Public Health and Health Equity, which shall be the body responsible for it.

3. The characteristics and content of the register shall be determined by order of the Minister of Health.

Twelve. Article 33 is amended to read as follows:

'Article 33. *Operation of the register*.

1. The register shall contain the following information concerning manufacturers, importers and distributors of electronic cigarettes and nicotine-free electronic cigarettes and refill containers with or without nicotine, having their registered office 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 placed on the market, with the identification reference of the product, 'ID,' assigned by the EU-CEG Portal.

2. In the case of manufacturers and importers, the inclusion of this information in the register shall be carried out ex officio by the Directorate-General for Public Health and Health Equity, on the basis of the data provided to the EU-CEG Portal in the context of the reporting obligations referred to in Article 26. In the case of distributors, they shall communicate the information to the Directorate-General for Public Health and Health Equity, which shall incorporate it into the register.

3. The amendment and cancellation of the information contained in the register shall be carried out by the Directorate-General for Public Health and Health Equity, in accordance with the regulations governing the register.'

Thirteen. Article 34 is amended to read as follows:

'Article 34. *Information collection system*.

1. Manufacturers, importers and distributors of electronic cigarettes and nicotine-free electronic cigarettes, and refill containers with or without nicotine shall have in place a system for collecting information on the potential adverse effects of the products they manufacture, import or place on the market, with the following minimum content:

a) Information on possible adverse effects.

b) Information on the safety and hazards of their products.

c) Information on the quality of their products.

2. This information shall be available to the Directorate-General for Public Health and Health Equity, and to the competent health authorities for consultation.'

Fourteen. Article 35 is amended to read as follows:

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

1. Manufacturers, importers and distributors of electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with or without nicotine shall be obliged to take immediate corrective action, including withdrawal or recall of products from the market, where there are indications that any of these circumstances may occur:

a) That the products are dangerous or not safe.

b) That they do not comply with the quality standards relating to ingredients and emissions established in this Royal Decree.

c) That any other obligation established for these products in this Royal Decree is breached.

2. In the cases provided for in the previous paragraph, manufacturers, importers and distributors of electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with or without nicotine shall be obliged to submit, in detail and within 24 hours of the adoption of the measure, to the Directorate-General for Public Health and Equity in Health, the following information:

a) The risk to human health and safety.

b) Corrective action(s) taken.

The Directorate-General for Public Health and Health Equity will forward this information to the autonomous communities and the cities of Ceuta and Melilla.

3. In addition, manufacturers, importers and distributors of electronic cigarettes and nicotine-free electronic cigarettes, and refill containers shall be obliged to submit the market surveillance authorities of the Member States in which the product is made available or is intended to be made available.'

Fifteen. Article 36 is amended to read as follows:

'Article 36. *Monitoring and adoption of measures*.

1. In accordance with the provisions of Chapter I of Title II of Law 33/2011 of 4 October, and within the scope of their powers to organise and manage public health surveillance, the Ministry of Health, the Autonomous Communities, and the cities of Ceuta and Melilla are responsible for monitoring the risks to human health caused by electronic cigarettes or nicotine-free electronic cigarettes, and refill containers with or without nicotine, and may adopt any of the measures provided for in Article 54 of Law 33/2011 of 4 October 2011, and Article 26 of Law 14/1986 of 25 April 1986

2. The measures taken and the data on which they are based shall be communicated to the European Commission and to the competent authorities of the other Member States.'

Sixteen. A new Title V is added with the following wording:

'TITLE V

Related products other than electronic cigarettes, nicotine-free electronic cigarettes, or herbs for smoking.

CHAPTER I

Nicotine pouches

Article 51. *Reporting obligations relating to placing on the market.*

1. Manufacturers or importers intending to place nicotine pouches on the market shall, to the Directorate-General for Public Health and Health Equity via the EU-CEG

Portal in the format set out in Commission Implementing Decision (EU) 2015/2183 of 24 November 2015, communicate the following information:

a) Name and contact details of the manufacturer and, where applicable, the importer in the European Union.

b) The description of the composition of the product.

c) Nicotine content in milligrams, per pouch or individual unit.

~~c~~) d) The list of all ingredients, including the quantities of those ingredients.

~~d~~) e) A declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

2. In addition, prior to placing on the market, manufacturers and importers of nicotine pouches shall submit to the Directorate-General for Public Health and Health Equity, the design of the labelling and packaging for each brand and type of product, in order to verify its compliance with the labelling and packaging requirements.

3. The Directorate-General for Public Health and Health Equity will verify that the documentation provided complies with the provisions of Paragraphs 1 and 2, and may require the submission of other data to complete this documentation.

4. The communications referred to in Paragraphs 1 and 2 shall be made six months before the date of their placing on the market through the EU-CEG Portal.

Article 52. *Quality and safety requirements.*

1. It shall be prohibited to place on the market, sell, distribute, or offer free of charge, nicotine pouches containing

a) more than 0.99 mg of nicotine per pouch;

b) additives that facilitate nicotine absorption;

c) caffeine, taurine, CBD, or other additives and stimulants associated with energy or relaxation.

d) flavouring ingredients other than those that impart tobacco aromas and/or flavours to the final product.

2. The outside packaging containing the nicotine pouches shall be equipped with a child- and tamper-proof device.

3. Manufacturers of nicotine pouches are required to comply with the hygiene rules laid down in Article 4 of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs for food business operators.

Article 53. *Labelling and packaging requirements*.

1. Unit packets and outside packaging of nicotine pouches shall comply with the following requirements.

a) Include a list of all ingredients contained in the product in descending order, and an indication of the nicotine content of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children;

b) Not include elements or features referred to in Article 19(1), except as provided for in Subparagraphs (a) and (c) thereof concerning information on the nicotine content and on flavourings;

c) Carry the following health warning: “This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers”. This warning shall comply with the requirements specified in Article 18(2).

2. The unit packets and outside packaging of nicotine pouches must include a leaflet, written at least in Spanish, with information on:

a) Instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;

b) Contra-indications;

c) Warnings for specific risk groups;

d) Possible adverse effects.

e) Addictiveness and toxicity;

f) Contact details of the manufacturer or importer and a legal or natural contact person within the Union.

3. Unit packets and outside packaging shall not include elements which, due to their content or design, are likely to attract the attention or particular interest of minors.

CHAPTER II

Heated herbal product

Article 54. *Reporting obligations relating to placing on the market*.

1. Manufacturers or importers intending to place on the market heated herbal products shall, to the Directorate-General for Public Health and Health Equity, through the EU-CEG Portal, and following the format set out in Commission Implementing Decision (EU) 2015/2183 of 24 November 2015, report the following information:

a) Name and contact details of the manufacturer and, where applicable, the importer in the European Union.

b) The description of the composition of the product.

c) The list of all ingredients, including the quantities of those ingredients.

d) A declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

2. In addition, prior to placing on the market, manufacturers and importers of heated herbal products with or without nicotine, shall submit to the Directorate-General for Public Health and Health Equity, the design of the labelling and packaging for each brand and type of product, in order to verify its compliance with the labelling and packaging requirements.

3. The Directorate-General for Public Health and Health Equity will verify that the documentation provided complies with the provisions of Paragraphs 1 and 2, and may require the submission of other data to complete this documentation.

4. The communications referred to in Paragraphs 1 and 2 shall be made six months before the date of their placing on the market through the EU-CEG Portal.

Article 55. *Quality and safety requirements*.

1. It shall be prohibited to place on the market, sell, distribute, or offer free of charge, heated herbal products with or without nicotine, containing

a) where applicable, more than 5 mg of nicotine per unit;

b) additives that facilitate nicotine absorption;

c) caffeine, taurine, CBD, or other additives and stimulants associated with energy or relaxation.

d) flavouring ingredients other than those that impart tobacco aromas and/or flavours to the final product.

2. Heated herbal products with or without nicotine shall be equipped with a child- and tamper-proof device.

Article 56. *Labelling and packaging requirements*.

1. Unit packets and outside packaging of heated herbal products with or without nicotine shall comply with the following requirements:

a) Include a list of all ingredients contained in the product in descending order, and an indication of the nicotine content, in milligrams, of the product and the delivery per dose, if any. The batch number and a recommendation to keep the product out of reach of children;

b) Not include elements or features referred to in Article 19(1), except as provided for in Subparagraphs (a) and (c) thereof concerning information on the nicotine content and on flavourings;

c) For heated herbal products with nicotine, carry the following health warning: “This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers”. This warning shall comply with the requirements specified in Article 18(2).

d) For nicotine-free heated herbal products, carry the following health warning: “This product damages your health”. This warning shall comply with the requirements specified in Article 18(2).

2. Unit packets and outside packaging of heated herbal products with or without nicotine must include a leaflet, written at least in Spanish, with information on:

a) Instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;

b) Contra-indications;

c) Warnings for specific risk groups;

d) Possible adverse effects.

e) Addictiveness and toxicity;

f) Contact details of the manufacturer or importer and a legal or natural contact person within the Union.

3. Unit packets and outside packaging shall not include elements which, due to their content or design, are likely to attract the attention or particular interest of minors.'

Single additional provision. *Competences in the evaluation and classification of new products.*

In order to guarantee the safety and protection of the public health, it is the responsibility of the Ministry of Health to evaluate and classify any other related product that is not included in any of the categories set out in this Royal Decree.

Single transitional provision. *Extension of manufacturing and placing on the market*.

Notwithstanding the single final provision, the following shall be allowed to continue to manufacture or put into free circulation up to 10 months after the entry into force of this Royal Decree:

a) Tobacco products labelled in accordance with the provisions of Royal Decree 579/2017 of 9 June 2017.

b) Electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with and without nicotine, packaged and labelled under the previously applicable regulations.

c) Electronic cigarettes, nicotine-free electronic cigarettes, and refill containers with and without nicotine manufactured in accordance with safety and quality requirements under the previously applicable regulations.

2. The products referred to in the previous paragraph may continue to be marketed up to 12 months after the entry into force of this Royal Decree.

Single final provision. *Entry into force*.

This Royal Decree shall enter into force on the day after its publication in the Spanish Official State Gazette.