



EUROPEAN COMMISSION

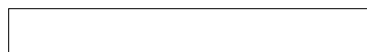
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Subject: **Notification No 2025/0044/ES**

On the draft Royal Decree amending Royal Decree 579/2017 on the manufacture, presentation, and marketing of tobacco and related products.

Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535



On 24 January 2025, within the framework of the notification procedure laid down in Directive (EU) 2015/1535¹, the Spanish authorities notified to the Commission the Draft Royal Decree amending Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and marketing of tobacco and related products (hereinafter ‘the notified draft’).

According to the notification message, the notified draft aims to update the national legislation on tobacco products and related products, with regard to requirements on content, quality and safety, labelling and outside packaging.

The examination of the notified draft has prompted the Commission to issue the following comments.

¹ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification), OJ L 241, 17.9.2015, p. 1.

i) Definitions

• Disposable electronic cigarettes

Section 2 of the notified draft introduces Article 3 subparagraph (aq) to the basic act. This provision defines ‘disposable or single-use electronic cigarette or nicotine-free electronic cigarette’ as ‘a device containing a liquid with or without nicotine, ready for consumption and intended to be discarded after use’.

In addition, Section 2 of the notified draft introduces Article 3 subparagraph (ap) to the basic act, which provides that nicotine-free electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.

The latter provision reflects Article 2(16) of Directive 2014/40/EU according to which *“electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges”*.

Therefore, the definition of disposable electronic cigarettes introduced by the notified draft in Article 3 subparagraph (aq) of the basic text is broader than what is covered by the same term in Directive 2014/40/EU, and the term included in the amended Article 3 subparagraph (ap).

To ensure legal certainty, the Commission invites the Spanish authorities to ensure that the definition of ‘disposable electronic cigarettes’ in the notified draft will not create confusion as to the scope of application of the relevant requirements of Directive 2014/40/EU, applicable to disposable electronic cigarettes within the meaning of its Article 2(16).

• Related products

Section 2 of the notified draft introduces Article 3 subparagraph (an) to the basic act. The provision defines related products as a ‘tobacco-free product[s] 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.’

While Directive 2014/40/EU does not include a definition of ‘related products’, its Article 1(f), which sets out the scope of application of the Directive, refers to ‘related products’ as covering electronic cigarettes and refill containers, and herbal products for smoking.

It follows that the definition of ‘related products’ in the notified draft is broader than what the same term covers under Directive 2024/40/EU. In the notified draft ‘related products’ do not only refer to (nicotine-containing) electronic cigarettes, refill containers and herbal products for smoking, but also to other products, including nicotine-free electronic cigarettes, nicotine-free refill containers, nicotine pouches and other nicotine products.

To ensure legal certainty, the Commission invites the Spanish authorities to ensure that the definition of ‘related products’ in the notified draft will not create confusion as to the

scope of application and the relevant requirements for tobacco and related products under Directive 2014/40/EU.

- **Ingredients hazardous to human health**

Section 2 of the notified draft introduces Article 3 subparagraph (ar) to the basic act, which reads as follows:

‘(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.’

In addition, in accordance with Section 7 of the notified draft, Article 28(e) of the basic act requires that in electronic cigarettes and nicotine-free electronic cigarettes and refill containers, with the exception of nicotine, only ingredients are used that are not hazardous to human health, within the meaning of Article 3(ar) of the basic act.

The Commission reminds the Spanish authorities that regulation of ingredients is a harmonised area under Directive 2014/40/EU. Pursuant to Article 20(3)(e) of the Directive, Member States are to ensure that, except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form.

It is noted that the Directive does not contain a definition of ‘risk to human health’. In this regard, the definition of ‘ingredients hazardous to human health’ in the notified draft cross refers to a close catalogue of substances. While the reference in Directive 2014/40/EU to ‘ingredients that do not pose a risk to human health’ is broad and does not specify any particular substances, it allows some discretion to Member States in their efforts to protect public health when determining prohibited ingredients. Nevertheless, Member States should not limit this category of ingredients to only specific, defined substances meeting certain criteria as laid down in a referred act, i.e. Regulation (EC) No 1272/2008. The Commission invites the Spanish authorities to ensure the correct application of Article 20(3)(e) of Directive 2014/40/EU, namely to ensure that in nicotine containing liquids all ingredients are prohibited which pose a risk to human health, except for nicotine.

- **Nicotine**

Section 2 of the notified draft amends Article 3(v) of the basic act and defines ‘nicotine’ as ‘nicotinic alkaloids and any nicotine derivatives’.

The Commission would like to draw the attention of the Spanish authorities to the fact that the definition of ‘nicotine’ in the notified draft deviates from Article 2(19) of Directive 2014/40/EU, which defines ‘nicotine’ as meaning ‘nicotinic alkaloids’. That definition does not differentiate between tobacco-derived nicotinic alkaloids and synthetic nicotinic alkaloids, which include also nicotine derivatives.

This deviation risks creating a false impression that nicotine derivatives are not considered nicotinic alkaloids and would not be covered by the definition of ‘nicotine’ in Directive 2014/40/EU. The Commission therefore invites the Spanish authorities not to

add “any nicotine derivatives” to the definition of “nicotine”, in order to ensure that the provision of Article 3(v) of the basic act, as amended by the notified draft, is in line with the definition of ‘nicotine’ laid down in Article 2(19) of Directive 2014/40/EU.

ii) The use of EU-CEG

Section 5 of the notified draft amends Article 26 of the basic act 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 [...].’*

The Commission notes that the information that manufacturers and importers need to provide for tobacco products and e-cigarettes and refill containers in the EU-CEG is set out in Commission Implementing Decision (EU) 2015/2186 establishing a format for the submission and making available of information on tobacco products, and in Commission Implementing Decision (EU) 2015/2183 establishing a common format for the notification of electronic cigarettes and refill containers.

Article 1 of Implementing Decision (EU) 2015/2186 establishes the scope of the Decision and provides that the Decision establishes a common format for the reporting and making available of information on ingredients and emissions of tobacco products and on sales volumes. Similarly, Article 1 of Implementing Decision (EU) 2015/2183 provides that this Decision establishes a common format for the notification of information on electronic cigarettes and refill containers. The tools for submission of information on ingredients and emissions could also facilitate the submission of information on herbal products for smoking pursuant to Article 22 of Directive 2014/40/EU ⁽²⁾.

The Commission stresses that nicotine-free electronic cigarettes, nicotine-free refill containers, heated herbal products and nicotine pouches do not fall within the scope of the above Implementing Decisions. Should the Spanish authorities wish to use EU-CEG for the storage of information concerning these products, they should take due regard of the following elements:

- (i) all information encoded in the EU-CEG system is visible to the Commission;
- (ii) the Commission cannot be held liable for access, loss or damage of that information;
- (iii) the Spanish authorities must ensure that the reporting of information related to these products, does not impact on and/or interfere (i.e. does not create confusion) with the reporting of information for the products required by Directive 2014/40/EU and the above Implementing Decisions.

² (2) See recital 5 of Commission Implementing Decision (EU) 2015/2186.

Hence, the Commission would like to invite the Spanish authorities to explain how the relevant provision in Section 5 of the notified draft, will be implemented in practice so that it is ensured that the reporting of information related to products which do not fall within the scope of Implementing Decisions (EU) 2015/2186 and (EU) 2015/2183, does not impact on and/or interfere (i.e. does not create confusion) with the reporting of information for the products that is required by Directive 2014/40/EU and those decisions.

iii) Labelling of electronic cigarettes

Section 9 of the notified draft amends Article 30(d) of the basic act and requires nicotine-free electronic cigarettes to carry the following health warning: ‘Consuming this product damages your health’. The provision also requires that this warning shall comply with the requirements specified in Article 18(2) of the basic act.

It is noted that the definition of ‘nicotine-free electronic cigarette’ in Article 3 (ap) of the basic act (as amended by Section 2 of the notified draft) refers to ‘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’.

The Commission notes that such products that can be used for the consumption of nicotine-free vapour can also be used for the consumption of nicotine-containing vapour, and as such, should comply with the requirement to carry a health warning as set in Article 20(4)(b)(iii) of Directive 2014/40/EU.

The Commission invites the Spanish authorities to ensure that the definition of ‘nicotine-free electronic cigarettes’ in the notified draft will not interfere with the requirements applicable to electronic cigarettes under Directive 2014/40/EU as defined in Article 1(16) of that Directive. In particular, the Commission invites the Spanish authorities to ensure that implementation of the notified draft will not allow to circumvent compliance with Article 20(4)(b)(iii) of Directive 2014/40/EU as regards the requirement that unit packets and any outside packaging of electronic cigarettes, as defined in Article 1(16) of Directive 2014/40/EU, must carry a health warning on nicotine content.

The Spanish authorities are invited to take these comments into account.



For the Commission

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