EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Notification Number : 2025/0044/ES (Spain)

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

Date received : 24/01/2025
End of Standstill : 28/04/2025 (28/07/2025)

Message

Message 001

Communication from the Commission - TRIS/(2025) 0221

Directive (EU) 2015/1535

Notification: 2025/0044/ES

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta’ dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20250221.EN

1. MSG 001 IND 2025 0044 ES EN 24-01-2025 ES NOTIF

2. Spain

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4. 2025/0044/ES - X60M - Tobacco

5. 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

6. Tobacco and related products
Electronic cigarettes and nicotine refill containers
Electronic cigarettes and nicotine-free refill containers
Nicotine pouches
Heated herbal products

7.

8. The draft Royal Decree involves updating the health regulations on tobacco products and related aspects, such as their content, quality and safety requirements, or their packaging and outside packaging. This standard regulates not only the products already included in the scope of Directive 2014/40/EU, but also extends its scope to other products not regulated therein, i.e., nicotine-free electronic cigarettes, nicotine pouches, and heated herbal products, establishing a series of health-related requirements and obligations necessary for their proper control and supervision.

The draft Royal Decree includes a single article with 16 paragraphs for the adoption of the different changes proposed. In addition, the rule includes an additional provision, a transitional provision, and a final provision. Thus, the following is worth highlighting:

- 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.
- Paragraphs 4 to 15 regulate nicotine-free electronic cigarettes. They regulate reporting obligations in relation to these products, testing, as well as control and verification requirements.
- Paragraph 7 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.

9. The standard is a response to recent developments in the market of tobacco and related products, with a wide and diverse variety of products with differentiated characteristics emerging in Spain, 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. These products are in many cases not covered by any health regulations, whether local, national, or European, and it is, therefore, necessary to offer an urgent response to them.

This standard is the development of one of the main measures set out in the recently approved 2024-2027 Comprehensive Plan for the Prevention and Control of Tobacco. The Plan, agreed upon with different social, governmental, and scientific sectors, has identified the need to introduce various improvements not yet contemplated in the harmonised regulation of the Union, as a result of 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.

10. References to basic texts:

11. No

12.

13. No

14. No

15. Yes

16.
TBT aspects:
The draft is a technical regulation or a conformity assessment

SPS aspects: No

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