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

Message 007

Communication from the Commission - TRIS/(2025) 0561

Directive (EU) 2015/1535

Notification: 2025/0044/ES

Communication by Member State (Spain) containing general information regarding the above-mentioned notification.

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MSG: 20250561.EN

1. MSG 007 IND 2025 0044 ES EN 28-04-2025 26-02-2025 ES COMMUNICAT 28-04-2025

2. Spain

3A. Subidrección de Asuntos Industriales, Energéticos, de Transportes, Comunicaciones y de Medioambiente
DG de Mercado Interior y Otras Políticas Comunitarias
Ministerio de Asuntos Exteriores, UE y Cooperación
D83-189@maec.es

3B. Ministerio de Sanidad

4. 2025/0044/ES - X60M - Tobacco

5.

6. Please find enclosed the 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 marketing of tobacco and related products, which was sent to the European Commission on 24 January 2025 as part of the information procedure on technical regulations (Directive 2015/1535/EU).

The aforementioned change concerns Article 28 “Quality and safety requirements”.

In that article, the maximum concentration of nicotine noted under point (b) has been changed from 15 mg/ml to 20 mg/ml.

The wording would read as follows:

"Article 28. Quality and Safety Requirements.

Electronic cigarettes as well as electronic cigarettes without nicotine and refill containers with or without nicotine must meet the following requirements:
.....
b) That, in the case of electronic cigarettes, the nicotine-containing liquid does not contain more than 20 mg/ml of nicotine’

Justification for the change: the concentration referred to in Royal Decree 579/2017 of 9 June 2017 (maximum 20 mg/ml nicotine) is restored, in line with the maximum concentration set out in Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, in Article 20(3)(b)

“Article 20. Electronic cigarettes.

3. Member States shall ensure that:
.....

b) the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml.”

It should also be noted that the regulations of the other European Union countries set the maximum nicotine content at 20 mg/ml.

It is therefore the intention of Spain to maintain the maximum concentration of nicotine in electronic cigarettes at 20 mg/ml, aligning our regulations on the issue with both the current provisions of the Directive and with the current provisions for the development of the Directive by the other countries of the European Union.

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European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu