



EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP
AND SMES

The Director-General

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Subject: Notification 2025/9001/NO

**Draft Regulations on standardised electronic cigarettes and refill
containers**

**Delivery of comments pursuant to Article 5(2) of Directive (EU)
2015/1535 of 9 September 2015**

Sir,

On 23 January 2025, within the framework of the notification procedure laid down in Directive (EU) 2015/1535¹, the Norwegian authorities notified to the Commission the ***Draft Regulations on standardised electronic cigarettes and refill containers*** (hereinafter ‘the notified draft’).

According to the notification message, the notified draft aims to establish a uniform and harmonised approach to the design and labelling of e-cigarettes and refill containers, both with and without nicotine. The notified draft proposes common design standards for the packaging of e-cigarettes and refill containers, including rules on colour, gloss, surface, material, and design. More specifically, the notified draft proposes banning the design of electronic cigarettes that may appeal to children, such as toy-like figures, as well as packaging that emits sound, light, odour, or taste and changes its appearance after sale. The notified draft also regulates the shape, surface, design, and colour of refill containers to ensure consistency and safety. Furthermore, the colour of e-cigarettes liquid is also regulated, with a ban on colour additives and other elements that alter the liquid's colour or character. Finally, the notified draft prohibits the inclusion of inserts or additional elements in individual packages or external packaging, except for the mandatory user manual.

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.

1. COMMENTS

First of all, the Commission would like to bring to the attention of the Norwegian authorities that the process of incorporating Directive 2014/40/EU into the European Economic Area (EEA) Agreement by way of the Decision No 6/2022 of the EEA Joint Committee² is pending. This incorporation would require Norway to align its legislation with the standards and rules on the manufacturing, presentation and sale of tobacco and related products as they are laid down in that Directive.

In particular, the regulation of labelling and information provision on tobacco and related products is a harmonised area under Directive 2014/40/EU. The Commission would therefore like to remind the Norwegian authorities that – as soon as Directive 2014/40/EU is incorporated in the EEA Agreement – they must ensure the correct alignment of their national legislation with Directive 2014/40/EU.

The notified draft standardises the design and labelling of e-cigarettes and refill containers, regulating their colour, material, surface, and packaging to ensure uniformity. It also bans child-appealing designs, sensory-emitting packaging, and colour additives in e-cigarette liquids. In particular, the Commission notes that Section 11 of the notified draft lays down a prohibition to include inserts or additional elements in an individual package or external packaging, beyond the user manual that must be included with electronic cigarettes and refill containers.

The Commission recalls that Article 20(4) of Directive 2014/40/EU provides the following:

‘4. Member States shall ensure that:

(a) unit packets of electronic cigarettes and refill containers include a leaflet with information on:

(i) 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;

(ii) contra-indications;

(iii) warnings for specific risk groups;

(iv) possible adverse effects;

(v) addictiveness and toxicity; and

(vi) contact details of the manufacturer or importer and a legal or natural contact person within the Union;

(b) unit packets and any outside packaging of electronic cigarettes and refill containers:

(i) include a list of all ingredients contained in the product in descending order of the weight, 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;

² Decision of the EEA Joint Committee No 6/2022 of 4 February 2022 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2022/1054]; entry into force of the Decision is pending fulfilment of constitutional requirements by Iceland, Liechtenstein and/or Norway pursuant to Article 103 of the EEA Agreement.

(ii) without prejudice to point (i) of this point, do not include elements or features referred to in Article 13, with the exception of Article 13(1)(a) and (c) concerning information on the nicotine content and on flavourings; and

(iii) carry one of the following health warnings:

‘This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers’.

Or ‘This product contains nicotine which is a highly addictive substance.’

Member States shall determine which of these health warnings is to be used;

(c) health warnings comply with the requirements specified in Article 12(2).’

The Commission therefore invites the Norwegian authorities to ensure that the requirements in the notified draft regarding electronic cigarettes and refill containers comply with these requirements.

Based on the above provisions, the Commission considers, in particular, that it is unclear whether Section 11 of the notified draft complies with Article 20(4)(a) of Directive 2014/40/EU requiring that specific information be available in the leaflet.

The Commission invites the Norwegian authorities to take into account the above comments.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

Yours faithfully

For the Commission

Kerstin Jorna
Director-General

Directorate-General for Internal
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