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Minister for Foreign Affairs Elina
Valtonen

Ministry for Foreign Affairs
P.O.Box 176, FI-00023 Government,
Finland

Subject: Notification No 2024/0321/FI

**Draft Decree of the Ministry of Social Affairs and Health amending the
Decree of the Ministry of Social Affairs and Health on standards and
notifications concerning tobacco and related products**

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

Dear Madam,

Within the framework of the notification procedure laid down in Directive (EU) 2015/1535¹, the Finnish authorities notified to the Commission on 14 June 2024 the draft **Decree of the Ministry of Social Affairs and Health amending the Decree of the Ministry of Social Affairs and Health on standards and notifications concerning tobacco and related products** (hereinafter ‘the notified draft’).

According to the notification message, the notified draft amends the national legislation² in order to include notifications of sales volumes for smokeless nicotine products in the notifications of studies and sales volumes. It also introduces a new provision, laying down the format for the notification of smokeless nicotine products.

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

On the use of the EU Common Entry Gate

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.

² Decree of the Ministry of Social Affairs and Health on standards and notifications concerning tobacco and related products (592/2016).

Section 6b ‘Format of notification concerning smokeless nicotine products’ of the notified draft provides that for the purposes of the notification of smokeless nicotine products the format for the notification of smokeless tobacco products set out in Commission Implementing Decision (EU) 2015/2186 establishing a format for the submission and making available of information on tobacco products shall be used.

In the notification message, the Finnish authorities explain that given the close similarity between smokeless nicotine products and smokeless tobacco products, smokeless nicotine products should be notified as smokeless tobacco products in the EU-CEG. In accordance with the notification message, the national competent authority may issue further guidance on the notification of smokeless nicotine products.

The Commission notes that the information that manufacturers and importers need to provide for tobacco products and e-cigarettes in the EU-CEG is set out in the Commission Implementing Decision (EU) 2015/2186 establishing a format for the submission and making available of information on tobacco products, and in the 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 set up in Implementing Decision (EU) 2015/2186 could also facilitate the submission of information on herbal products for smoking pursuant to Article 22 of Directive 2014/40/EU ⁽³⁾.

The Commission stresses that smokeless nicotine products do not fall within the scope of the above decisions. Should the Finnish authorities wish to use EU-CEG for the storage of information relevant to these products, (i) they should be aware that all information encoded in the EU-CEG system is visible to the Commission; (ii) such storage occurs at Finland’s own risk; and (iii) the Finnish authorities should ensure that the reporting of information related to products which do not fall within the scope of the two Implementing Decisions, does not impact on and/or interfere (i.e. does not create confusion) with the reporting of information for the products envisaged therein.

In this regard, the Commission is not in the position to provide any specific support for such reporting. Hence, the Commission would like to invite the Finnish authorities to explain what kind of guidance they would provide to operators in order to ensure that the reporting of information related to products which do not fall within the scope of the two Implementing Decisions, does not impact on and/or interfere (i.e. does not create confusion) with the reporting of information for the products envisaged therein.

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

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.

³ (3) 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, OJ L 127, 29.4.2014, p. 1.

Yours faithfully,

For the Commission

Sandra GALLINA
Directorate-General for Health and
Food Safety