



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2024/0321/FI (Finland)

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

Date received : 14/06/2024

End of Standstill : 17/09/2024

Message

Message 001

Communication from the Commission - TRIS/(2024) 1558

Directive (EU) 2015/1535

Notification: 2024/0321/FI

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – 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 - Καμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéset - Non fa decorrere la mora - Atidējimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ 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: 20241558.EN

1. MSG 001 IND 2024 0321 FI EN 14-06-2024 FI NOTIF

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4. 2024/0321/FI - X00M - GOODS AND MISCELLANEOUS PRODUCTS

5. 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

6. Tobacco products, electronic cigarettes, refill containers, nicotine-containing liquids, liquids other than nicotine-containing liquids for use in electronic cigarettes

7.

8. The Tobacco Act (549/2016) has been amended by Act xx/2024, which enters into force on [day] [month] 202x. A definition of smokeless nicotine products which covers nicotine pouches and products closely resembling these was added to the Act. Nicotine pouches also meet the definition of tobacco substitutes.

Under Section 29a of the Tobacco Act, the manufacturer or importer of a smokeless nicotine product must inform the National Supervisory Authority for Welfare and Health (Valvira) in advance of products which it intends to start selling or otherwise making available to consumers. Similarly, any significant changes to products must also be notified before the product is offered for sale or otherwise made available to consumers. The notification shall include:

- 1) the name and contact details of the manufacturer, the legal or natural person responsible for the product in the EU, and the importer of the product into the EU;
- 2) a list of all the ingredients contained in the product sorted by brand and type, and the quantities of ingredients;
- 3) toxicological data on the ingredients and emissions of the product, considering in particular their addictive effect;
- 4) information on the dosage and absorption of nicotine when the product is used under normal or reasonably foreseeable conditions;
- 5) information stating that the manufacturer or importer bears full responsibility for the quality and safety of the product when it is placed on the market and when it is used under normal or reasonably foreseeable conditions.

Under Section 29b of the Tobacco Act, manufacturers or importers of smokeless nicotine products must provide the National Supervisory Authority for Welfare and Health (Valvira) annually with information on the sales volumes of smokeless nicotine products by brand and type of product.

According to section 30, subsection 3 of the Tobacco Act, further provisions may be laid down by decree of the Ministry of Social Affairs and Health on the manner and format for the submission of the information referred to in sections 26, 27, 29a and 29b and on the date of the submission of the information referred to in section 27; section 28, subsection 1; and section 29b.

It is proposed to amend the Decree of the Ministry of Social Affairs and Health on standards and notifications concerning tobacco and related products (592/2016) so that section 4 on the date of notification of studies and sales volumes would include notifications of sales volumes for smokeless nicotine products. It is also proposed to add a new section 6b, which would lay down the format for the notification of smokeless nicotine products.

9. It is proposed to add a new section 6b, which would lay down the format for the notification of nicotine products.

Smokeless nicotine products largely correspond to smokeless tobacco products in terms of their characteristics, but they do not contain tobacco plant. Smokeless tobacco products may not be sold or otherwise supplied or brokered in Finland. However, smokeless tobacco products are within the scope of the Tobacco Products Directive and the format for the notification of their ingredients and sales volumes is laid down in Commission Implementing Decision (EU) 2015/2186 establishing a format for the submission and making available of information on tobacco products.



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In practice, the notifications laid down in the Tobacco Products Directive are made through the EU notification portal, the EU Common Entry Gate (EU-CEG). The notification portal is also used to report products not covered by the Tobacco Products Directive. The EU-CEG does not have a category of smokeless nicotine products, but the category of smokeless tobacco products is never used in Finland due to the national sales ban. Given the close similarity between smokeless nicotine products and smokeless tobacco products, it is logical that smokeless nicotine products should be notified as smokeless tobacco products through the EU-CEG portal. The products are easy to identify on the notification portal, as no further notifications will be made for Finland in this category due to the sales ban. The Czech Republic has also laid down that notifications concerning nicotine pouches are to be made on the EU-CEG portal as smokeless tobacco products under the sub-category tobacco products for oral use.

For the above reasons, it is proposed that the format for the notification of smokeless tobacco products, as provided for in Commission Implementing Decision (EU) 2015/2186 establishing a format for the submission and making available of information on tobacco products, should be used for the notification of smokeless nicotine products. On the basis of section 6 of the Tobacco Act, the National Supervisory Authority for Welfare and Health (Valvira) may issue further guidance on the notification of smokeless nicotine products.

10. Basic text references: The basic texts have been provided in connection with an earlier notification:
2024/0210/FI

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

European Commission

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