



EUROPEAN COMMISSION

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

Message 201

Communication from the Commission - TRIS/(2024) 3160

Directive (EU) 2015/1535

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Forwarding of the response of the Member State notifying a draft (Finland) to comments (5.2) of European Commission.

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

5.

6. In response to your comments (C(2024) 6484 final), we respectfully state the following:

The draft Decree of the Ministry of Social Affairs and Health proposes that smokeless nicotine products be declared as smokeless tobacco products in the EU-CEG system. In addition to tobacco intended for oral use, chewing tobacco and nasal snuff are also prohibited in Finland. For this reason, Finland does not, as a rule, receive notifications in the EU-CEG system for smokeless tobacco products. The National Supervisory Authority for Welfare and Health (hereinafter Valvira) checked the current status of the notifications for smokeless tobacco products in the EU-CEG system on 14 November 2024. So far, 20 product notifications have been submitted to Finland in this category. All product notifications concern nicotine pouches (footnote 1).

Finland has carefully weighed the different options for reporting smokeless nicotine products to the EU-CEG system. The following factors, among others, speak in favour of the option chosen:

- o Smokeless nicotine products have the same characteristics as smokeless tobacco products, which is why the most suitable data fields for the product in the EU-CEG system are in the category of smokeless tobacco products (e.g. data fields such as nicotine content, humidity, and pH). Data fields suitable for the product ensure the availability of structured information and facilitate giving instructions on how to submit a notification.
- o Tobacco for oral use, chewing tobacco, and nasal snuff are prohibited in Finland. For this reason, Finland has not been



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notified of smokeless tobacco products, and, as a rule, should not be in the future either.

o In any case, EU-CEG notifications for smokeless nicotine products can be distinguished from possible notifications for smokeless tobacco products by, inter alia, instructing that the quantity of tobacco be marked as 0 in the notification for smokeless nicotine products (data field Tobacco_Quantity). This approach is in line with the practice of EU-CEG notifications for nicotine-free liquids, where the Commission considers that the notifications can be distinguished from nicotine liquids by entering the nicotine content as 0.

Valvira is currently preparing guidance for operators who will submit notifications for smokeless nicotine products to the EU-CEG system. The guidance would advise operators on how to fill in the notification, particularly concerning data fields that are not specifically applicable to smokeless nicotine products. Such data fields are generally those which provide information on the tobacco contained in the product and its characteristics. In practice, operators would be instructed to select the 'other' option for these data fields and to specify in the description that the product is a nicotine pouch, for example. In addition, the guidance would advise operators to enter the amount of tobacco as 0, which would be the clearest indication that the product is a smokeless nicotine product. Valvira intends to have the instructions translated into English as well. The guideline will be published on Valvira's website once it has been completed, but it can be sent to the Commission for information if necessary. Valvira also advises the notifying parties with regard to individual notifications submitted to the EU-CEG system, for example in situations where the notification has been made incorrectly. This will ensure maximum accuracy of the EU-CEG data.

For the above reasons, Finland is of the opinion that the notification of smokeless nicotine products to the EU-CEG in the category of smokeless tobacco products will not affect, interfere with, or be confused with product notifications of products within the scope of the Tobacco Products Directive. However, it is good that the Commission is aware of the approach chosen by Finland so that it can take this into account in its own activities if necessary.

Finland is aware that the information provided on smokeless nicotine products would also be available to the Commission and that the storage of the information would be Finland's responsibility.

For the reasons explained above, Finland considers that the notification of smokeless nicotine products in the category 'smokeless tobacco products' in the EU-CEG system would be justified and logical, and that the approach would not affect other information in the system.

(1) Valvira stated on 14 November 2024 that it intends to instruct notifying parties to delete their product notifications from the EU-CEG system, as notifications for smokeless nicotine products should not be made until the relevant legislation is in force.

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