

Guideline

Record No. V/32882/2025

Published 4 August 2025

Product notifications of smokeless nicotine products (including nicotine pouches)

Guideline for submitting a product notification to the EU-CEG portal



Valvira

National Supervisory Authority
for Welfare and Health

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Introduction

The National Supervisory Authority for Welfare and Health (Valvira) is a market surveillance authority that monitors compliance with the provisions concerning the ingredients, emissions and properties of certain products subject to the Tobacco Act, as well as compliance with the provisions concerning the unit packets of such products.

With the Tobacco Act amendment that entered into force on 1 August 2025, a new definition of a smokeless nicotine product has been added to the Tobacco Act. The Tobacco Act lays down various restrictions on smokeless nicotine products and their properties.

A smokeless nicotine product refers to a tobacco substitute that corresponds to the intended use of chewing tobacco, nasal tobacco or tobacco for oral use and contains nicotine. For example, nicotine pouches and closely related products are smokeless nicotine products.

Product notifications to be submitted to Valvira in accordance with the Tobacco Act are made in the EU Common Entry Gate (hereinafter EU-CEG) maintained by the Commission. The EU-CEG portal is not designed for the reporting of smokeless nicotine products but can also be used for this purpose. However, this requires Valvira's guidance to economic operators in submitting product notifications.

This guideline is intended for manufacturers and importers of smokeless nicotine products, who will from now on be obliged to notify Valvira in advance of the smokeless nicotine product that they intend to start selling or otherwise supplying to consumers. The guideline advises on how to prepare product notifications of smokeless nicotine products and what information the product notification should contain. For products available for sale when the amended Tobacco Act enters into force, product notifications must be submitted within six months of the entry into force of the act, i.e. no later than 31 January 2026.

Finally, it should be noted that the manufacturers and importers are primarily responsible for ensuring that a product intended for commercial sale or other supply complies with the applicable provisions and regulations.

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1 Submitting a notification of smokeless nicotine products to Valvira

1.1 Regulatory background

Manufacturers and importers submit the information in accordance with the Tobacco Products Directive (2014/40/EU) and the national Tobacco Act (549/2016) to the Member States on the EU-CEG portal, as provided for in the Ministry of Social Affairs and Health Decree (592/2016). Common formats for the submission of information on tobacco products, electronic cigarettes and refill containers have been established by Commission Implementing Decisions (EU) 2015/2186 (tobacco products) and (EU) 2015/2183 (electronic cigarettes and refill containers). The EU-CEG portal must be used to submit information on these product groups. The same applies to nicotine-free liquids intended for vaporization, as well as novel tobacco products. Product notifications of herbal products intended for smoking are also submitted through the EU-CEG portal.

Unlike other products controlled by Valvira and subject to notification to it under the Tobacco Act, smokeless nicotine products are a category of products excluded from the EU Tobacco Products Directive (2014/40/EU). However, national legislation obliges manufacturers and importers of smokeless nicotine products to submit product notifications to Valvira in accordance with the Tobacco Act through the EU-CEG portal.

Thus, the notification system is also used to submit notifications for a product group that is excluded from the Tobacco Products Directive. In practice, however, this results in the fact that the EU-CEG portal does not have a separate category of smokeless nicotine products for submitting a product notification. Since smokeless nicotine products and smokeless tobacco products have largely similar characteristics, smokeless nicotine products are reported to the EU-CEG portal as smokeless tobacco products.

Accordingly, the template used for submitting a notification of smokeless tobacco products, provided for in Commission Implementing Decision (EU) 2015/2186 establishing a template for the submission and making available of information on tobacco products, is used for the notification of smokeless nicotine products.

Due to the regulatory context, not all data fields on the EU-CEG portal are suitable for the product notification of smokeless nicotine products. For this reason, Valvira provides more detailed instructions on the submission of the notification

of smokeless nicotine products. The purpose of the instructions is to clarify the special features related to the notification of smokeless nicotine products.

1.2 General information about the submission of a product notification

The manufacturer or importer of a smokeless nicotine product must notify Valvira in advance of the product it intends to start selling or otherwise supplying to consumers. The manufacturer or importer must also annually provide Valvira with information on the sales volumes of smokeless nicotine products by brand and type.

However, it should be noted that the amendment to the Tobacco Act which gives rise to the obligation to submit a notification of smokeless nicotine products includes several transitional provisions. For example, the requirements for smokeless nicotine products, such as nicotine content (16.6 milligrams per gram), flavour bans (other than mint or menthol) and nicotine warning labels required for packaging will enter into force six months after the entry into force of the Act, i.e. on 1 February 2026. Thus, an operator who, at the time of the entry into force of the Act, sells in Finland smokeless nicotine products containing flavours that will become prohibited, for example, may sell such products until 31 January 2026.

With regard to the product notification obligation, it should be noted that for smokeless nicotine products that are sold or otherwise supplied to consumers in Finland at the time of entry into force of the Act, i.e. on 1 August 2025, a product notification must be submitted within six months of that date. Therefore, the product notification must be submitted to Valvira no later than 31 January 2026. Smokeless nicotine products that do not meet the requirements of the Tobacco Act that enters into force on 1 August 2025 and will thus exit the market by the end of the transition period (31 January 2026) are not subject to the requirement to submit a product notification.

Information on sales volumes must be submitted to Valvira for the first time by 20 May 2026.

In addition, it should be noted that the product notification obligation is not a licensing procedure. This means that the legality of the product and the related notification is checked and assessed only after the product notification has been submitted, in connection with a review. Therefore, Valvira does not give prior approval for the compliance of products by e-mail, for example.

For more information on registering for the EU-CEG portal and using the system, please see the [European Commission's EU-CEG website](#).

The CIRCABC website provides a general guideline prepared by the European Commission on how to submit a product notification for tobacco products. The guideline is called [TPD submission data dictionary tobacco products](#). Make sure you use the latest version of the general guideline.

1.3 Nicotine contained in products

According to Section 2, subsection 1 (28) of the Tobacco Act, nicotine means nicotine alkaloid. Nicotine may be synthetic or natural and may have been added to the product in the form of powder, particles, paste, or a combination thereof, for example. According to Valvira's policy, 6-methylnicotine is classified as nicotine alkaloid, and therefore it is subject to the same requirements as nicotine.

1.4 Product name and characterising flavour or aroma

According to Section 2, subsection 1 of the Tobacco Act, characterising flavour or aroma means a smell or taste other than one of tobacco, resulting from an additive or a combination of additives, which is clearly noticeable in a tobacco product, nicotine-containing liquid or nicotine-free liquid intended for vaporization, before or during its consumption.

The starting point is that a smokeless nicotine product may only taste like an unflavoured tobacco product, for example, conventional snus, in other words, tobacco. In addition, however, a smokeless nicotine product may taste like menthol or mint (Section 25a, subsection 1 (2) of the Tobacco Act). This constitutes an exception to the general prohibition of characterising aromas or flavours. It should be noted that flavour combinations (e.g. menthol-mint or menthol-tobacco) cannot be reported as a characterising flavour or aroma. The permitted flavours or aromas are therefore only the characterising flavours or aromas in accordance with the aforementioned section of the Act.

In addition, only one characterising flavour or aroma per product or retail package is allowed in smokeless nicotine products. **Therefore, only one characterising flavour or aroma may be indicated in connection with the product name.** This is also related to the regulation of unit packets of smokeless nicotine products (see Chapter 3 for more details). The unit packet of a smokeless nicotine product may, for example, display the product name and product group (i.e. nicotine pouch), as well as the flavour in a manner that the labelling of the unit

packet does not stand out from other unit packets of smokeless nicotine products and the labelling does not promote the product (Section 39a, sub section 3 of the Tobacco Act, which will enter into force on 1 August 2026).

No additional attachments, e.g. "frozen menthol" may be displayed in connection with the characterising flavour or aroma of a smokeless nicotine product. Additional characterisations (e.g. ice, max, slim, light) in connection with the indication of a characterising flavour or aroma can be interpreted as presenting the characterising aroma or flavour in an advertising manner, which is problematic from the point of view of the marketing ban provided in the Tobacco Act (Section 68 of the Tobacco Act) and the regulation concerning unit packets (Sections 39a – b).

1.5 Prohibited additives and properties of smokeless nicotine products

According to Section 25a, subsection 3 of the Tobacco Act, the provisions of Section 11, subsection 1 items (2), (3), (5), (7) and (9) of the Act concerning tobacco products also apply to smokeless nicotine products. The regulation will enter into force six months after the entry into force of the Act, that is, on 1 February 2026.

Therefore, the following may not be sold or otherwise supplied to the consumer:

- smokeless nicotine products containing additives that are liable to create the impression that the product has a health benefit or presents reduced health risks compared to other tobacco products;
- a smokeless nicotine product containing stimulant compounds or other additives that are liable to create an impression of energy and vitality (for example, a smokeless nicotine product containing vitamins, caffeine or taurine)
- tobacco products containing additives that have CMR properties in unburnt form;
- a smokeless nicotine product with flavourings in any part so that the aroma, flavour or smoke intensity of the product can be altered (for example, nicotine pouches containing a flavour capsule that the consumer themselves can pop may not be sold); or

- a smokeless nicotine product containing additives in quantities that increase the toxic or addictive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measurable degree.

1.6 CLP classification and labelling of smokeless nicotine products

In addition to the Tobacco Act, the chemicals legislation applies to smokeless nicotine products. Smokeless nicotine products fall within the scope of the CLP Regulation (Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of chemicals) and the REACH regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals). Thus, the unit packets of smokeless nicotine products must bear CLP-compliant labels based on the classification of the mixture, indicating the dangerousness of the product.

In addition, when submitting a product notification, the EU-CEG portal requires information on the possible CLP classification of the product's ingredients in accordance with the CLP Regulation. In addition, information is required on whether the ingredient has a registration number in accordance with REACH regulation.

It should be noted that the Finnish Safety and Chemicals Agency (Tukes) acts as the supervisory authority in accordance with the REACH and CLP regulations and maintains a chemical information service and monitors compliance with the CLP regulation. Tukes also provides more detailed advice and guidance regarding the requirements of the CLP regulation.

1.7 Payments

Valvira charges 150 euros per product notification for smokeless nicotine product notifications submitted under the Tobacco Act.

In addition, Valvira charges EUR 75 per sales volume report on the sales volume reports of smokeless nicotine products submitted annually under the Tobacco Act. The manufacturer or importer of a smokeless nicotine product must submit to Valvira by 20 May each year information on the sales volumes of smokeless nicotine products by brand and type.

In addition to the sales volume notification fee, Valvira charges an annual supervision fee to cover the costs arising from the supervision of the Tobacco Act. The supervision fee is determined as follows, based on the sales volumes manufacturers or importers have reported to Valvira during the previous year:

- Smokeless nicotine products sold in dose units: EUR 0.001 per item;
- other smokeless nicotine products: EUR 1.7 per kg.

The supervision fee shall be a minimum of EUR 300 and a maximum of EUR 70,000 per manufacturer or importer. The submitter of the notification must indicate the total sales volume for the previous calendar year in the product notification. The sales volume must be provided even if there are no sales at all (mandatory reporting of "zero sales").

Under Section 100 of the Tobacco Act, Valvira may prohibit the sale and other supply of a smokeless nicotine product if the manufacturer or importer has failed to pay the product notification or annual sales volume notification fees.

1.8 Change notifications

The manufacturer or importer of a smokeless nicotine product must notify Valvira of any significant change to the product, such as any change affecting the user's body. In practice, it is a change where, for example, the composition of the product is changed so that the change affects the product's ingredient information.

2 Detailed product notification information for a smokeless nicotine product

2.1 Information to be reported on the EU-CEG portal

In this guideline, Valvira covers in detail the information that the manufacturer or importer must provide pursuant to Section 29a of the Tobacco Act when submitting a product notification for a smokeless nicotine product. The guideline has been drawn up especially for smokeless nicotine products that are on the market at the time of preparing the guideline, in other words, in practice for nicotine pouches. Thus, the guideline does not necessarily cover the guidance needs of all product notifications for smokeless nicotine products.

The most important practical guide for the party submitting a smokeless nicotine product notification is the European Commission's guide TPD Submission Data Dictionary Tobacco Products (hereinafter the "Data Dictionary"). Valvira's guideline has been prepared using the following version of the Data Dictionary, downloaded from CIRCABC: TPD_submission_data_dictionary_tobacco products v. 1.2.2 (published 1 August 2024). Valvira is not responsible if this guide is not up-to-date with the functionality of the notification portal.

The Data Dictionary has been prepared as a general guideline for product notifications for all EU Member States. However, when using it, the requirements of the national legislation of each Member State must also be taken into account. In addition, it should be taken into account that smokeless nicotine products are a product group not included in the EU's Tobacco Products Directive, in which case the Data Dictionary may not be suitable as such for all information required in the product notification. However, as stated above, it serves as a general practical guideline.

The language of use of the EU-CEG Portal is English, and the Data Dictionary has been published in English only. For this reason, the instructions concerning the sections to be filled in in the product notifications have also been provided in English in this guideline, to correspond with the functionality of the portal.

The product notification for smokeless nicotine products is prepared on the EU-CEG portal using the product notification template for tobacco products. Further down in this guideline, we will go through the Data Dictionary data fields ("field") with their respective identification numbers ("item #"), which must be completed for smokeless nicotine products. Valvira has defined a mandatory response option or response clause for some data fields in advance. The instructions also indicate which of the data fields are optional. Valvira strongly recommends that the optional data fields are also completed, if information on them is available. In addition, it should be noted that the data fields presented in the Data Dictionary may include individual "Priority" and "Values" fields, where new data fields to be filled in or additional instructions for fulfilling the data field requirement can be provided. It is the responsibility of the submitter of the notification to take these into account when submitting the product notification.

There are no separate product types in the Data Dictionary (data field #29) for smokeless nicotine products. A Data Dictionary product type 7–9 that best corresponds to the intended use of the product in question (oral tobacco, nasal tobacco or chewing tobacco) is selected as the product type. The product type of nicotine pouches is oral tobacco (product group 7).

Below is an example for filling in the data fields of the product notification, provided in the guideline, in accordance with the Data Dictionary. Table 1 displays the descriptions of the Data Dictionary table structure.

Table 1. *Data Dictionary table structure descriptions.*

Item #	Field	Description	Data Type	Cardinality	Priority	Values
1	Submitter_ID	Submitter ID is the identification number attributed pursuant to Article 4.	Submitter ID	Simple	M	
2	Submitter_SME	Indication whether the submitter, or its parent company if it exists, is an SME as defined in Commission Recommendation 2003/361/EC ¹ .	Boolean	Simple	M	

"Item #" = Unique identification number of the data field

"Field" = Name of the data field

"Description" = Detailed description of the data field

"Data type" = Data type

"Cardinality" = Cardinality

"Priority" = The priority of completing the data field. The data field entry is mandatory (M), or optional (O), or the system fills in the data field automatically (A).

"Values" =The priority of the data field for separately mentioned product groups, additional information on the topic, values to be selected from the specified options.

Figure 1 shows an example of the data fields to be completed in the product notification, which are presented in section 2.1.2 of this guideline.



Figure 1. *Example of data fields to be completed, required in this guideline, for adding parent company information to a product notification.*

Data field #6 in Figure 1 (Submitter Has Parent Company) asks the submitter if the submitter has a parent company. If the company does not have a parent company, "False" is selected, and the next data field to be completed is #7 (presented in section 2.1.2).

If the company has a parent company, select "True" to move to field rows #9 and #10, which can be found in the Data Dictionary with the corresponding data field identification numbers (#9 Submitter Parent Has ID and #10 Submitter Parent ID). The content descriptions and instructions for these data fields can be found in the Data Dictionary. After adding the data required in the Data Dictionary to data fields #9 and #10, the required data from the parent company will be completed in data fields #143–147.

2.1.1 Submitter Details

This section presents the data fields in the Submitter Details tab of the product notification which are mandatory, optional or require the product notification submitter's discretion. In the guideline, specific instructions have been added to the data fields concerning them, or Valvira has defined a mandatory response option or response clause in advance. The optional data fields are marked separately.

#5 Submitter Type

- #143 Company Name**
- #144 Company Address**
- #145 Company Country**
- #146 Company Phone**
- #147 Company E-Mail**
- #3 Submitter Has VAT**
- #2 Submitter SME**
- #1 Submitter ID**

#20 Submission type

#23 Product ID

#21 Submission General Comment – *Enter the characterising flavour or aroma of the product in this data field.*

#5 Submitter Type

#143 Company Name

#144 Company Address

#145 Company Country

#146 Company Phone

#147 Company E-Mail

#3 Submitter Has VAT

#2 Submitter SME

#1 Submitter ID

2.1.2 Product details

This section presents the data fields in the Product Details tab of the product notification which are mandatory, optional or require the product notification submitter's discretion. In the guideline, specific instructions have been added to the data fields concerning them, or Valvira has defined a mandatory response option or response clause in advance. The optional data fields are marked separately.

#23 Product number

#24 Product Previous ID (TP-ID)

#25 Product ID Other Exist

#27 Product Same Composition Exist

#28 Product Same Composition Other

#29 Product Type – *Select the most appropriate product type 7, 8 or 9 for the intended use. Nicotine pouches belong to product type 7 (oral tobacco).*

#32 Product Weight – *Weight of one nicotine pouch including moisture and pouch weight. Indicate the weight at the accuracy of two decimal places (mg).*

#33 Product Tobacco Weight – *Enter weight as 0 mg.*

#132 Smokeless pH – *Enter the value at the accuracy of one decimal place.*

#133 Smokeless Total Moisture – *Optional. Enter the value as a percentage at the accuracy of one decimal place.*

#134 Smokeless Nicotine Content – *Enter the nicotine content of the product (mg) per dose unit at the accuracy of two decimal places. One dose unit corresponds to one nicotine pouch. In the case of a loose product, the manufacturer determines one usage dose in grams.*

#135 Smokeless Unionised Nicotine Content – *Optional*

#136 Smokeless Analysis Methods – *Optional*

#15-16 Manufacturer Has ID

Manufacturer Company Details

#143 Company Name

#144 Company Address

#145 Company Country

#146 Company Phone

#147 Company E-Mail

Product Production Site Address

#148 Production Site Address

#149 Production Site Country

#150 Production Site Phone – *Optional*

#151 Production Site Email – *Optional*

#6 Submitter Has Parent Company

#9 & #10

#143 Company Name

#144 Company Address

#145 Company Country

#146 Company Phone

#147 Company E-Mail

#7 Submitter Has Affiliate Company

#11 & #12

#143 Company Name

#144 Company Address

#145 Company Country

#146 Company Phone

#147 Company E-Mail

#8 Submitter Appoints Enterer

#13 & #14

#143 Company Name

#144 Company Address

#145 Company Country

#146 Company Phone

#147 Company E-Mail

#17 Supplier Has ID

#143 Company Name

#144 Company Address

#145 Company Country

#146 Company Phone

#147 Company E-Mail

#36 Product Technical File – *Optional*

#37 Product Market Research File – *Optional*

2.1.3 Tobacco Ingredients

This section presents the data fields in the Tobacco Ingredients tab of the product notification which are mandatory, optional or require the product notification submitter's discretion. In the guideline, specific instructions have been added to the data fields concerning them, or Valvira has defined a mandatory response option or response clause in advance. The optional data fields are marked separately.

#57 Tobacco Part Type – *Select the type “Other/Unspecified” (5).*

#58 Tobacco Part Type Other – *For example for nicotine pouches, enter the text: “This is a nicotine pouch not containing tobacco”.*

#59 Tobacco Leaf Type – *Select type 'Other' (7).*

#60 Tobacco Leaf Type Other – *For example, for nicotine pouches, enter the text: “This is a nicotine pouch not containing tobacco”.*

#61 Tobacco Leaf Cure Method – *Select type 'Other' (7).*

#62 Tobacco Leaf Cure Method Other – *For example for nicotine pouches, enter the text: “This is a nicotine pouch not containing tobacco”.*

#63 Tobacco Quantity – *Enter weight as 0 mg.*

2.1.4 Product Presentation

This section presents the data fields in the Product Presentation tab of the product notification which are mandatory, optional or require the product notification submitter's discretion. Specific instructions have been added to the data fields or Valvira has defined a mandatory response option or response clause in advance. The optional data fields are marked separately.

It should be noted that if the products are presented for sale in different forms, for example under different version names, the following variables must be filled in for each form. However, if the compositions (ingredient information) of the products differ, a separate product notification must be submitted for each product.

#38 Product National Market

#39 Product National Comment – *Optional*

#40 Product Brand Name

#41 Product Brand Subtype Name Exist

#42 Product Brand Subtype Name

#43 Tobacco Product Presentation Launch Date

#44 Tobacco Product Presentation Withdrawal

Please fill in at least one of the product identification numbers #46–50 below.

#46 Product Presentation Submitter Number

#47 Product Presentation UPC Number

#48 Product Presentation EAN Number

#49 Product Presentation GTIN Number

#50 Product Presentation SKU Number

#51 Product Presentation Package Type – *Select the plastic container (28) option for the plastic disc-shaped package. For other packaging types, use your own judgement regarding the appropriate package type.*

#52 Product Presentation Package Units – *Enter the quantity of dose units in the unit packet. One nicotine pouch corresponds to one dose unit. In the case of a loose product, the manufacturer determines one usage dose in grams.*

#53 Product Presentation Package Net Weight – *Specify the weight of the unit packet in grams.*

#54 Product Presentation Other Market Has Data

#55 Product Presentation Other Market Data

#56 Product Presentation Unit Packet Picture File – *Optional, but it is recommended to add a picture of the package.*

Annual sales volume data

#152 Product Presentation Maximum Sales – Optional

#153 Product Presentation Sales Volume – *The sales volume of smokeless nicotine products sold in dose units, such as nicotine pouches, is expressed as the quantity of dose units. For example, if 20 000 retail packages have been sold, one retail package contains 20 dose units of nicotine pouches, the annual sales volume is reported as 20 x 20 000 = 400 000 dose units. For other smokeless nicotine products, the sales volume is expressed in kilograms.*

#154 Product Presentation Sales Volume Year – *If there were product sales in the previous calendar year, please report the sales volumes by the given date of the following year (20 May).*

2.1.5 Other Ingredients

This section presents the data fields in the Other Ingredients tab of the product notification which are mandatory, optional or require the product notification submitter's discretion. In the guideline, specific instructions have been added to the data fields concerning them, or Valvira has defined a mandatory response option or response clause in advance. The optional data fields are marked separately.

For smokeless nicotine products, report all ingredients contained in the product, including their CAS numbers. If an additive is a compound, indicate all the ingredients of the compound separately. For example, for nicotine pouches, please indicate the pouch materials, adhesives and fillers, in addition to the additives.

The amount of ingredients is expressed as one dose unit (mg). One dose unit is one nicotine pouch, for example. In the case of a loose product, the manufacturer determines one usage dose in grams.

#65 Ingredient Category – *Choose the most appropriate unburnt form for the category. If you are not sure which category the ingredient belongs to, use the category "other (unburnt)" (15).*

#67 Ingredient Name

#68 Ingredient CAS exist

#69 Ingredient CAS

#70 Ingredient CAS additional – Optional

If a CAS number is not available for an ingredient, please indicate one of the following:

#71 Ingredient FEMA Number

#72 Ingredient Additive Number

#73 Ingredient FL Number

#74 Ingredient EC Number

#75 Ingredient Other Number – Only use if no other identifier is available.

#77 Ingredient Recipe Quantity – Quantity of ingredient in one dose unit (mg).

#76 Ingredient Quantity Fluctuate

#78 Ingredient Recipe Range Min Level

#79 Ingredient Recipe Range Max Level

#80 Ingredient Measured Mean Quantity

#81 Ingredient Measured SD

#82 Ingredient Measured Min Level

#83 Ingredient Measured Max Level

#84 Ingredient Measured Number

#85 Ingredient Function – Choose the option that best matches the intended use of the ingredient. Please note that the option “other” (26) is selected for the material of the nicotine pouch.

#86 Ingredient Function Other – Enter “pouch material” for the material of the nicotine pouch.

#87 Ingredient Priority Additive – For smokeless nicotine products, select “False”. Therefore, no attachment file concerning the main additive (#105 Ingredient Priority Additive Files) is required either.

#88 Ingredient Unburnt Status

#89 Ingredients REACH Registration – Optional

#90 Ingredient REACH Registration Number

#91 Ingredient CLP Whether Classification – *If the ingredient has a CLP classification, please complete the classification for at least one of the following (classifications in the Data Dictionary):*

- #92 Ingredient CLP Acute Tox Oral**
- #93 Ingredient CLP Acute Tox Dermal**
- #94 Ingredient CLP Acute Tox Inhalation**
- #95 Ingredient CLP Skin Corrosive/Irritant**
- #96 Ingredient CLP Eye Damage/Irritation**
- #97 Ingredient CLP Respiratory Sensitisation**
- #98 Ingredient CLP Skin Sensitisation**
- #99 Ingredient CLP Mutagen/Genotox**
- #100 Ingredient CLP Carcinogenicity**
- #101 Ingredient CLP Reproductive Tox**
- #102 Ingredient CLP STOT**
- #103 Ingredient CLP STOT Description**
- #104 Ingredient CLP Aspiration Tox**

Toxicological data of ingredients

#106 Ingredient Tox Data

#107 Ingredient Tox Emission – *If there are toxicological data for an ingredient in this classification, please also add an attachment file:*

#112 Ingredient Tox Emission File

#108 Ingredient Tox CMR – *If there are toxicological data for an ingredient in this classification, please also add an attachment file:*

#113 Ingredient Tox CMR File

#109 Ingredient Tox Cardiopulmonary – *If there are toxicological data for an ingredient in this classification, please also add an attachment file:*

#114 Ingredient Tox CardioPulmonary File

#110 Ingredient Tox Addictive – *If there are toxicological data for an ingredient in this classification, please also add an attachment file:*

#115 Ingredient Tox Addictive File

#111 Ingredient Tox Other – *If there are toxicological data for an ingredient in this classification, please also add an attachment file:*

#116 Ingredient Tox Other File

2.1.6 TNCO and other emissions

Emission data is not required for smokeless nicotine products. The emissions data value can be 0, unavailable or blank.

3 Unit packets of smokeless nicotine products

3.1 Overview of unit packets

Smokeless nicotine products may only be sold and otherwise supplied to consumers in unit packets that comply with the Tobacco Act, regulations issued pursuant to it, and EU legislation.

The Tobacco Act and the Decree of the Ministry of Social Affairs and Health on the labelling and other layout elements of tobacco and related products and their unit packets (591/2016), issued on the basis of the Act, strictly provide for the mandatory, permissible and prohibited labelling of the unit packets of smokeless nicotine products.

This guideline is a compilation of the requirements related to the unit packets of smokeless nicotine products, which the product notification submitter must take into account when submitting the product notification.

3.1.1 Mandatory labelling of unit packets of smokeless nicotine products

The unit packets of smokeless nicotine products **must** contain (Section 39a (1) of the Tobacco Act):

1. a list of the ingredients contained in the product in descending order based on weight;
2. an indication of the nicotine content of the product and the delivery per dose*;
3. the manufacturer's batch number;
4. a recommendation to keep the product out of reach of children;

5. health warnings in Finnish and Swedish.

**the nicotine content of the product = the nicotine content in milligrams per one gram of product*

**product dosage = how much nicotine one dose unit contains, for example, one nicotine pouch.*

The unit packet of a smokeless nicotine product **must bear** the following nicotine warning label with text: "Tämä tuote sisältää nikotiinia, joka on voimakkaasti riippuvuutta aiheuttava aine." ("This product contains nicotine, which is a highly addictive substance".) (Decree of the Ministry of Social Affairs and Health Decree of the Ministry of Social Affairs and Health on the labelling and other layout elements of tobacco and related products and their unit packets (591/2016), Section 14a).

The requirements for the warning text are as follows:

- printed in black with Helvetica font in bold on a white background;
- the point size of the font must be such that the text covers as much of the area reserved for it as possible;
- to be placed on the two largest surfaces of the unit packet;
- to be positioned in the middle of its intended area and must be aligned with the main text on the surface.

These mandatory labelling requirements for unit packets of smokeless nicotine products will apply from 1 February 2026.

3.1.2 Permitted labelling on the unit packets of smokeless nicotine products

The unit packet of a smokeless nicotine product **may display** (Section 39a (3) of the Tobacco Act):

- the product's product name and product category;
- the manufacturer's or importer's business name and contact details, and

- the package size*, flavour and barcode of the product.

*package size = the number of nicotine pouches in the unit packet or the total weight of the loose product in grams. The minimum size of the unit packet of a smokeless nicotine product is 20 dose units and 30 grams of the loose product.

However, the information must be presented so that the labelling does nothing to help the unit packet stand out from other unit packets of smokeless nicotine products. Labelling may not be used to promote the product. **For example, only one flavour or aroma may be indicated in connection with the product name.**

The permitted markings must only be printed once on two surfaces of the unit packet. The labelling must be printed using the Helvetica font type in a matte colour using the Pantone Cool Gray 2 C tone. The maximum font size is 10. The text of the product name and any version name must be aligned with the nicotine warning label. The labelling must be written in lower case letters except for the first letter.

The barcode on the unit packet of a smokeless nicotine product must be either black on a white background or matte Pantone Cool Gray 2 C or Pantone 448 C on a white background. The barcode must be printed on the bottom or side of the unit packet.

The unit packet of a smokeless nicotine product must be a straight circular cylinder in shape, its colour must be Pantone 448 C (the inner surface of the unit packet must be Pantone 448 C or white), and its material must be plastic or cardboard with a smooth and matte surface.

The wrapping of the unit packet must be smooth, transparent and colourless, and it must not include any labelling. The tear strip in the wrapping must be smooth, transparent and colourless or black. It cannot be wider than three millimetres, and it must be aligned with the top of the packet. The tear strip can include a continuous transparent and colourless or black line of at most 23 millimetres in length to indicate the start of the strip.

These provisions on the permitted labelling of unit packets of smokeless nicotine products will apply from 1 August 2026.

3.1.3 Prohibited labelling on unit packets of smokeless nicotine products

The labelling of smokeless nicotine products or their unit packets, **such as the product name on the packet or an indication of the permissible flavour, must not** (Section 39a (2) of the Tobacco Act):

- promote the product or encourage its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;
- suggest that the product is less harmful than others or aims to reduce the effect of some of the harmful components (e.g. natural, organic, additive-free);
- suggest that the product has vitalising, energetic, healing, rejuvenating, natural or organic properties, or that its use has other health or lifestyle benefits (e.g. energy, organic, or prefixes such as “fresh”, “light”, “max”, etc.);
- resemble a food or a cosmetic product;
- suggest that the product has environmental advantages.

These prohibited labelling requirements for unit packets of smokeless nicotine products will apply from 1 February 2026.

3.1.4 Other appearance of unit packets of smokeless nicotine products

The unit packet of a smokeless nicotine product must not stand out from other unit packets of smokeless nicotine products with regard to its shape, colour, material or other appearance, and the appearance of the unit packet must not promote the product (Section 39b). Further provisions may be issued by a decree of the Ministry of Social Affairs and Health regarding: the permitted shape, colour, material and other appearance of the unit packet of the nicotine product. This requirement concerning the harmonisation of unit packets will take effect on 1 August 2026

3.1.5 Appearance of smokeless nicotine products

The smokeless nicotine product itself must not differ in shape, colour, surface or other appearance from other smokeless nicotine products of the same product group, and its appearance must not promote the product (Section 39c of the Tobacco Act). A smokeless nicotine product must also not be coloured. In addition, it must have an even and matte surface and be homogeneous in composition. A smokeless nicotine product in a pre-packaged dose unit must have the shape of a rectangle. The material of the dose unit must be white and must not have any markings (Decree of the Ministry of Social Affairs and Health on the labelling and other layout elements of tobacco and related products and their unit packets 591/2016, Section 19k). The requirements will apply from 1 August 2026.



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