

141**DECREE**

of 16 May 2023

on tobacco-free nicotine pouches

Pursuant to Section 19(4) of Act No 110/1997 Coll., on foodstuffs and tobacco products and on amendments to certain related acts, as amended by Act No 174/2021 Coll. (hereinafter the 'Act'), the Ministry of Health lays down the following:

Section 1

Subject matter

This Decree regulates

- a) requirements for the composition, appearance, quality and characteristics of tobacco-free nicotine pouches (hereinafter 'nicotine pouch');
- b) the labelling of nicotine pouches, including prohibited elements and features; and
- c) the method, deadlines and scope of the notification obligation for manufacturers and importers of nicotine pouches.

Section 2

Nicotine pouches quality and composition requirements

(1) Nicotine pouches may contain only nicotine or nicotine salt and substances, which, in oral, dermal or inhalation form, do not pose a risk to human health at the concentration used, when used according to the instructions for use.

(2) Only additives listed in Annex II, Part B to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, as amended, may be used as additives in nicotine pouches. Ingredients other than those listed in the list pursuant to Section 5(2) may be contained in nicotine pouches in trace quantities only if it is technically impossible to avoid the presence of such traces during the manufacture of nicotine pouches.

(3) The following must not be added to nicotine pouches as separate substances:

- a) vitamins¹), minerals¹), or other ingredients that give the impression that they are beneficial to health or present a reduced health risk;
- b) addictive substances²) with the exception of nicotine and nicotine salts;
- c) caffeine, taurine or other stimulants associated with energy and vitality;
- d) ingredients having carcinogenic, mutagenic or reproductive toxic properties, with the exception of nicotine and nicotine salts; and
- e) substances listed in Annex 1 to this Decree.

(4) A unit packet must not contain more than 240 mg of nicotine and must contain at least 20 nicotine pouch doses. Pursuant to Section 12k(2)(c) of the Act, the total nicotine content of the product shall be indicated in milligrams.

(5) One nicotine pouch dose may contain a maximum of 12 mg of nicotine.

(6) A nicotine pouch dose, pursuant to Section 12k(2)(d) of the Act, consists of:

- a) an individually packaged nicotine pouch contained in a unit packet that does not pose a serious risk³) to human health; and
- b) edible or inedible packaging safe for human health in accordance with the requirements of Article 3(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, the requirements of Article 4(a) and (e) in the part concerning the composition requirements of Commission Regulation (EU) No 10/2011 of 14

1) Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, as amended.

2) Act No 167/1998 on addictive substances and on amendments to certain other acts, as amended.

3) Act No 102/2001 on general product safety and amending certain acts (the General Product Safety Act), as amended.

January 2011 on plastic materials and articles intended to come into contact with food and the requirements of Section 3(1) of Decree No 38/2001 on hygiene requirements for products intended to come into contact with food and meals, as amended; and

- c) an enclosed chemical mixture containing nicotine or nicotine salt in accordance with the relevant European Union legislation⁴).

Section 3

Appearance and properties of nicotine pouches

(1) The unit packet itself and any outer packaging of the nicotine pouch must not resemble food, a cosmetic product or toy by its shape, size, colour, drawing, sticker or description. The outer packaging of the nicotine pouch is the packaging in which the nicotine pouches are placed on the market and which contains a unit packet or a set of unit packets; transparent packaging shall not be considered as outer packaging.

(2) The unit packet of a nicotine pouch, which means the smallest unit packet placed on the market, must be protected against any unwanted handling that would, in particular, undermine the integrity of the product and would be contrary to the purpose for which the nicotine pouches are intended, especially against the handling of unit packets by children.

Section 4

Labelling of unit packets and outer packaging

(1) Information pursuant to Section 12k(2) of the Act

- a) is printed indelibly;
b) is visible; and

⁴) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

c) must not be covered when being placed on the market.

(2) The packaging of the unit and outer packaging must be marked with the name of the brand as well as the name of the subtype⁵), if one exists for the given product. The brand name may take up only one line. The name of the subtype must take up only one line and must appear directly below the brand name. The inscribed text must run parallel to the health warning text. The name of the nicotine pouch subtype means the name used to distinguish various nicotine pouches of the same brand name.

(3) Outer packaging containing more than one unit packet must bear the information 'tobacco-free nicotine pouch' once and the number of unit packets contained in the outer packaging.

(4) The packaging of the unit packet and the outer packaging of a nicotine pouch bear:

- a) the product identification number under which the product is notified via the electronic Common Entry Gate⁶);
b) nicotine content in mg per one nicotine pouch dose;
c) the number of nicotine pouch doses in a unit packet;
d) the best-before date;
e) a graphic sign together with the text 'This product is not intended for persons under the age of 18' and the following sentences: 'This product is not intended for pregnant women.', 'This product is not intended for breastfeeding women.' and 'Keep out of the reach of children.'; the appearance of the graphic label 'This product is not intended for persons under the age of 18' is set out in Annex 2 to this Decree; and
f) information pursuant to Article 9(1)(c) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the

⁵) Point 3 of the Annex to Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products.

⁶) Commission Implementing Decision (EU) 2015/2186.

Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

Section 5

(1) The packaging of the unit packet and the outer packaging of the nicotine pouch may bear one black barcode on a white background. The barcode must not depict an image, pattern, or symbol that resembles anything other than a barcode.

(2) The ingredients contained in nicotine pouches must be listed in descending order by weight. If one of the ingredients is nicotine salt, the amount of nicotine salt contained in the dose shall be indicated in mg.

(3) Health warning means a warning concerning the adverse effects of nicotine pouches on human health. The health warnings on each unit packet and on any outer packaging of the nicotine pouch shall read: 'This product contains nicotine and is highly addictive.' No additional text may appear on the packaging pursuant to the second sentence that would comment, paraphrase or refer to the health warning in any way.

(4) The health warning specified in paragraph 3 must:

- a) be positioned parallel to the main text on the area reserved for this warning;
- b) be printed with black, bold Helvetica font while preserving the default character spacing, which is 100 %, and normal spaces, on a white background; the point size of the font must be such that the relevant text covers as much as possible of the surface reserved for it;
- c) be centred on the area reserved for it;
- d) be parallel to the side edge of the unit packet or the outer packaging in the case of packets of a cuboidal and similar shape;
- e) cover 30 % of the area of the surface of the unit packaging and of any external packaging on which the health warning is printed;
- f) be indicated on the area together with the brand name and the name of the subtype; and
- g) remain undamaged when the unit packaging is opened in the usual manner.

(5) The labelling of the unit packet itself and of any outer packaging of the nicotine pouch must not contain

any element or feature that

- a) promotes the nicotine pouch or promotes its consumption by creating a false impression of the product's characteristics, health effects, risks and emissions;
- b) suggests that the nicotine pouch is less harmful than other products, has vitalising, energising, healing or rejuvenating effects, or the characteristics of an organic farming product, is of natural origin, has other health or lifestyle benefits;
- c) resembles a food, cosmetic product or toy; or
- d) suggests that the nicotine pouch has increased biodegradability or other environmental benefits.

(6) The unit packet and any outer packaging of the nicotine pouch must not

- a) indicate financial benefits, including through printed vouchers, discount offers, free distribution, 'two-for-one' offers or other similar offers;
- b) contain any elements associated with illegal or dangerous substances, or promote socially undesirable behaviour, or suggest the increased possibility of achieving social success;
- c) contain any elements that directly or indirectly target minors based on the culture of minors;
- d) contain any elements related to flavours and flavourings that evoke candy or confectionery products that may be particularly attractive to minors.

(7) An element or feature that is prohibited under paragraphs 5 or 6 may be a text, symbol, name, brand name, a figurative or other mark. Elements related to the flavour of the product may be listed on the product only in the form of text.

Section 6

Method and scope of the notification obligation when placing nicotine pouches on the market

(1) Notifications under Section 12k(4)(a) of the Act are made through the EU Common Entry Gate (hereinafter 'EU-CEG') pursuant to the Implementing Decision establishing the format for the submission and disclosure of information on tobacco products. The notification is similar to that for tobacco products for oral use⁶), by brand and type of tobacco for oral use. This

notification includes at least:

- a) a list of all ingredients contained in nicotine pouches by brand name and type, including their quantity;
- b) toxicological data on the ingredients referred to in point (a), in particular with regard to their oral, dermal and inhalation effects on the health of consumers, and any addictive effect thereof, in Czech language;
- c) a safety data sheet drawn up in accordance with directly applicable European Union legislation governing chemicals⁷);
- d) information on nicotine doses and intake when used under normal or foreseeable conditions; and
- e) the name and contact information of the manufacturer, responsible corporate entity or natural person in the European Union, and if applicable, the importer to the European Union.

(2) Prior to the first notification pursuant to Section 12k(4)(a) of the Act, the manufacturer or importer shall ask the operator of the EU-CEG for a Submitter ID. The manufacturer or importer shall, upon request, submit information containing his identification data and verification of activities in accordance with the national law of the Member State in which he is established. The Submitter ID shall be used for all subsequent notifications made through the EU-CEG and in all subsequent correspondence with the Ministry of Health.

(3) On the basis of the Submitter ID, the manufacturer or importer shall assign a nicotine pouch ID number to each product that need to be notified. When submitting notifications of products of the same composition and appearance, the manufacturer and the importer shall use the same nicotine pouch ID number, unless specified otherwise in this Decree.

(4) The procedure pursuant to paragraph 3 shall apply irrespective of product brand and subtype and the number of markets on which the products are marketed. If

it cannot be ensured that the same nicotine pouch ID number is used for products having the same composition and appearance, different nicotine pouch ID numbers assigned to these products must be provided.

(5) Notifications pursuant to Section 12k(4)(a) and (5) of the Act shall be submitted before the nicotine pouches are placed on the market.

(6) Any information that the manufacturer or importer considers to be a trade secret or otherwise confidential shall be identified upon submission of the notification. The name of the submitter, the country in which the submitter is domiciled or resident, the type of submitter pursuant to the Annex to Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products, the nicotine pouch ID number, brand name, subtype name, type of product, first filing date, date of last update of the submission, date on which the submitter placed or intends to place the product on the market are not considered a trade secret.

Section 7

Notification of information on nicotine pouches market

(1) A notification pursuant to Section 12k(4)(b) of the Act contains:

- a) aggregated information on sales volume by brand name and product type;
- b) all information about the preferences of different consumer groups, including young people, non-smokers and the main types of current users.

(2) The information pursuant to paragraph 1(a) shall always be submitted by the manufacturer or importer through the relevant part of the EU-CEG in the form of newly added numerical information for each calendar year. Information pursuant to paragraph 1(a) shall be submitted by the manufacturer or importer by 31 May of the calendar year following the end of the calendar year in which the sale took place. Information pursuant to paragraph 1(b) shall be submitted by the manufacturer or importer by 31 December of the calendar year following the end of the calendar year in which the sale took place.

Section 8

Transitional provisions

Nicotine pouches that do not comply with the

⁷) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

requirements laid down in this Decree and that have been produced or placed on the market and labelled before the effective date of this Decree may be offered for sale and sold no later than 12 months after the effective date of this Decree.

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.

Section 9

Final provisions

This Decree was notified in accordance with

Section 10

Effective date

This Decree shall take effect on 1 July 2023.

Minister:

prof. Dr. **Válek**, CSc., MBA, EBIR, m. p.

List of prohibited substances that cannot be added to nicotine pouches as stand-alone ingredients

Substance name	CAS number(s)
agaricic acid	666-99-9
aloin	1415-73-2
capsaicin	404-86-4
hypericin	548-04-9
beta-asaron	5273-86-9
estragol	140-67-0
hydrogen cyanide	3017-23-0
menthofuran	494-90-6
methyl eugenol	93-15-2
pulegone	89-82-7; 15932-80-6
quassin	76-78-8
safrole	94-59-7
teucrin A	12798-51-5
thujone (alpha and beta)	546-80-5; 76231-76-0
coumarin	91-64-5
colchicine	64-86-8
bergamottin (furanocoumarin)	7380-40-7
6,7 - dihydroxibergamottin (furanocoumarin)	145414-76-2

Graphic label

The graphic label 'This product is not intended for persons under the age of 18 years.' with the character of the prohibited symbol (Figure 1) has a circular shape with a diameter of at least 1 cm on a white background and a circle with a red thicker edge, a red diagonal stripe over black text 18 on a white background.

Figure 1

