**37**

**IMPLEMENTING DECREE**
of 2 February 2017

**on electronic cigarettes, refill containers and herbal products for smoking**

Pursuant to § 19(4) of Act No 110/1997 on foodstuffs and tobacco products and on amendments to certain related acts, as amended by Act No 180/2016 (hereinafter: the ‘Act’), the Ministry of Health lays down the following:

§ 1

**Subject matter**

This Implementing Decree incorporates relevant European Union legislation[[1]](#footnote-2)1) and regulates:

* 1. requirements for the composition, appearance, quality, and properties of electronic cigarettes and refill containers;
	2. labelling of electronic cigarettes, refill containers and herbal products for smoking, including forbidden elements and characteristics;
	3. compulsory notification methods, deadlines, and scope for manufacturers and importers of electronic cigarettes, refill containers and herbal products for smoking
	4. , and;
	5. the scope of information required for registration for cross-border distance sales of electronic cigarettes and refill containers, as well as how this registration is performed.

§ 2

**Definitions**

For the purposes of this Implementing Decree, the following definitions shall apply:

* 1. a ‘common electronic entry gate for data submission’ is an information portal set up and operated by the European Commission to ensure a common method for notifying electronic cigarettes and refill containers and herbal products for smoking;
	2. a ‘health warning’ is a warning regarding the harmful effects of an electronic cigarette or of an refill container or of an herbal product for smoking on human health;
	3. a retail outlet is any natural person or corporate entity that places electronic cigarettes or refill containers or herbal products for smoking on the market.

§ 3

**General requirements for electronic cigarettes and refill containers**

(1) Electronic cigarettes and refill containers must be:

* 1. secured from handling by children and any tampering that would especially compromise the integrity of the product and would be contrary to the intended purpose of electronic cigarettes and refill containers;
	2. protected from being breaking open and liquid leaking out; and
	3. must feature a mechanism that ensures that no liquid leaks out when refilling, pursuant to § 4, in the case of refillable electronic cigarette;

(2) Electronic cigarettes containing nicotine must release nicotine uniformly under normal conditions of use.

(3) Only highly pure ingredients may be used in the production of liquid electronic cigarette refills. Substances other than the ingredients on the list pursuant to § 6(1)(a) may be present in a liquid cartridge in trace amounts only if such trace amounts are technically unavoidable during the manufacture of liquid refill containers.

(4) Liquid refill containers may only contain substances that do not pose a risk to human health in heated or unheated form, as well as nicotine.

(5) Liquid refill containers must not contain:

a) vitamins or other additives that create the impression that a liquid cartridge has a health benefit or presents reduced health risks;

b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

c) additives having colouring properties for emissions; and

d) additives that in their unburned form have carcinogenic, mutagenic, or reprotoxic properties.

(6) Liquid refill containers containing nicotine may contain at most 20 mg nicotine/ml.

(7) The volume of an electronic cigarette refill containers must not exceed 10 ml.

(8) The volume of the tank or dispenser in a disposable electronic cigarettes or disposable dispensers must not exceed 2 ml.

§ 4

**Further requirements for refillable electronic cigarettes that can be used for the consumption of nicotine-containing vapours and their refill containers**

(1) Refillable electronic cigarettes that can be used for the consumption of nicotine-containing vapour and their refill containers containing nicotine can be placed on the market only if the refill mechanism:

* 1. entails the use of a refill container possessing a securely attached nozzle at least 9 mm long, which is narrower than and slots comfortably into the opening of the tank of the electronic cigarette with which it is used and possessing a flow control mechanism that emits no more than 20 drops of refill liquid per minute when placed vertically and subjected to atmospheric pressure alone at 20 °C ± 5 °C; or
	2. operates by means of a docking system which only releases refill liquids into the tank of the electronic cigarette when the electronic cigarette and refill container are connected.

(2) A user manual pursuant to § 12h(3)(a) of the Act for refillable electronic cigarettes that can be used to consume nicotine-containing vapour, and for refill containers containing nicotine, must also contain:

1. refill procedure instructions, including diagrams;
2. information on the width of the nozzle or the width of the tank opening if a mechanism pursuant to point (a) of paragraph 1 is used in the stated manner, that allows the consumer to verify that the refill container and the electronic cigarette are compatible; and
3. the type of docking system with which the electronic cigarette or refill container is compatible if a mechanism pursuant to point (b) of paragraph 1 is used. .

(3) The volume of the tank of a refillable electronic cigarette for refilling refill containers containing nicotine must not exceed 2 ml.

§ 5

**Labelling of electronic cigarettes and refill containers**

(1) Information pursuant to § 12h(2) of the Act must:

* 1. be printed in a way that can not be removed;
	2. be visible; and
	3. not be covered or interrupted when being placed on the market.

(2) The constituents of a liquid cartridge must be specified on the list pursuant to § 12h(2)(b) of the Act in descending order by weight.

(3) The health warning on each unit package and on any external packaging of electronic cigarettes containing nicotine and refill containers containing nicotine shall read: “Tento výrobek obsahuje nikotin, který je vysoce návykovou látkou. Jeho užití nekuřáky se nedoporučuje.”[[2]](#footnote-3)\* Any other text commenting, paraphrasing or referring to in any way the health warning may not be mentioned on the package according to the first sentence.

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

* 1. run parallel to the main text on the area reserved for this warning;
	2. be printed in 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 letters must be such that the relevant text covers as much of the surface reserved for it as possible;
	3. be centred on the area reserved for it;
	4. be, on a unit packaging of a cuboidal shape and any external packaging, in parallel with the side edge of the unit packaging or external packaging;
	5. cover 30 % of the area of the surface of the unit packaging and any external packaging on which the health warning is printed;
	6. be present on the two largest areas of unit packaging and any external packaging; and
	7. remain undamaged when the unit packaging is opened in the customary manner.

(5) The labelling of the electronic cigarette and refill container, unit packaging, and any external packaging must not contain any element or feature that:

* 1. promotes the electronic cigarette or refill container or supports their consumption by creating an erroneous impression as regards the properties of the product, its health effects, risks, and emissions;
	2. indicates that the electronic cigarette or refill container is less harmful than other products, or that its objective is to reduce the effects of some harmful smoke components or that it has vitalising, energising, medicinal, rejuvenating, or natural effects, or the properties of an ecological agriculture product, or other health benefits or lifestyle benefits;
	3. resembles a food or a cosmetic product; or
	4. indicates that the electronic cigarette or refill container has increased biodegradability or other environmental advantages.

(6) Unit packaging and any external packaging of electronic cigarettes or refill containers must not indicate economic advantages, including advantages through printed vouchers, discount offers, free distributions, offers of the type ‘two for the price of one’, or other similar offers.

(7) An element or a feature that is prohibited pursuant to paragraph 5 or 6 may be text, a symbol, a name, a commercial brand or a figurative or other sign.

§ 6

**The notification process when placing electronic cigarettes and refill containers on the market**

(1) Notification pursuant to § 12h(4)(a) of the Act is performed via a common electronic entry gate for data submission in a format stipulated in an annex to the Commission Implementing Decision establishing a common format for the notification of electronic cigarettes and refill containers, and according to the brand and type of electronic cigarette or refill container. These notifications shall contain:

1. a list of all ingredients of liquid cartridges and emissions created through the use of an electronic cigarette or refill container by brand and type, including their quantity;
2. toxicology information on ingredients and emissions pursuant to point a, including when heated, especially with regards to their effects on consumer health if they are inhaled, and any habit-forming effect they may have;
3. information on nicotine doses and its intake during use under normal or predictable conditions, in the case of electronic cigarettes and refill containers containing nicotine;
4. a description of the parts of the electronic cigarette and refill container, including any opening and filling mechanism these products may have;
5. a description of the manufacturing process, including information on whether the manufacturing process includes mass production, and a declaration that the manufacturing process ensures compliance with requirements stipulated in this decree, in a act, other legislation and directly applicable European union legislation;
6. a declaration that the manufacturer or importer bears full responsibility for the quality and safety of the product when it is placed on the market and during its use under normal or predictable conditions; and
7. 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 § 12h(4)(a), the manufacturer or importer shall ask the Ministry of Health for an ID number (hereinafter: the ‘submitter's ID number’) created by the operator of the common electronic entry gate. The manufacturer or importer shall, upon request, submit a document providing its identification and authentication of activities in accordance with the national legislation where it is established. ID number of submitter shall be used in all subsequent notifications performed via the common electronic entry gate and during all other correspondence with the Ministry of Health.

(3) Based on the submitter's ID number, the manufacturer or importer shall assign an electronic cigarette or refill container ID number to every product that is to be notified. When submitting notifications regarding products that have the same ingredients and appearance, the manufacturer and importer shall use the same electronic cigarette or refill container ID number, unless specified otherwise by this Implementing Decree. This process shall apply regardless of the brand and product sub-type and the number of markets upon which the products are placed. If it cannot be arranged that products that have the same ingredients and appearance use the same electronic cigarette or refill container ID number, the different electronic cigarette or refill container ID numbers that were assigned to these products must be provided.

(4) A notification pursuant to § 12h(4)(a) of the Act is submitted at least six months prior to the intended placement on the market.

(5) A notification pursuant to § 12h(5) of the Act is submitted prior to placement on the market.

(6) When submitting a notification, it is necessary to mark all information that the manufacturer and importer consider to be business secrets or otherwise confidential, and when requested to do so by the Ministry of Health, to duly justify this claim.

§ 7

**The scope of data required for registration prior to placing electronic cigarettes or refill containers on the market via cross-border distance sales**

(1) The notification based on which a retail outlet is registered pursuant to § 13c(4) and (5) of the Act contains:

* 1. the name(s) and surname or company name of the retail outlet and the address of the location from which electronic cigarettes or refill containers will be supplied;
	2. the date the activity will commence, which is offering electronic cigarettes or refill containers to consumers within the scope of cross-border remote sales via information society services; and
	3. the address of the website being used for distance sales, including all information needed to identify this website.

(2) Information pursuant to paragraph 1 is notified in electronic form via remote data transmission.

§ 8

**Notification of information on the electronic cigarette and refill container market**

(1) Notification pursuant to § 12h(4)(b) of the Act contains:

* 1. summary sales volume information by brand and product type;
	2. information on the preferences of various consumer groups, including young people, non-smokers, and the main types of current users;
	3. information on how products are sold; and
	4. summaries of any market research performed to determine information pursuant to points (a) to (c).

(2) Information pursuant to point (d) of paragraph 1 regarding electronic cigarettes and refill containers that contain nicotine is submitted in Czech and English. Information pursuant to point (d) of paragraph 1 regarding electronic cigarettes and refill containers that do not contain nicotine is submitted in Czech.

(3) Information pursuant to paragraph 1 is submitted for each calendar year, by 31 May of the following calendar year.

§ 9

**Labelling of herbal products for smoking**

1. Information pursuant to § 12j(2) of the Act must:
	1. be printed in a way that can not be removed;
	2. be visible; and
	3. not be covered or interrupted when being placed on the market.

The health warning on each unit package and on any external packaging of herbal products for smoking shall read: “Kouření tohoto výrobku škodí Vašemu zdraví”.[[3]](#footnote-4)\*\* Any other text commenting, paraphrasing or referring to in any way the health warning may not be mention on the package according to the first sentence.

1. The health warning pursuant to paragraph 2 must be printed on the front and back side of the surface of the unit packaging and any outer packaging.
2. The health warning specified in paragraph 2 must:
	1. be printed in 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 letters must be such that the relevant text covers as much of the surface reserved for it as possible;
	2. be centred on the area reserved for it;
	3. be, on a unit packaging of a cuboidal shape and any external packaging, in parallel with the side edge of the unit packaging or external packaging;
	4. cover 30 % of the area of the surface of the unit packaging and any external packaging on which the health warning is printed; and
	5. remain undamaged when the unit packaging is opened in the customary manner.

(5) The labelling of the herbal product for smoking itself, unit packaging, and any external packaging must not contain any element or feature that:

* 1. promotes the herbal product for smoking or supports its consumption by creating an erroneous impression as regards the its properties, health effects, risks, and emissions;
	2. indicates that the herbal product for smoking is less harmful than other products, or that its objective is to reduce the effects of some harmful smoke components or that it has vitalising, energising, medicinal, rejuvenating, or natural effects, or the properties of an ecological agriculture product, or other health benefits or lifestyle benefits;
	3. resembles a food or a cosmetic product; or
	4. states that the given herbal product for smoking does not contain any additives or aromas.

(6) An element or a feature that is prohibited pursuant to paragraph 5 may be text, a symbol, a name, a commercial brand or a figurative or other sign.

§ 10

**The notification process when placing herbal products for smoking on the market**

(1) Notification pursuant to § 12j(3) of the Act is performed via a common electronic entry gate for data submission in a format stipulated in an annex to the Commission Implementing Decision (EU) 2015/2186 establishing a format for the submission and making available of information on tobacco products, and by brand and type of herbal product for smoking. These notifications shall contain:

1. the name and contact information of the manufacturer, responsible corporate entity or natural person in the European Union, or the importer to the European Union; and
2. a list of all ingredients used in the manufacture of the herbal product for smoking by brand and type, including their quantities.

(2) Prior to the first notification pursuant to § 12j(3), the manufacturer or importer shall ask the Ministry of Health for an ID number created by the operator of the common electronic entry gate. The manufacturer or importer shall, upon request, submit a document providing its identification and authentication of activities in accordance with the national legislation where it is established. ID number of submitter shall be used in all subsequent notifications performed via the common electronic entry gate and during all other correspondence with the Ministry of Health.

(3) Based on the submitter's ID number, the manufacturer or importer shall assign an herbal product for smoking ID number to every product that is to be notified. When submitting information regarding products that have the same ingredients and appearance, the manufacturer and importer shall use the same herbal product for smoking ID number, unless specified otherwise by this Implementing Decree. This process shall apply regardless of the brand and product sub-type and the number of markets upon which the products are placed. If it cannot be arranged that products that have the same ingredients and appearance use the same herbal product for smoking ID number, the different herbal product for smoking ID numbers that were assigned to these products must be provided.

(4) Notifications pursuant to § 12j(3) and § 12j(4) of the Act are submitted at least two months prior to their intended placement on the market.

(5) When submitting a notification, it is necessary to mark all information that manufacturers and importers consider to be business secrets or otherwise confidential, and when requested to do so by the Ministry of Health, to duly justify this claim.

§ 11

**Transitional provisions**

The notification obligations pursuant to §§ 6 and 10 for electronic cigarettes and refill containers and herbal products for smoking placed on the market prior to the entry into force of this Implementing Decree must be fulfilled by the end of the third calendar month following the entry into force of this Implementing Decree.

§ 12

**Final provisions**

This Implementing Decree was notified in accordance with 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.

§ 13

**Entry into force**

This Implementing Decree shall enter into force on the fifteenth day following its publication.

Minister for Health:

JUDr. Ing. Ludvik, MBA

1. 1) 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.

Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers.

Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes. [↑](#footnote-ref-2)
2. \* English: “This product contains nicotine, which is a highly addictive substance. It is not recommended for use by non-smokers.” [↑](#footnote-ref-3)
3. \*\* English: “Smoking this product damages your health” [↑](#footnote-ref-4)