

Government Decree 39/2013 (II. 14.) Korm.

on the Production, Placing on the Market and Control of Tobacco Products, on Combined Warnings, and the Detailed Provisions on the Application of Healthcare Penalties

Pursuant to the authorization granted in

Paragraph *a*) of Subsection (5) of Section 8 of Act XLII of 1999 on the Protection of Non-Smokers and Certain Regulations on the Consumption and Distribution of Tobacco Products,

Paragraph *b*) of Subsection (5) of Section 8 of Act XLII of 1999 on the Protection of Non-Smokers and Certain Regulations on the Consumption and Distribution of Tobacco Products, with respect to Section 12 and Paragraph *d*) of Subsection (2) of Section 24,

Paragraph *a*) of Subsection (4) of Section 15 of Act XI of 1991 on the Supervisory and Administrative Activities of the Health Authority, with respect to Subsection (1) of Section 24 and Paragraph *c*) of Subsection (2) of Section 24,

Paragraph *a*) of Subsection (1) of Section 31 of Act CXXX of 2010 on Legislation, with respect to Paragraph *b*) of Subsection (2) of Section 24,

acting within its legislative competence conferred under Article 15(1) of the Fundamental Law, the Government has adopted the following Decree:

1. General provisions

Section 1

(1)¹ The provisions of this Decree - except as specified in Subsection (2) hereof - shall apply to tobacco products, electronic cigarettes, refill liquids and electronic devices imitating smoking manufactured, and - except as specified in Section 16 - placed on the market in the territory of Hungary.

(2) The provisions of this Decree shall not apply to tobacco products that have been brought into the territory of Hungary for personal use.

Section 2²

For the purposes of this Decree:

1.³ ‘registered trader’ shall mean the registered trader defined in the Act on Excise Tax (hereinafter referred to as “Excise Act”);

2. raw materials and additives used for the manufacture of tobacco products:

¹ Established by Section 1 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

² Established by Section 2 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

³ Established by Subsection (1) of Section 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

a) 'tobacco' shall mean leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco,

aa) 'raw tobacco' shall mean the leaves of a plant of the *Nicotiana tabacum* species, capable of industrial processing, dried by natural or artificial process,

ab) 'fermented, cured tobacco' shall mean raw tobacco processed after drying to induce changes under heat and dry matter losses to make the tobacco products suitable for smoking or other forms of consumption,

b) 'homogenized tobacco leaf' shall mean a paper-like sheet or tape made with the use of binders and additives, containing at least 75 per cent tobacco,

c) 'cut tobacco' shall mean uniform strips of smoking tobacco or homogenized tobacco leaf cut to even width,

d) 'cigarette paper' shall mean a special paper cut to a specific size, made into a roll of cut tobacco,

e) 'additive' shall mean a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging;

3. 'tobacco products for smoking' shall mean tobacco products other than a smokeless tobacco product of the following types:

a) 'cigarette' shall mean a roll of tobacco that can be consumed via a combustion process which are capable of being smoked as they are containing cut tobacco or cut tobacco and homogenized tobacco leaf covered by cigarette paper glued lengthwise or by tobacco foil, and which are not cigars or cigarillos, including rolls of tobacco which, by simple non-industrial handling, are inserted into cigarette-paper tubes or wrapped in cigarette paper,

b) 'cigar' shall mean a roll of tobacco that can be consumed via a combustion process, meaning:

ba) rolls of tobacco with an outer wrapper of natural tobacco,

bb) rolls of tobacco with a threshed blend filler and with an outer wrapper of the normal color of a cigar, of reconstituted tobacco, covering the product in full, including, where appropriate, the filter but not, in the case of tipped cigars, the tip, where the unit weight, not including filter or mouthpiece, is not less than 2.3 grams and not more than 10 grams and the circumference over at least one third of the length is not less than 34 millimeter,

c) 'cigarillo' shall mean a small type of cigar of a maximum weight of 3 grams each,

d) 'smoking tobacco' shall mean cured cut tobacco provided for in Paragraphs e)-g), capable of being smoked without further industrial processing,

e) 'roll-your-own tobacco (fine cut smoking tobacco)' shall mean tobacco which can be used for making cigarettes by consumers, in which more than 25 per cent by weight of the tobacco particles have a cut width of less than 1.5 millimeter,

f) 'pipe tobacco (other smoking tobacco)' shall mean tobacco, other than those covered under Paragraph e), that can be consumed via a combustion process and exclusively intended for use in a pipe,

g) 'waterpipe tobacco' shall mean a tobacco product that can be consumed via a waterpipe,

h) any other products made for the purpose of smoking, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not;

3a.⁴ 'health warning' shall mean text warnings, combined health warnings, general warnings and information messages;

⁴ Enacted by Section 1 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

4. ‘export’ shall mean the sale of excise goods into a State outside the territory of the European Union, exited by the customs authority into a State outside the territory of the European Union as the final destination;

5. ‘placing on the market’ shall mean to make products, irrespective of their place of manufacture, available to consumers located in the Union, in any way or form;

6. ‘distributor’ shall mean an economic operator or natural person pursuing the activity specified in Point 5;

7. ‘addictiveness’ shall mean the pharmacological potential of a substance to cause addiction, that is to say a state which affects an individual’s ability to control his or her behavior, typically by instilling a reward or a relief from withdrawal symptoms, or both;

8. ‘smokeless tobacco product’ shall mean a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use:

a) ‘chewing tobacco’ shall mean a smokeless tobacco product exclusively intended for the purpose of chewing,

b) ‘nasal tobacco’ shall mean a smokeless tobacco product that can be consumed via the nose,

c) ‘tobacco for oral use’ shall mean all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms;

9. ‘filter’ shall mean the part of a cigarette, cigar, cigarillo for filtering the primary smoke passing through the tobacco product;

10. ‘manufacturer’ shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark;

11. ‘foreign substance’ shall mean any non-tobacco substance mixed into the raw material in the course or growing or processing, or into the finished product, that can be isolated by simple physical methods;

12.⁵ ‘importation’ shall have the meaning defined in the Excise Act;

13.⁶ ‘importer’ shall have the meaning defined in the Excise Act;

14. ‘flavoring’ shall mean an additive that imparts smell and/or taste;

15. ‘characterizing flavor’ shall mean a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;

16. ‘tar’ shall mean the raw anhydrous nicotine-free condensate of smoke;

17. ‘emissions’ shall mean substances that are released when a tobacco or related product - provided for in Point 2 of Section 3 of Act CXXXIV of 2012 on Anti-Smoking Programs for Young People and on the Retail Sale of Tobacco Products - is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;

18. ‘maximum emission level’ shall mean the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams;

19. ‘nicotine’ shall mean nicotinic alkaloids;

⁵ Established by Subsection (2) of Section 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

⁶ Established by Subsection (2) of Section 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

20. 'nicotine-containing liquid' shall mean a liquid used in electronic cigarettes, which can be used to refill an electronic cigarette, containing nicotine in any concentration, however small;

21. 'ingredient' shall mean tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;

22.⁷ 'release for free circulation' shall have the meaning defined in the Excise Act;

23. 'transport packaging' shall mean packaging conceived so as to facilitate transport of a product, not intended for the retail market;

24. 'personal use' shall mean tax free importation of tobacco products - in accordance with the Excise Act - by private individuals on a non-commercial basis;

25. 'carbon monoxide' shall mean a constituent of cigarette smoke in gaseous phase;

26. 'mouthpiece' shall mean the part of a cigarette, cigar, cigarillo, electronic cigarette, electronic device imitating smoking in direct contact with the mouth;

27.⁸ 'authorized tax warehouse operator' shall mean the authorized operator of a tax warehouse provided for the Excise Act;

28. 'toxicity' shall mean the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure;

29. 'novel tobacco product' shall mean a tobacco product which:

a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use, and

b) is placed on the market after 19 May 2014.

Section 2/A⁹

In addition to what is contained in Section 2 the definitions provided for in Section 1 of Act XLII of 1999 on the Protection of Non-Smokers and Certain Regulations on the Consumption and Distribution of Tobacco Products (hereinafter referred to as "NSA") shall also apply.

2. Conditions for manufacturing tobacco products and their importation from inside and outside the European Union

Section 3

⁷ Established by Subsection (3) of Section 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

⁸ Established by Subsection (4) of Section 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

⁹ Enacted by Section 49 of Government Decree 413/2015 (XII. 23.), effective as of 20 May 2016.

(1)¹⁰ Authorized tax warehouse operators, importers and registered traders are required to complete the registration form on all tobacco products containing the data provided for in Annex 1 before the beginning of the manufacturing process, or before releasing the tobacco products for free circulation.

(2)¹¹ One copy of the registration form shall be kept in the tax warehouse, or at the registered office of the importer, registered trader, or at the place of storage, where it can be accessed for the purpose of regulatory inspection, insofar as the tobacco products in question are being manufactured, imported, or until being marketed.

(3)¹² Importers, registered traders and authorized tax warehouse operators shall send a copy of the registration form to the minister in charge of consumer protection prior to release for free circulation for the purpose of registration. Following registration, the minister in charge of consumer protection shall forward the copy of the registration form to the Nemzeti Népegészségügyi Központ (*National Center for Public Health*) (hereinafter referred to as “NNK”) by way of electronic means.

(4)¹³ The minister in charge of consumer protection shall maintain an official register on the data contained in the registration forms provided for in Annex 1.

Section 4¹⁴

(1) Tobacco products shall not contain prohibited additives and foreign substances. The list of prohibited additives is contained in Annex 4.

(2) Tobacco products that contain any of the additives listed in Annex 4 may not be placed on the market.

(2a)¹⁵ Apart from the additives and foreign substances listed in Annex 4, placing on the market cigarettes and roll-your-own tobacco containing additives such as menthol or menthol derivatives is prohibited.

¹⁰ Established by Subsection (5) of Section 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

¹¹ Established by Subsection (6) of Section 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

¹² Established by Subsection (1) of Section 224 of Government Decree 379/2016 (XII. 2.). Amended by Paragraph a) of Subsection (9) of Section 8 of Government Decree 419/2016 (XII. 14.), Paragraph a) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

¹³ Amended by Paragraph a) of Section 21 of Government Decree 239/2016 (VIII. 16.), Paragraph b) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.).

¹⁴ Established by Section 3 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

¹⁵ Enacted by Section 1 of Government Decree 794/2021 (XII. 27.) Korm., effective as of 26 January 2022.

(3)¹⁶ The use of any novel additive in the manufacture of tobacco products shall be reported to the NNK six months before the date proposed for the commencement of use, at the latest 30 days before the proposed date of use by the user, registered trader, importer or authorized tax warehouse operator (hereinafter referred to collectively as “notifier”). The notification shall be made with the content specified in Annex 3. The NNK shall maintain an official register on the data reported, and shall publish it on its website. Use of the natural parts of raw tobacco need not be reported.

(4) The notification shall be accompanied by:

a) the license of use issued by any State that is a party to the Agreement on the European Economic Area, if available; and

b) a test report issued by an accredited laboratory on the findings of its examination.

(5)¹⁷ Upon receipt of the report, the NNK shall examine within thirty days from the date of receipt thereof as to whether the additive planned to be used is included in the list of prohibited additives contained in Annex 4, with the proviso that it shall acknowledge the report if the additive is not included in, and there is no reason to add it to, the list, and shall inform the notifier thereof. The NNK shall inform the minister in charge of consumer protection concerning the report. If the NNK fails to make a statement within thirty days, the reported additive may be used.

(6)¹⁸ The notifier shall send studies relating to the additives reported according to Subsection (3) to the NNK after two years following the date of commencement of use. Based on the documents submitted, the NNK shall examine within six months from the time of submission whether the additive in question should be admitted - relying on those documents - to the list prohibited additives under Annex 4.

(7)¹⁹ If the chief medical officer is of the opinion that the additive should be added to the list referred to in Annex 4, he shall prohibit further use of the additive and shall recommend to the minister in charge of the healthcare system to initiate legislative amendments for expanding the list of prohibited additives.

(8) The use of additives other than those registered, and the use of tobacco additives in derogation from the conditions registered is prohibited.

(9) Cigarettes released for free circulation must be in conformity with the safety requirements set out in MSZ EN 16156:2011.

(10) In the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located.

¹⁶ Established by Subsection (1) of Section 115 of Government Decree 360/2019 (XII. 30.) Korm., effective as of 1 January 2020.

¹⁷ Established by Subsection (2) of Section 115 of Government Decree 360/2019 (XII. 30.) Korm., effective as of 1 January 2020.

¹⁸ Amended by Paragraph i) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph c) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

¹⁹ Established by Section 21 of Government Decree 162/2018 (IX. 10.) Korm., effective as of 1 October 2018.

(11)²⁰ For the purposes of this Section, any additive that the manufacturer rightfully used before 20 August 2016 pursuant to legal authority or individual authorization for the production of tobacco products shall not be considered a novel additive and shall not be subject to the reporting obligation specified in Subsection (3), provided that it is not included in the list of prohibited additives contained in Annex 4.

Section 4/A²¹

(1) The placing on the market of tobacco products with a characterizing flavor is prohibited, except for the use of additives which are essential for the manufacture of tobacco products, for example sugar to replace sugar that is lost during the curing process, provided those additives do not result in a product with a characterizing flavor and do not increase to a significant or measurable degree the addictiveness, toxicity of the tobacco product, or its carcinogenic, mutagenic or toxic for reproduction properties (hereinafter referred to as “CMR properties”).

(2) The placing on the market of tobacco products containing flavorings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity is prohibited.

(3) Filters, papers and capsules shall not contain tobacco or nicotine.

(4) The placing on the market of tobacco products 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 is prohibited.

(5) Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in Subsections (1)-(3).

3. Limits

Section 5²²

(1) The maximum emission levels from cigarettes placed on the market shall not be greater than:²³

- a) 10 mg of tar per cigarette;
- b) 1 mg of nicotine per cigarette;
- c) 10 mg of carbon monoxide per cigarette.

(2) The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of MSZ ISO 4387 for tar, MSZ ISO 10315 for nicotine, and MSZ ISO 8454 for carbon monoxide.

²⁰ Enacted by Section 1 of Government Decree 244/2018 (XII. 13.) Korm., effective as of 14 December 2018.

²¹ Enacted by Section 4 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

²² Established by Section 5 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

²³ Amended by Paragraph b) of Subsection (10) of Section 8 of Government Decree 419/2016 (XII. 14.).

(3) The accuracy of the tar, nicotine and carbon monoxide measurements shall be determined in accordance with MSZ ISO 8243.

(4) The measurements referred to in Subsections (2) and (3) shall be verified by laboratories which are approved and monitored by the competent accreditation body. Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.

(5) The accreditation body shall communicate to the minister in charge of the healthcare system a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied within thirty days from the date of approval. Whenever any change is made in the data submitted, the accreditation body shall forthwith notify the minister in charge of the healthcare system.

(6) The minister in charge of the healthcare system shall communicate to the European Commission the information in his possession concerning the approved laboratories. The European Commission shall make the lists of approved laboratories publicly available.

4. Labeling

Section 6²⁴

(1) The unit packets of tobacco products shall indicate

a) the type of tobacco product as follows:

aa) “cigarette”,

ab) “cigar”,

ac) “cigarillo”,

ad) “roll-your-own tobacco”,

ae) “pipe tobacco”,

af) “chewing tobacco”,

ag) “nasal tobacco”,

ah) “waterpipe tobacco”;

b) brand name or trademark of the tobacco product;

c) the type under the brand name or trademark of the tobacco product, if available;

d) an indication of the manufacturer or distributor, and the name of the manufacturer or distributor as shown in the register of companies;

e) an indication of the tobacco products’ place of origin if originating from a place other than the European Economic Area;

f) in product units in the case of cigarettes, cigars and cigarillos, or weight in the case of smoking tobacco, chewing tobacco or nasal tobacco;

g) an indication if it has a filter (“füstsűrős” or “filteres”); and

h) the date of manufacture (day, month, year) and the place, or batch number or code from which the place and date of manufacture can be identified.

(2) In addition to health warnings, the outside packaging shall carry the indications provided for in Paragraphs *a)-f)* of Subsection (1) under the conditions applicable to unit packets.

(3) On transport packaging the indications provided for in Paragraphs *a)-f)* of Subsection (1) shall be used.

²⁴ Established by Section 6 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

(4) A unit packet of cigarettes may consist of carton or soft material and shall not have an opening that can be re-closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid. For packets with a flip-top lid and hinged lid, the lid shall be hinged only at the back of the unit packet. Unit packets of cigarettes shall have a cuboid shape.

(5) Unit packets of roll-your-own tobacco may either take the form of a rectangular pouch or a standing pouch.

(6) If a product can be used both via waterpipes and as roll-your-own tobacco, it shall be deemed to be roll-your-own tobacco.

(7) The unit packets of mentholated tobacco products shall carry the sign “mentol” (*menthol*).

Section 6/A²⁵

(1) Placing tobacco products for smoking on the market is allowed only if the following health warnings on all unit packets and outside packaging are irremovably printed in Hungarian, indelible and fully visible with a contrasting background,

a) the general warning “A dohányzás halált okoz - szokjon le most!” (*Smoking kills - quit now*) on one of the lateral surfaces, covering at least 50 per cent of the surface on which it is printed,

b) the information message “A dohányfüst több mint 70 rákkeltő anyagot tartalmaz.” (*Tobacco smoke contains over 70 substances known to cause cancer.*) on the other lateral surface, covering at least 50 per cent of the surface on which it is printed, and

c) on both main sides covering at least 65 per cent of the surface, a combined health warning selected by the manufacturer from among the options listed in Annex 5.

(2) The general warning defined in Paragraph a) of Subsection (1) must also be posted in commercial establishments selling tobacco products and in the service area of mobile vendors. The provisions contained in Subsection (1) shall apply mutatis mutandis to the display method of the warning, with the proviso that the provision regarding the minimum size of the warning shall not apply.

(3)²⁶ The text of the general warning installed as provided for in Subsection (2) shall also include the message “Segítség a leszokáshoz: (*Get help to stop smoking:*) 06 80 200 493, www.leteszemacigit.hu” covering at least 420 × 594 mm of the surface.

(4)²⁷ The health warnings shall in no way hide or interrupt the excise seals, price marks, tracking and tracing marks, or security features on unit packets.

(5)²⁸ The health warnings on a unit packet and any outside packaging must be irremovably printed and must be indelible, including not being partially or totally hidden or interrupted by excise seals, price marks, security features, wrappers, jackets, boxes, or other items, when tobacco products are placed on the market. On tobacco products other than cigarettes and roll-your-own tobacco in pouches, the texts and health warnings may be affixed by means of stickers, provided that such stickers are irremovable.

²⁵ Enacted by Section 7 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

²⁶ Amended by Section 37 of Government Decree 507/2017 (XII. 29.) Korm.

²⁷ Amended by Paragraph b) of Subsection (9) of Section 8 of Government Decree 419/2016 (XII. 14.).

²⁸ Amended by Paragraph c) of Subsection (9) of Section 8 of Government Decree 419/2016 (XII. 14.).

(6) Health warnings shall cover the entire surface of the unit packet or outside packaging that is reserved for them and they shall not be commented on, paraphrased or referred to in any form.

(7) The health warnings shall remain intact when opening the unit packet other than packets with a flip-top lid, where the health warnings may be split when opening the packet, but only in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.

(8) The general warning and the information message shall be printed in black Helvetica bold type on a white background. The warning shall be printed in lower-case type fonts, except for the first letter of the message and where required by grammar usage.

(9) Health warnings shall be surrounded by a black border of a width of 1 mm inside the surface area that is reserved for these warnings. This border shall in no way interfere with the text of the health warnings. General warnings and information messages shall be at the center of the surface reserved for them, whereas text warnings and combined health warnings shall be parallel to the lateral edge of the unit packet or of the outside packaging. General warnings and information messages on cuboid packets and any outside packaging - except for smoking tobacco pouches - shall be parallel to the lateral edge of the unit packet or of the outside packaging. The font size used shall be such as to ensure that the text of the health warning occupies the greatest possible proportion of the surface reserved for these health warnings.

(10) For cigarette packets and roll-your-own tobacco in outside packaging the general warning shall appear on the bottom part of one of the lateral surfaces of the packets and packages, and the information message shall appear on the bottom part of the other lateral surface. For cigarette packets and in the case of outside packaging the general warning and the information message shall have a width of not less than 20 mm, and shall be printed parallel to the lateral sides of the unit packets.

(11) For packets in the form of a shoulder box with a hinged lid that result in the lateral surfaces being split into two when the packet is open, the general warning and the information message shall appear in their entirety on the larger parts of those split surfaces. The general warning shall also appear on the inside of the top surface that is visible when the packet is open. The lateral surfaces of this type of packet shall have a height of not less than 16 mm.

(12) According to Commission Implementing Decision (EU) 2015/1735, for roll-your-own tobacco the general warning and the information message shall appear on the surfaces that ensure the full visibility of those health warnings.

(13) The dimensions of the health warnings shall be calculated in relation to the surface concerned when the packet is closed.

Section 6/B²⁹

(1)³⁰ The packaging of tobacco products defined in Paragraphs *a*) and *e*) of Point 3 of Section 2 may contain only the elements provided for in Sections 6 and 6/A, or as specified by law, and in the binding legislation of the European Union, with the proviso that the provisions of Sections 6 and 6/A shall apply subject to the exceptions specified in Subsections (2)-(12) hereof.

²⁹ Enacted by Section 7 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

³⁰ Established by Subsection (1) of Section 23 of Government Decree 349/2021 (VI. 22.) Korm., effective as of 3 July 2021.

(2) Cigarettes and roll-your-own tobacco may be placed on the market under the conditions set out in Subsections (3)-(12).

(3) As regards cigarettes and roll-your-own tobacco:

a) the external surfaces of each unit packet and each outside packaging shall be of PANTONE 448 M in FORMULA GUIDE/solid matte color chart, matte finish, packaging material matte white,

b) the inside surfaces of each unit packet and each outside packaging shall be matte white identical to the packaging material, except for the unit packet of roll-your-own tobacco, where the inside is transparent and uncoated,

c) the external surfaces of unit packets and outside packaging may not feature any decorative grooves, embossing or other decoration,

d) unit packets and outside packaging may not contain any color-coated or non-transparent adhesive,

e) unit packets and outside packaging may not contain any element or feature in derogation of the provisions set out in Section 6/A of the NSA, placed inside or attached to the packaging, and

f) as regards Paragraphs *b)* and *c)* of Subsection (1) of Section 6, the unit packet and/or the outside packaging may contain the following information only:

fa) the brand name, and

fb) the type of the cigarette, roll-your-own tobacco.

(4) The information referred to in Paragraph *f)* of Subsection (3) shall meet the following conditions:

a) color shall be PANTONE Cool Gray 1 M in FORMULA GUIDE/solid matte color chart,

b) the brand name and the type of the cigarette or roll-your-own tobacco must appear in a single row each,

c) the type of the cigarette or roll-your-own tobacco must appear directly below the brand name,

d) the brand name and the type of the cigarette or roll-your-own tobacco must be printed in Helvetica type font,

e) the font size of the brand name may be 14 pt at most,

f) the font size of the name of a specific type of cigarette or roll-your-own tobacco may be 10 pt at most,

g) each character shall be printed in lower-case type fonts, except for the first letter, and

h) the health warnings on a unit packet may not be hidden or interrupted by such texts.

(5) Each unit packet and outside packaging of cigarettes shall have the brand name referred to in Paragraph *f)* of Subsection (3) and the type of the given product printed on the packaging in compliance with the following conditions:

a) it shall be printed at the top of the principal display area on the front external surface, positioned in the center, directly below the health warning, and

b) it may appear on the front external surface, and/or at the top of the principal display area only once.

(6) Each unit packet and outside packaging of roll-your-own tobacco shall have the brand name referred to in Paragraph *f)* of Subsection (3) and the type of the given product printed on the packaging in compliance with the following conditions:

a) it shall be printed on the front and back external surface at the principal display areas, positioned in the center, directly below or next to the health warning, and

b) it may appear on both external surfaces at the principal display areas only once.

(7) If the unit packets of cigarettes contain a lining also, the lining:

a) shall be matte white or matte silver,

b) may not feature any decorative grooves, embossing or other decoration, except for any graining by the packaging machine over the entire surface for reasons other than decoration,

c) may not contain any color-coated or non-transparent adhesive, and

d) may not contain any element or feature in derogation of the provisions set out in Section 6/A of the NSA, attached to the packaging.

(8) The wrapper or any other form of outer packaging of cigarettes and roll-your-own tobacco, not regarded as outside packaging or transport packaging, shall be in conformity with the following conditions:

a) must be transparent;

b) may not be color-coated;

c) may not feature any decorative grooves, embossing or other decoration;

d) may not feature any marking or trademark, or any component other than a tear strip in compliance with specific regulations;

e) may not contain any color-coated or non-transparent adhesive; and

f) may not contain any element or feature in derogation of the provisions set out in Section 6/A of the NSA, attached to the packaging.

(9) The tear strip on the wrappers of cigarettes and roll-your-own tobacco shall be in conformity with the following conditions:

a) must be transparent;

b) may not feature any decorative grooves, embossing or other decoration;

c) may not display the brand name or any other marking;

d) may not contain any element or feature in derogation of the provisions set out in Section 6/A of the NSA, attached to the packaging;

e) may not contain any color-coated or non-transparent adhesive;

f) must be continuous and of the same width throughout; and

g) must be as close to the flip-top lid as possible, parallel to the flip-top lid.

(10) Subsections (1)-(9) shall not apply:

a) to health warnings,

b) to other elements prescribed by the NSA, and

*c)*³¹ to excise seals.

(11) By way of derogation from Subsections (1)-(10), the bar code or other technical feature installed for price marks, tracking and tracing marks may appear on the bottom part or one of the lateral surfaces of the unit packet, and on the outside packaging.

(12) The provisions set out in Subsections (1)-(11) shall apply to the packaging of cigarettes and roll-your-own tobacco planned to be sold in the territory of Hungary.

Section 6/C³²

(1) The cigarettes in a unit packet shall meet the following conditions:

a) the external surfaces may not feature any decorative grooves, embossing or other decoration,

b) may not contain any color-coated or non-transparent adhesive;

³¹ Established by Subsection (7) of Section 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

³² Enacted by Section 7 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

- c) may not contain any elements other than what is prescribed by the NSA;
- d) the paper in which the cigarettes are wrapped must be white; and
- e) the cigarettes shall have filters, with the proviso that
 - ea) the visible part of the filter shall be white, and
 - eb) the part of the cigarette paper overlapping the filter shall be either white or cork imitation.
- (2) The text printed on each cigarette in a unit packet may indicate:
 - a) the brand name; and
 - b) the type of the cigarette.
- (3) The text referred to in Subsection (2) shall be in conformity with the following conditions:
 - a) shall be of PANTONE 444 M color in FORMULA GUIDE/solid matte color chart;
 - b) the brand name and the type of the cigarette shall be positioned on the roll of tobacco as close as possible to the filter, printed in a concentric pattern;
 - c) the brand name and the type of the cigarette may be displayed once, both being in a single row;
 - d) the name of the cigarette must appear directly below the brand name;
 - e) each character shall be printed in lower-case type fonts, except for the first letter; and
 - f) the brand name and the type of the cigarette must be printed in Helvetica type font.

Section 6/D³³

- (1) In respect of tobacco products for smoking not regarded as tobacco products provided for in Paragraphs *a)*, *e)* and *g)* of Point 3 of Section 2, the provisions of Section 6/A shall apply subject to the exceptions specified in Subsections (2)-(10) hereof.
- (2) In respect of tobacco products for smoking not regarded as tobacco products provided for in Paragraphs *a)*, *e)* and *g)* of Point 3 of Section 2, of the health warnings provided for in Subsection (1) of Section 6/A:
 - a)³⁴ the general warning provided for in Paragraph *a)* of Subsection (1) of Section 6/A shall be displayed on the bottom part of one of the principal display areas, covering at least 30 per cent of the surface on which it is printed, with the following text: “A dohányzás halált okoz - szokjon le most! (*Smoking kills - quit now*) Segítség a leszokáshoz: (*Get help to stop smoking*) 06 80 200 493, www.leteszemacigit.hu”; and
 - b) the combined health warning provided for in Paragraph *c)* of Subsection (1) of Section 6/A shall be displayed on the bottom part of the other principal display area, covering at least 40 per cent of the surface on which it is printed.
- (3) As regards the combined health warnings referred to in Paragraph *b)* of Subsection (2), grouped into three sets as set out in Annex 5, each set shall be used in a given year and rotated on an annual basis in such a way as to guarantee their regular appearance.
- (4) The general warnings shall be surrounded by a black border of a width of not less than 3 millimeters and not more than 4 millimeters. This border shall appear outside the surface reserved for the general warnings.

³³ Established by Section 3 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

³⁴ Amended by Section 37 of Government Decree 507/2017 (XII. 29.) Korm.

(5) In respect of tobacco products for smoking not regarded as tobacco products provided for in Paragraphs *a)*, *e)* and *g)* of Point 3 of Section 2, the provisions of Subsection (8) of Section 6/A shall apply to the general warning referred to in Paragraph *a)* of Subsection (2) hereof.

(6) In respect of tobacco products for smoking not regarded as tobacco products provided for in Paragraphs *a)*, *e)* and *g)* of Point 3 of Section 2, the general warning referred to in Paragraph *a)* of Subsection (2) hereof shall be positioned in the center of the display area, whereas the combined health warning shall be parallel to the top edge of the unit packet. The display area may be positioned in a place other than the center of the lateral surface of the packet.

(7) The font size used for printing the health warnings provided for in Subsection (2) shall be such as to ensure that the text of the health warning occupies the greatest possible proportion of the surface reserved for these health warnings.

(8) In respect of tobacco products for smoking not regarded as tobacco products provided for in Paragraphs *a)*, *e)* and *g)* of Point 3 of Section 2, the provisions of Subsection (10) of Section 6/A and Subsection (2) of Section 7 shall not apply.

(9) In respect of tobacco products provided for in Paragraph *c)* of Point 3 of Section 2, the provisions of Subsection (11) of Section 6/A shall not apply.

(10) As regards the tobacco products provided for in Paragraph *f)* of Point 3 of Section 2, the general warning and the combined health warning - if printed in the principal display area on the back of the tobacco product - may appear at the top edge of the principal display area, positioned in the same direction as any other information appearing on that surface of the packaging.

Section 6/E³⁵

(1) Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning: “Ez a dohánytermék károsítja az Ön egészségét és függőségre vezet.” (*This tobacco product damages your health and is addictive.*)

(2) The health warnings referred to in Subsection (1) shall comply with the requirements specified in Subsections (9) and (10) of Section 6/A. The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings. In addition, it shall:

- a)* appear on the two largest surfaces of the unit packet and any outside packaging; and
- b)* cover 30 per cent of the surfaces of the unit packet and any outside packaging.

Section 6/F³⁶

(1) Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning printed on the front and back external surface of the unit packet and on any outside packaging: “E termék dohányzási célú fogyasztása károsítja egészségét.” (*Smoking this product damages your health.*)

(2) The health warning shall comply with the requirements set out in Subsections (9) and (10) of Section 6/A. It shall cover 30 per cent of the area of the corresponding surface of the unit packet and of any outside packaging.

³⁵ Enacted by Section 7 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

³⁶ Enacted by Section 7 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

(3) The labeling of unit packets and any outside packaging of herbal products for smoking shall not include any element or feature that:

a) promotes the product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the product;

b) suggests that a particular product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalizing, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits; or

c) refers to taste, smell, any flavorings or other additives or the absence thereof by way of means liable to mislead the consumer.

(4) In addition to what is contained in Subsection (3), unit packets and any outside packaging of herbal products for smoking shall not state that the product is free of additives or flavorings.

Section 6/G³⁷

(1) All unit packets of tobacco products shall be marked with a unique identifier. In order to ensure the integrity of the unique identifier, it shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through excise seals or price marks, and/or by the opening of the unit packet.

(2) The unique identifier shall allow the following to be determined:

a) the date and place of manufacturing;

b) the manufacturing facility;

c) the machine used to manufacture the tobacco products;

d) the production shift or time of manufacture;

e) the product description;

f) the intended market of retail sale;

g) the intended shipment route;

h) where applicable, the importer into the European Union;

i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure and consignee;

j) the identity of all purchasers from manufacturing to the first retail outlet; and

k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

(3) The information referred to in Paragraphs *a)*, *b)*, *c)*, *d)*, *e)*, *f)*, *g)* and, where applicable, *h)* of Subsection (2) shall form part of the unique identifier.

(4) The information mentioned in Paragraphs *i)*, *j)* and *k)* of Subsection (2) shall be electronically accessible by means of a link to the unique identifier.

(5) All economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, shall record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.

³⁷ Enacted by Section 12 of Government Decree 72/2018 (IV. 16.) Korm., effective as of 6 May 2018.

(6) All natural and legal persons engaged in the supply chain of tobacco products shall maintain complete and accurate records of all relevant transactions.

(7) The manufacturers of tobacco products shall provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility provided for in Subsection (8).

(8) Manufacturers and importers of tobacco products shall conclude data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant data. The data storage facility shall be physically located on the territory of the European Union. The suitability of the third party, in particular its independence and technical capacities, as well as the data storage contract, shall be approved by the European Commission.

(9) The activities of the third party provided for in Subsection (8) shall be monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the European Commission. The external auditor shall submit an annual report to the customs authority and to the European Commission, assessing in particular any irregularities in relation to access.

(10)³⁸ Full access to the data storage facilities shall be given to the customs authority, the Szabályozott Tevékenységek Felügyeleti Hatósága (*Supervisory Authority of Controlled Activities*), the European Commission and the external auditor. In duly justified cases the customs authority may grant manufacturers or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant legislation.

(11) Recorded data shall not be modified or deleted by an economic operator involved in the trade of tobacco products.

Section 6/H³⁹

(1) All unit packets of tobacco products, which are placed on the market, shall carry a tamper proof security feature, composed of visible and invisible elements that will facilitate the verification of whether or not tobacco products are authentic. The security feature shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through excise seals and price marks, or other elements imposed by legislation.

(2) The security feature referred to in Subsection (1) is contained in the excise seal provided for in the Excise Act.

Section 7⁴⁰

³⁸ Amended by Section 4 of Government Decree 500/2021 (VIII. 18.) Korm.

³⁹ Enacted by Section 12 of Government Decree 72/2018 (IV. 16.) Korm., effective as of 6 May 2018.

⁴⁰ Established by Section 8 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

(1)⁴¹ Tobacco products for smoking provided for in Paragraphs *a)*, *e)* and *g)* of Point 3 of Section 2 shall carry combined health warnings. The combined health warnings shall:

a) cover 65 per cent of both the external front and back surface of the unit packet and both the external front and back surface of any outside packaging;

b) show the same text warning and corresponding color photograph on both sides of the unit packets and any outside packaging, with the proviso that the text warning and corresponding color photograph printed on the unit packets contained in an outside packaging may differ from the text warning and corresponding color photograph displayed on that outside packaging;

c) appear at the top edge of a unit packet and any outside packaging, and be positioned in the same direction as any other information appearing on that surface of the packaging; and

d) for unit packets of cigarettes, respect the following dimensions:

da) height: not less than 44 mm,

db) width: not less than 52 mm.

(2) Brand names and - where applicable - logos may not appear above the combined health warnings even if the combined health warnings are not positioned at the top edge of a unit packet and any outside packaging by virtue of the variations permitted until 20 May 2019 under Subsection (13) of Section 21/A.

Section 8⁴²

(1) As regards the combined health warnings grouped into three sets as set out in Annex 5, each set shall be used in a given year and rotated on an annual basis for each tobacco product brand name in such a way as to guarantee their regular appearance.

(2) By tobacco product brand name, if production of a given product in a given year has been suspended, for the next batch manufactured combined warnings for the next set shall be used.

(3) In a given year, the combined health warnings of the set used in that year shall be used equally among the tobacco product brand names.

(4)⁴³ If technical requirements for complying with the provision set out in Subsection (3) are not provided for, the difference between the number of the most common combined health warnings and the number of the least common ones may not exceed 10 per cent in a calendar year for cigarettes, or 15 per cent for other tobacco products. In order to enable conformity with the obligation of rotated use of combined health warnings to be verified, importers, registered traders and authorized tax warehouse operators shall maintain records with facilities to allow access every three months to information as to the number of combined health warnings used.

Section 9⁴⁴

(1) The combined health warnings:

⁴¹ Established by Section 4 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

⁴² Established by Section 8 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁴³ Amended by Paragraph c) of Subsection (10) of Section 8 of Government Decree 419/2016 (XII. 14.).

⁴⁴ Established by Section 8 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

a) shall be printed on the packaging of tobacco products - having regard to Subsection (3) - respecting the format and proportions provided for in Annex 5 and the graphical integrity of the picture and the text;

b) shall occupy the entire area reserved for the health warning, and be positioned parallel to the top edge of the package, and in the same direction as the other information on the package; and

c) shall be reproduced in accordance with the technical specifications for printing set out in Annex 6.

(2) The combined health warnings shall not be commented on, paraphrased or referred to in any form on the tobacco package.

(3)⁴⁵ By way of derogation from Paragraph *a)* of Subsection (1), in respect of tobacco products where it is not possible to occupy the 40 per cent external area prescribed under Paragraph *b)* of Subsection (2) of Section 6/D by the combined health warning having regard to the dimensions of the individual packaging of such tobacco products without breaching the requirements provided for in Annex 5 as to format and proportions and the graphical integrity of the picture and the text, the combined health warning shall be displayed adjusted to the dimensions of the individual packaging, or the 40 per cent coverage ratio prescribed under Paragraph *b)* of Subsection (2) of Section 6/D, in accordance with the specifications set out in Point 2 of Annex 6.

(4)⁴⁶ In order to facilitate the application of Subsection (3), the minister in charge of consumer protection shall publish on his website the guidelines adopted by the European Commission on the subject.

(5) The combined health warnings shall:

a) be printed in a manner that ensures that it is in no way hidden or interrupted by the opening of the packet; and

b) be displayed in a manner that ensures that none of the textual or visual elements of the combined warnings will be severed when the package is opened.

(6)⁴⁷ Upon request the NNK shall electronically make available the electronic source documents for printing combined health warnings to manufacturers of tobacco products.

*Section 10*⁴⁸

*Section 11*⁴⁹

(1) Areas and spaces where smoking is prohibited and designated smoking areas, premises, public places and non-smoking institutions shall be clearly marked as such by means of a symbol

⁴⁵ Established by Section 5 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

⁴⁶ Amended by Paragraph *b)* of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.).

⁴⁷ Amended by Paragraph *j)* of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph *d)* of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

⁴⁸ Repealed by Paragraph *b)* of Section 21 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁴⁹ Established by Section 10 of Government Decree 169/2014 (VII. 18.), effective as of 19 July 2014.

or other explicit sign with the mandatory contents and form shown in Annex 7. The symbol or sign shall be at least size A/4. The words “DOHÁNYZÁSRA KIJELÖLT HELY” (*DESIGNATED SMOKING AREA*) or “TILOS A DOHÁNYZÁS” (*NO SMOKING*) on the symbol or sign shall be printed in red Helvetica bold type, font size at least 30 pt, other texts shall be printed in Helvetica bold type, font size at least 18 pt.

(1a)⁵⁰ The symbol or sign provided for in Subsection (1) shall also be understood to restrict the use of electronic cigarettes and electronic devices imitating smoking, and apply to the smoking areas, premises, public places designated for the use thereof.

(2)⁵¹ Upon request, the district (Budapest district) office acting in public health supervisory capacity shall authorize the applicant to use symbols or signs derogating from the requirements set out in Subsection (1) hereof and Annex 7:⁵²

a) if the number of signs to be used by the applicant in accordance with Subsection (2) of Section 2 of the NSA and Subsection (1) hereof exceeds ten;

b) if using symbols or signs which conform to the requirements set out in Subsection (1) hereof and Annex 7 is likely to entail unreasonable difficulties upon the applicant due to technical or economic reasons, and the form proposed by the applicant serves the applicant’s interest within reason;

c) the symbol or sign proposed by the applicant contains the same data and information as laid down in Annex 7, and no data or information has been left out;

d) the proposed symbol or sign is at least 62,370 square millimeters; and

e) the fonts used are in compliance with the font size requirements set out in Subsection (1).

(3) The application for the authorization provided for in Subsection (2) shall have enclosed the graphics design of the proposed symbol or sign, and a detailed description of its planned location.

(4)⁵³ The district (Budapest district) office acting in public health supervisory capacity shall keep a register on the applicants referred to in Subsection (2), and shall send a list of the applicants and the authorizations granted to the NNK by way of electronic means on a yearly basis, by 31 March each year.

5. Provisions on Healthcare Penalty

Section 12

⁵⁰ Enacted by Section 50 of Government Decree 413/2015 (XII. 23.), effective as of 20 May 2016.

⁵¹ Amended by Paragraph c) of Section 20 of Government Decree 239/2016 (VIII. 16.).

⁵² Amended by Paragraph l) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph a) of Subsection (2) of Section 15 of Government Decree 171/2017 (VI. 29.) Korm.

⁵³ Enacted by Section 9 of Government Decree 239/2016 (VIII. 16.). Amended by Paragraphs k)-l) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph a) of Subsection (2) of Section 15 of Government Decree 171/2017 (VI. 29.) Korm., Paragraph d) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

(1)⁵⁴ Healthcare penalties are payable to the account specified in Annex 8 of the Budapest and county government agency acting in public health supervisory capacity that levied the penalty.

(1a)⁵⁵ The amount of the healthcare penalty:

a) in the event of any breach of the prohibitions or restrictions with regard to smoking is between 20,000 and 50,000 forints;

b) in the event of non-compliance with the obligation regarding the designation of smoking areas, or any infringement of the supervisory obligation with regard to the enforcement of prohibitions and restrictions concerning smoking, or in the absence of a symbol or other explicit sign in areas and spaces where smoking is prohibited, and areas, premises and public places designated for smoking, of if the symbol or sign used is inadequate or unclear, or not visible:

ba) is between 100,000 and 250,000 forints if imposed upon the person held liable to fulfill these obligation, or

bb) between 1,000,000 and 2,500,000 forints if imposed upon an institution, organization, operator or business association.

(1b)⁵⁶ The healthcare penalty shall be determined in such a way that it conforms to the gravity of the act and the circumstances of the person concerned. In the case of Paragraph *a)* of Subsection (1a) - by way of derogation from the amount limit specified therein - the competent authority may impose an instant healthcare penalty upon the perpetrator of up to 30,000 forints. In the event of non-payment of the instant penalty within thirty days the provisions of Subsection (1a) shall apply.

(2)⁵⁷ The Budapest and county government agency acting in public health supervisory capacity and the district (Budapest district) office acting in public health supervisory capacity shall keep records on the amount of healthcare penalties they have imposed in a given month in accordance with the NSA. The Budapest and county government agency acting in public health supervisory capacity shall inform the NNK concerning the data compilations of those records in a manner so as not to allow the identification of specific individuals by way of electronic means, by the 20th of the month following the reference month.

(3)⁵⁸ By way of derogation from Subsections (1) and (2), if the body vested with powers in the first instance in public health and epidemiological matters under the Government Decree on the Delegation of Specific Agencies for Carrying Out the Public Health and Epidemiological Responsibilities of Business Associations Over Which any Law Enforcement Agency, the Hungarian Armed Forces, the Military Intelligence Service, the Parliament Guard or the Minister in Charge of Defense is Entitled to Exercise Ownership Rights functions as the government body in charge of the healthcare system:

⁵⁴ Amended by Paragraph a) of Subsection (2) of Section 220 of Government Decree 70/2015 (III. 30.).

⁵⁵ Enacted by Section 28 of Government Decree 464/2016 (XII. 23.), effective as of 1 May 2017.

⁵⁶ Enacted by Section 28 of Government Decree 464/2016 (XII. 23.), effective as of 1 May 2017.

⁵⁷ Established by Subsection (1) of Section 220 of Government Decree 70/2015 (III. 30.). Amended by Paragraph m) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph b) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

⁵⁸ Enacted by Section 11 of Government Decree 169/2014 (VII. 18.), effective as of 19 July 2014.

a) the healthcare penalty shall be payable to the body provided for in Annex 8/A, to the designated centralized clearing account therein specified,

b) the obligation of keeping records and the duty to provide information under Subsection (2) shall be discharged by the body vested with powers in the first instance in public health and epidemiological matters.

(4)⁵⁹ Operating the 06 80 200 493 phone line and the website at www.leteszemacigit.hu for receiving notices and comments from the general public in terms of compliance with the provisions of the NSA - which are indicated also in places provided for in Annexes 5 and 7, and in Subsection (3) of Section 6 of the NSA - and processing the information thus received falls within the competence of the ministry of the minister in charge of the healthcare system.

6. Requirements for placing tobacco products on the market

Section 13

(1) Tobacco products may be released for free circulation or placed on the market only if they are in compliance with the provisions set out in this Decree and are in conformity with the data shown on the registration form.

(2) Tobacco for oral use may not be released for free circulation or placed on the market.

(3)⁶⁰ In connection with the manufacture of tobacco products, or in the process of, or in connection with, placing them on the market any product, in particular additional packaging, box or pouch which are capable to obscure the excise seals, or the health warnings or combined warnings may not be used.

Section 14

The conditions of storage deemed necessary to preserve the quality of tobacco products shall be ensured throughout all stages of placing them on the market. Crates used as part of the transport packaging must be kept on a pallet of a minimum height of 10 centimeters for ensuring the free flow of air. The distributor shall check the storage conditions and the impact such conditions may have on the quality of tobacco products on a regular basis.

Section 15

Tobacco products - with the exception of the ones sold by the piece - shall be placed on the market in the original retail unit packet or outside packaging. In the process of placing tobacco products on the market they may not be re-packaged, except for the opening of outside packaging for the purpose of accessing retail unit packets. Retail unit packets shall not be opened.

⁵⁹ Enacted by Section 10 of Government Decree 239/2016 (VIII. 16.). Amended by Paragraph n) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Section 37 of Government Decree 507/2017 (XII. 29.) Korm., Paragraph c) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm., Section 1 of Government Decree 300/2018 (XII. 27.) Korm.

⁶⁰ Amended by Paragraph d) of Subsection (9) of Section 8 of Government Decree 419/2016 (XII. 14.).

Section 15/A⁶¹

A unit packet means:

- a)* in the case of cigarettes, a pack that contains at least 20 and not more than 25 cigarettes;
- b)* in the case of Subparagraph *ba)* of Paragraph *b)* of Point 3 of Section 2 and Subparagraph *bb)* of Paragraph *b)* of Point 3 of Section 2:
 - ba)* a piece or a box in respect of cigars other than cigarillos,
 - bb)* regarding cigarillos, a box containing at least five pieces;
 - c)* regarding smoking tobacco, is the rectangular pouch or standing pouch containing not less than 30 grams and not more than 50 grams, where the net weight expressed in grams must be exactly divisible by ten in all cases;
 - d)* in the case of chewing or nasal tobacco, a pouch or box.

7. Exporting tobacco products

Section 16

Tobacco products manufactured in Hungary for export or for sale in other Member States of the European Union shall meet the requirements set out in Section 5.

8. Market surveillance in respect of tobacco products, electronic cigarettes, refill liquids and electronic devices imitating smoking⁶²

Section 17

- (1) The provisions of this Decree shall be enforced:
- a)*⁶³ by the NNK having regard to the notification referred to in Section 4;
 - b)*⁶⁴ by the district (Budapest district) office acting in public health supervisory capacity having regard to Section 11;
 - c)* by the consumer protection authority having regard to the provisions not mentioned in Paragraphs *a)* and *b)*, and shall take action within its vested competence in the event of any infringement of the provisions of this Decree.

⁶¹ Enacted by Section 11 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁶² Established by Section 12 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁶³ Amended by Paragraph d) of Section 20 of Government Decree 239/2016 (VIII. 16.), Paragraph h) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Subsection (3) of Section 115 of Government Decree 360/2019 (XII. 30.) Korm.

⁶⁴ Amended by Paragraph b) of Subsection (2) of Section 220 of Government Decree 70/2015 (III. 30.).

(2)⁶⁵ Responsibility for the compliance of tobacco products with the data contained in the registration form lies with the importers, registered traders and authorized tax warehouse operators. Importers, registered traders and authorized tax warehouse operators may carry out the requisite tests in their own laboratory, or in other laboratories designated by the chief medical officer for that purpose.

(3) Tar, nicotine and carbon monoxide emission levels of cigarettes shall be examined and certified by the consumer protection authority. The costs of testing and for issuing the certificate shall be covered by the manufacturer, importer or registered trader who requested the certificate.

(4)⁶⁶ The minister in charge of consumer protection shall report annually to the minister in charge of the healthcare system, the minister in charge of the agricultural sector and the minister in charge of supervising the food supply chain the tar, nicotine and carbon monoxide emission levels of tobacco products measured as provided for in Subsection (3).

(5)⁶⁷ The tar, nicotine and carbon monoxide emission levels of cigarettes may be measured and certified by any laboratory accredited by the competent authority of any State that is a party to the Agreement on the European Economic Area. Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.

(6) For the purposes and in the application of this Decree, the standards listed in Annex 9 shall apply.

(7)⁶⁸ In the case of cigarettes, conformity of the data indicated on the registration form relating to smoke shall be verified according to MSZ ISO 8243 standard.

9. Disclosure of data

Section 18⁶⁹

(1) The manufacturers and importers of tobacco products, before placing them on the market, shall submit through the common entry gate provided for in Commission Implementing Decision (EU) 2015/2186 the following information by brand name and type, in Hungarian or English:

a) a list of all ingredients in descending order of the weight of each ingredient included in the tobacco products; and

b) the emission levels of tobacco products referred to in Subsection (1) of Section 5, and information on other emissions and their levels.

⁶⁵ Amended by Paragraph e) of Section 20 of Government Decree 239/2016 (VIII. 16.), Paragraph a) of Subsection (9) of Section 8, Paragraph d) of Subsection (10) of Section 8 of Government Decree 419/2016 (XII. 14.).

⁶⁶ Established by Subsection (3) of Section 224 of Government Decree 379/2016 (XII. 2.).

⁶⁷ Established by Subsection (1) of Section 13 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁶⁸ Established by Subsection (2) of Section 13 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁶⁹ Established by Section 14 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

(2) The manufacturers and importers of tobacco products, before placing them on the market, shall submit - by 31 March each year - through the common entry gate provided for in Commission Implementing Decision (EU) 2015/2186 information on the sales volumes of tobacco products by brand name and type, in Hungarian or English. The reference year begins on 1 January and ends on 31 December of the year preceding the date when the lists are submitted.

(3) The information specified in Subsection (1) shall be re-submitted before placing the products on the market if the composition of a product is modified in a way that affects the information submitted.

(4)⁷⁰ The information submitted as provided for in Paragraph *a*) of Subsection (1) shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in the tobacco products concerned, and shall also indicate the status of the ingredients, including whether they have been registered, as well as their classification. The list shall also be accompanied by the toxicological data available to the importer, registered trader or authorized tax warehouse operator regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on human health and taking into account, inter alia, any addictive effects. In the case of cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties, shall be submitted by the manufacturer or importer.

(5) Other than for tar, nicotine and carbon monoxide, manufacturers and importers shall indicate the methods of measurement of emissions used. Manufacturers and importers are required to carry out studies prescribed by the minister in charge of consumer protection in order to assess the effects of ingredients on health, taking into account, inter alia, their addictiveness and toxicity.

(6) In the interest of reporting and making available information on tobacco products publicly, manufacturers and importers are required to submit by 31 March each year internal and external studies available to them on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys they carry out when launching new products. All data and information shall be provided in electronic form, through the common entry gate. The information shall be provided in Hungarian or English.

(7)⁷¹ The minister in charge of the agricultural sector shall make publicly available the information uploaded through the common entry gate by 30 April each year, through the website of his ministry, taking the need to protect trade secrets duly into account, and shall send it to the minister in charge of the healthcare system and the NNK by way of electronic means.

Section 18/A⁷²

(1) In addition to the reporting obligations laid down in Subsection (1) of Section 18, manufacturers and importers are under enhanced reporting obligations with respect to certain additives contained in the priority list provided for in the implementing regulation adopted by the European Commission.

⁷⁰ Amended by Paragraph e) of Subsection (10) of Section 8 of Government Decree 419/2016 (XII. 14.).

⁷¹ Amended by Paragraph a) of Subsection (6) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph e) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

⁷² Enacted by Section 15 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

(2) In the context of the reporting obligation provided for in Subsection (1), manufacturers and importers of tobacco products are required to carry out comprehensive studies, which shall examine for each additive whether it:

a) contributes to the toxicity or addictiveness of the products concerned, and whether this has the effect of increasing the toxicity or addictiveness of any of the products concerned to a significant or measurable degree;

b) results in a characterizing flavor;

c) facilitates inhalation or nicotine uptake; or

d) leads to the formation of substances that have CMR properties, including the quantities thereof, and whether this has the effect of increasing the CMR properties in any of the products concerned to a significant or measurable degree.

(3) The studies referred to in Subsection (2) shall take into account the intended use of the products concerned and examine in particular the emissions resulting from the combustion process involving the additive concerned. The studies shall also examine the interaction of that additive with other ingredients contained in the products concerned. Manufacturers or importers using the same additive in their tobacco products may carry out a joint study when using that additive in a comparable product composition.

(4)⁷³ Manufacturers or importers shall establish a report on the results of the studies performed according to Subsections (2) and (3). That report shall include an executive summary, and a comprehensive overview compiling the available scientific literature on that additive and summarizing internal data on the effects of the additive. Manufacturers or importers shall submit these reports to the European Commission and a copy thereof to the NNK at the latest eighteen months after the additive concerned has been included in the priority list.

(5)⁷⁴ The European Commission and the NNK may also request supplementary information from manufacturers or importers regarding the additive concerned. This supplementary information shall form part of the report.

Section 18/B⁷⁵

(1)⁷⁶ Manufacturers, importers and registered traders of tobacco products shall submit a notification of any novel tobacco product they intend to place on the market. The notification shall be submitted to the minister in charge of the agricultural sector, the minister in charge of supervising the food supply chain, the minister in charge of the healthcare system and the NNK in electronic form six months before the intended placing on the market. The notification shall be accompanied by a detailed description of the novel tobacco product concerned as well as

⁷³ Amended by Paragraph o) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph f) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

⁷⁴ Amended by Paragraph j) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph d) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

⁷⁵ Enacted by Section 15 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁷⁶ Amended by Paragraph b) of Subsection (6) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph e) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

instructions for its use and information on ingredients and emissions subject to data content requirements provided for in Commission Implementing Decision (EU) 2015/2186.

(2) The manufacturers, importers and registered traders of tobacco products submitting a notification of a novel tobacco product shall also provide the authorities referred to in Subsection (1) with:

a) available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product;

b) available studies, executive summaries thereof and market research on the preferences of various consumer groups, including young people and current smokers; and

c) other available and relevant information, including a risk/benefit analysis of the product, its expected effects on cessation of tobacco consumption, its expected effects on initiation of tobacco consumption and predicted consumer perception.

(3) Manufacturers, importers and registered traders of novel tobacco products are required to transmit to the authorities referred to in Subsection (1) any new or updated information on the studies, research and other information referred to in Paragraphs *a)*-*c)* of Subsection (2). Manufacturers, importers and registered traders of novel tobacco products may be required to carry out additional tests or submit additional information.

(4)⁷⁷ Based on the data and information submitted, the NNK shall consider whether or not the product in question should be prohibited.

(5) The minister in charge of the agricultural sector shall make all information received pursuant to this Section available to the European Commission.

Section 18/C⁷⁸

(1) Manufacturers and importers of herbal products for smoking are required to submit to the minister in charge of the agricultural sector a list of all ingredients, and quantities thereof that are used in the manufacture of such products by brand name and type. Manufacturers or importers shall also inform the minister in charge of the agricultural sector when the composition of a product is modified in a way that affects the information submitted pursuant to this Section. The information aforementioned shall be submitted six months prior to the placing on the market of a new or modified herbal product for smoking.

(2)⁷⁹ The information submitted as required under Subsection (1) shall be made publicly available on the website of the ministry of the minister in charge of the agricultural sector, and the minister in charge of the agricultural sector shall send such information to the minister in charge of the healthcare system and the NNK. In making such information publicly available, it shall be ensured that due account is taken of trade secrets so specified by the economic entity.

⁷⁷ Amended by Paragraph j) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph d) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

⁷⁸ Enacted by Section 15 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁷⁹ Amended by Paragraph a) of Subsection (6) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph e) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

Section 18/D⁸⁰

Manufacturers and importers of tobacco and related products are required to provide complete and correct information within the time limits set out in Subsection (1) of Section 18/B. The obligation to provide the requested information shall lie primarily with the manufacturer, if the manufacturer is established in any Member State of the European Union. The obligation to provide the requested information shall lie primarily with the importer, if the manufacturer is established outside the European Union and the importer is established in any Member State of the European Union. The obligation to provide the requested information shall lie jointly with the manufacturer and the importer if both are established outside the European Union.

Section 19⁸¹

(1)⁸² The minister in charge of the agricultural sector and the minister in charge of supervising the food supply chain shall make publicly available the information they received with a view to informing consumers and in so doing shall take account of any information which constitutes a trade secret through the website of their respective ministry on a yearly basis, and shall keep the minister in charge of the healthcare system, the minister in charge of industrial production and the minister in charge of consumer protection informed.

(2) The minister in charge of the agricultural sector and the minister in charge of supervising the food supply chain shall make the information provided for in Subsection (1) available to the European Commission on a yearly basis.

9/A.⁸³ Provisions applicable to electronic cigarettes, electronic devices imitating smoking and refill containers

Section 19/A⁸⁴

(1) The notification referred to in Subsection (1) of Section 7/D of the NSA shall be submitted to the Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (*National Pharmaceutical and Food Health Institute*) (hereinafter referred to as “OGYÉI”) through the common entry gate provided for in Commission Implementing Decision (EU) 2015/2183, in Hungarian or English, subject to data content requirements provided for in Commission Implementing Decision (EU) 2015/2183.

(2) The notification referred to in Subsection (1) shall contain the following information:

a) the name and contact details of the manufacturer, importer;

⁸⁰ Enacted by Section 15 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁸¹ Established by Section 716 of Government Decree 221/2014 (IX. 4.), effective as of 5 September 2014.

⁸² Amended by Paragraph f) of Section 20 of Government Decree 239/2016 (VIII. 16.).

⁸³ Established by Section 16 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁸⁴ Established by Section 16 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

b) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;

c) toxicological data regarding the product's ingredients and emissions, primarily their effects on the health of consumers when inhaled and taking into account any addictive effect they may have;

d) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;

e) a description of the components of the product, including the opening and refill mechanism of the electronic cigarette or refill containers;

f) a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements set out in the relevant legislation; and

g) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

(3) When any change is made in the product affecting the information referred to in Subsection (2) a new notification shall be submitted.

(4) In the case of electronic devices imitating smoking the notification shall be submitted through the common entry gate provided for in Commission Implementing Decision (EU) 2015/2183, subject to data content requirements provided for in Paragraphs *a)*-*c)* and *e)*-*g)* of Subsection (2).

Section 19/B⁸⁵

(1) Electronic cigarettes and refill containers may be placed on the market and distributed only if the following conditions are met:

a) it may not contain any flavorings;

*b)*⁸⁶ nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges filled with nicotine-containing liquid and that the cartridges or tanks do not exceed a volume of 2 ml;

c) the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml;

d) the nicotine-containing liquid does not contain:

da) additives listed in Annex 4,

db) vitamins or other additives that create the impression that a product has a health benefit or presents reduced health risks,

dc) caffeine or taurine or other additives and stimulant compounds that are associated with perceived energy and vitality,

dd) additives having coloring properties for emissions,

de) additives that facilitate inhalation or nicotine uptake, and

df) additives that have CMR properties;

e) the nicotine-containing liquid does not contain an ingredient with more than 0.1 per cent contaminants;

⁸⁵ Established by Section 16 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁸⁶ Established by Subsection (1) of Section 6 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

f) substances other than the ingredients referred to in Paragraph *b*) of Subsection (2) of Section 19/A are only present in the nicotine-containing liquid in trace levels, and may be used only if such traces are technically unavoidable during manufacture;

g) except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form;

h) electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;

i) electronic cigarettes and refill containers are child-proof; and

j) electronic cigarettes and refill containers are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

(2) Unit packets of electronic cigarettes and refill containers shall include a leaflet with information on:

a) instructions for use and storage of the product - including appropriate instructions for refilling, and diagrams -, including a reference that the product is not recommended for use by young people and non-smokers;

b) contra-indications;

c) warnings for specific risk groups;

d) possible adverse effects;

e) addictiveness and toxicity; and

f) contact details of the manufacturer or importer and a contact person.

(3) Unit packets and any outside packaging of electronic cigarettes and refill containers shall include:

a) a list of all ingredients contained in the product in descending order of the weight;

b) an indication of the nicotine content of the product and the delivery per dose;

c) the batch number; and

d) the warning: “A termék gyermekektől elzárva tartandó.” (*Keep out of reach of children.*)

(4) Unit packets and any outside packaging of electronic cigarettes and refill containers shall comply with the requirements set out in Paragraphs *b*), *d*) and *e*) of Subsection (1) of Section 6/A of the NSA and in Subsections (2) and (3) hereof.

(5)⁸⁷ Electronic cigarettes filled with nicotine-containing refill liquids and refill containers shall contain the following health warning, printed on the two largest surfaces of the unit packet and any outside packaging, covering at least 30 per cent of those surfaces: “Ez a termék nikotint tartalmaz, amely erős függőséget okozó anyag.” (*This product contains nicotine which is a highly addictive substance.*)

(6) The health warning provided for in Subsection (5) shall be printed in black Helvetica bold type on a white background. The warning shall be printed in lower-case type fonts, except for the first letter of the message and where required by grammar usage. Health warnings shall be at the center of the surface reserved for them, parallel to the lateral edge of the unit packet or of the outside packaging.

(7) The OGYÉI shall provide a certificate verifying compliance with the notification requirement, and the conformity of the product with Sections 19/A and 19/B within sixty days after the time of notification.

⁸⁷ Established by Subsection (2) of Section 6 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

Section 19/C⁸⁸

(1) Electronic devices imitating smoking may be placed on the market and distributed only if the following conditions are met:

- a) the liquid used in electronic devices imitating smoking may not contain nicotine;
- b) the liquid used in electronic devices imitating smoking may not contain flavorings;
- c) the liquid used in electronic devices imitating smoking may not contain:
 - ca) additives listed in Annex 4,
 - cb) vitamins or other additives that create the impression that the product has a health benefit or presents reduced health risks,
 - cc) caffeine or taurine or other additives and stimulant compounds that are associated with perceived energy and vitality,
 - cd) additives having coloring properties for emissions,
 - ce) additives that facilitate inhalation, and
 - cf) additives that have CMR properties;
- d) the liquid used in electronic devices imitating smoking may not contain an ingredient with more than 0.1 per cent contaminants;
- e) only ingredients are used in the electronic device imitating smoking that do not pose a risk to human health in heated or unheated form;
- f) electronic device imitating smoking are child-proof; and
- g) electronic devices imitating smoking are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

(2) Unit packets of electronic devices imitating smoking shall include a leaflet with information specified in Subsection (2) of Section 19/B.

(3) Unit packets and any outside packaging of electronic devices imitating smoking shall include:

- a) a list of all ingredients contained in the product in descending order of the weight;
- b) the batch number; and
- c) the warning: “A termék gyermekektől elzárva tartandó.” (*Keep out of reach of children.*)

(4) Unit packets and any outside packaging of electronic devices imitating smoking shall comply with the requirements set out in Paragraphs b), d) and e) of Subsection (1) of Section 6/A of the NSA and in Subsections (2) and (3) hereof.

(5) Electronic devices imitating smoking shall contain - in accordance with Subsection (6) of Section 19/B - the following health warning, printed on the two largest surfaces of the unit packet and any outside packaging, covering at least 30 per cent of those surfaces: “Ez a termék dohányzást imitáló elektronikus eszköz. Használata gyermekek számára nem ajánlott.” (*This product is an electronic device imitating smoking. It is not recommended for use by children.*)

Section 19/D⁸⁹

(1) Manufacturers and importers of electronic cigarettes, electronic devices imitating smoking and refill containers are required to submit, annually, through the common entry gate, by 31 March of the year following the given year:

⁸⁸ Established by Section 16 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁸⁹ Enacted by Section 16 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

a) data on sales volumes, by brand name and type of the product;
b) information on the preferences of various consumer groups, including young people, non-smokers and the main types of smokers;
c) the mode of sale of the products; and
d) executive summaries of any market surveys carried out in respect of Paragraphs a)-c), including an English translation thereof;
with the proviso that the reference year begins on 1 January and ends on 31 December of the year preceding the date when the lists are submitted.

(2) The OGYÉI may request information about the data provided for in Subsection (1) also from the authorities of other countries, and may comply with the requests of the authorities of other countries for information received from manufacturers or importers. Information classified as trade secret may not be made available to the authorities of countries who are not members of the European Union.

(3)⁹⁰ The OGYÉI shall send data referred to in Subsections (1) and (2) to the NNK.

(4)⁹¹ The OGYÉI shall analyze on an annual basis the data and information received according to Subsection (1) and shall send such analysis to the minister in charge of the healthcare system by 31 May each year. The ministry of the minister in charge of the healthcare system shall examine the data thus received and shall assess whether the use of electronic cigarettes, electronic devices imitating smoking and refill containers should be considered as a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers.

(5) The OGYÉI shall make the information received pursuant to Subsection (1) and the report referred to in Subsection (4) made publicly available on its website taking the need to protect trade secrets duly into account.

Section 19/E⁹²

(1) Manufacturers, importers and distributors of electronic cigarettes and refill containers are required to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products.

(2) Should any of these manufacturers, importers and distributors consider or have reason to believe that products, which are in their possession and are intended to be placed on the market or are placed on the market, are not safe or are not of good quality or are otherwise not in conformity with the relevant legislation, it shall immediately take the corrective action necessary to bring the product concerned into conformity with the relevant legislation, to withdraw or to recall it, as appropriate. The manufacturer, importer or distributor of the product shall be required to immediately inform the market surveillance authorities of the Member States in which the product is made available or is intended to be made available, giving details, in particular, of the risk to

⁹⁰ Amended by Paragraph k) of Subsection (5) of Section 224 of Government Decree 379/2016 (XII. 2.), Paragraph d) of Section 22 of Government Decree 162/2018 (IX. 10.) Korm.

⁹¹ Established by Subsection (4) of Section 224 of Government Decree 379/2016 (XII. 2.), effective as of 1 April 2017.

⁹² Enacted by Section 16 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

human health and safety and of any corrective action taken, and of the results of such corrective action.

10. Closing provisions

Section 20

(1) This Decree shall enter into force on 1 March 2013.

(2) Any symbol or sign installed in accordance with the NSA before the date of this Decree entering into force which, however, fails to comply with the requirements set out in Section 11 and Annex 7, shall be corrected to comply with the requirements set out in Section 11 and Annex 7 or replaced within twelve months from the date of this Decree entering into force.

(3)⁹³

Section 21

The provisions of Sections 2 and 4 implementing measures of a technical nature shall not apply - apart from the provisions of Point 6 of Section 2 on retail unit packets - to tobacco products that were manufactured in or placed on the market of any Member State of the European Union or Turkey, or that have been manufactured in any EFTA Member State that is a party to the Agreement on the European Economic Area in compliance with the relevant national laws, provided that these national laws afford equal or better protection than what is contained in this Decree in terms of health protection.

Section 21/A⁹⁴

(1)⁹⁵ Unless otherwise provided for by Subsections (3)-(6), tobacco products in conformity with the provisions in force on 19 May 2016:

a) may be manufactured and imported, and received by registered traders until 31 December 2016,

b) may be deposited into the warehouse of a retail supplier of tobacco products until 28 February 2017,

c) may be placed on the market until 20 May 2017.

(2) Herbal products for smoking manufactured or released for free circulation before 20 May 2016 may be placed on the market until 20 May 2017 in accordance with the provisions of this Decree in force on 19 August 2016.

⁹³ Repealed by Paragraph c) of Section 21 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁹⁴ Enacted by Section 17 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

⁹⁵ Established by Subsection (1) of Section 7 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

(3)⁹⁶ Sections 6/B and 6/C, as established by Government Decree 239/2016 (VIII. 16.) on the Amendment of Government Decree 39/2013 (II. 14.) on the Production, Placing on the Market and Control of Tobacco Products, on Combined Warnings, and the Detailed Provisions on the Application of Healthcare Penalties (hereinafter referred to as “Amending Decree”), shall not apply until 31 December 2021 to tobacco products that were registered on or before 30 April 2016 by the Nemzeti Fogyasztóvédelmi Hatóság (*National Consumer Protection Authority*) or the ND Nemzeti Dohánykereskedelmi Nonprofit Zrt. (*ND National Tobacco Nonprofit Company*) subject to data content requirements provided for in Annex 1, and if containing changes only to the extent required for compliance with the Excise Act, the NSA and this Decree (hereinafter referred to collectively as “directive transposition regulations”) entered into force after 19 May 2016. After 1 January 2022, these products may be placed on the market only in retail unit packets in conformity with Sections 6/B and 6/C as established by the Amending Decree.

(4)⁹⁷ The provisions of Sections 6/B and 6/C, as established by the Amending Decree:

a) shall apply to new brands and new types registered after 30 April 2016 and placed on the market after 19 August 2016 without delay,

b) shall apply to new brands and new types registered after 30 April 2016 and placed on the market before 20 August 2016 - other than the product provided for in Subparagraph *cb*) of Paragraph *c*) hereof - after 19 August 2016 where the retail unit packets on the market must be brought into conformity with Sections 6/B and 6/C as established by the Amending Decree at the latest by 20 May 2018,

c) shall immediately apply

ca) to tobacco products that were registered on or before 30 April 2016 by the Nemzeti Fogyasztóvédelmi Hatóság or the ND Nemzeti Dohánykereskedelmi Nonprofit Zrt. subject to data content requirements provided for in Annex 1, or

cb) to new brands and new types of tobacco products registered after 30 April 2016 and placed on the market before 20 August 2016, if containing changes in excess of what is required for compliance with directive transposition regulations.

(4a)⁹⁸ By way of derogation from Subsection (3) hereof, from 1 January 2022 tobacco products falling within the scope of Subsection (3) which are not in conformity with Sections 6/B and 6/C as established by the Amending Decree, but which are in retail unit packets in compliance with the legal provisions in effect before the final deadline referred to in Subsection (3) may be placed on the market without any restriction as to time, provided that the tobacco products in question had already been stocked by the tobacco retailer before the final deadline referred to in Subsection (3).

⁹⁶ Established by Section 2 of Government Decree 244/2018 (XII. 13.) Korm., effective as of 14 December 2018.

⁹⁷ Established by Subsection (2) of Section 7 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

⁹⁸ Enacted by Section 3 of Government Decree 244/2018 (XII. 13.) Korm., effective as of 14 December 2018.

(5)⁹⁹ Mentholated tobacco products and mentholated roll-your-own tobacco may be marketed until 20 May 2020, with the proviso that:

a) menthol flavor shall be added to the tobacco product (to any ingredient or packaging) in the production or packaging process, and

b) adding or dosing flavorings must not be allowed to be controlled by the consumer in any extent, in particular no capsules may be used for adding menthol flavoring.

(6) Subsection (1) shall apply to any mentholated tobacco products and mentholated roll-your-own tobacco that fail to meet the requirements set out in Paragraphs *a)* and *b)* of Subsection (5).

(7)¹⁰⁰ Electronic cigarettes, refill containers and electronic devices imitating smoking manufactured before 20 November 2016 may be placed on the market until 20 May 2017. By way of derogation from Paragraph *a)* of Subsection (1) of Section 19/B and Paragraph *b)* of Subsection (1) of Section 19/C, electronic cigarettes, refill containers and electronic devices imitating smoking with menthol or fruit flavoring may be placed on the market until 20 May 2020.

(8) In the case of electronic cigarettes, refill containers and electronic devices imitating smoking already placed on the market by 19 May 2016 the notification under Section 19/A, as established by the Amending Decree, shall be submitted by 20 December 2016, for which OGYÉI shall make out the certificate provided for in Subsection (7) of Section 19/B, as established by the Amending Decree, by 20 May 2017.

(9)¹⁰¹ In the case of electronic cigarettes, refill containers and electronic devices imitating smoking already placed on the market by 19 May 2016 the data disclosure obligation under Section 19/D, as established by the Amending Decree, shall be met for the first time by 31 December 2017.

(10) The information prescribed in Subsection (1) of Section 18, as established by the Amending Decree, on ingredients contained in tobacco products, and on emission levels shall be made available by 20 November 2016 with respect to products placed on the market before 20 August 2016.

(11) The information prescribed in Subsection (2) of Section 18, as established by the Amending Decree, on sales volumes shall be submitted for the first time by 20 November 2016, with the proviso that such information shall be made available for the first time with respect to the period between 1 January 2015 and 20 August 2016.

(12) The studies and executive summaries provided for in Subsection (6) of Section 18, as established by the Amending Decree, including studies and executive summaries made before 20 August 2016, shall be submitted for the first time by 20 November 2016.

(13) Paragraph *c)* of Subsection (1) of Section 7, as established by the Amending Decree, shall apply until 20 May 2019 with the derogation that:

⁹⁹ Established by Subsection (2) of Section 7 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

¹⁰⁰ Established by Subsection (3) of Section 7 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

¹⁰¹ Established by Subsection (4) of Section 7 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

a)¹⁰² where the excise seal or national identification mark used for fiscal purposes is affixed at the top edge of a unit packet made of carton material, the combined health warning that is to appear on the back surface may be positioned directly below the tax stamp or national identification mark;

b)¹⁰³ where a unit packet is made of soft material, a rectangular area shall be reserved for the excise seal or national identification mark used for fiscal purposes of a height not exceeding 13 mm between the top edge of the packet and the top end of the combined health warnings;

c) on the unit packet of smoking tobacco in standing pouches

ca) the combined health warning cover 65 per cent of both the external front and back surface of the standing pouch,

cb) the top end of the combined health warnings is positioned on the standing pouch below the opening strip or the perforation of that strip - if any - or close to it, in a manner that ensures that the combined health warnings will not be severed when the package is opened, and

cc)¹⁰⁴ the combined health warning is displayed on the front of the pouch covering the full width of the packet - in due consideration of print tolerance limits -, whereas on the back surface where the excise seals is located, it shall be printed left aligned, next to the area reserved for the excise seals.

(14) The list provided for Subsection (1) of Section 18/C, as established by the Amending Decree, regarding the ingredients of herbal products for smoking placed on the market before 20 August 2016, shall be submitted by 20 November 2016.

(15)¹⁰⁵ The year referred to in Subsection (1) of Section 8 and Subsection (3) of Section 6/D, as established by the Amending Decree, shall be construed for the first time as the period between 20 August 2016 and 31 December 2017, thereafter year shall mean the calendar year.

(16) The report provided for in Subsection (4) of Section 18/A, as established by the Amending Decree, shall be submitted for the first time by 1 July 2018.

(17)¹⁰⁶

(18)¹⁰⁷ For the purpose of enforcement of Subsection (2) of Section 4/A and Subsection (5) of Section 21/A, after 20 May 2017 any filter, cigarette tube or other ingredients that contain capsules or any technical features allowing the consumer to modify the tobacco product by adding or dosing flavorings is prohibited, irrespective of the fact that it is the consumer who ultimately produces the tobacco product using such ingredients and tobacco in any form.

¹⁰² Amended by Paragraph e) of Subsection (9) of Section 8 of Government Decree 419/2016 (XII. 14.).

¹⁰³ Amended by Paragraph e) of Subsection (9) of Section 8 of Government Decree 419/2016 (XII. 14.).

¹⁰⁴ Amended by Paragraphs d), f) of Subsection (9) of Section 8 of Government Decree 419/2016 (XII. 14.).

¹⁰⁵ Established by Subsection (5) of Section 7 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

¹⁰⁶ Repealed by Section 4 of Government Decree 244/2018 (XII. 13.) Korm., effective as of 14 December 2018.

¹⁰⁷ Enacted by Subsection (6) of Section 7 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

(19)¹⁰⁸ A non-exhaustive list of changes stemming from directive transposition regulations is set out in Annex 10.

Section 21/B¹⁰⁹

(1) The provisions of Subsection (3) of Section 6/A, Paragraph *a*) of Subsection (2) of Section 6/D of and Annex 5 to this Decree, as established by Government Decree 507/2017 (XII. 29.) on the Amendment of Government Decrees Relating to Health Insurance and the Healthcare System (hereinafter referred to as “Government Decree 507/2017”), shall apply as of 1 May 2018 with the derogation provided for in this Section.

(2) Any symbol or sign which fails to comply with the requirements set out in Annex 7, as established by Government Decree 507/2017, shall be corrected or replaced by 31 December 2019.

(3) Any general warning which fails to comply with Subsection (3) of Section 6/A, as established by Government Decree 507/2017, shall be corrected or replaced by 1 July 2018 at the latest.

(4) Tobacco products manufactured before 31 December 2018 which comply with other legal requirements:

a) and which are provided for in Paragraphs *a*) and *e*) of Point 3 of Section 2 may be distributed up to the time specified in Subsections (3) and (4) of Section 21/A, not exceeding 19 May 2019,

b) and which are not covered by Paragraph *a*) may be distributed without any limitation, even if the package thereof contains the phone number “06 40 200 493”.

Section 21/C¹¹⁰

(1) Sections 6/G and 6/H shall apply:

a) to cigarettes and roll-your-own tobacco from 20 May 2019,

b) to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

(2) Cigarettes and roll-your-own tobacco manufactured in or imported to the European Union before 20 May 2019, that does not have the unique identifier provided for in Section 6/G, may be sold until 20 May 2020.

(3) Tobacco products, other than cigarettes and roll-your-own tobacco, manufactured in or imported to the European Union before 20 May 2024, that does not have the unique identifier provided for in Section 6/G, may be sold until 20 May 2026.

Section 22

In connection with the draft of this Decree, the prior notification procedure provided for in Articles 8-10 of Directive 98/34/EC of the European Parliament and of the Council of 22 June

¹⁰⁸ Enacted by Subsection (6) of Section 7 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

¹⁰⁹ Established by Section 13 of Government Decree 72/2018 (IV. 16.) Korm., effective as of 17 April 2018.

¹¹⁰ Enacted by Section 14 of Government Decree 72/2018 (IV. 16.) Korm., effective as of 6 May 2018.

1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services has been fulfilled.

Section 23

(1)¹¹¹ This Decree serves the purpose of compliance with:

a) 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;

b) Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products;

c) Commission Implementing Decision (EU) 2015/1842 of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking;

d) Commission Implementing Decision (EU) 2015/1735 of 24 September 2015 on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches;

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

f) Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products; and

g) Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes.

(2)¹¹² This Decree contains provisions for the implementation of Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020 laying down rules on harmonized marking specifications on single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment.

Section 24¹¹³

The provisions of this Decree established by Government Decree 421/2016 (XII. 14.) on the Amendment of Government Decree 39/2013 (II. 14.) on the Production, Placing on the Market and Control of Tobacco Products, on Combined Warnings, and the Detailed Provisions on the Application of Healthcare Penalties (hereinafter referred to as “Amending Decree 2”) shall also apply to cases in progress at the time of entry into force thereof.

¹¹¹ Established by Section 18 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

¹¹² Established by Subsection (2) of Section 23 of Government Decree 349/2021 (VI. 22.) Korm., effective as of 3 July 2021.

¹¹³ Established by Section 8 of Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

Section 25¹¹⁴

Cases opened before the time of entry into force of Subsections (2) and (4) of Section 11 of this Decree, as established by Government Decree 171/2017 (VI. 29.) Korm. on the Amendment of Government Decrees With a View to the Further Strengthening of District (Budapest District) Offices, which are still pending at such time of entry into force shall be concluded according to the provisions in effect on 30 June 2017.

Annex 1 to Government Decree 39/2013 (II. 14.)

Registration form contents list

- 1.¹¹⁵ Name and address of authorized tax warehouse operator, importer or registered trader.
- 2.¹¹⁶ Information relating to the description of tobacco products:
 - a) type [pursuant to Paragraph a) of Subsection (1) of Section 6 for products other than novel tobacco products];
 - b) brand name/trade mark;
 - c) type (if applicable);
 - d) product identification number [as used in the reports submitted in accordance with Commission Implementing Decision (EU) 2015/2186].
3. The following particulars of tobacco products:
 - a) dominating brand of tobacco (for example, Virginia, oriental, Burley), whether genetically modified or not;
 - b) ingredients, tobacco additives used categorized by function group (for example, natural flavoring substances, burn enhancers);
 - c) size (mm):
 - ca) total length (cigarette, cigarillo, cigar),
 - cb) cut width (smoking tobacco);
 - d) chemical properties:
 - da) nicotine content (mg/cigarette),
 - db) tar content (mg/cigarette),
 - dc) carbon-monoxide content (mg/cigarette);
 - e) quantitative parameters:
 - ea) number of sticks in a retail unit packet (cigarette, cigar, cigarillo),
 - eb) weight of the product in a retail unit packet (smoking tobacco, chewing tobacco or nasal tobacco).
 4. Filtered or unfiltered.

¹¹⁴ Enacted by Subsection (1) of Section 15 of Government Decree 171/2017 (VI. 29.) Korm., effective as of 1 July 2017.

¹¹⁵ Established by Subsection (8) of Section 8, Annex 8 of Government Decree 419/2016 (XII. 14.), effective as of 1 July 2017.

¹¹⁶ Established by Subsection (1) of Section 19, Point 1 of Annex 1 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

5. Graphics design (full text) of the retail unit packet.
6. Type of retail unit packet, outside packaging and transport packaging.

Done at: on

.....
head of the tobacco product manufacturing plant
name of the importer, registered trader or
authorized tax warehouse operator

Annex 2 to Government Decree 39/2013 (II. 14.)¹¹⁷

Annex 3 to Government Decree 39/2013 (II. 14.)

Content requirements for notifications for the use of any novel additive in the manufacture of tobacco products¹¹⁸

1. General information

- 1.1. Description, identification number of the additive (E, CoE, FEMA, CAS)
- 1.2. Exact composition of the additive (for natural materials it shall suffice to indicate the origin and the production method)
- 1.3. Name and address of the manufacturer
- 1.4. Name and address of the distributor
- 1.5. Means of storage, shelf life of the additive

2. Physico-chemical properties

- 2.1. Chemical and physical properties of active substance(s) (chemical name, structural formula, state of matter, color, odor, solubility, acidity, alkalinity, etc.)
- 2.2. Information about the microbiological and chemical purity and identity of the additive (active substance content, description of by-products and contaminants, quantities)

3. Information on use

- 3.1. Intended purpose of the additive (for example moisturizer, burn enhancer, flavoring)
- 3.2. Technological reasons for using the material
- 3.3. Means of use
- 3.4. Proposed concentration

4. Data in proof of the harmlessness of the additive, for example JECFA survey, EC SCF assessment, FEMA GRAS, I.O.F.I or CE lists in the case of flavorings

¹¹⁷ Repealed by Paragraph e) of Section 21 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

¹¹⁸ Established by Subsection (2) of Section 19, Point 1 of Annex 2 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

4/a.¹¹⁹ If not included in the assessments referred to in Point 4, information about the toxicological properties of the additive and its combustion products, with particular regard to carcinogenic properties and adverse effects on the heart, lungs and reproduction

5. In the case of additives and mixtures of additives produced in Hungary, technological specification of the manufacturing process, purity of the materials used, in the case of blended additives, a list of ingredients, quantity of components

6. Samples of additives in quantities sufficient for testing

CoE:	Council of Europe (Európa Tanács)
FEMA	Flavor and Extract Manufacturers Association (Aroma és Extrakt Gyártók Egyesülése)
GRAS:	GRAS = substances generally recognized as safe
CAS:	Chemical Abstracts Service (Kémiai Referáló Szolgálat)
JECFA:	Joint FAO/WHO Expert Committee on Food Additives (a FAO/WHO Egyesített Élelmiszer Szakértői Bizottsága)
EC SCF:	EC Scientific Committee on Food (az Európai Tanács Élelmiszer Tudományos Bizottsága)
I.O.F.I.:	International Organization of the Flavour Industry (Aromaipari Nemzetközi Szervezet)

Annex 4 to Government Decree 39/2013 (II. 14.)¹²⁰

Prohibited additives

A	B
1	Description
2	2-methyl-3-(para-isopropyl-phenyl)propionaldehyde
3	Agar-agar
4	Aluminium oxide
5	Ammonium acetate
6	Ammonium citrate
7	Ammonium formate
8	Ammonium acid carbonate
9	Ammonium acid malate
10	Ammonium hydroxide
11	Ammonium carbamate
12	Ammonium chloride
13	Ammonium lactate
14	Ammonium malate
15	Ammonium succinate
16	Ammonium sulphamate
17	Ammonium tartrate
18	Anthraquinone blue
19	Basic blue 26
20	Succinic acid (E 363)
21	Dehydro-mentho-furolactone

¹¹⁹ Enacted by Subsection (2) of Section 19, Point 2 of Annex 2 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

¹²⁰ Established by Subsection (3) of Section 19, Annex 3 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.

22	Di-2-ethyl-hexyl-adipate
23	Diammonium hydrogenphosphate
24	Diammonium carbonate
25	Diammonium malate
26	Diammonium succinate
27	Dibutyl phthalate
28	Phenol formaldehyde modified colophony
29	Galactose
30	Formic acid (E 236)
31	Urea (E 927b)
32	Carmine red
33	Caffeine
34	Crisein S
35	Coumarin-free tonquin beans
36	Lactose
37	Maltose
38	Mannose
39	Methyl violet
40	Honey
41	Monoammonium phosphate
42	Sodium silicate
43	Solvent red 1
44	Pectins
45	Polyethylene glycol (E 1251)
46	Riboflavin-5-phosphate
47	Sucrose octaacetate
48	Saccharin (E 954)
49	Sudan blue 11
50	Taurine
51	Tea
52	Theobromine

Annex 5 to Government Decree 39/2013 (II. 14.)¹²¹

Combined warnings

Group I

¹²¹ Established by Subsection (1) of Section 36, Annex 8 of Government Decree 507/2017 (XII. 29.) Korm., effective as of 1 January 2018.

1.



**A tüdőrákot tízből
kilenc esetben a
dohányzás okozza**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

2.



**A dohányzás száj-,
garat- és gégerákot okoz**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

3.



**A dohányzás
roncsolja a tüdőt**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

4.



A dohányzás szívinfarktust okoz

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

5.



A dohányzás agyvérzést és fogyatékossgot okoz

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

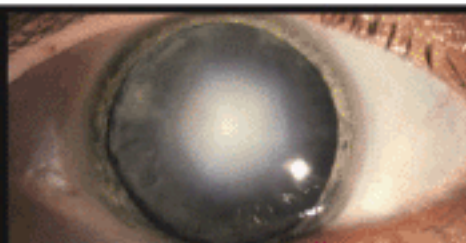
6.



A dohányzás következtében elzáródnak az artériák

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

7.



A dohányzás növeli a szürkenyílás kockázatát

8.



A dohányzás roncsolja a fogakat és a fogínyt

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

9.



A dohányzás megölheti születendő gyermekét

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

10.



A dohányfüsttel árt gyermekeinek, családjának és barátainak

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

11.



A dohányosok gyermekei körében nagyobb a

12.



**Szokjon le, hogy
tovább élhessen
szerettei körében**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

13.



**A dohányzás csökkenti
a termékenységet**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

14.



**A dohányzás növeli az
impotencia kockázatát**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

Group II

1.



**A tüdőrákot tízből
kilenc esetben a
dohányzás okozza**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

2.



**A dohányzás száj-,
garat- és gégerákot okoz**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

3.



**A dohányzás
roncsolja a tüdőt**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

4.



**A dohányzás
szívinfarktust okoz**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

5.



A dohányzás agyvérzést és fogyatékoságot okoz

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

6.



A dohányzás következtében elzáródnak az artériák

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

7.



A dohányzás növeli a vakság kockázatát

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

8.



A dohányzás rontsolja a fogakat és a fogínyt

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

9.



**A dohányzás megölheti
születendő gyermekét**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

10.



**A dohányfüsttel
árt gyermekeinek,
családjának és barátainak**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

11.



**A dohányosok gyermekei
körében nagyobb a
dohányzás valószínűsége**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

12.



**Szokjon le, hogy
tovább élhessen
szerettei körében**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

13.



**A dohányzás csökkenti
a termékenységet**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

14.



**A dohányzás növeli az
impotencia kockázatát**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

Group III

1.



**A tüdőrákot tízből
kilenc esetben a
dohányzás okozza**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

2.



**A dohányzás száj-,
garat- és gégerákot okoz**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

3.



**A dohányzás ron-
csolja a tüdőt**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

4.



A dohányzás

5.



**A dohányzás agyvérzést
és fogyatékossgot okoz**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

6.



**A dohányfüsttel
árt gyermekeinek,
családjának és barátainak**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

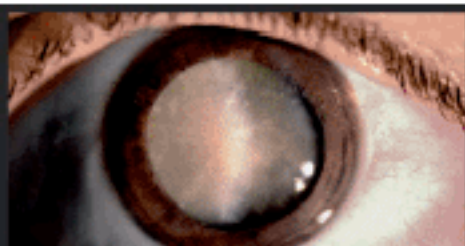
7.



**A dohányzás
következtében
elzáródnak az artériák**

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

8.



A dohányzás növeli

9.



A dohányzás roncsolja a fogakat és a fogínyt

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

10.



A dohányzás megölheti születendő gyermekét

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

11.



A dohányosok gyermekei körében nagyobb a dohányzás valószínűsége

Segítség a leszokáshoz:
06 80 200 493, www.leteszemacigit.hu

12.



Szokjon le, hogy tovább élhessen

13.



14.



Annex 6 to Government Decree 39/2013 (II. 14.)¹²²

Technical specifications for printing

1. Layout and shape of the combined health warning

1.1. Where the height of the combined health warning is greater than 70 per cent of its width, manufacturers shall lay out the combined health warnings in a stacked format as illustrated in Subpoint 4.1 of Point 4.

1.2. Where the height of the combined health warning is greater than 20 per cent but less than 65 per cent of its width, manufacturers shall lay out the combined health warnings in a side-by-side format as illustrated in Subpoint 4.2 of Point 4.

¹²² Established by Subsection (2) of Section 53 of, Annex 10 to Government Decree 413/2015 (XII. 23.), effective as of 20 May 2016.

1.3. Where the height of the combined health warning is greater than or equal to 65 per cent but less than or equal to 70 per cent of its width, manufacturers may choose whether to use the stacked or side-by-side format, as long as all the elements of the combined health warning remain fully visible and are not distorted.

1.4. Where a stacked format is used, the photograph shall be placed at the top of the combined health warning, with the text warning and cessation information printed underneath as illustrated in Subpoint 4.2 of Point 4. The photograph shall occupy 50 per cent, the text warning 38 per cent and the cessation information 12 per cent of the surface area of the combined health warning inside the outer black border.

1.5. Where the side-by-side format is used, the photograph shall be placed on the left half of the combined health warning, with the text warning at the top right and the cessation information at the bottom right of the warning as illustrated in Subpoint 4.2 of Point 4. The photograph shall occupy 50 per cent, the text warning 38 per cent and the cessation information 12 per cent of the surface area of the combined health warning inside the outer black border.

1.6. Where, due to the shape of the unit packet or outside packaging, the height of the combined health warning is less than or equal to 20 per cent of its width, the combined health warning shall be laid out in a side-by-side extra-wide format as illustrated in Subpoint 4.3 of Point 4. The photograph shall occupy 35 per cent, the text warning 50 per cent and the cessation information 15 per cent of the surface area of the combined health warning inside the outer black border.

2. Design of the combined health warning

2.1. The combined health warning shall be printed in four-color CMYK. All elements in black shall be C0, M0, Y0 and K100 and those in warm yellow shall be C0, M10, Y100 and K0.

2.2. The combined health warning shall be reproduced at a minimum resolution of 300 dpi when printed in actual size.

2.3. The text warning shall be printed in white on a black background. The cessation information shall be printed in black on a warm yellow background, as illustrated in Point 4.

2.4. Where a side-by-side, stacked reversed or side-by-side extra-wide format is used, a 1 mm black border shall be printed between the cessation information and the photograph within the cessation information panel.

2.5. The manufacturers or importers shall ensure that the photograph:

2.5.1. is reproduced without applying effects, adjusting the colors, retouching, or extending the background;

2.5.2. is not cropped too close or too far from the focal point of the image; and

2.5.3. is scaled proportionally without being stretched or condensed.

2.6. The manufacturers shall ensure that:

2.6.1. the text warning and cessation information are left aligned and centered vertically;

2.6.2. the text warning and cessation information are printed in Neue Frutiger Condensed Bold;

2.6.3. the text warning is printed in a uniform font size;

2.6.4. the font size of the text warning and of the cessation information is as large as possible to ensure maximum visibility of the text;

2.6.5. the minimum font size of the text warning is 6 pt and the minimum font size of the cessation information is 5 pt;

2.6.6. the space between lines is 2 pt larger than the font size of the text warning and is 1-2 pt larger than the font size of the cessation information;

2.6.7. the text warning is reproduced as set out in Annex 5 for the texts of combined health warnings, including as regards the use of capital letters, but excluding the numbering.

By way of derogation from Points 2.6.5 and 2.6.6, manufacturers or importers of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco may reduce the font size or space between the lines of the text warning and cessation information where unavoidable, provided that all elements of the combined health warning remain fully visible.

3. Special rules for certain unit packets with a flip-top lid

3.1. By way of derogation from Subpoint 1.5 of Point 1, the following rules shall apply to combined health warnings to be placed on the front of unit packets having a flip-top lid:

a) where the lid is smaller than the surface area foreseen for the photograph in Subpoint 1.5 of Point 1 and compliance with that provision would result in the photograph being split upon opening:

aa) the text warning shall be placed at the top of the combined health warning, with the cessation information and photograph underneath as illustrated in Subpoint 4.4 of Point 4, and

ab) the photograph shall occupy at least 50 per cent of the surface area of the combined health warning, the text warning at least 30 per cent and the cessation information at least 10 per cent but no more than 12 per cent of the surface area of the combined health warning inside the outer black border;

b) where the lid is larger than the surface area foreseen for the photograph in Subpoint 1.5 of Point 1 and compliance with that provision would result in the text warning or cessation information being split upon opening:

ba) the photograph shall be placed at the top of the combined health warning, with the text warning and cessation information underneath as illustrated in Subpoint 4.1 of Point 4, and

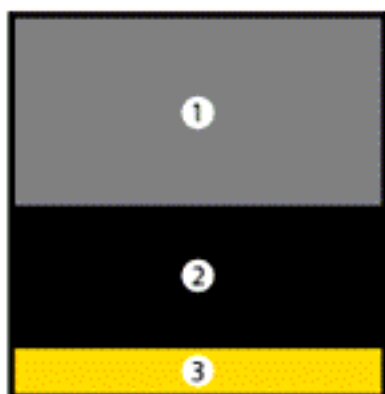
bb) the photograph shall occupy at least 50 per cent of the surface area of the combined health warning, the text warning at least 30 per cent and the cessation information at least 10 per cent but no more than 12 per cent of the surface area of the combined health warning inside the outer black border.

Manufacturers shall ensure that none of the three elements of the combined health warning is split upon opening of the unit packet.

3.2. By way of derogation from Points 2.6.5 and 2.6.6 of Subpoint 2.6 of Point 2, manufacturers or importers of cigarettes, roll-your-own tobacco and waterpipe tobacco in unit packets with a flip-top lid may reduce the font size or space between the lines of the text warning and cessation information on the front of packages where the combined health warning is in more than one language, provided that all elements of the combined health warning remain fully visible.

4. Illustrations on the position of combined health warnings

4.1. Stacked format



1. Fénykép

2. Szöveges figyelmeztetés

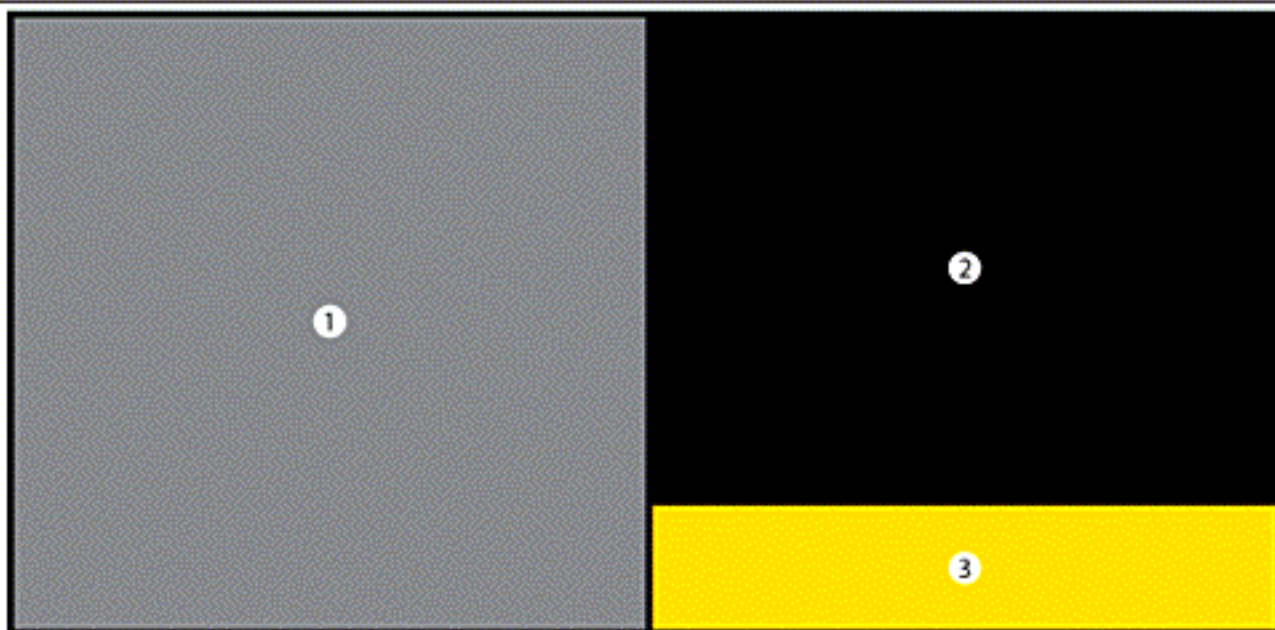
3. A dohányzásról való leszokással kapcsolatos információk

1. Photograph

2. Text warning

3. Cessation information

4.2. Side-by-side format



1. Fénykép

2. Szöveges figyelmeztetés

3. A dohányzásról való leszokással kapcsolatos információk

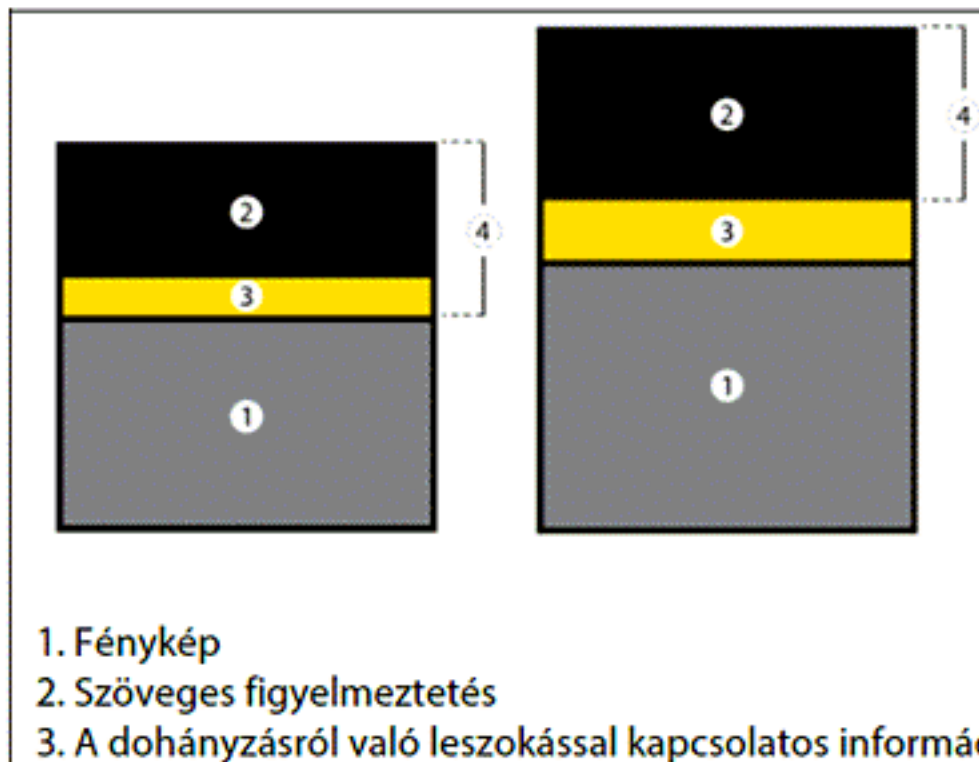
1. Photograph
2. Text warning
3. Cessation information

4.3. Side-by-side extra-wide format



1. Photograph
2. Text warning
3. Cessation information

4.4. Stacked reversed format



1. Photograph
2. Text warning
3. Cessation information

*Annex 7 to Government Decree 39/2013 (II. 14.)*¹²³

¹²³ Established by Subsection (2) of Section 36, Annex 9 of Government Decree 507/2017 (XII. 29.) Korm., effective as of 1 January 2018.



DOHÁNYZÁSRA KIJELÖLT



DOHÁNYZÁSRA KIJELÖLT HELY

SMOKING AREA
ZONE FUMEUR
RAUCHERZONE
МЕСТО ДЛЯ КУРЕНИЯ

A dohányzásról leszokáshoz segítséget kaphat, illetve
törvényszegés észlelése esetén észrevételt tehet
az alábbi telefonszámon:
06 80 200 493

www.leteszemacigit.hu



TILOS A DOHÁNYZÁS

NO SMOKING
INTERDICTION DE FUMER
RAUCHEN VERBOTEN
КУРЕНИЕ ЗАПРЕЩЕНО

A dohányzásról leszokáshoz segítséget kaphat, illetve
törvényszegés észlelése esetén észrevételt tehet
az alábbi telefonszámon:
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Annex 8 to Government Decree 39/2013 (II. 14.)¹²⁴

	A	B
1.	Bács-Kiskun Megyei Kormányhivatal (<i>Bács-Kiskun County Government Agency</i>)	10025004-00301181-00000000
2.	Baranya Megyei Kormányhivatal (<i>Baranya County Government Agency</i>)	10024003-00301019-00000000
3. ¹²⁵	Békés Megyei Kormányhivatal (<i>Békés County Government Agency</i>)	10026005-01040030-00000000
4.	Borsod-Abaúj-Zemplén Megyei Kormányhivatal (<i>Borsod-Abaúj-Zemplén County Government Agency</i>)	10027006-00302852-00000000
5. ¹²⁶	Csongrád-Csanád Megyei Kormányhivatal (<i>Csongrád-Csanád County Government Agency</i>)	10028007-00302584-00000000
6.	Fejér Megyei Kormányhivatal (<i>Fejér County Government Agency</i>)	10029008-00305350-00000000
7.	Fővárosi Kormányhivatal (<i>Budapest Government Agency</i>)	10023002-00301253-00000000
8.	Győr-Moson-Sopron Megyei Kormányhivatal (<i>Győr-Moson-Sopron County Government Agency</i>)	10033001-00301655-00000000
9.	Hajdú-Bihar Megyei Kormányhivatal (<i>Hajdú-Bihar County Government Agency</i>)	10034002-00301954-00000000
10.	Heves Megyei Kormányhivatal (<i>Heves County Government Agency</i>)	10035003-00302113-00000000
11.	Jász-Nagykun-Szolnok Megyei Kormányhivatal (<i>Jász-Nagykun-Szolnok County Government Agency</i>)	10045002-00301947-00000000
12.	Komárom-Esztergom Megyei Kormányhivatal (<i>Komárom-Esztergom County Government Agency</i>)	10036004-00304270-00000000
13.	Nógrád Megyei Kormányhivatal (<i>Nógrád County Government Agency</i>)	10037005-00302144-00000000
14.	Somogy Megyei Kormányhivatal (<i>Somogy County Government Agency</i>)	10039007-00301129-00000000
15.	Szabolcs-Szatmár-Bereg Megyei Kormányhivatal (<i>Szabolcs-Szatmár-Bereg County Government Agency</i>)	10044001-00302285-00000000
16.	Tolna Megyei Kormányhivatal (<i>Tolna County Government Agency</i>)	10046003-00306014-00000000
17.	Vas Megyei Kormányhivatal (<i>Vas County Government Agency</i>)	10047004-00301459-00000000
18.	Veszprém Megyei Kormányhivatal (<i>Veszprém County Government Agency</i>)	10048005-00301703-00000000
19.	Zala Megyei Kormányhivatal (<i>Zala County Government Agency</i>)	10049006-00303066-00000000

Annex 8/A to Government Decree 39/2013 (II. 14.)¹²⁷

	A	B
1.	Országos Rendőr-főkapitányság (<i>National Police Headquarters</i>)	10023002-01451715-30006009

¹²⁴ Established by Subsection (3) of Section 220 of, Annex 51 to Government Decree 70/2015 (III. 30.), effective as of 1 April 2015.

¹²⁵ Amended by Paragraph b) of Subsection (2) of Section 15 of Government Decree 171/2017 (VI. 29.) Korm.

¹²⁶ Amended by Section 22 of Government Decree 371/2020. (VII. 30.) Korm.

¹²⁷ Enacted by Section 12 of, Annex 2 to Government Decree 169/2014 (XII. 18.), effective as of 19 July 2014.

2.	Terrorelhárítási Központ (<i>Counter-Terrorism Center</i>)	10023002-00294267-30006009
3.	Belügyminisztérium Országos Katasztrófavédelmi Főigazgatóság (<i>National Directorate General for Disaster Management, Ministry of the Interior</i>)	10023002-00283494-30006009
4.	Büntetés-végrehajtás Országos Parancsnoksága (<i>National Department of Corrections</i>)	10023002-01393008-30006009
5.	Magyar Honvédség Közegészségügyi Járványügyi Szolgálat (<i>Public Health Epidemiology Center, Hungarian Armed Forces</i>)	payment account maintained by the Magyar Államkincstár (<i>Hungarian State Treasury</i>) for the Magyar Honvédség Közegészségügyi Járványügyi Szolgálat, indicated in the resolution on the health fine and healthcare penalty

Annex 9 to Government Decree 39/2013 (II. 14.)

Standards relevant for the application of the provisions of this Decree

1. MSZ ISO 4387
Cigarettes. Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine
2. MSZ ISO 8243
Cigarettes. Sampling
3. MSZ ISO 10315
Cigarettes. Determination of nicotine in smoke condensates. Gas-chromatographic method
4. MSZ ISO 10362-1
Cigarettes. Determination of water in smoke condensates. Part 1: Gas-chromatographic method, or
5. MSZ ISO 10362-2
Cigarettes. Determination of water in smoke condensates Part 2: Karl Fischer method
6. MSZ ISO 8454
Cigarettes. Determination of carbon monoxide in the vapor phase of cigarette smoke. NDIR method
7. MSZ EN ISO 12863:2010
Standard test method for assessing the ignition propensity of cigarettes
8. MSZ EN 16156:2011
Cigarettes. Assessment of the ignition propensity. Safety requirements

Annex 10 to Government Decree 39/2013 (II. 14.)¹²⁸

Scope of changes made in compliance with directive transposition regulations

Within the meaning of Section 21/A the following shall, in particular, be construed as changes made in compliance with directive transposition regulations:

1. On areas of the packages of tobacco products, not occupied by health warnings provided for in this Decree, where such tobacco products

¹²⁸ Established by Section 9 of, Annex 1 to Government Decree 421/2016 (XII. 14.), effective as of 15 December 2016.

a) are registered on or before 30 April 2016 by the Nemzeti Fogyasztóvédelmi Hatóság (*National Consumer Protection Authority*) or the ND Nemzeti Dohánykereskedelmi Nonprofit Zrt. (*ND National Tobacco Nonprofit Company*), or

b) are presented for registration between 30 April 2016 and 19 August 2016 according to the regulations in force on 19 May 2016, and placed on the market also by 19 May 2016, display of elements on such tobacco packages (texts, diagrams and color features) adjusted to the area available, provided that such elements do not breach any prohibition expressly provided for in this Decree, the NSA or the Excise Act.

In fitting the elements specified in this Point to the area available for displaying them either of those elements may be abandoned, the size of any of those elements (including if made larger), the number of their occurrence (also if more), their positioning relative to each other and to the packaging, and their share may be changed, moreover, some elements may be altered so as to improve their fit to the revised surface available.

2. If the brand name or type, or the packaging of a tobacco product contains the word “Slim”, “Slims”, “Superslim”, “Superslims”, “Demislim” or “Demislims”, or any combination thereof, or any other elements, that may be contrary to what is contained in Section 6/A of the NSA:

a) removal of the word or element aforementioned from the brand name, type or packaging, and
b) replacing it at the same time with a new type name, word, package component, that is in conformity with the provisions of the NSA.

3. If the brand name or type of a tobacco product contains - in violation of Paragraph a) of Subsection (1) of Section 6/A of the NSA - any information relating to the nicotine, tar or carbon monoxide content of the tobacco product:

a) removal of the information relating to the nicotine, tar or carbon monoxide content of the tobacco product from the brand name or type, and

b) replacing it at the same time with a new type name that does not contain any information relating to the nicotine, tar or carbon monoxide content of the tobacco product, and that is otherwise in conformity with the provisions of the NSA.

4. In the case of mentholated tobacco products, displaying the word “menthol” on the packaging.

5. Where a tobacco product contains flavoring in a capsule form:

a) removal of the capsule from the tobacco product,
b) removal of any text or diagram from the packaging, referring to the capsule, or their conversion where they no longer contain any reference to the capsule,

c) if the text removed was a part of the name of the type of product, displaying a type name on the packaging that does not contain any reference to the capsule, and that is otherwise in conformity with the provisions of the NSA,

d) if the product contained a mentholated capsule (as well), adding menthol flavor to the product by way of means permitted by this Decree, furthermore, if the product contains any other capsule flavoring other than menthol, removal of texts, diagrams, colors referring to such other flavoring, or altering them so as to contain an indication to the menthol flavor only.

6. Changing the presentation of the tobacco product (weight, volume), introducing a new presentation with a view to

a) increasing the number of sticks in a packet of cigarettes from less than twenty to twenty, or
b) reducing to weight of roll-your-own tobacco packet to 30-50 grams, if it was larger than 50 grams previously.

7.¹²⁹ In the cases under Points 2-6, in the process of registration of the new packaging of a tobacco product, the registration form submitted to the minister in charge of consumer protection shall be accompanied by a note in which the party submitting the registration form explains the reason for changing the brand name or type of the tobacco product in question.

*Annex 11-12 to Government Decree 39/2013 (II. 14.)*¹³⁰

¹²⁹ Amended by Section 10 of Government Decree 421/2016 (XII. 14.).

¹³⁰ Repealed by Paragraph e) of Section 21 of Government Decree 239/2016 (VIII. 16.), effective as of 20 August 2016.