

**Government regulation 239/2016 (16 August)
on the amendment of government regulation 39/2013 (14 February) on the detailed rules of production, distribution and control of tobacco products, the combined warnings and the application of health protection fines**

Under the power delegated by points a) and c)–i) of subsection 8 (5) of Act XLII of 1999 on the protection of non-smokers and on certain rules of consuming and distributing tobacco products, acting within its duties specified by article 15 (1) of the Fundamental Law, the government makes the following regulations:

1. Subsection 1 (1) of government regulation 39/2013 (14 February) on the detailed rules of production, distribution and control of tobacco products, the combined warnings and the application of health protection fines (hereinafter: Implementation Regulation) is substituted with the following provision:
“(2) Apart from the exception specified in subsection (2), the provisions of this regulation apply to tobacco products, electronic cigarettes, refill liquids and electronic devices for the imitation of smoking manufactured and placed on the market in Hungary, with the exception specified in section 16.”
2. Section 2 of the Implementation Regulation is substituted with the following provision:
“2 For the purposes of this regulation:
 1. *registered trader* means the person specified in point 16 of section 7 of Act CXXVII of 2003 on excise duty and on the special rules applicable to placing products subject to excise duty on the market (hereinafter: Excise Duty Act);
 2. *raw materials and additives used for the production of tobacco products*:
 - a) *tobacco* means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;
 - aa) *raw tobacco* means the naturally or artificially dried leaves of the *Nicotiana tabacum* species that are suitable for industrial processing;
 - ab) *fermented cured tobacco* means raw tobacco, where apart from heat generation and dry matter loss, such changes occurred after drying that made it suitable for the purposes of enjoying as tobacco products;
 - b) *reconstituted tobacco* means a paper like sheet or tape made using binders and additives, where at least 75% of the dry matter is tobacco;
 - c) *cut rag* means tobacco cut onto strips of equal width or reconstituted tobacco cut onto strips of equal width;
 - d) *cigarette paper* means special paper cut onto size that is used for the wrapping of cut rag;
 - e) *additive* means material other than tobacco added to tobacco products, or their unit packets or outside packaging;
 3. *tobacco products for smoking* means a tobacco product other than a smokeless tobacco product; its types are:
 - a) *cigarette* means a roll of tobacco that can be consumed via a combustion process, suitable for smoking in its existing state, which is made of cut rag, or cut rag and reconstituted tobacco and its filling is wrapped with cigarette paper or reconstituted tobacco in a longitudinal direction and which does not constitute a cigar or a cigarillo, moreover, it means any tobacco roll that is pushed into cigarette paper tubes or wrapped with cigarette paper using a simple, non-industrial process;
 - b) *cigar* means a product that can be consumed via a combustion process, which is
 - ba) a roll of tobacco with an outer wrapper of natural tobacco leaves;
 - 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 g and not more than 10 g, and the circumference over at least one third of the length is not less than 34 mm;
 - c) *cigarillo* means a cigar of a maximum weight of 3 grams each;
 - d) *smoking tobacco* means cut rag falling under points e)–g) that is suitable for smoking without the need for further industrial processing;
 - e) *cigarette tobacco (fine cut smoking tobacco)* means tobacco that consumers can use for making cigarettes, where more than 25% of the mass of the tobacco is cut onto pieces not more than 1.5 mm wide;
 - f) *pipe tobacco (other smoking tobacco)* means smoking tobacco that can be consumed via a combustion process and that does not fall under point e), which is exclusively intended for smoking in a pipe;
 - g) *waterpipe tobacco* means a tobacco product that can be consumed via a waterpipe;
 - h) any other products manufactured for the purposes of smoking, which is, even partly, made of tobacco, whether genetically modified or not;

4. *export* means the sale of products subject to excise duty to a country outside the European Union, where the customs authority signs the products out from the country with a final destination of a country outside the European Union;
5. *placing on the market* means the provision of access to a product (by any means) for consumers within the European Union, regardless of the place of manufacture of the product;
6. *distributor* means the business organization or natural person conducting the activity specified in point 5;
7. *addictiveness* means the pharmacological potential of a substance to cause addiction, 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* means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use:
 - a) *chewing tobacco* means a smokeless tobacco product exclusively intended for the purpose of chewing;
 - b) *nasal tobacco* means a smokeless tobacco product that can be consumed via the nose;
 - c) *tobacco for oral use* means 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* means the part of a cigarette, cigar or cigarillo that is intended for filtering the main cigarette smoke going through the tobacco product;
10. *manufacturer* means any natural person or legal entity, who manufactures products or has products designed or manufactured, and places that product on the market under their name or trademark;
11. *foreign material* means non-tobacco based material that got into the raw material and/or the finished product during cultivation and processing and that can be separated by simple physical processes;
12. *import* means the term defined in point 2 of section 7 of the Act on excise duty;
13. *importer* means the term defined in point 29 of section 7 of the Act on excise duty;
14. *flavoring* means an additive that imparts smell and/or taste;
15. *characterizing flavor* means a clearly noticeable smell or taste other than one of tobacco, which is noticeable before or during the consumption of the tobacco product, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla;
16. *tar* means the raw anhydrous nicotine-free condensate of smoke;
17. *emissions* mean substances that are released when a tobacco product or a product specified under section 3 (2) of Act CXXXIV of 2012 on the reduction of smoking of minors and on the retail 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* means the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams;
19. *nicotine* means nicotinic alkaloids;
20. *nicotine-containing liquid* is liquid used during the use of electronic cigarettes and used for refilling electronic cigarettes that contains nicotine, regardless of the quantity;
21. *ingredient* means 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. *release for free circulation* means the term defined in point 22 of section 7 of the Act on excise duty;
23. *transport packaging* means the packaging designed for the transport of the product, which is not involved in retail distribution;
24. *personal consumption* means the tax-free import of tobacco products by a private individual for non-commercial purposes, as specified in the Act on excise duty;
25. *carbon monoxide* means a component of cigarette smoke in gas state;
26. *tip* means a component attached to cigarettes, cigars, cigarillos, electronic cigarettes or electronic devices for the imitation of smoking that is in direct contact with the mouth;
27. *authorised person of the tax warehouse* means the authorised person of the tax warehouse for the storage of tobacco falling under section 100 (1) d) of the Act on excise duty;
28. *toxicity* means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually upon repeated or continuous consumption or exposure;

29. *novel tobacco product* means a tobacco product which:
- does not fall into any of the following categories: cigarettes, cigarette tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and
 - is placed on the market after May 19, 2014."
3. Section 4 of the Implementation Regulation is substituted with the following provision:
- „4 (1) The tobacco product may not contain prohibited additives and foreign material. The list of prohibited additives is set out in Schedule 4.
- Tobacco products containing prohibited additives listed in Schedule 4 must not be placed on the market.
 - Six months before the planned start date of use, but at least 30 days before the planned start date of use, the consumer, the manufacturer, the registered trader, the importer or the authorized person of the tax warehouse (hereinafter together: notifier) must notify NPHS OCMO (Office of the Chief Medical Officer of the National Public Health Service) about the use of additives during the production of tobacco products. The notification must be made in the data content specified in Schedule 3. the NPHS OCMO maintains a registry on the submitted data, and publishes such data on its website. There is no notification requirement regarding the use of the natural parts of raw tobacco. There is no need to submit another notification if another notifier has already made a submission regarding the additive and the NPHS OCMO acknowledged its use and published this fact on its website.
 - The following must be attached to the notification:
 - the licence for use issued by the authority of a member state of the Agreement on the European Economic Area, if available; and
 - the report containing the results of the tests conducted by an accredited laboratory.
 - Based on the notification and within 30 days from the notification, the NPHS OCMO checks whether the additive intended to be used is on the list of prohibited additives specified in Schedule 4, and if the additive is not on the list and adding it to that list is not justified, the authority shall acknowledge the notification and inform the notifier. The NPHS OCMO informs the HACP (Hungarian Authority for Consumer Protection) and the NIHD SFP (Smoking Focal Point of the National Institute for Health Development). If the NPHS OCMO does not make a statement within 30 days, the additive subject to the notification may be used.
 - After 2 years from the commencement of use, the notifier must send the NPHS OCMO any studies made in relation to the additive subject to the notification under subsection (3). Based on the submitted documentation and within 6 months of submission, the NPHS OCMO verifies whether the submitted documentation justifies adding the additive to the list of prohibited additives in Schedule 4.
 - If the NPHS OCMO considers that the additive shall be added to the list in Schedule 4, it prohibits further use of the additive, informs the NIHD SFP and initiates the amendment of the legislation at the minister responsible for healthcare regarding the extension of the list.
 - Additives other than those subject to the notification as well as using the tobacco additive in a way other than the requirements specified in the notification are prohibited.
 - The cigarette release for free circulation must comply with the safety requirements specified in MSZ EN 16156:2011.
 - 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."
4. Chapter 2 of the Implementation Regulation is supplemented with the following section 4/A:
- "4/A (1) Tobacco products with characterizing flavor may not be placed on the market, except for the 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 or carcinogenic, mutagenic or reproduction related toxicity properties (hereinafter: CMR properties) of the tobacco product.
- 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.
 - Filters, papers and capsules shall not contain tobacco or nicotine.
 - 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 cigarette tobacco shall be exempted from the prohibitions laid down in subsections (1)–(3)."
5. Section 5 of the Implementation Regulation is substituted with the following provision:
- "(5) (1) The maximum emission levels from cigarettes released or manufactured for free circulation shall not be greater than:
- a) 10 mg of tar;
 - b) 1 mg of nicotine;
 - c) 10 mg of carbon monoxide.
- (2) The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of the MSZ ISO 4387 standard for tar, the MSZ ISO 10315 standard for nicotine, and the MSZ ISO 8454 standard for carbon monoxide.
- (3) The accuracy of the tar, nicotine and carbon monoxide measurements shall be determined in accordance with the MSZ ISO 8243 standard.
- (4) The measurements referred to in subsections (2) and (3) shall be certified by laboratories, which are approved and monitored by the accrediting organization. The laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.
- (5) Within 30 days after the authorization, the accrediting organization sends the list of laboratories authorized by it, the criteria used for the authorization of laboratories and its supervision methods to the minister responsible for healthcare. If there is a change in the submitted data, the accrediting organization informs the minister responsible for healthcare without delay.
- (6) The minister responsible for healthcare forwards the information available in relation to laboratories to the European Commission. The European Commission shall make the lists of approved laboratories publicly available."
6. Section 6 of the Implementation Regulation is substituted with the following provision:
- "6 (1) The following must be indicated on the unit packet:
- a) the type of tobacco product as follows:
 - aa) "cigarette";
 - ab) "cigar";
 - ac) "cigarillo";
 - ad) "cigarette tobacco";
 - ae) "pipe tobacco";
 - af) "chewing tobacco";
 - ag) "nasal tobacco";
 - ah) "waterpipe tobacco";
 - b) the brand or trademark of the tobacco product;
 - c) the type of the brand or trademark of the tobacco product (if applicable);
 - d) the registered name of the manufacturer or the distributor and whether the entity is a manufacturer or distributor;
 - e) the place of origin of the tobacco product if the goods are not from the European Economic Area;
 - f) the number of products (in case of cigarettes, cigars and cigarillos) or the weight (in case of smoking tobacco, chewing tobacco and nasal tobacco);
 - g) the "filter(ed)" word in case of filtered products; and
 - h) the time (by indicating the day, the month and the year) and place of manufacturing, or the order number and/or coded indication suitable for establishing the time and place of manufacturing.
- (2) Apart from the provisions regarding health warnings, the indications specified in subsection (1) a)–f) must be used on the outside packaging in accordance with the requirements specified for unit packets.
- (3) The indications specified in subsection (1) a)–f) must be used on the transport packaging.
- (4) The 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 may only be of cuboid shape.
- (5) The packaging of cigarette tobacco may be in the form of a rectangular pocket or a standing pouch.
- (6) If a product can be used both via waterpipes and as cigarette tobacco, it shall be deemed to be cigarette tobacco.

(7) In case of menthol flavored tobacco products, the indication of menthol may happen by the text "menthol".

7. The Implementation Regulation is supplemented with the following sections 6/A–6/F:

"6/A (1) Tobacco products for smoking may only be placed on the market if all its unit packets and all its outside packaging contain all of the following in a conspicuous, clearly legible and indelible way with high contrast background, with irremovable printing and in Hungarian:

a) on one lateral surface, in an area corresponding to at least 50% of the surface, the general warning of "Smoking kills – quit now";

b) on the other lateral surface, in an area corresponding to at least 50% of the surface, the information message of "Tobacco smoke contains over 70 substances known to cause cancer."; and

c) on both main sides, in an area corresponding to at least 65% of the surface, the combined health warning optionally selectable by the manufacturer from the possibilities specified in Schedule 5.

(2) The general warning specified in subsection (1) a) must also be used in case of the service areas of shops and mobile shops selling tobacco products. The provisions of subsection (1) appropriately apply to the method of indicating the warning, however, the provision regarding the minimum size of the warning does not apply.

(3) The text of general warning indicated in compliance with subsection (2) must be supplemented with the text of "Help for quitting: 06 40 200 493, www.leteszemacigit.hu" in a way that the area of the supplemented warning must be at least 420 x 594 mm.

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

(5) Health warnings on a unit packet and any outside packaging are irremovably printed and indelible, moreover, they must not be partially or totally hidden or interrupted by tax stamps, price marks, security features, wrappers, jackets, boxes, or other items, when tobacco products are placed on the market. In case of tobacco products other than cigarette and cigarette tobacco, texts and health warnings may be indicated on a sticker irremovably attached to the package.

(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 must be printed on a white background using black, bold, Helvetica bold font. The text must be written in lowercase letters, except for the first letter of the text and when uppercase letters shall be used according to the grammatical rules.

(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. The border must not interfere with the text of the health warnings in any way. The general warning and the information message must be aligned to the center of the surface reserved for its printing, and the text warning and the combined health warning must be parallel with the upper edge of the package. Apart from the pouches of smoking tobacco, general warnings and information messages shall be at the center of the surface reserved for them, and on cuboid packets and any outside packaging, they shall be parallel to the lateral edge of the unit packet or of the outside packaging. The size of the font must be chosen in a way that the text of the health warning covers the largest possible proportion of the surface available for it.

(10) For outside packaging of cigarette packets and cigarette tobacco, the general warning shall appear on the bottom part of one of the lateral surfaces of the packaging, and the information message shall appear on the bottom part of the other lateral surface. In case of unit packets and outside packaging of cigarette packages, the width of the general warning and the information message must be at least 20 mm, which must be printed parallel to the longer edge of the lateral surface of the unit packet.

(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) In accordance with Commission Implementing Decision 2015/1735, the general warning and the information message for cigarette tobacco 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. 6/B (1) For tobacco products specified in section 2 (3) a) and e), only the elements prescribed by

sections 6 and 6/A, and those prescribed by another piece of legislation may be indicated, however, the provisions of sections 6 and 6/A apply with the differences detailed in subsections (2)–(12).

(2) Cigarettes and cigarette tobacco may be placed on the market with the requirements specified in subsections (3)–(12).

(3) For cigarettes and cigarette tobacco,

a) the outside surface of all unit packets and all outside packaging must be PANTONE 448 M color in the FORMULA GUIDE/solid matte color scale, must have a matte surface, the packaging raw material must be matte and white color;

b) the inside surface of all unit packets and all outside packaging must be the same matte and white color as the packaging raw material, except for the clear and thin internal foil of the unit packets of cigarette tobacco;

c) the outside surface of the unit packets and the outside packaging may not contain decorative grooving, embossing or other decorative elements;

d) the unit packets and outside packaging may not contain tinted or non-transparent adhesives;

e) the unit packets and outside packaging may not contain any components located inside the packaging or attached to it, apart from elements specified in section 6/A of the Act on the protection of non-smokers; and

f) for the purposes of points b) and c) of subsection 6 (1), the unit packets and the outside packaging may only indicate the following:

fa) the brand name; and

fb) the type of the relevant cigarette or cigarette tobacco brand.

(4) The markings specified in subsection (3) f) must comply with the following requirements:

a) its color is PANTONE Cool Gray 1 M in the FORMULA GUIDE/solid matte color scale,

b) the brand name and the type of the relevant cigarette or cigarette tobacco may only occupy one line each;

c) the type of the relevant cigarette or cigarette tobacco may only be indicated directly below the brand name;

d) the font of the brand name and the type of the relevant cigarette or cigarette tobacco may only be Helvetica;

e) the font size of the brand name may not be more than 14 points;

f) the font size of type of the relevant cigarette or cigarette tobacco may not be more than 10 points;

g) Apart from the first character of the word, every character must be lowercase; and

h) the indication may not cover the health warnings printed on the unit packets, and may not interfere with their visibility in any way.

(5) The brand name and the type of cigarettes detailed in subsection (3) f), printed on the packaging of all unit packets and all outside packaging must comply with the following requirements:

a) it must be located at the outside surface of the front side and the top of the packaging, aligned to the center, and under the health warning on the front side; and

b) it may be indicated once on the front side and once on top of the packaging.

(6) The brand name and the type of cigarette tobacco detailed in subsection (3) f), printed on the packaging of all unit packets and all outside packaging must comply with the following requirements:

a) it must be located at the outside surface of the two main sides of the packaging, aligned to the center, and under or next to the health warning; and

b) it may be indicated once on each of the two main sides.

- (7) If the packaging of the cigarettes also contains lining, the lining:
- may be white or matte silver color;
 - may not have decorative grooving, embossing or other decorative elements, excluding roughening used on the packaging machine used on the whole surface for non-decorative purposes;
 - may not contain tinted or non-transparent adhesives; and
 - may not contain any components attached to it, apart from elements specified in section 6/A of the Act on the protection of non-smokers.
- (8) The covering packaging material or any form cover packaging of cigarettes and cigarette tobacco that do not constitute outside packaging or transport packaging must comply with the following requirements:
- transparent;
 - non-tinted
 - may not have decorative grooving, embossing or other decorative elements;
 - may not have marking or trademarks or any other element apart from the opening strip as specified in the relevant provisions;
 - may not contain tinted or non-transparent adhesives; and
 - may not contain any components attached to it, apart from elements specified in section 6/A of the Act on the protection of non-smokers.
- (9) The opening strip located on the packing material of cigarettes and cigarette tobacco must comply with the following requirements:
- transparent;
 - may not have decorative grooving, embossing or other decorative elements;
 - may not have a brand name or marking on it;
 - may not contain any components attached to it, apart from elements specified in section 6/A of the Act on the protection of non-smokers;
 - may not contain tinted or non-transparent adhesives;
 - may have one, continuous line with constant width; and
 - must be located parallel with the lid, as close to the lid as possible.
- (10) The provisions mentioned in subsections (1)–(9) do not apply to:
- health warnings;
 - other elements prescribed by the Act on the protection of non-smokers; and
 - tax stamps.
- (11) Notwithstanding the provisions in subsection (1)–(10), the barcode or technical mark serving distribution and tracing purposes as specified in a separate piece of legislation may be indicated in the bottom surface or one of the side surfaces of the unit packet.
- (12) The provisions specified in subsections (1)–(11) apply to the packaging of cigarettes and cigarette tobacco intended to be sold in Hungary.
- 6/C (1) The individual cigarettes in the unit packet must comply with the following requirements:
- their outside surface may not contain decorative grooving, embossing or other decorative elements;
 - they may not contain tinted or non-transparent adhesives;
 - they may not contain any elements other than those specified in the Act on the protection of non-smokers;
 - the paper covering of cigarettes shall be white; and
 - if the cigarette has a filter,
 - the visible part of the filter shall be white; and
 - the part of the cigarette paper covering the filter shall be white or cork imitation.
- (2) The text printed on the individual cigarettes in the unit packet may contain the following:
- the brand name; and
 - the type of the relevant cigarette.
- (3) The text specified in subsection (2) must comply with the following requirements:
- its color is PANTONE 444 M in the FORMULA GUIDE/solid matte color scale;
 - the brand name and the type of the cigarette may only be indicated on the roll of tobacco in a way that it is as close to the end of the filter as possible and it is indicated around the circumference;
 - the brand name and the type of the relevant cigarette or cigarette tobacco may only be indicated once and they may only occupy one line each;
 - the type of the relevant cigarette may only be indicated directly below the brand name;
 - Apart from the first character of the word, every character must be lowercase; and

- f) the font of the brand name and the type of the relevant cigarette may only be Helvetica.
- 6/D (1) For tobacco products for smoking, other than those specified in section 2 (3) a) e) and g), the provisions of section 6/A apply with the differences detailed in subsections (2)–(4).
- (2) For tobacco products for smoking, other than those specified in section 2 (3) a) e) and g), from the health warning specified by subsection 6/A (1)
- a) the general warning prescribed by subsection 6/A (1) a) must be indicated on at least 30% of the surface of one of the main sides, which must contain the following text: “Smoking kills – quit now! Help for quitting: 06 40 200 493, www.leteszemacigit.hu”; and
- b) the combined health warning prescribed by subsection 6/A (1) c) must be indicated on at least 40% of the surface of the other main side.
- (3) In order for the regular publication of the combined health warnings specified by subsection (2) b), as grouped into three sets according to Schedule 5, one set of them may be used in a particular year and the sets shall be changed annually.
- (4) The general warning shall be surrounded by a black border of a width of not less than 3 mm and not more than 4 mm. This border shall appear outside the surface reserved for the general warning.
- 6/E (1) Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning: “This tobacco product damages your health and is addictive.”
- (2) The health warning laid down in subsection (1) shall comply with the requirements specified in subsections 6/A (9) and (10). The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings; and they must
- a) (a) appear on the two largest surfaces of the unit packet and any outside packaging; and
- b) (b) cover 30% of the surfaces of the unit packet and any outside packaging.
1. Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning on the outside of their front and back surfaces: “Smoking this product damages your health.”
- (2) The health warning shall comply with the requirements specified in subsections 6/A (9) and (10). It shall cover 30% of the area of the corresponding surface of the unit packet and of any outside packaging.
- (3) The labelling of unit packets and any outside packaging of the herbal product 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 it has other health or lifestyle benefits; or
- c) refers to taste, smell, any flavorings or other additives or their absence in a way that is suitable to mislead consumers.
- (4) Apart from the provisions of 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.”
- 8.** Sections 7–9 of the Implementation Regulation are substituted with the following provisions:
- “7 (1) Combined health warning must be indicated on tobacco products for smoking, in case of tobacco products falling under points b) and C9 of subsection 2 (3), it shall be done in a way prescribed by section 6/D. The combined health warning must
- a) cover 65% 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) indicate the same textual warning and the relevant color photograph on both sides of the unit packet and all outside packaging, however, the textual warning and the relevant photograph used on the unit packets within the outside packaging may be different from the textual warning and the relevant photograph used on the 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) in the case of 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 logos (if it can be indicated) may not be indicated above the combined health warnings even if, based on the deviation allowed by subsection 21/A (13), the health warnings are not located on the upper edge of the packaging until 20 May 2019.
 - 8. In order for the regular publication of the combined health warnings, as grouped into three sets according to Schedule 5, one set of them may be used in a particular year for one particular tobacco brand and the sets shall be changed annually.
 - (2) For each tobacco brand, if the production of the relevant product is suspended in the relevant year, the combined warnings of the following set must be used during subsequent manufacturing.
 - (3) In one particular year, combined health warnings in the set used in that year for that tobacco brand shall be used in the same proportion.
 - (4) If the technical conditions are not available for compliance with the provision specified in subsection (3), the difference between the number of the most frequently used and least frequently used combined health warnings may not exceed 10% in case of cigarettes and 15% in case of other types of tobacco products. In order to enable the verification of the compliance with the requirement to use the combined health warnings in an alternating way, the manufacturer, the importer, the registered trader and the authorized person of the tax warehouse must maintain a register, where the number of the used combined health warnings may be established for each three-month period.
 - 9. (1) The combined health warning must
 - a) be printed on the packaging of the tobacco product in a way that the format and proportions specified in Schedule 5 and the integrity of the picture and the text are maintained, also having regard to the provisions specified in subsection (3);
 - b) occupy the entire area prescribed for it, 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) be printed in line with the technical requirements specified in Schedule 6.
 - (2) The combined health warnings shall not be commented on, paraphrased or referred to in any form on the packaging of the tobacco product.
 - (3) Notwithstanding the provisions of subsection (1) a), in case of tobacco products, where, due to the aspect ratios of its unique packaging, the prescribed surface area cannot be covered without changing the format, proportions or the graphical integrity of the text or the picture, the combined health warning shall be used by aligning it to the dimensions of the unique packaging according to the provisions specified in point 2 of Schedule 6.
 - (4) In order to assist the application of subsection (3), the HACCP publishes the guidance issued by the European Commission in the subject.
 - (5) The combined health warning must
 - a) be printed in a way that opening the package does not cover it or interfere with it; and
 - b) be displayed in a manner that ensures that none of the textual or visual elements of the combined warnings is severed when the package is opened.
 - (6) On request, the NPHS OCMO shall provide the manufacturer the electronic source documents suitable for the implementation of combined health warnings by the printer."
9. Section 11 of the Implementation Regulation is supplemented with the following subsection (4):
"(4) The NPHS OCMO shall maintain a registry on applicants falling under subsection (2), and it sends the list of applicants and license recipients to the NIHD SFP annually, by 31 March."
10. Section 12 of the Implementation Regulation is supplemented with the following subsection (4):
"The NIHD SFP is competent to maintain the www.leteszemacigit.hu website and 06 40 200 493 phone number, which is used for recording residential comments in relation to compliance with the provisions prescribed by the Act on the protection of non-smokers, which are also indicated at the locations detailed in Schedules 5 and 7 as well as at the location specified in subsection 6 (3) of the Act on the protection of non-smokers."

11. Chapter 6 of the Implementation Regulation is supplemented with the following section 15/A:
"15/A The unit packet
a) in case of cigarettes, it is a packet containing not less the 20 but not more than 25 cigarettes;
b) if subsection 2 (3) b) ba) or subsection 2 (3) b) bb) applies,
ba) in case of a cigars not constituting cigarillos, it is a piece or a packet;
bb) in case of cigarillos, it is a packet containing at least 5 pieces;
c) in case of smoking tobacco, it is a rectangular shape or standing pouch containing at least 30 grams, but not more than 50 grams of smoking tobacco, but the weight must be divisible with 10 without remainder;
d) in case of chewing tobacco or nasal tobacco, it is a pouch or packet."
12. Section 8 of the Implementation Regulation is substituted with the following chapter:
"8. Market surveillance of tobacco products, electronic cigarettes, refill liquids and electronic devices for the imitation of smoking"
13. (1) Regulation 17 (5) of the Implementation Regulation is substituted with the following provision:
"(5) Any laboratory accredited by the competent authority of a member state of the Agreement on the European Economic Area is also entitled to test and certify the tar, nicotine and carbon monoxide values of cigarettes. The laboratories shall not be owned or controlled directly or indirectly by the tobacco industry."
(2) Section 17 (7) of Implementation Regulation is substituted with the following provision:
"(7) In case of cigarettes, the appropriateness of the smoke related values indicated on the registration sheet must be certified according to the MSZ ISO 8243 standard."
14. Section 18 of the Implementation Regulation is substituted with the following provision:
"18 (1) Before the tobacco product is placed on the market, its manufacturer and importer must submit the following data for each brand and type in Hungarian or in English, through the common entry gate specified in Commission Implementing Decision 2015/2186:
a) the data regarding the ingredients of the tobacco product, in descending order based on the weight of each ingredient; and
b) the data regarding the emission levels specified in subsection 5 (1) and the emissions exceeding these thresholds.
(2) Before the tobacco product is placed on the market, its manufacturer and importer must submit the data regarding the volume of sales for each brand and type in Hungarian or in English by 31 March each year, through the common entry gate specified in Commission Implementing Decision 2015/2186. The applicable year shall run from 1 January to 31 December before the lists are submitted.
(3) The data submitted under subsection (1) must be re-submitted before the product is placed on the market, if the composition of a product changes in a way that affects the submitted information.
(4) Apart from the submission of data referred to in subsection (1) (a), the reasons for the inclusion of such ingredients in the relevant tobacco products must be set out, moreover, the status and type of the ingredients must be submitted, including the fact whether they are registered. The list shall also be accompanied by the toxicological data available to the manufacturer, the importer, the registered trader and the authorized person of the tax warehouse regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on the health of consumers and taking into account, inter alia, any addictive effects. For cigarettes and cigarette 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, importers shall indicate the methods used for the measurement of emissions. Manufacturers and importers must also carry out the studies prescribed by the minister responsible for consumer protection in order to assess the effects of ingredients on health, taking into account, inter alia, their addictiveness and toxicity.
(6) For the purposes of submitting the information regarding tobacco products and making them publicly available, the manufacturer and the importer of tobacco products must 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 and executive summaries of any market surveys they carry out before launching new products.

The information is submitted electronically through the common entry gate. The information must be submitted in Hungarian or in English.

(7) Having regard to the protection of trade secrets, the minister responsible for the agricultural policy publishes the data uploaded through the common entry gate on the website of the ministry led by him by 30 April each year, and sends it to the minister responsible for healthcare as well as to the NPHS OCMO and the NIHD SFP."

15. The Implementation Regulation is supplemented with the following sections 18/A–18/D:

"18/A (1) Apart from the data disclosure prescribed by subsection 18 (1), the manufacturer and the importer of the tobacco product has an enhanced obligation to submit a report regarding the additives included on the priority list defined in the European Commission Implementation Regulation.

(2) Within the reporting obligation specified in subsection (1), manufacturers and importers of tobacco products must 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, 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 detailed 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) Manufacturers or importers must draw up a report on the studies made under subsection (2) and (3), and it 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. At the latest 18 months after the additive concerned has been included in the priority list, the reports drawn up this way shall be submitted to the European Commission by the manufacturers or importers and a copy thereof must be sent to the NPHS OCMO.

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

18/B (1) Manufacturers and importers of tobacco products and the registered traders must make a notification if they intend to place on the market tobacco products belonging to new categories of tobacco products. Six months before the intended placement to the market, the notification must be made electronically to the minister responsible for the agricultural policy, to the minister responsible for the monitoring of the food chain, to the minister responsible for healthcare and to the NPHS OCMO. The detailed description of the novel tobacco product and a copy of the user manual must be attached to the notification, and information must be provided regarding the ingredients and emissions of the product containing the data prescribed by Commission Implementation Decision 2015/2186.

(2) Manufacturers, importers and registered traders submitting the notification regarding the new categories of tobacco products must also submit the following to the recipients specified in subsection (1):

- 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 tobacco products belonging to new categories of tobacco products must transmit to the recipients specified in subsection (1) any new or updated information on the studies, research and other information referred to in points (a) to (c) of subsection (2).

Manufacturers, importers and registered traders of tobacco products belonging to new categories of tobacco products may be obliged to conduct further tests or submit further information.

(4) Based on the submitted data and information, the NPHS OCMO considers whether the product shall be banned.

(5) The minister responsible for the agricultural policy sends the information received under this section to the European Commission.

18/C (1) Manufacturers and importers of herbal products for smoking must submit to the minister responsible for the agricultural policy a list of all ingredients, and their quantities used in the manufacture of such products for each brand name and type. Manufacturers or importers shall also inform the minister responsible for the agricultural policy, when the composition of a product is modified in a way that affects the information submitted pursuant to this section. The information shall be submitted six months before placing on the market the new or modified herbal product for smoking.

(2) The information submitted in accordance with subsection (1) is public through the website maintained by the minister responsible for agricultural policy, and the minister responsible for agricultural policy sends the information to the minister responsible for healthcare, the NPHS OCMO and the NIHD SFP. During publication, the protection of trade secrets identified by the economic entity must be taken into consideration.

18/D The manufacturers and importers of tobacco products and associated products must submit complete and appropriate information within the time limit specified by subsection 18/B (1). The obligation to provide the requested information lies primarily with the manufacturer, if the manufacturer is established within a 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 one of the Member States of the European Union. The obligation to provide the requested information lies jointly with the manufacturer and the importer if both are established outside the European Union."

16. Section 9/A of the Implementation Regulation is substituted with the following provision:

"9/A The rules applicable to electronic cigarettes, refill containers and electronic devices for the imitation of smoking

19/A (1) The notification prescribed by subsection 7/D (1) of the Act on the protection of non-smoker must be submitted to the National Institute of Pharmacy and Nutrition (hereinafter: NIPN) through the common entry gate specified in Commission Implementing Decision 2015/2186 in Hungarian or in English, with the data content prescribed by Commission Implementing Decision 2015/2186.

(2) Notifications pursuant to subsection (1) must contain the following data:

- a) name and contact details of the manufacturer or importer,
- b) 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, referring primarily to their effects on the health of consumers when inhaled and taking into account any potential addictive effect;
- 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 mechanisms of the electronic cigarette or refill containers;
- f) a description of the production process, including whether the product was manufactured by series production, and a declaration that the production process ensures conformity with the requirements of the 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) A new notification must be submitted in case of any changes in the product that affect the data specified in subsection (2).

(4) In case of electronic devices for the imitation of smoking, the notification must be made through the common entry gate specified in Commission Implementing Decision 2015/2186, with the data content prescribed by points a)–c) and e)–g) of subsection (2).

19/B (1) Electronic cigarettes and refill containers may be placed on the market and distributed with the following conditions:

- a) they may not contain flavorings;
- b) nicotine-containing liquid may only be placed on the market in dedicated refill containers not exceeding the volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks may

not exceed the volume of 2 ml;

- c) the nicotine-containing liquid may not contain nicotine in excess of 20 mg/ml;
- d) the nicotine-containing liquid may not contain
 - da) additives listed in Schedule 4;
 - db) vitamins or other additives that create the impression that the product has a health benefit or presents reduced health risks;
 - dc) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;
 - dd) additives having coloring properties for emissions;
 - de) additives facilitating inhalation or nicotine uptake; and
 - df) additives that have CMR properties;
- e) the nicotine-containing liquid may not contain an ingredient with more than 0.1% of contamination;
- f) substances other than the ingredients referred to in point (b) of subsection 19/A (2) may only be present in the nicotine-containing liquid in trace levels, and only if such traces are technically unavoidable during manufacture;
- g) except for nicotine, the nicotine-containing liquid may only contain ingredients that do not pose a risk to human health in heated or unheated form;
- h) electronic cigarettes may deliver the nicotine doses at consistent levels under normal conditions of use;
- i) electronic cigarettes and refill containers must be child-proof; and
- j) electronic cigarettes and refill containers must be protected against breakage and leakage and must have a mechanism that ensures refilling without leakage.

(2) A manual must be attached to unit packets and any outside packaging of electronic cigarettes and refill containers that contains the following:

- a) instructions for use and storage of the product, including refill instructions and figures within the instructions of use as well as a reference that the product is not recommended for use by young people and non-smokers;
- b) information regarding contra-indications;
- c) warnings for specific risk groups;
- d) information regarding possible adverse effects;
- e) information regarding addictiveness and toxicity; and
- f) contact details of the manufacturer or importer and those of the contact person.

(3) Unit packets and any outside packaging of electronic cigarettes and refill containers must indicate:

- a) all ingredients of the product in descending order by weight;
- b) the nicotine content and nicotine emission of the product per dose;
- c) the batch number; and
- d) the following warning: "Keep out of the reach of children."

(4) The unit packets and any outside packaging of electronic cigarettes and refill containers must comply with the provisions specified in points b), d) and e) of subsection 6/A (1) of the Act on the protection of non-smokers, as well as subsection (2) and (3).

(5) On the two largest surfaces of the unit packets and any outside packaging of electronic cigarettes and refill containers, the following health warning must be printed in a way that it covers at least 30% of both surfaces: "This product contains nicotine which is a highly addictive substance."

(6) The health warning under subsection (5) must be printed on a white background using black, bold, Helvetica bold font. The text must be written in lowercase letters, except for the first letter of the text and when uppercase letters shall be used according to the grammatical rules. The health warning must be aligned to the center of the surface reserved for its printing, and it must be parallel with the upper edge of the package.

(7) Within 60 days from the notification, NIPN shall issue a certificate on the discharge of the notification duty and on the compliance of the product subject to the notification with sections 19/A and 19/B.

19/C (1) Electronic devices for the imitation of smoking may be placed on the market and distributed with the following conditions:

- a) the liquid used in the electronic devices for the imitation of smoking may not contain nicotine;
- b) the liquid used in the electronic devices for the imitation of smoking may not contain flavorings;
- c) the liquid used in the electronic devices for the imitation of smoking may not contain
 - ca) additives listed in Schedule 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 energy and vitality;
 - cd) additives having coloring properties for emissions;

- ce) additives facilitating inhalation; and
- cf) additives that have CMR properties;
- d) the liquid used in the electronic devices for the imitation of smoking may not contain an ingredient with more than 0.1% of contamination;
- e) the liquid used in the electronic devices for the imitation of smoking may only contain ingredients that do not pose a risk to human health in heated or unheated form;
- f) electronic devices for the imitation of smoking must be child-proof; and
- g) electronic devices for the imitation of smoking must be protected against breakage and leakage and must have a mechanism that ensures refilling without leakage.

(2) An information leaflet containing the information specified in subsection 19/B (2) must be attached to unit packets of electronic devices for the imitation of smoking.

(3) Unit packets and any outside packaging of electronic devices for the imitation of smoking must indicate:

- a) all ingredients of the product in descending order by weight;
- b) the batch number; and
- c) the following warning: "Keep out of the reach of children."

(4) The unit packets and any outside packaging of electronic devices for the imitation of smoking must comply with the provisions specified in points b), d) and e) of subsection 6/A (1) of the Act on the protection of non-smokers, as well as subsection (2) and (3).

(5) In accordance with the provisions detailed in section 19/B (6), on the two largest surfaces of the unit packets and any outside packaging of electronic cigarettes and refill containers, the following health warning must be printed in a way that it covers at least 30% of both surfaces: "This product is an electronic device for the imitation of smoking. It is not recommended for use by children."

19/D (1) Manufacturers and importers of electronic cigarettes, electronic devices for the imitation of smoking and refill containers must provide the following data annually through the common entry gate, by 31 March after the relevant year:

- a) 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 points a)–c), including an English translation thereof;

and the applicable year shall run from 1 January to 31 December before the lists are submitted.

(2) NIPN may request the data specified in subsection (1) from authorities of other countries, and, on the request of authorities of other countries, it may provide information about the data made available to it by the manufacturers or importers. Data constituting trade secret may not be provided to an authority of a country outside the European Union.

(3) NIPN sends the data specified in subsections (1) and (2) to the NIHD SFP.

(4) NIPN and NIHD SFP makes an analysis annually based on the data provided under subsection (1), and informs NPHS OCMO and the minister responsible for healthcare by 30 June each year whether, based on the data, the use of the electronic cigarette, the electronic device for the imitation of smoking and the refill containers can lead to nicotine addiction or may induce young people and non-smokers to use tobacco products.

(5) NIPN publishes the data provided under subsection (1) and the summary made under subsection (4) on its website, without breaching any trade secret.

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

(2) Should the manufacturer, the importer or the distributor consider or have reason to believe that the product, 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 applicable legislation, it shall immediately take the corrective action necessary to bring the product concerned into conformity with the requirements, or to withdraw or to recall it, as appropriate. The manufacturer, the importer or the distributor shall 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 human health and safety and of any corrective action taken, and of the results of such corrective action."

17. The Implementation Regulation is supplemented with the following section 21/A:

“21/A (1) Unless subsections (3)–(6) specify otherwise, tobacco products complying with the rules applicable on 19 August 2016

- a) may be manufactured, imported and received by a registered trader by 31 December 2016;
- b) may be supplied to a tobacco retail warehouse by 28 February 2017;
- c) may be placed on the market by 20 May 2017.

(2) Herbal products for smoking manufactured or released for free circulation before 20 August 2016 may be placed on the market by 20 May 2017 according to the provisions of this regulation applicable on 19 August 2016.

(3) The provisions of sections 6/B and 6/C, as established by government regulation 239/2016 (16 August) on the amendment of government regulation 39/2013 (14 February) on the detailed rules of production, distribution and control of tobacco products, the combined warnings and the application of health protection fines (hereinafter: Amending Regulation) do not apply until 19 May 2019 in case of tobacco products that have been registered at the HACP or at the ND Nemzeti Dohánykereskedelmi Nonprofit Zrt. by 30 April 2016 with the data content specified in Schedule 1, and only the changes prescribed by the Amending Regulation have been implemented in relation to them. From 20 May 2019, these products may be distributed only in primary packaging complying with the provisions established by sections 6/B and 6/C.

(4) The provisions of sections 6/B and 6/C as established by the Amending Regulation

- a) apply immediately to new brands and new types registered after 30 April 2016 and placed on the market after 19 August 2016;
- b) apply after 19 August 2016 to new brands and new types registered after 30 April 2016 and placed on the market before 20 August 2016, excluding products falling under point c) cb), provided, that they may be on the market after 20 May 2018 only in primary packaging in compliance with the provisions established by section 6/B and 6/C;
- c) apply immediately to tobacco products

ca) registered at the HACP or at the ND Nemzeti Dohánykereskedelmi Nonprofit Zrt. by 30 April 2016 with the data content specified in Schedule 1; and

cb) new brands and new types registered after 30 April 2016 and placed on the market after 20 August 2016; where changes are made that do not exclusively involve the provisions established by the Amending Regulation.

(5) Menthol flavored cigarettes and menthol flavored cigarette tobacco may be distributed until 20 May 2020 provided that

- a) the menthol flavoring is added to the tobacco product during the manufacturing or packaging process; and
- b) adding the flavoring must not be dependent on the consumer even in part, so it is especially prohibited to use capsules for adding the menthol flavoring.

(6) In case of menthol flavored cigarettes and cigarette tobacco not complying with the requirements specified in points a) and b) of subsection (5), the provisions of subsection (1) apply.

(7) Electronic cigarettes, refill containers and electronic devices for the imitation of smoking, which are manufactured before 20 November 2016, may be placed to the market until 20 May 2017.

(8) In case of electronic cigarettes, refill containers and electronic devices for the imitation of smoking, which are already on the market on 19 May 2016, the notification under section 19/A established by the Amending Regulation must be made until 20 December 2016, and NIPN issues the certificate for these notifications by 20 May 2017 according to section 19/B (7) as established by the Amending Regulation.

(9) In case of electronic cigarettes, refill containers and electronic devices for the imitation of smoking, which are already on the market on 19 May 2016, the first data disclosure under section 19/D established by the Amending Regulation must be made until 31 March 2017.

(10) For products placed on the market before 20 August 2016, the information specified by subsection 18 (1) as established by the Amending Regulation regarding the ingredients of tobacco products and the emission levels must be submitted by 20 November 2016.

(11) The information specified by subsection 18 (2) as established by the Amending Regulation regarding sales volumes must be submitted by 20 November 2016, and the data submitted on the first occasion must cover the time period between 1 January 2015 and 20 August 2016.

(12) The studies and summaries specified by subsection 18 (6) as established by the Amending Regulation, including studies and summaries made before 20 August 2016, must be submitted on the first occasion by 20 November 2016.

2016.

(13) Until 20 May 2019, point c) of subsection 7 (1) as established by the Amending Regulation shall apply with the difference that

a) if the tax stamp or national identification mark used for fiscal purposes is affixed at the top edge of a unit packet is 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) if a unit packet is made of soft material, a rectangular area may be reserved for the tax stamp 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 a smoking tobacco distributed in a standing pouch,

ca) the combined health warning shall cover 65% of the front and back surface of the standing pouch; cb) the upper side of the combined health warning shall be on the standing pouch under or close to the opening strip or the perforation for the removal thereof (if it exists) in a way that the combined health warning is not damaged when the pouch is opened; and

cc) the combined health warning on the front side of the pouch shall cover the full width of the packet, taking into account printing tolerances, while on the back side containing the tax stamp, it shall be aligned to the left leaving space for the tax stamp on the right of the combined health warning.

(14) In relation to the ingredients of herbal products for smoking placed to the market before 20 August 2016, the list specified by subsection 18/C (1) as established by the Amending Regulation, must be submitted by 20 November 2016.

(15) On the first occasion, the year specified by subsection 8 (3), as established by the Amending Regulation, means the time period from 20 August 2016 to 19 August 2017.

2017.

(16) On the first occasion, the report specified by subsection 8 (3), as established by the Amending Regulation, must be submitted by 1 July 2018."

18. Regulation 23 (1) of Implementation Regulation is substituted with the following provision:

"(1) The present Regulation 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 (4).

b) Directive 2014/109/EU of the European Commission 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

"

19. (1) Schedule 1 of the Enforcing Regulation is amended according to Schedule 1.

(2) Schedule 3 of the Enforcing Regulation is amended according to Schedule 2.

(3) Schedule 4 of the Enforcing Regulation is substituted with Schedule 3.

(4) Schedule 4 of the Enforcing Regulation is substituted with Schedule 4.

20. In the Enforcing Regulation,

a) in subsections 3 (1)–(3), the text "the storage tax warehouse" is substituted with the text "the tax warehouse";

- b) in subsection 3 (3), the text “Office of the Chief Medical Officer of the National Public Health Service hereinafter (NPHS OCMO)” is substituted with the text “Office of the Chief Medical Officer of the National Public Health Service (hereinafter: NPHS OCMO) and Smoking Focal Point of the National Institute for Health Development (hereinafter: NIHD SFP)”;
 - c) in subsection 11 (2), the text “Office of the Chief Medical Officer” is substituted with the text “NPHS OCMO”;
 - d) in subsection 17 (1) a) the text “contents of the license issued under subsection (2)” is substituted with the text “notification according to”;
 - e) in subsection 17 (2), the texts “the storage tax warehouse” are substituted with the text “the tax warehouse”;
 - f) in subsection 19 (1), the text “the list detailed in Schedule 12” is substituted with the text “all data provided to him, having regard to the protection of trade secret, the ministry led by him”;
 - g) on point 1 of Schedule 1, the text “the storage tax warehouse” is substituted with the text “the tax warehouse”.
- 21.** The following is repealed in the Implementation Regulation
- a) in subsection 3 (4), the text “and on the data content of documents specified in subsection 4 (2)”;
 - b) section 10;
 - c) subsection 20 (3);
 - d) subsection 23 (2);
 - e) Schedules 2 and 10–12.
- 22.** (1) Apart from the exception specified in subsection (2), this Regulation shall enter into force on 20 August 2016.
(2) Subsection 19 (4) and Schedule 4 shall enter into force on 20 May 2020.
- 23.** (1) The consultation specified in Articles 8–10 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 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 done.
(2) The present Regulation 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 (4).
 - b) 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;
 - c) Commission implementing decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers;
 - d) 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
 - e) Commission implementing decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes.

Dr. Semjén Zsolt signed,
Deputy Prime Minister

1. *Schedule 1 to government regulation 239/2016 (16 August)*

1. Point 2 of the Schedule 1 of the Implementation Regulation is substituted with the following provision:

„2 The information regarding the name of the tobacco product:

- a) category [in case of products not belonging to a new category of tobacco products, according to subsection 6 (1) a)];
- b) brand name / trademark;
- c) type (if can be specified);
- d) product identifier (the identifier used in the reporting format specified in commission implementation decision 2015/2186)“

2. *Schedule 2 to government regulation 239/2016 (16 August)*

1. The title of Schedule 3 of the Enforcing Regulation is substituted with the following title:

“The content of the notification made in relation to the use of a new additive in the production of tobacco products”

2. Schedule 3 of the Enforcing Regulation is supplemented with the following point 4/a:

„4/a The assessments made under point 4 do not contain data regarding the toxicological characteristics of additives and their combustion products, especially the carcinogen effects, and the heart, lung and reproduction toxicity.“

Schedule 3 to government regulation 239/2016 (16 August)

“Schedule 4 to government regulation 39/2013 (14 February)

Prohibited additives

A	B
1	Material
2	2-metil-3-(para-isopropyl-phenyl)propionaldehyde
3	Agar-agar
4	Aluminium oxide
5	Ammonium acetate
6	Ammonium citrate
7	Ammonium formate
8	Ammonium hydrogen carbonate
9	Ammonium hydrogen malate
10	Ammonium hydroxide
11	Ammonium carbamate
12	Ammonium chloride
13	Ammonium lactate
14	Ammonium malate
15	Ammonium succinate
16	Ammonium sulfamate
17	Ammonium tartarate
18	Anthraquinone blue
19	Basic blue 26
20	Succinic acid (E363)
21	Dehydro-menthol-furolacton
22	Di-2-etil-hexil-adipate

23	Diammonium hydrogen phosphate
24	Diammonium carbonate
25	Diammonium malate
26	Diammonium succinate
27	Dibutyl phthalate
28	Rosin-modified phenol-formaldehyde
29	Galactose
30	Formic acid (E236)
31	Carbamide (E927b)
32	Carminic acid
33	Caffeine
34	Alkannin
35	Cumarin 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 (E1251)
46	Riboflavin-5-phosphate
47	Sucrose-octa-acetate
48	Saccharin (E954)
49	Sudan blue 11
50	Taurine
51	Tea
52	Theobromine

Schedule 3 to government regulation 239/2016 (16 August)

"Schedule 4 to government regulation 39/2013 (14 February)

Prohibited additives

A	B
1	Material
2	2,6-Ditertiary-butyl-4-methylphenol
3	2-phenyl-propionaldehyde
4	2-metil-3-(para-isopropyl-phenyl)propionaldehyde
5	Acetyl tributyl citrate
6	Agar-agar
7	Aluminium oxide
8	Ammonium acetate

9	Ammonium citrate
10	Ammonium formate
11	Ammonium hydrogen carbonate
12	Ammonium hydrogen malate
13	Ammonium hydroxide
14	Ammonium carbamate
15	Ammonium chloride
16	Ammonium lactate
17	Ammonium malate
18	Ammonium succinate
19	Ammonium sulfamate
20	Ammonium tartarate
21	Anthraquinone blue
22	Acacia gum (E414)
23	Gold bronze (copper)
24	Basic blue 26
25	Succinic acid (E363)
26	Brilliant blue
27	Dehydro-menthol-furo lacton
28	Di-2-etil-hexil-adipate
29	Diammonium hydrogen phosphate
30	Diammonium carbonate
31	Diammonium malate
32	Diammonium succinate
33	Dibutyl phthalate
34	Ethylc itrates (triethyl citrate E1505)
35	Rosin-modified phenol-formaldehyde
36	Galactose
37	Formic acid (E236)
38	Isopropyl alcohol
39	Maple syrup
40	Cocoa and cocoa products
41	Carbamide (E927b)
42	Carminic acid
43	Carrageenan (E407)
44	Coffee
45	Caffeine
46	Alkannin
47	Cumarin free tonquin beans
48	Lactose
49	Maltose
50	Mannans, modified mannans
51	Mannose
52	Molasses
53	Methyl violet
54	Honey
55	Monoammonium phosphate

56	Sodium silicate
57	Solvent red 1
58	Pectins
59	Polyethylene glycol (E1251)
60	Ponceau 4R
61	Riboflavin-5-phosphate
62	Sucrose-octa-acetate
63	Saccharin (E954)
64	Silicon dioxide (E551)
65	Sudan blue 11
66	Talc (E553b)
67	Tartrazine
68	Taurine
69	Tea
70	Theobromine
71	Titanium dioxide (E171)
72	Triethyl citrate (E1505)
73	Iron oxide (Fe ₃ O ₄)
74	Xanthan gum (E415)