

**Decree No. 261/2016**

**Decree on tobacco products**

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Part 101/2016

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261

DECREE

dated 28 July 2016

on tobacco products

The Ministry of Agriculture stipulates pursuant to section 18(1) (a), (b), (k) and (o) of Act No. 110/1997, on foodstuffs and tobacco products and amending and supplementing some related Acts, as amended by 180/2016

**Section 1**

Subject of the legislation

This Decree promulgates the relevant regulations of the European Union <sup>1)</sup> and regulates

- a) the provision of information about tobacco products,
- b) the requirements for appearance, properties, content, composition and method for placing on the market,
- c) the maximum emission levels for cigarettes,
- d) location and characteristics of the unique identifier and the scope of the statements contained therein,
- e) the location and properties of the security feature,
- f) prohibited elements and features of the tobacco products and their unit and special packets,
- g) information on smoking cessation and groups of combined health warnings,
- h) the scope, timing, method of informing a way of dealing with information in the placing of tobacco products on the market,
- i) the priority list of ingredients, scope, elements and method of processing, focus and method of presentation of the study for the additives listed in the priority list and the scope, timing and manner of presentation of the report on the outcome of a study for the additives listed in the priority list
- j) the scope of data required for registration before commencing the placing on the market of tobacco products to the market through cross-border distance selling and how to implement this authorisation,
- k) List of prohibited substances, which may not contain tobacco products placed on the market,
- l) scope, timing and manner of information on novel tobacco products,
- m) types of tobacco product and their division into groups and subgroups.

## Section 2

### Definitions

For the purposes of this Decree

- a) 'tar' means the raw anhydrous nicotine-free condensate of smoke,
- b) 'emissions' means substances that are released when a tobacco or related product is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products,
- c) 'pouch' means a unit packet of roll-your own tobacco, either in the form of a rectangular pocket or in the form of a standing pouch,
- d) 'rectangular pocket' means a rectangular pouch closed with a flap.

## Section 3

### List of prohibited substances

Prohibited substances in tobacco products placed on the market are

- a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks,
- b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality,
- c) additives having colouring properties for emissions,
- d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and
- e) additives that have carcinogenic, mutagenic and reprotoxic properties in unburnt form.

## Section 4

### Prohibited elements and features

- (1) The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that
  - a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions,
  - b) includes any information about the nicotine, tar or carbon monoxide content of the tobacco product,
  - c) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits,
  - d) refers to taste, smell, any flavourings or other additives or the absence thereof,
  - e) resembles a food or a cosmetic product, or
  - f) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.
- (2) The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.
- (3) The elements and features that are prohibited pursuant to paragraphs 1 and 2 may include but are not limited to texts, symbols, names, trademarks, figurative or other signs.

## Section 5

### Appearance, characteristics and content of the unit packets

- (1) Unit packets of cigarettes shall have a cuboid shape. Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch.
- (2) A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30 g.
- (3) 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.
- (4) A unit packet of cigarettes shall include at least 20 cigarettes.

## Section 6

### Maximum emission levels for cigarettes

- (1) The maximum emission levels shall not be greater than 10 mg of tar per cigarette.
- (2) The maximum emission levels shall not be greater than 1 mg of nicotine per cigarette.
- (3) The maximum emission levels shall not be greater than 10 mg of carbon monoxide per cigarette.

## Section 7

### Means of identification of tobacco products with a unique identifier

- (1) The unique identifier shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps or price marks, or by the opening of the unit packet.
- (2) The unique identifier shall allow the following to be determined:
  - a) 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, being its trade name, type of group and subgroup and method of packaging,
  - f) the intended market of retail sale,
  - g) the intended shipment route,
  - h) the name or names and surname and registered office or name or business name and address of the importer in the case of imports 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 name or names and surname and registered office or name or business name and address 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 subsection 2(a) to (h) shall form part of the unique identifier.
- (4) The information referred to in subsection 2(i), (j) and (k) must be electronically accessible by means of a link to the unique identifier.

## **Section 8**

Means for identification of tobacco products with a security feature

- (1) The security feature is composed of visible and invisible elements. The security feature shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form.
- (2) The tobacco label applied to unit packaging of tobacco products acts as a security feature provided that it meets the conditions specified in paragraph 1.

## **Section 9**

Breakdown of tobacco products

- (1) Types of tobacco products and their division into groups and subgroups are listed in Annex 1 hereto.
- (2) The tobacco product shall be labelled with the name of the type and group.
- (3) Tobacco is marked with the name of the type, group and subgroup.

Methodology for the general warning and information messages on tobacco products intended for smoking

## **Section 10**

- (1) The wording of the general warning on tobacco products designed for smoking is "Smoking kills - quit now". This information must cover 50% of the surface on which it is printed.
- (2) The information message on tobacco products designed for smoking is "Tobacco smoke contains over 70 substances known to cause cancer". This information must cover 50% of the surface on which it is printed.
- (3) For cigarette packets and roll-your-own tobacco in cuboid packets the general warning shall appear on the bottom part of one of the lateral surfaces of the unit packets, and the information message shall appear on the bottom part of the other lateral surface. These health warnings shall have a width of not less than 20 mm. The width is measured in direction of the text placement.
- (4) For unit packets of cigarettes and roll-your-own tobacco 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.
- (5) For roll-your-own tobacco marketed in pouches the general warning and the information message shall appear on the surfaces that ensure the full visibility of those health warnings. For roll-your-own tobacco in cylindrical packets the general warning shall appear on the outside surface of the lid and the information message on the inside surface of the lid.
- (6) The general warning and information messages on tobacco products intended for smoking must be
  - a) printed in black Helvetica bold type on a white background while maintaining the default character spacing, which is 100%, and normal gaps, on a white background, ensuring that the relevant text occupies the greatest possible proportion of the surface reserved for these health warnings,
  - b) positioned at the centre of the surface reserved for them and

- c) on cuboid packets and any outside packaging of tobacco products for smoking they shall be parallel to the lateral edge of the unit packet or of the outside packaging.

#### **Section 11**

- (1) For roll-your-own tobacco in the form of a rectangular pouch the general warning and information messages shall be printed on both surfaces, which will be visible when the unit package is fully opened as specified in points 1 and 2 of Annex 2 hereto. General warnings and information notices must be placed on the upper edge of the rectangular pouch and must cover 50% of the surfaces on which they are printed, as outlined in points 1 and 2 of Annex 2 hereto. The general warning must be printed on the upper surface of the rectangular pouches.
- (2) For roll-your-own tobacco in standing pouches the general warning and information message must be placed on the surfaces on the bottom of the standing pouch (hereinafter referred to as "base of the unit packet"), which will be visible when placing the pouch on the rear side, as mentioned in point 4 of Annex 2 hereto.
- (3) For roll-your-own tobacco in standing pouches the general warning shall be printed on the surface above the crease on the base of the unit packet and the information message on the surface below the crease. The general warning and information message are to cover 50 % of the surfaces of the standing pouches on which they are printed. The surfaces shall be calculated using their dimensions after the edges are sealed.

Method of statement of combined health warnings on tobacco products intended for smoking

#### **Section 12**

- (1) Combined health warnings on tobacco products for smoking must
  - a) be indicated on each unit packet and any outside packaging of tobacco products for smoking,
  - b) contain one of the text warnings listed in Annex 3 hereto and a corresponding colour photograph specified in the picture library in Annex 4 hereto,
  - c) include smoking cessation information, which reads "How to quit smoking: [www.koureni-zabiji.cz](http://www.koureni-zabiji.cz)",
  - d) cover 65 % of both the external front and back surface of the unit packet and any outside packaging. Cylindrical packets shall display two combined health warnings, equidistant from each other, each covering 65 % of their respective half of the curved surface,
  - e) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging,
  - f) 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,
  - g) be reproduced in accordance with the format, layout, design and proportions specified in Annexes 4 and 5 hereto, and
  - h) in the case of unit packets of cigarettes, respect the following dimensions: height: not less than 44 mm, width: not less than 52 mm.
- (2) Where the height of the combined health warning is greater than 70 % of its width, a stacked format should be used, as specified in point 1 of Annex 5 hereto. Where the height of the combined health warning is greater than 20 % but less than 65 % of its width, a side-by-side format should be used, as specified in section 2 of Annex 5 hereto. Where the height of the combined health warning is greater than or equal to 65 % but less than or equal to 70 % of its width, either a stacked or a side-by-side format may be used, as long as all the elements of the combined health warning remain fully visible and are not distorted.

- (3) 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 point 1 of Annex 5 hereto, The photograph shall occupy 50 %, the text warning 38 % and the cessation information 12 % of the surface area of the combined health warning inside the outer black border. 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 point 2 of Annex 5 hereto, The photograph shall occupy 50 %, the text warning 40 % and the cessation information 10 % of the surface area of the combined health warning inside the outer black border.
- (4) 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 % of its width, the combined health warning shall be laid out in a side-by-side extra-wide format as illustrated in point 3 of Annex 5 hereto, The photograph shall occupy 35 %, the text warning 50 % and the cessation information 15 % of the surface area of the combined health warning inside the outer black border.
- (5) The splitting of the combined health warnings into three groups is set out in Annex 4 hereto,

### **Section 13**

- (1) The combined health warning shall be printed in four-colour CMYK. All elements in black shall be C0, M0, Y0 and K100 and those in warm yellow shall be C0, M10, Y100 and K0. The combined health warning shall be reproduced at a minimum resolution of 300 dpi when printed in actual size.
- (2) The text warning shall be printed in white on a black background.
- (3) 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.
- (4) The photograph
  - a) must be reproduced without applying effects, adjusting the colours, retouching, or extending the background,
  - b) must not be cropped too close or too far from the focal point of the image, and
  - c) should be scaled proportionally without being stretched or condensed.
- (6) The text warning must
  - a) be left aligned and centred vertically,
  - b) be printed in Neue Frutiger Condensed Bold,
  - c) be printed in a uniform font size,
  - d) have font size as large as possible to ensure maximum visibility of the text,
  - e) have a minimum font size of 6 pt,
  - f) the space between lines must be 2 pt larger than the font size of the text warning, and
  - g) must be reproduced as set out in Annex 3 hereto, including as regards the use of capital letters, but excluding the numbering.
- (7) By way of derogation from subsection 5(e) and (f), 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.

### **Section 14**

- (1) Information regarding smoking cessation must

- a) be left aligned and centred vertically,
  - b) be printed in Neue Frutiger Condensed Bold,
  - c) have font size as large as possible to ensure maximum visibility of the text,
  - d) have a minimum font size of 5 pt,
  - e) have a space between lines of 1-2 pt greater than the size of the font of the information relating to smoking cessation, and
  - f) The cessation information shall be printed in black on a warm yellow background, as illustrated in Annex 5 hereto,
- (2) By way of derogation from subsection 1(e) and (d), 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.

### **Section 15**

- (1) By way of derogation from section 12(3) first and second sentences the combined health warnings shall be placed on the front of unit packets with a flip-top lid, in the manner provided for in paragraphs 2 and 3.
- (2) Where the lid is smaller than the surface area foreseen for the photograph under section 12(3) and compliance with section 12(3) would result in the photograph being split upon opening
- a) the text warning shall be placed at the top of the combined health warning, with the cessation information and photograph underneath as illustrated in point 4 of Annex 5 hereto, and
  - b) the photograph shall occupy at least 50 % of the surface area of the combined health warning, the text warning at least 30 % and the cessation information at least 10 % but no more than 12 % of the surface area of the combined health warning inside the outer black border.
- (3) where the lid is larger than the surface area foreseen for the photograph in section 12(4) and compliance with section 12(4) would result in the text warning or cessation information being split upon opening,
- a) the photograph shall be placed at the top of the combined health warning, with the text warning and cessation information underneath as illustrated in point 1 of Annex 5 hereto, and
  - b) the photograph shall occupy at least 50 % of the surface area of the combined health warning, the text warning at least 30 % and the cessation information at least 10 % but no more than 12 % of the surface area of the combined health warning inside the outer black border.
- (4) Manufacturers shall ensure that none of the three elements of the combined health warning on a unit packet with flip-top lid is split upon opening of the unit packet.

Presentation of warnings and text warnings on tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco

### **Section 16**

- (1) The general warning on tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco reads "Smoking kills – quit now".

- (2) Information on smoking cessation, which is connected to the general warning, reads “How to quit smoking: [www.koureni-zabiji.cz](http://www.koureni-zabiji.cz)”.
- (3) The general warning on tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco
  - a) shall appear on the most visible surface of the unit packet and any outside packaging and
  - b) shall cover 30 % of the relevant surface of the unit packet and any outside packaging.
- (4) For the purposes of labelling of tobacco products intended for smoking, other than cigarettes, roll-your-own tobacco and waterpipe tobacco under section 12e of Act No. 110/1997, on foodstuffs and tobacco products and amending and supplementing some related Acts, as amended (hereinafter the “Act”), the text warning is considered to be a health warning. A list of text warnings and their terms are listed in Annex 3 hereto.
- (5) For each brand of tobacco products intended for smoking, other than cigarettes, roll-your-own tobacco and waterpipe tobacco each text warning is displayed to the extent possible in equal numbers. The text warnings shall appear on the next most visible surface of the unit packet and any outside packaging. For unit packets with a hinged lid, the next most visible surface is the one that becomes visible when the packet is open.

### **Section 17**

- (1) Text warnings shall cover 40 % of the relevant surface of the unit packet and any outside packaging of tobacco intended for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco.
- (2) General warnings and text warnings
  - a) 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 health warnings,
  - b) shall cover an area of 45 cm<sup>2</sup>, if they appear on the surface of a unit packet or any outside packaging of tobacco intended for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco exceeding 150 cm<sup>2</sup>, and
  - c) must comply with the requirements specified in section 10(6), whereby the text of the general warnings shall be parallel to the main text on the surface reserved for these warnings.

### **Section 18**

Methodology for the placement of health warnings on smokeless tobacco products

- (1) Health warnings on smokeless tobacco products shall read “This tobacco product damages your health and is addictive.”.
- (2) Health warnings on smokeless tobacco products
  - a) must comply with the requirements specified in section 10(6), whereby the text of the health warnings shall be parallel to the main text on the surface reserved for these warnings, and
  - b) appear on the two largest surfaces of the unit packet and any outside packaging and also must cover 30 % of the surfaces of the unit packet and any outside packaging.

### **Section 19**

Other requirements for labelling with general warnings, communications, text warnings, health warnings and the combined health warnings on tobacco products



- (1) General warnings, communications, text warnings, health warnings and the combined health warnings on tobacco products
  - a) must be given in the Czech language
  - b) 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,
  - c) must be irremovably printed, indelible and fully visible,
  - d) should 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. On unit packets of tobacco products other than cigarettes and roll-your-own tobacco in pouches, the health warnings may be affixed by means of stickers, provided that such stickers are irremovable,
  - e) 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,
  - f) shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets, and
  - g) shall be surrounded by a black border of a width of 1 mm inside the surface area that is reserved for these warnings, except for health warnings pursuant to section 15.
- (2) The dimensions of the information according to section 10(1), (2) and (3), section 12(1)(d) and (h), section 16(3)(b), section 17(1), section 17(2)(b), and section 18(2)(b) shall be calculated in relation to the surface concerned when the packet is closed.

## Section 20

Methodology for fulfilling the information obligations in the placing on the market of novel tobacco products

- (1) Notification of the novel tobacco product in accordance with section 12g(1) of the Act is administered through a common electronic gateway for submitting data in the format specified in the Annex to the establishing a format for the submission and making available of information on tobacco products <sup>2)</sup> and by brand and type of new tobacco product shall contain
  - a) available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product, in particular as regards its ingredients and emissions,
  - b) available studies, executive summaries thereof and market research on the preferences of various consumer groups, including young people and current smokers,
  - 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,
  - d) a detailed description of the novel tobacco product concerned,
  - e) instructions for using the novel tobacco product,
  - f) a list of all additives and their amount used in the manufacture of a novel tobacco product in descending order of the weight of each ingredient contained in the novel tobacco product,
  - g) information on emission levels, if available, including the methods used for the measurement of emissions,
  - h) a technical document setting out a general description of the additives used and their properties,

- i) internal and external studies available to them on market research and preferences of various consumer groups, including young people and smokers, about the ingredients and emissions, as well as summaries of all market research performed when placing novel products on the market, and
  - j) information on sales volumes of novel tobacco products per brand and type, reported in sticks or kilograms.
- (2) Manufacturers and importers of novel tobacco products shall submit with the list of additives under subsection (1)(f) a justification for the use of these additives in novel tobacco products. The list shall also include information about whether the ingredients were registered under the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals <sup>3)</sup> and whether they have been classified according to the Regulation on classification, labelling and packaging of substances and mixtures <sup>4)</sup>.
- (3) The list referred to in subsection (1)(f) shall also be accompanied by the relevant toxicological data regarding the 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.
- (4) Before a manufacturer or importer first submits a notification under section 12g(1) of the Act, the Czech Agriculture and Food Inspection Authority shall request a submitter identification number created by the operator of the common entry gate. This number is used for all subsequent submission of information and all further correspondence.
- (5) Using this submitter identification number the manufacturer or importer shall assign an identification number to any novel tobacco product, that should be notified. When submitting information on novel tobacco products with the same composition and design, manufacturers and importers should, to the extent possible, use the same product identification number of the novel tobacco product, in particular where data is submitted by various members of a group of companies. This shall apply regardless of brand, subtype and the number of markets on which the novel tobacco products are placed. Where it is not possible to ensure that the same identification number of the novel tobacco product is used for products with the same composition and design, it shall provide the different identification numbers of the novel tobacco product that were assigned to such products.
- (6) The notification pursuant to subsection (1)(a) to (i) must be submitted electronically no later than six months prior to the planned introduction of a novel tobacco product on the market. Information pursuant to subsection (1)(j) shall be notified by 31 January of the calendar year and shall relate to the previous calendar year.

Methodology for fulfilling the information obligations in the placing on the market of tobacco products

## **Section 21**

- (1) Information pursuant to section 13(1) of the Act is transmitted through a common electronic gateway for submitting data in the format specified in the Annex to the establishing a format for the submission and making available of information on tobacco products and by brand and type of new tobacco product shall contain
- a) a list of all additives and their amount used in the manufacture of tobacco products in descending order of the weight of each ingredient contained in the tobacco products,
  - b) emission levels for tar, nicotine and carbon monoxide for cigarettes,
  - c) information on other emission levels, if available, including the methods used for the measurement of emissions,

- d) information on sales volumes of tobacco products per brand and type, reported in sticks or kilograms.
  - e) for cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties, and
  - f) information on the withdrawal of the tobacco product from the market.
- (2) Before a manufacturer or importer first submits a notification under section 13(1) of the Act, the Czech Agriculture and Food Inspection Authority shall request a submitter identification number created by the operator of the common entry gate. This number is used for all subsequent submission of information and all further correspondence.
- (3) Using this submitter identification number the manufacturer or importer shall assign an identification number to any product, that should be notified. When submitting information on products with the same composition and design, manufacturers and importers should, to the extent possible, use the same product identification number of the tobacco product, in particular where data is submitted by various members of a group of companies. This shall apply regardless of brand, subtype and the number of markets on which the products are placed. If it is not possible to ensure that the same identification number of the tobacco product is used for products with the same composition and design, it shall the different identification numbers of the product that were assigned to such products.
- (4) Manufacturers and importers of tobacco products shall submit with the list of additives under subsection (1)(a) a justification for the use of these additives in tobacco products. The list shall also include information about whether the ingredients were registered under the Regulation on the registration, evaluation, authorisation and restriction of chemicals and whether they have been classified according to the Regulation on classification, labelling and packaging of substances and mixtures.
- (5) The list referred to in subsection (1)(a) shall also be accompanied by the relevant toxicological data regarding the 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.
- (6) When newly placing tobacco products on the market or the placement of modified tobacco products altered the information required under subsection (1)(a) to (c) and (e), subsections 4 and 5 and section 13(4) of the Act shall be submitted prior to the placing on the market of those products.

## **Section 22**

- (1) Information pursuant to section 21(1)(d) shall be notified by 31 January of the calendar year and shall relate to the previous calendar year.
- (2) In their submission, manufacturers and importers shall mark all information which they consider to be a trade secret or otherwise confidential and shall, upon request of the Czech Agricultural and Food Inspection Authority, duly justify their claims.

## **Section 23**

Comprehensive study for the additives listed in the priority list and report on the outcome of the study

- (1) The comprehensive study under section 13a(1) of the Act 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 characterising flavour,
  - c) facilitates inhalation or nicotine uptake, or
  - d) leads to the formation of substances that have carcinogenic, mutagenic or reprotoxic properties, the quantities thereof, and whether this has the effect of increasing the carcinogenic, mutagenic or reprotoxic properties in any of the products concerned to a significant or measurable degree.
- (2) The study referred to in subsection 1 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.
- (3) The report on the results of the study in accordance with section 13a(2) of the Act contains a comprehensive overview compiling the available scientific literature on that additive and internal data on the effects of the additive.
- (4) The manufacturer and importer of cigarettes or roll-your-own tobacco containing an additive specified in the priority list shall submit a report pursuant to section 13a(2) 2 of the Act to the European Commission and the Czech Agricultural and Food Inspection Authority at the latest 18 months after the additive concerned has been included in the priority list pursuant to section 13a(1) of the Act. The report shall include supplementary information which the manufacturer or importer of cigarettes or roll-your-own tobacco containing an additive specified in the priority list and shall be submitted to the European Commission or the Czech Agricultural and Food Inspection in accordance with section 13a(3) of the Act.
- (5) All data and information provided under subsection 4 shall be transferred electronically.

#### **Section 24**

Methodology for registration before commencing the placing on the market of tobacco products to the market through cross-border distance selling

- (1) The notification on the basis of which the registration of a retailer is carried out under section 13c(2) to (5) of the Act, contains at least
- a) the name or corporate name and permanent address of the place of activity from where the tobacco products will be supplied,
  - b) the starting date of the activity of offering tobacco products for cross-border distance sales to consumers by means of Information Society services,
  - c) the address of the website or websites used for that purpose, and
  - d) all relevant information necessary to identify the website.
- (2) The information referred to in subsection 1 shall be notified electronically by remote data transmission.

#### **Section 25**

Priority list of additives

The priority list of additives in cigarettes and roll-your-own tobacco which are subject to enhanced reporting obligations is presented in Annex 6 hereto.

## **Section 26**

### Interim provisions

- (1) For products placed on the market before the effective date of this decree, a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products, in descending order of the weight of each ingredient included in the tobacco products, the emission levels of tar, nicotine and carbon monoxide, and information on other emission levels, if available, shall be provided by 20 November 2016.
- (2) In those cases where the tax stamp 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 until 20 May 2019. Brand names or logos shall not be positioned above the health warnings.
- (3) Where a unit packet is made of soft material, a rectangular area may be reserved for the tax stamp of a height not exceeding 13 mm between the top edge of the packet and the top end of the combined health warnings until 20 May 2019. Brand names or logos shall not be positioned above the health warnings.
- (4) Until 20 May 2018, the following rules shall apply to roll-your-own tobacco in rectangular wraparound pouches made of polyethylene, polypropylene or laminate material, as illustrated in point 3 of Annex 2 hereto:
  - a) the information message may be positioned on the surface that becomes visible when the unit packet is partly unwrapped,
  - b) the general warning may be positioned on the bottom surface, which becomes visible when the unit packet is fully opened,
  - c) the inside of the flap, which becomes visible when the unit packet is fully opened, shall not be printed upon or used in any other way,
  - d) the general warning and information message shall be positioned at the top edge of the respective surfaces on which they are printed.
- (5) Roll-your-own tobacco in pouches manufactured or released for free circulation until 20 May 2018 and labelled with a general warning and information message in accordance with subsection 4 may be placed on the market until 20 May 2019.
- (6) The first group of combined health warnings is used under section 12d(3) and (4) of the Act for the period from the effective date of this decree until 31 December 2017.
- (7) Until 31 December 2017 tobacco products may be divided into types, groups and subgroups according to Annex 1 to Decree No. 344/2003, as amended, as effective prior to the effective date of this Act.

## **Section 27**

### Repealing provisions

The following are repealed:

1. Decree No. 344/2003, laying down the requirements for tobacco products.
2. Decree No. 316/2012, amending Decree No. 344/2003, laying down the requirements for tobacco products.

## **Section 28**

### Effectivity

This decree comes into force on 7 September 2016.

Unofficial Translation

Minister:

Jurečka, m.p.

Annex No. 1 to Decree No. 261/2016

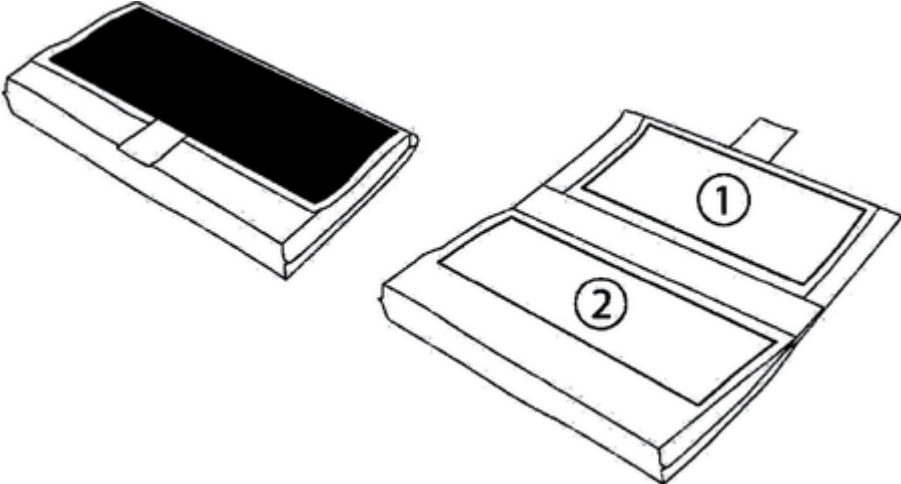
**TYPES OF TOBACCO PRODUCTS AND THEIR DIVISION INTO GROUPS AND SUBGROUPS**

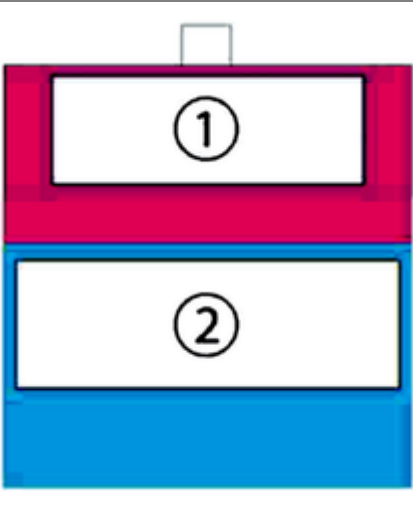




Type	Group	Subgroup
cigarettes		
cigars		
cigarillos		
tobacco	for smoking	roll-your-own
		waterpipe
		tobacco
	smokeless	snuff
		chewing
		intended for oral use
novel tobacco product	for smoking	
	smokeless	

Annex No. 2 to Decree No. 261/2016

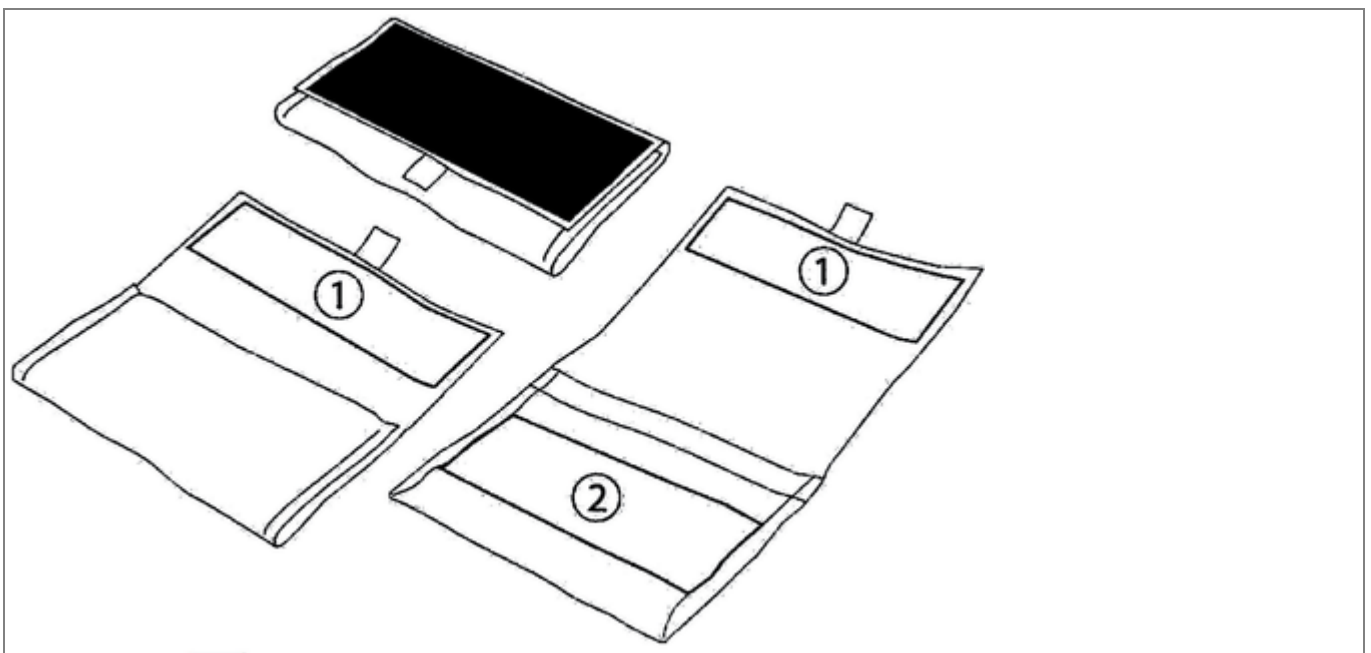
Graphical representation of the exact location of the general warning and health warning

1. FLAT-BOTTOMED POUCH



		<p>Calculation of surface area: surface of the flap when the pouch is closed Location of warning: inside the flap when the pouch is opened</p>
		<p>Calculation of the surface area: surface of the jacket when the pouch is closed Location of warning: surface of the jacket when the pouch is opened</p>
		<p>General warning</p>
		<p>Health warning</p>

2. WRAPAROUND POUCH



		<p>Calculation of surface area: surface of the flap when the pouch is sealed</p> <p>Location of warning: inside the flap when the pouch is fully unwrapped (inside of the surface calculated when the pouch is closed)</p>
		<p>Calculation of the surface area: surface of the jacket when the pouch is closed</p> <p>Location of warning: surface of the jacket when the pouch is fully unwrapped (inside surface calculated when the pouch is sealed)</p>
		<p>General warning</p>
		<p>Health warning</p>

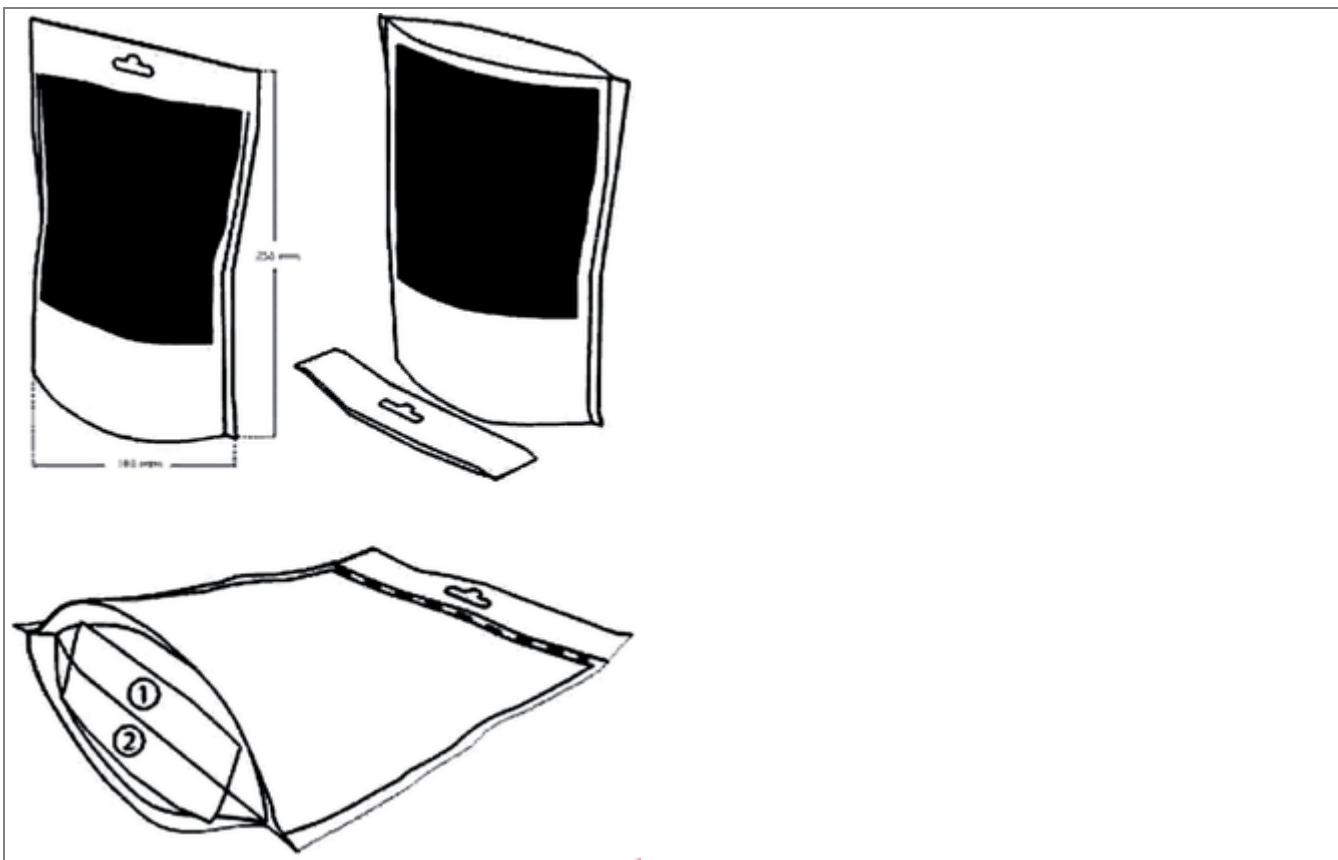
**3. POUCH WITH A WRAPAROUND FLAP (ALTERNATIVE LOCATION)**

		<p>Calculation of surface area: surface of the flap when the pouch is closed</p> <p>Location of warning: the interior part of the jacket when the pouch is partially unwrapped</p>
		<p>Calculation of the surface area: surface of the jacket when the pouch is closed</p> <p>Location of warning: surface of the jacket when the pouch is fully unwrapped (inside surface calculated when the pouch is sealed)</p>
		<p>General warning</p>



2 Health warning

4. STANDING POUCH



	Calculation of area: base of the pouch, up to the central crease when straightened (without sealed edges)
	Calculation of area: base of the pouch, up to the central crease when straightened (without sealed edges)
	General warning
	Health warning

Annex No. 3 to Decree No. 261/2016

**LIST OF TEXT WARNINGS**

1. Smoking causes 9 out of 10 lung cancers
2. Smoking causes mouth and throat cancer
3. Smoking damages your lungs
4. Smoking causes heart attacks
5. Smoking causes strokes and disability
6. Smoking clogs your arteries
7. Smoking increases the risk of blindness
8. Smoking damages your teeth and gums

Unofficial Translation

- 9. Smoking can kill your unborn child
- 10 Your smoke harms your children, family and friends
- 11. Smokers' children are more likely to start smoking
- 12. Quit smoking - stay alive for those close to you
- 13. Smoking reduces fertility
- 14. Smoking increases the risk of impotence

Annex No. 4 to Decree No. 261/2016

**PICTURE LIBRARY (combined health warnings)**

Group 1



Group 2



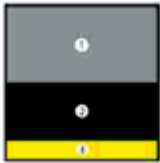
Group 3



Annex No. 5 to Decree No. 261/2016

**METHOD OF STATEMENT OF COMBINED HEALTH WARNINGS ON TOBACCO PRODUCTS INTENDED FOR SMOKING**

**1. Stacked format**



- 1. Photograph
- 2. Text warning
- 3. Information about cessation

**2. Side-by-side format**



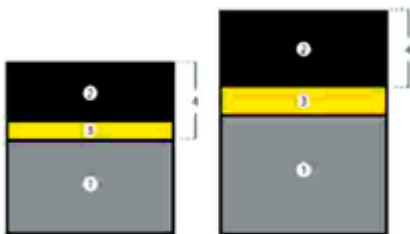
- 1. Photograph
- 2. Text warning
- 3. Information about cessation

**3. Side-by-side extra-wide format**



- 1. Photograph
- 2. Text warning
- 3. Information about cessation

**4. Stacked reversed format**



- 1. Photograph
- 2. Text warning
- 3. Information about cessation
- 4. Flip-top lid

**4. Flip-top lid**

**Annex No. 6 to Decree No. 261/2016**

PRIORITY LIST OF ADDITIVES IN CIGARETTES AND ROLL-YOUR-OWN TOBACCO WHICH ARE SUBJECT TO ENHANCED REPORTING OBLIGATIONS

Additive	Chemical formula (If applicable)	Chemical formula   (if applicable)   CAS number(s) applicable to the substance (not exhaustive)
Carob bean		9000-40-2, 84961-45-5
Cocoa		84649-99-0, 84649-99-3, 95009-22-6, 8002-31-1
Diacetyl	C <sub>4</sub> H <sub>6</sub> O <sub>2</sub>	431-03-8
Fenugreek		68990-15-8, 977018-53-3, 84625-40-1
Fig		90028-74-3
Geraniol	C <sub>10</sub> H <sub>18</sub> O	106-24-1, 8000-46-2
Glycerol	C <sub>3</sub> H <sub>8</sub> O <sub>3</sub>	56-81-5
Guaiacol	C <sub>6</sub> H <sub>4</sub> (OH)(OCH <sub>3</sub> )	90-05-1
Guar gum		9000-30-0
Licorice		68916-91-6
Maltol	C <sub>6</sub> H <sub>6</sub> O <sub>3</sub>	118-71-8
Menthol	C <sub>10</sub> H <sub>20</sub> O	2216-51-5, 15356-60-2, 89-78-1, 1490-04-6, 8006-90-4, 68606-97-3, 84696-51-5, 8008-79-5
Propylene glycol	C <sub>3</sub> H <sub>8</sub> O <sub>2</sub>	57-55-6
Sorbitol	C <sub>6</sub> H <sub>14</sub> O <sub>6</sub>	50-70-4
Titanium dioxide	TiO <sub>2</sub>	13463-67-7, 1317-70-0

**Footnotes**

1) Directive 2014/40/EU of the European Parliament and Council Directive of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

Commission 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

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.

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.

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

Commission Implementing Decision (EU) 2016/787 of 18 May 2016 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations

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

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

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

## Contexts

### Implementing regulations

110/1997      The Act on foodstuffs and tobacco products

### Repealing regulation

316/2012      Decree amending Decree No. 344/2003, laying down the requirements for tobacco products.

344/2003      Decree laying down the requirements for tobacco products.

## Version no.

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07.09.2016      Amendments      Notes

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