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ACT

of 25 November 2015

on the manufacture and labelling of tobacco products and related products and amending certain Acts

The National Council of the Slovak Republic has adopted this Act:

Part I

Section 1
Subject matter

This Act regulates

a) the requirements for the ingredients and emissions of tobacco products and related reporting obligations, including maximum emission levels of tar, nicotine and carbon monoxide in cigarettes.
b) conditions for the labelling and packaging of tobacco products, including health warnings to be placed on the consumer packs of tobacco products and any outside packaging,
c) the prohibition on the placing on the market of tobacco for oral use,
d) cross-border distance sales of tobacco products,
e) conditions for the placing on the market of new categories of tobacco product
f) conditions for the placing on the market products related to tobacco products, their labelling, including health warnings.

Section 2
Basic terms

(1) Nicotine means nicotinic alkaloids.

(2) Tar means the raw anhydrous nicotine-free condensate of smoke

(3) For the purposes of this Act
a) tobacco means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco,
b) pipe tobacco means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe,
c) roll-your-own tobacco means tobacco which can be used for making cigarettes by consumers,
d) tobacco products means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not,
e) Smokeless tobacco product means a tobacco product not involving a combustion process.
f) chewing tobacco means a smokeless tobacco product intended for the purpose of chewing,

g) nasal tobacco means a smokeless tobacco product that can be consumed via the nose,
h) 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, particularly those presented in sachet portions or porous sachets,
i) tobacco products for smoking means tobacco products other than a smokeless tobacco product,
j) cigarette means a roll of tobacco[1]) for smoking
k) cigar means a roll of tobacco[1]) that can be consumed via a combustion process.
l) cigarillo means a small type of cigar[1])
m) waterpipe tobacco means a tobacco product that can be consumed via a waterpipe. If a product can be used both via waterpipes and as roll-your-own tobacco, it shall be deemed to be roll-your-own tobacco;
n) novel tobacco product means a tobacco product which
   1. does not fall under points b), c), j), f) and h) and k) to m), and
   2. was placed on the market after 19 May 2014,
o) herbal product for smoking means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process,
p) electronic cigarette means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank; electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges,
q) refill container means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette,
r) 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,
s) 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,
t) maximum level or maximum emission level means the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams,
u) additive means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging,
v) flavouring means an additive that imparts smell and/or taste,
w) characterising flavour means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product,
x) addictiveness means the pharmacological potential of a substance to cause addiction, a state which affects an individual's ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both,
y) toxicity means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure,
z) outside packaging means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging,

aa) unit packet means the smallest individual packaging of a tobacco or related product that is placed on the market,

ab) pouch means a unit packet of roll-your own tobacco, either in the form of a rectangular pocket with a flap that covers the opening or in the form of a standing pouch,

ac) health warning means a warning concerning the adverse effects on human health of a product or other undesired consequences of its consumption, including text warnings, combined health warnings, general warnings and information messages,

ad) the text warnings are the health warnings set out in Annex 1,

ae) means a health warning consisting of a combination of a text warning and a corresponding photograph or illustration set out in Annex 2,

af) cross-border distance sales means distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in an EU Member State or a stage which is a signatory to the European Economic Area (hereinafter “Member State”), or a third country where that retail outlet is established,

ag) means a natural person who is acting for purposes which are outside his or her trade, business, craft or profession,

ah) means a computing system that unambiguously confirms the consumer's age electronically in accordance with national requirements,

ai) the manufacturer is a person that under a special regulation,[2]) manufactures a tobacco or related product, or a person that is not a person under a special regulations[2]) that has a tobacco or related product designed or manufactured, and markets said tobacco or other related product under their name or trademark,

aj) import of tobacco or related products means the entry of tobacco products and related products into the territory of any Member State unless the tobacco or related products are placed under a customs suspensive procedure or arrangement upon their entry into the territory of any of the Member States, as well as their release from a customs suspensive procedure or arrangement,

ak) importer of tobacco or related products means the owner of, or a person having the right of disposal over, tobacco or related products, that have been brought into the territory of the Union;

aj) placing on the market means to make products, irrespective of their place of manufacture, available to consumers, with or without payment, including by means of distance sale; 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,

am) retail outlet means any outlet where tobacco products are placed on the market by a natural person - entrepreneur, or a legal entity,

an) related products means electronic cigarettes, refill containers and herbal products for smoking,

ao) distributor of tobacco products is a natural person - entrepreneur, or legal person, handling tobacco products, other than the manufacturer, importer or person that places the tobacco product on the market.

Section 3
Ingredients and emissions

(1) In cigarettes manufactured or cigarettes placed on the market tar content shall not be greater than 10 mg in 1 cigarette (hereinafter “mg/cig.”).

(2) In cigarettes manufactured or cigarettes placed on the market nictine content shall not be greater than 1 mg/cig.

(3) In cigarettes manufactured or cigarettes placed on the market carbon monoxide content shall not be greater than 10 mg/cig.

(4) The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured and verified in accordance with technical standards.[3])

(5) The measurements referred to in subsection 4 shall be verified by accredited test laboratories.

(6) The Ministry of Health of the Slovak Republic (hereinafter the "Ministry") shall communicate to the Commission (hereinafter the "Commission") a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and shall update that list whenever any change is made; laboratories may not be directly or indirectly owned or controlled by the manufacturer.

(7) The Ministry shall notify the Commission of any maximum emission levels they set for emissions from cigarettes other than the emissions referred to in subsections (1) and (3) and for emissions from tobacco products other than cigarettes.

Section 4
Reporting of ingredients and emissions

(1) Manufacturers, importers and distributors of tobacco products shall submit to the Ministry 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, information on emissions and their levels by under section 3(1)-(3) and, where available, information on other emissions and their levels.

(2) The list referred to in subsection (1) shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in the tobacco products concerned, stating their function and toxicological data regarding the ingredients in burnt or unburnt form, referring in particular to their effects on health of consumers and addictive effects that may be available to the manufacturer, importer or distributor. The list of all the ingredients shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in the tobacco products concerned. That list shall also indicate the status of the ingredients, including whether they have been registered under special regulations. [4])

(3) The Ministry shall, for the purpose of consumer information, ensure that the information provided in subsections (1) and (2) is made publicly available on its website, also in a format accessible to persons with disabilities, except for information that is a trade secret or confidential information of the manufacturer or importer of tobacco products.

(4) Manufacturers, importers or distributors shall immediately inform the Ministry if the composition of a tobacco product is modified in a way that affects the information submitted pursuant to this subsection.

(5) If this concerns a novel tobacco product or a modified tobacco product, the information required under subsection 1 shall be submitted before such tobacco product is placed on the market.

(6) The manufacturer, importer or distributor is required when submitting the information under this subsection to indicate that the information is a trade secret or confidential information.

(7) Manufacturers, importers and distributors shall submit 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.

(8) Manufacturer, importer or distributor shall submit to the Ministry their sales volumes per brand name and type for tobacco products, in sticks or kilograms, on a yearly basis, by 30 June at the latest, for the previous calendar year.

(9) For cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties, shall be submitted by the manufacturer or importer. Other than for tar, nicotine and carbon monoxide and for emissions, manufacturers and importers shall indicate the methods of measurement of emissions used.

(10) The information referred to in subsections (1), (2) and (4) and subsections (7) - (9) shall be provided in electronic form by the manufacturer, importer or distributor. The Ministry shall ensure that Member States and the Commission have access to that information and shall ensure that trade secrets and other confidential information are treated in a confidential manner.

Section 5
Tobacco product ingredients

(1) Manufacturers, importers and distributors are prohibited from placing on the market tobacco products with a characterising flavour. This prohibition shall not apply to additives which are essential for the manufacture of tobacco products, provided those additives do not result in a product with a characterising flavour and do not increase to a significant or measureable degree the addictiveness, toxicity or the carcinogenic, nmutagenic or reprotoxic properties of the tobacco product.

(2) Manufacturers, importers and distributors are prohibited from placing on the market tobacco products containing the following additives:

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) substances that have carcinogenic, mutagenic and reprotoxic properties in unburned form.

(3) Manufacturers, importers and distributors are prohibited from placing on the market tobacco products containing flavourings 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. Filters, paper and capsules shall not contain tobacco or nicotine.

(4) The placing on the market of tobacco products containing additives in quantities that increase the toxic or addictive effect of a tobacco product at the stage of consumption to a significant or measureable degree is prohibited.

Article 6
Health warnings

(1) Each unit packet of a tobacco product and any outside packaging shall carry the health warnings in the official language

(2) 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.

(3) The health warnings on a unit packet and any outside packaging shall be irremovably printed, indelible and fully visible, including not being partially or totally hidden or interrupted by tax stamps,[5]) price marks, security features, wrappers, jackets, boxes, or other items, when tobacco products are placed on the market.

(4) 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. 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.

(5) The dimensions of the health warnings provided for in section 7 to 10 shall be calculated in relation to the surface concerned when the packet is closed.

(6) 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, except for health warnings pursuant to section 11.

(7) A list of pictorial health warnings to be used on tobacco products is given in Annex 2.

Section 7
General warnings and information messages on tobacco products for smoking

(1) Each unit packet and any outside packaging of tobacco products for smoking shall carry one of the following general warnings “Smoking kills”.

(2) Each unit packet and any outside packaging of tobacco products for smoking shall carry the following information message: "Tobacco smoke contains over 70 substances known to cause cancer."

(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 the direction of text placement.

(4) 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.

(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) Both the general warning and the information message shall cover 50 % of the surfaces on which they are printed.

(7) The general warning and information message referred to in subsections 1 and 2 shall be:

a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, the font size must ensure that the relevant text occupies the greatest possible proportion of the surface reserved for these health warnings, and

b) at the centre 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.

Section 8
Combined health warnings for tobacco products for smoking

(1) Each unit packet and any outside packaging of tobacco products for smoking shall carry combined health warnings. The combined health warnings shall

a) contain one of the text warnings listed in Annex 1 and a corresponding color photograph specified in the picture library in Annex 2,

b) include a phone number “Helpline 0908 222 722” on which to obtain information on stopping smoking,

c) 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,

d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging,

e) 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,

f) unit packets of cigarettes must be not less than 44 mm in height and not less than 52 mm in width.

(2) The combined health warnings are grouped into three sets as set out in Annex 2 and each set shall be used in a given year and rotated on an annual basis. Manufacturers shall ensure that each combined health warning available for use in a given year is displayed to the extent possible in equal numbers on each brand of tobacco products.

Section 9
Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco

(1) Tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco must include on each user packet and outside packaging of such products

a) a general warning laid down in section 7 (1)(a)

b) one of the text health warnings listed in Annex 1.

(2) The general warning shall appear on the most visible surface of the unit packet and any outside packaging. The general warning shall contain information under section 8 (1)(b).

(3) The text warnings shall appear on the next most visible surface of the unit packet and any outside packaging. Text warnings are displayed to the extent possible in equal numbers on each brand of these products.

(4) For unit packets with a hinged lid, the next most visible surface is the one that becomes visible when the packet is open.

(5) The general warning referred to in subsection (1)(a) shall cover 30 % of the relevant surface of the unit packet and any outside packaging.

(6) The text warning referred to in subsection (1)(b) shall cover 40 % of the relevant surface of the unit packet and any outside packaging.

(7) Where the health warnings referred to in paragraph 1 are to appear on a surface exceeding 150 cm2, the warnings shall cover an area of 45 cm2.

(8) The health warnings referred to in subsection (1) shall comply with the requirements specified in section 7(7). The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings. The health warnings 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.

Section 10
Labelling of smokeless tobacco products

(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 section 7(7). The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings.

a) It shall appear on the two largest surfaces of the unit packet and any outside packaging, and
b) shall cover 30 % of the surfaces of the unit packet and any outside packaging.

Section 11
Product presentation

(1) The labelling of unit packets and any outside packaging of the tobacco product 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; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product,
b) 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 a positive effect on health or has lifestyle benefits,
c) refers to taste, smell, any flavourings or other additives or the absence thereof,
d) resembles a food or a cosmetic product,
e) 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 subsections (1) and (2) may include but are not limited to texts, symbols, names, trademarks, figurative or other signs.

Section 12
Appearance and content of unit packs

(1) Unit packets of cigarettes shall have a cuboid shape. Rounded or bevelled edges are acceptable, provided the health warning laid down in section 6 covers a surface area that is equivalent to that on a unit packet without such edges. A unit packet of cigarettes shall include 20 cigarettes

(2) Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch. 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. A unit packet of cigarettes 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 unit packets of cigarettes with a flip-top lid and hinged lid, the lid shall be hinged only at the back of the unit packet.

Section 13
Tobacco for oral use

The placing on the market of tobacco for oral use is prohibited.

Section 14
Notification of novel tobacco products

(1) Manufacturers, importers or distributors of tobacco are products obliged to submit a notification of novel tobacco products, including the labelling of said novel tobacco products and information on the packaging, to the Slovak Trade Inspection. The notification shall be submitted in electronic form six months before the intended placing on the market. It shall be accompanied by a detailed description of the novel tobacco product concerned as well as instructions for its use and information on ingredients and emissions in accordance with section 4; manufacturers, importers or distributors of tobacco products must submit information on ingredients and emissions to the Ministry.

(2) When submitting a notification of a novel tobacco product the manufacturer, importer or distributor shall submit to the Slovak Trade Inspection

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.

(3) The manufacturer, importer or distributor of novel tobacco products shall transmit to the Slovak Trade Inspection any new or updated information on the studies, research and other information referred to subsection (2). The Ministry shall introduce generally applicable legislation on the studies, research and other information containing scientific evidence needed to inform consumers about the harmful effects of tobacco.
(4) The provisions of this Act shall apply to the novel tobacco product, depending on whether it is a tobacco product according to section 2(3)(e), or section 2(3)(i).

Section 15
Electronic cigarettes

(1) Manufacturers, importers or distributors of electronic cigarettes and filling bottles shall submit a notification to the Slovak Trade Inspection and the Ministry of any such products that they intend to place on the market. The notification shall be submitted in electronic form six months before the intended placing on the market. For electronic cigarettes and refill containers already placed on the market on 20 May 2016, the notification shall be submitted within six months of that date. A new notification shall be submitted for each substantial modification of the electronic cigarette or refill container at least one month before the placing of a product with such a substantial modification is placed on the market.

(2) The notification pursuant to subsection 1 shall contain the following information

a) The name and contact details of the manufacturer, importer or distributor,

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

d) toxicological data regarding the product's ingredients and emissions according to point (b), including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect, 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, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers,

f) a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Act,

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) The manufacturer, importer or distributor of electronic cigarettes and refill containers is required to ensure that

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

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

c) the nicotine-containing liquid does not contain additives listed in section 5(2),

d) only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in subsection 2(b) are only present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture,

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

f) electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use,

g) electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

(4) Manufacturers, importers or distributors of electronic cigarettes and refill containers shall ensure that unit packs of electronic cigarettes and refill containers include a leaflet with information on:

a) use and storage of electronic cigarettes and refill containers, including a reference that electronic cigarettes and refill containers are not recommended for use by young people and non-smokers,

b) contraindications,

c) warnings for specific risk groups,

d) possible adverse effects,

e) addictiveness and toxicity, and

f) contact details of the manufacturer, importer or distributor,

(5) Manufacturers, importers or distributors of electronic cigarettes and refill containers shall ensure that unit packs and any outside packaging of electronic cigarettes and refill containers:

a) include a list of all ingredients contained in the product in descending order of the weight, and an indication of the nicotine content of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children.

b) do not include elements or features referred to in section 11, except for section 11(1)(a) and (c) concerning information on the content of nicotine and flavourings.

c) carry this health warning: “This product contains nicotine which is a highly addictive substance.”

(6) The health warning laid down in subsection (5)(c) shall comply with the requirements specified in section 10(2).

(7) It is prohibited to use

a) commercial communications in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers, except for publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union market,

b) any form of public or private contribution to any event, activity or individual person with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers and involving or taking place in several Member States or otherwise having cross-border effects.

(8) Manufacturers, importers or distributors of electronic cigarettes and refill containers are required to submit to the Ministry annually for the previous calendar year by 30 June

a) comprehensive data on sales volumes, by brand name and type of the product,

b) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users,

c) the mode of sale of the products, and

d) executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

(9) The Ministry shall publish on its website the information received under subsection 2, also a format accessible for people with disabilities, except for the information that is a trade secret or other confidential information of the manufacturer, importer or distributor of electronic cigarettes and refill containers.

(10) Manufacturers, importers or distributors of electronic cigarettes and refill containers shall establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products, if it is suspected that any exist.

(11) If a manufacturer, importer or distributor considers that electronic cigarettes or refill containers, 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 this Act, it shall immediately take the corrective action necessary to bring the product concerned into conformity with this Act, or to recall it. It shall also be required to immediately inform the State Veterinary and Food Administration of the Slovak Republic,

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.

(12) Commercial media communications media[6]) relating to electronic cigarettes and refill containers are subject to specific regulations. [7])

Section 16
Herbal products for smoking

(1) Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning: “Smoking this product damages your health”.

(2) The health warning referred to in subsection 1 shall be printed on the front and back external surface of the unit packet and on any outside packaging.

(3) The health warning shall comply with the requirements specified in section 7(7) and shall cover 30 % of the corresponding surfaces of the unit packet and any outside packaging.

(4) Unit packets and any outside packaging of herbal products for smoking shall not include any of the elements or features set out in section 11(1), (a), (b) and (d) and shall not state that the product is free of additives or flavourings.

Section 17
Reporting of ingredients of herbal products for smoking

(1) Manufacturer, importer or distributor of herbal products for smoking shall submit to the Ministry a list of all ingredients, and quantities thereof that are used in the manufacture of such products by brand name and type, which are used in the manufacture of such products. The manufacturer, importer or distributor of these products shall also notify the Ministry when the composition of a product is modified in a way that affects the information submitted pursuant to this subsection. The information required under this subsection shall be submitted prior to the placing on the market of a new or modified herbal product for smoking.

(2) The Ministry shall ensure that the information submitted in accordance with subsecton 1 is made publicly available on a website, also in a format accessible for people with disabilities, except for information that is a trade secret or other confidential information of the manufacturer or importer of herbal products for smoking; in the list referred to in subsection 1 it shall indicate which information is a trade secret or other confidential information.

Section 18
Cross-border distance sales

(1) Natural persons - entrepreneurs or legal entities involved in cross-border sales of tobacco, electronic cigarettes and refill containers may not supply such products to consumers in Member States where such sales have been prohibited.

(2) Natural persons - entrepreneurs or legal entitles involved in cross-border distance sales to consumers located in a Member State are required to register with the Slovak Trade Inspection and the competent authority in the Member State where the actual or potential consumers are located. Natural persons - entrepreneurs or legal entities eestablished outside the Union shall be required to register with the competent authorities in the Member State where the actual or potential consumers are located.

(3) Natural persons - entrepreneurs or legal entities referred to in subsections (1) and (2) shall submit to the Slovak Trade Inspection documents

a) on the corporate name and place of business or establishment from where the tobacco, electronic cigarettes and refill containers will be supplied.

b) the starting date of the activity of offering tobacco products for cross-border distance sales to consumers,

c) the address of the website or websites used for that purpose.

(4) The Slovak Trade Inspection shall ensure that consumers have access to the list of all retail outlets registered with them under subsection 2.

(5) Natural persons - entrepreneurs or legal entities may only start placing electronic cigarettes and refill containers on the market via cross-border distance sales when they have received confirmation of their registration with the Slovak Trade Inspection.

(6) Natural persons - entrepreneurs or legal entities engaged in cross-border distance sales shall operate an age verification system, which verifies, at the time of sale, that the purchasing consumer complies with minimum age requirements provided for under the national law of the Member State of destination, and shall provide the Slovak Trade Inspection a description of the details and functioning of the age verification system.

(7) Retail outlets shall only process personal data of the consumer in accordance with specific regulations[8]) and those data shall not be disclosed to the manufacturer of tobacco products or companies forming part of the same group of companies or to other third parties. Personal data shall not be used or transferred for purposes other than the actual purchase. This also applies if the retail outlet forms part of a manufacturer of tobacco products.

Section 19
Obligations of manufacturers, importers and distributors, and the control thereof

(1) Manufacturers, importers or distributors are is obliged to fulfill the obligations set out in sections 4 to 18.

(2) Monitoring of compliance with obligations under this Act shall be performed by the following inspection bodies:

a) Slovenská obchodná inšpekcia [Slovak Trade Inspection]

b) Štátna veterinárna a potravinová správa Slovenskej republiky Slovak state veterinary and food administration,

c) state administration authorities in the field of public health.[9])

Section 20
Administrative offences

(1) An administrative offence is committed by a manufacturer, importer or distributor, if

a) it fails to provide health warnings in accordance with section 6,
b) it fails to provide general warnings and information messages in accordance with section 7,
c) it fails to provide combined health warnings in accordance with section 8,
d) it fails to label tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco according to section 9,
e) it fails to label smokeless tobacco products accoridng to section 10,
f) it fails to fulfill its obligations in the presentation of the products referred to in section 11,

g) it violates the obligations regarding the appearance and content of unit packets according to section 12,
h) it fails to to comply with the reporting obligations according to section 14,
i) it fails to to comply with the reporting obligations according to section 15(1) and (2) or violates its obligation according to section 15(4) to (6),
j) it violates the provision for entering commercial communications in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers according to section 15(7)
k) fails to fulfill its obligations regarding the placement of health warnings referred to in section 16,
l) fails to fulfil the obligations laid down under section 18.

(2) An administrative offence is committed by a manufacturer, importer or distributor, if
a) it violates the limits on ingredients and emissions specified in section 3,
b) it places on the market products containing banned ingredients in accordance with section 5,
c) it places on the market tobacco for oral use in contravention of section 13,
d) fails to ensure limits on the substances listed in section 15(3).

(3) An administrative offence is committed by a manufacturer, importer or distributor, if
a) it fails to comply with the reporting obligations on ingredients and emissions as set out in section 4,
b) it fails to comply with the reporting obligations in the field of electronic cigarettes referred to in section 15(8),
c) it fails to comply with the reporting obligations set out in section 17.

(4) The Slovak Trade Inspection shall impose a fine from EUR 100 to EUR 10,000 for the administrative offenses referred to in subsection 1.

(5) The State Veterinary and Food Administration of the Slovak Republic will impose a fine of EUR 100 to EUR 10,000 for the administrative offence as defined in subsection 2.

(6) The state administration in the field of public health shall impose a fine from EUR 100 to EUR 10,000 for the administrative offences referred to in subsection 3.

(7) The penalties under this Act may be imposed within two years from the date when the control authority ascertains a violation of the obligations, but not later than five years from the date on which the obligation was violated.

(8) When imposing fines account is taken of the severity of the infringement, the duration thereof and the incurred or imminent adverse effects on health.

(9) Fines constitute state budgetary income.

(10) The imposition of fines is governed by the general regulation on administrative proceedings.[10])

Section 21

Transitional provisions

(1) For products already placed on the market on 20 May 2016, manufacturers, importers or distributors are obliged to November 20, 2016 to submit information to the competent authority under section 4, section 15(2) and (8) and section 17.

(2) The prohibition provided for in section 5(1) and (3) the cigarettes and tobacco relating to roll-your-own cigarettes containing containing flavourings 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, whose aggregate Union-wide sales volumes represent 3 % or more, shall apply from 20 May 2020.

(3) In the period from 20 May 2016 to 20 May 2019, the combined health warnings under section 8(1)(e) shall be placed directly under the control label.[5]) For soft unit packets, the health

warnings on both surfaces shall be placed up to 13 mm below the top edge of the unit packet of cigarettes. No labels or logos may be placed over health warnings.

(4) Tobacco products and other related products manufactured according to the regulations in force before 20 May 2016 may

a) be released for free circulation under a special regulation11) as follows:
   1. cigarettes until 31 July 2016,
   2. cigars and cigarillos until 31 December 2016,
   3. pipe tobacco and tobacco for roll-your-own cigarettes until 31 August 2016,
b) sold as follows:
   1. cigarettes until 31 August 2016,
   2. cigars and cigarillos until 20 May 2017,
   3. pipe tobacco and tobacco for roll-your-own cigarettes until 31 August 2016,
c) placed on the market as follows:
   1. electronic cigarettes until 20 November 2016,
   2. herbal products for smoking until 20 May 2017,
   3. tobacco products pursuant to section 2(3)(e) and (m) until 20 May 2017.

(5) During the period from 20 May 2016 to 31 December 2017 one group of combined health warnings shall be used, whilst manufacturers shall ensure that for each brand of tobacco products each combined health warning available for use in a given year is displayed to the extent possible in equal numbers on each brand of tobacco products without prejudice to the provisions of section 8(2).

Section 22
Final provisions

This Act promulgates the legally binding acts of the European Union listed in Annex No. 3.

Part II

Act No. 377/2004 on the protection of non-smokers and amending certain acts as amended by Act No. 465/2005, Act No. 378/2008, Act No. 461/2008, Act No. 87/2009, Act No. 547/2010, Act No. 142/2013, Act No. 241/2015 is amended as follows:

1. In section 1, letter c) is deleted.
2. In Section 2, subsection (4)(a) reads as follows:

"a) tobacco products are products under a special regulation,[1])".

The footnote under reference 1 reads as follows:
"[1]) Section 2(3)(d) of Act No. 89/2016 on the manufacture, labelling and sale of tobacco products and related products and amending certain Acts."

3. In Section 2, subsection (4) letter (b) is deleted.

The existing letters (c) to (n) inclusive are marked as letters (b) to (m).

4. sections 3 to 5 are deleted.
5. In Section 6(1) the letter (f) is deleted.
6. In Section 6, subsection (4) is deleted

The existing subsections (5) and (6) shall be renumbered (4) and (5).

7. In Section 6, subsection (5) is deleted
8. In Section 9(3) the words "pursuant to sections 4 and 6" are replaced by "pursuant to section 6".
9. In Section 9(3) the words "pursuant to sections 4 to 7" are replaced by "pursuant to sections 6 and 7".

10. In Section 10, subsection (1) is deleted.

The existing paragraphs (2) to (11) shall be renumbered (1) to (10).

11. In Section 10(2) the words “subsections (1) and (2)” are replaced by “subsection (1)”.

12. In Section 10, subsection (4) is deleted.

The existing subsections (5) to (10) shall be renumbered (4) to (9).

13. The words “placing into circulation of tobacco products” in all forms throughout the text of the Act shall be replaced by “placing on the market of tobacco products” in the appropriate form.

Part III

Act No. 335/2011 on tobacco products shall be amended as follows: 1. Section 3, incuding the title, shall read as follows:

“Section 3
Registration

(1) Manufacturers[1]) shall produce tobacco products, if the manufacturer or its appointed executive representative

a) has completed a university degree in the food sector or vocational training in the food industry, or a recognised educational equivalent[1]) and

b) has at least two years’ experience in the field of manufacturing of tobacco products.

(2) Compliance with the conditions under subsection 1 shall be demonstrated by the manufacturer

a) in the form of evidence of formal qualifications referred to in subsection (1)(a) and

b) evidence of the duration of experience under subsection (1)(b).

(3) The trade authority[1b]) shall send to the Ministry of Agriculture and Rural Development of the Slovak Republic (hereinafter "Ministry") a list of issued, suspended, expired and revoked licenses for the production of tobacco products within 30 days from the date of issue of the business license.

(4) The manufacturer, importer[1c]) or distributor[1d]) of tobacco products (hereinafter “operator”) is required under subsection 6 to notify the purpose of registration to the relevant Regional Veterinary and Food Administration establishment in which it operates at any stage of the manufacture of tobacco products or the placing on the market thereof (hereafter “establishment”) before commencing operations.

(5) The operator shall notify the District Veterinary and Food Administration

a) of its identification data in case of a natural person - entrepreneur, name and identification number of the person if a legal entity, the name, address and identification number of the person,

b) identification data of the establishment,

c) change in activity of the establishment,

d) closure of operations.

(6) The State Veterinary and Food Administration of the Slovak Republic (hereinafter the “State Veterinary and Food Administration”) shall maintain a list of registered establishments.”

Footnotes 1 to 1d shall read as follows:
"[1]) Section 17(2) of Act No. 106/2004, on excise duty on tobacco products, as amended.
1a) Section 24(1) of Act No. 293/2007 on the recognition of professional qualifications, as amended.
1b) Section 66(a) of Act No. 455/1991 on trading, as amended,
1c) Section 2(3)(ao) of Act 89/2016 on the manufacture, labelling and sale of tobacco products and related products and amending certain Acts.
1d) Section 2(3)(ao) of Act No. 89/2016."

2. In Section 4(2)(a) (a) and (b) the words "raw materials" shall be replaced by "additives".

3. In Section 4(2)(a) footnote 1e is placed by the word "additives".

The footnote under reference 1e reads as follows:
"[1e]) section 2(3)(u) of Act No. 89/2016."

4. In Section 4(2)(c) footnote 1f is placed by the word "ingredients".

The footnote under reference 1f reads as follows:
"[1f]) section 2(3)(r) of Act No. 89/2016."

5. In Section 4(2)(c) footnote 1g is placed by the word "products".

The footnote under reference 1g reads as follows:
"[1g] Section 4 of Act No. 89/2016."

6. In section 7 the introductory sentence is replaced by the reference 1h.

The footnote under reference 1h reads as follows:
"[1h]) section 6 to 12 and section 14 of Act No. 89/2016."

7. In section 8(a) the word "raw materials"" is replaced by the word "ingredients".

8. In Section 11(1)(a) the fourth point is deleted.

9. In Section 13(1) letters (a) and (b) are deleted.

The existing letters (c) to (h) inclusive are marked as letters (a) to (f).

10. In Section 13(1)(f) the words "subsection (1)" are replaced by the words "subsection (4)".

11. In Section 13(1)(f) the words "subsection (2)" are replaced by the words "subsection (5)".

12. Section 16a is inserted after section 16, and reads as follows:

"Section 16a
Transitional provisions for regulations effective from 20 May 2016

The operator is obliged to update data under section 3(5) by 31 December 2016 otherwise the registration shall expire".

13. Section 17a is inserted after section 17, and reads as follows:

"Section 17a
Final provisions effective from 20 May 2016

1. Act No. 63/1950 regulating the management of tobacco, alcohol and salt and repealing state financial monopolies, as amended, is repealed

2. Decree of the Ministry of Agriculture of the Slovak Republic No. 2609/1995-100, laying down the conditions for issuing certificates for the production of tobacco products is repealed."

14. The word "placement" in all forms throughout the text of the Act is replaced by the word "placing" in the appropriate form.

Part IV

Act No. 455/1991 on Trades (Trade Act), as amended by Act No. 600/1992, Act No. 231/1992, Act No. 132/1994, Act No. 200/1995, Act No. 233/1995, Act No. 216/1995, Act No. 123/1996, Act No. 222/1996, Act No. 164/1996, Act No. 289/1996, Act No. 290/1996, Act No. 288/1997, Act No. 379/1997, Act No. 76/1998, Act No. 140/1998, Act No. 144/1998, Act No. 70/1998, Act No. 126/1998, Act No. 129/1998, Act No. 143/1998, Act No. 161/1998, Act No. 178/1998, Act No. 179/1998, Act No. 194/1998, Act No. 263/1999, Act No. 264/1999, Act No. 119/2000, Act No. 142/2000, Act No. 236/2000, Act No. 238/2000, Act No. 268/2000, Act No. 338/2000, Act No. 223/2001, Act No. 279/2001, Act No. 488/2001, Act No. 554/2001, Act No. 261/2002, Act No. 284/2002, Act No. 506/2002, Act No. 279/2001, Act No. 245/2003, Act No. 219/2003, Act No. 423/2003, Act No. 190/2003, Act No. 515/2003, Act No. 586/2003, Act No. 602/2003, Act No. 279/2001, Act No. 506/2002, Act No. 347/2004, Act No. 350/2004, Act No. 365/2004, Act No. 420/2004, Act No. 533/2004, Act No. 544/2004, Act No. 578/2004, Act No. 624/2004, Act No. 650/2004, Act No. 656/2004, Act No. 725/2004, Act No. 8/2005, Act No. 93/2005, Act No. 331/2005, Act No. 340/2005, Act No. 351/2005, Act No. 470/2005, Act No. 473/2005, Act No. 491/2005, Act No. 555/2005, Act No. 567/2005, Act No. 124/2006, Act No. 126/2006, Act No. 17/2007, Act No. 99/2007, Act No. 193/2007, Act No. 218/2007, Act No. 358/2007, Act No. 577/2007, Act No. 112/2008, Act No. 445/2008, Act No. 448/2008, Act No. 186/2009, Act No. 492/2009, Act No. 568/2009, Act No. 129/2010, Act No. 136/2010, Act No. 556/2010, Act No. 249/2011, Act No. 324/2011, Act No. 362/2011, Act No. 392/2011, Act No. 395/2011, Act No. 251/2012, Act No. 314/2012, Act No. 321/2012, Act No. 351/2012, Act No. 314/2012, Act No. 447/2012, Act No. 39/2013, Act No. 94/2013, Act No. 95/2013, Act No. 180/2013, Act No. 218/2013, Act No. 1/2014, Act No. 35/2014, Act No. 58/2014, Act No. 182/2014, Act No. 204/2014, Act No. 219/2014, Act No. 321/2014, Act No. 333/2014, Act No. 399/2014, Act No. 77/2015, Act No. 79/2015, Act No. 128/2015, Act No. 266/2015, Act No. 272/2015, Act No. 274/2015, Act No. 278/2015, Act No. 331/2015, Act No. 348/2015, Act No. 387/2015, Act No. 412/2015, Act No. 440/2015 are amended as follows:

In Annex No. 2 Bounded trades in group 214 - Other, sequence number 39 in the column headed Certificate of elegibility the word “certificate” is replaced by the words “- a university degree in the food sector or vocational training in food sciences and at least two years’ experience in the field of manufacture of tobacco products” and the in the column headed Notes the words “section 8 of Act No. 63/1950 regulating the management of tobacco, alcohol and salt and repealing state financial monopolies, as amended” are replaced by “section 3(1) of Act No. 335/2011 on tobacco products.”

Part V

This Act shall enter into force on 1 January 2014.

Andrej Kiska m.p.

Peter Pellegrini m.p.

Robert Fico m.p.

1) Section 4 of Act No. 106/2004, on excise duty on tobacco products, as amended.

2) Section 17(2) of Act No. 106/2004, as amended.

4) Regulation (EC) of the European Parliament and of the Council No 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 (OJ L 353, 31.12.2008).

3) ISO 4387:2000 Cigarettes. Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine (56 9570).
ISO 10315:2013 Cigarettes. Determination of nicotine in smoke condensates. Gas chromatographic method (56 9566).
ISO 8454:2007 Cigarettes. Determination of carbon monoxide in the vapur phase of the cigarette smoke. NDIR method (56 9575).
ISO 8243:2006 Cigarettes. Sampling (56 9563).

Section 9(1) of Act No. 106/2004, as amended.

6) Section 31a of Act No. 308/2000 on broadcasting and retransmission and on amendments to Act No. 195/2000 on telecommunications, as amended.

8) Act No. 12/2013 on the protection of personal data and amending certain acts as amended by Act No. 84/2014

9) Section 5 of Act No. 355/2007 on protection, support and development of public health and amending certain Acts, as amended.

10) Act No. 71/1967 on Administrative Procedure (Administrative Procedure Act), as amended.

11) Act No. 106/2004.

(7) Section 31a(8) section 39(7) and section 39a(7) of Act No. 308/2000, as amended. Section 18(6)(b) and (c) of Act No. 40/2015 on audiovision and on amendments and additions to certain acts as amended by Act No. 278/2015.

Annex no. 1
to Act No. 89/2016

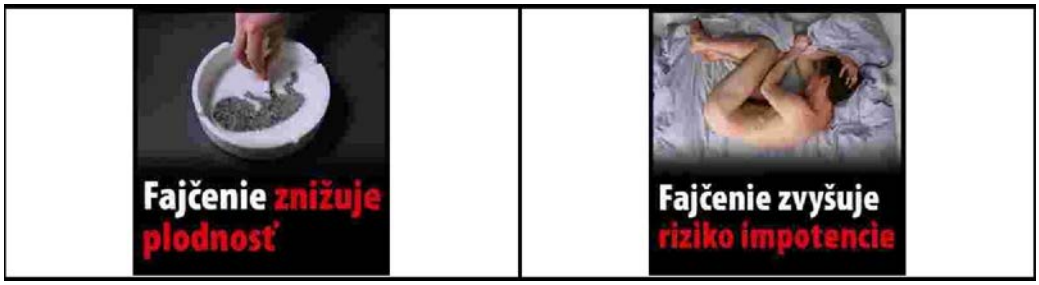
LIST OF TEXT WARNINGS

Smoking causes 9 out of 10 lung cancers.
Smoking causes mouth and throat cancer.
Smoking damages your lungs.
Smoking causes heart attacks.
Smoking causes strokes and disability.
Smoking clogs your arteries.
Smoking increases the risk of blindness.
Smoking damages your teeth and gums.
Smoking can kill your unborn child.
Your smoke harms your children, family and friends.
Smokers' children are more likely to start smoking.
Quit smoking - stay alive for those close to you.
Smoking reduces fertility.
Smoking increases the risk of impotence.

Annex no. 2
to Act No. 89/2016

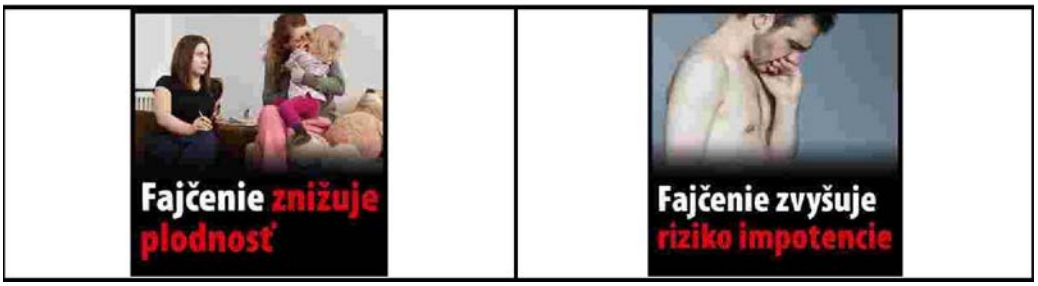
Picture library

Group 1


Fajčenie znižuje plodnosť
Fajčenie zvyšuje riziko impotencie

Group 2


Fajčenie je príčinou 9 z 10 prípadov rakoviny pľúc
Fajčenie spôsobuje rakovinu úst a hrdla
OTVORENÁ RANA PO OPERÁCII PEČ
Fajčenie vám poškodzuje pľúca
Fajčenie spôsobuje infarkt
Fajčenie spôsobuje mŕtvicu a zdravotné postihnutie
Fajčenie vám upcháva tepny
Fajčenie zvyšuje riziko slepoty
Fajčenie vám poškodzuje zuby a ďasná
Fajčenie môže zabiť vaše nenarodené dieťa
Dym z vašej cigarety škodí vašim deťom, rodine a priateľom
U detí fajčiarov je vyššia pravdepodobnosť, že začnú fajčiť
Prestaňte fajčiť – zostaňte nažive pre vašich blízkych


Fajčenie znižuje plodnosť
Fajčenie zvyšuje riziko impotencie

Group 3


Fajčenie je príčinou 9 z 10 prípadov rakoviny pľúc
Fajčenie spôsobuje rakovinu úst a hrdla
Fajčenie vám poškodzuje pľúca
Fajčenie spôsobuje infarkt
Fajčenie spôsobuje mŕtvicu a zdravotné postihnutie
Fajčenie vám upcháva tepny
Fajčenie zvyšuje riziko slepoty
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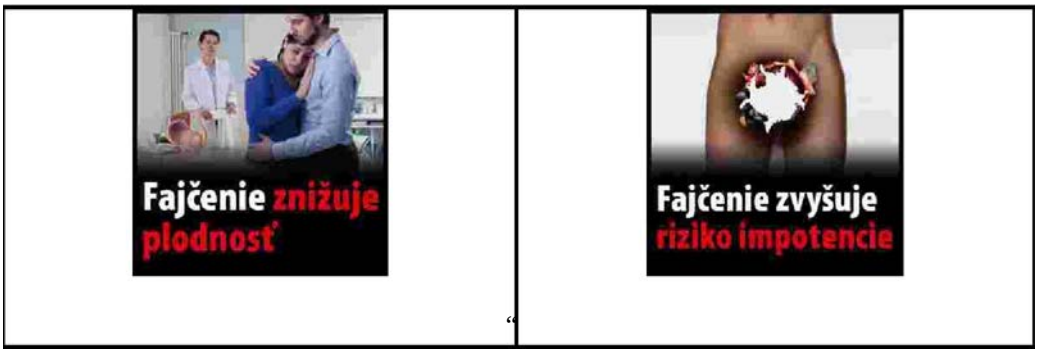
Prestaňte fajčiť – zostaňte naživo pre vašich blízkych


Fajčenie znižuje plodnosť
Fajčenie zvyšuje riziko impotencie

“

Annex no. 3
to Act No. 89/2016

LIST OF ADOPTED LEGALLY BINDING LAWS OF THE EUROPEAN UNION

Directive 2014/109/EU of the European Parliament and of the Council of 3 April 2014 oon 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 (OJ L 127, 29.4.2014), as delegated by Commission Directive 2014/109/EU of 10 October 2014 (OJ L 360, 17.12.2014).

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