

ACT
ON RESTRICTIONS ON THE USE OF TOBACCO AND RELATED
PRODUCTS

I. GENERAL PROVISIONS

Subject matter of the Act

Article 1

This Act lays down measures to reduce and restrict the use of tobacco and related products, harmful ingredients of tobacco and related products, and mandatory marks to appear on the packaging of tobacco and related products, preventive measures against smoking, and supervision of the implementation of this Act, with a view to protecting human health, especially for young people, and meeting the obligations under the WHO Framework Convention for Tobacco Control.

Article 2

(1) This Act transposes into the legal order of the Republic of Croatia the following pieces of the European Union legislation:

- Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127/1, 29. 4. 2014) – hereinafter: Directive;
- 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 warning to be used on tobacco products (OJ L 360, 17.12.2014);
- 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 (OJ L 267, 14.10.2015).

(2) This Act was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codified text) (Text with EEA relevance) (OJ L 241, 17.9.2015).

Definitions

Article 3

For the purposes of this Act, the following terms shall have the following meanings:

- 1) *tobacco* means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;
- 2) *pipe tobacco* means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe;
- 3) *roll-your-own tobacco* means tobacco which can be used for making cigarettes by consumers;
- 4) *tobacco products* means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;
- 5) *smokeless tobacco product* means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;
- 6) *chewing tobacco* means a smokeless tobacco product exclusively intended for the purpose of chewing;
- 7) *nasal tobacco* means a smokeless tobacco product that can be consumed via the nose;
- 8) *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;
- 9) *tobacco products for smoking* means tobacco products other than a smokeless tobacco product;
- 10) *cigarette* means a roll of tobacco that can be consumed via a combustion process and is further defined in a special regulation governing excise duty;
- 11) *cigar* means a roll of tobacco that can be consumed via a combustion process and is further defined in a special regulation governing excise duty;
- 12) *cigarillo* means a small type of cigar and is further defined in a special regulation governing excise duty;
- 13) *waterpipe tobacco* means a tobacco product that can be consumed via a waterpipe is deemed to be a tobacco product for smoking. 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;
- 14) *novel tobacco product* means a tobacco product which does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco,

cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use, and is placed on the market after 19 May 2014;

15) *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;

16) *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;

17) *refill container* means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette;

18) *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;

19) *nicotine* means nicotinic alkaloids;

20) *tar* means the raw anhydrous nicotine-free condensate of smoke;

21) *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;

22) *maximum level* or *maximum emission level* means the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams;

23) *additive* means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging;

24) *flavouring* means an additive that imparts smell and/or taste;

25) *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;

26) *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, by instilling a reward or a relief from withdrawal symptoms, or both;

27) *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;

28) *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;

29) *substantial change of circumstances* means an increase of the sales volumes by product category by at least 10 % in at least five Member States based on sales data transmitted in accordance with the provision of Article 6, paragraph 9 of this Act or an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies; a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2,5 % of total sales of tobacco products at European Union level;

30) *unit packet* means the smallest individual packaging of a tobacco or related product that is placed on the market;

31) *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;

32) *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, as provided for in this Act;

33) *combined health warning* means a health warning consisting of a combination of a text warning and a corresponding photograph or illustration, as provided for in this Act;

34) *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 a Member State other than the Member State or the third country where that retail outlet has its registered head office or is established; a retail outlet is deemed to have its registered head office or to be established in a Member State:

a) in the case of a natural person: if he or she has his or her place of business in that Member State;

b) in other cases: if the retail outlet has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that Member State;

35) *consumer* means a natural person who is acting for own purposes which are outside his or her trade, business, craft or profession;

36) *age verification system* means a computing system that unambiguously confirms the consumer's age electronically;

- 37) *manufacturer* means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark;
- 38) *trade in tobacco or related products* means the import, export, storage for the purpose of sale, and sale;
- 39) *import of tobacco or related products* means the entry into the territory of the European Union of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry into the European Union, as well as their release from a customs suspensive procedure or arrangement;
- 40) *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 European Union;
- 41) *placing on the market* means to make products, irrespective of their place of manufacture, available to consumers located in the European Union, 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;
- 42) *retail outlet* means any outlet where tobacco products are placed on the market including by a natural person;
- 43) *advertising and promotion* means any form of commercial communication, including Information Society services;
- 44) *Information Society* means the society pursuant to special regulations governing the procedures for the official provision of information in the field of technical regulations and rules on Information Society services;
- 45) *sponsorship and promotion* means any form of contribution of a legal or natural person to an event, activity or individual with the aim, effect or likely effect of directly or indirectly promoting tobacco or related products or smoking or the use of tobacco;
- 46) *smoking* means the use of tobacco or other related products by inhaling the smoke resulting from their combustion;
- 47) *harmful effects of smoking* means scientifically proven occurrences of damage to health and diseases that shorten the life span of smokers and non-smokers exposed to smoke in indoor areas;
- 48) *preventive measures against smoking* means systematic activities aimed at improving the health, life expectancy and life quality of the population;
- 49) *public place* means an indoor area intended for common use, including areas in buildings used to pursue activities in the fields of healthcare, child protection, social welfare, education,

trade, sports and recreation, catering and tourism, culture and arts, and transport, including waiting rooms, meeting rooms, event venues, auditoriums, means of public transport, elevators, cable cars, public toilets and outdoor areas designed for theatre and cinema performances, schoolyards and other areas in which non-smokers may be exposed to tobacco against their will;

50) *smoking room* means a completely enclosed space physically separated from other enclosed spaces

51) *proportionate fee* means a fee corresponding to the actual cost of the service for which it is charged.

Gender equality

Article 4

The terms used in this Act in a gender-specific form, be it masculine or feminine, shall refer to both male and female genders alike.

II TOBACCO AND RELATED PRODUCTS

Maximum emission levels for tar, nicotine, carbon monoxide and other substances

Article 5

(1) It is prohibited to manufacture and trade in cigarettes that contain more than:

- 10 mg of tar per cigarette,
- 1 mg of nicotine per cigarette,
- 10 mg of carbon monoxide per cigarette.

(2) The tar, nicotine and carbon monoxide emissions shall be measured on the basis of the following ISO standards:

- ISO standard 4387 for tar,
- ISO standard 10315 for nicotine,
- ISO standard 8454 for carbon monoxide.

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

(4) The ministry responsible for health (hereinafter: the Ministry) shall charge manufacturers and importers of tobacco products a proportionate fee for the verification of the measurements referred to in this Article.

(5) The measurements of the levels of the substances referred to in this Article shall be verified by an approved laboratory, which shall not be owned or controlled directly or indirectly by the tobacco industry.

(6) The laboratory referred to in paragraph 5 of this Article:

- must be accredited according to HRN EN ISO/IEC 17025:2007 – General requirements for the competence of testing and calibration laboratories,
- must have adequate premises,
- must have appropriately qualified staff,
- must have adequate equipment to perform the required analyses.

(7) The laboratory referred to in paragraph 5 of this Article shall submit to the Ministry an application for the issue of a decision authorising it to measure the levels of the substances referred to in this Article.

(8) The Ministry shall issue the authorisation decision referred to in paragraph 7 of this Article within 30 days of the day of submission of the complete application referred to in paragraph 7 of this Article.

(9) The decision referred to in paragraph 8 of this Article may not be appealed against, but an administrative dispute may be initiated against it.

(10) The Ministry shall communicate to the European Commission (hereinafter: the Commission) a list of laboratories referred to in paragraph 5 of this article situated in the Republic of Croatia. The list shall specify the criteria used for approval and the methods of monitoring applied. The list shall be updated whenever any change is made.

(11) The minister responsible for health (hereinafter: the Minister) shall issue a decision on the level of the proportionate fee referred to in paragraph 4 of this Article.

(12) The Minister shall issue an ordinance laying down the requirements that the laboratory referred to in paragraph 5 of this Article must meet as regards premises, staff and equipment.

Reporting of ingredients and emissions

Article 6

(1) Before placing tobacco products on the market, manufacturers and importers shall submit to the Ministry the following information by brand name and type:

- a) 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;
- b) the emission levels referred to in Article 5, paragraph 1 of this Act;
- c) where available, information on other emissions and their levels.

(2) For products placed on the market before the entry into force of this Act, the information referred to in paragraph 1 of this Article shall be provided by a deadline to be determined by the Minister by way of a decision.

(3) If the composition of a product is modified in a way incompatible with the information provided under this Article, manufacturers or importers shall inform the Ministry thereof before the product is placed on the market.

(4) The list of ingredients referred to in point a) of paragraph 1 of this Article shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in the tobacco products concerned. That list shall indicate the status of the ingredients, including whether they have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (hereinafter: Regulation (EC) No 1907/2006), as well as their classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council 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.

(5) The list referred to in point a) of paragraph 1 of this Article shall 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 to any addictive effects.

(6) 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.

(7) Other than for tar, nicotine and carbon monoxide and for emissions referred to in Article 5, paragraph 5 of this Act, manufacturers and importers shall indicate the methods of measurement of emissions used.

(8) The Ministry shall make the information submitted in accordance with paragraph 1 of this Article and with Article 5 of this Act publicly available on its website, taking duly into account the need to protect information that the manufacturers and importers designated as trade secrets at the time of its submission.

(9) Manufacturers and importers shall submit to the Ministry internal and external studies available to them on market research and preferences of various consumer groups, including young people and smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys they carry out when launching new products, and a report on their sales volumes per brand and type, reported in cigarette, cigarillo or cigar sticks or kilograms.

(10) All data and information referred to in this Article and Article 7 of this Act shall be provided in electronic form. The information shall be stored electronically and the

Commission and other Member States shall have access to that information, taking account of data protection and ensuring that trade secrets and other confidential information are treated in a confidential manner.

(11) The Ministry shall charge manufacturers and importers of tobacco products a proportionate fee for receiving, storing, handling, analysing and publishing the information submitted to it pursuant to the provisions of this Article.

(12) The level of the fee referred to in paragraph 11 of this Article shall be determined by the Minister by way of a decision.

(13) The Minister shall issue an ordinance on the form and availability of the data and information on tobacco products referred to in paragraph 10 of this Article.

Priority list of additives and enhanced reporting obligations

Article 7

(1) In addition to the reporting obligations laid down in Article 6 of this Act, enhanced reporting obligations laid down in this Article shall apply to additives contained in cigarettes and roll-your-own tobacco that are included in a priority list.

(2) Manufacturers and importers of cigarettes and roll-your-own tobacco containing an additive that is included in the priority list provided for in paragraph 1 of this Article shall carry out comprehensive studies, which shall examine for each additive whether it:

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

b) results in a characterising flavour;

c) facilitates inhalation or nicotine uptake; and

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

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

(4) Manufacturers or importers shall establish reports on the results of the studies referred to in paragraph 2 of this Article and submit them to the Commission and to the Ministry. These reports shall include an executive summary, and a comprehensive overview compiling the available scientific literature on that additive and summarising internal data on the effects of the additive. The Ministry may request supplementary information from manufacturers or importers regarding the additive concerned. This supplementary information shall form part of the report.

(5) The Ministry shall be entitled to require the reports referred to in paragraph 4 of this Article to be peer reviewed by an independent scientific body, in particular as regards their comprehensiveness, methodology and conclusions.

(6) The Ministry may charge manufacturers and importers of tobacco products proportionate fees for the peer reviews referred to in paragraph 5 of this Article.

(7) Small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC shall be exempted from the obligations pursuant to this Article, if a report on the additive referred to in paragraph 1 of this Article is prepared by another manufacturer or importer.

(8) The Minister shall issue a decision on the level of the proportionate fee referred to in paragraph 6 of this Article.

Ingredients

Article 8

(1) It is prohibited to place on the market tobacco products with a characterising flavour. This prohibition shall not apply to the use of additives which are essential for the manufacture of tobacco products, for example sugar to replace sugar that is lost during the curing process, provided those additives do not result in a product with a characterising flavour and do not increase to a significant or measureable degree the addictiveness, toxicity or the CMR properties of the product.

(2) The Ministry may request the Commission to determine whether a tobacco product falls within the scope of paragraph 1 of this Article or may consult an independent advisory panel established at European Union level.

(3) It is prohibited to place 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;
 - e) additives that have CMR properties in unburnt form.
- (4) It is prohibited to place 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, papers and capsules shall not contain tobacco or nicotine.
- (5) It is prohibited, where based on scientific evidence, to place on the market tobacco products containing additives in quantities that increase the toxic or addictive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measureable degree. The Ministry shall notify to the Commission the measures taken to prevent the placing on the market of tobacco products containing additives listed in this paragraph.
- (6) The Ministry may request the Commission to determine whether a tobacco product falls within the scope of paragraph 5 of this Article.
- (7) Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 4 of this Article.
- (8) The Ministry may charge a proportionate fee to manufacturers and importers of tobacco products for assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the CMR properties of the tobacco product concerned.
- (9) The conditions laid down in Regulation (EC) No 1907/2006 shall apply to tobacco products as appropriate.
- (10) The Minister shall issue a decision on the level of the proportionate fee referred to in paragraph 8 of this Article.

Labelling and packaging

Article 9

- (1) Each unit packet of a tobacco product and any outside packaging shall carry the health warnings provided for in Articles 9 to 13 of this Act in the Croatian language and Latin script.
- (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 must be irremovably printed, indelible and fully visible, including not being partially or totally hidden or interrupted by tax stamps, price marks, security features, wrappers, jackets, boxes, or other items. 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.

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

(5) The dimensions of the health warnings provided for in Articles 10 to 13 of this Act 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 Article 12 of this Act.

General warnings and information messages on tobacco products for smoking

Article 10

(1) Each unit packet and any outside packaging of tobacco products for smoking shall carry the following general warning „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 that 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. the information message shall appear on the bottom part of the other lateral surface. These warnings shall have a width of not less than 20 mm.

(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.

(6) 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.

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

(8) The general warning and information message referred to in paragraphs 1 and 2 of this Article shall be:

a) printed in black Helvetica bold type on a white background; 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.

(9) The Minister shall issue an ordinance determining the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches as referred to in this Article.

Combined health warnings for tobacco products for smoking

Article 11

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

(2) The combined health warnings shall:

a) contain a text warning provided for in Annex I to this Act, which forms an integral part hereof, and a corresponding colour photograph specified in the picture library in Annex II to this Act, which forms an integral part hereof;

b) include the following text: „For help with stopping smoking call 0800 7999“;

c) cover 65 % of both the external front and back surface of the unit packet and any outside packaging; cylindrical packets shall display the 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 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. Transitional exemptions from that obligation on the position of the combined health warning may apply as follows:

– where the tax stamp used for fiscal purposes is affixed at the top edge of a unit packet made of carton material, the combined health warning that is to appear on the back surface may be positioned directly below the tax stamp,

– where a unit packet is made of soft material, a rectangular area of a height not exceeding 13 mm between the top edge of the packet and the top end of the combined health warnings may be reserved for the tax stamp used for fiscal purposes.

The exemptions referred to in point e) of this paragraph shall apply for a period of three years from 20 May 2016; brand names or logos shall not be positioned above the health warnings;

f) be reproduced in accordance with the format, layout, design and proportions specified in point c) of this paragraph;

g) in the case of unit packets of cigarettes, respect the following dimensions:

– height: not less than 44 mm,

– width: not less than 52 mm.

(3) The combined health warnings are grouped into three sets as set out in Annex II to this Act. Each set shall be used in a given year and rotated on an annual basis. The first rotation shall begin on the day of entry into force of this Act. Each combined health warning available for use in a given year shall be displayed to the extent possible in equal numbers on each brand of tobacco products.

(4) The rules concerning the position, design and shape of the combined health warnings for tobacco products for smoking are contained in Annex II to this Act.

(5) The provisions in this Article shall also apply to unit packets with rounded or bevelled edges.

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

Article 12

(1) Tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco shall be exempt from the obligations to carry the information message referred to in Article 10, paragraph 2 of this Act and the combined health warnings laid down in Article 11 of this Act.

(2) In addition to the general warning provided for in Article 10, paragraph 1 of this Act, each unit packet and any outside packaging of the products referred to in paragraph 1 of this Article shall carry one of the text warnings listed in Annex I to this Act. The general warning specified in Article 10, paragraph 1 of this Act shall include the cessation information referred to in Article 11, paragraph 2, point b) of this Act.

(3) The general warning shall appear on the most visible surface of the unit packet and any outside packaging.

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

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

(6) The general warning referred to in paragraph 2 of this Article shall cover at least 30 % of the relevant surface of the unit packet and any outside packaging.

(7) The text warning referred to in paragraphs 1 and 2 of this Article shall cover at least 40 % of the relevant surface of the unit packet and any outside packaging.

(8) Where the health warnings referred to in paragraphs 1 and 2 of this Article are to appear on a surface exceeding 150 cm², the warnings shall cover an area of at least 45 cm².

(9) The health warnings referred to in paragraph 1 of this Article shall comply with the requirements specified in Article 10 of this Act. The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings.

(10) 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.

Labelling of smokeless tobacco products

Article 13

(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 referred to in paragraph 1 of this Article shall comply with the requirements specified in Article 10, paragraph 8 of this Act. The text of the warning shall be parallel to the main text on the surface reserved for these warnings.

(3) The health warning referred to in paragraph 1 of this Article shall:

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

Product presentation

Article 14

(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; 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 vitalising, energetic, healing, rejuvenating, natural or organic properties or has other health or 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 prohibition laid down in paragraphs 1 and 2 of this Article shall include texts, symbols, names, trademarks, figures or other signs or symbols of any type.

Appearance and content of unit packets

Article 15

- (1) Unit packets of cigarettes shall have a cuboid shape.
- (2) Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch.
- (3) A unit packet of cigarettes shall include at least 20 cigarettes.
- (4) A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30 g.
- (5) 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.

Traceability

Article 16

- (1) All unit packets of tobacco products which are placed on the market shall be marked with a unique identifier, which 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. In the case of tobacco products that are manufactured outside of the European

Union, the obligations laid down in this Article shall apply only to those that are destined for, or placed on, the European Union market.

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

- a) the date and place of manufacturing;
- b) the manufacturing facility;
- c) the machine used to manufacture the tobacco products;
- d) the production shift or time of manufacture;
- e) the product description;
- f) the intended market of retail sale;
- g) the intended shipment route;
- h) where applicable, the importer into the European Union;
- i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure and consignee;
- j) the identity of all purchasers from manufacturing to the first retail outlet; and
- k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

(3) The information referred to in paragraph 2, points a) to g) and, where applicable, point h) of this Article shall form part of the unique identifier.

(4) All the information referred to in paragraph 2, points i), j) and k) of this Article shall be electronically accessible by means of a link to the unique identifier.

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

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

(7) The manufacturers of tobacco products shall provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored,

transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to paragraph 8 of this Article.

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

(9) The activities of the third party referred to in paragraph 8 of this Article shall be monitored by an external auditor, who shall be proposed and paid by the tobacco manufacturer and approved by the Commission. The external auditor shall submit an annual report to the ministry responsible for finance - customs administration and to the Commission, assessing in particular any irregularities in relation to access.

(10) The competent authority and the external auditor shall have full access to the data storage facilities. In duly justified cases the competent authority may grant manufacturers or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant European Union and Croatian law.

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

(12) Personal data shall only be processed in accordance with the rules and safeguards laid down in the special regulation governing personal data protection.

(13) The minister responsible for finance shall, by means of an ordinance:

- a) determine the technical standards for the establishment and the operation of the tracking and tracing system as provided for in this Article, including the marking with a unique identifier, the recording, transmitting, processing and storing of data and access to stored data;
- b) determine the technical standards for ensuring that the systems used for the unique identifier and the related functions are fully compatible with each other across the European Union.

Security feature

Article 17

In addition to the unique identifier referred to in Article 16 of this Act, all unit packets of tobacco products that are placed on the market shall carry a tamper proof security feature, composed of visible and invisible elements. The security feature shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps

imposed by special regulations governing excise duties, or through price marks or other elements. Tax stamps may be used for the security feature provided that they fulfil all of the required technical standards and functions.

Notification of novel tobacco products

Article 18

(1) Manufacturers and importers of novel tobacco products shall submit a notification to the Ministry of any novel product they intend to place on the market in the Republic of Croatia. The notification shall be submitted in electronic form six months before the intended placing on the market. The notification shall contain 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 Article 7 of this Act. The manufacturers and importers submitting a notification of a novel tobacco product shall also provide the Ministry with:

- 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.

(2) Manufacturers and importers of novel tobacco products shall transmit to the Ministry any new or updated information on the studies, research and other information referred to in paragraph 1, points a) to c) of this Article. The Ministry may require manufacturers or importers of novel tobacco products to carry out additional tests or submit additional information. All information received pursuant to this Article shall be made available to the Commission.

(3) Novel tobacco products placed on the market shall fully respect the relevant requirements of this Act, depending on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking.

Electronic cigarettes

Article 19

(1) Electronic cigarettes and refill containers may only be placed on the market in accordance with this Act and with the relevant European Union legislation. This Act does not apply to

electronic cigarettes and refill containers that are subject to an authorisation requirement under special regulations governing the placing of medicinal products or medical devices on the market.

(2) Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the Ministry of any such products which 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 the date of entry into force of this Act, the notification shall be submitted within six months of that date. A new notification shall be submitted for each substantial modification of the product. The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

- a) the name and contact details of the manufacturer, a responsible legal or natural person within the European Union, and, if applicable, the importer into the European Union;
- b) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;
- c) toxicological data regarding the product's ingredients and emissions, 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;
- d) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;
- e) a description of the components of the product, including, 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 Article;
- g) a declaration that the manufacturer and importer bear full responsibility for the quantity and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

(3) Where the Ministry considers that the information submitted is incomplete, it shall request the completion of the information.

(4) The Ministry shall charge manufacturers and importers proportionate fees for receiving, storing, handling and publishing the information submitted to it.

(5) Manufacturers and importers shall 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 referred to in Article 8, paragraph 3 of this Act;

d) only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in paragraph 2, point b) of this Article may only be 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;

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.

(6) Each unit packet of electronic cigarettes and refill containers shall include a leaflet with information on:

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

b) contra-indications;

c) warnings for specific risk groups;

d) possible adverse effects;

e) addictiveness and toxicity; and

f) contact details of the manufacturer or importer and a legal or natural contact person within the European Union.

(7) Each unit packet and any outside packaging of electronic cigarettes and refill containers shall:

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) contain information on the nicotine content of the container and on flavourings;

c) carry the following health warning: „This product contains nicotine which is a highly addictive substance.“

(8) Each unit packet and any outside packaging shall carry health warnings in compliance with the provisions in Article 13, paragraphs 2 and 3 of this Act.

(9) The following is prohibited:

- a) commercial communications in Information Society services, 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 European Union market;
- b) commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers;
- c) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers;
- d) 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;
- e) audiovisual commercial communications to which to which a special regulation governing electronic media applies, for electronic cigarettes and refill containers.

(10) Manufacturers and importers of electronic cigarettes and refill containers shall submit to the Ministry and to the ministry responsible for finance, not later than 31 March of the current year for the preceding year:

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

(11) The Ministry shall make the information received pursuant to paragraph 2 of this Article publicly available on its website, taking duly into account the need to protect information that the manufacturers and importers designated as trade secrets at the time of its submission.

(12) Manufacturers, importers and 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.

(13) Should any of these manufacturers, importers or distributors consider or have reason to believe 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, they shall immediately take all the corrective action necessary to bring the product concerned into conformity with this Act, to withdraw or to recall it, as appropriate. In such cases, the manufacturer, importer or distributor shall immediately inform the market surveillance authorities of the Member States in which the product is made available or is intended to be made available, giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action.

(14) The Ministry shall be entitled to request additional information from the manufacturer, importer or distributor, for example on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers.

(15) In the case of electronic cigarettes and refill containers that comply with the requirements of this Article, where the Ministry ascertains or has reasonable grounds to believe that specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, could present a serious risk to human health, it may take measures laid down in a special regulation governing the procedures to be followed by the sanitary inspection service. The Ministry shall immediately inform the Commission and the competent authorities of other Member States of the measures taken and shall communicate any supporting data.

(16) Retail outlets engaged in cross-border distance sales of electronic cigarettes, refill containers and single use cartridges may only start selling these products after registering with the Ministry and with the competent authorities in the Member State where the actual or potential consumers are located, provided that cross-border distance sales are allowed in that Member State, and shall submit the following information when registering:

- a) the name of the retail outlet and the address of the place from where the products will be supplied;
- b) the starting date of the cross-border distance sales of products to consumers by means of Information Society services;
- c) the address of the websites used for distance sales, including all information necessary to identify these websites,

and after obtaining confirmation of registration with the Ministry.

(17) The Ministry shall publish on its website information about the registered retail outlets referred to in paragraph 16 of this Article.

(18) Retail outlets engaged in cross-border distance sales referred to in paragraph 16 of this Article shall operate an age verification system and shall provide to the Ministry a description of the details and functioning of this system.

(19) Retail outlets shall only process personal data of the consumer in accordance with a special law governing the protection of personal data. Those data shall not be disclosed to the manufacturer of electronic cigarettes, refill containers and single use cartridges or to 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. The protection of personal data within the meaning of this paragraph also applies if the retail outlet forms part of a manufacturer of electronic cigarettes, refill containers and single use cartridges.

(20) The Minister shall issue a decision on the level of the proportionate fee referred to in paragraph 4 of this Article.

(21) The Minister shall issue an ordinance determining the method of submitting a notification of electronic cigarettes and refill containers referred to in paragraph 2 of this Article.

(22) The Minister shall issue an ordinance on the technical standards for the refill mechanism for electronic cigarettes referred to in paragraph 5, point g) of this Article.

Herbal products for smoking

Article 20

(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 specified in paragraph 1 of this Article shall be printed on the front and back surface of the unit packet and on any outside packaging.

(3) The health warning shall comply with the requirements set out in Article 10, paragraph 8 of this Act and shall cover 30 % of the area of the corresponding surface of the unit packet and of 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 Article 14, paragraph 1, points a), b) and d) of this Act and shall not state that the product is free of additives or flavourings.

Reporting of ingredients of herbal products for smoking

Article 21

(1) Manufacturers and importers 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. Manufacturers or importers shall inform the Ministry when the composition of a product is modified in a way that affects the information submitted pursuant to this Article. The information referred to in this Article shall be submitted to the Ministry prior to the placing on the market of a new or modified herbal product for smoking.

(2) The Ministry shall make the information submitted in accordance with paragraph 1 of this Article publicly available on its website, taking duly into account the need to protect information that the manufacturers and importers designated as trade secrets at the time of its submission.

III MEASURES AIMED AT REDUCING AND RESTRICTING THE USE OF TOBACCO AND RELATED PRODUCTS

Article 22

(1) It is prohibited to sponsor events, activities or individuals with the aim, effect or likely effect of, directly or indirectly, promoting tobacco and related products, including smokeless tobacco products and herbal products for smoking, electronic cigarettes, refill containers and single use cartridges.

(2) It is prohibited to directly or indirectly promote and advertise the products referred to in paragraph 1 of this Article. Direct promotion of the products referred to in paragraph 1 of this Article means the display of individual packets of cigarettes and other tobacco and related products, electronic cigarettes, refill containers and single use cartridges in conspicuous places and at points of sale of any kind where tobacco and related products are sold, including the offering of such products for sale.

(3) Indirect promotion of the products referred to in paragraph 1 of this Article means the organising of events at which names, logos or other visual characteristics associated with individual products referred to in paragraph 1 of this Article are displayed, and the displaying of logos and other distinctive features associated with the products referred to in paragraph 1 of this Article on items which are not tobacco or related products within the meaning of this Act. Indirect promotion also means the distribution of products referred to in paragraph 1 of this Article free of charge in public areas or public places.

(4) It is prohibited to display the names and logos of the products referred to in paragraph 1 of this Article by means of illuminated advertising, plates, sales racks, leaflets, catalogues or other promotional materials.

(5) It is prohibited to advertise or promote products that are not considered to be the products referred to in paragraph 1 of this Article, but whose shape, name or intended purpose indirectly encourage the consumption of those products, or to use any other form of advertisement whose shape, name or intended purpose encourage the consumption of products referred to in paragraph 1 of this Article.

(6) The publication of information on the quality and other characteristics of products referred to in paragraph 1 of this Article in professional books, journals and other professional publications intended to inform the manufacturers or vendors of these products shall not be considered to be advertising within the meaning of this Act. Professional books, journals and other professional publications intended to inform the manufacturers and vendors shall be packaged in opaque film closed on both ends.

(7) The information referred to in this Article shall not be made available through Information Society services.

Article 23

(1) It is prohibited to sell tobacco and related products, including smokeless tobacco products and herbal products for smoking, electronic cigarettes, refill containers and single use cartridges to persons under 18 years of age.

(2) The products referred to in paragraph 1 of this Article shall not be sold by persons under 18 years of age.

(3) All points of sale selling products referred to in paragraph 1 of this Article shall display an indication of the prohibition of sale of tobacco and related products, smokeless tobacco products and herbal products for smoking and electronic cigarettes, refill containers and single use cartridges to persons under 18 years of age.

(4) The indication referred to in paragraph 3 of this Article shall be displayed in a prominent place and shall be readable from a distance of ten metres.

(5) The vendor shall request a person he or she believes is under 18 years of age to provide appropriate evidence of having reached the legal age. If the person fails to provide evidence of legal age, the vendor shall refuse to sell the requested product referred to in paragraph 1 of this Article.

(6) It is prohibited to sell to minors other products intended for smoking that may encourage minors to smoke.

(7) The sale and purchase via the Internet and the cross-border distance sale of products referred to in paragraph 1 of this Article other than electronic cigarettes, refill containers and single use cartridges is prohibited.

(8) It is prohibited to sell products referred to in paragraph 1 of this Article through vending machines.

(9) It is prohibited to sell individual cigarettes or other products referred to in paragraph 1 of this Article outside the original manufacturer's packaging.

(10) It is prohibited to sell tobacco for oral use.

Article 24

(1) It is prohibited to smoke and consume tobacco and related products, including smokeless tobacco products, electronic cigarettes and herbal products for smoking, during public performances or to show persons smoking or consuming the products referred to in this paragraph on television.

(2) The prohibition laid down in paragraph 1 of this Article shall not apply to films and works of art.

(3) It is prohibited to publish in the press, for promotional purposes, photographs or drawings of persons smoking.

Article 25

(1) It is prohibited to smoke tobacco and related products or herbal products, and to use nicotine-containing or non-nicotine-containing electronic cigarettes and waterpipes in all indoor public places.

(2) An indoor public place referred to in paragraph 1 of this Article means a space having a roof and more than one half of the entire partition surface area consisting of deck-to-deck partitions, or a terrace enclosed by partitions made of glass or other material. In addition, an indoor public place is a space having a roof in which more than one half of the partition surface area is closable, provided that such partitions are closed. It is also prohibited to smoke in areas not considered indoor public places under this Act, which constitute a functional part of a space used to carry out an educational activity.

(3) It is prohibited to smoke in an area situated less than 20 metres away from the entrance to a healthcare facility.

(4) It is prohibited to smoke in an area situated less than 20 metres away from the entrance to an educational establishment.

(5) Smoking rooms are prohibited in spaces where healthcare or education-related activities are carried out.

(6) By way of derogation from the provision in paragraph 1 of this Article, smoking shall be permitted:

- a) in specially designated smoking areas used to accommodate guests pursuant to regulations governing the hospitality industry, which shall display a 'smoking permitted in this area' sign;
- b) in specially designated smoking areas in psychiatric wards and special designated smoking areas in other facilities providing healthcare or welfare services to mental patients, as well as in penitentiary institutions and prisons, which shall display a 'smoking permitted in this area' sign; and
- c) in smoking rooms in hospitality establishments.

Article 26

The smoking room shall fulfil the following requirements:

- a) it must be designed so as to prevent the outflow of air contaminate with tobacco smoke into other areas;
- b) it must have a surface area of at least 10 m²;
- c) it must not take up more than 20 % of the total surface area of the public space, or 20 % of the space intended for providing catering services in a catering facility;
- d) it must not be intended as a passageway to other areas;
- e) no food or drink may be served in the smoking room.

Article 27

(1) The smoking room shall be completely enclosed along its entire wall and ceiling surface area, and shall have a self-closing door that must not be propped open. Closed windows and doors shall be considered to form part of the walls.

(2) A „smoking room“ sign shall be displayed above or beside the door to the smoking room, indicating the number of persons the room can accommodate at a time.

(3) It must be ensured that an automatic “Smoking prohibited due to the failure of the ventilation system” indication appears outside the entrance to the smoking room and inside the room in the event of ventilation system failure.

Article 28

(1) The smoking room shall be equipped with a ventilation system and a filtering system, which shall form part of the smoking room and shall be physically separated from other ventilation systems in the indoor public place in which the smoking room is situated. Air contaminated with tobacco smoke must not diffuse into other enclosed spaces of the indoor public place.

(2) The ventilation system in the smoking room shall be automatic and ensure that no tobacco smoke escapes into other enclosed spaces of the indoor public place.

Article 29

(1) With the doors to the smoking room closed, the ventilation system in the smoking room shall operate exhaust sufficient to create a negative pressure of at least 5 Pa with respect to the adjacent space giving into the smoking room.

(2) Smoking rooms shall be equipped with a device that measures and displays the negative pressure level.

Article 30

(1) The ventilation system in smoking rooms shall ensure a supply of air from outdoor areas or non-smoking indoor areas.

(2) The air exchange system shall purify the air by ensuring a minimum air supply rate of 30 litres per second per person, based on the occupancy load of 0.7 persons/m².

Article 31

The design, installation and maintenance of smoking room ventilation systems shall be in compliance with special technical regulations laying down the essential requirements for ventilation systems.

Article 32

(1) In facilities serving drinks only, where the requirements specified in Article 26, points b) and c) of this Act cannot be met, the owner or user of the facility may designate the serving area as a smoking area, displaying a “smoking area” sign in the room.

(2) The smoking area referred to in paragraph 1 of this Article shall meet the following requirements:

- a) have a ventilation system ensuring at least 10 air exchanges per hour;
- b) have a filtering system to extract air contaminated with tobacco smoke from the smoking room to outdoor areas;
- c) be equipped with items advertising the harmful effects of use of tobacco products (poster, leaflets, stickers, etc.).

Article 33

(1) A legal or natural person performing a catering activity shall submit to the Ministry an application for the issue of a decision on the fulfilment of the requirements laid down in Articles 26 to 32 of this Act.

(2) The Ministry shall issue the decision referred to in paragraph 1 of this Article within 30 days of the day of submission of the complete application referred to in paragraph 1 of this Article.

(3) The decision referred to in paragraph 2 of this Article may not be appealed against, but an administrative dispute may be initiated against it.

(4) If the circumstances referred to in Articles 26 to 32 of this Act change, the Ministry shall revoke the decision referred to in paragraph 2 of this Article.

Article 34

The owner or user of the non-smoking space shall ensure the enforcement of the smoking ban.

IV PREVENTIVE MEASURES AGAINST SMOKING

Article 35

(1) Educational institutions shall, during their regular education activities, promote awareness of the harmful effects of use of tobacco and related products on the health of children and youth of all ages.

(2) The minister responsible for education shall, after having obtained the opinion of the Minister, adopt a programme for the promotion of awareness of the harmful effects of use of tobacco and related products on the health of children and youth of all ages, referred to in paragraph 1 of this Article.

Article 36

(1) In the exercise of his or her social care duties to protect the health of the population against harmful effects of smoking of tobacco and tobacco and related products, the Minister shall establish and appoint the members of the National Anti-Smoking Committee (hereinafter: the Committee).

(2) The Committee shall have 10 members:

- a) three health care professionals working on raising health awareness;
- b) two prominent anti-smoking experts;
- c) one media representative;
- d) one representative of the education sector;
- e) two representatives of the Ministry;
- f) one representative of the ministry responsible for education.

(3) The Chair and members of the Committee referred to in paragraph 2 of this Article shall be appointed by the Minister for a period of four years.

(4) The Committee shall adopt its Rules of Procedure.

(5) The Committee shall carry out the following activities:

- a) monitor the prevalence of smoking, examine and propose measures to reduce the effects of tobacco and related products on human health;
- b) propose enforcement activities aimed at reducing the use of tobacco and related products;
- c) propose smoking cessation programmes;
- d) propose and organise the publishing of occasional publications aimed at promoting a healthy non-smoking lifestyle and smoking cessation;
- e) cooperate with international bodies that monitor the issues related to the reduction of smoking prevalence;
- f) prepare reports on the prevalence of smoking and the outcomes of permanent preventive actions;
- g) cooperate with government agencies and non-governmental organisations and associations;
- h) carry out other tasks in the area of restriction of smoking of tobacco, tobacco products and related products; and
- i) submit to the Minister, not later than 31 March of the current year for the preceding year, an annual report on the Committee's activities.

Article 37

Funds shall be allocated in the state budget for the carrying out systematic educational, informative and promotional activities aimed at reducing and restricting the use of tobacco and related products.

V SUPERVISION

Article 38

Inspectional supervision of the implementation of this Act shall be carried out by sanitary inspectors, health inspectors, education inspectors, labour inspectors, market inspectors, electricity and heating inspectors and authorised customs officers, within the respective powers vested in them by the law.

Article 39

(1) Where the competent inspector finds that tobacco and related products, electronic cigarettes, refill containers or single use cartridges are sold contrary to the provisions of this Act, he or she shall issue, in respect of the legal or natural person carrying out the selling activity, a decision prohibiting that person from selling tobacco and related products.

(2) The decision referred to in paragraph 1 of this Article shall specify the period of the ban on the sale of tobacco and related products, electronic cigarettes, refill containers and single use cartridges, which may not exceed six months.

(3) A recourse to a legal remedy against the decision referred to in paragraph 1 of this Article may be taken in accordance with the provisions of the law regulating the activities of the competent inspectors.

(4) By way of derogation from the provision in paragraph 1 of this Article, where the competent inspector finds that tobacco and related products, electronic cigarettes, refill containers or single use cartridges are being sold to or by persons under 18 years of age, he or she shall issue a verbal decision, in accordance with the trade regulations, prohibiting the legal or natural person concerned from carrying out the trade activity for a period of 30 days to six months. The verbal decision shall be submitted to the legal or natural person in writing not later than eight days after the day of its issue.

VI PENAL PROVISIONS

Article 40

(1) A legal person shall be guilty of a misdemeanour and shall be fined a sum between HRK 70 000.00 and HRK 150 000.00 for:

1. selling cigarettes containing more than 10 mg of tar per cigarette (Article 5, paragraph 1, sub-paragraph 1);
2. selling cigarettes containing more than 1 mg of nicotine per cigarette (Article 5, paragraph 1, sub-paragraph 2);
3. selling cigarettes containing more than 10 mg of carbon monoxide per cigarette (Article 5, paragraph 1, sub-paragraph 3);
4. failing to submit to the Ministry the required information on the ingredients and emissions of tobacco products prior to the placing of these products on the market (Article 6, paragraph 1);
5. failing to submit to the Ministry, by a deadline determined by the Minister by way of a decision, the required information on the ingredients and emissions of tobacco products placed on the market before the entry into force of this Act (Article 6, paragraph 2);
6. failing to inform the Ministry, before a product is placed on the market, that the composition of the product is modified in a way incompatible with the information provided under Article 6 of this Act (Article 6, paragraph 3);
7. failing to carry out studies examining additives and to submit it to the competent authorities or to provide supplementary information within the prescribed time frame (Article 7, paragraphs 2 and 4 and Article 50, paragraph 1).
8. placing on the market tobacco products with a characterising flavours or with additives in any of their components (Article 8, paragraphs 1, 3 and 4);

9. placing on the market tobacco products containing additives in quantities that increase the toxic or addictive effect or the CMR properties of a tobacco product to a significant or measureable degree (Article 8, paragraph 5);
10. placing on the market tobacco products labelled contrary to Article 9, paragraphs 1, 2, 5 and 6 of this Act or packaged contrary to Article 9, paragraphs 3 and 4 of this Act;
11. placing on the market tobacco products for smoking labelled contrary to Article 10, paragraphs 1, 2, 3, 4, 5, 6, 7 and 8 of this Act;
12. placing on the market tobacco products for smoking labelled contrary to Article 11, paragraphs 1, 2 and 3 of this Act;
13. placing on the market tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco labelled contrary to Article 12, paragraphs 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 of this Act;
14. placing on the market smokeless tobacco products labelled contrary to Article 13, paragraphs 1, 2 and 3 of this Act;
15. selling tobacco products using elements and features contrary to Article 14, paragraphs 1, 2 and 3 of this Act;
16. selling unit packets of cigarettes that are not cuboid in shape (Article 15, paragraph 1);
17. selling unit packets of roll-your-own tobacco that do not have a cuboid or cylindrical shape, or the form of a pouch (Article 15, paragraph 2);
18. selling unit packets of cigarettes that do not contain at least 20 cigarettes (Article 15, paragraph 3);
19. selling unit packets of roll-your-own tobacco that do not contain at least 30 g of tobacco (Article 15, paragraph 4);
20. selling unit packets of cigarettes whose appearance or content are contrary to Article 15, paragraph 5 of this Act;
21. selling unit packets of tobacco products that are not marked with a unique identifier in accordance with Article 16, paragraphs 1 and 2 of this Act;
22. failing to record the entry of unit packets and to keep records of movements and transactions in accordance with Article 16, paragraphs 5, 6 and 7 of this Act;
23. failing to conclude a contract with an independent third party in accordance with Article 16, paragraph 8 of this Act;
24. modifying or deleting recorded data contrary to Article 16, paragraph 11 of this Act;
25. selling unit packets of tobacco products that do not carry a security feature in accordance with Article 17 of this Act;

26. failing to submit to the Ministry within the prescribed time limit a notification of a novel tobacco product it intends to place on the market (Article 18, paragraph 1);
27. failing to submit to the Ministry within the prescribed time limit a notification provided for in Article 19, paragraph 2 of this Act before placing electronic cigarettes and refill containers on the market;
28. failing to ensure that 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 (Article 19, paragraph 5, point a));
29. failing to ensure that nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml (Article 19, paragraph 5, point b));
30. failing to ensure that nicotine-containing liquid does not contain additives referred to in Article 8, paragraph 3 of this Act (Article 19, paragraph 5, point c));
31. failing to ensure that only ingredients of high purity are used in the manufacture of the nicotine-containing liquid (Article 19, paragraph 5, point d));
32. failing to ensure that, 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 (Article 19, paragraph 5, point e));
33. failing to ensure that electronic cigarettes deliver the nicotine doses at consistent levels (Article 19, paragraph 5, point f));
34. failing to ensure that 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 (Article 19, paragraph 5, point g));
35. selling electronic cigarettes and refill containers without a leaflet containing the information referred to in Article 19, paragraph 6 of this Act;
36. selling electronic cigarettes and refill containers without the list, information or warning provided for in Article 19, paragraph 7 of this Act;
37. making commercial communications contrary to the provisions of Article 19, paragraph 9 of this Act;
38. failing to submit to the Ministry and to the ministry responsible for finance, within the prescribed time limit, the required data, information or executive summaries (Article 19, paragraph 10);
39. engaging in cross-border distance sales of electronic cigarettes, refill containers and single use cartridges contrary to the provision of Article 19, paragraph 16 of this Act;

40. engaging in cross-border distance sales of electronic cigarettes, refill containers and single use cartridges without operating an age verification system, or failing to submit to the Ministry a description of the details and functioning of this system (Article 19, paragraph 18);
41. selling herbal products for smoking labelled or packaged contrary to the provisions of Article 20 of this Act;
42. failing to submit a list of all ingredients of herbal products or modified herbal products and quantities thereof prior to placing the products on the market, as required by Article 21, paragraph 1 of this Act;
43. sponsoring events, activities or individuals with the aim, effect or likely effect of, directly or indirectly, promoting the use of tobacco and related products (Article 22, paragraph 1);
44. directly or indirectly promoting tobacco and related products or electronic cigarettes (Article 22, paragraph 2);
45. displaying the names or logos of tobacco and related products, including electronic cigarettes, contrary to Article 22, paragraphs 4 and 5 of this Act;
46. failing to display, at points of sale selling tobacco and related products referred to in Article 23, paragraph 1 of this Act, an indication of the prohibition of sale of the products referred to in Article 23, paragraphs 3 and 4 to persons under 18 years of age, or failing to display it in a prominent place so that it is readable from a distance of ten meters (Article 23, paragraphs 3 and 4);
47. selling to minors the products referred to in Article 23, paragraph 6 of this Act that may encourage them to smoke;
48. selling tobacco and related products via the Internet and cross-border distance sales (Article 23, paragraph 7);
49. selling tobacco and related products, including smokeless tobacco products, herbal products for smoking, electronic cigarettes, refill containers and single use cartridges, through vending machines (Article 23, paragraph 8);
50. selling individual cigarettes or tobacco and related products and electronic cigarettes outside the original manufacturer's packaging (Article 23, paragraph 9);
51. selling tobacco for oral use (Article 23, paragraph 10);
52. allowing for tobacco and related products or electronic cigarettes to be smoked during live public television broadcasts or publishing in the press photographs or drawings of persons smoking, for promotional purposes (Article 24, paragraphs 1 and 3);
53. failing to ensure compliance with the prohibition of smoking in an indoor public place (Article 25, paragraphs 1 and 2);

54. failing to ensure compliance with the prohibition of smoking in an area situated less than 20 metres away from the entrance to a healthcare facility (Article 25, paragraph 3);
55. failing to ensure compliance with the prohibition of smoking in an area situated less than 20 metres away from the entrance to an educational establishment (Article 25, paragraph 4);
56. having smoking rooms in spaces where healthcare or education-related activities are carried out (Article 25, paragraph 5);
57. having a smoking room that does not meet the requirements laid down in Article 26 of this Act;
58. having a smoking room that is not enclosed along its entire wall and ceiling surface area and does not have a self-closing door that must not be propped open (Article 27, paragraph 1);
59. failing to display the „smoking room“ sign above or beside the door to the smoking room, indicating the number of persons the room can accommodate at a time (Article 27, paragraph 2);
60. failing to ensure that an automatic “Smoking prohibited due to the failure of the ventilation system” indication appears outside the entrance to the smoking room and inside the room in the event of ventilation system failure (Article 27, paragraph 3);
61. having a smoking room that is not equipped with a ventilation system and a filtering system which form part of the smoking room and are physically separated from other ventilation systems in the indoor public place, or air contaminated with tobacco smoke diffuses into other enclosed spaces of the indoor public place, or the ventilation system is not automatic and does not prevent the escape of tobacco smoke into other enclosed spaces of the indoor public place (Article 28);
62. failing to ensure that the smoking room is equipped with a ventilation system that, with the doors to the smoking room closed, operates exhaust sufficient to create a negative pressure of at least 5 Pa with respect to the adjacent space giving into the smoking room, failing to ensure that the smoking room is equipped with a device that measures and displays the negative pressure level (Article 29);
63. not having a ventilation system in the smoking room that ensures a supply of air from outdoor areas or non-smoking indoor areas, or the air exchange system does not purify the air by ensuring a minimum air supply rate of 30 litres per second per person, based on the occupancy load of 0.7 persons/m² (Article 30);
64. failing to ensure that the design, installation and maintenance of smoking room ventilation systems are in compliance with special technical regulations laying down the essential requirements for ventilation systems (Article 31);

65. designating as a smoking area an area not meeting the prescribed requirements (Article 32, paragraph 2).

(2) A natural person and the responsible person of the legal person shall be fined a sum between HRK 5 000.00 and HRK 15 000.00 for committing a misdemeanour referred to in paragraph 1 of this Article.

Article 41

(1) A legal person shall be guilty of a misdemeanour and shall be fined a sum between HRK 2 000.00 and HRK 20 000.00 for serving food and/or drink in a catering facility where persons have been found smoking outside the area that meets the requirements laid down in Articles 26 to 32 of this Act (Article 25, paragraphs 1 and 2).

(2) A natural person – craftsman shall be guilty of a misdemeanour and shall be fined a sum between HRK 2 000.00 and HRK 5 000.00 for serving food and/or drink in a catering facility where persons have been found smoking outside the area that meets the requirements laid down in Articles 26 to 32 of this Act (Article 25, paragraphs 1 and 2).

Article 42

A fine of HRK 1 000.00 shall be imposed by the competent inspector referred to in Article 38 of this Act on the spot for a misdemeanour committed by a natural person who distributes tobacco products free of charge in public areas or public places (Article 22, paragraph 3).

Article 43

A fine of HRK 1 000.00 shall be imposed by the competent inspector referred to in Article 38 of this Act on the spot for a misdemeanour committed by a natural person who:

1. is found smoking a tobacco or related product or herbal product or using a nicotine-containing or non-nicotine-containing electronic cigarette or a waterpipe in an indoor public place (Article 25, paragraph 1);
2. is found smoking in an area situated less than 20 metres away from the entrance to a healthcare facility (Article 25, paragraph 3);
3. is found smoking in an area situated less than 20 metres away from the entrance to an educational establishment (Article 25, paragraph 4).

VII TRANSITIONAL AND FINAL PROVISIONS

Article 44

(1) The Minister shall issue the ordinances referred to in Article 5, paragraph 12, Article 6, paragraph 13, Article 19, paragraph 21 and Article 19, paragraph 22 of this Act within two months from the day of entry into force of this Act.

(2) The Minister shall issue the ordinance referred to in Article 10, paragraph 9 of this Act within six months from the day of entry into force of this Act.

(3) The minister responsible for finance shall issue the ordinances referred to in Article 16, paragraph 13, point a) and Article 16, paragraph 13, point b) of this Act within 12 months from the day of entry into force of the relevant Commission implementing regulations laying down the technical standards for the traceability of tobacco products.

Article 45

A decision determining the deadline for the submission of the information referred to in Article 6, paragraph 2 of this Act shall be issued by the Minister within one month from the day of entry into force of this Act.

Article 46

A decision determining the level of the proportionate fee referred to in Article 5, paragraph 11, Article 6, paragraph 12, Article 7, paragraph 8, Article 8, paragraph 10 and Article 19, paragraph 20 of this Act shall be issued by the Minister within one month from the day of entry into force of this Act.

Article 47

The programme for the promotion of awareness of the harmful effects of use of tobacco and related products on the health of children and youth of all ages referred to in Article 35, paragraph 2 of this Act shall be adopted by the minister responsible for education within three months from the day of entry into force of this Act.

Article 48

Until the entry into force of the ordinance referred to in Article 6, paragraph 13 of this Act, the Ordinance on the content of information on all ingredients and quantities thereof that are used in the manufacture of tobacco products by brand name and type and on the manner of informing the public (Official Gazette 39/09) shall remain in force to the extent that it is not contrary to the provisions of this Act.

Article 49

(1) The Minister shall appoint the National Anti-Smoking Committee within 30 days from the day of entry into force of this Act.

(2) The National Anti-Smoking Committee established pursuant to the Act on Restrictions on the Use of Tobacco Products (Official Gazette 125/08, 55/09 – corrigendum, 119/09 and 94/13) shall continue with its work until the appointment of the National Anti-Smoking Committee pursuant to this Act.

Article 50

Manufacturers and importers shall submit to the Ministry the studies, executive summaries and reports referred to in Article 6, paragraph 9 of this Act for each year starting from 1 January 2015.

Article 51

(1) Manufacturers or importers shall submit the reports referred to in Article 7 of this Act to the Commission and to the Ministry at the latest 18 months after the additive concerned has been included in the priority list referred to in Article 7, paragraph 1 of this Act.

(2) In the case of tobacco products with a characterising flavour whose European Union-wide sales volumes represent 3 % or more in a particular product category, the provisions of Article 8 of this Act shall apply from 20 May 2020.

(3) Article 16, paragraphs 1 to 12 of this Act shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

(4) Article 17 of this Act shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

(5) The provisions of Article 40, paragraph 1, points 21, 22, 23, 24 and 25 of this Act shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

Article 52

It shall be allowed to sell the following products, which are not in compliance with this Act, until 20 May 2017:

- a) tobacco products manufactured or released for free circulation and labelled in accordance with the Act on Restrictions on the Use of Tobacco Products (Official Gazette 125/08, 55/09 – corrigendum, 119/09 and 94/13) before the entry into force of this Act;
- b) electronic cigarettes or refill containers manufactured or released for free circulation before the entry into force of this Act;
- c) herbal products for smoking manufactured or released for free circulation before the entry into force of this Act.

Article 53

Manufacturers and importers of tobacco and related products shall bring their work and business operations into compliance with the provisions of this Act by 20 May 2017, unless otherwise provided for in this Act.

Article 54

On the day of entry into force of this Act, the Act on Restrictions on the Use of Tobacco Products (Official Gazette 125/08, 55/09 – corrigendum, 119/09 and 94/13) shall cease to have effect.

Article 55

This Act shall enter into force on the eighth day following the day of its publication in the Official Gazette.

Class: 022-03/17-01/35

Zagreb, 4 May 2017

THE CROATIAN PARLIAMENT

The President
of the Croatian Parliament
Božo Petrov, m. p.

ANNEX I

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
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 II

LAYOUT AND SHAPE OF THE COMBINED HEALTH WARNING

(a) Where the height of the combined health warning is greater than 70 % of its width, manufacturers shall lay out the combined health warnings in a stacked format as illustrated in point IV, sub-point 1 of this Annex.

Where the height of the combined health warning is greater than 20 % but less than 65 % of its width, manufacturers shall lay out the combined health warnings in a side-by-side format as illustrated in point IV, sub-point 2 of this Annex.

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, manufacturers may choose whether to use the stacked or side-by-side format, as long as all the elements of the combined health warning remain fully visible and are not distorted.

(b) 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 IV, sub-point 1 of this Annex. 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 IV, sub-point 2 of this Annex. 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.

(c) 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 IV, sub-point 3 of this Annex. 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.

DESIGN OF THE COMBINED HEALTH WARNING

II

(a) 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.

(b) The text warning shall be printed in white on a black background.

The cessation information shall be printed in black on a warm yellow background, as illustrated in point IV of this Annex.

(c) 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.

(d) The manufacturers or importers shall ensure that the photograph:

1. is reproduced without applying effects, adjusting the colours, retouching, or extending the background; and
2. is not cropped too close or too far from the focal point of the image; and
3. is scaled proportionally without being stretched or condensed.

(e) The manufacturers shall ensure that:

1. the text warning and cessation information are left aligned and centred vertically;
2. the text warning and cessation information are printed in Neue Frutiger Condensed Bold;
3. the text warning is printed in a uniform font size;
4. the font size of the text warning and of the cessation information is as large as possible to ensure maximum visibility of the text;
5. the minimum font size of the text warning is 6 pt and the minimum font size of the cessation information is 5 pt;
6. the space between lines is 2 pt larger than the font size of the text warning and is 1 to 2 pt larger than the font size of the cessation information;
7. the text warning is reproduced as set out in Annex I to this Act, including as regards the use of capital letters, but excluding the numbering.

By way of derogation from paragraph (e), sub-paragraphs 5 and 6 of this point, 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.

SPECIAL RULES FOR CERTAIN UNIT PACKETS WITH A FLIP-TOP LID

III

(a) By way of derogation from point I, paragraph (b), sub-paragraph 1 of this Annex, the following rules shall apply to combined health warnings to be placed on the front of unit packets having a flip-top lid:

– where the lid is smaller than the surface area foreseen for the photograph in point I, paragraph (a) of this Annex and compliance with that provision would result in the photograph being split upon opening:

1. 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 IV, sub-point 4 of this Annex; and

2. 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;

– where the lid is larger than the surface area foreseen for the photograph in point I, paragraph (a) of this Annex and compliance with that provision would result in the text warning or cessation information being split upon opening:

1. 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 IV, sub-point 1 of this Annex; and

2. 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.

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

(b) By way of derogation from point II, paragraph (e), sub-paragraphs 5 and 6 of this Annex, manufacturers or importers of cigarettes, roll-your-own tobacco and waterpipe tobacco in unit packets with a flip-top lid may reduce the font size or space between the lines of the text warning and cessation information on the front of packages where the combined health warning is in more than one language, provided that all elements of the combined health warning remain fully visible.

TYPES OF FORMATS

IV.

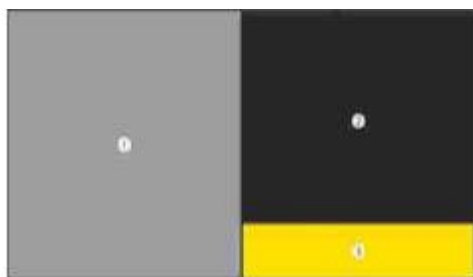
1. Stacked format (point I. paragraphs (a) and (b) and point III, paragraph (a) of this Annex)



1. Fotografija
2. Tekstualno upozorenje
3. Informacije o prestanku pušenja

/1. = Photograph; 2.=textual warning; 3.= information on smoking discontinuation/

2. Side-by-side format (point I, paragraph (a) of this Annex)



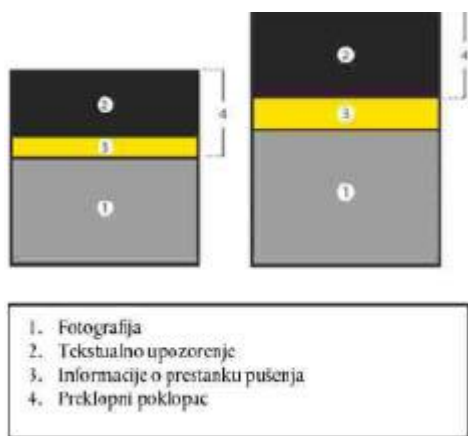
1. Fotografija
2. Tekstualno upozorenje
3. Informacije o prestanku pušenja

3. Side-by-side extra-wide format (point I, paragraph (c) of this Annex)



1. Fotografija
2. Tekstualno upozorenje
3. Informacije o prestanku pušenja

4. Stacked reversed format (point III of this Annex)



/1. = Photograph; 2.=textual warning; 3= information on smoking discontinuation/,4.=flap-top lid

PICTURE LIBRARY (OF COMBINED HEALTH WARNINGS)

V

Set 1

 Pušenje uzrokuje 9 od 10 slučajeva raka pluća	 Pušenje uzrokuje rak usta i grla	 Pušenje šteti vašim plućima
 Pušenje uzrokuje srčane udare	 Pušenje uzrokuje moždane udare i invaliditet	 Pušenje začepljuje vaše arterije
 Pušenje povećava rizik od sljepoće	 Pušenje oštećuje vaše zube i desni	 Pušenje može ubiti vaše nerođeno dijete
 Vaš dim šteti vašoj djeci, obitelji i prijateljima	 Djeca pušača imaju veće izgleda da će i sama početi pušiti	 Prestanite pušiti – ostanite živi radi onih koji su vam bliski
 Pušenje smanjuje plodnost		 Pušenje povećava rizik od impotencije

 <p>Pušenje uzrokuje 9 od 10 slučajeva raka pluća</p>			 <p>Pušenje uzrokuje rak usta i grla</p>		 <p>Pušenje šteti vašim plućima</p>
 <p>Pušenje uzrokuje srčane udare</p>			 <p>Pušenje uzrokuje moždane udare i invaliditet</p>		 <p>Pušenje začepljuje vaše arterije</p>
 <p>Pušenje povećava rizik od sljepoće</p>			 <p>Pušenje oštećuje vaše zube i desni</p>		 <p>Pušenje može ubiti vaše nerođeno dijete</p>
 <p>Vaš dim šteti vašoj djeci, obitelji i prijateljima</p>			 <p>Djeca pušača imaju veće izgleda da će i sama početi pušiti</p>		 <p>Prestanite pušiti – ostanite živi radi onih koji su vam bliski</p>
 <p>Pušenje smanjuje plodnost</p>					 <p>Pušenje povećava rizik od impotencije</p>

Set 3.

 Pušenje uzrokuje 9 od 10 slučajeva raka pluća	 Pušenje uzrokuje rak usta i grla	 Pušenje šteti vašim plućima
 Pušenje uzrokuje srčane udare	 Pušenje uzrokuje moždane udare i invaliditet	 Pušenje začepljuje vaše arterije
 Pušenje povećava rizik od sljepoće	 Pušenje oštećuje vaše zube i desni	 Pušenje može ubiti vaše nerođeno dijete
 Vaš dim šteti vašoj djeci, obitelji i prijateljima	 Djeca pušača imaju veće izgleda da će i sama početi pušiti	 Prestanite pušiti – ostanite živi radi onih koji su vam bliski
 Pušenje smanjuje plodnost		 Pušenje povećava rizik od impotencije

- (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
- (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

PROVISIONAL TRANSLATION