

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 (Text with EEA relevance)

TITLE II

TOBACCO PRODUCTS

CHAPTER II

Labelling and packaging

Article 8

General provisions

- 1 Each unit packet of a tobacco product and any outside packaging shall carry the health warnings provided for in this Chapter in the official language or languages of the Member State where the product is placed on the market.
- 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 Member States shall ensure that the health warnings on a unit packet and any outside packaging are 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, when tobacco products are placed on the market. On unit packets of tobacco products other than cigarettes and roll-your-own tobacco in pouches, the health warnings may be affixed by means of stickers, provided that such stickers are irremovable. 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 9, 10, 11 and 12 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 11.
- 7 When adapting a health warning pursuant to Articles 9(5), 10(3) and 12(3), the Commission shall ensure that it is factual or that Member States shall have a choice of two warnings, one of which is factual.

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8 Images of unit packets and any outside packaging targeting consumers in the Union shall comply with the provisions of this chapter.

Article 9

General warnings and information messages on tobacco products for smoking

1 Each unit packet and any outside packaging of tobacco products for smoking shall carry one of the following general warnings:

Smoking kills – quit now

or

Smoking kills

Member States shall determine which of the general warnings referred to in the first subparagraph is to be used.

2 Each unit packet and any outside packaging of tobacco products for smoking shall carry the following information message:

Tobacco smoke contains over 70 substances known to cause cancer.

3 For cigarette packets and roll-your-own tobacco in cuboid packets the general warning shall appear on the bottom part of one of the lateral surfaces of the unit packets, and the information message shall appear on the bottom part of the other lateral surface. These health warnings shall have a width of not less than 20 mm.

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.

For roll-your-own tobacco marketed in pouches the general warning and the information message shall appear on the surfaces that ensure the full visibility of those health warnings. For roll-your-own tobacco in cylindrical packets the general warning shall appear on the outside surface of the lid and the information message on the inside surface of the lid.

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

4 The general warning and information message referred to in paragraphs 1 and 2 shall be:

- a printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States may determine the font size, provided that the font size specified in national law ensures that the relevant text occupies the greatest possible proportion of the surface reserved for these health warnings; and
- b at the centre of the surface reserved for them, and on cuboid packets and any outside packaging they shall be parallel to the lateral edge of the unit packet or of the outside packaging.

5 The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the wording of the information message laid down in paragraph 2 to scientific and market developments.

6 The Commission shall, by means of implementing acts, determine the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches, taking into account the different shapes of pouches.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

Article 10

Combined health warnings for tobacco products for smoking

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

- a contain one of the text warnings listed in Annex I and a corresponding colour photograph specified in the picture library in Annex II;
- b include smoking cessation information such as telephone numbers, e-mail addresses or Internet sites intending to inform consumers about the programmes that are available to support persons who want to stop smoking;
- c cover 65 % of both the external front and back surface of the unit packet and any outside packaging. Cylindrical packets shall display two combined health warnings, equidistant from each other, each covering 65 % of their respective half of the curved surface;
- d show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;
- e appear at the top edge of a unit packet and any outside packaging, and be positioned in the same direction as any other information appearing on that surface of the packaging. Transitional exemptions from that obligation on the position of the combined health warning may apply in Member States where tax stamps or national identification marks used for fiscal purposes remain mandatory, as follows:
 - (i) in those cases, where the tax stamp or national identification mark used for fiscal purposes is affixed at the top edge of a unit packet made of carton material, the combined health warning that is to appear on the back surface may be positioned directly below the tax stamp or national identification mark;
 - (ii) where a unit packet is made of soft material, Member States may allow for a rectangular area to be reserved for the tax stamp or national identification mark used for fiscal purposes of a height not exceeding 13 mm between the top edge of the packet and the top end of the combined health warnings.

The exemptions referred to in points (i) and (ii) shall apply for a period of three years from 20 May 2016. Brand names or logos shall not be positioned above the health warnings;

[^{XI}f be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 4;]

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

- (i) height: not less than 44 mm;

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(ii) width: not less than 52 mm.

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

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to:

- a adapt the text warnings listed in Annex I taking into account scientific and market developments;
- b establish and adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments.

4 The Commission shall by means of implementing acts define the technical specifications for the layout, design and shape of the combined health warnings, taking into account the different packet shapes.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

Editorial Information

- X1** Substituted by [Corrigendum to 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 \(Official Journal of the European Union L 127 of 29 April 2014\)](#).

Article 11

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

1 Member States may exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message laid down in Article 9(2) and the combined health warnings laid down in Article 10. In that event, and in addition to the general warning provided for in Article 9(1), each unit packet and any outside packaging of such products shall carry one of the text warnings listed in Annex I. The general warning specified in Article 9(1) shall include a reference to the cessation services referred to in Article 10(1)(b).

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

Member States shall ensure that each text warning is 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.

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

2 The general warning referred to in paragraph 1 shall cover 30 % of the relevant surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for

Member States with two official languages and to 35 % for Member States with more than two official languages.

3 The text warning referred to in paragraph 1 shall cover 40 % of the relevant surface of the unit packet and any outside packaging. That proportion shall be increased to 45 % for Member States with two official languages and 50 % for Member States with more than two official languages.

4 Where the health warnings referred to in paragraph 1 are to appear on a surface exceeding 150 cm², the warnings shall cover an area of 45 cm². That area shall be increased to 48 cm² for Member States with two official languages and 52,5 cm² for Member States with more than two official languages.

5 The health warnings referred to in paragraph 1 shall comply with the requirements specified in Article 9(4). The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings.

The health warnings shall be surrounded by a black border of a width of not less than 3 mm and not more than 4 mm. This border shall appear outside the surface reserved for the health warnings.

6 The Commission shall adopt delegated acts in accordance with Article 27, to withdraw the possibility of granting exemptions for any of the particular product categories referred to in paragraph 1 if there is a substantial change of circumstances as established in a Commission report for the product category concerned.

Article 12

Labelling of smokeless tobacco products

1 Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning:

This tobacco product damages your health and is addictive.

2 The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 9(4). The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings.

In addition, it shall:

- a appear on the two largest surfaces of the unit packet and any outside packaging;
- b cover 30 % of the surfaces of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with more than two official languages.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the wording of the health warning laid down in paragraph 1 to scientific developments.

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Article 13

Product presentation

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, 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 elements and features that are prohibited pursuant to paragraphs 1 and 2 may include but are not limited to texts, symbols, names, trademarks, figurative or other signs.

Article 14

Appearance and content of unit packets

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

2 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.

Article 15

Traceability

1 Member States shall ensure that all unit packets of tobacco products are marked with a unique identifier. In order to ensure the integrity of the unique identifier, it shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through 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 Union, the obligations laid down in this Article apply only to those that are destined for, or placed on, the 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 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 points (a), (b), (c), (d), (e), (f), (g) and, where applicable, (h) of paragraph 2 shall form part of the unique identifier.

4 Member States shall ensure that the information mentioned in points (i), (j) and (k) of paragraph 2 is electronically accessible by means of a link to the unique identifier.

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

6 Member States shall ensure that all natural and legal persons engaged in the supply chain of tobacco products maintain complete and accurate records of all relevant transactions.

7 Member States shall ensure that the manufacturers of tobacco products 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.

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

The third party's activities shall be monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. The external auditor shall submit an annual report to the competent authorities and to the Commission, assessing in particular any irregularities in relation to access.

Member States shall ensure that the Commission, the competent authorities of the Member States, and the external auditor have full access to the data storage facilities. In duly justified cases the Commission or the Member States may grant manufacturers

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or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant Union and national law.

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

10 Member States shall ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC.

11 The Commission shall, by means of implementing acts:

- 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 Union.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

12 The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to define the key elements of the data storage contracts referred to in paragraph 8 of this Article, such as duration, renewability, expertise required or confidentiality, including the regular monitoring and evaluation of those contracts.

13 Paragraphs 1 to 10 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 16

Security feature

1 In addition to the unique identifier referred to in Article 15, Member States shall require that all unit packets of tobacco products, which are placed on the market, 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 and price marks, or other elements imposed by legislation.

Member States requiring tax stamps or national identification marks used for fiscal purposes may allow that they are used for the security feature provided that the tax stamps or national identification marks fulfil all of the technical standards and functions required under this Article.

2 The Commission shall, by means of implementing acts, define the technical standards for the security feature and their possible rotation and adapt them to scientific, market and technical developments.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

3 Paragraph 1 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.