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 I

Ingredients and emissions

Article 3

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

1 The emission levels from cigarettes placed on the market or manufactured in the Member States ('maximum emission levels') shall not be greater than:

a 10 mg of tar per cigarette;

b 1 mg of nicotine per cigarette;

c 10 mg of carbon monoxide per cigarette.

2 The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to decrease the maximum emission levels laid down in paragraph 1, where this is necessary based on internationally agreed standards.

3 Member States shall notify the Commission of any maximum emission levels they set for emissions from cigarettes other than the emissions referred to in paragraph 1 and for emissions from tobacco products other than cigarettes.

4 The Commission shall adopt delegated acts in accordance with Article 27 to integrate standards agreed by the parties to the FCTC or by the WHO relating to maximum emission levels for emissions from cigarettes other than the emissions referred to in paragraph 1 and for emissions from tobacco products other than cigarettes into Union law.

Article 4

Measurement methods

1 The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide.

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

2 The measurements referred to in paragraph 1 shall be verified by laboratories which are approved and monitored by the competent authorities of the Member States.

Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.

Member States shall communicate to the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and shall update that list whenever any change is made. The Commission shall make those lists of approved laboratories publicly available.

3 The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the methods of measurement of the tar, nicotine and carbon monoxide emissions, where this is necessary, based on scientific and technical developments or internationally agreed standards.

4 Member States shall notify the Commission of any measurement methods they use for emissions from cigarettes other than the emissions referred to in paragraph 3 and for emissions from tobacco products other than cigarettes.

5 The Commission shall adopt delegated acts in accordance with Article 27 to integrate standards agreed by the parties to the FCTC or by the WHO for measurement methods into Union law.

6 Member States may charge manufacturers and importers of tobacco products proportionate fees for the verification of the measurements referred to in paragraph 1 of this Article.

Article 5

Reporting of ingredients and emissions

1 Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities 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 3(1) and (4);

c where available, information on other emissions and their levels.

For products already placed on the market that information shall be provided by 20 November 2016.

Manufacturers or importers shall also inform the competent authorities of the Member States concerned, if the composition of a product is modified in a way that affects the information provided under this Article.

For a new or modified tobacco product the information required under this Article shall be submitted prior to the placing on the market of those products.

2 The list of ingredients referred to in point (a) of paragraph 1 shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in the tobacco products concerned. That list shall also indicate the status of the ingredients, including whether they have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(1)] as well as their classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(2)].

3 The list referred to in point (a) of paragraph 1 shall also be accompanied by the relevant toxicological data regarding the ingredients in burnt or unburnt form, as appropriate, referring in particular to their effects on the health of consumers and taking into account, inter alia, any addictive effects.

Furthermore, for cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties, shall be submitted by the manufacturer or importer.

Other than for tar, nicotine and carbon monoxide and for emissions referred to in Article 4(4), manufacturers and importers shall indicate the methods of measurement of emissions used. Member States may also require manufacturers or importers to carry out studies as may be prescribed by the competent authorities in order to assess the effects of ingredients on health, taking into account, inter alia, their addictiveness and toxicity.

4 Member States shall ensure that the information submitted in accordance with paragraph 1 of this Article and of Article 6 is made publicly available on a website. The Member States shall take the need to protect trade secrets duly into account when making that information publicly available. Member States shall require manufacturers and importers to specify, when submitting the information pursuant to paragraph 1 of this Article and Article 6, the information which they consider to constitute trade secrets.

5 The Commission shall, by means of implementing acts, lay down and, if necessary, update the format for the submission and the making available of information referred to in paragraphs 1 and 6 of this Article and Article 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

6 Member States shall require manufacturers and importers to submit internal and external studies available to them on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys they carry out when launching new products. Member States shall also require manufacturers and importers to report their sales volumes per brand and type, reported in sticks or kilograms, and per Member State on a yearly basis starting from 1 January 2015. Member States shall provide any other sales volume data that is available to them.

7 All data and information to be provided to and by Member States under this Article and under Article 6 shall be provided in electronic form. Member States shall store the information electronically and shall ensure that the Commission and other Member States have access to that information for the purposes of applying this Directive. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

8 Member States may charge manufacturers and importers of tobacco products proportionate fees for receiving, storing, handling, analysing and publishing the information submitted to them pursuant to this Article.

Article 6

Priority list of additives and enhanced reporting obligations

1 In addition to the reporting obligations laid down in Article 5, enhanced reporting obligations shall apply to certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list. The Commission shall adopt implementing acts laying down and subsequently updating such a priority list of additives. This list shall contain additives:

a for which initial indications, research, or regulation in other jurisdictions exist suggesting that they have one of the properties set out in points (a) to (d) of paragraph 2 of this Article; and

b which are amongst the most commonly used additives by weight or number according to the reporting of ingredients pursuant to paragraphs 1 and 3 of Article 5.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2). A first list of additives shall be adopted by 20 May 2016 and shall contain at least 15 additives.

2 Member States shall require 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, to 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; or

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

3 Those studies 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 a report on the results of these studies. That report 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.

Manufacturers or importers shall submit these reports to the Commission and a copy thereof to the competent authorities of those Member States where a tobacco product containing this additive is placed on the market at the latest 18 months after the additive concerned has been included in the priority list pursuant to paragraph 1. The Commission and the Member States concerned may also request supplementary information from manufacturers or importers regarding the additive concerned. This supplementary information shall form part of the report.

The Commission and the Member States concerned may require these reports to be peer reviewed by an independent scientific body, in particular as regards their comprehensiveness, methodology and conclusions. The information received shall assist the Commission and Member States in taking the decisions pursuant to Article 7. The Member States and the Commission may charge manufacturers and importers of tobacco products proportionate fees for those peer reviews.

5 Small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC[(3)] shall be exempted from the obligations pursuant to this Article, if a report on that additive is prepared by another manufacturer or importer.

Article 7

Regulation of ingredients

1 Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.

Member States shall not prohibit 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 tobacco product.

Member States shall notify the Commission of the measures taken pursuant to this paragraph.

2 The Commission shall, at the request of a Member State, or may, on its own initiative, determine by means of implementing acts whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

3 The Commission shall adopt implementing acts laying down uniform rules for the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

4 An independent advisory panel shall be established at Union level. Member States and the Commission may consult this panel before adopting a measure pursuant to paragraphs 1 and 2 of this Article. The Commission shall adopt implementing acts laying down the procedures for the establishment and operation of this panel.

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

5 Where the content level or concentration of certain additives or the combination thereof has resulted in prohibitions pursuant to paragraph 1 of this Article in at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 to set maximum content levels for those additives or combination of additives that result in the characterising flavour.

6 Member States shall prohibit the placing on the market of tobacco products containing the following additives:

a vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;

b caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

c additives having colouring properties for emissions;

d for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and

e additives that have CMR properties in unburnt form.

7 Member States shall prohibit the placing on the market of 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.

8 Member States shall ensure that the provisions and conditions laid down in Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.

9 Member States shall, on the basis of scientific evidence, prohibit the placing on the market of tobacco products containing additives in quantities that increase the toxic or addictive effect, or the CMR properties of a tobacco product at the stage of consumption to a significant or measureable degree.

Member States shall notify to the Commission the measures they have taken pursuant to this paragraph.

10 The Commission shall, at the request of a Member State, or may, on its own initiative, determine by means of an implementing act whether a tobacco product falls within the scope of paragraph 9. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2) and shall be based on the latest scientific evidence.

11 Where an additive or a certain quantity thereof has been shown to amplify the toxic or addictive effect of a tobacco product, and where this has resulted in prohibitions pursuant to paragraph (9) of this Article in at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 to set maximum content levels for those additives. In this case, the maximum content level shall be set at the lowest maximum level that led to one of the national prohibitions referred to in this paragraph.

12 Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 7. The Commission shall adopt delegated acts in accordance with Article 27 to withdraw that exemption for a particular product category, if there is a substantial change of circumstances as established in a Commission report.

13 The Member States and the Commission may charge proportionate fees 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.

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

15 This Article shall not apply to tobacco for oral use.

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.

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;

f be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;

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

(i) height: not less than 44 mm;

(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).

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 cm^2, the warnings shall cover an area of 45 cm^2. That area shall be increased to 48 cm^2 for Member States with two official languages and 52,5 cm^2 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.

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 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.

CHAPTER III

Tobacco for oral use, cross-border distance sales of tobacco products and novel tobacco products

Article 17

Tobacco for oral use

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

Article 18

Cross-border distance sales of tobacco products

1 Member States may prohibit cross-border distance sales of tobacco products to consumers. Member States shall cooperate to prevent such sales. Retail outlets engaging in cross-border distance sales of tobacco products may not supply such products to consumers in Member States where such sales have been prohibited. Member States which do not prohibit such sales shall require retail outlets intending to engage in cross-border distance sales to consumers located in the Union to register with the competent authorities in the Member State, where the retail outlet is established, and in the Member State, where the actual or potential consumers are located. Retail outlets established outside the Union shall be required to register with the competent authorities in the Member State where the actual or potential consumers are located. All retail outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities when registering:

a name or corporate name and permanent address of the place of activity from where the tobacco products will be supplied;

b the starting date of the activity of offering tobacco products for cross-border distance sales to consumers by means of Information Society services, as defined in point 2 of Article 1 of Directive 98/34/EC;

c the address of the website or websites used for that purpose and all relevant information necessary to identify the website.

2 The competent authorities of the Member States shall ensure that consumers have access to the list of all retail outlets registered with them. When making that list available,

Member States shall ensure that the rules and safeguards laid down in Directive 95/46/EC are complied with. Retail outlets may only start placing tobacco products on the market via cross-border distance sales when they have received confirmation of their registration with the relevant competent authority.

3 The Member States of destination of tobacco products sold via cross-border distance sales may require that the supplying retail outlet nominates a natural person to be responsible for verifying — before the tobacco products reach the consumer — that they comply with the national provisions adopted pursuant to this Directive in the Member State of destination, if such verification is necessary in order to ensure compliance and facilitate enforcement.

4 Retail outlets engaged in cross-border distance sales shall operate an age verification system, which verifies, at the time of sale, that the purchasing consumer complies with minimum age requirements provided for under the national law of the Member State of destination. The retail outlet or natural person nominated pursuant to paragraph 3 shall provide to the competent authorities of that Member State a description of the details and functioning of the age verification system.

5 Retail outlets shall only process personal data of the consumer in accordance with Directive 95/46/EC and those data shall not be disclosed to the manufacturer of tobacco products or companies forming part of the same group of companies or to other third parties. Personal data shall not be used or transferred for purposes other than the actual purchase. This also applies if the retail outlet forms part of a manufacturer of tobacco products.

Article 19

Notification of novel tobacco products

1 Member Stes shall require manufacturers and importers of novel tobacco products to submit a notification to the competent authorities of Member States of any such product they intend to place on the national market concerned. The notification shall be submitted in electronic form six months before the intended placing on the market. It shall be accompanied by a detailed description of the novel tobacco product concerned as well as instructions for its use and information on ingredients and emissions in accordance with Article 5. The manufacturers and importers submitting a notification of a novel tobacco product shall also provide the competent authorities 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 Member States shall require manufacturers and importers of novel tobacco products to transmit to their competent authorities any new or updated information on the studies, research and other information referred to in points (a) to (c) of paragraph 1. Member States may require manufacturers or importers of novel tobacco products to carry out additional tests or submit additional information. Member States shall make all information received pursuant to this Article available to the Commission.

3 Member States may introduce a system for the authorisation of novel tobacco products. Member States may charge manufacturers and importers proportionate fees for that authorisation.

4 Novel tobacco products placed on the market shall respect the requirements of this Directive. Which of the provisions of this Directive apply to novel tobacco products depends on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking.

(**1**) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(**2**) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(**3**) Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).