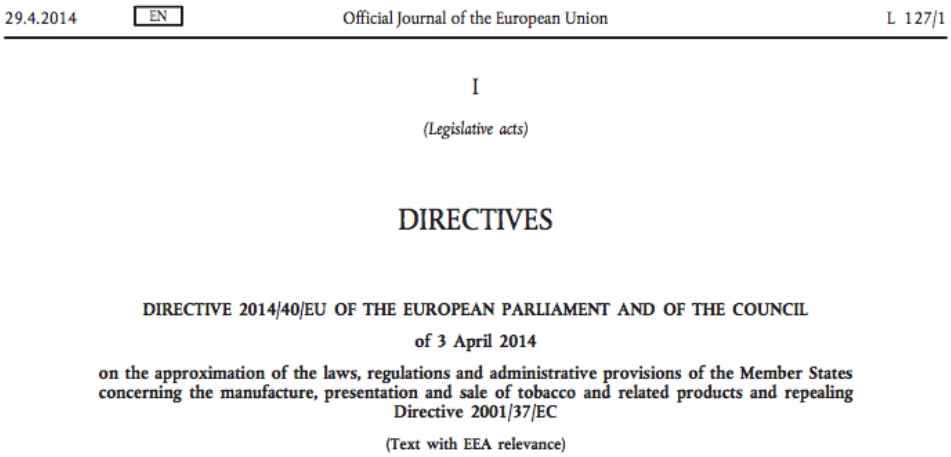
Updated info post: TPD – provisions relating to e-cigarettes

written by Clive Bates | 7 May 2014



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(Legislative acts)

DIRECTIVES

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)

Text below is aligned with the final directive text

Update 20 May 2016. This Directive is implemented in the UK through the Tobacco and Related Products Regulations 2016 (SI 2016 no. 507)

Updated 22 May 2015. This is the full Tobacco Products Directive 2014/40/EU (PDF) or HTML as published in the Official Journal of the EU). It entered into force on 19 May 2014, with several compliance dates of 20 May in 2016 , 20 November 2016 and 20 May 2017. The text below is designed to help you work out more easily what will apply to e-cigarettes, liquids and vaping devices.

Article 20 is divided into 13 paragraphs and cross references several other articles. It is also supported by a set of recitals. The following are the broad themes and structure of the article – click on these to navigate to the relevant text:

1. Relation to medicines regulation

2. Notification regime – ingredients, toxicology, pharmacology, production process

3. Technical design restrictions and requirements

4. Leaflet, packaging and warning

5. Advertising, promotion, sponsorship

6. Cross border sales

7. Disclosure commercial data and market surveillance

8. Public disclosure of commercial data

9. Surveillance for adverse effects

10. Commission report on refillable devices

11. Basis for controlling products that present a serious risk to health

12. Process for adapting the wording of health warnings

13. Delegated responsibility to design notification regime and refill mechanism

Recitals

Other relevant articles or articles referred to from Article 20 include: 1. Subject matter, 2. Definitions, 7.6 Regulation of ingredients, 9.4 General warnings , 12.2 Labelling, 13. Product presentation, 18. Cross border sales, 24. Free movement, 25. Committee procedure, 26. Competent authority, 27.Delegation, 28. Report, 29. Transposition, 30. Transitional provisions.

Update: added links to other harm reduction articles: 12. Labelling of smokeless tobacco products, 17. Tobacco for oral use, 19. Notification of novel tobacco products

TITLE III – ELECTRONIC CIGARETTES AND HERBAL PRODUCTS FOR SMOKING

Article 20

Electronic cigarettes

1. The Member States shall ensure that electronic cigarettes and refill containers are only placed on the market if they comply with this Directive and with all other relevant Union legislation. This Directive does not apply to electronic cigarettes and refill containers that are subject to an authorisation requirement under Directive 2001/83/EC or to the requirements set out in Directive 93/42/EEC.

2. Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States 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 20 May 2016, the notification shall be submitted within six months of that date. A new notification shall be submitted for each substantial modification of the 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 Union, and, if applicable, the importer into the 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 quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

Where Member States consider that the information submitted is incomplete, they shall be entitled to request the completion of the information concerned.

Member States may charge manufacturers and importers proportionate fees for receiving, storing, handling and analysing the information submitted to them.

3. Member States 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 listed in Article 7(6);

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

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

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

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

4. Member States shall ensure that:

(a) unit packets of electronic cigarettes and refill containers include a leaflet with information on:

(i) 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;
(ii) contra-indications;
(iii) warnings for specific risk groups;
(iv) possible adverse effects;
(v) addictiveness and toxicity; and
(vi) contact details of the manufacturer or importer and a legal or natural contact person within the Union;

(b) unit packets and any outside packaging of electronic cigarettes and refill containers:

(i) 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;
(ii) without prejudice to point (i) of this point, do not include elements or features referred to inArticle 13, with the exception of Article 13(1)(a) and (c) concerning information on the nicotine content and on flavourings; and
(iii) carry one of the following health warnings:
'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'.
or
'This product contains nicotine which is a highly addictive substance.'
Member States shall determine which of these health warnings is to be used;

(c) health warnings comply with the requirements specified in Article 12(2).

5. Member States shall ensure that:

(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 are prohibited, except for publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union

market;

(b)commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers, are prohibited;

(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 is prohibited;

(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 is prohibited;

(e) audiovisual commercial communications to which Directive Directive 2010/13/EU applies, are prohibited for electronic cigarettes and refill containers.

6. Article 18 of this Directive shall apply to cross-border distance sales of electronic cigarettes and refill containers.

7. Member States shall require manufacturers and importers of electronic cigarettes and refill containers to submit, annually, to the competent authorities:

(i) comprehensive data on sales volumes, by brand name and type of the product;
(ii) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;
(iii) the mode of sale of the products; and
(iv) executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers..

8. Member States shall ensure that the information received pursuant to paragraph 2 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, upon request, make all information received pursuant to this Article available to the Commission and other Member States. The Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

9. Member States shall require manufacturers, importers and distributers of electronic cigarettes and refill containers to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products.

Should any of these economic operators 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 Directive, that economic operator shall immediately take the corrective action necessary to bring the product concerned into conformity with this Directive, to withdraw or to recall it, as appropriate. In such cases the economic operator shall also be required to 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.

Member States may also request additional information from the economic operators, for example on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers.

10. The Commission shall submit a report to the European Parliament and the Council on the potential risks to public health associated with the use of refillable electronic cigarettes by 20 May 2016 and whenever appropriate thereafter.

11. In the case of electronic cigarettes and refill containers that comply with the requirements of this Article, where a competent authority 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 appropriate provisional measures. It shall immediately inform the Commission and the competent authorities of other Member States of the measures taken and shall communicate any supporting data. The Commission shall determine, as soon as possible after having received

that information, whether the provisional measure is justified. The Commission shall inform the Member State concerned of its conclusions to enable the Member State to take appropriate follow-up measures.

Where, in application of the first subparagraph of this paragraph, the placing on the market of specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container has been prohibited on duly justified grounds in at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 to extend such a prohibition to all Member States, if such an extension is justified and proportionate.

12. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the wording of the health warning in paragraph 4(b) of this Article. When adapting that health warning, the Commission shall ensure that it is factual.

13. The Commission shall, by means of an implementing act, lay down a common format for the notification provided for in paragraph 2 and technical standards for the refill mechanism provided for in paragraph 3(g). These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25.

Article 1

The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:

(a) the ingredients and emissions of tobacco products and related reporting obligations, including the maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;

(b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products to ensure their compliance with this Directive;

(c) the prohibition on the placing on the market of tobacco for oral use;

(d) cross-border distance sales of tobacco products;

(e) the obligation to submit a notification of novel tobacco products;

(f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, and herbal products for smoking;
in order to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people, and to meet the obligations of the Union under the WHO Framework Convention for Tobacco Control ('FCTC').

Article 2

(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;

Article 7 paragraph 6

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.

Article 9 paragraph 4

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.

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

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 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 States 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.

Article 24

Free movement

1. Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.

2. This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is

justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.

3. A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection of human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within the period of six months, the national provisions shall be deemed to be approved.

Article 25

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so requests.

4. Where the Committee delivers no opinion, the Commission shall not adopt the

draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 26

Competent authorities

Member States shall designate the competent authorities that shall be responsible for the implementation and enforcement of the obligations provided for in this Directive within three months of 20 May 2016. Member States shall inform the Commission about the identity of the designated authorities without delay. The Commission shall publish that information in the Official Journal of the European Union.

Article 27

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 3(2) and (4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) shall be conferred on the Commission for a period of five years from 19 May 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of powers referred to in Articles 3(2) and(4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 3(2) and (4), 4(3) and (5), 7(5), (11) and (12), 9(5), 10(3), 11(6), 12(3), 15(12), 20(11) and (12) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 28

Report

1. No later than five years from 20 May 2016, and whenever necessary thereafter, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.
When drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information at its disposal.

2. In the report, the Commission shall indicate, in particular, the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco and related products. The Commission shall pay special attention to:

(a) the experience gained with respect to the design of package surfaces not governed by this Directive taking into account national, international, legal, economic and scientific developments;

(b) market developments concerning novel tobacco products considering, inter alia, notifications received under Article 19;

(c) market developments which constitute a substantial change of circumstances;

(d) the feasibility, benefits and possible impact of a European system for the

regulation of the ingredients used in tobacco products, including the establishment, at Union level, of a list of ingredients that may be used or present in, or added to tobacco products, taking into account, inter alia, the information collected in accordance with Articles 5 and 6;

(e) market developments concerning cigarettes with a diameter of less than 7,5 mm, and consumer perception of their harmfulness as well as the misleading character of such cigarettes;

(f) the feasibility, benefits and possible impact of a Union database containing information on ingredients and emissions from tobacco products collected in accordance with Articles 5 and 6;

(g) market developments concerning electronic cigarettes and refill containers considering, amongst others, information collected in accordance with Article 20, including on the initiation of consumption such products by young people and non-smokers and the impact of such products on cessation efforts as well as measures taken by Member States regarding flavours;

(h) market developments and consumer preferences as regards waterpipe tobacco, with a particular focus on its flavours.

The Member States shall assist the Commission and provide all available information for carrying out the assessment and preparing the report.

3. The report shall be followed-up by proposals for amending this Directive, which the Commission deem necessary to adapt it – to the extent necessary for the smooth functioning of the internal market – to developments in the field of tobacco and related products, and to take into account new developments based on scientific facts and developments concerning internationally agreed standards for tobacco and related products.

Article 29 paragraph 1

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 May 2016. They shall forthwith communicate to the Commission the text of those provisions. The

Member States shall apply those measures from 20 May 2016, without prejudice to Articles 7(14), 10(1)(e), 15(13) and 16(3).

Article 30

Transitional provision

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until 20 May 2017:
(a) tobacco products manufactured or released for free circulation and labelled in accordance with Directive 2001/37/EC before 20 May 2016;

(b) electronic cigarettes or refill containers manufactured or released for free circulation before 20 November 2016;

(c) herbal products for smoking manufactured or released for free circulation before 20 May 2016.

Recitals

(36) Electronic cigarettes and refill containers should be regulated by this Directive, unless they are – due to their presentation or function – subject to Directive 2001/83/EC of the European Parliament and of the Council or to Council Directive 93/42/EEC . Diverging legislation and practices as regards these products, including on safety requirements, exist between Member States, hence, action at Union level is required to improve the smooth functioning of the internal market. A high level of public health protection should be taken into account when regulating these products. In order to enable Member States to carry out their surveillance and control tasks, manufacturers and importers of electronic cigarettes and refill containers should be required to submit a notification of the relevant products before they are placed on the market.

(37) Member States should ensure that electronic cigarettes and refill containers comply with the requirements of this Directive. Where the manufacturer of the relevant product is not established in the Union, the importer of that product should bear the responsibilities relating to the compliance of those products with this Directive.

(38) Nicotine-containing liquid should only be allowed to be placed on the market under this Directive, where the nicotine concentration does not exceed 20 mg/ml. This concentration allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette. In order to limit the risks associated with nicotine, maximum sizes for refill containers, tanks and cartridges should be set.

(39) Only electronic cigarettes that deliver nicotine doses at consistent levels should be allowed to be placed on the market under this Directive. Delivery of nicotine doses at consistent levels under normal conditions of use is necessary for health protection, safety and quality purposes, including to avoid the risk of accidental consumption of high doses.

(40) Electronic cigarettes and refill containers could create a health risk when in the hands of children. Therefore, it is necessary to ensure that such products are child- and tamperproof, including by means of child-proof labelling, fastenings and opening mechanisms.

(41) In view of the fact that nicotine is a toxic substance and considering the potential health and safety risks, including to persons for whom the product is not intended, nicotine-containing liquid should only be placed on the market in electronic cigarettes or in refill containers that meet certain safety and quality requirements. It is important to ensure that electronic cigarettes do not break or leak during use and refill.

(42) The labelling and packaging of these products should display sufficient and appropriate information on their safe use, in order to protect human health and safety, should carry appropriate health warnings and should not include any misleading elements or features.

(43) Disparities between national laws and practices on advertising and sponsorship concerning electronic cigarettes present an obstacle to the free movement of goods and the freedom to provide services and create an appreciable risk of distortion of competition. Without further action at Union level, those disparities are likely to increase over the coming years, also taking into account the growing market for electronic cigarettes and refill containers. Therefore, it is necessary to approximate the national provisions on advertising and sponsorship of those products having cross-border effects, taking as a base a

high level of protection of human health. Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising electronic cigarettes and refill containers.

(44) In order to perform their regulatory tasks, the Commission and Member States need comprehensive information on market developments as regards electronic cigarettes and refill containers. To this end manufacturers and importers of these products should be subject to reporting obligations on sales volumes, preference of various consumer groups and mode of sales. It should be ensured that this information is made available to the general public, taking the need to protect trade secrets duly into account.

(45) In order to ensure appropriate market surveillance by Member States, it is necessary that manufacturers, importers and distributors operate an appropriate system for monitoring and recording suspected adverse effects and inform the competent authorities about such effects so that appropriate action can be taken. It is warranted to provide for a safeguard clause that would allow Member States to take action to address serious risks to public health.

(46) In the context of an emerging market for electronic cigarettes, it is possible that, although complying with this Directive, specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, placed on the market could pose an unforeseen risk to human health. It is therefore advisable to provide for a procedure to address this risk, which should include the possibility for a Member State to adopt provisional appropriate measures. Such provisional appropriate measures could involve the prohibition of the placing on the market of specific electronic cigarettes or refill containers, or of a type of electronic cigarette or refill container. In this context, the Commission should be empowered to adopt delegated acts in order to prohibit the placing on the market of specific electronic cigarettes or refill containers, or of a type of electronic cigarette or refill container. The Commission should be empowered to do so, when at least three Member States have prohibited the products concerned on duly justified grounds and it is necessary to extend this prohibition to all Member States in order to ensure the smooth functioning of the internal market for products complying with this Directive but not presenting the same health risks. The Commission should report on the potential risks associated with refillable

electronic cigarettes by 20 May 2016.

(47) This Directive does not harmonise all aspects of electronic cigarettes or refill containers. For example, the responsibility for adopting rules on flavours remains with the Member States. It could be useful for Member States to consider allowing the placing on the market of flavoured products. In doing so, they should be mindful of the potential attractiveness of such products for young people and non smokers. Any prohibition of such flavoured products would need to be justified and notification thereof submitted in accordance withDirective 98/34/EC. of the European Parliament and of the Council (10).

(48) Moreover, this Directive does not harmonise the rules on smoke-free environments, or on domestic sales arrangements or domestic advertising, or brand stretching, nor does it introduce an age limit for electronic cigarettes or refill containers. In any case, the presentation and advertising of those products should not lead to the promotion of tobacco consumption or give rise to confusion with tobacco products. Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so.