I

(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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 53(1), 62 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) Directive 2001/37/EC of the European Parliament and of the Council ([4]) lays down rules at Union level concerning tobacco products. In order to reflect scientific, market and international developments, substantial changes to that Directive would be needed and it should therefore be repealed and replaced by a new Directive.

(2) In its reports of 2005 and 2007 on the application of Directive 2001/37/EC the Commission identified areas in which further action was considered useful for the smooth functioning of the internal market. In 2008 and 2010 the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) provided scientific advice to the Commission on smokeless tobacco products and tobacco additives. In 2010 a broad stakeholder consultation took place, which was followed by targeted stakeholder consultations and accompanied by studies by external consultants. Member States were consulted throughout the process. The European Parliament and the Council repeatedly called on the Commission to review and update Directive 2001/37/EC.

(3) In certain areas covered by Directive 2001/37/EC, Member States are legally or in practice prevented from effectively adapting their legislation to new developments. This is in particular relevant for the labelling rules, where Member States have not been permitted to increase the size of the health warnings, change their location on an individual packet ('unit packet') or replace misleading warnings on the tar, nicotine and carbon monoxide (TNCO) emission levels.

([1]) OJ C 327, 12.11.2013, p. 65.
([2]) OJ C 280, 27.9.2013, p. 57.
([3]) Position of the European Parliament of 26 February 2014 (not yet published in the Official Journal) and decision of the Council of 14 March 2014.
([4]) Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, p. 26).

(4) In other areas there are still substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco and related products which present obstacles to the smooth functioning of the internal market. In the light of scientific, market and international developments these discrepancies are expected to increase. This also applies to electronic cigarettes and refill containers for electronic cigarettes ('refill containers'), herbal products for smoking, ingredients and emissions from tobacco products, certain aspects of labelling and packaging and to cross-border distance sales of tobacco products.

(5) Those obstacles should be eliminated and, to this end, the rules on the manufacture, presentation and sale of tobacco and related products should be further approximated.

(6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the entire Union in only a small number of production plants within the Union and the resulting significant cross-border trade of tobacco and related products calls for stronger legislative action at Union rather than national level to achieve the smooth functioning of the internal market.

(7) Legislative action at Union level is also necessary in order to implement the WHO Framework Convention on Tobacco Control ('FCTC') of May 2003, the provisions of which are binding on the Union and its Member States. The FCTC provisions on the regulation of the contents of tobacco products, the regulation of tobacco product disclosures, the packaging and labelling of tobacco products, advertising and illicit trade in tobacco products are particularly relevant. The Parties to the FCTC, including the Union and its Member States, adopted a set of guidelines for the implementation of FCTC provisions by consensus during various Conferences.

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (TFEU), a high level of health protection should be taken as a base for legislative proposals and, in particular, any new developments based on scientific facts should be taken into account. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco on human health, health protection should be given high importance, in particular, to reduce smoking prevalence among young people.

(9) It is necessary to establish a number of new definitions in order to ensure that this Directive is uniformly applied by Member States. Where different obligations imposed by this Directive apply to different product categories and the relevant product falls into more than one of those categories (e.g. pipe, roll your-own tobacco), the stricter obligations should apply.

(10) Directive 2001/37/EC established maximum limits for tar, nicotine and carbon monoxide yields of cigarettes that should also be applicable to cigarettes which are exported from the Union. Those maximum limits and that approach remain valid.

(11) For measuring the tar, nicotine and carbon monoxide yields of cigarettes (hereinafter referred to as 'emission levels'), reference should be made to the relevant, internationally recognised ISO standards. The verification process should be protected from tobacco industry influence by using independent laboratories, including State laboratories. Member States should be able to use laboratories situated in other Member States of the Union. For other emissions from tobacco products, there are no internationally agreed standards or tests for quantifying maximum levels. The ongoing efforts at international level to develop such standards or tests should be encouraged.

(12) As regards establishing maximum emission levels, it could be necessary and appropriate at a later date to reduce the emission levels for tar, nicotine and carbon monoxide or to establish maximum levels for other emissions from tobacco products, taking into consideration their toxicity or addictiveness.

(13) In order to carry out their regulatory tasks, Member States and the Commission require comprehensive information on the ingredients and emissions from tobacco products to assess the attractiveness, addictiveness and toxicity of tobacco products and the health risks associated with the consumption of such products. To this end, the existing reporting obligations for ingredients and emissions should be strengthened. Additional enhanced reporting obligations should be provided for in respect of additives included in a priority list in order to assess, inter alia their toxicity, addictiveness and carcinogenic, mutagenic or reprotoxic properties ('CMR properties'), including in combusted form. The burden of such enhanced reporting obligations for SMEs should be limited to the extent possible. Such reporting obligations are consistent with the obligation placed on the Union to ensure a high level of protection for human health.

(14) The use of differing reporting formats, as is currently the case, makes it difficult for manufacturers and importers to fulfil their reporting obligations and burdensome for the Member States and the Commission to compare, analyse and draw conclusions from the information received. Therefore, there should be a common mandatory format for the reporting of ingredients and emissions. The greatest possible transparency of product information should be ensured for the general public, whilst ensuring that appropriate account is taken of the trade secrets of the manufacturers of tobacco products. Existing systems for the reporting of ingredients should be taken into account.

(15) The lack of a harmonised approach to regulating the ingredients of tobacco products affects the smooth functioning of the internal market and has a negative impact on the free movement of goods across the Union. Some Member States have adopted legislation or entered into binding agreements with the industry allowing or prohibiting certain ingredients. As a result, some ingredients are regulated in certain Member States, but not in others. Member States also take differing approaches as regards additives in the filters of cigarettes as well as additives colouring the tobacco smoke. Without harmonisation, the obstacles to the smooth functioning of the internal market are expected to increase in the coming years, taking into account the implementation of the FCTC and the relevant FCTC guidelines throughout the Union and in the light of experience gained in other jurisdictions outside the Union. The FCTC guidelines in relation to the regulation of the contents of tobacco products and regulation of tobacco product disclosures call in particular for the removal of ingredients that increase palatability, create the impression that tobacco products have health benefits, are associated with energy and vitality or have colouring properties.

(16) The likelihood of diverging regulation is further increased by concerns over tobacco products having a characterising flavour other than one of tobacco, which could facilitate initiation of tobacco consumption or affect consumption patterns. Measures introducing unjustified differences of treatment between different types of flavoured cigarettes should be avoided. However, products with characterising flavour with a higher sales volume should be phased out over an extended time period to allow consumers adequate time to switch to other products.

(17) The prohibition of tobacco products with characterising flavours does not preclude the use of individual additives outright, but it does oblige manufacturers to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives necessary for the manufacture of tobacco products, for example sugar to replace sugar that is lost during the curing process, should be allowed, as long as they do not result in a characterising flavour or increase the addictiveness, toxicity or CMR properties of the product. An independent European advisory panel should assist in such decision making. The application of this Directive should not lead to discrimination between different tobacco varieties, nor should it prevent product differentiation.

(18) Certain additives are used to create the impression that tobacco products have health benefits, present reduced health risks or increase mental alertness and physical performance. These additives, as well as additives that have CMR properties in unburnt form, should be prohibited in order to ensure uniform rules throughout the Union and a high level of protection of human health. Additives that increase addictiveness and toxicity should also be prohibited.

(19) Considering this Directive's focus on young people, tobacco products other than cigarettes and roll-your-own tobacco, should be granted an exemption from certain requirements relating to ingredients as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people.

(20) Given the general prohibition of the sale of tobacco for oral use in the Union, the responsibility for regulating the ingredients of tobacco for oral use, which requires in-depth knowledge of the specific characteristics of this product and of its patterns of consumption, should, in accordance with the principle of subsidiarity, remain with Sweden, where the sale of this product is permitted pursuant to Article 151 of the Act of Accession of Austria, Finland and Sweden.

(21) In line with the purposes of this Directive, namely to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of health protection, especially for young people, and in line with Council Recommendation 2003/54/EC ([1]), Member States should be encouraged to prevent sales of such products to children and adolescents, by adopting appropriate measures that lay down and enforce age limits.

(22) Disparities still exist between national provisions regarding the labelling of tobacco products, in particular with regard to the use of combined health warnings consisting of a picture and a text, information on cessation services and promotional elements in and on unit packets.

(23) Such disparities are liable to constitute a barrier to trade and to impede the smooth functioning of the internal market in tobacco products, and should, therefore, be eliminated. Also, it is possible that consumers in some Member States are better informed about the health risks of tobacco products than consumers in other Member States. Without further action at Union level, the existing disparities are likely to increase in the coming years.

(24) Adaptation of the provisions on labelling is also necessary to align the rules that apply at Union level to international developments. For example, the FCTC guidelines on the packaging and labelling of tobacco products call for large picture warnings on both principal display areas, mandatory cessation information and strict rules on misleading information. The provisions on misleading information will complement the general ban on misleading business to consumer commercial practices laid down in Directive 2005/29/EC of the European Parliament and of the Council ([2]).

Member States that use tax stamps or national identification marks for fiscal purposes on the packaging of tobacco products may, in some cases, have to provide for these stamps and marks to be repositioned in order to allow for the combined health warnings to be at the top of the principal display areas, in line with this Directive and the FCTC guidelines. Transitional arrangements should be put in place to allow Member States to maintain tax stamps or national identification marks used for fiscal purposes at the top of unit packets for a certain period after transposition of this Directive.

(25) The labelling provisions should also be adapted to new scientific evidence. For example, the indication of the emission levels for tar, nicotine and carbon monoxide on unit packets of cigarettes has proven to be misleading as it leads consumers to believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings comprised of a text warning and a corresponding colour photograph are more effective than warnings consisting only of text. As a consequence, combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the surface of unit packets. Minimum dimensions should be set for all health warnings to ensure their visibility and effectiveness.

([1]) Council Recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control (OJ L 22, 25.1.2003, p. 31).

([2]) Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') (OJ L 149, 11.6.2005, p. 22).

(26) For tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers and small groups of the population, it should be possible to continue to grant an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people. The labelling of these other tobacco products should follow rules that are specific to them. The visibility of health warnings on smokeless tobacco products should be ensured. Health warnings should, therefore, be placed on the two main surfaces of the packaging of smokeless tobacco products. As regards waterpipe tobacco, which is often perceived as less harmful than traditional tobacco products for smoking, the full labelling regime should apply in order to avoid consumers being misled.

(27) Tobacco products or their packaging could mislead consumers, in particular young people, where they suggest that these products are less harmful. This is, for example, the case if certain words or features are used, such as the words 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours' or 'slim', or certain names, pictures, and figurative or other signs. Other misleading elements might include, but are not limited to, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Certain packaging and tobacco products could also mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Likewise, the size and appearance of individual cigarettes could mislead consumers by creating the impression that they are less harmful. Neither the unit packets of tobacco products nor their outside packaging should include printed vouchers, discount offers, reference to free distribution, two-for-one or other similar offers that could suggest economic advantages to consumers thereby inciting them to buy those tobacco products.

(28) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimensions of the health warnings as well as regarding certain aspects of the appearance of the unit packets of tobacco products, including the shape and opening mechanism. When prescribing a cuboid shape for a unit packet, rounded or bevelled edges should be considered acceptable, provided the health warning covers a surface area that is equivalent to that on a unit packet without such edges. Member States apply different rules on the minimum number of cigarettes per unit packet. Those rules should be aligned in order to ensure free circulation of the products concerned.

(29) Considerable volumes of illicit products, which do not fulfil the requirements laid down in Directive 2001/37/EC, are placed on the market and there are indications that these volumes might increase. Such illicit products undermine the free circulation of compliant products and the protection provided for by tobacco control legislation. In addition, the FCTC requires the Union to combat illicit tobacco products, including those illegally imported into the Union, as part of a comprehensive Union policy on tobacco control. Provision should, therefore, be made for unit packets of tobacco products to be marked with a unique identifier and security features and for their movements to be recorded so that such products can be tracked and traced throughout the Union and their compliance with this Directive can be monitored and better enforced. In addition, provision should be made for the introduction of security features that will facilitate the verification of whether or not tobacco products are authentic.

(30) An interoperable tracking and tracing system and security features should be developed at Union level. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system and the security features. This would allow manufacturers of other tobacco products to benefit from the experience gained prior to the tracking and tracing system and security features becoming applicable to those other products.

(31) In order to ensure independence and transparency of the tracking and tracing system, manufacturers of tobacco products should conclude data storage contracts with independent third parties. The Commission should approve the suitability of those independent third parties and an independent external auditor should monitor their activities. The data related to the tracking and tracing system should be kept separate from other company related data and should be under the control of, and accessible at all times by, the competent authorities from Member States and the Commission.

(32) Council Directive 89/622/EEC ([1]) prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC reaffirmed that prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants Sweden a derogation from the prohibition. The prohibition of the sale of tobacco for oral use should be maintained in order to prevent the introduction in the Union (apart from Sweden) of a product that is addictive and has adverse health effects. For other smokeless tobacco products that are not produced for the mass market, strict provisions on labelling and certain provisions relating to their ingredients are considered sufficient to contain their expansion in the market beyond their traditional use.

(33) Cross-border distance sales of tobacco products could facilitate access to tobacco products that do not comply with this Directive. There is also an increased risk that young people would get access to tobacco products. Consequently, there is a risk that tobacco control legislation would be undermined. Member States should, therefore, be allowed to prohibit cross-border distance sales. Where cross-border distance sales are not prohibited, common rules on the registration of retail outlets engaging in such sales are appropriate to ensure the effectiveness of this Directive. Member States should, in accordance with Article 4(3) of the Treaty on European Union (TEU) cooperate with each other in order to facilitate the implementation of this Directive, in particular with respect to measures taken as regards cross-border distance sales of tobacco products.

(34) All tobacco products have the potential to cause mortality, morbidity and disability. Accordingly, their manufacture, distribution and consumption should be regulated. It is, therefore, important to monitor developments as regards novel tobacco products. Manufacturers and importers should be obliged to submit a notification of novel tobacco products, without prejudice to the power of the Member States to ban or to authorise such novel products.

(35) In order to ensure a level playing field, novel tobacco products, that are tobacco products as defined in this Directive, should comply with the requirements of this Directive.

(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 ([2]) or to Council Directive 93/42/EEC ([3]). 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.

([1]) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use (OJ L 359, 8.12.1989, p. 1).

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

([3]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

(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 with Directive 98/34/EC of the European Parliament and of the Council [1].

[1] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204, 21.7.1998, p. 37).

(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.

(49) The regulation of herbal products for smoking differs between Member States and these products are often perceived as harmless or less harmful despite the health risk caused by their combustion. In many cases consumers do not know the content of these products. In order to ensure the smooth functioning of the internal market and improve information to consumers, common labelling rules and ingredients reporting for these products should be introduced at Union level.

(50) In order to ensure uniform conditions for the implementation of this Directive implementing powers should be conferred on the Commission concerning the laying down and updating of a priority list of additives for enhanced reporting, the laying down and updating of the format for the reporting of ingredients and for the dissemination of that information, determining whether a tobacco product has a characterising flavour or has increased levels of toxicity, addictiveness or CMR properties, the methodology for determining whether a tobacco product has a characterising flavour, the procedures for the establishment and operation of an independent advisory panel for determining tobacco products with characterising flavours, the precise position of health warnings on pouches of roll-your-own tobacco, the technical specifications for the layout, design, and shape of combined health warnings, the technical standards for the establishment and operation of the tracking and tracing system, for ensuring the compatibility of the systems for the unique identifiers and for the security features, as well as establishing a common format for notification of electronic cigarettes and refill containers and the technical standards for the refill mechanisms for such products. Those implementing powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council [1].

(51) In order to ensure that this Directive is fully operational and to adapt it to technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of adopting and adapting maximum emission levels and methods for measuring those emissions, setting maximum levels for additives that result in a characterising flavour or that increase toxicity or addictiveness, withdrawing certain exemptions granted to tobacco products other than cigarettes and roll-your-own tobacco, adapting the health warnings, establishing and adapting the picture library, defining the key elements of the data storage contracts to be concluded for the purposes of the tracking and tracing system, and extending measures adopted by Member States to the entire Union concerning specific electronic cigarettes or refill containers or a type of electronic cigarette or refill container. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(52) The Commission should monitor the developments as regards the implementation and impact of this Directive and submit a report by 21 May 2021, and when necessary thereafter, in order to assess whether amendments to this Directive are necessary. The report should include information on the surfaces of unit packets of tobacco products that are not governed by this Directive, market developments concerning novel tobacco products, market developments that amount to a substantial change of circumstances, market developments concerning, and the consumer perception of, slim cigarettes, of waterpipe tobacco and of electronic cigarettes and refill containers.

The Commission should prepare a report regarding the feasibility, benefits and impact of a European system for the regulation of ingredients in tobacco products, including the feasibility and benefits of establishing a list of

[1] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

ingredients at Union level that can be used, or present in or added to tobacco products (so-called 'positive list'). In preparing that report, the Commission should evaluate, inter alia, the available scientific evidence on the toxic and addictive effects of ingredients.

(53) Tobacco and related products which comply with this Directive should benefit from the free movement of goods. However, in light of the different degrees of harmonisation achieved by this Directive, the Member States should, under certain conditions, retain the power to impose further requirements in certain respects in order to protect public health. This is the case in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules. Accordingly, Member States could, for example, introduce provisions providing for further standardisation of the packaging of tobacco products, provided that those provisions are compatible with the TFEU, with WTO obligations and do not affect the full application of this Directive.

(54) Moreover, in order to take into account possible future market developments, Member States should also be allowed to prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in the Member State concerned and provided the provisions are justified by the need to protect public health, taking into account the high level of protection achieved through this Directive. Member States should notify such stricter national provisions to the Commission.

(55) A Member State should remain free to maintain or introduce national laws applying to all products placed on its national market for aspects not regulated by this Directive, provided they are compatible with the TFEU and do not jeopardise the full application of this Directive. Accordingly and under those conditions, a Member State could, inter alia, regulate or ban paraphernalia used for tobacco products (including waterpipes) and for herbal products for smoking as well as regulate or ban products resembling in appearance a type of tobacco or related product. Prior notification is required for national technical regulations pursuant to Directive 98/34/EC.

(56) Member States should ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC of the European Parliament and of the Council [1].

(57) This Directive is without prejudice to Union laws governing the use and labelling of genetically modified organisms.

(58) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents [2], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

(59) The obligation to respect the fundamental rights and legal principles enshrined in the Charter of Fundamental Rights of the European Union is not changed by this Directive. Several fundamental rights are affected by this Directive. It is therefore necessary to ensure that the obligations imposed on manufacturers, importers and distributors of tobacco and related products not only guarantee a high level of health and consumer protection, but also protect all other fundamental rights and are proportionate with respect to the smooth functioning of the internal market. The application of this Directive should respect Union law and relevant international obligations.

(60) Since the objectives of this Directive, namely to approximate the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, cannot be

[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).
[2] OJ C 369, 17.12.2011, p. 14.

sufficiently achieved by the Member States, but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

TITLE I

COMMON PROVISIONS

Article 1

Subject matter

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

Definitions

For the purposes of this Directive, the following definitions shall apply:

(1) 'tobacco' means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;

(2) 'pipe tobacco' means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe;

(3) 'roll-your-own tobacco' means tobacco which can be used for making cigarettes by consumers or retail outlets;

(4) 'tobacco products' means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;

(5) 'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;

(6) 'chewing tobacco' means a smokeless tobacco product exclusively intended for the purpose of chewing;

(7) 'nasal tobacco' means a smokeless tobacco product that can be consumed via the nose;

(8) 'tobacco for oral use' means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets;

(9) 'tobacco products for smoking' means tobacco products other than a smokeless tobacco product;

(10) 'cigarette' means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 3(1) of Council Directive 2011/64/EU [1];

(11) 'cigar' means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 4(1) of Directive 2011/64/EU;

(12) 'cigarillo' means a small type of cigar and is further defined in Article 8(1) of Council Directive 2007/74/EC [2];

(13) 'waterpipe tobacco' means a tobacco product that can be consumed via a waterpipe. For the purpose of this Directive, waterpipe tobacco is deemed to be a tobacco product for smoking. If a product can be used both via waterpipes and as roll-your-own tobacco, it shall be deemed to be roll-your-own tobacco;

(14) 'novel tobacco product' means a tobacco product which:

(a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and

(b) is placed on the market after 19 May 2014;

(15) 'herbal product for smoking' means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process;

(16) 'electronic cigarette' means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges;

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

(18) 'ingredient' means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;

(19) 'nicotine' means nicotinic alkaloids;

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

(21) 'emissions' means substances that are released when a tobacco or related product is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;

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

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

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

(25) 'characterising flavour' means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;

(26) 'addictiveness' means the pharmacological potential of a substance to cause addiction, a state which affects an individual's ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both;

[1] Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco (OJ L 176, 5.7.2011, p. 24).

[2] Council Directive 2007/74/EC of 20 December 2007 on the exemption from value added tax and excise duty of goods imported by persons travelling from third countries (OJ L 346, 29.12.2007, p. 6).

(27) 'toxicity' means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure;

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

(29) 'outside packaging' means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;

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

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

(32) 'health warning' means a warning concerning the adverse effects on human health of a product or other undesired consequences of its consumption, including text warnings, combined health warnings, general warnings and information messages, as provided for in this Directive;

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

(34) 'cross-border distance sales' means distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in a Member State other than the Member State or the third country where that retail outlet is established; a retail outlet is deemed to be established in a Member State:

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

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

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

(36) 'age verification system' means a computing system that unambiguously confirms the consumer's age electronically in accordance with national requirements;

(37) 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark;

(38) 'import of tobacco or related products' means the entry into the territory of the Union of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry into the Union, as well as their release from a customs suspensive procedure or arrangement;

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

(40) 'placing on the market' means to make products, irrespective of their place of manufacture, available to consumers located in the Union, with or without payment, including by means of distance sale; in the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located;

(41) 'retail outlet' means any outlet where tobacco products are placed on the market including by a natural person.

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.

[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).

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 [1] 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;

[1] 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).

(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.

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 in Article 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 2010/13/EU of the European Parliament and of the Council [1] 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.

[1] Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 95, 15.4.2010, p. 1).

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(2).

Article 21

Herbal products for smoking

1. Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning:

'Smoking this product damages your health.'

2. The health warning shall be printed on the front and back external surface of the unit packet and on any outside packaging.

3. The health warning shall comply with the requirements set out in Article 9(4). It shall cover 30 % of the area of the corresponding surface of the unit packet and of 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.

4. Unit packets and any outside packaging of herbal products for smoking shall not include any of the elements or features set out in Article 13(1)(a), (b) and (d) and shall not state that the product is free of additives or flavourings.

Article 22

Reporting of ingredients of herbal products for smoking

1. Member States shall require manufacturers and importers of herbal products for smoking to submit to their competent authorities a list of all ingredients, and quantities thereof that are used in the manufacture of such products by brand name and type. Manufacturers or importers shall also inform the competent authorities of the Member States concerned when the composition of a product is modified in a way that affects the information submitted pursuant to this Article. The information required under this Article shall be submitted prior to the placing on the market of a new or modified herbal product for smoking.

2. Member States shall ensure that the information submitted in accordance with paragraph 1 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. Economic operators shall specify exactly which information they consider to constitute a trade secret.

TITLE IV

FINAL PROVISIONS

Article 23

Cooperation and enforcement

1. Member States shall ensure that manufacturers and importers of tobacco and related products provide the Commission and the competent authorities of the Member States with complete and correct information requested pursuant to this Directive and within the time limits set out herein. The obligation to provide the requested information shall lie primarily with the manufacturer, if the manufacturer is established in the Union. The obligation to provide the requested information shall lie primarily with the importer, if the manufacturer is established outside the Union and the importer is established inside the Union. The obligation to provide the requested information shall lie jointly with the manufacturer and the importer if both are established outside the Union.

2. Member States shall ensure that tobacco and related products which do not comply with this Directive, including the implementing and delegated acts provided for therein, are not placed on the market. Member States shall ensure that tobacco and related products are not placed on the market if the reporting obligations set out in this Directive are not complied with.

3. Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures that are necessary to ensure that these penalties are enforced. The penalties provided for shall be effective, proportionate and dissuasive. Any financial administrative penalty that may be imposed as a result of an intentional infringement may be such as to offset the economic advantage sought through the infringement.

4. The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the correct application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive in a uniform manner.

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

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).

2. When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. The Member States shall determine how such reference is to be made and how that statement is to be formulated.

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

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.

Article 31

Repeal

Directive 2001/37/EC is repealed with effect from 20 May 2016, without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law of that Directive.

References to the repealed Directive shall be construed as references to this Directive and read in accordance with the correlation table in Annex III to this Directive.

Article 32

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 33

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 3 April 2014.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	D. KOURKOULAS

ANNEX I

LIST OF TEXT WARNINGS

(referred to in Article 10 and Article 11(1))

(1) Smoking causes 9 out of 10 lung cancers

(2) Smoking causes mouth and throat cancer

(3) Smoking damages your lungs

(4) Smoking causes heart attacks

(5) Smoking causes strokes and disability

(6) Smoking clogs your arteries

(7) Smoking increases the risk of blindness

(8) Smoking damages your teeth and gums

(9) Smoking can kill your unborn child

(10) Your smoke harms your children, family and friends

(11) Smokers' children are more likely to start smoking

(12) Quit smoking – stay alive for those close to you

(13) Smoking reduces fertility

(14) Smoking increases the risk of impotence

ANNEX II

PICTURE LIBRARY

(REFERRED TO IN ARTICLE 10(1))

[To be established by the Commission pursuant to Article 10(3)(b).]

ANNEX III

CORRELATION TABLE

Directive 2001/37/EC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3(1)	Article 3(1)
Article 3(2) and (3)	—
Article 4(1)	Article 4(1)
Article 4(2)	Article 4(2)
Article 4(3) to (5)	—
Article 5(1)	—
Article 5(2) point (a)	Article 9(1)
Article 5(2) point (b)	Article 10(1) point (a) and 10(2), Article 11(1)
Article 5(3)	Article 10(1)
Article 5(4)	Article 12
Article 5(5) first subparagraph	Article 9(3) fifth subparagraph Article 11(2) and (3) Article 12(2) point (b)
Article 5(5) second subparagraph	Article 11(4)
Article 5(6) point (a)	Article 9(4) point (a)
Article 5(6) point (b)	—
Article 5(6) point (c)	Article 9(4) point(b)
Article 5(6) point (d)	Article 8(6) and Article 11(5) second subparagraph
Article 5(6) point (e)	Article 8(1)
Article 5(7)	Article 8(3) and (4)
Article 5(8)	—

Directive 2001/37/EC	This Directive
Article 5(9) first subparagraph	Article 15(1) and (2)
Article 5(9) second subparagraph	Article 15(11)
Article 6 (1) first subparagraph	Article 5(1) first subparagraph
Article 6 (1) second subparagraph	Article 5(2) and (3)
Article 6 (1) third subparagraph	—
Article 6(2)	Article 5(4)
Article 6(3) and (4)	—
Article 7	Article 13(1) point (b)
Article 8	Article 17
Article 9(1)	Article 4(3)
Article 9(2)	Article 10(2) and (3) point (a)
Article 9(3)	Article 16(2)
Article 10(1)	Article 25(1)
Article 10(2) and (3)	Article 25(2)
Article 11 first and second subparagraphs	Article 28(1) first and second subparagraphs
Article 11 third subparagraph	Article 28(2) first subparagraph
Article 11 fourth subparagraph	Article 28(3)
Article 12	—
Article 13(1)	Article 24(1)
Article 13(2)	Article 24(2)
Article 13(3)	
Article 14(1) first subparagraph	Article 29(1) first subparagraph

Directive 2001/37/EC	This Directive
Article 14(1) second subparagraph	Article 29(2)
Article 14(2) and (3)	Article 30 point (a)
Article 14(4)	Article 29(3)
Article 15	Article 31
Article 16	Article 32
Article 17	Article 33
Annex I (List of additional health warnings)	Annex I (List of text warnings)
Annex II (Time-limits for transposition and implementation of repealed Directives)	—
Annex III (Correlation table)	Annex III (Correlation table)