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)

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market and international developments, substantial changes to that Directive would be needed and it should therefore be repealed and replaced by a new Directive.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.

(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[(5)], 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[(6)].
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.

(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[(7)] 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[(8)] or to Council Directive 93/42/EEC[(9)]. Diverging legislation and practices as regards these products, including on safety requirements, exist between Member States, hence, action at Union level is required to improve the smooth functioning of the internal market. A high level of public health protection should be taken into account when regulating these products. In order to

enable Member States to carry out their surveillance and control tasks, manufacturers and importers of electronic cigarettes and refill containers should be required to submit a notification of the relevant products before they are placed on the market.

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

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

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

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

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

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

(43) Disparities between national laws and practices on advertising and sponsorship concerning electronic cigarettes present an obstacle to the free movement of goods and the freedom to provide services and create an appreciable risk of distortion of competition. Without further action at Union level, those disparities are likely to increase over the coming years, also taking into account the growing market for electronic cigarettes and refill containers. Therefore, it is necessary to approximate the national provisions on advertising and sponsorship of those products having cross-border effects, taking as a base a high level of protection of human health. Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising electronic cigarettes and refill containers.

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

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

(46) In the context of an emerging market for electronic cigarettes, it is possible that, although complying with this Directive, specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, placed on the market could pose an unforeseen risk to human health. It is therefore advisable to provide for a procedure to address this risk, which should include the possibility for a Member State to adopt provisional appropriate measures. Such provisional appropriate measures could involve the prohibition of the placing on the market of specific electronic cigarettes or refill containers, or of a type of electronic cigarette or refill container. In this context, the Commission should be empowered to adopt delegated acts in order to prohibit the placing on the market of specific electronic cigarettes or refill containers, or of a type of electronic cigarette or refill container. The Commission should be empowered to do so, when at least three Member States have prohibited the products concerned on duly justified grounds and it is necessary to extend this prohibition to all Member States in order to ensure the smooth functioning of the internal market for products complying with this Directive but not presenting the same health risks. The Commission should report on the potential risks associated with refillable electronic cigarettes by 20 May 2016.

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

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

(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[(11)].

(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 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[(12)].

(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[(13)], 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 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:

(**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).

(**5**) 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).

(**6**) 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).

(**7**) 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).

(**8**) 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).

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

(**10**) 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).

(**11**) 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).

(**12**) 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).

(**13**) OJ C 369, 17.12.2011, p. 14.