PE-CONS No/YY - 2012/0366 (COD)

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(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,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) 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[1] lays down rules at Union level concerning tobacco products. ***In order*** to ***reflect*** scientific, market and international developments, substantial changes are to be made ***and the Directive should be repealed and replaced*** it by a new Directive.

[1] OJ L 194, 18.7.2001, p. 26.

(2) In its reports of 2005 and 2007 on the application of Directive 2001/37/EC, submitted in accordance with Article 11 of that Directive, the Commission identified areas in which further action was considered useful[1]. 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[2]. In 2010 a broad stakeholder consultation took place[3], 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[4].

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1 Reports of the Commission to the European Parliament, the Council and the European Economic and Social Committee: First Report on the Application of the Tobacco Products Directive, COM (2005)339 final. Second Report on the Application of the Tobacco Products Directive, COM (2007)754 final.

2 SCENIHR. Health effects of smokeless tobacco products. 6 February 2008 http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf
SCENIHR. Addictiveness and attractiveness of Tobacco Additives. 12 November 2010 http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_031.pdf

3 European Commission, Health and Consumer Directorate-General, July 2011, Report on the public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC. The report and contributions are published on: http://ec.europa.eu/health/tobacco/consultations/tobacco_cons_01_en.htm

4 Council Recommendation of 30 November 2009 on smoke free environments; Council Conclusions of 1-2 December 2011 on prevention, early diagnosis and treatment of chronic respiratory diseases in children invites the Commission to consider strengthening the tobacco control legislation; EP Resolution of 15 September 2011 on European Union position and commitment in advance to the UN high-level meeting on the prevention and control of non-communicable disesases; EP Resolution of 24 October 2007 on the Green Paper 'Towards a Europe free from tobacco smoke: policy options at EU level; EP Resolution of 26 November 2009 on smoke free environments.

(3) In certain areas covered by Directive 2001/37/EC Member States are de jure or de facto prevented from effectively adapting their legislation to new developments. This is of relevance in particular for the labelling rules, where Member States cannot increase the size of the health warnings, change their location on the unit packets or replace the misleading warnings on the tar, nicotine and carbon monoxide (TNCO) 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 impede the functioning of the internal market. In the light of scientific, market and international developments these discrepancies are expected to increase. This applies ***also to electronic cigarettes and refill containers*** , herbal products for smoking, ingredients and emissions, certain aspects of labelling and packaging and the cross-border distance sales of tobacco products.

(5) Those barriers should be eliminated and, to this end, the rules relating to 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 whole of the Union in only a small number of production plants within the Member States 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 operation of the internal market.

(7) Legislative action at Union level is also necessary to implement the WHO Framework Convention on Tobacco Control (hereinafter: "FCTC") of May 2003 to which the European Union and its Member States are Parties ▌ ***and are bound by its provisions***. ***Of particular*** relevance are ▌ its Articles 9 (regulation of the contents of tobacco products), 10 (regulation of tobacco product disclosures), 11 (packaging and labelling of tobacco products), 13 (advertising) and 15 (illicit trade in tobacco products). A set of guidelines for the implementation of FCTC provisions was adopted by consensus during various Conferences of the Parties to the FCTC with the support of the Union and the Member States.

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (hereinafter: "Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people. ▌

(8a) A number of definitions are required in order to ensure that the Directive is uniformly applied by Member States. When different measures apply to different product categories and the product can fall into more than one category (e.g. pipe, roll your-own tobacco) the stricter measures should apply.

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

(10) For measuring the tar, nicotine and carbon monoxide yields of cigarettes, reference should be made to ISO standards 4387, 10315 and 8454, which are internationally recognised standards. ***The verification process should be protected from tobacco industry influence by using independent laboratories, including State laboratories. Member States may make use of laboratories situated in other Member States of the Union.*** For other emissions there are no internationally agreed standards or tests for quantifying the yields**.** ***The*** ongoing ***efforts at international level*** to develop ***such standards or tests should be encouraged.***

(11) In relation to the fixing of maximum yields, it might be necessary and appropriate at a later date to ***reduce*** the yields fixed or to fix maximum thresholds for emissions, taking into consideration their toxicity or addictiveness.

(12) In order to exercise their regulatory function, Member States and the Commission require comprehensive information on ingredients and emissions to assess the attractiveness, addictiveness and toxicity of tobacco products and the risks to health associated with the consumption of such products. To this end, the existing reporting obligations for ingredients and emissions should be ***strengthened . Additional re-enforced reporting obligations should be foreseen for additives put on a priority list in order to assess inter alia their toxicity, addictiveness and carcinogenic, mutagenic or reprotoxic (CMR) properties, also in combusted form. The burden for SMEs should be limited to the extent possible***. This is consistent with the obligation placed on the Union to ensure a high level of protection for human health.

(13) The current use of different reporting formats 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. In this light 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, while ensuring that appropriate account is taken of the commercial and intellectual property rights of the manufacturers of tobacco products. ***Existing systems for the reporting of ingredients should be taken into account.***

(14) The lack of a harmonised approach on ingredients regulation affects the functioning of the internal market and impacts on the free movement of goods across the EU. 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 some Member States, but not in others. Member States are also taking different approaches as regards additives integrated in the filter of cigarettes as well as additives colouring the tobacco smoke. Without harmonisation, the obstacles on the internal market are expected to increase in the coming years taking into account the implementation of the FCTC and its guidelines and considering experience gained in other jurisdictions outside the Union. The guidelines on Articles 9 and 10 FCTC call in particular for the removal of ingredients that increase palatability, create the impression that the tobacco products have health benefits, are associated with energy and vitality or have colouring properties.

(15) The likelihood of diverging regulation is further increased by concerns over tobacco products ▌ having a characterising flavour other than tobacco, which may facilitate uptake of tobacco consumption or affect consumption patterns. ▌ Measures introducing unjustified differences of treatment between flavoured cigarettes ▌ should be avoided ▌ . ***However, flavoured products with a higher sales volume should be phased out over a longer time period to give consumers the adequate time to switch to other products.***

(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the ***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 manufacturing 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***. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. ***An independent European advisory panel*** should be used ▌ to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties***, nor should it prevent product differentiation***.

(17) Certain additives are used to create the impression that tobacco products have health benefits, present reduced health hazards or increase mental alertness and physical performance. These additives ***as well as the additives that are carcinogenic, mutagenic or toxic to reproduction (CMRs)*** should be prohibited in order to ensure uniform rules and a high level of health protection. ***Additives that increase addictiveness and toxicity should also be prohibited.***

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

(18a) In line with the purpose of this Directive which is to facilitate the functioning of the internal market in 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, Member States should be encouraged to prevent sales of such products to children and adolescents, by adopting appropriate measures laying down and enforcing age limits.

(19) 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 packets.

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

(21) Adaptation of the labelling provisions is also necessary to align the rules at Union level with international developments. For example the guidelines on Article 11 FCTC 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 of 11 May 2005 concerning unfair buiness-to-consumer commercial practices in the internal market[1].

Those Member States that use tax stamps or national identification marks used for fiscal purposes may, in some cases, have to reposition these in order to allow for the 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 MS to maintain their tax stamps or national identification marks used for fiscal purposes at the top of the packets for a period after transposition of the Directive.

[1] OJ L 149, 11.6.2005, p. 22-39.

(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings ***comprised of the text warning and a corresponding colour photograph*** are more effective than text-only warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. ***Minimum dimensions*** should be set for all health warnings to ensure their visibility and effectiveness.

(23) Tobacco products for smoking, other than cigarettes and roll-your-own tobacco products , which are mainly consumed by older consumers ***and small population groups, can continue to*** be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people. The labelling of these other tobacco products should follow specific rules. The visibility of the health warnings on smokeless tobacco products needs to be ensured. Warnings should therefore be placed on the two main surfaces of smokeless tobacco product packaging. ***As regards water pipe tobacco, which is often perceived as less harmful than traditional tobacco for smoking, the full labelling regime should apply in order to avoid misleading the consumers.***

(24) The package and the products may mislead consumers, in particular young people, suggesting that products are less harmful. For instance, this is the case with certain texts or features, such as ‘low-tar’, ‘light’, ‘ultra-light’, ‘mild’, 'natural', 'organic', ‘without additives’, ‘without flavours’, 'slim', 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 packages and products could also mislead 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 can mislead consumers by creating the impression that they are less harmful. ***The unit packets of tobacco products and their outside packaging should not include printed material, discount offers, coupons or any other similar offers that may suggest economic advantages to consumers thus inciting them to buy those tobacco products.***

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

(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit ***tobacco*** products***, including those illegally imported into the Union***, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets of tobacco products to be marked in a unique and secure way and their movements to be recorded so that these products can be tracked and traced in 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 products are authentic.

(27) An interoperable tracking and tracing system and a common security feature should be developed. 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 experiences gained in the meantime.

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

(29) 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 ▌ prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC confirmed this prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden derogation from this prohibition ▌. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction ***in the EU (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 labelling and some ingredients rules are considered sufficient to contain market expansion beyond their traditional use***.

(29a) ***Given the general prohibition of the sale of tobacco for oral use in the Union, the responsibility for regulating the content of tobacco for oral use, which requires a deep knowledge of the specific characteristics of this product and of its patterns of consumption, should remain, in accordance with the principle of subsidiarity, with the Member State where the sale of this product is permitted in accordance with Article 151 of the Act of Accession of Austria, Finland and Sweden.***

▌

(*30*) ***Cross-border distance sales of tobacco can facilitate access to tobacco products that do not comply with the rules set out in this Directive. There is also the increased risk of access to tobacco products by young people. Consequently, there is a risk that tobacco control legislation will be undermined. Therefore Member States may prohibit cross-border distance sales . Where cross-border distances sales are not prohibited, common rules on the registration of retail outlets engaging in such sales are necessary to ensure the effectiveness of the provisions of this Directive. Member States should, in accordance with Article 4(3) TEU cooperate with each other in order to facilitate the implementation of this Directive, in particular with respect to measures taken regarding cross-border distance sales of tobacco products.***

(31) All tobacco products have the potential to cause mortality, morbidity and disability and their ***manufacture, distribution and*** consumption should be ***regulated***. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 5 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

(32) In order to ensure a level playing field, novel tobacco products, which are tobacco products in the sense of this Directive, should respect the requirements provided for in this Directive.

(32a) Electronic cigarettes and refill containers should be regulated within this Directive, unless they are due to their presentation or function subject to Directive 2001/83/EC or to Directive 93/42/EEC. Diverging legislation and practices including on safety require Diverging legislation and practices including on safety requirements exist in Member States as regards these products requiring action at Union level to improve the functioning of the internal market. A high level of public health protection should be taken into account when regulating these products. In order to allow Member States to exercise their functions of surveillance and control, manufacturers and importers of electronic cigarettes and refill containers should be required to notify their products before the intended placing of the market

(32b) Responsibility for ensuring that the products comply with the essential requirements should rest with manufacturers. If manufacturers are not established in the European Union, the natural or legal person who imports electronic cigarettes into the European Union should bear the responsibility.

(32c) ***Nicotine containing liquid should only be allowed under this Directive where the nicotine concentration does not exceed 20 mg/ml. This level of concentration is similar to the dose of nicotine derived from a standard cigarette during the same duration of smoking. In order to limit risks associated with nicotine, maximum sizes for containers, cartridges and tanks are set.***

(32d) ***Only electronic cigarettes that deliver the nicotine doses consistently should be allowed under this Directive. Consistent delivery of the nicotine doses under normal use is necessary for health, safety and quality purposes including to avoid the risk of accidental consumption of high doses.***

(32e) ***Electronic cigarettes and refill containers may create a risk when they are in the hands of children. Therefore, it is necessary to ensure that these products are child- and tamperproof including child-proof labelling, design, fastenings and opening mechanism.***

(32f) ***Given that nicotine is a toxic substance and considering the potential risks also to those for whom the product is not intended, nicotine-containing liquid should be placed on the market in electronic cigarettes or in refill containers that meets certain safety and quality requirements. It is important to ensure that electronic cigarettes do not break or leak during use and refill.***

(32g) ***The labelling and packaging of these products should display sufficient and appropriate information on safe use, in order to protect human health and safety, should carry appropriate health warnings and should not include any misleading elements or features.***

(32h) ***Disparities existing between national legislations and practices on advertising and sponsorship impede the free movement of goods and the freedom to provide services and create an appreciable risk of distortions to competition. Without further action at Union level, the existing disparities are likely to increase in the coming years, considering also the growing market for electronic cigarettes and refill containers. Therefore, it is necessary to approximate the national rules on advertising and sponsoring, taking as a base a high level of health protection. 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 of electronic cigarettes and refill containers.***

(32i) ***In order to exercise their regulatory function, Member States and the Commission require comprehensive information on market developments in electronic cigarettes and refill containers. To this end reporting obligations on sales volumes, preference of various consumers groups and mode of sales should be put on manufacturers and importers of these products. The transparency of this information should be ensured for the general public with due regard for trade secrets.***

(32j) ***In order to ensure appropriate market surveillance by Member States, it is necessary that manufacturers, importers and distributors have an appropriate system for monitoring, recording and informing the competent authorities about suspected adverse effects, so that appropriate action can be taken. A safeguard clause is warranted allowing Member States to act against serious risks to public health.***

(32k) ***In the context of an emerging market on electronic cigarettes, it is possible that, although conforming to the provisions of this Directive, a given electronic cigarette or refill container, or a type of electronic cigarettes or refill containers, placed on the market could pose an unforeseen risk to human health. It is therefore advisable to provide for a procedure intended to address this risk, which should include the possibility for a Member State to adopt provisional appropriate measures. Such provisional measures could involve the prohibition on the placing on the market of a given electronic cigarette or refill container, or of a type of electronic cigarettes or refill containers. In this context, the Commission should be empowered to adopt delegated acts in order to prohibit a given electronic cigarette or refill container, or a type of electronic cigarettes or refill containers, when at least three Member States have prohibited these products on justified grounds and it is necessary to extend this prohibition to all the Member States in order to ensure the smooth functioning of the internal market for compliant products not presenting the same safety concerns. The Commission should report on the potential risks associated with refillable electronic cigarettes at the latest at the date of the entry into force of this Directive.***

(32l) ***This Directive does not harmonise all aspects of electronic cigarettes or refill containers, and leaves for example the regulation of flavours to the Member States. It may be useful for Member States to consider allowing flavours in the products. However, they should be mindful of the potential attractiveness for young people and non smokers. Such prohibitions of flavours would need to be justified and notified according to Directive 98/34/EC.***

(32m) ***Moreover, this Directive does not harmonise rules on smoke-free environments, or on domestic sales arrangements or advertising, brand stretching, nor does it introduce an age limit for electronic cigarettes or refill containers. In any case, the presentation and advertising of the products should not be used to promote tobacco consumption or give rise to confusion with tobacco products. Member States are free to regulate such matters in their own domain and are encouraged to do so.***

(36) 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 proper functioning of the internal market and improve information to consumers, common labelling rules ***and ingredients reporting*** should be introduced at Union level.

(37) In order to ensure uniform conditions for the implementation of this Directive ▌ concerning the ***establishment and update of the priority list of ingredients for re-enforced reporting, the*** format of ingredients reporting, the determination of products with characterising flavours or with increased levels of toxicity***,*** addictiveness ***or CMR properties,*** the methodology for determining whether a tobacco product has characterising flavour, ***the technical standards for the unique identifiers and security features, and the technical specificications for the design, layout an dshape of health warnings and their precise positioning for roll-your-own tobacco in pouches, and the technical standards of the refill mechansims for electronic cigarettes and refill containers,*** implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011[1].

[1] OJ L 55, 28.2.2011, p. 13-18.

(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission ▌ in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, ***the establishing and adapting the picture library and adapting the health warnings and*** reviewing certain exemptions granted to tobacco products other than cigarettes ***and*** roll-your-own tobacco ▌ , ***defining key elements of the data storage contracts to be concluded in the context of the tracking and tracing system and adapting the health warnings and extending Member States' measures concerning a given electronic cigarette or refill container or a type thereof.*** It is of particular importance that the Commission carries 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 Council.

(39) The Commission should monitor the developments and submit a report 5 years after the date of transposition of this Directive, ***and, when necessary thereafter,*** in order to assess whether amendments to this Directive are necessary. ***The report should include information on the package surfaces not governed by this Directive, market developments in novel tobacco products, market developments that amount to a substantial change of circumstance, market development and consumer perception of slim cigarettes, of waterpipe tobacco and of electronic cigarettes and refill containers.***

When preparing the report regarding the feasibility, benefits and impacts of a European system for the regulation of ingredients in tobacco products, including the establishment of a Union list of ingredients that may be used, or present in or added to tobacco products (so called 'positive list'), the available scientific evidence on the toxic and addictive effects of ingredients should be evaluated.

(39a) ***Tobacco products 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 retain, under certain conditions, the power to impose further requirements in certain respects 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 instance, introduce provisions providing for further standardisation of packaging of tobacco products provided that those provisions are compatible with the Treaty, with WTO obligations and do not affect the full application of this Directive.

▌

(40a) ***Moreover, in order to take into account possible future evolutions of the market, Member States should also be allowed to prohibit a certain category of tobacco or related products, on grounds relating to the specific situation of this Member State 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 stricter national provisions to the Commission.***

(41) ***A*** Member ***State*** should remain free to maintain or introduce national legislations applying to all products ***placed on its market*** for aspects ***not regulated by*** this Directive, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly ***and under these conditions, Member States 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***. A prior notification is required for technical regulations pursuant to 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 on rules on Information Society services[1].

(42) 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 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[2].

(43) The provisions of this Directive are without prejudice to Union legislation governing the use and labelling of genetically modified organisms.

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1 OJ L 204, 21.7.1998, p. 37-48.

2 OJ L 281, 23.11.1995, p. 31.

(44) In accordance with the Joint Political Declaration of Member States and the Commission of 28 September 2011 on explanatory documents, 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.

(45) 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 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 functioning of the internal market***. The application of this Directive should respect the ***Union*** law and relevant international obligations.

HAVE ADOPTED THIS DIRECTIVE:

TITLE I – COMMON PROVISIONS

Article 1

Subject matter

The ***purpose*** 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 yields 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 to ensure compliance with this Directive;

(c) the prohibition to place on the market tobacco for oral use;

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

(e) the notification obligation for 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 functioning of the internal market in tobacco and related products, taking as a base a high level of health protection, especially for young people, and to meet obligations under the WHO Framework Convention for Tobacco Control.

Article 2

Definitions

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

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

(2) 'additive' means substance ***other than*** tobacco leaves and other natural or unprocessed parts of tobacco plants ***added to a tobacco product, its unit packet or any outside packaging*** ;

(3) 'age verification system' means a computing system that unambigouisly confirms the consumer's age in electronic form according to national requirements;

(4) 'characterising flavour' means a ***clearly noticeable smell*** or taste other than tobacco, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy, menthol or vanilla ***which is*** observable before or upon ***the*** use of the tobacco product;

(5) 'chewing tobacco' means a smokeless tobacco product exclusively designed for the purpose of chewing;

(6) 'cigar' means a roll of tobacco consumed via a combustion process and further defined in Article 4(1) of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco[1];

(7) 'cigarette' means a roll of tobacco consumed via a combustion process and further defined in Article 3(1) of Council Directive 2011/64/EU;

[1] OJ L 176, 5.7.2011, p. 24.

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

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

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

(11) 'cross-border distance sales' means a distance sales ***to consumers*** where, at the time the consumer orders the product, the consumer is located in a Member State other than the Member State or the third country where the 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/she has his/her place of business in that Member State;

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

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

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

(14) 'health warning' means a warning provided for in this Directive, including text warnings, combined health warnings, general warnings and information messages;

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

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

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

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

(18a) 'tobacco' means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;

(18b) 'manufacturer' shall mean 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.

(19) 'maximum level' or 'maximum yield' means the maximum content or emission, including 0, of a substance in a tobacco product measured in ***milligrams***;

(20) 'nasal tobacco' means a smokeless tobacco product consumed via the nose;

(21) 'nicotine' means nicotinic alkaloids;

(21a) 'electronic cigarette' means a product, or any component thereof, including cartridges and the device without cartridge, that can be used for consumption of nicotine-containing vapour via a mouth piece. Electronic cigarettes can be disposable, refillable by means of a refill container or rechargable with single use cartridges;

▌

(22a) 'refill container' means a recepticle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette.

(23) 'novel tobacco product' means a tobacco product ***which :***

a) does not fall into any of the following categories: a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use***; and***

b) is placed on the market after entry into force of this Directive;

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

(25) 'place 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 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;

(25a) 'pouch' means a unit packet of roll-your own tobacco, either in the form of rectangular pocket with a flap that covers the opening or in the form of a standing pouch;

(26) 'pipe tobacco' means tobacco consumed via a combustion process and exclusively designed for the purpose of being used in a pipe;

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

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

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

(30) 'substantial change of circumstances' means an increase of the sales volumes by product category ▌ by at least 10% in at least ***5*** Member States based on sales data transmitted in accordance with Article 5(4) or an increase of the prevalence level in the consumer group under 25 years of age by at least 5 percentage points in at least ***5*** Member States for the respective product category based on ____ [this date will be set at the moment of adoption of the Directive] Eurobarometer report or equivalent prevalence studies; ***a substantial change of circumstance 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 EU level;***

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

(32) 'tobacco for oral use' means all 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;

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

(34) 'tobacco products' means products usable for consumption by consumers and consisting of, even partly, tobacco, whether genetically modified or not;

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

(36) 'unit packet' means the smallest individual packaging of a product that is placed on the market.

(37) 'water pipe tobacco' means a tobacco product which can be used for consumption via a water pipe. For the purpose of this Directive, water pipe tobacco is deemed to be a tobacco product for smoking. If a product can be used both in water pipes and as roll-your-own tobacco, the stricter rules shall apply.

TITLE II – TOBACCO PRODUCTS

Chapter I: Ingredients and emissions

Article 3

Maximum tar, nicotine, carbon monoxide and other yields

1. The yield of cigarettes placed on the market or manufactured in the Member States shall not be greater than:

   a) 10 mg per cigarette for tar,

   b) 1 mg per cigarette for nicotine,

   c) 10 mg per cigarette for carbon monoxide.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to ***decrease*** the maximum yields laid down in paragraph 1, ***where this is necessary based on*** internationally agreed standards.

3. Member States shall notify the Commission of ***any*** maximum yields ▌ they set for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. ▌

3a. ***The Commission shall adopt delegated acts in accordance with Article 22 to integrate into Union law standards agreed by the parties to the FCTC or WHO relating to maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes.***

Article 4

Measurement methods

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

   The accuracy of the tar***, nicotine and carbon monoxide*** indications shall be verified in accordance with ISO standard 8243.

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

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

   Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the methods of measurement of the tar, nicotine and carbon monoxide yields, ***where this is necessary based on*** scientific and technical developments ***or*** internationally agreed standards.

4. Member States shall notify the Commission of ***any*** methods of measurement ▌ they use for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. ▌

4a. The Commission shall adopt delegated acts in accordance with Article 22 to integrate into Union law standards agreed by the parties to the FCTC or WHO, relating to methods of measurement.

4b. Proportionate fees may be charged by Member States for the verification of measurements referred to in paragraph 1.

Article 5

Reporting of ingredients and emissions

1. Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields ***referred to in Article 3, paragraphs 1 and 3a, and, where available, information on other emissions and yields. For products already placed on the market the information shall be provided six months following the date defined in Article 25.*** Manufacturers or importers shall also inform the competent authorities of the concerned Member States if the composition of a product is modified affecting the information provided under this Article. Information required under this Article shall be submitted prior to the placing of the market of a new or modified tobacco product.

   The list ***of ingredients*** shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. The list shall ***also*** indicate their status, including whether the ingredients have been registered under 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)[1] as well as their classification under 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[2].

[1] OJ L 396, 30.12.2006, p. 1.
[2] OJ L 353, 31.12.2008, p. 1–1355.

The list shall also be accompanied by the ***relevant*** toxicological data ▌ regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health of consumers and taking into account, *inter alia*, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product. ***Furthermore, for cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives in use and their properties, shall be submitted by the maunfacturer or importer.***

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

1a. (new) The Commission shall adopt implementing acts laying down and subsequently updating a priority list of additives contained in cigarettes and roll-your-own tobacco, which shall be subject to the re-enforced reporting obligations pursuant to this paragraph. 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 the subsequent subparagraph; and

b) which are amongst the most commonly used additives by weight or number according to the reporting under this Article;

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21. A first list of additives shall be adopted by the date referred to in Article 25 and shall contain at least fifteen additives.

For the additives on this priority list, the reporting obligations in this paragraph apply in addition to the other obligations in this Article.

For each additive on the priority list the Member States shall require manufacturers or importers of the products containing that additive 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 to increase the toxicity or addictiveness in any of the products concerned in a significant or measurable manner;

b) leads to a characterising flavour;

c) facilitates inhalation or nicotine uptake; or

d) leads to the formation of substances that are carcinogenic, mutagenic or toxic to reproduction, the quantities thereof, and whether this has the effect to increase the carcinogenic, mutagenic or reprotoxic properties in any of the products concerned in a significant or measurable manner.

The studies shall take into account the intended use of the products and assess in particular the emissions resulting from the combustion process involving the additive concerned. The studies shall also assess the interaction 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 the comparable product composition.

Manufacturers or importers shall prepare a report consisting of the results of these studies, including their executive summary, and a comprehensive overview which compiles the available scientific literature on that additive and summarises internal data on the effects of that additive.

Manufacturers or importers shall submit these reports to the Commission and a copy to the competent authorities of those Member States where a product containing this additive is placed on the market at the latest 18 months after the additive in question has been put on the list established according to this paragraph. The Commission and the Member States concerned are also entitled to request supplementary information from manufacturers or importers regarding the additive in question. This supplementary information shall form part of the final report.

The Commission and the Member States concerned may require these reports to be peer reviewed by an independent scientific body, in particular in terms of comprehensiveness, methodology and conclusions. The information received shall assist in the decision making process pursuant to Article 6.

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

2. Member States shall ensure the dissemination of information submitted in accordance with paragraph 1 ***and 1a new*** on a ▌ website, which is available to the general public. In doing so Member States shall take due account of the need to protect information which constitues a trade secret***. Member States shall require manufacturers and importers to specify, when submitting the information pursuant to paragraph 1 and 1a (new), the information which they consider to constitute trade secrets***.

3. The Commission shall, by means of implementing acts, lay down and if necessary update the format for the submission and dissemination of the information specified in paragraphs ***1, 1a (new)*** and ***4.*** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

4. 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 the sales volume data per product, reported in sticks or kilograms, and per Member State on a yearly basis starting from the full calendar year following that of the entry into force of this Directive. Member States shall provide ▌ additional ***available*** sales volume ***data***.

5. All data and information to be provided to and by Member States under this Article 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 ***the*** information ***for the purpose of applying this Directive***. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

6. ***Proportionate fees may be*** charged by Member States for receiving, storing, handling, analysing and publishing the information submitted to them under this Article**.** ***Proportionate fees may also be charged by Member States and the Commission for the peer reviews pursuant to paragraph 1a new.***

Article 6

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,*** as long as the additives do not result in a product with a characterising flavour ***and do not increase in a significant or measureable manner the addictiveness, toxicity or the carcinogenic, mutagenic or reprotoxic properties of the product***.

   Member States shall notify the Commission of 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 21.

2a. The Commission shall adopt by means of ***implementing*** acts uniform rules on 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 21.***

▌

2b.` ***An independent advisory panel shall be established at Union level. Member States and the Commission may consult this panel before taking the decisions pursuant to paragraphs 1 and 2. The Commission shall adopt by means of implementing acts 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 21.

3. ***Where the level of presence or concentration of certain additives or the combination thereof has resulted in prohibitions pursuant to Article 6(1) in at least 3 Member States,*** the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives or combination of additives that cause the characterising flavour.

4. Member States shall prohibit the ***placing on the market of tobacco products containing*** the following additives ▌:

(a) vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards, ▌

(b) caffeine and taurine and other additives and stimulant compounds that are associated with energy and vitality, ▌

(c) additives having colouring properties for emissions***,***

(d) for tobacco for smoking, additives that facilitate inhalation or nicotine uptake, and

(e) additives that are carcinogenic, mutagenic or toxic to reproduction in unburnt form.

5. Member States shall prohibit the ***placing on the market of tobacco products containing*** flavourings in ***their*** components ▌ such as filters, papers, packages, capsules or any technical features allowing modification of ***smell or taste*** or smoke intensity. Filters***,*** ***papers*** and capsules ***and*** shall not contain tobacco ***or nicotine***.

6. Member States shall ensure that provisions or conditions set out under Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.

7. Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in ***a significant and measureable*** manner at the stage of consumption the toxic or addictive effect***, or the carcinogenic, mutagenic or reprotoxic properties*** of a tobacco product.

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

8. 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 7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21 and shall be based on the latest scientific evidence.

9. ***Where an*** additive or a ▌ quantity thereof ***has been shown to*** amplify the toxic or addictive effect of a tobacco product ***that has resulted in prohibitions pursuant to Article 6(7) in at least 3 Member States,*** the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives. ***In this case, the maximum level shall be set at the lowest maximum level of those that informed the national prohibitions.***

10. Tobacco products other than cigarettes ***and*** roll-your-own tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 5. The Commission shall adopt delegated acts in accordance with Article 22 to withdraw this exemption ***for a particular product category*** if there is a substantial change of circumstances as established in a Commission report.

10a. Tobacco for oral use shall be exempted from the provisions of this Article

11. Proportionate fees may be charged to manufacturers and importers of tobacco products for assessing whether a product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase in a significant and measurable manner the toxic or addictive effect or the carcinogenic, mutagenic or reprotoxic properties of the tobacco product.

12. As regards products of a particular characterising flavour whose Union wide sale volumes represent 3% or more in a particular product category, the provisions of this Article shall apply from [Publications Office, please insert the exact date: ***date referred to in paragraph 1 of Article 25 + 4 years***].

Chapter II: Labelling and packaging

Article 7

General provisions

1. Each unit packet of tobacco products and any outside packaging shall carry health warnings in the official language or languages of the Member State where the product is placed on the market.

2. Health warnings shall occupy the entire surface reserved for them and they shall not be commented on, paraphrased or referred to in any form.

2a. Member States shall ensure that the health warnings on the 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, jacket, boxes, or other devices 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 not be broken by the opening of the unit packet other than for packets with a flip-top lid where the health warnings may be broken by the opening, but only in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.

5. 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.

5a. ***The size of the health warnings shall be calculated in relation to the surface in question when the packet is closed.***

5b. ***Health warnings shall be surrounded by a black border of 1 mm in width inside the surface reserved for the warning, with the exception of warnings pursuant to Article 10.***

▌

6a. ***When adapting a health warning pursuant to Articles 8.5, 9.3 and 11.3, the Commission shall ensure that they are factual or that Member States shall have a choice of two warnings, one of which is factual.***

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

Article 8

Text warnings for tobacco for smoking

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

   Smoking kills – quit now

   or

   Smoking kills

   Member States shall determine which of these general warnings shall be used.

2. Each unit packet and any outside packaging of tobacco 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 and the information message shall be printed on the ***bottom part of the*** lateral ***surfaces*** of the unit packets. These warnings shall have a width of not less than 20 mm ▌**.**

For packets in the form of a hinged lid shoulder box that result in the lateral surface being split into two when the packet is open, the general warning and the information message shall be printed in its entirety on the larger 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 side of this type of packet shall have a height of not less then 16 mm.

For roll-your-own tobacco in pouches the general warning and the information message shall be printed on the surfaces that ensure the full visibility of the health warnings. For roll-your-own tobacco in cylindric packets the general warning shall be printed 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 surface on which they are printed.

▌

4a. ***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 their legislation is such as to occupy the greatest possible proportion of the area set aside for the text required; and***

(b) ***centred in the area in which they are required to be printed, and on cuboid packets and any outside packaging they shall be parallel to the lateral edge of the unit packet;***

5. ***The Commission shall be empowered to adopt delegated acts in accordance with Article 22 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 positioning of the general warning and information message on roll-your-own tobacco in pouches, in light of the various shapes of pouches.***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Article 9

Combined health warnings for tobacco for smoking

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

(a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library ***in Annex II***;

(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;

(c) cover ***65*** % of the external area of both the front and back surface of the unit packet and any outside packaging***. Cylindric packets shall display two 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) be positioned at the top edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on ***that surface of the packaging. Transitional exemptions may apply in Member States where tax stamps or national identification marks used for fiscal purposes remain mandatory in that the combined health warning on the back surface may be positioned directly below the tax stamp or national identification mark used for fiscal purposes which is affixed at the top edge of a unit packet made of carton material. In case of a unit packet made of soft material, Member States may allow for a rectangular surface with a height not exceeding 13mm between the top edge of the packet and the top end of the combined health warnings. These exemptions shall apply for a period of three years following the date referred to in paragraph 1 of Article 25. Brand names or logos shall not be positioned above the health warning.***

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

(g) for 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 shall be divided into three sets rotating on an annual basis. Member States shall ensure that each combined health warning ***available for use in any one year*** is displayed as nearly as possible ***in*** equal numbers ***on*** each brand.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:

a) adapt the text warnings listed in Annex I to this Directive 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, layout, design and shape of the health warnings, taking into account different packet shapes.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Article 10

Labelling of tobacco for smoking other than cigarettes,
roll-your-own tobacco *and water pipe tobacco*

1. ***Member States may exempt tobacco*** for smoking other than cigarettes***,*** roll-your-own tobacco ***and water pipe tobacco*** from the obligations to carry the information message laid down in Article 8(2) and the combined health warnings in Article 9. In ***this case, and in*** addition to the general warning specified in Article 8(1), each unit packet and any outside packaging of these products shall carry a text warning listed in Annex I. The general warning specified in Article 8(1) shall include a reference to the cessation services in accordance with Article 9(1)(b).

The general warning shall be printed on the most visible surface of the unit packet and any outside packaging. ***Member States shall ensure that each text warning is displayed as nearly as possible in equal numbers on each brand.*** The text warnings ▌ shall be printed on the other most visible surface of the unit packet and any outside packaging.

For packets with the hinged lid, the other 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 external area of the corresponding surface 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 text warning referred to in paragraph 1 shall cover 40 % of the external area of the corresponding 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.

3a. In case the warnings referred to in paragraph 1 are to be placed on a surface exceeding 150 cm², the warning shall cover an area of 45 cm². That area shall be increased to 48 cm² for Member States with two official languages and 52.5 cm² for Member States with more then two official languages.

4a. ***The health warnings referred to in paragraph 1 shall comply with the requirements specified in Article 8(4a), paragraphs (a) and (b). However, the text of the warnings shall be parallel to the main text on the surface concerned.***

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

5. The Commission shall ▌ adopt delegated acts in accordance with Article 22, to withdraw the ***posssibility to grant exemptions for a particular product category*** laid down in paragraph 1 if there is a substantial change of circumstances as established in a Commission report ***for the product category concerned***.

Article 11

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 ***8***(4a)***, paragraphs (a) and (b). However, the text of the warnings shall be parallel to the main text on the surface concerned.***

In addition, it shall:

a) be printed on the two largest surfaces of the unit packet and any outside packaging;

b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with ***more than*** two official languages and 35 % for Member States with three official languages.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the ***wording of the health warning laid down in paragraph 1 to*** scientific ▌ developments.

Article 12

Product *presentation*

1. The labelling of a unit packet 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, hazards or emissions; ***labels shall not include any information about nicotine, tar or carbon monoxide content;***

(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.

1a. ***The unit packet and any outside packaging shall not suggest economic advantage by including printed vouchers, offering discounts, free distribution, two-for one or other similar offers.***

2. Prohibited elements and features may include but are not limited to texts, symbols, names, trade marks, figurative or other signs ▌ .

Article 13

Appearance and content of unit packets

1. A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall have ***cuboid or cylindric shape, or have*** 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 at least ***30*** g.

2. A cigarette packet can be of carton or soft material and shall not contain an opening that can be re-closed or re-sealed after ***it*** is first opened, other than the flip-top lid ***and shoulder box hinged lid. For packets with a*** flip-top lid ***and hinged lid opening, the lid*** shall be hinged only at the back of the packet.

▌

Article 14

Traceability ▌

1. Member States shall ensure that all unit packets of tobacco products shall be marked with a unique identifier. In order to ensure their integrity, unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or by the opening of the packet. In relation to products manufactured outside the Union the obligations laid down in this Article apply only to those destined to or placed on the Union market.

2. The unique identifier shall allow determining:

   (a) the date and place of manufacturing;

   (b) the manufacturing facility;

   (c) the machine used to manufacture the 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 shipment date, shipment destination, point of departure and consignee***;

(j) the identity of all purchasers from manufacturing to the first retail outlet;

(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

2a. The information in subparagraphs (a), (b), (c), (d), (e), (f), (g) and, where applicable, (h) shall form part of the unique identifier.

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

3. 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 from their possession. This obligation can be fulfilled by ***marking and*** recording ***of*** aggregated ▌ packaging ***such as carton, mastercase or pallet***, provided that tracking and tracing of unit packets remains possible.

3a. 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.

4. Member States shall ensure that 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 necessary equipment allowing for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. The equipment shall be able to read and transmit the data electronically to a data storage facility pursuant to paragraph 6.

▌

6. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host 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 contract, shall be approved ***by the Commission and its activities shall be*** monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. ***The auditor shall submit an annual report to the competent authorities and the Commission, assessing in particular any violations of accessibility.*** Member States shall ensure full ▌ accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party ▌. In duly justified cases Member States or the Commission can provide manufacturers or importers access to this information, provided commercially sensitive information remains adequately protected in conformity with the relevant national and Union legislations.

6a. Recorded data cannot be modified or deleted by any economic operator involved in the trade of tobacco products.

7. 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 defined in this Article, including marking, recording, transmitting, processing, storing of data and their accessibility;

(b) determine the technical standards to ensure that the systems used for the unique identifiers 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 21.

12. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to define the key elements, such as duration, renewability, expertise required or confidentiality, of the contract referred to in paragraph 6, including its regular monitoring and evaluation.

13. ***Paragraph 1 to 7 shall apply to cigarettes and roll-your-own tobacco 3 years following the date referred to in paragraph 1 of Article 25 and to tobacco products other than cigarettes and roll-your-own tobacco 8 years following the date referred to in paragraph 1 of Article 25.***

Article 14a new

Security Feature

1. ***In addition to the unique identifier referred to Article 14, Member States shall require that all unit packets of tobacco products which are placed on the market carry a visible and invisible, tamper proof security feature, which shall be irremovably printed or affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation.***

Member States requiring tax stamps or national identification marks used for fiscal purposes may make use of them for the security feature provided that the tax stamps fulfill all technical standards and functions required by this article.

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

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

3. Paragraph 1 shall apply to cigarettes and roll-your-own tobacco 3 years following the date referred to in paragraph 1 of Article 25 and to tobacco products other than cigarettes and roll-your-own tobacco 8 years following the date referred to in paragraph 1 of Article 25.

Chapter III: Tobacco for oral use

Article 15

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.

Chapter IV: Cross-border distance sales of tobacco products

Article 16

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 consumers in Member States where such sales have been prohibited. Member States which do not prohibit these sales*** shall oblige 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 consumer is located. Retail outlets established outside the Union have to register with the competent authorities in the Member State where the actual or potential consumer is located. All retail outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities:

   (a) name or corporate name and permanent address of the place of activity from where the tobacco products are 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;

(c) the address of the website/-s 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 in accordance with the rules and safeguards laid down in Directive 95/46/EC**.** Retail outlets may only start placing tobacco products on the market in form of ***cross-border*** distance sales as of the moment ***they have received confirmation of their registration*** in the relevant Member States.

3. If it is necessary in order to ensure compliance and facilitate enforcement, Member States of destination may require that the retail outlet nominates a natural person who is responsible for verifying the tobacco products before reaching the consumer comply with the national provisions adopted pursuant to this Directive in the Member State of destination.

4. Retail outlets engaged in ***cross-border*** distance sales shall be equipped with an age verification system, which verifies at the time of sale, that the purchasing consumer respects the minimum age foreseen under the national legislation of the Member State of destination. The retailer or nominated natural person shall report to the competent authorities a description of the details and functioning of the age verification system.

5. Personal data of the consumer shall only be processed in accordance with Directive 95/46/EC and not be disclosed to the manufacturer of tobacco products or companies forming part of the same group of companies or to any other third parties. Personal data shall not be used or transferred beyond the purpose of this actual purchase. This also applies if the retail outlet forms part of a manufacturer of tobacco products.

Chapter V: Novel tobacco products

Article 17

Notification of novel tobacco products

1. Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco product they intend to place on the markets of the Member States concerned. The notification shall be submitted in electronic form six months before the intended placing on the market and shall be accompanied by a detailed description of the product in question as well as ***as instructions for use and*** information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with:

   (a) available scientific studies on toxicity, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions;

(b) available studies***, executive summaries thereof*** and market research on 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, the expected effects on cessation of tobacco consumption, the expected effects on initiation of tobacco consumption and other predicted consumer perception.

2. Member States shall require that manufacturers and importers of tobacco products inform their competent authorities of any new or updated information referred to in point (a) to (c) of paragraph 1. Member States shall be entitled to require tobacco manufacturers or importers to carry out additional tests or submit additional information. Member States shall make available to the Commission all information received pursuant to this Article. Member States shall be entitled to introduce an authorisation system and charge a proportionate fee.

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

TITLE III – ELECTRONIC CIGARETTES

▌

Article 18a

Electronic cigarettes

1. ***The Member States shall ensure that electronic cigarettes and refill containers are only placed on the market if they comply with the relevant provisions of 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 notify the product with the competent authorities of the Member States in which the product is intended to be placed on the market. The notification shall be submitted in electronic form 6 months before the intended placing on the market. For products already placed on the market on the date referred to in paragraph 1 of Article 25, the notification shall be submitted within 6 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. ***name and contact details of the manufacturer, a responsible legal or natural person within the European Union, and, if applicable, the importer into the European Union;***

b. ***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 these ingredients and their emissions, including when heated, referring in particular to their effects on health of consumers when inhaled and taking into account, inter alia, any addictive effect;

d. information on nicotine dosing and uptake when used under normal or reasonably foreseeable conditions;

e. description of the components of the product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;

f. description of the production process including series production and declaration that the production process ensures conformity with the requirements in this article;

g. 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 data are incomplete, they are entitled to request the completion of such data.

Proportionate fees may be charged by Member States 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 liquid does not contain nicotine in excess of 20 mg/ml;

c) the liquid does not contain additives listed in paragraph 4 of Article 6;

d) only ingredients of high purity are used in the manufacture of the liquid; substances other than the ingredients referred to in paragraph 2(b) are only present in trace levels, if they are technically unavoidable during manufacture;

e) ***only ingredients are used in the liquid that are not hazardous to human health in heated or unheated form, with the exception of nicotine;***

f) ***electronic cigarettes deliver the nicotine doses consistently;***

g) ***electronic cigarettes and refill containers are child- and tamperproof; electronic cigarettes and the refill containers are protected against breakage and leakage and have a mechanism ensuring leakage free refilling.***

4. ***Member States shall require manufacturers and importers to ensure that***:

(a) ***unit packets of electronic cigarettes and refill containers include a leaflet with information instructions for use and storage, including a reference that the product is not recommended for use by young people and non-smokers, contra-indications, warnings for specific risk groups, information on possible adverse effects, on addictiveness and toxicity, and contact details of the manufacturer or importer and a legal or natural contact person within the European 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, and an indication of nicotine content and delivery per dose, the batch number and a recommendation to keep out of reach of children;

ii. do not include elements or features referred to in Article 12, with the exception of paragraph 1(a) of Article 12 concerning the nicotine content;

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 are used.

(c) the health warnings shall comply with the provisions in paragraph 2 of Article 11.

5. Member States shall ensure that:

a) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited in information society services as defined in Article 1(2) of Directive 98/48/EC, in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of the products and for publications which are printed and published in third countries, where those publications are not principally intended for the European Union market;

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

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 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 falling under Directive 2010/13/EU are prohibited for electronic cigarettes and refill containers;

f) cross-border distance sales of electronic cigarettes and refill containers are regulated in accordance with Article 16.

6. Member States shall require manufacturers and importers of electronic cigarettes and refill containers to submit to competent authorities on an annual basis comprehensive data on sales volumes, by brand name and type, as well as information on preferences of various consumer groups, including young people, non-smokers and main types of current users, as well as the mode of sale of the products. They shall also submit executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the development of the electronic cigarette market as well as the market for refill containers, including any evidence of gateway use among young people and non-smokers.

7. ***Member States shall ensure the dissemination of information received pursuant to paragraph 2 on a website with due regard to the protection of trade secrets.***

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

8. ***Member States shall require that manufacturers, importers or distributers establish and maintain a system to collect information about all suspected adverse effects. If any of these operators considers or has reason to believe that electronic cigarettes or refill containers, which are in its possession and are intended to be placed on the market, are not of good safety or quality or is otherwise not in conformity with this Directive, the operator shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, as appropriate. In such a case the operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available, giving details, in particular, of the risk to 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 operator, for example on safety and quality aspects or any adverse effects.***

9. ***The Commission shall report on the potential risks to public health associated with the use of refillable electronic cigarettes at the latest on the date referred to in Article 25(1) and whenever needed thereafter.***

10. ***In the case of products meeting the requirements of this Article, where a competent authority ascertains or has reasonable grounds for concerns that a given electronic cigarette or a refill container, or a type of electronic cigarettes or refill containers, could present a serious risk to human health, it may take appropriate provisional measures and shall immediately communicate to the Commission and the competent authorities of other Member States the measures taken and any supporting data. The Commission shall determine, as soon as possible, whether the provisional measure is justified. The Commission shall inform the Member State concerned of its assessment, in order for the Member State to ensure appropriate follow-up.***

Where, in the application of the first subparagraph of this paragraph, a given type of electronic cigarette or refill container, or a type of electronic cigarettes or refill containers has been banned on justified ground by at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to extend such a ban to all Member States, if that measure is justified and proportionate.

11. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the wording of the health warning in paragraph 4(b). When adapting that health warning, the Commission shall ensure that it is factual.

12. The Commission shall adopt by means of implementing acts a common notification format pursuant to paragraph 2 and the technical standards of the refill mechanism.

These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Article 19

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 laid down in Article ***8***(4a). 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 35 % for Member States with ***more then two*** official languages.

4. Unit packets and any outside packaging of herbal products for smoking shall not include elements or features referred to in points (a), (b) and (d) of Article 12 and shall not state that the product is free of additives or flavourings.

Article 19 a (new)

Reporting of ingredients

1. Member States shall require manufacturers and importers of herbal products to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the products by brand name and type. Manufacturers or importers shall also inform the competent authorities of the concerned Member States if the composition of a product is modified affecting the information provided under this Article. Information required under this Article shall be submitted prior to the placing of the market of a new or modified product.

2. Member States shall ensure the dissemination of information submitted in accordance with paragraph 1 on a website, which is available to the general public. In doing so Member States shall take due account of the need to protect information which constitues a trade secret. Economic operators shall specify exactly what information qualifies for this protection.

TITLE IV – FINAL PROVISIONS

Article 20

Cooperation and enforcement

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

2. Member States shall ensure that products which do not comply with this Directive, including its implementing and delegated acts, are not placed on the market. ***Member States shall ensure that a product is not placed on the market, if the reporting obligations set out in this directive are not complied with.***

3. Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive. ***Any financial administrative penalties applicable to intentional infringements 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 proper application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive uniformly.***

Article 21

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 request.

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 21a new

Competent authorities

Member States shall designate the competent authorities responsible for the implementation and enforcement of obligations provided for in this Directive within the period of 3 months after the transposition pursuant to Article 25. Member States shall, without delay, inform the Commission about the identity of these. The Commission shall publish that information in the Official Journal of the European Communities.

Article 22

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), 3(3***a***), 4(3), 4(4***a***), 6(3), 6(9), 6(10), 8(***5***), 9(3), 10(5), 11(3), ▌ 14(9), 18a(***9***) and 18a(***10***) shall be conferred on the Commission for ***a period of 5 years after*** [*Office of Publications: please insert the date of the entry into force of this Directive*]***. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-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 3 months before the end of each period***.

3. The delegation of powers referred to in Articles 3(2), 3(3***a***), 4(3), 4(4***a***), 6(3), 6(9), 6(10), 8(***5***), 9(3), 10(5), 11(3), ▌ 14(9), 18a(***9***) and 18a(***10***) 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 pursuant to Articles 3(2), 3(3***a***), 4(3), 4(4***a***), 6(3), 6(9), 6(10), 8(***5***), 9(3), 10(5), 11(3), ▌ 14(9), 18a(***9***) and 18a(***10***) 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 23

Report

1. No later than five years from the date specified in Article 25 paragraph 1, ***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.

With a view to drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available.

2. In the report, the Commission shall indicate in particular the features which should be reviewed or developed in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, and shall pay special heed 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 in novel tobacco products considering, inter alia, notifications received under Article 17;

(c) market developments which amount to a substantial change of circumstances***;***

(d) the feasibility, benefits and possible impacts of a European system for the regulation of ingredients used in tobacco products, including the establishment of a Union list of ingredients that may be used or present in, or added to tobacco products, taking into account inter alia the information gathered pursuant to Article 5;

(e) market developments in cigarettes with a diameter of less than 7.5mm, as well as consumer perception of their harmfulness and misleading character.

(f) the feasibility, benefits and possible impacts of a central Union database of information on ingredients and emissions of tobacco products collected pursuant to Article 5;

(g) market developments in electronic cigarettes and refill containers considering, inter alia, information received under Article 18a, including uptake by young people and non-smokers and impacts on cessation efforts as well as measures taken by Member States regarding flavours.

(h) market developments and consumer preferences as regards water pipe tobacco, with a particular focus on their flavours.

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

3. The report shall be ***followed-up*** by any proposals for amendments to this Directive which the Commission deems necessary to adapt it to developments in the field of tobacco and related products, to the extent necessary for the operation of the internal market, and to take into account any new developments based on scientific facts and developments on internationally agreed product standards.

Article 24

Free movement

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

2a. ***This Directive shall not affect the right of a Member State to maintain and introduce further requirements , applicable to all products placed on its market , in relation to standardisation of packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection 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. They shall be notified to the Commission together with the grounds for maintaining or introducing them.***

2b. A Member State may also ***prohibit a certain category of tobacco or related products***, on grounds relating to the specific situation of this Member State 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***. Such national provisions shall be notified to the Commission together with the grounds for ▌ introducing them.

The Commission shall, within six months from the date of receiving the notification ***under this paragraph***, approve or reject the provisions after having verified, taking into account the high level of health protection 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 this period the national provisions shall be deemed to be approved.

Article 25

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [Publications Office, please insert the exact date: entry into force + ***24*** months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those measures from [Publications Office, please insert the exact date: entry into force + 24 months], without prejudice to Articles 6.12, 9.1(e), 14.10 and 14a.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.*** 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 26

Transitional provision

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + ***36*** months]:

(a) tobacco products ***manufactured or released for free circulation and labelled in accordance with Directive 2001/37/EC before [Publications Office, please insert exact date: entry into force + 24 months]***;

(b) ***electronic cigarettes or refill containers manufactured or released for free circulation before [Publications Office, please insert the exact date: entry into force + 30 months]***;

(c) herbal products for smoking ***manufactured or released for free circulation before [Publications Office, please insert the exact date: entry into force + 24 months]***;

Article 27

Repeal

Directive 2001/37/EC is repealed ***with effect from [Publications Office, please insert exact date: entry into force + 24 months], 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***.

Article 28

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 29

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

List of text warnings

(referred to in Article 9 and Article 10(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 9(1))

Existing list according to Commission Decision of 26/5/2005 on the library of selected source documents containing colour photographs or other illustrations for each of the additional warnings listed in Annex 1 to Directive 2001/37/EC of the European Parliament and of the Council (doc. (C2005) 1452 final) shall be inserted here before the adoption of the Directive.

ANNEX III

Correlation table to be inserted.