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NOTE

from:	Presidency
to:	Council
No. Cion prop.:	18068/12 SAN 377 MI 850 FISC 206 CODEC 3117
No. prev. doc.:	10335/13 SAN 187 MI 473 FISC 114 CODEC 1268
Subject:	**Council (Employment, Social Policy, Health and Consumer Affairs) on 20-21 June 2013** Proposal for a 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 (First reading) - *General approach*

I. INTRODUCTION

1. On 19 December 2012, the Commission submitted to the Council the above proposal, based on Article 114 of the TFEU.

2. In the European Parliament, ENVI is the responsible committee for this proposal and Ms Linda McAvan (S&D/UK) has been appointed rapporteur. Other EP committees for opinion are AGRI, IMCO, JURI, INTA and ITRE. The ENVI Committee organised a public hearing on 25 February and held a debate on 20 March, 24 April (presentation of the draft report) and 29 May (consideration of amendments). A workshop was organised on the subject of "electronic cigarettes" on 7 May 2013. The vote on the report for the plenary, including draft EP amendments, is planned in the ENVI Committee for 10-11 July 2013.

3. The Economic and Social Committee is consulted on a mandatory basis (Article 114.1 TFEU) and plans to adopt its opinion at plenary session on 10-11 July 2013 (Rapporteur: Mr Rodríguez García-Caro (ES)).

4. On 25 January 2013, the Coreper decided to consult the Committee of the Regions, which plans to adopt its opinion at plenary session on 3-4 July 2013 (Rapporteur: Mr Monago Terazza (ES/EPP)).

5. During the Irish Presidency, the Working party on Public Health held 13 meetings on this subject.

6. Until 4 March 2013 (deadline for National Parliaments to submit opinions on the application of the principles of subsidiarity and proportionality), the Commission received 7 reasoned opinions on this proposal. These opinions were submitted by the Swedish Parliament, the Romanian Chamber of Deputies, the Czech Chamber of Deputies, the Hellenic Parliament, the Italian Senate, the Portuguese Parliament and the Danish Parliament. The threshold of 18 votes provided by Protocol 2 to the TFEU was not reached. The additional reasoned opinions by the Bulgarian Parliament and the Italian Chamber of Deputies were issued on the EU Interparliamentary exchange system (IPEX) after the deadline mentioned above.

II. PRESIDENCY'S PROPOSAL

The Permanent Representatives Committee discussed the proposal on 14 June 2013. Taking into account that discussion, the Presidency is submitting to the Council the text in the Annex that in the Presidency's view represents a balanced compromise that should be agreeable to the majority of the Member States.

The key elements of the Presidency proposal are as follows:

1) With regard to the **labelling and packaging** of tobacco products, the Presidency is proposing to reduce the combined picture and text warnings for cigarettes, roll-your-own and water pipe tobacco from 75% to 70% on the front and back surface of a unit packet (Article 9.1 (c)) coupled with the black border of 1 mm outside of the surface reserved for the warning (Article 7.6). The Member States would have flexibility in deciding whether or not they apply these measures to other tobacco products for smoking (e.g. cigars, cigarillos and pipe tobacco). In addition, the use of stickers in certain situations is provided for in Article 7.3 (c). It is also possible for Member States to use tax stamps or identification marks for fiscal purposes on the top edge of the unit packets for an additional 3 years (Article 9.1 (e)). Different forms of packets for cigarettes and roll-your-own tobacco can continue to be used as a result of changes made in Article 8.3 and 9(1)(g);

2) The Presidency is proposing not to introduce a ban on **"slim" cigarettes** (Article 12 .2), but instead the Commission will report on market developments in cigarettes with a diameter less than 7.5mm (Article 23.2(e));

3) In relation to **characterising flavours**, the Presidency has clarified certain provisions of Article 6 while keeping the thrust of the Commission's proposal. Additives essential for the production process (e.g. sugar lost during the curing process) would not be prohibited. Those that result in a characterising flavour or increase addictiveness and toxicity should be prohibited (Article 6.1). The Member States and the Commission would be able to consult the independent advisory panel at Union level when making decisions on whether or not a product has a characterising flavour. Member State representatives will decide by QMV on implementing acts for uniform rules for the procedures to determine whether a product has a characterising flavour and the procedures for the independent advisory panel. The Commission would set maximum levels for additives based on specific experience gained in the EU, where product differentiation is permitted (Article 6.3 and 6.9). The Commission would be asked to report on the feasibility, benefits and possible impacts of a Union wide system for the regulation of ingredients used in tobacco products (Article 23.2(d)), a so called positive list;

4) The Presidency believes that Article 14 has an important role to play in **combating illicit trade** in tobacco products thus protecting Member States' tax revenues and legitimate businesses from the effects of illicit trade. In this regard, the ability to track and trace products beyond the first customer is of utmost importance. Unit packets of tobacco products would have to be marked with a unique identifier to ensure the traceability of the product through the supply chain, and with a security feature to guarantee the authenticity of the product. Technical standards, procedures and rules for tracking and tracing should be established by means of implementing acts by the Commission with the involvement of Member States experts.

5) A **ban on cross-border distance sales** is considered to be a very effective way of controlling the supply of non-compliant tobacco products, especially to young people. Given the existing evidence from Member States that have such a ban in place, the Presidency is proposing to introduce one at Union level (Article 16).

6) Member States would be able to introduce **stricter national measures** in certain areas, such as additives or certain aspects of labelling when justified for public health reasons. This has been clarified in Article 24.2. Such measures would have to be proportionate and not constitute a disguised restriction on trade between Member States.

7) Many concerns had been expressed about the number of **delegated acts** contained in the Commission's proposal. Therefore, the Presidency deleted or amended all but one in order to limit or better define the scope of the delegation. Where legally possible, some of the proposed delegated acts have been changed to implementing acts to ensure the full involvement of Member States experts.

Parliamentary reservations have been introduced by DK and UK.

III. CONCLUSION

The Council is invited to reach a general approach on the basis of the text set out in the Annex to this note.

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Proposals for additions to the Commission text are presented in ***bold italics*** while deletions to the Commission text are in ~~strikethrough~~. The latest proposals are indicated by ***bold italics underlined*** for additions and ~~strikethrough underlined~~ for deletions.

ANNEX

2012/0366 (COD)

Proposal for a

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 Article 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. ~~Due to~~ ***In order to reflect*** scientific, market and international developments, substantial changes are to be made ~~to that~~ ***and the*** Directive ***should be repealed and*** ~~For the sake of clarity it is appropriate to repeal Directive 2001/37/EC and to~~ replace***d*** it by a new Directive.

(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[2]. 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[3]. In 2010 a broad stakeholder consultation took place[4], 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[5].

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1 OJ L 194, 18.7.2001, p. 26.

2 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.

3 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

4 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

5 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 in particular to nicotine containing products, 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 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[6]. Of relevance are in particular 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 falls into more than one category, 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 ~~products~~ ***cigarettes*** which are exported from the Union. These maximum limits and this approach remain valid.

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[6] Council Decision (2004/513/EC) of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control, OJ L 213, 15.6.2004, p. 8.

(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, but efforts are ongoing to develop them.

(11) In relation to the fixing of maximum yields, it might be necessary and appropriate at a later date to adapt 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 reinforced. 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 where possible.***

(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 ~~,including smokeless tobacco products,~~ having a characterising flavour other than tobacco, which may facilitate uptake of tobacco consumption or affect consumption patterns. For example, in many countries, sales of mentholated products gradually increased even as smoking prevalence overall declined. A number of studies indicated that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people. Measures introducing unjustified differences of treatment between flavoured cigarettes (e.g. menthol and clove cigarettes) should be avoided.

(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 or toxicity of the product***. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. ~~Independent panels~~ ***An independent European advisory panel*** should be used ~~by the Member States and by the Commission~~ 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 should be prohibited in order to ensure uniform rules and a high level of health protection.

(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco ***and chewing tobacco*** ~~and smokeless tobacco which are mainly consumed by older consumers~~, 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.

(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[7].

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 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.

(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 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. ~~A~~ ***M***inimum ***dimensions*** ~~size~~ should be set for all health warnings to ensure their visibility and effectiveness.

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

(23) 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 opening mechanism. 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. ~~A recent study has also shown that smokers of slim cigarettes were more likely to believe that their own brand might be less harmful. This should be addressed.~~

(24) Tobacco products for smoking, other than cigarettes, ~~and~~ roll-your-own tobacco products ***and water pipe tobacco***, which are mainly consumed by older consumers ***and small population groups***, ~~should~~ ***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.

(25) 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 products, 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 ~~producers~~ ***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, under the auspices of an 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[8] 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[9]. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction to the internal market of a product that is addictive, has adverse health effects and is attractive to young people. For other smokeless tobacco products that are not produced for the mass market, ~~a strict~~ labelling and ingredients regulation is considered sufficient to contain market expansion beyond their traditional use.

(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 cross-border distance sales should be prohibited.***

~~Cross-border distance sales of tobacco facilitate access to tobacco products of young people and risk to undermine compliance with the requirements provided for by tobacco control legislation and in particular by this Directive.~~

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8 OJ L 359, 8.12.1989, p. 1.
9 OJ C 241, 29.8.1994.

~~Common rules on a notification system are necessary to ensure that this Directive achieves its full potential. The provision on notification of cross-border distance sales of tobacco in this Directive should apply notwithstanding the notification procedure set out in Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services[10]. Business to consumer distance sale of tobacco products is further regulated by Directive 97/7/EC of the European Parliament and the Council of 20 May 1997 on the protection of consumers in respect of distance contracts, which will be replaced by Directive 2011/83/EU of the European Parliament and the Council of 25 October 2011 on consumer rights, as of 13 June 2014.~~[11]

(31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. 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.

(33) Nicotine-containing products are sold on the Union market. The different regulatory approaches taken by Member States to address health and safety concerns associated with these products have a negative impact on the functioning of the internal market, in particular considering that these products are subject to significant cross-border distance sales including via the internet.

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10 OJ L 178, 17.7.2000, p. 1-16.

11 OJ L 144, 4.6.1997, p. 19-27 and OJ L 304, 22.11.2011, p. 64-88.

(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[12] provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. ***The transitional period should also be envisaged to allow those products that would in the future be subject to Directive 2001/83/EC to obtain marketing authorisation according to that Directive.*** This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

(35) Labelling provisions should be introduced for nicotine containing products below the threshold set out in this Directive drawing the attention of consumers to potential health risks. ***According to the WHO Study Group on Tobacco Product Regulation report (WHO Technical Report Series, no. 955) the chemical composition of these products is often unknown and there are few data on their emissions or actual human exposure and their health effects. Therefore ingredients reporting should be introduced.***

(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 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.

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12 OJ L 311, 28.11.2001, p. 67, as last amended by Directive 2011/62/EU, OJ L 174, 1.7.2011, p. 74.

(37) In order to ensure uniform conditions for the implementation of this Directive ~~, in particular~~ concerning the format of ingredients reporting, the determination of products with characterising flavours or with increased levels of toxicity and addictiveness**,** ~~and~~ the methodology for determining whether a tobacco product has characterising flavour, ***rules and standards for the unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties and the use of health warnings***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011[13].

(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 particular~~ 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 use of health warnings, ~~unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties,~~ reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco ***and chewing tobacco*** ~~and smokeless tobacco products~~ and reviewing the nicotine levels for nicotine containing products. 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.

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13 OJ L 55, 28.2.2011, p. 13-18.

(39) The Commission should monitor the developments and submit a report 5 years after the date of transposition of this Directive, ***and every 5 years thereafter,*** in order to assess whether amendments to this Directive are necessary. ***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.***

(40) ***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 take more restrictive measures in certain respects to protect public health. This is the case in relation to additives contained in tobacco products and to elements and features of the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of minimum common rules. Accordingly, Member States could, for instance, introduce provisions providing for 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.***

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.

(40a) In line with Article 114(4) of the Treaty, for aspects regulated by this Directive, Member States may maintain national provisions on grounds of public health if they so deem necessary.

(41) Member States should remain free to maintain or introduce national legislations applying to all products alike for aspects ***not regulated by*** ~~falling outside the scope of~~ 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), for nicotine containing products 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[14].

(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[15].

(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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[14] OJ L 204, 21.7.1998, p. 37-48.
[15] 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 proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), and the right to property (Article 17). The obligations imposed on manufacturers, importers and distributors of tobacco products are necessary to improve the functioning of the internal market while ensuring a high level of health and consumer protection as set out in Articles 35 and 38 of the Charter of Fundamental Rights of the European Union. The application of this Directive should respect the EU law and relevant international obligations.

HAVE ADOPTED THIS DIRECTIVE:

TITLE I – COMMON PROVISIONS

Article 1

Subject matter ~~**Aim**~~

The ~~aim~~ ***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) 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 nicotine-containing products and herbal products for smoking;

in order to facilitate the functioning of the internal market in tobacco and related products, taking as a basis a high level of health protection.

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 ***added to*** ~~contained in~~ a tobacco product, its unit packet or any outside packaging with the exception of tobacco leaves and other natural or unprocessed parts of tobacco plants;

(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 ~~distinguishable~~ ***clearly noticeable*** ~~aroma~~ ***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 observable before or upon intended use of the tobacco product;

(5) 'chewing tobacco' means a smokeless tobacco product ~~***made from spun tobacco***~~ 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[16];

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

(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;

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

(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 ~~service~~ ***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 ~~aroma~~ ***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, ~~or~~ 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 (leaves and other natural, processed or unprocessed parts of tobacco plants including expanded and reconstituted tobacco), as well as any substance ***or element*** present in a finished tobacco product including paper, filter, inks, capsules and adhesives;

(18)a '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 ***milli***grams;

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

(21) 'nicotine' means nicotinic alkaloids;

(22) 'nicotine-containing product' means a product usable for consumption by consumers via inhalation, ingestion or in other forms and to which nicotine is either added during the manufacturing process or self-administered by the user before or during consumption;

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

a) ***does not fall into any of the following categories***: ~~other than~~ 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 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;

(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~~, such as pipe tobacco, cigar, cigarillo~~ by at least 10% in at least ~~10~~ ***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 ~~10~~ ***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 0.3% 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 ~~adapt~~ ***decrease*** the maximum yields laid down in paragraph 1, ~~taking into account~~ ***where this is necessary based on*** scientific development***s*** ~~and~~ ***or*** internationally agreed standards.

3. Member States shall notify the Commission of ~~the~~ ***any*** maximum yields ~~that~~ they set for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. ~~Taking into account internationally agreed standards, where available, and based on scientific evidence and the yields notified by Member States, the~~

3a. ***The*** Commission shall ~~be empowered to~~ 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*** ~~adopt and adapt~~ maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes**.** ~~that increase in an appreciable manner the toxic or addictive effect of tobacco products beyond the threshold of toxicity and addictiveness stemming from the yields of tar, nicotine and carbon monoxide fixed in paragraph 1.~~

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**,** ~~and~~ nicotine ***and carbon monoxide*** indications shall be verified in accordance with ISO standard 8243.

2. The measurement referred to in paragraph 1 shall be ~~carried outor~~ verified by ~~testing~~ 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, ~~taking into account~~ ***where this is necessary based on*** scientific and technical developments ~~and~~ ***or*** internationally agreed standards.

4. Member States shall notify the Commission of ~~the~~ ***any*** methods of measurement ~~that~~ they use for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. ~~Based on these methods, and taking into account scientific and technical developments as well as internationally agreed standards, the~~

4a. ***The*** Commission shall ~~be empowered to~~ 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*** ~~adopt and adapt~~ 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***. 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)[17] 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[18].

The list shall also be accompanied by the ***relevant*** toxicological data ~~available to the manufacturer or importer~~ 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 other tests as may be laid down by the competent national authorities in order to assess the effects of substances on health, taking into account, *inter alia*, their addictiveness and toxicity.

2. Member States shall ensure the dissemination of information submitted in accordance with paragraph 1 on a ~~dedicated~~ 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 when discharging their obligations pursuant to paragraph 1.***

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17 OJ L 396, 30.12.2006, p. 1.
18 OJ L 353, 31.12.2008, p. 1–1355.

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 and 2. 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, relating to ingredients and emissions. 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 ~~alternative or~~ additional ***available*** sales ***volume*** data. ~~, as appropriate, to ensure that information on sales volume requested under this paragraph is reliable and complete~~.

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*** ~~has~~ access to the information ***for the purpose of applying this Directive.*** ~~at all times~~. ~~Other Member States shall have access to this information upon justified request.~~ Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

6. ~~Fees charged by Member States for receiving, storing, handling, analysing and publishing the information submitted to them under this Article, if any, shall not exceed the cost attributable to those activities.~~ ***Proportionate fees may be charged by Member States for receiving, storing, handling, analysing and publishing the information submitted to them under this Article.***

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 or toxicity 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. ~~In case the~~ ***Where the level of presence or concentration of certain additives or the combination thereof has resulted in the prohibition of a tobacco product pursuant to Article 6(1) in at least 3 Member States,*** ~~experience gained in the application of paragraphs 1 and 2 shows that a certain additive or a combination thereof typically impart a characterising flavour when it exceeds a certain level of presence or concentration~~ 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. ***In this case, the maximum level shall be set at the lowest maximum level of those that informed the national prohibitions.***

4. Member States shall prohibit the ~~use of 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, ~~or~~

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

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

   (d) additives that facilitate inhalation or nicotine uptake.

5. Member States shall prohibit the ~~use of~~ ***placing on the market of tobacco products containing*** flavourings in the***ir*** components ~~of tobacco products~~ such as filters, papers, packages, capsules or any technical features allowing modification of ~~flavour~~ ***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 ~~an appreciable~~ ***a significant and measureable*** manner at the stage of consumption the toxic or addictive effect 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. ~~In case scientific evidence and the experience gained in the application of paragraphs 7 and 8 shows that a certain additive or a certain quantity thereof amplify in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product~~ ***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, roll-your-own tobacco ***and chewing tobacco*** ~~and smokeless tobacco products~~ shall be exempted from the prohibitions laid down in paragraphs 1 and 5. The Commission shall ~~be empowered to~~ 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.

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 of the tobacco product.***

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.

~~3. In order to ensure their graphic integrity and visibility, health warnings shall be irremovably printed, indelible and in no way hidden or interrupted, including by tax stamps, price marks, tracking and tracing marks, security features or by any type of wrapper, pouch, jacket, box or other device or by the opening of the unit packet.~~

~~(4)~~***3***. Member States shall ensure that the health warnings ~~of the main surface of~~ ***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, pouches, 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 in pouches, on which printing is not technically possible due to the packaging material in use or economically disproportionate due to low production or sales volumes, the health warnings may be affixed by means of stickers, provided that such stickers are irremovable. The health warning 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)~~***4***. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets.

~~(6)~~***5***. ~~Member States shall not increase the size of the health warnings including by introduction of an obligation to surround the health warnings by a border.~~ The ~~actual~~ size of the health warnings shall be calculated in relation to the surface ***in question when the packet is closed*** ~~on which they are placed before the unit packet is opened.~~

6. ***Health warnings shall be surrounded by a black border of 1 mm in width outside the surface reserved for the warning.***

6a. When adapting a health warning pursuant to Articles 8.5, 9.3, 11.3 and 18.5, 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 warning***s.***

   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*** ~~sides~~ of the unit packets. ***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.*** These warnings shall have a width of not less than ~~20~~ ***16*** mm ~~and a height of not less than 43 mm~~. For roll-your-own tobacco ***in pouches the general warning and*** the information message shall be printed on the surface***s*** that become~~s~~ visible when opening the unit packet. ***For roll-your-own tobacco in cylindric packets the general warning shall be printed on the top surface of the packet and the information message on the bottom surface.*** Both the general warning and the information message shall cover 50% of the surface on which they are printed.

4. The general warning and information message referred to in paragraphs 1 and 2 shall be:

(a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States may determine the font size provided that the font size specified in 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;

4. ***5.*** The Commission shall be empowered to adopt delegated acts in accordance with Article 22

~~(a)~~ to adapt the wording of the ***information message*** ~~health warnings~~ laid down in paragraph ~~s 1 and~~ 2 to scientific and market developments;

~~(b) to define the position, format, layout and design of the health warnings laid down in this Article, including their font type and background colour.~~

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 ~~75~~ ***70*** % 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 70% 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 10mm 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 ~~64~~ ***53*** mm;

(ii) width: not less than ~~55~~ ***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 is displayed as nearly as possible ~~on~~ ***in*** equal numbers ~~of~~ ***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 ~~technical~~ ***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

~~c)~~ define the position, ~~format~~, layout, design, rotation and proportions of the health warnings. ***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.***

~~d) by way of derogation from Article 7(3), lay down the conditions under which health warnings may be broken during unit packet opening in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.~~

Article 10

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

1. ***Member States may exempt t***obacco for smoking other than cigarettes ~~and~~**,** roll-your-own tobacco ***and water pipe tobacco*** ~~shall be exempted~~ 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 i***n 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. ~~The text warnings listed in Annex I shall be rotated in such a way as to guarantee their regular appearance~~ ***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.

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 three 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 three official languages.

4. The health warning***s*** referred to in paragraph 1 shall comply with the requirements specified in Article 8(4), ***paragraphs (a) and (b).*** ~~The general warning and the text warning referred to in paragraph 1 shall be:~~

~~a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States may determine the point size of the font, 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;~~

~~b) centred in the area in which they are required to be printed, parallel to the top edge of the unit packet and any outside packaging;~~

~~c) surrounded by a black border not less than 3 mm and not more than 4 mm in width inside the surface reserved for the text of the warning.~~

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

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 ~~can~~ damage**s** your health and is addictive*

2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article ~~10~~ ***8***(4). 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 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*** ~~requirements~~ in paragraph~~s~~ 1 ~~and 2~~ ~~taking in~~to ~~account~~ scientific ~~and market~~ developments.

Article 12

Product ~~descriptions~~ *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 ~~by means that are false, misleading, deceptive or likely to~~ ***by*** create***ing*** an erroneous impression about its characteristics, health effects, hazards or emissions;

   (b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic ***properties or has other health or lifestyle benefits*** ~~otherwise positive health or social effects~~**;**

   (c) refers to ~~flavour,~~ taste, ***smell,*** any flavourings or other additives or the absence thereof;

   (d) resembles a food product.

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

   ~~Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.~~

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, i.e. a rectangular pocket with a flap that covers the opening. The flap of the pouch shall cover at least 70% of the front of the packet. 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 40 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 ~~the opening~~ ***it*** is first opened, other than the flip-top lid ***and shoulder box hinged lid.*** ~~The~~ ***For packets with a*** flip-top lid ***and hinged lid opening*** ~~of a cigarette packet~~, ***the lid*** shall be hinged only at the back of the packet.

3. ~~The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to define more detailed rules for the shape and size of unit packets in so far as these rules are necessary to ensure the full visibility and integrity of the health warnings before the first opening, during the opening and after reclosing of the unit packet.~~

4. The Commission shall ~~be empowered to~~ adopt delegated acts in accordance with Article 22 to make ~~either cuboid or cylindric~~ ***the packet*** shape***s for roll-your-own tobacco also*** mandatory for unit packets of ***other*** tobacco products ~~other than cigarettes and roll-your-own tobacco~~ if there is a substantial change of circumstances as established in a Commission report.

Article 14

Traceability ~~and security features~~

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 ~~name~~ ***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 accesible 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 ~~in~~ ***of*** aggregated ~~form~~ ***packaging*** ~~, e.g. of outside 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.~~ ***5.*** 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. ~~relating to the manufacturer and importer concerned.~~ 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 ~~transparency and~~ accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party ~~on a permanent basis~~. 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.

~~5.~~ ***6.*** Recorded data cannot be modified or deleted by any economic operator involved in the trade of tobacco products. ~~, but the economic operator that introduced the data and other economic operators directly concerned by the transaction such as the supplier or the recipient can comment on previously introduced data. The economic operator concerned shall add the correct data and a reference to the previous entry which requires rectification in their view. In exceptional circumstances and upon submission of adequate evidence, the competent authority in the Member State in which the recording took place or if the recording took place outside the Union the competent authority in the Member State of importation, can authorise the modification or deletion of data previously registered.~~

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.

~~8. In addition to the unique identifier, Member States shall require that all unit packets of tobacco products which are placed on the market carry a visible, tamper proof security feature of at least 1 cm², 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.~~

~~9~~ ***8***. The Commission shall, ***by means of implementing acts*** ~~be empowered to adopt delegated acts in accordance with Article 22 to~~:

(a) determine the rules and standards for the tracking and tracing system as defined in this Article, including marking, recording, transmitting, processing, storing of data and their accessibility;

(b) ~~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;

~~8a. The Commission shall,be empowered to adopt delegated acts in accordance with Article 22:~~

(c) ~~to define~~ ***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.~~ and~~

~~(c) to 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.

9. Paragraph 1 to 7 shall apply to cigarettes and roll-your-own tobacco 2 years following the date referred to in paragraph 1 of Article 25 and to tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the application of paragraphs 1 to 7 during a period of 7 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, tamper proof security feature ~~of at least 1 cm²~~, 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 2 years following the date referred to in paragraph 1 of Article 25 and to tobacco products other than cigarettes and roll-your-own tobacco 7 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. ***The placing on the market of tobacco products by means of cross-border distance sales to consumers shall be prohibited with effect from two years following the date referred to in paragraph 1 of Article 25.***

   ~~***Member States may prohibit cross-border distance sales of tobacco products on grounds of public health. Retail outlets engaging in cross-border distance sales of tobacco products may not supply consumers in Member States where such sales have been prohibited. In all other cases*** Member States 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 the public ***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*** publish the complete 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*** the name of the retail outlet is published 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 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 and market research on preferences of various consumer groups, including young people and

(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 – NON TOBACCO PRODUCTS

Article 18

Nicotine-containing products

1. The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:

(a) products with a nicotine level ***equal to or*** exceeding ***1*** ~~2~~ mg per unit, or

(b) products with a nicotine concentration ***equal to or*** exceeding ***2*** ~~4~~ mg per ml. ~~or~~

~~(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.~~

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 ~~taking into account~~ ***where this is necessary based on*** scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine ***which is an addictive substance*** *and can damage your health.*

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article ~~10~~ ***8***(4). 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~~ ***size*** shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the ***wording of the health warning*** ~~requirements~~ in paragraph~~s~~ 3 ~~and taking into account~~ ***based on*** scientific and market developments ~~and to adopt and adapt the position, format, layout, designand rotation of the health warnings~~.

5a. The provisions of of paragraphs (3) to (5) of this article shall be without prejudice to the application of Directive 2001/83/EC.

6. Nicotine-containing products referred to in Article 18(1) and which are placed on the market before [entry into force + 24 months], may continue to be marketed until [entry into force + 36 months].

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:

   ~~*This*~~ *Smoking this product ~~can~~ 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 ~~10~~ **8**(4). It shall cover ~~not less than~~ 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 three 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 and nicotine-containing products not authorised pursuant to Directive 2001/83/EC and which fall below the thresholds set out in Article 18(1) 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.

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.

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 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), 4(3), 4(4***a***), 6(3), 6(9), 6(10), 8(***5***), 9(3), 10(5), 11(3), ~~13(3),~~ 13(4), ~~14(9),~~ 18(2) and 18(5) shall be conferred on the Commission ~~for an indeterminate period of time from~~ ***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), 4(3), 4(4***a***), 6(3), 6(9), 6(10), 8(***5***), 9(3), 10(5), 11(3), ~~13(3),~~ 13(4), ~~14(9),~~ 18(2) and 18(5) 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), 4(3), 4(4***a***), 6(3), 6(9), 6(10), 8(***5***), 9(3), 10(5), 11(3), ~~13(3),~~ 13(4), ~~14(9),~~ 18(2) and 18(5**)** 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 every five years 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;

(e) market developments in cigarettes with a diameter of less than 7.5mm.

(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.

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 ~~accompanied~~ ***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

Import, sale and consumption of tobacco and related products

1. Member States ~~shall~~ ***may*** not ***for considerations relating to aspects regulated by this Directive, and with the exception of those set out in paragraphs 2 and 3*** prohibit or restrict the import, sale or consumption of tobacco or related products which comply with this Directive.

2. ***This Directive shall not affect the right of Member States to introduce more stringent rules, applicable to all products alike, in relation to additives or a combination thereof which lead to a prohibition of placing a tobacco product on the market, and in relation to the prohibition of elements and features on a unit packet and any outside packaging, including colours, and the tobacco product itself for reasons beyond those provided for in Article 12(1) of this Directive, 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 introducing them.***

3. ~~However, a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health.~~

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, 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.

~~3. This Directive shall not affect the right of Member States to maintain or introduce, in accordance with the Treaty, national provisions concerning aspects not regulated by this Directive. These national provisions must be justified by overriding reasons of public interest and be necessary and proportionate to their aim. They must not be a means of arbitrary discrimination or a disguised restriction on trade between the Member States and must not jeopardise the full application of this Directive.~~

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 + ~~18~~ ***24*** months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those measures from [insert entry into force + 24 months], without prejudice to Articles 9.1(e), 14.9, 14a.3 and 16.

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 + ~~24~~ ***36*** months]:

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

(b) nicotine containing products below the threshold set out in Article 18(1);

(c) herbal products for smoking.

Article 27

Repeal

Directive 2001/37/EC is repealed ***with effect from [insert 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 II**I**.

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.