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AMENDMENTS 001-086

by the Committee on the Environment, Public Health and Food Safety

Report

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A7-0276/2013

Manufacture, presentation and sale of tobacco and related products

Proposal for a directive (COM(2012)0788 – C7-0420/2012 – 2012/0366(COD))

Amendment 1

Proposal for a directive

Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) Health warnings serve as part of an organised, effective and long term anti-smoking strategy, with well defined scope and objectives.

Justification

The effectiveness of a health warning is linked to its being part of an organised, anti-smoking strategy, with well defined scope and objectives.

Amendment 2

Proposal for a directive

Recital 6

Text proposed by the Commission

Amendment

(6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production

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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.

for the whole of the Union in only a small number of production plants within the Member States and the resulting significant cross-border trade of tobacco and related products calls for ***stronger*** legislative action at Union level to achieve the smooth operation of the internal market.

Amendment 3

Proposal for a directive

Recital 7

Text proposed by the Commission

(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***. 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.

Amendment

(7) Legislative action at Union level is also necessary to implement the ***landmark*** WHO Framework Convention on Tobacco Control ("FCTC") of May 2003. ***All Member States, and*** the European Union ***itself, have signed and ratified the FCTC and as a result are bound under international law by its provisions***. Of particular ***relevance are*** 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.

Justification

The WHO FCTC is the first international treaty on health. Its provisions are legally binding on Member States in the same way as, for example, WTO rules.

Amendment 4

Proposal for a directive

Recital 8

Text proposed by the Commission

(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.

Amendment

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union ("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. ***To that end, Member States should promote smoking prevention campaigns, especially in schools and through the media. In accordance with the principle of producer responsibility, manufacturers of tobacco products should be made responsible for all health costs arising as a consequence of tobacco consumption.***

Amendment 5

**Proposal for a directive
Recital 9 a (new)**

Text proposed by the Commission

Amendment

(9a) Given that in many Member States large percentages of smokers are unlikely to stop smoking entirely, legislation should take into account their right to know objectively the impact the possible use of tobacco has on their health - information which they also receive through the packaging of the product they are likely to use.

Justification

Given that there are still large percentages of smokers in the EU, the Directive should also seek to improve the health of those who already smoke and who for whatever reason seek to continue to use tobacco or nicotine products.

Amendment 6

Proposal for a directive

Recital 10

Text proposed by the Commission

(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. For other emissions there are no internationally agreed standards or tests for quantifying the yields, but efforts are ongoing to develop them.

Amendment

(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. For other emissions there are no internationally agreed standards or tests for quantifying the yields, but ***Member States and the Commission should actively encourage*** ongoing efforts ***at international level*** to develop such standards or tests.

Amendment 7

Proposal for a directive

Recital 10 a (new)

Text proposed by the Commission

Amendment

(10a) Polonium 210 has been shown to be a significant carcinogen in tobacco. Its presence in cigarettes could be eliminated almost completely by a combination of simple measures. It is thus appropriate to set a maximum yield for Polonium 210 that would result in a reduction of 95% of the current average content of Polonium 210 in cigarettes. An ISO standard to measure Polonium 210 in tobacco should be developed.

Justification

Polonium 210 is a decay product of uranium that is present in fertilizers made from uranium-rich phosphate rock. It contaminates tobacco leaves through the air via Radon 222 and through the roots via Lead 210. When burnt, Polonium 210 evaporates, and is thus inhaled by smokers. It is an alpha emitter. Alpha radiation is innocuous outside the body, but once inside the human body it is 'the most hazardous form of radiation' (The Polonium Brief, Brianna Rego, Isis, 2009).

Amendment 8

Proposal for a directive

Recital 11

Text proposed by the Commission

(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.

Amendment

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

Justification

The Commission should only need to reduce TNCO yields, and any other levels set for toxic or addictive emissions in the future, in line with the direction of international standards.

Amendment 9

Proposal for a directive

Recital 13

Text proposed by the Commission

(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.

Amendment

(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, **in particular the rights of small and medium sized enterprises (SMEs).**

Justification

Common electronic format valid for all Member States will make reporting obligations easier. This should be an advantage for SMEs.

Amendment 10

Proposal for a directive Recital 14

Text proposed by the Commission

(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.

Amendment

(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.
Ingredients that increase addictiveness and toxicity should also be removed.

Amendment 11

Proposal for a directive Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) In order to protect human health, an assessment should be carried out on

the safety of additives for use in tobacco products. Additives should only be allowed in tobacco products if they are included in a Union list of authorised additives. That list should also indicate any conditions or restrictions on the use of allowed additives. Tobacco products containing additives not included in the Union list or used in a manner that does not comply with this Directive should not be placed on the Union market

Amendment 12

Proposal for a directive Recital 14 b (new)

Text proposed by the Commission

Amendment

(14b) It is important not only to consider the properties of additives as such, but also of their combustion products. Additives as well as their combustion products should not be such that they meet the criteria for classification as hazardous in accordance with 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 mixtures¹.

¹ OJ L 353, 31.12.2008, p. 1.

Justification

Only additives that are not hazardous - as such or upon combustion - should be allowed.

Amendment 13

Proposal for a directive Recital 15

Text proposed by the Commission

(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.

Amendment

(15) The likelihood of diverging regulation is further increased by concerns over tobacco products having a characterising flavour other than tobacco, which may facilitate uptake of tobacco consumption or affect consumption patterns. 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.

Amendment 14

Proposal for a directive

Recital 16

Text proposed by the Commission

(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufactures 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 should be allowed, as long as they do not result in a characterising flavour.. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels 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

Amendment

deleted

between different tobacco varieties.

Amendment 15

Proposal for a directive

Recital 17

Text proposed by the Commission

(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.

Amendment

(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. ***In order to ensure uniform rules and a high level of health protection, those additives should not be approved. In addition, additives which impart a characterising flavour should not be approved. This should not result in prohibiting the use of individual additives altogether. Manufactures should, however, be required to reduce the use of an additive or of a combination of additives to such an extent that the additives no longer result in a characterising flavour. It should be possible to approve the use of additives that are essential for manufacturing of tobacco products, as long as those additives do not result in a characterising flavour and are not linked to the attractiveness of such products.***

Amendment 16

Proposal for a directive

Recital 17 a (new)

Text proposed by the Commission

Amendment

(17a) An increasing number of people, most of them children, suffer from asthma and various allergies. Not all causes of asthma are understood, as indicated by WHO, but it is necessary for risk factors including allergens, tobacco and chemical

irritants to be prevented in order to improve people's quality of life.

Amendment 17

Proposal for a directive Recital 18

Text proposed by the Commission

(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own 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.

Amendment

(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco and **water-pipe** 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.

Amendment 18

Proposal for a directive Recital 18 a (new)

Text proposed by the Commission

Amendment

(18a) Member States should be encouraged, if they have not already done so, to formulate their national laws on the protection of young people in such a way that tobacco products may not be sold to, or consumed by, young people under the age of 18; Member States should also ensure that such prohibitions are respected;

Amendment 19

Proposal for a directive Recital 18 b (new)

(18b) The FCTC in article 16 points to the responsibility of Parties to the Convention to address products aimed at underage consumers, such as food products and toys in the form of tobacco products that may be appealing to minors. In recent years, several products, such as shisha vaping sticks, have been placed on the market that do not contain nicotine but have the form of cigarettes and try to imitate the smoking process through vaporising substances, the harmless nature of which is not yet scientifically proven, and through an electric light imitating the burning process of a cigarette. Such products are clearly produced to be appealing to young and underage consumers, and are increasingly popular by minors in several Member States. Increasing concern is expressed at the habits created by young consumers and minors by the use of such imitation cigarettes. Therefore, these products should be prohibited through this directive.

Amendment 20

Proposal for a directive Recital 20

(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.

(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 ***harmonising*** action at Union level, the existing disparities are likely to increase in the coming years.

Amendment 21

Proposal for a directive

Recital 22

Text proposed by the Commission

(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 minimum size should be set for all health warnings to ensure their visibility and effectiveness.

Amendment

(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 ***picture and text*** 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 ***on the field of vision on all sides*** of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.

Amendment 22

Proposal for a directive

Recital 23

Text proposed by the Commission

(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',

Amendment

(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. 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',

'without additives', 'without flavours', 'slim', names, pictures, and figurative or other signs. 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.

'slim', names, pictures, and figurative or other signs. ***Certain packages and products could also mislead by suggesting benefits relating to 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.

Amendment 23

Proposal for a directive Recital 23 a (new)

Text proposed by the Commission

Amendment

(23a) Tobacco products have been shown to contain and emit many noxious substances and known carcinogens hazardous to human health when burnt. Scientific studies have clearly proven that passive smoking is a cause of death, illness and disability and that passive smoking is dangerous in particular to unborn children and infants. It can cause or aggravate respiratory problems in persons inhaling smoke. Health warnings should therefore also draw attention to the dangers to health of passive smoking.

Justification

This recital is contained in the current Directive 2001/37/EC. There should be specific text and pictorial warnings drawing attention to the dangers of passive smoking.

Amendment 24

Proposal for a directive Recital 24

Text proposed by the Commission

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

Amendment

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

Amendment 25

Proposal for a directive

Recital 26

Text proposed by the Commission

(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

Amendment

(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 **and any outside transport packaging** 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

of whether or not products are authentic.

features that will facilitate the verification of whether or not products are authentic, ***and to ensure that the unique identifiers of unit packets are linked to the unique identifier on the outside transport packaging.***

Amendment 26

Proposal for a directive

Recital 28

Text proposed by the Commission

(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.

Amendment

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

Amendment 27

Proposal for a directive

Recital 29

Text proposed by the Commission

(29) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC confirmed this prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden

Amendment

(29) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC confirmed this prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden

grants the Kingdom of Sweden derogation from this prohibition. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction 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.

grants the Kingdom of Sweden derogation from this prohibition. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction to the internal market of a product that is addictive, has adverse health effects and is attractive to young people.

Amendment 28

Proposal for a directive Recital 29 a (new)

Text proposed by the Commission

Amendment

(29a) Given the general prohibition of the sale of oral tobacco (snus) in the Union, there is no cross-border interest in regulating the content of snus. The responsibility for regulating the content of snus thus lies with the Member State where the sale of snus is permitted in accordance with Article 151 of the Act of Accession of Austria, Finland and Sweden. Snus should therefore be exempt from the provisions of Article 6 of this Directive.

Amendment 29

Proposal for a directive Recital 30

Text proposed by the Commission

Amendment

(30) 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. ***Common rules on a notification system are***

(30) Cross-border distance sales of tobacco ***should be prohibited as they*** facilitate ***young people's*** access to tobacco products and risk ***undermining*** compliance with the requirements ***of*** this Directive.

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. 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.

Amendment 30

Proposal for a directive Recital 30 a (new)

Text proposed by the Commission

Amendment

(30a) Directive 2003/33/EC on advertising and sponsorship of tobacco products already prohibits the free distribution of such products in the context of the sponsorship of events. This Directive, which regulates aspects relating to the presentation and sale of tobacco and aims to achieve a high level of health protection and prevention of tobacco consumption among young people, extends the scope of the ban on free distribution to public places and specifically prohibits the distribution of printed material, discount coupons and similar special offers inside packages and wrappings.

Amendment 31

Proposal for a directive

Recital 30 b (new)

Text proposed by the Commission

Amendment

(30b) The Commission and the Member States should commit themselves to the effective implementation of the Protocol to the FCTC to eliminate illicit trade in tobacco products. Efforts should be made to prevent and improve the control of illegal trafficking of tobacco products manufactured in third countries.

Amendment 32

Proposal for a directive

Recital 31

Text proposed by the Commission

Amendment

(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.

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

Amendment 33

Proposal for a directive

Recital 33

Text proposed by the Commission

(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.**

Amendment

(33) Nicotine-containing products - **including e-cigarettes** - are sold on the Union market. **However Member States have taken** different regulatory approaches to **address** health and safety concerns associated with these products. **There is a need for harmonized rules, and all nicotine-containing products should be regulated through a medicines regime which recognises the well-established use of nicotine. Given the potential of such products to aid with smoking cessation, Member States should ensure that they can be made available outside pharmacies.**

Amendment 34

Proposal for a directive
Recital 34

Text proposed by the Commission

(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 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

Amendment

(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 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. **However, measuring nicotine delivery has proven to be difficult, as it depends on the products and how they are being used. Therefore, making all nicotine-containing products, regardless of their nicotine content, subject to Directive 2001/83/EC, while recognising the well-established use of nicotine,** clarifies the legal situation, levels out differences between national legislations,

purposes and creates incentives for research and innovation in smoking cessation. 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.

ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. 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.

Amendment 35

Proposal for a directive

Recital 35

Text proposed by the Commission

(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.

Amendment

deleted

Amendment 36

Proposal for a directive

Recital 35 a (new)

Text proposed by the Commission

(35a) Member States should ensure that nicotine-containing products are not sold to persons below the age required for purchasing tobacco products or related products.

Amendment

Amendment 37

Proposal for a directive

Recital 37

Text proposed by the Commission

(37) In order to ensure uniform conditions

Amendment

(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***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

for the implementation of this Directive, in particular concerning the format of ingredients reporting, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.

Amendment 38

Proposal for a directive Recital 38

Text proposed by the Commission

(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 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

Amendment

(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, ***approving additives as necessary***, 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, ***and*** reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco, ***water pipe tobacco***. 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

ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Council.

Amendment 39

Proposal for a directive

Recital 39

Text proposed by the Commission

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

Amendment

(39) The Commission should monitor the developments and submit a report **three** years after the date of transposition of this Directive, in order to assess whether amendments to this Directive are necessary, ***in particular as regards packaging.***

Amendment 40

Proposal for a directive

Recital 39 a (new)

Text proposed by the Commission

Amendment

(39a) Member States have an important responsibility in protecting public health and taking preventive action, providing public guarantees, monitoring and advice for young people, and carrying out preventive public anti-smoking campaigns, particularly in schools. Universal free access to smoking cessation consultations and corresponding treatments is considered vital.

Amendment 41

Proposal for a directive

Recital 40

Text proposed by the Commission

(40) A Member State that deems it necessary to maintain more stringent national provisions for aspects falling inside the scope of this Directive should be allowed to do so, for all products alike, ***on grounds of overriding needs relating to the protection of public health. A Member State should also be allowed to introduce more stringent provisions, applying to all products alike, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. More stringent national provisions should be necessary and proportionate, not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.*** Stricter national provisions require prior notification to, and approval from, the Commission taking into account the high level of health protection achieved through this Directive.

Amendment

(40) A Member State that deems it necessary to maintain ***or introduce*** more stringent national provisions for aspects falling inside the scope of this Directive should be allowed to do so, for all products alike, ***insofar as such measures are compatible with the TFEU.*** Stricter national provisions require prior notification to, and approval from, the Commission taking into account the high level of health protection achieved through this Directive.

Amendment 42

Proposal for a directive

Recital 42

Text proposed by the Commission

(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.

Amendment

(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. ***It is essential that National data protection provisions also be taken into account.***

Amendment 43

Proposal for a directive

Recital 45

Text proposed by the Commission

(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.

Amendment

(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 **of trademark holders** (Article 17). **It is therefore necessary to ensure that the** obligations imposed on manufacturers, importers and distributors of tobacco products **not only guarantee** a high level of health and consumer protection, **but also protect all other fundamental rights and are proportionate with respect to the functioning of the internal market.** The application of this Directive should respect the Union law and relevant international obligations.

Amendment 44

Proposal for a directive

Recital 45 a (new)

Text proposed by the Commission

Amendment

(45a) Member States should respect the right to clean air within the spirit of Articles 7 (b) and 12 of the International Covenant on Economic, Social and Cultural Rights providing for rights for safe and healthy working conditions and the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. This is within the aim of article 37 of the Charter of Fundamental rights where a high level of environmental protection and the improvement of the quality of the

environment must be integrated into the policies of the Union.

Amendment 45

Proposal for a directive Article 1

Text proposed by the Commission

The aim 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.

Amendment

The aim 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) ***the prohibition of*** 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 ***meet obligations under the WHO Framework Convention for Tobacco Control and in order*** to facilitate the functioning of the internal market in tobacco and related products, taking as a ***base*** a high level of health protection, ***especially for young people.***

Amendment 46

Proposal for a directive Article 2

Text proposed by the Commission

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 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 unambiguously confirms the consumer's age in electronic form according to national requirements;
- (4) 'characterising flavour' means a distinguishable aroma 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 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;
- (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

Amendment

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 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 unambiguously confirms the consumer's age in electronic form according to national requirements;
- (4) 'characterising flavour' means a distinguishable aroma or taste other than tobacco, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy, menthol or vanilla *which is* observable before or upon use of the tobacco product;
- (5) 'chewing tobacco' means a smokeless tobacco product exclusively designed for the purpose of chewing;
- (6) 'cigar' means a roll of tobacco consumed via a combustion process and further defined in Article 4(1) of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco;
- (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

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 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 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 which contains no tobacco and is consumed via a combustion process;

(16) 'import of tobacco and related

and is further defined in Article 8 paragraph 1 of Council Directive 2007/74/EC;

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

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

(11) 'cross-border distance sales' means a distance sales service 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 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 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 present in a finished tobacco product including paper, filter, inks, capsules and adhesives;

(19) 'maximum level' or 'maximum yield' means the maximum content or emission, including 0, of a substance in a tobacco product measured in 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 other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use placed on the market after entry into force of this Directive;

(24) 'outside packaging' means any packaging in which products are placed on

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

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

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

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

(19) 'maximum level' or 'maximum yield' means the maximum content or emission, including 0, of a substance in a tobacco product measured in 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 other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use 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** 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

the market and which include a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;

(24a) 'outside transport packaging' means any packaging, consisting of an aggregation of unit packets, in which tobacco products are transported from the manufacturer to the subsequent economic operators before being placed on the market, such as cartons, master cases and pallets;

(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;

(26a) 'water pipe tobacco' means tobacco intended solely for use in a water 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 **five** 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** 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;

(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;

(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 occurring 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.

least **five** 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;

(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;

(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 occurring 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.

(36a) 'imitation tobacco products' means sweets, snacks, toys or any other objects in the form of tobacco products which may appeal to minors. These products shall be prohibited.

(36b) 'passive smoking' means the involuntary inhalation of smoke from the combustion of cigarettes or cigars or from the exhalation of one or more smokers.

Justification

According to the Article 16 of the WHO FCTC which was ratified by the European Community 30/06/2005 conference of parties shall prohibit the sales of tobacco products to persons under

the age by banning imitation tobacco products. The EU legislation shall be adjusted to international obligations.

Amendment 47

Proposal for a directive

Article 3

Text proposed by the Commission

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** the maximum yields laid down in paragraph 1, **taking** into account scientific development and internationally agreed standards.

3. Member States shall notify the Commission of the 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 on the yields notified by Member States**, the Commission shall **be empowered to** adopt delegated acts in accordance with Article 22 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**

Amendment

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 **reduce** the maximum yields laid down in paragraph 1, **where necessary, in order to take** into account scientific development and internationally agreed standards.

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

in paragraph 1.

Amendment 48

Proposal for a directive

Article 4

Text proposed by the Commission

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 indications shall be verified in accordance with ISO standard 8243.

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

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

Amendment

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

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

2. The measurement referred to in paragraph 1 shall be carried out or verified by **independent** testing laboratories which are approved and monitored by the competent authorities of the Member States.

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.

2a. The Commission shall ask ISO to develop a standard to measure Polonium 210 in tobacco.

2b. Tests verifying the validity of the result supplied by the tobacco companies shall be done on a regular basis by independent testing laboratories monitored by the competent authorities of the Member States.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to **supplement or amend** the methods of measurement of the tar,

carbon monoxide yields, taking into account scientific and technical developments and internationally agreed standards.

4. Member States shall notify the Commission of the 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 Commission shall **be empowered** to adopt delegated acts in accordance with Article 22 to **adopt and adapt** methods of measurement.

nicotine and carbon monoxide yields, taking into account scientific and technical developments and internationally agreed standards.

4. Member States shall notify the Commission of the methods of measurement that they use for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. The Commission shall adopt delegated acts in accordance with Article 22 to **integrate into Union law methods agreed by the parties to the FCTC or WHO**.

4a. The accuracy of the indications for the other emissions of other combustible tobacco products shall be verified in accordance with ISO standard 8243.

Amendment **49Proposal for a directive**
Article 5

Text proposed by the Commission

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. 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 shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. The list shall indicate

Amendment

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. 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 shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. The list shall 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) 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. The list shall also be accompanied by the 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. 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

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) 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. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt *and* unburnt form, *and that is at least sufficient to classify those substances pursuant to Regulation 1272/2008*, referring in particular to their effects on health of consumers and taking into account, inter alia, any addictive effects. Regarding the emissions and yields of tobacco products, The list shall be established in descending order of the weight of each ingredient included in the product. *Manufacturers and importers of tobacco products shall submit the list of ingredients and all the accompanying information referred to above no later than ...* *

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 website, which is available to the general public. In doing so Member States shall take due

shall take due account of the need to protect information which constitutes a trade secret.

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 sales 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 has access to the information at all times. Other Member States shall have access to this information upon justified request. Member States and the

account of the need to protect information which constitutes a trade secret.

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 ***and chronic heavy smokers, as well as working summaries of any market surveys they carry out when launching new products.*** Member States shall also require manufacturers and importers to report the sales volume data per product, reported in sticks or kilograms, and per Member State on a yearly basis starting from the full calendar year following that of the entry into force of this Directive. Member States shall provide alternative or additional sales data, as appropriate, to ensure that information on sales volume requested under this paragraph is reliable and complete.

4a. Member States shall require manufacturers and importers to disclose their expenditure on advertising, promotion and sponsorship per Member State, on a yearly basis starting from the full calendar year following ...**

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 has access to the information 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.

Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

5a. The Commission shall analyse all the information made available under this Article (particularly information relating to the addictiveness and toxicity of ingredients, market research and sales data) and shall produce a regular report to the European Parliament and the Council summarising the main findings.

5b. The information collected pursuant to this Article shall be taken into account for the purpose of the approval of additives in accordance with Article 6(10a).

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.

6. ***Proportionate fees*** may be charged by Member States for receiving, storing, handling, analysing and publishing the information submitted to them under this Article.

* OJ: Please insert the date: 18 months after the entry into force of this Directive.

** OJ: Please insert the ***year of the entry into force of this Directive.***

Justification

As per the requirements of Article 13 of the WHO FCTC. This figure is currently not available for the EU.

Amendment 50

Proposal for a directive Article 6

Text proposed by the Commission

1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour.

Amendment

1. Additives shall not be used in tobacco products unless they are approved in accordance with this Directive. Approved additives shall be included in the list set out in Annex [-I]. Any conditions or restrictions on use of approved additives

shall also be indicated in the list. The placing on the market of tobacco products containing additives not listed in Annex [-I] or used not in compliance with any conditions or restrictions laid down in that Annex to this Directive shall be prohibited.

The following additives may not be approved:

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

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

(c) additives having colouring properties for emissions;

(d) additives that meet the criteria for classification as hazardous substances in accordance with Regulation (EC) No 1272/2008, or that result in such substances upon combustion;

(e) additives which, when used, may impart a characterising flavour.

(f) additives that increase at the stage of consumption the toxic or addictive effect of a tobacco product.

Notwithstanding point (e) of the previous subparagraph, where a certain additive or combination thereof typically imparts a characterising flavour only when it exceeds a certain level of presence or concentration, the additive or additives in question may be approved provided that maximum allowed levels are set.

Notwithstanding point (f) of the second subparagraph, where a certain additive amplifies at the stage of consumption the toxic or addictive effect of a tobacco product only when it exceeds a certain level of presence or concentration, including standard safety margins, the additive in question may be approved provided that maximum allowed levels are

Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products, as long as the additives do not result in a product with a characterising flavour.

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.

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.

3. In case the 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.

4. Member States shall prohibit the use of the following additives in tobacco products:

set.

*Additives which are essential for the manufacture of tobacco products **may be approved** as long as the additives do not result in a product with a characterising flavour **and are not linked to the attractiveness of tobacco products**. **The reconstitution of sugar compounds in tobacco products up to the levels present in tobacco leaves prior to cutting shall be deemed as not resulting in a characterising flavour or increasing attractiveness of tobacco products.***

(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.

5. Member States shall prohibit the use of flavourings in the components of tobacco products such as filters, papers, packages, capsules or any technical features allowing modification of flavour or smoke intensity. Filters and capsules shall not contain tobacco.

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 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

5. The use of flavourings in the components of tobacco products such as filters, papers, packages, capsules or any technical features allowing modification of flavour or smoke intensity shall be prohibited. Filters and capsules shall not contain tobacco.

stage of consumption the toxic or addictive effect of a tobacco product the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives.

10. Tobacco products other than cigarettes, roll-your-own 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 if there is a substantial change of circumstances as established in a Commission report.

10. Tobacco products other than cigarettes, roll-your-own tobacco and *water pipe tobacco* shall be exempted from the *application of point (e) of the second subparagraph of paragraph 1, and paragraph 5*. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is a substantial change of circumstances as established in a Commission report.

10a. In order to obtain the approval of an additive, manufacturers and importers shall make an application to the Commission. The application shall be accompanied by the following particulars:

(a) name or corporate name and permanent address of the applicant;

(b) chemical name of the additive;

(c) function of the additive and maximum quantity to be used per cigarette;

(d) clear evidence supported by scientific data that the additive does not fall under any of the exclusion criteria listed in this Article.

The Commission may ask the relevant scientific committee whether the additive concerned falls under any of the exclusion criteria listed in this Article as such, or only as of a certain concentration. The Commission shall take a decision on the application no later than six months after receiving the application.

The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to approve the additive, with allowed maximum levels where relevant, and amend Annex [-I] accordingly.

10b. This Article shall be without prejudice to the application to tobacco

products of the relevant provisions of Regulation (EC) No 1907/2006 or of any conditions set pursuant to that Regulation.

10c. This Article shall apply as from*

** OJ: Please insert date: 36 months from the entry into force of this Directive*

Amendment 51

Proposal for a directive Article 7

Text proposed by the Commission

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. Member States shall ensure that the health warnings *of the main surface* of the unit packet and any outside packaging are fully visible, including not being partially or totally hidden or interrupted by wrappers, pouches, jacket, boxes or other

Amendment

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. ***In the case of tobacco products other than cigarettes, roll-your-own, water-pipe tobacco and smokeless tobacco products health warnings may be affixed by means of stickers, provided that such stickers cannot be removed.***
4. Member States shall ensure that the health warnings ***on the fields of vision on all sides*** of the unit packet and any outside packaging are fully visible, including not being partially or totally hidden or interrupted by wrappers, pouches, jacket,

devices when tobacco products are placed on the market.

5. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets.

6. 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 on which they are placed before the unit packet is opened.

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

boxes or other devices when tobacco products are placed on the market.

5. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets.

6. 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 on which they are placed before the unit packet is opened.

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

7a. The regulation of other aspects of the packet falls outside the scope of this Directive.

7b. The unit packet and its surrounding packaging shall not include printed vouchers offering discounts, free distribution, two-for-one or other similar offers involving any type of tobacco product covered by this Directive...

Amendment 52

Proposal for a directive Article 8 – paragraphs 1 to 3

Text proposed by the Commission

1. Each unit packet and any outside packaging of tobacco for smoking shall carry the following general warning:

Smoking kills – quit now

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

Amendment

1. Each unit packet and any outside packaging of tobacco for smoking shall carry the following general warning:

Smoking kills – quit now

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

3. For cigarette packets the general warning and the information message shall be printed on the lateral sides of the unit packets **in black Helvetica bold type on a white background**. These warnings shall have a width of not less than 20 mm. For roll-your-own tobacco **in pouches** the information message shall be printed on the surface that becomes visible when opening the unit packet, **for cylindrical containers the warnings shall be printed on the lid, and for cuboid containers the warnings shall be printed on the lateral sides**. Both the general warning and the information message shall cover 50% of the surface on which they are printed.

Amendment 53

Proposal for a directive Article 8 – paragraph 4

Text proposed by the Commission

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

(a) to adapt the wording of the **health warnings** laid down in paragraphs 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.

Amendment

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

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

Amendment 54

Proposal for a directive Article 9 – paragraphs 1 and 2

Text proposed by the Commission

Combined health warnings for tobacco for smoking

1. Each unit packet and any outside

Amendment

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;

(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 % of the external area of both the front and back surface of the unit packet and any outside packaging;

(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 the packaging;

(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 mm;

(ii) width: not less than 55 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 equal numbers of each brand.

packaging of tobacco for smoking shall carry combined picture and text 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 % of the external area of both the front and back surface of the unit packet and any outside packaging.

Cylindrical containers shall display two combined health warnings, equidistant from each other, covering 75% 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 the packaging;

(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 55 mm;

(ii) width: not less than 53 mm;

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

Amendment 55

Proposal for a directive Article 9 – paragraph 3

Text proposed by the Commission

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 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;

(c) define the position, format, layout, design, rotation and proportions of the health warnings;

(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.

Amendment

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 developments;

(b) adapt the picture library **in Annex II**, taking into account scientific and market developments;

(c) define the position, format, layout, design, rotation and proportions of the health warnings;

Amendment 56

Proposal for a directive Article 10 – paragraphs 1 to 4

Text proposed by the Commission

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

1. Tobacco for smoking other than cigarettes **and** roll-your-own 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 addition to the general warning specified in Article 8(1), each unit packet and any outside packaging

Amendment

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

1. Tobacco for smoking other than cigarettes, 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 addition to the general warning specified in Article 8(1), each unit packet and any

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. These 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 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

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. These 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 *more than two* official languages.

3. The text warning referred to in paragraph 1 shall cover 40 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 45 % for Member States with two official languages and 50 % for Member States with *more than two* official languages.

3a. In the case of packets whose most visible side has an area exceeding 75 cm², the warnings referred to in paragraphs 2 and 3 must, however, cover an area of at least 22.5 cm² on each side. That area shall be increased to 24 cm² for Member States with two official languages and 26.25 cm² for Member States with three official languages.

4. 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. ***The warnings may be affixed by means of stickers, provided that such stickers are irremovable.*** In order to accommodate language requirements,

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.

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.

Justification

For reasons of proportionality, this provision from Directive 2001/37/EC is reincorporated in the proposal for a directive.

Amendment 57

Proposal for a directive Article 10 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Amendment 58

Proposal for a directive Article 11 – paragraphs 1 to 2

Text proposed by the Commission

1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning:

This tobacco product **can damage** your

Amendment

1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning:

This tobacco product **damages** your health

health and is addictive

2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 10(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.

and is addictive

2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 10(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 *more than two* official languages

Amendment 59

Proposal for a directive Article 11 – paragraph 3

Text proposed by the Commission

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 1 *and 2* taking into account scientific and market developments.

Amendment

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraph 1 taking into account scientific and market developments.

Amendment 60

Proposal for a directive Article 12 – paragraph 1

Text proposed by the Commission

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 create an erroneous impression about its characteristics, health effects, hazards or emissions;

Amendment

1. The labelling of a unit packet and any outside packaging and the tobacco product itself *and / or its brand name* shall *not* include any element or feature that:

(a) promotes a tobacco product *and encourages its consumption* by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions. *Labels shall not include any*

- (b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health or social effects;
- (c) refers to flavour, taste, any flavourings or other additives or the absence thereof;
- (d) resembles a food product.

information about nicotine, tar or carbon monoxide content;

- (b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health or ***lifestyle*** effects;
- (c) refers to flavour, taste, any flavourings or other additives or the absence thereof;
- (d) resembles a food ***or a cosmetic*** product.

(da) aims to reduce the effect of some harmful components of smoke or increase the biodegradability of tobacco products

Amendment 61

Proposal for a directive

Article 12 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

In the case of filter cigarettes, the tipping paper shall afford sufficient protection against product counterfeiting by means of its complexity. To this end it shall, at least possess the following characteristics:

- (a) several visible print colours and production using gravure printing;***
- (b) all white areas are coated;***
- (c) complex printing with partially thin structures;***
- (d) printing on white base paper;***
- (e) pre-perforation situated sufficiently far from the end of the cigarette.***

Justification

Products with many different printed colours and, in part, very thin structures, as well as the pre-perforation technique, are available only to established suppliers. Together with special requirements relating to paper, for example their degree of whiteness, this will effectively obstruct the illegal cigarette market. The location of the perforation zone will ensure that consumers cannot cover the holes, thereby making the smoke stronger.

Amendment 62

Proposal for a directive

Article 12 – paragraph 2 – subparagraph 1 b (new)

Text proposed by the Commission

Amendment

The cigarette paper shall include watermarks.

Justification

This is a safeguard against counterfeiting.

Amendment 63

Proposal for a directive

Article 12 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. The variety of tobacco used to manufacture the product, its country of origin, or both, may be indicated on the unit packet.

Amendment 64

Proposal for a directive

Article 13 – paragraph 1

Text proposed by the Commission

Amendment

1. A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall 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.

1. A unit packet of cigarettes shall ***contain*** at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing at least 40 g.

Amendment 65

Proposal for a directive Article 13 – paragraphs 1 a and 2

Text proposed by the Commission

Amendment

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 is first opened, other than the flip-top lid. **The flip-top lid of a cigarette packet** shall be hinged only at the back of the packet.

1a. A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall have a cuboid or a cylindrical shape, or have the form of a pouch i.e. a rectangular packet with a flap that covers the opening. The flap of the pouch shall cover at least 70% of the front of the packet.

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 is first opened, other than the flip-top lid **or a shoulder box hinged lid. For packets with a flip-top lid opening, the lid** shall be hinged only at the back of the packet.

Amendment 66

Proposal for a directive Article 13 – paragraph 3

Text proposed by the Commission

Amendment

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.

deleted

Amendment 67

Proposal for a directive

Article 14

Text proposed by the Commission

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 machine used to manufacture the product;

(c) the production shift or time of manufacture;

(d) the product *name*;

(e) the intended market of retail sale;

(f) the intended shipment route;

(g) where applicable, the importer into the Union;

(h) the actual shipment route from manufacturing to the first retail outlet,

Amendment

1. Member States shall ensure that all unit packets ***and any outside transport packaging*** of tobacco products shall be marked with a unique identifier. In order to ensure their integrity, unique identifiers shall be ***secure***, 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.

1a. Member States shall ensure that the unique identifiers of unit packets are linked to the unique identifier on the outside transport packaging. Any changes in links between unit packs and the outside transport packaging shall be recorded in the database mentioned in paragraph 6.

2. The unique identifier shall allow determining:

(a) the date and place of manufacturing;

(b) the machine used to manufacture the products;

(c) the production shift or time of manufacture;

(d) the product ***description***;

(e) the intended market of retail sale;

(f) the intended ***and actual*** shipment route ***from the place of manufacturing to the first retail outlet, including all warehouses used, the shipment date, shipment destination, consignee and point of departure***;

(g) where applicable, the importer into the Union;

including all warehouses used;

(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.

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 recording in aggregated form, e.g. of outside packaging, *provided that tracking and tracing of unit packets remains possible.*

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.

5. 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

(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.

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 *and outside* packets into their possession, as well as all intermediate movements and the final exit from their possession, *and transmit the data electronically to a data storage facility pursuant to paragraph 6.* This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging,

3a. The technology used for tracking and tracing should belong to and be operated by economic entities without any legal or commercial link to the tobacco industry.

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, *as determined by those Member States,* 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.

5. 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.

6. Member States shall *ensure* that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host the data storage facility for 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 and monitored by an external auditor, who is *proposed and* paid by the tobacco manufacturer and approved by the Commission. 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.

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

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.

6. Member States shall *verify* that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall be physically located on the territory of the Union. ***The independent third party shall be free from commercial and other vested interests of the tobacco industry and other related industries.*** The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be approved and monitored ***by the Commission, assisted*** by an ***independent*** external auditor, who is paid by the tobacco manufacturer and approved by the Commission. 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.

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.

placed on the market carry a visible **and invisible**, 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. ***In those Member States where tax stamps are applied on tobacco products and the tax stamps applied comply with the requirements of this paragraph, no additional security feature is required.***

Amendment 68

Proposal for a directive Article 16

Text proposed by the Commission

Chapter IV: ***Cross-border*** distance sales of tobacco products

Article 16

Cross-border distance sales of tobacco products

1. 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

Amendment

Chapter IV: ***Promotional distribution*** and distance sales of tobacco products

Article 16

Distance sales of tobacco products

1. Member States shall ***prohibit*** retail outlets ***established on their territory*** from engaging in cross border distance sales.

supplied;

(b) the starting date of the activity of offering tobacco products for cross-border distance sales to the public 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.

1a. Member States shall retain the power to decide whether to widen the scope of the above-mentioned prohibition to include national distance sales. Where Member States allow national distance sales, they shall ensure that retail outlets are equipped with an age verification system.

1b. A Member State may, for public health reasons, impose restrictions on imports of tobacco for personal use. A Member State must be able to apply such restrictions in particular when the price in the Member State where the product is purchased is significantly lower than the price in the Member State of origin or if the health warnings are not in its official language(s).

2. The competent authorities of the Member States shall 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 distance sales as of the moment the name of the retail outlet is published in the relevant Member States.

2. The competent authorities of the Member States shall 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 distance sales as of the moment the name of the retail outlet is published in the relevant Member States.

2. Member States which have implemented a national anti-smoking strategy may set quantitative limits on cross-border movements.

deleted

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 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.

Amendment 69

Proposal for a directive Article 16a (new)

Article 16a

Member States shall prohibit retail outlets established on their territory from distributing free or discounted tobacco products through cross border distance channels or through any other channel.

Amendment 70

Proposal for a directive

Article 17

Text proposed by the Commission

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

Amendment

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 ***any proposed labelling, instructions for use, details of the product's composition, the manufacturing process and associated controls*** and information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with:

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

(b) ***working summaries of the*** available studies and market research on preferences of various consumer groups, including young people and ***chronic heavy smokers***;

(c) other available and relevant information, including a risk/benefit analysis of the product, the expected effects on cessation of tobacco consumption, the expected effects on initiation of tobacco consumption and other predicted consumer perception.

2. ***After the placing on the market of a tobacco product***, 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

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.

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.

Amendment 71

Proposal for a directive Article 18

Text proposed by the Commission

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 exceeding 2 mg per unit, or

b) products with a nicotine concentration exceeding 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 scientific developments and marketing authorisations granted to nicotine- containing products pursuant to

Amendment

1. Nicotine-containing products may only be placed on the market if they ***are*** authorised pursuant to Directive 2001/83/EC, ***taking into account the well-established use of nicotine.***

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 and can damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(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.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.

Amendment 72

Proposal for a directive Article 19

Text proposed by the Commission

Herbal products for smoking

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

This product can damage your health

2. The health warning shall be printed on

Amendment

Herbal products for smoking

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

This product can damage 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(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.

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(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 *more than two* official languages.

Amendment 73

Proposal for a directive Article 19 a (new)

Text proposed by the Commission

Amendment

Article 19a

Imitation tobacco products

Imitation tobacco products which appeal to minors and consequently form a potential gateway to using tobacco products shall be prohibited.

Justification

Imitation tobacco products targeted at minors can encourage the use of tobacco products by children. Most smokers start smoking when they are still minors. We should therefore focus on deterring young people from smoking and avoid the use of imitation tobacco products, such as the shisha-pen or hookah pen, which are particularly attractive to young people and familiarise them with smoking behaviour thereby endangering public health.

Amendment 74

Proposal for a directive Article 20 - Paragraph 3

Text proposed by the Commission

Amendment

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.

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.

The penalties provided for shall be effective, proportionate and dissuasive.
Any financial penalties applicable to intentional infringements shall be such as to offset the economic advantage sought through the infringement.

Justification

Financial penalties should be at least equivalent to the profits made. This principle has been included in legislative proposals in other areas, for example ship recycling and the revision of the official control legislation in the context of the horsemeat scandal.

Amendment 75

Proposal for a directive Article 22

Text proposed by the Commission

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), **6(3), 6(9), 6(10)**, 8(4), 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 [Office of Publications: please insert the date of the entry into force of this Directive].

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), **6(3), 6(9), 6(10)**, 8(4), 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

Amendment

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), **6(10a)**, 8(4), 9(3), 10(5), 11(3), 13(4) **and** 14(9) shall be conferred on the Commission for ***a*** period of ***five years*** from [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 nine months before the end of five-year period. The delegation of power shall be tacitly extended for periods of identical duration unless the European Parliament or Council opposes such an extension not later than three months before the end of each period.***

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), **6(10a)**, 8(4), 9(3), 10(5), 11(3), 13(4) **and** 14(9) 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

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), **6(3), 6(9), 6(10)**, 8(4), 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.

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), **6(10a)**, 8(4), 9(3), 10(5), 11(3), 13(4) **and** 14(9) 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.

Amendment 76

Proposal for a directive

Article 23 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

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

Amendment 77

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) evaluation of the addictive effects of those ingredients which encourage addiction;

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 78

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(cb) development of standardised testing methods to measure the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide;

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 79

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(cc) toxicological data to be required from manufacturers on ingredients and the manner in which they should be tested in order to allow public health authorities to assess their use;

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 80

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(cd) development of standards concerning products other than cigarettes.

Amendment 81

Proposal for a directive

Article 23 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Member States shall report every two years to the Commission on the enforcement of the measures taken pursuant to Council Recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control, in particular with regard to age limits set in national legislation, as well as their plans to increase the age limit to achieve the goal of a "smoke-free generation".

Justification

According to the Commission, 70% of the smokers start before the age of 18. According to the Council recommendation of 2002, 60 % of smokers start the habit before 13 years of age, and 90 % before 18. The legal buying age is 18 years in 22 Member States and 16 years in the remaining five (AT, BE, IT, LU and NL). There is thus a serious problem of non-enforcement of the age limit in most Member States. The reporting obligation in the Council recommendation should become legally binding.

Amendment 82

Proposal for a directive

Article 24

Text proposed by the Commission

Amendment

1. Member States shall not prohibit or restrict the import, sale or consumption of

1. ***Subject to paragraphs 2 and 3***, Member States shall not prohibit or restrict the

tobacco or related products which comply with this Directive.

2. 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.*** Such national provisions shall be notified to the Commission together with the grounds for maintaining or 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.

import, sale or consumption of tobacco or related products which comply with this Directive.

2. However, a Member State may maintain ***or introduce*** more stringent national provisions in areas covered by the Directive, ***insofar as such measures are compatible with the Treaty.*** Such national provisions ***shall apply equally to all products , including those imported from another Member State or a third country.*** ***They shall*** be notified to the Commission together with the grounds for maintaining or 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 national provisions concerning aspects not regulated by this Directive, ***insofar as they are compatible with the Treaty.*** ***They shall apply equally to all products, including those imported from another Member State or a third country,*** 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.

Amendment 83

Proposal for a directive Article 25 – paragraph 1

Text proposed by the Commission

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 months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

Amendment

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 months] **and in the case of Article 6 by [Publications Office, please insert the exact date: entry into force + 36 months]** at the latest. They shall forthwith communicate to the Commission the text of those provisions.

Justification

Follow-up amendment: this amendment is necessary because it takes time to draw up the full list of additives under Articles 6.

Amendment 84

Proposal for a directive Article 26

Text proposed by the Commission

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 months]:

- (a) tobacco products;
- (b) nicotine containing products below the threshold set out in Article 18(1);**
- (c) herbal products for smoking.

Amendment

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 months]:

- (a) tobacco products;
- (b) herbal products for smoking.

Member States may allow nicotine containing products which are not in compliance with this Directive to be placed on the market until [Publications Office, please insert the exact date: entry

into force + 36 months]:

Amendment 85

Proposal for a directive

Annex -I (new)

Text proposed by the Commission

Amendment

Annex -I

Additives approved for use in tobacco products

Chemical name of the additive - function - maximum level permitted

Amendment 86

Proposal for a directive

Annex I

Text proposed by the Commission

Amendment

List of text warnings

List of text warnings

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

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

(1) Smoking causes 9 out of 10 lung cancers

(1) Smoking causes 9 out of 10 lung cancers

(2) Smoking causes mouth and throat cancer

(2) Smoking causes mouth and throat cancer

(2a) Smoking causes bladder cancer

(3) Smoking damages your lungs

(3) Smoking damages your lungs

(4) Smoking causes heart attacks

(4) Smoking causes heart attacks

(5) Smoking causes strokes and disability

(5) Smoking causes strokes and disability

(6) Smoking clogs your arteries

(6) Smoking clogs your arteries

(7) Smoking increases the risk of blindness

(7) Smoking increases the risk of blindness

(8) Smoking damages your teeth and gums

(8) Smoking damages your teeth and gums

(9) Smoking can kill your unborn child

(9) Smoking can kill your unborn child

10) Your smoke harms your children, family and friends

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

(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

(14 a) Smoking can cause cot death

(14 b) Smoking during pregnancy causes premature birth

(14 c) Passive smoking can worsen asthma or meningitis in children.