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Committee on Legal Affairs

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AMENDMENTS 62 - 170

Draft opinion
Klaus-Heiner Lehne
(PE510.591v01-00)

Approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

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

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EN

United in diversity

EN

Amendment 62
Zbigniew Ziobro

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 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.

deleted

Or. pl

Amendment 63
Sebastian Valentin Bodu

Proposal for a directive
Recital 11

Text proposed by the Commission

Amendment

(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.

(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 **scientific development and standards generally agreed to assess** their toxicity or addictiveness.

Or. en

Amendment 64
Sergio Gaetano Cofferati

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 adapt the yields fixed or to fix maximum thresholds for emissions, taking into consideration ***scientific development and internationally agreed standards to assess*** their toxicity or addictiveness.

Or. it

Amendment 65
Zbigniew Ziobro

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***

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.

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.

Or. pl

Amendment 66
Zbigniew Ziobro

Proposal for a directive
Recital 15

Text proposed by the Commission

Amendment

(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.

deleted

Or. pl

Amendment 67
Rebecca Taylor

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, including smokeless tobacco products, having a characterising flavour other than tobacco, which may ***make tobacco products more palatable, and therefore*** 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.

Or. en

Amendment 68
Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg

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***

Amendment

(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 ***is*** allowed. The Commission should ensure uniform conditions for the

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 between different tobacco varieties.

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 between different tobacco varieties.

Or. en

Amendment 69

Tadeusz Zwiefka, Alajos Mészáros, Lidia Joanna Geringer de Oedenberg

Proposal for a directive

Recital 16 a (new)

Text proposed by the Commission

Amendment

(16a) One of the aims of the Directive is to reduce the consumption of tobacco products, especially among young and vulnerable consumers, which will result in the decrease of the production of the tobacco in the European Union and can lead to loss of jobs, moving the industry outside the European Union and need to restructure the farms traditionally basing its production on tobacco. Therefore appropriate measures and financial support must be envisaged in the framework of the EU budget in order to counteract the economic and social consequences of the Directive.

Or. en

Amendment 70

Sergio Gaetano Cofferati

Proposal for a directive

Recital 25

Text proposed by the Commission

Amendment

(25) Member States apply different rules on minimum number of cigarettes per packet. Those rules should be aligned in order to ensure free circulation of the concerned products.

deleted

Or. it

Amendment 71

Tadeusz Zwiefka, Alajos Mészáros

Proposal for a directive

Recital 29

Text proposed by the Commission

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.

(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. Upholds the ban on tobacco products for oral use, however, such a ban should not affect historically traditional tobacco products for oral use, which may be allowed by individual Member States.** 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.

Or. en

Amendment 72

Nils Torvalds, Cecilia Wikström

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 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.

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. ***Member States and regions of Member States with a tradition of using oral tobacco shall have an opportunity to apply for a national or regional derogation from the prohibition on cultural or historical grounds.*** 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.

Or. en

Justification

The prohibition of tobacco for oral use is inconsistent and, inter alia, affects areas all around the Baltic Sea that have traditionally made use of tobacco for oral use. The general public in these countries and regions does not understand why a product that has been used throughout history and is part of a region's cultural identity should be prohibited, especially when the product is less harmful to health than cigarettes.

Amendment 73
Rebecca Taylor

Proposal for a directive
Recital 30 a (new)

Text proposed by the Commission

Amendment

(30a) The Commission and the Member States should commit themselves to the effective implementation of the FCTC's protocol 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.

Or. en

Amendment 74
Sergio Gaetano Cofferati

Proposal for a directive
Recital 30 a (new)

Text proposed by the Commission

Amendment

(30a) The Commission and Member States should increase their efforts to further control, prevent and suppress the illegal trade in tobacco goods manufactured in third countries.

Or. it

Amendment 75
Rebecca Taylor

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 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

(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 ***which claim to have properties beneficial to human health. A significant number of nicotine-containing products presenting such claims have already been authorised under this regulatory regime. Member States are obliged to ensure nicotine containing products which do not fall under Directive 2001/83/EC and which are placed on the common market comply with the appropriate legislation listed in [new] Annex IV.***

Or. en

Justification

Clarifies that a 'two track' approach should be taken regarding nicotine containing products. Those which do not fall under Directive 2001/83/EC have to comply with the broad range of consumer and product safety legislation listed in [new] Annex IV.

Amendment 76
Rebecca Taylor

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

(35) Labelling provisions should be introduced for nicotine containing products ***falling outside of the scope of Directive 2001/83/EC*** drawing the attention of consumers to potential health risks, ***and Member States should be obliged to ensure that national age restrictions for buying nicotine containing products are kept in line with those for the sale of tobacco products.***

Or. en

Justification

A level playing field between age restrictions for the sale of nicotine-containing products and tobacco products should be maintained, so as to discourage minors from taking up either product for the first time.

Amendment 77
Sergio Gaetano Cofferati

Proposal for a directive
Recital 35 a (new)

Text proposed by the Commission

Amendment

(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.

Or. it

Amendment 78
Zbigniew Ziobro

Proposal for a directive
Recital 36

Text proposed by the Commission

(36) The regulation of herbal products for smoking differs between Member States and these products are often perceived as harmless or less harmful despite the health risk caused by their combustion. ***In order to ensure the proper functioning of the internal market and improve information to consumers, common labelling rules should be introduced at Union level.***

Amendment

(36) The regulation of herbal products for smoking differs between Member States and these products are often perceived as harmless or less harmful despite the health risk caused by their combustion.

Or. pl

Amendment 79
Sergio Gaetano Cofferati

Proposal for a directive
Recital 37

Text proposed by the Commission

(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.

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

Or. it

Justification

The methodology for determining whether a tobacco product has characterising flavour should be established under delegated acts rather than through conferral of implementing powers.

Amendment 80
Sebastian Valentin Bodu

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

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 **the measurement methods** for emissions, setting maximum levels for ingredients that increase toxicity **or addictiveness**, 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 ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Or. en

Amendment 81
Sergio Gaetano Cofferati

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

Amendment

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 methodology for determining whether a tobacco product has characterising flavour***, 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 ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Or. it

Amendment 82
Sergio Gaetano Cofferati

Proposal for a directive
Recital 41

Text proposed by the Commission

(41) Member States should remain free to maintain or introduce national legislations applying to all products alike for aspects falling outside the scope of this Directive, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly, Member States could, for instance, maintain or introduce provisions ***providing standardisation of packaging of tobacco products provided that those provisions*** are compatible with the Treaty, with WTO obligations and do not affect the full application of this Directive. A prior notification is required for technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on Information Society services.

Amendment

(41) Member States should remain free to maintain or introduce national legislations applying to all products alike for aspects falling outside the scope of this Directive, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly, Member States could, for instance, maintain or introduce provisions compatible with the Treaty, with WTO obligations and do not affect the full application of this Directive. A prior notification is required for technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on Information Society services.

Or. it

Amendment 83
Lidia Joanna Geringer de Oedenberg

Proposal for a directive
Article 2 – paragraph 1 – point 3

Text proposed by the Commission

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

Amendment

(3) 'age verification system' means a computing system that unambiguously confirms the consumer's age in electronic form according to national requirements; ***it can also mean a physical verification***

system in form accordant to national requirements, that unambiguously confirms the consumer age in situations other than direct purchase for example by the usage of vending machines;

Or. en

Amendment 84
Sebastian Valentin Bodu

Proposal for a directive
Article 2 – paragraph 1 – point 19

Text proposed by the Commission

Amendment

(19) ‘maximum level’ or ‘maximum yield’ means the maximum content or emission, including 0, of a substance in a tobacco product measured in grams;

deleted

Or. en

Amendment 85
Lidia Joanna Geringer de Oedenberg

Proposal for a directive
Article 2 – paragraph 1 – point 25

Text proposed by the Commission

Amendment

(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;

(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 **or by use of vending machines**; 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;

Or. en

Amendment 86
Nuno Teixeira

Proposal for a directive
Article 2 – paragraph 1 – point 36 a (new)

Text proposed by the Commission

Amendment

(36a) ‘reduced-harm tobacco product’ means a tobacco product which has been shown, on the basis of scientific evidence, to demonstrably reduce the harmful effects of smoking, regardless of whether the product in question qualifies as a novel tobacco product under the terms of Article 2(23).

Or. pt

Amendment 87
Sebastian Valentin Bodu

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission

Amendment

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. ***deleted***

Or. en

Justification

Parliament and Council should be involved in the decision. A delegated act would born effects that cannot be reviewed by the Parliament and the Council, as legislators, at the time of the issuance by the Commission. Commission can legislate through delegated acts only on technical issues with no difficulties to reverse the adverse effects born at the time of the issuance. Therefore, the Parliament and the Members States (through the Council) should be all the time involved in the legislative procedure that has a material impact on any market.

Amendment 88
Sebastian Valentin Bodu

Proposal for a directive
Article 3 – paragraph 3

Text proposed by the Commission

Amendment

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 in paragraph 1.

deleted

Or. en

Justification

Parliament and Council should be involved in deciding the eliminated because a delegated act would born its effects that cannot be reviewed by the Parliament and the Council, as legislators at the time of the issue by the Commission packsCommission can legislate through delegated acts on technical issues with no financial so, not on those that are difficult to reverse the adverse effects born at the time of the issuance. Therefore, the Parliament and the Members States (through the Council) should be all the time involved in the legislative procedure that has a material impact on any market

Amendment 89
Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Alajos Mészáros

Proposal for a directive
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

Member States shall prohibit the placing on the market of tobacco products with a characterising flavour, ***where it was unequivocally proved by scientific studies that the additive increases toxicity of the products or facilitate addiction.***

Or. en

Amendment 90
Cecilia Wikström

Proposal for a directive
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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

Amendment

Member States shall prohibit the placing on the market of tobacco products with a characterising flavour, ***without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.***

Or. en

Justification

In regards to article 15 of this directive the Swedish cultural derogation of oral tobacco, this principle should also apply to the regulation of ingredients since Swedish cultural tobacco often is flavoured.

Amendment 91
Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Alajos Mészáros

Proposal for a directive
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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.***

Amendment

Member States shall not prohibit the use of additives which are essential for the manufacture of tobacco products,

Or. en

Amendment 92

Sergio Gaetano Cofferati

Proposal for a directive

Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission

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***.

Amendment

The Commission shall adopt by means of implementing acts ***criteria, procedures and methodologies*** 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 ***22***.

Or. it

Justification

The methodology for determining whether a tobacco product has characterising flavour should be established under delegated acts rather than through conferral of implementing powers.

Amendment 93

Juan Fernando López Aguilar, Alejandro Cercas

Proposal for a directive

Article 6 – paragraph 3

Text proposed by the Commission

Amendment

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.

deleted

Or. es

Justification

Maximum levels for additives or combination of additives are considered as essential elements of a legislative act, and any amendment to those elements should be subject to the ordinary legislative procedure.

Amendment 94

Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Alajos Mészáros

Proposal for a directive

Article 6 – paragraph 5

Text proposed by the Commission

Amendment

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.

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, **where it was unequivocally proved by scientific studies that the additive increases toxicity of the products or facilitate addiction.** Filters and capsules shall not contain tobacco.

Or. en

Amendment 95
Rebecca Taylor

Proposal for a directive
Article 6 – paragraph 5

Does not affect English version

Or. fr

Justification

For linguistic consistency reasons it is necessary to change the French text from ‘intensité de la combustion’ to ‘intensité de la fumée’ to reflect the English version. Intensity of combustion and intensity of smoke are not the same things.

Amendment 96
Rebecca Taylor

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission

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.

Amendment

5. Member States shall prohibit the use of **characterising** 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.

Or. en

Justification

Needed for compliance with Article 2, paragraph 1, point 4, and the rest of the proposal, which systematically associates 'flavour' with the adjective 'characterising' in order to improve legal clarity.

Amendment 97
Sergio Gaetano Cofferati

Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission

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.

Amendment

5. Member States shall prohibit the use of **characterising** 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.

Or. it

Amendment 98
Juan Fernando López Aguilar, Alejandro Cercas

Proposal for a directive
Article 6 – paragraph 9

Text proposed by the Commission

9. In case scientific evidence and the experience gained in the application of paragraphs 7 and 8 shows that a certain additive or a certain quantity thereof amplify in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives.

Amendment

deleted

Or. es

Justification

The decision to limit or prohibit a particular product for its additives referred to in paragraphs 7 and 8 must be based on sound and measurable scientific evidence and discussed in the context of a future revision of the Directive. Furthermore, these are essential

elements of a legislative act, and any amendment to them should be subject to the ordinary legislative procedure

Amendment 99

Tadeusz Zwiefka, Alajos Mészáros

Proposal for a directive

Article 6 – paragraph 10

Text proposed by the Commission

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.***

Amendment

10. Tobacco products other than cigarettes ***and roll-your-own*** tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 5.

Or. en

Amendment 100

Juan Fernando López Aguilar, Alejandro Cercas

Proposal for a directive

Article 6 – paragraph 10

Text proposed by the Commission

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.***

Amendment

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, ***at the request of a Member State or on its own initiative, be able to determine by means of implementing acts whether or not*** to withdraw this exemption if there is a ***significant*** change of circumstances ***involving an increase in sales volume by product category of at least 20 % in the***

ten largest Member State markets by volume. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21 and shall not apply in the case of new tobacco products regulated in Article 17.

Or. es

Justification

Las decisiones acerca de la eliminación de estas excepciones han de tomarse en el contexto de futuras revisiones de la Directiva de conformidad con el proceso legislativo ordinario, habida cuenta de la evolución del mercado a medio y largo plazo. También es importante redefinir “cambio significativo en las circunstancias” al considerar la eliminación de excepciones ya que la definición actual de un cambio de volumen del 10 % en al menos diez Estados miembros (mercados) podría producirse fácilmente sin generar ningún cambio significativo en el volumen del mercado. Asimismo, la excepción para productos del tabaco nuevos debería excluirse, ya que se encuentran cubiertos en el artículo 17.

Amendment 101
Cecilia Wikström

Proposal for a directive
Article 7 – paragraph 1

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.

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, ***without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.***

Or. en

Justification

With regards to article 15 of this directive, regulation of oral tobacco is not within the scope of this directive.

Amendment 102
Sebastian Valentin Bodu

Proposal for a directive
Article 8 – paragraph 4 – point b

Text proposed by the Commission

Amendment

(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.

deleted

Or. en

Justification

Parliament and Council should be involved in deciding the eliminated because a delegated act would born its effects that cannot be reviewed by the Parliament and the Council, as legislators at the time of the issue by the Commission packs. The Commission can legislate through delegated acts on technical issues with no financial so, not on those that are difficult to reverse the adverse effects born at the time of the issuance. Therefore, the Parliament and the Members States (through the Council) should be all the time involved in the legislative procedure that has a material impact on any market.

Amendment 103
Lidia Joanna Geringer de Oedenberg

Proposal for a directive
Article 9 – paragraph 1 – point b (new)

Text proposed by the Commission

Amendment

(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;

(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; ***those platforms designed to inform consumers about the programmes available to support those who want to stop smoking should play active role in promoting knowledge on the severe effects of smoking among children and youth as***

those most at risk of becoming dependent on tobacco;

Or. en

Amendment 104
Arlene McCarthy

Proposal for a directive
Article 9 – paragraph 1 – point c

Text proposed by the Commission

(c) cover **75** % of the external area of both the front and back surface of the unit packet and any outside packaging;

Amendment

(c) cover **80** % of the external area of both the front and back surface of the unit packet and any outside packaging;

Or. en

Amendment 105
Rebecca Taylor

Proposal for a directive
Article 9 – paragraph 1 – point c

Text proposed by the Commission

(c) cover 75 % of the external area of both the front and back surface of the unit packet and any outside packaging;

Amendment

(c) cover **at least** 75 % of the external area of both the front and back surface of the unit packet and any outside packaging;

Or. en

Justification

The implementing guidelines of the WHO FCTC call for warnings covering more than 50% of the surface of packaging, and go as far as to say warnings should "aim to cover as much of the principal display areas as possible". Several EU countries already have health warnings covering well over 50% of the surface of packaging and minimum harmonisation should aim to strengthen provisions in this area.

Amendment 106
Rebecca Taylor

Proposal for a directive
Article 9 – paragraph 1 – point g – introductory part

Text proposed by the Commission

Amendment

(g) for unit packets of cigarettes, respect the following dimensions:

(g) for unit packets of cigarettes, respect the following dimensions *as a minimum*:

Or. en

Amendment 107
Rebecca Taylor

Proposal for a directive
Article 9 – paragraph 1 – point g – point i

Text proposed by the Commission

Amendment

(i) height: *not less than* 64 mm;

(i) height: 64 mm;

Or. en

Amendment 108
Rebecca Taylor

Proposal for a directive
Article 9 – paragraph 1 – point g – point ii

Text proposed by the Commission

Amendment

(ii) width: *not less than* 55 mm.

(ii) width: 55 mm.

Or. en

Amendment 109
Sebastian Valentin Bodu

Proposal for a directive
Article 9 – paragraph 3 – point c

Text proposed by the Commission

Amendment

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

deleted

Or. en

Justification

Parliament and Council should be involved in deciding the eliminated because a delegated act would born its effects that cannot be reviewed by the Parliament and the Council, as legislators at the time of the issue by the Commission packs. The Commission can legislate through delegated acts on technical issues with no financial so, not on those that are difficult to reverse the adverse effects born at the time of the issuance. Therefore, the Parliament and the Members States (through the Council) should be all the time involved in the legislative procedure that has a material impact on any market

Amendment 110

Juan Fernando López Aguilar, Alejandro Cercas

Proposal for a directive

Article 10 – paragraph 5

Text proposed by the Commission

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.

deleted

Or. es

Justification

The establishment of new obligations with regard to the relevant tobacco products impacts the scope of Articles 8-10; this should therefore remain at the discretion of the co-legislators and subject to the ordinary legislative procedure.

Amendment 111

Rebecca Taylor

Proposal for a directive
Article 12 – paragraph 1 – point a

Text proposed by the Commission

(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

(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, ***in particular by suggesting that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural or otherwise positive health effects.***

Or. en

Justification

Tobacco products should not be allowed to be promoted in a way that attempts directly or indirectly to suggest they are less harmful to health or have any positive health effects. The concept of “social effects” is deleted as this is legally vague and could be interpreted a myriad of different ways.

Amendment 112
Rebecca Taylor

Proposal for a directive
Article 12 – paragraph 1 – point b

Text proposed by the Commission

(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;

Amendment

deleted

Or. en

Justification

This point is deleted as its content has been merged with point a of the same paragraph.

Amendment 113
Alajos Mészáros

Proposal for a directive
Article 12 – paragraph 1 – point b

Text proposed by the Commission

(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;***

Amendment

(b) suggests that a particular tobacco product is less harmful than others

Or. en

Amendment 114
Alajos Mészáros

Proposal for a directive
Article 12 – paragraph 1 – point b a (new)

Text proposed by the Commission

(ba) suggests that a particular tobacco product has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health or social effects;

Amendment

Or. en

Amendment 115
Alajos Mészáros

Proposal for a directive
Article 12 – paragraph 2

Text proposed by the Commission

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

Amendment

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

other signs, misleading colours, inserts or other additional material such as adhesive labels, stickers, inserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. ***Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.***

other signs, misleading colours, inserts or other additional material such as adhesive labels, stickers, inserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself.

Or. en

Amendment 116
Alajos Mészáros

Proposal for a directive
Article 12 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(1a) A Member State may exempt a product from the provisions under paragraph 1(b) if a manufacturer demonstrates that such product as it is actually used by the consumer will significantly reduce the risk of tobacco related disease to the tobacco user. Manufacturers shall submit to the competent authorities in the Member States scientific evidence substantiating the reduced risk benefit of the product. Member States shall be entitled to determine the criteria of such authorization taking as a basis a high level of protection of consumers and public health;

Or. en

Amendment 117
Rebecca Taylor

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission

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.**

Amendment

1. A unit packet of cigarettes shall have a cuboid shape **and include at least 20 cigarettes**. A unit packet of **any other** tobacco **for smoking shall be packaged in a cuboid or cylindrical composite can or have the form of a pouch i.e. rectangular packet with a flap that covers the opening, and** shall contain tobacco weighing at least **40g**.

Or. en

Justification

The original Proposal does not take into account the requirement for the composite can for specific uses of fine-cut loose tobacco i.e. 'make-your-own' cigarettes & pipes. The goal of this revision is to make the uptake of smoking much less attractive to young people, but the composite can is usually purchased by older adults and owing to its weight and volume is less financially affordable for young people. No internal market or public health goal will be achieved by prohibiting their use.

Amendment 118

Sergio Gaetano Cofferati

Proposal for a directive

Article 13 – paragraph 1

Text proposed by the Commission

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.**

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.

Amendment 119
Rebecca Taylor

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission

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.

Amendment

2. A cigarette packet can be of carton or soft material and shall contain an opening that can be ***in the form of a*** flip-top lid. The flip-top lid of a cigarette packet shall be hinged only at the back of the packet..

Or. en

Justification

This would allow for resealable inner security features, such as inner liners, which can help in combating counterfeiting, but would not hinder in any way the visibility and integrity of the health warnings on the pack.

Amendment 120
Arlene McCarthy

Proposal for a directive
Article 13 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. All outer surfaces of the unit packet and any outside packaging of tobacco for smoking shall be standardised in the following way:

a) not contain any trade mark or any other mark, apart from the brand name and any variant name for the tobacco products;

b) be of a dark, unattractive colour set by the Commission;

c) the brand name, and any variant name shall:

i) not appear more than once on any one surface

ii) appear horizontally below, and in the same orientation as, the combined health warning, in the centre of the space remaining on the front and back surfaces of the unit packet and any outside packaging;

iii) comply with any more detailed rules set out in paragraph 3;

Or. en

Amendment 121
Sergio Gaetano Cofferati

Proposal for a directive
Article 14 – paragraph 1

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.

Amendment

1. ***For the purposes of effective tracking and tracing***, Member States shall ensure that all unit packets of tobacco products ***including any external packaging***, shall be marked with a unique, ***safe and indelible*** 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.

Or. it

Amendment 122

Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Alajos Mészáros

Proposal for a directive

Article 14 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. The unique identifier shall allow determining:

2. The unique, ***safe and impossible to duplicate*** identifier shall allow determining:

Or. en

Amendment 123

Sebastian Valentin Bodu

Proposal for a directive

Article 14 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) the intended shipment route;

deleted

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

Amendment 124

Sebastian Valentin Bodu

Proposal for a directive

Article 14 – paragraph 2 – point h

Text proposed by the Commission

Amendment

(h) where applicable, the importer into the Union; **deleted**

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

Amendment 125

Sebastian Valentin Bodu

Proposal for a directive

Article 14 – paragraph 2 – point i

Text proposed by the Commission

Amendment

(i) the actual shipment route from manufacturing to the first **retail outlet**, including all warehouses used;

(i) the actual shipment route from manufacturing to the first **client (buyer)**, including all warehouses used;

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

Amendment 126
Sebastian Valentin Bodu

Proposal for a directive
Article 14 – paragraph 2 – point j

Text proposed by the Commission

Amendment

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

(j) the identity of all purchasers from manufacturing to the first **client (buyer)**;

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

Amendment 127
Sebastian Valentin Bodu

Proposal for a directive
Article 14 – paragraph 2 – point k

Text proposed by the Commission

Amendment

(k) the invoice, order number and payment records 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 **client (buyer)**.

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

appearance of authenticity).

Amendment 128
Sebastian Valentin Bodu

Proposal for a directive
Article 14 – paragraph 3

Text proposed by the Commission

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.

Amendment

3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the first ***client (buyer)***, 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.

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

Amendment 129
Sebastian Valentin Bodu

Proposal for a directive
Article 14 – paragraph 4

Text proposed by the Commission

4. Member States shall ensure that

Amendment

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.

manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the first *client (buyer)*, 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.

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

Amendment 130 **Sebastian Valentin Bodu**

Proposal for a directive **Article 14 – paragraph 6**

Text proposed by the Commission

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

Amendment

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 **and accessible** on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the

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.

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.

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

Amendment 131

Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Alajos Mészáros

Proposal for a directive Article 14 – paragraph 8

Text proposed by the Commission

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

Amendment

8. In addition to the unique, ***safe and impossible to duplicate*** 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

tax stamps and price marks, or other elements mandated by legislation.

interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation

Or. en

Amendment 132
Sebastian Valentin Bodu

Proposal for a directive
Article 14 – paragraph 8

Text proposed by the Commission

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.

Amendment

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 tamper proof security feature, which shall be irremovably printed or affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation.

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeit and create the appearance of authenticity).

Amendment 133
Sebastian Valentin Bodu

Proposal for a directive
Article 14 – paragraph 9 – point c

Text proposed by the Commission

(c) to define the technical standards for the security feature and their possible rotation and to adapt them to scientific, market and technical development.

Amendment

(c) to define the technical standards for the security feature and their possible rotation and to adapt them to scientific, market and technical development.

Delegated acts shall be based on current practices, technologies and commercial uses and shall consider international accepted standards for tracking, tracing and authentication of fast moving consumer goods, including provision of the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products.

Or. en

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol. Description of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeited and create the appearance of authenticity).

Amendment 134

Tadeusz Zwiefka, Alajos Mészáros

Proposal for a directive

Article 15 – paragraph 1

Text proposed by the Commission

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

Amendment

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden. ***This ban should, however, not affect historically traditional tobacco products for oral use, which may be allowed by individual Member States;***

Amendment 135
Nils Torvalds, Cecilia Wikström

Proposal for a directive
Article 15 – paragraph 1

Text proposed by the Commission

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

Amendment

Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.

Member States and regions of Member States with a tradition of using oral tobacco shall have an opportunity to apply for a national or regional derogation from the prohibition on cultural or historical grounds.

Justification

The prohibition of tobacco for oral use is inconsistent and, inter alia, affects areas all around the Baltic Sea that have traditionally made use of tobacco for oral use. The general public in these countries and regions does not understand why a product that has been used throughout history and is part of a region's cultural identity should be prohibited, especially when the product is less harmful to health than cigarettes.

Amendment 136
Arlene McCarthy

Proposal for a directive
Article 16 – title

Text proposed by the Commission

Cross-border distance sales of tobacco products

Amendment

Online sales of tobacco products

Amendment 137
Arlene McCarthy

Proposal for a directive

Article 16 a (new)

Text proposed by the Commission

Amendment

Article 16 a

Point-of-sale displays of tobacco

- 1. Member States shall prohibit point-of-sale displays of tobacco in their territory.***
- 2. Tobacco products shall be completely concealed from the customer except during the purchase or sale of tobacco products, or stocktaking, restocking, staff training or maintenance of the storage unit.***
- 3. Display of tobacco products for those reasons listed in paragraph 2 may only last as long as is necessary to complete those tasks.***
- 4. Prices of tobacco products shall be listed in a standardised format. No package deals or special discounts shall be displayed.***

Amendment 138
Lidia Joanna Geringer de Oedenberg

Proposal for a directive
Article 16 – paragraph 4

Text proposed by the Commission

Amendment

4. Retail outlets engaged in distance sales shall be equipped ***with*** an age verification

4. Retail outlets engaged in distance sales ***as well as owners of premises where there***

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.

are tobacco vending machine shall *use or* be equipped *in* 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 *or place of purchase*. The retailer or nominated natural person shall report to the competent authorities a description of the details and functioning of the age verification system.

Or. en

Amendment 139
Lidia Joanna Geringer de Oedenberg

Proposal for a directive
Article 16 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. Advertising of tobacco product via internet as well as using for that purpose profiling of personal data's shall not be permitted.

Or. en

Amendment 140
Nuno Teixeira

Proposal for a directive
Article 17 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. In connection with the marketing of reduced-harm tobacco products, Member States shall introduce an authorisation system and charge a proportionate fee. They shall also specify rules applicable to the scientific assessment of risk and the type of evidence to be presented, including, but not only, clinical and non-

clinical information and other available studies examining how consumers use and perceive the product. Member States may diverge from the requirements laid down by this Directive in relation to authorised reduced-harm products in order to illustrate their less harmful nature.

Or. pt

Amendment 141
Sebastian Valentin Bodu

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission

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

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.

Nonetheless, novel tobacco products which, based on the information provided in accordance with this Article, are less harmful than cigarettes are exempted from the provision of the Article 12 paragraph 1 letter (b).

Or. en

Justification

It is normal that provision in paragraph 12 (b) to be applied to the tobacco products that fall under a certain category of health risk. If a new product is not in such a category, the extension of such provision is not necessary. But is also important that lower health risk to the scientifically proven.

Amendment 142
Nuno Teixeira

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission

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

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive, ***unless otherwise authorised as provided for in paragraph 2 of this Article***. 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.

Or. pt

Amendment 143
Sergio Gaetano Cofferati

Proposal for a directive
Article 18 – paragraph 1

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.

Amendment

deleted

Or. it

Amendment 144
Rebecca Taylor

Proposal for a directive
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

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

1. **Nicotine-containing products that are presented as having properties for treating or preventing disease in human beings, other than through any message specified in paragraph 3,** may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC

Or. en

Justification

This makes a medicines marketing authorisation mandatory if a health claim is made using strictly the definition in the medicines directive: ‘presented as having properties for treating or presenting disease’ is quoted from the first part of the medicines directive definition of a medicine 2001/83/EC Article 1.2(a)

Amendment 145
Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) products with a nicotine level exceeding 2 mg per unit, or

deleted

Or. en

Justification

Thresholds make no sense as the products above and below still need to be regulated appropriately – the distinction between whether medicines regulation or consumer regulation is applied rests on whether a therapeutic health claim is made, not on an arbitrary threshold.

Amendment 146
Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) products with a nicotine concentration exceeding 4 mg per ml or ***deleted***

Or. en

Amendment 147
Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 – point c

Text proposed by the Commission

Amendment

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

Or. en

Amendment 148
Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. This Directive shall not apply to nicotine containing products authorised pursuant to Directive 2001/83/EC.

Justification

Makes it clear that provisions of the directive do not apply to NCPs regulated as medicines.

Amendment 149

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. For nicotine-containing products where paragraph 1 does not apply, the products may be placed on the market if they comply with this Directive

Or. en

Justification

Ensures that the TPD applies to all other NCPs, and limits the application of medicines regulation to those vendors making health claims consistent with the medicines regulation definition. It rules out member states classifying NCPs as medicines under Article 1.2(b) of 2001/83/EC – the ‘functional’ definition based on changes to physiology – an approach that has been repeatedly struck down in courts in several Member States.

Amendment 150

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

1c. Member States shall ensure that nicotine containing products comply with European Union consumer protection, safety and other relevant legislation in force.

Justification

Member States should apply the body of existing consumer and safety legislation to nicotine containing products.

Amendment 151

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 d (new)

Text proposed by the Commission

Amendment

1d. No later than 12 months from entry into force of this Directive, each Member State shall provide the Commission with a report on the measures it has taken to implement and enforce the legislation set out in [new] Annex IV as it applies to nicotine containing products and the effectiveness of those measures.

Justification

The requirement to report will mean a more systematic approach is taken, and will provide data for a future Commission review of the regulatory framework for NCPs. .

Amendment 152

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 e (new)

Text proposed by the Commission

Amendment

1e. Member States shall ensure that nicotine-containing products are not sold to persons below the national legal age for purchasing tobacco products.

Justification

A level playing field in the age sale requirements between nicotine-containing products and tobacco products should be maintained, so as to prevent young people from buying NCPs.

Amendment 153

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 f (new)

Text proposed by the Commission

Amendment

If. Where appropriate, Member States may impose marketing restrictions on nicotine-containing products similar to those which apply to the marketing of tobacco products.

Justification

Member States should be able to apply certain restrictions to the marketing of nicotine containing products, so as to prevent for example manufacturers from using marketing techniques aimed at minors such as advertising near schools, or promoting their products in a way which glamorises them, thus indirectly appealing to minors.

Amendment 154

Sergio Gaetano Cofferati

Proposal for a directive

Article 18 – paragraph 2

Text proposed by the Commission

Amendment

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 ***deleted***

marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC.

Or. it

Amendment 155
Rebecca Taylor

Proposal for a directive
Article 18 – paragraph 2

Text proposed by the Commission

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 Directive 2001/83/EC.*

Amendment

2. The Commission shall, *by 1 April 2017, carry out a study on nicotine-containing products in consultation with relevant stakeholders and the Member States. This study will consider whether there is a need for specific legislation in regard to nicotine-containing products.*

Or. en

Justification

Nicotine containing products are potentially a huge market and can play a key role in public health as a less harmful alternative to cigarettes. It is important that regulation is designed with care and is legally robust – not to be excessively burdensome or too general to capture any specific risks arising from the products. There are currently too many unanswered questions in relation to NCPs, hence the need for further study including by the Commission.

Amendment 156
Sergio Gaetano Cofferati

Proposal for a directive
Article 18 – paragraph 3

Text proposed by the Commission

3. Each unit packet and any outside packaging of nicotine-containing

Amendment

deleted

products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

Or. it

Amendment 157
Rebecca Taylor

Proposal for a directive
Article 18 – paragraph 3

Text proposed by the Commission

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.

Amendment

3. Each unit packet and any outside packaging of nicotine-containing products *which do not fall under the scope of Directive 2001/83/EC* shall carry the following health warning:

This product contains nicotine *which is addictive and may* damage your health.

Or. en

Justification

Consumers should be informed of the addictive characteristics of nicotine, and that such an addiction may be detrimental to health. While the effects of nicotine on the human body are well established, and for the most part do not pose serious risks to health, the effect of long-term use of nicotine-containing products cannot currently be confirmed, so caution is needed.

Amendment 158
Sergio Gaetano Cofferati

Proposal for a directive
Article 18 – paragraph 4

Text proposed by the Commission

4. The health warning referred to in paragraph 3 shall comply with the

Amendment

deleted

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.

Or. it

Amendment 159

Sergio Gaetano Cofferati

Proposal for a directive

Article 18 – paragraph 5

Text proposed by the Commission

Amendment

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.

deleted

Or. it

Amendment 160

Sergio Gaetano Cofferati

Proposal for a directive

Article 18 a (new)

Text proposed by the Commission

Amendment

Article 18a

nicotine-containing products

The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC or under the simplified procedure referred to in paragraphs 2 and 3:

Simplified procedure

2. Under the simplified procedure, Member States shall require manufacturers and importers of nicotine-containing products to submit an application for a marketing authorisation, which shall contain the following:

(a) evidence that the product is manufactured in accordance with the principles and guidelines of good manufacturing practice;

(b) a detailed description of the product in question, including all ingredients and quantities thereof, as well as information on emissions;

(c) a risk-management plan, including a system for monitoring and recording any adverse reactions.

Member States may also require manufacturers or importers to carry out additional tests or submit additional information.

Each Member State shall take due account of authorisations previously granted by another Member State.

3. For products authorised under the simplified procedure, Member States shall ensure that the following conditions are fulfilled:

(a) the product is clearly labelled with the nicotine content, instructions for use, instructions for reporting adverse reactions, and details of the manufacturer;

(b) each unit packet and any outside packaging shall carry the following health warning:

This products is intended for use by existing smokers aged 18 or over as an alternative to tobacco cigarettes. It contains nicotine which is a highly addictive substance. Consult your doctor if you are pregnant, breast feeding, allergic to nicotine or propylene glycol, or have high blood pressure;

(c) the use of characterising aromas shall not be authorised;

(d) sale of the product shall be subject to the statutory age restrictions for the sale of tobacco products in the Member State in question;

(e) advertising and promotion shall be appropriately regulated.

4. Member States shall ensure that nicotine-containing products are not sold to persons below the age required for purchasing tobacco products.

5. Member States shall monitor the development of the nicotine-containing products market, including any progress made in harm reduction, as well as any evidence of gateway use amongst young people. Based on the evidence, the Commission shall report back to the European Parliament and the Council five years after the transposition date of this Directive. The report shall assess whether amendments to this Directive are necessary.

Or. it

Amendment 161
Sergio Gaetano Cofferati

Proposal for a directive
Article 20 – paragraph 3

Text proposed by the Commission

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.

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. The penalties provided for shall be effective, proportionate and dissuasive. ***All fines shall be greater than any financial rewards for infringement.***

Or. it

Amendment 162
Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Alajos Mészáros

Proposal for a directive
Article 20 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The negative economical and social consequences of the implementation of this Directive shall be counteracted by appropriate measures and financial support in the framework of the EU budget.

Or. en

Amendment 163
Sebastian Valentin Bodu

Proposal for a directive
Article 22 – paragraph 2

Text proposed by the Commission

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].

Amendment

2. The power to adopt delegated acts referred to in Articles 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].

Or. en

Justification

Parliament and Council should be involved in deciding the eliminated because a delegated act would born its effects that cannot be reviewed by the Parliament and the Council, as legislators at the time of the issue by the Commission packs. The Commission can legislate through delegated acts on technical issues with no financial so, not on those that are difficult to reverse the adverse effects born at the time of the issuance. Therefore, the Parliament and the Members States (through the Council) should be all the time involved in the legislative procedure that has a material impact on any market

Amendment 164
Sebastian Valentin Bodu

Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission

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 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.

Amendment

3. The delegation of powers referred to in Articles 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 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.

Justification

Parliament and Council should be involved in deciding the eliminated because a delegated act would born its effects that cannot be reviewed by the Parliament and the Council, as legislators at the time of the issue by the Commission packs. The Commission can legislate through delegated acts on technical issues with no financial so, not on those that are difficult to reverse the adverse effects born at the time of the issuance. Therefore, the Parliament and the Members States (through the Council) should be all the time involved in the legislative procedure that has a material impact on any market

Amendment 165
Sebastian Valentin Bodu

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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.

Amendment

5. A delegated act pursuant to Articles 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.

Justification

Parliament and Council should be involved in deciding the eliminated because a delegated act would born its effects that cannot be reviewed by the Parliament and the Council, as legislators at the time of the issue by the Commission packs. The Commission can legislate through delegated acts on technical issues with no financial so, not on those that are difficult to reverse the adverse effects born at the time of the issuance. Therefore, the Parliament and

the Members States (through the Council) should be all the time involved in the legislative procedure that has a material impact on any market.

Amendment 166

Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Alajos Mészáros

Proposal for a directive

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. No later than 2 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 economic and social consequences of the application of this Directive

Or. en

Amendment 167

Sergio Gaetano Cofferati

Proposal for a directive

Article 24 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

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.

Or. it

Amendment 168

Tadeusz Zwiefka, Lidia Joanna Geringer de Oedenberg, Alajos Mészáros

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 + **36** months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

Or. en

Amendment 169

Rebecca Taylor

Proposal for a directive

Article 26 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

(b) nicotine containing products;

Or. en

Amendment 170

Rebecca Taylor

Proposal for a directive

Annex I a (new)

Text proposed by the Commission

Amendment

ANNEX I a

EU legislation applicable to nicotine-containing products:

General safety:

***General Product Safety Directive
2001/95/EC***

The RAPEX system - notification and alerts of dangerous products

Packaging and labelling:

***Dangerous Substances Directive
67/548/EEC***

***Dangerous Preparations Directive
99/45/EC***

Classification, Labelling and Packaging of Substances and Mixtures - the CLP Regulation 1272/2008 applies from 2015.

Chemical safety:

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) 1907/2006

Electrical safety:

Low Voltage Directive 2006/95/EC

***Electro-Magnetic Compatibility Directive
2004/108/EC***

Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU (where appropriate)

Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU

Batteries Directive 2006/66/EC

Weights and measures:

Making-up by weight or by volume of certain prepackaged products - Directive 76/211/EEC

Nominal Quantities for Prepacked Products Directive 2007/45/EC

Commercial practice

Distance Selling Directive 97/7/EC

Directive on Electronic Commerce 2000/31/EC

Misleading and Comparative Advertising Directive 2006/114/EC

Unfair Commercial Practices Directive 2005/29/EC

Or. en

Justification

Member states should apply the body of existing consumer and safety regulation to nicotine containing products. The requirement to report will mean a more systematic approach is taken, and will form the basis of a Commission review to be completed by April 2017.