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Committee on Legal Affairs

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OPINION

of the Committee on Legal Affairs

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

on the proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products
(COM(2012)0788 – C7-0420/2012 – 2012/0366(COD))

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SHORT JUSTIFICATION

It is universally accepted today that tobacco consumption poses serious risks to human health. In this regard, it is particularly worrying that most smokers start before the age of 18. Therefore, young people in particular have to be fully informed about the toxicity and addictiveness of tobacco products. For those who already consume tobacco products, the promotion and development of less harmful products and products for smoking cessation is essential.

There is no doubt that efforts to reduce tobacco consumption should continue at national as well as at international level. However, certain provisions of the Commission's proposal raise significant legal concerns. These concerns relate, *inter alia*, to the legal base chosen by the Commission, to fundamental rights such as the right to property and to the principle of proportionality.

The Commission bases its proposal on Article 114(1) TFEU. This provision allows approximation measures aimed at improving the conditions for the establishment and functioning of the internal market. The measures must "*genuinely have that object, actually contributing to the elimination of obstacles to the free movement of goods or to the freedom to provide services, or to the removal of distortions of competition*".[1] Some of the measures proposed by the Commission, however, do not aim at improving the conditions of the internal market, but have as their only objective the protection of public health.

For example, it is difficult to see how the proposed (de facto) ban on menthol and on slim cigarettes could improve the functioning of the internal market. It is true that even prohibitions may, in certain circumstances, be regarded as harmonising measures, but this is only the case where "*there are obstacles to trade or it is likely that such obstacles will emerge in future*".[2] Currently, however, not a single Member State has banned slim cigarettes or menthol or is even considering it. Thus, the ban will neither remove nor prevent the emergence of obstacles to fundamental freedoms.[3]

As reflected in the recitals of the Commission's proposal, the true aim of these measures is the achievement of a higher level of health protection. It is feared that menthol and slim cigarettes might be particularly attractive to young people.[4] While the protection of health is of the utmost importance, it is up to the Member States and not the European Union to take measures in that regard. Article 168(5) TFEU explicitly excludes any harmonisation regarding measures "*having as their direct objective the protection of public health regarding tobacco*".

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[1] Case C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 60.
[2] Case C-210/03, *Swedish Match*, paragraphs 30, 33.
[3] There is also no obligation to ban menthol only because other flavours are banned. The Commission's proposal makes reference to a decision of a WTO Appellate Body (WTO Appellate Body, AB-2012-1, United States – Measures Affecting the Production and Sale of Clove Cigarettes (DS406)). This decision, however, only said that menthol and clove cigarettes were, under the specific circumstances of the case, "like products" and that they could not be treated differently. The WTO Appellate Body did not reason that the US could not distinguish between menthol and other characteristic flavours such as fruit and candy flavours.
[4] See e.g. recital 15: "*A number of studies indicated that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people.*" and recital 23: "*A recent study has also shown that smokers of slim cigarettes were more likely to believe that their own brand might be less harmful. This should be addressed.*"

The Commission can only take a high level of health protection as a basis pursuant to Article 114(3) TFEU if the requirements of Article 114(1) TFEU are fulfilled.[1] Otherwise, the European Union could circumvent the clear division of competences resulting from Article 168(5) TFEU.

Some provisions in the Commission's proposal also raise serious doubts as to their conformity with fundamental rights such as the right to property, the right to freedom of expression and information and the freedom to conduct business. These rights are enshrined in the Charter of Fundamental Rights of the European Union ("the Charter") and may only be limited pursuant to Article 52(1) of the Charter if the limitation is necessary, genuinely meets objectives of general interest and is proportional.

Certain of the proposed measures, especially regarding the packaging, do not meet these requirements. One example is the proposed increase in size of the health warnings to 75 % of both the front and back surface of the packs (Article 9(1)(c)). This would severely reduce the space available for trademarks and product description. In practice, not even 25 % of the front and back surface would be available for the information provided by the producer, as national law requires additional features such as tax stamps and security features.

Intellectual property rights such as trademarks are explicitly covered by the right to property in Article 17 of the Charter. The CJEU held that warnings on the unit packages are admissible "*in a proportion which leaves sufficient space for the manufacturers of those products to be able to affix other material, in particular concerning their trademarks*".[2] Reducing the space available on the front and back surfaces to less than 25% would, however, make it difficult to sufficiently distinguish the products of one producer from those of others, thereby depriving the trade marks of one of their main functions. The trade marks could also not properly fulfil their other functions such as its advertising function. This would also not be in accordance with national constitutional law[3] as well as international treaties such as the TRIPS Agreement.[4]

Bearing in mind the impact on intellectual property rights, it is more than surprising that the Commission did not even consider less restrictive measures such as smaller health warnings. Taking into account the importance of intellectual property rights and legitimate health objectives, it is suggested that health warnings should cover 50 % of the front and back surface. This would also be in line with the FCTC, the implementation of which is one of the aims of the Commission's proposal. Pursuant to Article 11(1) of the FCTC, health warnings describing the harmful effects of tobacco use "*should be 50% or more of the principal display*

[1] See C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 62.
[2] Case C-491/01, *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 132.
[3] See for example the judgment of the German Federal Constitutional Court, BVerGE 95, 173, paragraph 70.
[4] See e.g. Article 8.1 and 20 TRIPS. Contrary to what is sometimes asserted, the decision of the Australian High Court of 15 August 2012 regarding the compatibility of the so-called plain packaging rules with the Australian Constitution does not in any way suggest that plain packaging or similar measures would be in accordance with European law. Pursuant to section 51 of the Australian Constitution, a law violates the Australian Constitution if it deprives a person or company from its property and provides the Australian government with some proprietary benefit from that property. The plain packaging requirement was upheld because the Australia had not "acquired" the property. However, the Court found that plain packaging does indeed "deprive" tobacco manufacturers of their property. Under Article 17 of the Charter and thus EU law, an "acquisition" of property is no precondition for a breach of the right to property – a deprivation is sufficient. Therefore, if anything, the judgment of the Australian High Court speaks against the admissibility of similar measures under EU law.

areas but shall be no less than 30% of the principal display areas".

Other measures proposed by the Commission regarding the size and appearance of unit packs and regarding the product description meet similar concerns regarding fundamental rights. They deprive manufacturers of their intellectual property rights, reduce customer choice and do not contribute to a better functioning of the internal market.

By prohibiting any labelling that suggests that a particular tobacco product is less harmful than others, the proposal causes an additional problem. The development and promotion of less harmful means of tobacco use is essential in order to support tobacco users to stop smoking cigarettes and the like. Manufacturers must be able to communicate that a certain product is less harmful than others if this is scientifically proven and if it is not misleading. This is not the only measure proposed that would make it more difficult to access reduced risk products. Article 18 of the proposal prohibits nicotine-containing products (NCP) such as e-cigarettes containing a certain nicotine level if they are not authorised pursuant to Directive 2001/83/EC (the Medicinal Products Directive). It is, however, quite unclear if these products (which are much less harmful than tobacco products) even fall under the scope of the Medicinal Products Directive.[1] For products which do not fall under the Directive, this would effectively constitute a ban. Banning products which are less harmful than tobacco products and which can be a means of smoking cessation is certainly not in line with the public health aims of the proposal.[2]

Finally, the Commission's proposal contains a large number of provisions delegating powers to the Commission. However, pursuant to Article 290 TFEU, a delegation of powers is only possible with regard to non-essential elements of the legislative proposal. Some of the proposed provisions providing for delegated acts do not fulfil this requirement. For example, Article 3(2) in conjunction with Article 2(19) would grant the Commission to set the maximum yield of nicotine for cigarettes placed on the market to 0, effectively prohibiting cigarettes for good.

AMENDMENTS

The Committee on Legal Affairs
calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

[1] Relying on the strict jurisprudence of the CJEU, several national courts have already held that e-cigarettes cannot be qualified as a medicinal product by function under the Medicinal Products Directive, see e.g. Oberverwaltungsgericht Nordrhein-Westfalen, 24 April 2012, 16 L 2043/11.

[2] Article 18 also lacks a valid legal base as it is in no way aimed at improving the conditions for the establishment and functioning of the internal market. Pursuant to the Commission, the provision will allow NCP to move freely across borders as they would benefit from the mutual recognition procedure under the Medicinal Products Directive (Impact Assessment, page 8). However, this is already the case without Article 18, as any NCP which qualifies as a medicinal product is already now subject to the Medicinal Products Directive. The only effect Article 18 has is that it prohibits the placing on the market of NCP that are not authorised pursuant to the Medicinal Products Directive.

Amendment 1

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***

Amendment 2

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 internationally agreed standards to assess*** their toxicity or addictiveness.

Amendment 3

Proposal for a directive
Recital 14

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

Amendment 4

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***	(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 ***and traditional flavours such as menthol***, which may facilitate uptake of tobacco consumption or affect consumption patterns.

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 5

Proposal for a directive
Recital 16

Text proposed by the Commission	*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 ***should be*** allowed***, as long as they do not result in a characterising flavour***. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.	(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 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.

Amendment 6

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(23) In order to ensure the integrity and the	(23) In order to ensure the integrity and the

visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimension of the warnings as well as regarding certain aspects of the appearance of the tobacco package, including the opening mechanism. The package and the products may mislead consumers, in particular young people, suggesting that products are less harmful. For instance, this is the case with certain texts or features, such as ‘low-tar’, ‘light’, ‘ultra-light’, ‘mild’, ‘natural’***,*** ‘organic’***, ‘without additives’, ‘without flavours’, ‘slim’, names, pictures, and figurative or other signs***. ***Likewise, the size and appearance of individual cigarettes can mislead consumers by creating the impression that they are less harmful. A recent study has also shown that smokers of slim cigarettes were more likely to believe that their own brand might be less harmful. This should be addressed***.	visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimension of the warnings as well as regarding certain aspects of the appearance of the tobacco package, including the opening mechanism. The package and the products may mislead consumers, in particular young people, suggesting that products are less harmful. For instance, this is the case with certain texts or features, such as 'low-tar', 'light', 'ultra-light', 'mild', 'natural' ***or*** 'organic'.

Amendment 7

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***

Amendment 8

Proposal for a directive
Recital 26

Text proposed by the Commission	*Amendment*
(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive	(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive

2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets of tobacco products to be marked in a unique and secure way and their movements to be recorded so that these products can be tracked and traced in the Union and their compliance with this Directive can be monitored and better enforced. ***In addition, provision should be made for the introduction of security features that will facilitate the verification of whether or not products are authentic.***	2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets of tobacco products to be marked in a unique and secure way and their movements to be recorded so that these products can be tracked and traced in the Union and their compliance with this Directive can be monitored and better enforced.

Amendment 9

Proposal for a directive
Recital 27

Text proposed by the Commission	*Amendment*
(27) An interoperable tracking and tracing system ***and a common security feature*** should be developed. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system ***and the security features***. This would allow producers of other tobacco products to benefit from the experiences gained in the meantime.	(27) An interoperable tracking and tracing system should be developed. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system. This would allow producers of other tobacco products to benefit from the experiences gained in the meantime.

Amendment 10

Proposal for a directive
Recital 29

Text proposed by the Commission	*Amendment*
(29) Council Directive 89/622/EEC of 13	(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.	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. ***Upholding the ban on*** tobacco ***products for oral use should however 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.

Amendment 11

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.

Amendment 12

Proposal for a directive
Recital 33

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

Amendment 13

Proposal for a directive
Recital 34

Text proposed by the Commission	*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[42] 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	***deleted***

2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

Amendment 14

Proposal for a directive
Recital 35

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Amendment 15

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.

Amendment 16

Proposal for a directive
Recital 38

Text proposed by the Commission	*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	(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.	should be delegated to the Commission. 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 17

Proposal for a directive
Recital 40

Text proposed by the Commission	*Amendment*
(40) A Member State that deems it necessary to maintain more stringent national provisions for aspects falling inside the scope of this Directive should be allowed to do so, for all products alike, on grounds of overriding needs relating to the protection of public health. A Member State should also be allowed to introduce more stringent provisions, applying to all products alike, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. More stringent national provisions should be	***deleted***

necessary and proportionate, not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Stricter national provisions require prior notification to, and approval from, the Commission taking into account the high level of health protection achieved through this Directive.

Amendment 18

Proposal for a directive
Recital 41

Text proposed by the Commission	*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 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***.	(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. ***With regard to measures already harmonized by*** this Directive***, such as labelling und packaging requirements, the*** procedure ***foreseen in Article 114(8) TFEU shall apply***.

Amendment 19

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

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

Amendment 20

Proposal for a directive
Article 2 – point 4

Text proposed by the Commission	*Amendment*
(4) **'**characterising flavour**'** means a distinguishable aroma or taste other than tobacco, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy**,** ***menthol*** or vanilla observable before or upon intended use of the tobacco product;	(4) **'**characterising flavour**'** means a distinguishable aroma or taste other than tobacco ***and traditional flavours such as menthol***, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy or vanilla observable before or upon intended use of the tobacco product;

Justification

The ban on menthol cannot be based on Article 114(1) TFEU as it neither removes nor prevents the emergence of obstacles to the functioning of the internal market. Its direct aim is the protection of public health. Consequently, it falls under Article 168(5) TFEU and lacks a valid legal base.

Amendment 21

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

Text proposed by the Commission	*Amendment*
(19) 'maximum level' or 'maximum yield'	***deleted***

means the maximum content or emission, including 0, of a substance in a tobacco product measured in grams;

Amendment 22

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;

Amendment 23

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).

Amendment 24

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***

Justification

The establishment of maximum yields for tar, nicotine and carbon monoxide is an essential element of the proposed directive. Consequently, it should be subject to the ordinary legislative procedure.

Amendment 25

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***

Justification

The establishment of maximum yields for tar, nicotine and carbon monoxide is an essential

element of the proposed directive. Consequently, it should be subject to the ordinary legislative procedure.

Amendment 26

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

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

Justification

Article 15 provides for a Swedish cultural derogation for oral tobacco. The above principle should also apply to the regulation of ingredients since Swedish cultural tobacco is often flavoured..

Amendment 27

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

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

Amendment 28

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

Text proposed by the Commission	*Amendment*
The Commission shall at the request of a Member State or may on its own initiative determine by means of implementing acts whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.	***deleted***

Justification

The decision whether a tobacco product falls within the scope of paragraph 1 and is therefore to be prohibited is not a decision for the Commission, but for the legislator to make.

Amendment 29

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

Text proposed by the Commission	*Amendment*
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.	***deleted***

Amendment 30

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	***deleted***

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.	

Justification

This decision constitutes an essential element of the proposal and should therefore be left to the legislator.

Amendment 31

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

Amendment 32

Proposal for a directive
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
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	***deleted***

delegated acts in accordance with Article 22 to set maximum levels for those additives.

Justification

This decision constitutes an essential element of the proposal and should therefore be left to the legislator.

Amendment 33

Proposal for a directive
Article 6 – paragraph 10

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

Amendment 34

Proposal for a directive
Article 8 – paragraph 3

Text proposed by the Commission	*Amendment*
3. For cigarette packets the general warning and the information message shall be printed on the lateral sides of the unit packets. ***These warnings shall have a width of not less than 20 mm and a height of not less than 43 mm.*** For roll-your-own tobacco the information message shall be printed on the surface that becomes visible when opening the unit packet. Both the general warning and the information message shall cover 50% of the surface on	3. For cigarette packets the general warning and the information message shall be printed on the lateral sides of the unit packets. For roll-your-own tobacco the information message shall be printed on the surface that becomes visible when opening the unit packet. Both the general warning and the information message shall cover 50% of the surface on which they are printed.

which they are printed.

Justification

The prescription of a minimum size for health warnings effectively leads to a minimum size of packs. This reduces consumer choice and may infringe intellectual property rights. With a view to the uncertain potential benefits of a minimum size of packs, the measure is not in accordance with the principle of proportionality.

Amendment 35

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***

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 36

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;

Amendment 37

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

Text proposed by the Commission	*Amendment*
(c) cover ***75*** % of the external area of both the front and back surface of the unit packet and any outside packaging;	(c) cover ***50*** % of the external area of both the front and back surface of the unit packet and any outside packaging;

Justification

Requirements regarding the size of the health warnings must not lead to an infringement of intellectual property rights. Combined health warnings covering 50% of both the front and the back surface are proportionate and in line with international obligations resulting from the TRIPS agreement and the FCTC.

Amendment 38

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

Text proposed by the Commission	*Amendment*
(e) be positioned ***at the top edge of the unit packet and any outside packaging, and*** in the same direction as any other information appearing on the packaging;	(e) be positioned in the same direction as any other information appearing on the packaging;

Justification

This requirement together with the large size of the health warning is not a proportional limitation of the intellectual property rights of manufacturers.

Amendment 39

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:	***deleted***

Justification

The prescription of a minimum size for health warnings effectively leads to a minimum size of packs. This reduces consumer choice and may infringe intellectual property rights. With a view to the uncertain potential benefits of a minimum size of packs the measure is not in accordance with the principle of proportionality.

Amendment 40

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;	***deleted***

Amendment 41

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.	***deleted***

Amendment 42

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***

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 43

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***

Justification

This decision constitutes an essential element of the proposal and should therefore be left to the legislator.

Amendment 44

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

Text proposed by the Commission	*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;	(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 unless independent scientific evidence substantiates a significantly reduced health risk, or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health effects***;

Justification

Product description must not be misleading.

Amendment 45

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

Text proposed by the Commission	*Amendment*
(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;	***deleted***

Justification

Customers should not be deprived of information about the product as long as it is not misleading. To prevent producers from referring for example to flavours raises concerns regarding the right to freedom of expression and the right to receive information without interference by public authority as provided for in Article 11(1) of the Charter of Fundamental Rights of the European Union.

Amendment 46

Proposal for a directive
Article 12 – paragraph 2

Text proposed by the Commission	*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.	***deleted***

Justification

The provision relating to prohibited items and features is likely to lead to legal uncertainty and should therefore be deleted. Article 12(1) provides sufficient guidance as it clearly prohibits any product description which is misleading. The proposed de facto ban of cigarettes with a diameter of less than 7.5 mm lacks any legal base and was not even subject

to a proper impact assessment by the Commission. In addition, this measure would violate the intellectual property rights of manufacturers.

Amendment 47

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A unit packet of cigarettes ***shall have a cuboid shape.*** A unit packet of ***roll-your-own*** tobacco shall have the form of a pouch, i.e. a rectangular pocket with a flap that covers the opening. ***The flap of the pouch shall cover at least 70% of the front of the packet. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing at least 40 g.***	1. ***The length of one side of the bottom of*** *a unit packet of cigarettes* ***placed on the market shall be at least double that of its adjacent sides.*** 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.

Amendment 48

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A cigarette packet can be of carton or soft material and shall not contain an opening that can be re-closed or re-sealed after the opening is first opened, other than the flip-top lid. The flip-top lid of a cigarette packet shall be hinged only at the back of the packet.	***deleted***

Amendment 49

Proposal for a directive
Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall be empowered to	***deleted***

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

Amendment 50

Proposal for a directive
Article 13 – paragraph 4

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

Amendment 51

Proposal for a directive
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
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	1. ***For the purposes of effective tracking and tracing,*** Member States shall ***require that unique, secure and non-removable identification markings hereafter called unique identification markings, such as codes or stamps, are affixed to or form part of*** all unit packets ***and packages and any outside packaging of cigarettes***. In order to ensure their integrity, unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form,

the Union market.	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 52

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

Text proposed by the Commission	*Amendment*
(e) the product ***name***;	(e) the product ***description***;

Justification

The provision should be aligned with the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products.

Amendment 53

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 shipment ***date, the shipmemt destination, point of departure and consignee***;

Amendment 54

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 ***any known subsequent purchaser***;

Amendment 55

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 ***the first customer who is not affiliated with the manufacturer***.

Amendment 56

Proposal for a directive
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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.

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 57

Proposal for a directive
Article 14 – paragraph 4

Text proposed by the Commission	*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.	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 first ***customer who is not affiliated with the*** with the necessary equipment allowing for the recording of the tobacco products purchased, sold ***to the first customer who is not affiliated with the manufacturer***, 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.

Amendment 58

Proposal for a directive
Article 14 – paragraph 6

Text proposed by the Commission	*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 on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be approved and monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. Member States shall ensure full transparency and accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party on a permanent basis. In duly justified cases Member States or the	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 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

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.	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.

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 59

Proposal for a directive
Article 14 – paragraph 8

Text proposed by the Commission	*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 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.	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, 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.

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 60

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

Text proposed by the Commission	*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.	***deleted***

Amendment 61

Proposal for a directive
Article 14 – paragraph 10

Text proposed by the Commission	*Amendment*
10. Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the application of paragraph 1 to 8 during a period of ***5*** years following the date referred to in paragraph 1 of Article 25.	10. Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the application of paragraph 1 to 8 during a period of ***10*** years following the date referred to in paragraph 1 of Article 25.

Amendment 62

Proposal for a directive
Article 15 – paragraph 1

Text proposed by the Commission	*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 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 traditional tobacco products for oral use, which may be allowed by individual Member States on cultural or historical grounds***.

Amendment 63

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.

Amendment 64

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission	*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.	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.

Amendment 65

Proposal for a directive

Article 18

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.
(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.	
	1 a. This Directive shall not apply to nicotine-containing products authorised pursuant to Directive 2001/83/EC.
	1 b. For nicotine-containing products where paragraph 1 does not apply, the products may be placed on the market if they comply with this Directive
	1 c. Member States shall ensure that nicotine containing products comply with European Union consumer protection, safety and other relevant legislation in force
	1 d. 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.
	1 e. Member States shall ensure that nicotine-containing products are not sold to persons below the national legal age for purchasing tobacco products.
2. The Commission shall ***be empowered to***	2. The Commission shall***, by 1 April 2017,***

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.	***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***.
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:	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 ***and can*** damage your health.	This product contains nicotine ***which is addictive and may*** damage your health.
4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:	
(a) be printed on the two largest surfaces of the unit packet and any outside packaging;	
(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.	
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, designand rotation of the health warnings.	

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 66

Proposal for a directive
Article 20 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive.	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.***

Amendment 67

Proposal for a directive
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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].	2. The power to adopt delegated acts referred to in Articles 4(3), 4(4), 8(4), 9(3), 11(3) ***and*** 14(9) 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].

Justification

Some of the provisions on delegated acts foreseen in the Commission's proposal do not fulfil the requirements of Article 290 TFEU.

Amendment 68

Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The delegation of powers referred to in	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.	Articles 4(3), 4(4), 8(4), 9(3), 11(3) ***and*** 14(9) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the 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 69

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. A delegated act pursuant to Articles 4(3), 4(4), 8(4), 9(3), 11(3) ***and*** 14(9) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Amendment 70

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

Amendment 71

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 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.	***deleted***

Justification

The procedure foreseen in Article 24(2) of the proposal is not in accordance with the TFEU.

The procedure foreseen by the Commission matches the one foreseen in Article 114(5) and (6) TFEU which is explicitly only applicable to measures relating to the protection of the environment or the working environment.

Amendment 72

Proposal for a directive
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [Publications Office, please insert the exact date: entry into force + ***18*** months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.	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.

Amendment 73

Proposal for a directive
Article 26 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) nicotine containing products ***below the threshold set out in Article 18(1)***;	(b) nicotine containing products;

Amendment 74

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

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.

PROCEDURE

Title	Approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products
References	COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)
Committee responsible Date announced in plenary	ENVI 15.1.2013
Opinion by Date announced in plenary	JURI 15.1.2013
Rapporteur Date appointed	Klaus-Heiner Lehne 22.1.2013
Discussed in committee	24.4.2013 30.5.2013 19.6.2013
Date adopted	20.6.2013
Result of final vote	+: 14 –: 6 0: 4
Members present for the final vote	Raffaele Baldassarre, Luigi Berlinguer, Sebastian Valentin Bodu, Françoise Castex, Christian Engström, Marielle Gallo, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Klaus-Heiner Lehne, Antonio Masip Hidalgo, Jiří Maštálka, Alajos Mészáros, Bernhard Rapkay, Evelyn Regner, Dimitar Stoyanov, Rebecca Taylor, Alexandra Thein, Tadeusz Zwiefka
Substitute(s) present for the final vote	Sergio Gaetano Cofferati, Eva Lichtenberger, Angelika Niebler, Axel Voss
Substitute(s) under Rule 187(2) present for the final vote	Frédérique Ries, Nikolaos Salavrakos, Jacek Włosowicz