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Committee on the Internal Market and Consumer Protection

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DRAFT OPINION

of the Committee on the Internal Market and Consumer Protection

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 – C7-0420/2013 – 2012/0366(COD))

Rapporteur: Małgorzata Handzlik

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SHORT JUSTIFICATION

The Tobacco Products Directive (2001/37/EC) was adopted in 2001 and aimed at regulating cigarettes and other tobacco products and contributing to the reduction of the number of smokers in the European Union. The main areas regulated are health warnings, measures concerning ingredients and descriptions of tobacco products, maximum tar, nicotine and carbon monoxide yields of cigarettes. However, the developments in science and the market observed over the past ten years since the adoption of this Directive require its updating. Moreover, given the divergent levels of implementation of this Directive in the Member States, it is crucial to update this Directive in order to ensure the smooth functioning of the internal market.

Your Rapporteur welcomes the proposal by the European Commission and supports its overall objectives, i.e. the approximation of laws, regulations and administrative provisions of the Member States in areas such as labelling and packaging, ingredients, etc. in order to facilitate the functioning of the internal market in tobacco and related products, taking as a basis a high level of health protection.

Your Rapporteur therefore, supports the harmonisation of packaging in the internal market as currently, Member States cannot effectively adapt their legislation to new developments. Therefore, larger health warnings in comparison to the current Directive should be foreseen.

While your Rapporteur strongly supports one of the aims of the Commission proposal, which is to ensure health protection, she proposes some amendments in order to improve the functioning of the internal market. Your Rapporteur introduces the notion of "essential additive" and clarifies the provision on the possibility to use these additives in case they are necessary for the manufacturing process. Without this clarification, European producers could be prevented from producing tobacco products as such, given that the Commission foresaw an overall ban of additives with a characterising flavour even if such additives would be needed for the manufacturing process. Further, your Rapporteur is of the opinion that there should be no exemption from the regulation of ingredients for certain tobacco products. In order to ensure uniform treatment of all tobacco products and avoid fragmentation of the market, certain tobacco products should not be favoured over others.

There is no convincing evidence that the diameter of a cigarette itself, regardless of the specific advertising for cigarettes of a certain diameter, is a decisive factor for starting to smoke at an early age. Your Rapporteur therefore proposes not to regulate the minimum size of cigarettes. Your Rapporteur is of the opinion that the consumers should have the possibility to make informed choices. Therefore, disregarding the size of cigarette, the product should be packaged in a harmonised way, with text and pictorial warnings fully informing about negative health consequences of using tobacco products. Your Rapporteur is of the opinion that the measure to introduce limits with regard to the diameter of cigarettes is not proportionate and that the objective of avoiding misleading conceptions will be better achieved by proper information including pictorial and text warnings on packages.

As 70% of smokers start before the age of 18, the main focus of the proposal is to limit access of tobacco products to children and young adults. Your Rapporteur is of the view that cross-border distance sale of tobacco products should not be allowed, as there is no possibility to

effectively verify the age of a potential buyer. Therefore, there is the constant danger that a tobacco product could have been purchased by a minor.

Nicotine-containing products as for example e-cigarettes contain toxic chemicals and tobacco-specific components suspected of being dangerous to consumers. Moreover, analyses in the field show that e-cigarette cartridges labelled as containing no nicotine in many cases do in fact contain low levels of nicotine. For that reason, all nicotine-containing products should be subject to control. Otherwise, products with levels of nicotine concentration just below the proposed thresholds, could reach the market without any authorisation. As indicated above, not only a concentration of nicotine is relevant, but also the mixture of all substances as such. Consumers indicate as well, that they mainly use e-cigarettes to quit smoking, what suggests that e-cigarettes are perceived as a medicinal product. Your Rapporteur proposes therefore, to authorise all nicotine-containing products in accordance with the Directive on the Community code relating to medicinal products for human use (2001/83/EC).

Since some markets might be more affected by the proposed Directive than others your Rapporteur is of the opinion that it is necessary to introduce a longer transitional period for tobacco products, nicotine-containing products and herbal products for smoking.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1
Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) In order to exercise their regulatory function, Member States and the Commission require comprehensive information on ingredients and emissions to assess the attractiveness, addictiveness and toxicity of tobacco products and the risks to health associated with the consumption of such products. To this end, the existing reporting obligations for ingredients and emissions should be reinforced. This is consistent with the obligation placed on the Union to ensure a high level of protection for human health.	(12) In order to exercise their regulatory function, Member States and the Commission require comprehensive information on ingredients and emissions to assess the attractiveness, addictiveness and toxicity of tobacco products and the risks to health associated with the consumption of such products. To this end, the existing reporting obligations for ingredients and emissions should be reinforced***, but should not constitute an unnecessary and disproportionate burden in particular on small and medium-sized enterprises***. This is consistent with the obligation placed on the Union to ensure a

high level of protection for human health.

Or. en

Justification

It is very important to reinforce reporting obligations, however they must not only provide comprehensive information to Member States and the Commission and they should not create unnecessary burdens for companies, particularly for SMEs.

Amendment 2
Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) The current use of different reporting formats makes it difficult for manufacturers and importers to fulfil their reporting obligations and burdensome for the Member States and the Commission to compare, analyse and draw conclusions from the information received. In this light there should be a common mandatory format for the reporting of ingredients and emissions. The greatest possible transparency of product information should be ensured for the general public, while ensuring that appropriate account is taken of the commercial and intellectual property rights of the manufacturers of tobacco products.	(13) The current use of different reporting formats makes it difficult for manufacturers and importers to fulfil their reporting obligations and burdensome for the Member States and the Commission to compare, analyse and draw conclusions from the information received. In this light there should be a common mandatory format for the reporting of ingredients and emissions. The greatest possible transparency of product information should be ensured for the general public, while ensuring that appropriate account is taken of the commercial and intellectual property rights of the manufacturers of tobacco products***, in particular of small and medium sized enterprises***.

Or. en

Justification

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

Amendment 3
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 should be allowed, ***even if they*** result in a characterising flavour***, as long as these additives are essential for manufacturing***. 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.

Or. en

Justification

In conformity with the amendment to Article 6 of the proposed Directive.

Amendment 4
Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco which are mainly consumed by older consumers, should be granted an exemption from certain ingredients requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption	***deleted***

patterns in relation to young people.

Or. en

Justification

From the internal market perspective, some tobacco products should not be favoured over the others.

Amendment 5
Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(23) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimension of the warnings as well as regarding certain aspects of the appearance of the tobacco package, 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***.	(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 ***placed on the packages***, such as 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours', 'slim', names, pictures, and figurative or other signs. ***This should be addressed by defining which text may be placed on the package***.

Or. en

Justification

In conformity with the amendment to Article 12 of the proposed Directive.

Amendment 6
Proposal for a directive
Recital 30

Text proposed by the Commission	*Amendment*
(30) Cross-border distance sales of tobacco facilitate access to tobacco products of young people and risk to undermine compliance with the requirements provided for by tobacco control legislation and in particular by this Directive. ***Common rules on a notification system are necessary to ensure that this Directive achieves its full potential. The provision on notification of*** cross-border distance sales of tobacco ***in this Directive*** should ***apply notwithstanding the notification procedure set out in Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services. Business to consumer distance sale of tobacco products is further regulated by Directive 97/7/EC of the European Parliament and the Council of 20 May 1997 on the protection of consumers in respect of distance contracts, which will be replaced by Directive 2011/83/EU of the European Parliament and the Council of 25 October 2011 on consumer rights, as of 13 June 2014***.	(30) Cross-border distance sales of tobacco facilitate access to tobacco products of young people and risk to undermine compliance with the requirements provided for by tobacco control legislation and in particular by this Directive. ***Therefore,*** cross-border distance sales of tobacco should ***be prohibited***.

Or. en

Justification

In conformity with the amendment to Article 16 of the proposed Directive.

Amendment 7
Proposal for a directive
Recital 34

Text proposed by the Commission	*Amendment*
(34) Directive 2001/83/EC of the European	(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 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.	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 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.

Or. en

Justification

In conformity with the amendment to relevant Article 18 of the proposed Directive.

Amendment 8
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***

Or. en

Justification

In conformity with the amendment to relevant Article 18 of the proposed Directive.

Amendment 9
Proposal for a directive
Recital 37

Text proposed by the Commission	*Amendment*
(37) In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting**,** the determination of products with characterising flavours or with increased levels of toxicity and addictiveness ***and the methodology for determining whether a tobacco product has characterising flavour***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.	(37) In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting ***and*** 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. en

Justification

In conformity with the amendment to relevant Article of the proposed Directive.

Amendment 10
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, in particular in respect of ***the methodology for determining whether a tobacco product has a characterising flavour***, 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 ***and*** defining key elements for contracts on data storage with independent third parties. 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

Justification

In conformity with the amendment to relevant Article 3 of the proposed Directive.

Amendment 11
Proposal for a directive
Article 1 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) cross-border distance sales of tobacco products;	(d) ***the prohibition of*** cross-border distance sales of tobacco products;

Or. en

Justification

In conformity with the amendment to Article 16 of the proposed Directive.

Amendment 12
Proposal for a directive
Article 2 – paragraph 1 – point 2a (new)

Text proposed by the Commission	*Amendment*
	(2a) 'essential additive' means an ingredient which is indispensable for the manufacturing of a tobacco products;

Or. en

Justification

For the purpose of clarifying Article 6 of the proposed Directive it is necessary to provide a definition of "essential additive".

Amendment 13
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;	***deleted***

Or. en

Justification

In conformity with the amendment to Article 16 of the proposed Directive.

Amendment 14
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 ***any supply of products for distribution, consumption or use*** in the Union, with or without payment including by means of distance sale;

Or. en

Justification

In conformity with the amendment to Article 16 of the proposed Directive.

Amendment 15
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

Article 3(1) establishes maximum yields for cigarettes placed on the market or manufactured in the Member States and thus directly impacts the scope of the proposed Directive. Therefore maximum yields are considered as essential elements of a legislative act and any amendment to those elements should be subject to the ordinary legislative procedure.

Amendment 16
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, ***even if the essential additives*** result in a product with a characterising flavour.

Or. en

Justification

Use of all the additives which are indispensable for the manufacturing of tobacco products should be allowed under the proposed Directive; therefore it is necessary to clearly reflect this in the text.

Amendment 17
Proposal for a directive
Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Commission shall adopt ***by means of implemeting 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.***	The Commission shall ***be empowered to*** adopt ***delegated acts, in accordance with Article 22, to determine*** uniform rules on the procedures for determining whether a tobacco product falls within the scope of paragraph 1.

Or. en

Justification

The development and establishment of further rules should take a form of a delegated act and not of an implementing act. The latter could be used in cases where the implementation of the rules already established is sought.

Amendment 18
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.	3. In case the experience gained in the application of paragraphs 1 and 2 shows that a certain additive***, which is not essential,*** 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.

Or. en

Justification

Use of all the additives which are indispensable for the manufacturing of tobacco products should be allowed under the proposed Directive; therefore it is necessary to clearly reflect this in the text.

Amendment 19
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.	***deleted***

Or. en

Justification

In order to ensure uniform treatment of all tobacco products and avoid fragmentation of the market the exemption should be deleted.

Amendment 20
Proposal for a directive
Article 7 – paragraph 3

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

Or. en

Justification

Reference to graphic integrity and visibility is already provided in Recital 23 it is therefore not necessary to repeat the objective in the Article.

Amendment 21
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.	(b) to define the layout and design of the health warnings laid down in this Article, including their font type and background colour.

Or. en

Justification

Article 8(3) already defines that the general warning and the information message shall be printed on the lateral sides of the cigarette unit packets and that the information message

shall be printed on the surface that becomes visible when opening the unit package for roll-your-own tobacco. Format of the health warnings is also defined in the Article 9. Therefore it is inappropriate to leave it for the delegated act to define the position and format of the health warnings.

Amendment 22
Proposal for a directive
Article 9 – paragraph 1 – point f

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

Or. en

Justification

The aspects are already specified in Article 9(3), the provision is therefore repetitive.

Amendment 23
Proposal for a directive
Article 9 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) establish ***and*** adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments;	(b) establish ***by …* and if necessary thereafter*** adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments;
	* ***OJ: please insert date: six months after the entry into force of this Directive.***

Or. en

Justification

It is necessary to determine a deadline for the Commission to establish a picture library in order to provide for the appropriate implementation of Article 9.

Amendment 24
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;	(c) define the layout, design ***and*** rotation of the health warnings;

Or. en

Justification

Article 9(1) already defines that the combined health warnings shall be positioned at the top edge of the unit packet and any outside packaging. Moreover, the proportions and format are defined in Article 9(1) as well. Consequently, it is inappropriate to leave it for the delegated act to define the format, position and proportions.

Amendment 25
Proposal for a directive
Article 9 – paragraph 3 – point d

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

Or. en

Justification

Article 7(3) establishes general provisions to ensure graphic integrity and visibility of health warnings and thus contains essential elements of a legislative act any derogation thereof should be specified in the legislative act.

Amendment 26
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. en

Justification

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

Amendment 27
Proposal for a directive
Article 11 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
This tobacco product ***can damage*** your health and is addictive	This tobacco product ***is harmful to*** your health and is addictive

Or. en

Justification

A product either has a negative effect on health or not. The warning should be clear about harmfulness of the product.

Amendment 28
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	2. Prohibited elements and features may include but are not limited to texts, symbols, names, trade marks, figurative or other signs, misleading colours, inserts or other additional material such as adhesive

labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. ***Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.***	labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself.

Or. en

Justification

There is no direct link between a cigarette with a diameter of less than 7.5 mm and smoking initiation. It is not the diameter itself, but the symbols, figurative signs, texts, etc., i.e. the misleading portrayal of the product, that leads to a misguided belief in certain positive effects of a product. Council Directive 2011/64/EU defines a cigarette by its length and not a diameter.

Amendment 29
Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall have the form of a pouch, i.e. a rectangular pocket with a flap that covers the opening. The flap of the pouch shall cover at least 70% of the front of the packet. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing at least 40 g.	1. A unit packet of cigarettes shall have a cuboid shape ***with sharp edges***. 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.

Or. en

Justification

To address uncertainties with regard to the edges of a package a concrete reference to the type of edges should be provided.

Amendment 30
Proposal for a directive
Article 13 – paragraph 3

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

Or. en

Justification

Both the shape and the size have been clearly set out in the legislative act itself (cuboid package with 75% front/ back warning, height, width, etc.). The more far-reaching step would be full harmonisation, which is a decision that should be left to the legislator.

Amendment 31
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***

Or. en

Justification

The shape of the unit packet of cigarettes and the form of the unit packet of roll-your-own are determined in Article 13(1) of the proposed Directive; therefore the establishment of a mandatory shape for the unit packet of tobacco products other than cigarettes and roll-your-own tobacco should also be subject to the ordinary legislative procedure.

Amendment 32
Proposal for a directive
Article 14 – paragraph 9 – introductory part

Text proposed by the Commission	*Amendment*
9. The Commission shall be empowered to adopt delegated acts in accordance with Article 22:	9. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 ***by …****:
	_____
	**** OJ: please insert date: twelve months after the entry into force of this Directive.***

Or. en

Justification

It is necessary to determine a deadline for the Commission to define key elements of a contract and technical standards with regard to unique identifiers and security feature in order to provide for the appropriate implementation of Article 14.

Amendment 33
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***.	(c) to define the technical standards for the security feature and their possible rotation.

Or. en

Justification

The necessary adaption with regard to the proposed amendment to introductory wording of Article 14(9) of the proposed Directive.

Amendment 34
Proposal for a directive
Article 14 – paragraph 9a (new)

Text proposed by the Commission	*Amendment*
	9a. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt technical standards for the security feature to scientific, market and technical development.

Or. en

Justification

The necessary adaption with regard to the proposed amendment to introductory wording of Article 14(9) of the proposed Directive.

Amendment 35
Proposal for a directive
Title 2 – chapter 3 – title

Text proposed by the Commission	*Amendment*
Tobacco for oral use	***Smokeless tobacco products***

Or. en

Justification

Tobacco for oral use belongs to smokeless tobacco products category, therefore to reflect this relationship between the two terms the title of the chapter should be changed accordingly.

Amendment 36
Proposal for a directive
Article 16 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Member States shall ***oblige retail outlets intending to engage in*** cross-border distance sales ***to consumers located in the***	1. Member States shall ***prohibit*** cross-border distance sales ***of tobacco products to consumers*** located ***in*** the Union.

Union to register with the competent authorities in the Member State where the retail outlet is established and in the Member State where the actual or potential consumer is located***. Retail outlets established outside*** the Union ***have to register with the competent authorities in the Member State where the actual or potential consumer is located***. ***All retail outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities:***

Or. en

Justification

One of the goals of the proposed Directive is to limit access to tobacco product for children and youth. Allowing sale on-line would not ensure achieving this aim.

Amendment 37
Proposal for a directive
Article 16 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) name or corporate name and permanent address of the place of activity from where the tobacco products are supplied;	***deleted***

Or. en

Amendment 38
Proposal for a directive
Article 16 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the starting date of the activity of offering tobacco products for cross-border distance sales to the public by means of information society services;	***deleted***

Or. en

Amendment 39
Proposal for a directive
Article 16 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the address of the website/-s used for that purpose and all relevant information necessary to identify the website.	***deleted***

Or. en

Amendment 40
Proposal for a directive
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States shall publish the complete list of all retail outlets registered with them in accordance with the rules and safeguards laid down in Directive 95/46/EC Retail outlets may only start placing tobacco products on the market in form of distance sales as of the moment the name of the retail outlet is published in the relevant Member States.	***deleted***

Or. en

Amendment 41
Proposal for a directive
Article 16 – paragraph 3

Text proposed by the Commission	*Amendment*
3. If it is necessary in order to ensure compliance and facilitate enforcement, Member States of destination may require	***deleted***

that the retail outlet nominates a natural person who is responsible for verifying the tobacco products before reaching the consumer comply with the national provisions adopted pursuant to this Directive in the Member State of destination.

Or. en

Amendment 42
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 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.	***deleted***

Or. en

Amendment 43
Proposal for a directive
Article 16 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Personal data of the consumer shall only be processed in accordance with Directive 95/46/EC and not be disclosed to the manufacturer of tobacco products or companies forming part of the same group of companies or to any other third parties. Personal data shall not be used or transferred beyond the purpose of this	***deleted***

actual purchase. This also applies if the retail outlet forms part of a manufacturer of tobacco products.

Or. en

Amendment 44
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 may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC**.**

Or. en

Justification

Analyses show that e-cigarettes contain chemicals and components which pose danger to consumers. For that reason, all NCP should be subject to control. Otherwise, products with levels of nicotine concentration just below the proposed thresholds, could reach the market without any authorisation. Not only a concentration of nicotine is relevant but a mixture of all substances is too. Consumers indicate as well, that they mainly use e-cigarettes to quit smoking, seeing it as a medicinal product, therefore they should be authorised in accordance with Directive 2001/83/EC.

Amendment 45
Proposal for a directive
Article 18 – paragraph 1a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States shall ensure that nicotine-containing products are not sold to persons below the age required for purchasing tobacco products.

Or. en

Amendment 46
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

Amendment 47
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 48
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 mg of nicotine per ml.	***deleted***

Or. en

Amendment 49
Proposal for a directive
Article 18 – paragraph 2

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

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.

Or. en

Amendment 50
Proposal for a directive
Article 18 – paragraph 3

Text proposed by the Commission	*Amendment*
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:	***deleted***
This product contains nicotine and can damage your health.	

Or. en

Amendment 51
Proposal for a directive
Article 18 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:	***deleted***
(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. en

Amendment 52
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. en

Amendment 53
Proposal for a directive
Article 26 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + ***24*** months]:	Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + ***36*** months]:

Or. en

Justification

It is necessary to give Member States more time to adjust to the changes, as some Member States, and therefore companies, in particular small and medium-sized enterprises, and farmers will be affected by the Directive more than others.

Amendment 54
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;

Or. en

Justification

In conformity with the amendment to Article 18 of the proposed Directive.

ANNEX - LIST OF SUBMISSIONS BY STAKEHOLDERS[1]

Organisation
Confédération Européenne des Détaillants en Tabac
European Carton Makers Association
European Cigar Manufacturers Association
European Communities Trade Mark Association
European Heart Network
European Public Health Alliance
Polish Chamber of Commerce
Global Acetate Manufacturers' Association
Japan Tobacco International Poland
Kreab Gavin Anderson
MANE, a French Flavour Company/French Flavour Association (SNIAA)
NJOY Electronic Cigarettes
Phillip Morris
Polish Confederation of Private Employers Lewiatan
Polish Society for Health Programmes
Polish tobacco farmers association
Smoke Free Partnership
Action on Smoking and Health (UK)

[1] The list is not exhaustive