EUROPEAN PARLIAMENT

2009 - 2014

*Committee on the Internal Market and Consumer Protection*

**2012/0366(COD)**

20.6.2013

# 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**
**Citation 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Having regard to the Treaty on the Functioning of the European Union, and in particular ***Article*** 114 thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular ***Articles*** 114 ***and 168*** thereof, |

**Amendment 2**

**Proposal for a directive**
**Recital 8**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (8) In accordance with Article 114(3) of the Treaty of the Functioning of the | (8) In accordance with Article 114(3) of the Treaty of the Functioning of the |

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| European Union (hereinafter: "Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people. | European Union (hereinafter: "Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people. ***To that end, it is also essential to continue to provide education, information and prevention campaigns and programmes to help citizens who wish to give up smoking.*** |

*Justification*

*The objectives of stopping or reducing tobacco use can only be achieved by means of public education and information campaigns and action to help people give up smoking. This directive provides an additional means of achieving those objectives.*

**Amendment 3**

**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 4**
**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 | (12) In order to exercise their regulatory function, Member States and the Commission require comprehensive |

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| 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. | 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. |

*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 5**
**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***. |

*Justification*

*Common electronic format valid for all Member States will make reporting obligations*

*easier. This should be an advantage for SMEs.*

**Amendment 6**

**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. Without harmonisation, the obstacles on the internal market are expected to increase in the coming years taking into account the implementation of the FCTC and its guidelines and considering experience gained in other jurisdictions outside the Union. The guidelines on Articles 9 and 10 FCTC call in particular for the removal of ingredients that increase palatability, create the impression that the tobacco products have health benefits, are associated with energy and vitality or have colouring properties. ***Ingredients that increase addictiveness and toxicity should also be removed.*** |

**Amendment 7**

**Proposal for a directive**
**Recital 15**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (15) The likelihood of diverging regulation is further increased by concerns over tobacco products, including smokeless tobacco products, having a characterising flavour other than tobacco, which may facilitate uptake of tobacco consumption or affect consumption patterns. ***For example, in many countries, sales of mentholated products gradually increased even as smoking prevalence overall declined. A number of studies indicated that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people. Measures introducing unjustified differences of treatment between flavoured cigarettes (e.g. menthol and clove cigarettes) should be avoided.*** | (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 menthol***, which may facilitate uptake of tobacco consumption or affect consumption patterns. ***The Commission is urged to carry out a scientific study of the real influence of these products on smoking uptake***. |

*Justification*

*Menthol has been used in traditional tobacco products since the 1920's. There is no sufficient evidence that menthol has a bad influence on the smoking behaviour among youngsters.*

**Amendment 8**

**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 | (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 ***which are essential for the manufacture*** of tobacco products ***shall be allowed.*** The Commission should ensure uniform conditions for the implementation of the |

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| 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. | provision on characterising flavour. ***Exemption should be made for menthol cigarettes as they are considered being traditional tobacco flavour products and should not be classified with the other flavoured tobacco products.*** 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 9**
**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 patterns in relation to young people.*** | ***deleted*** |

*Justification*

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

**Amendment 10**

**Proposal for a directive**
**Recital 22**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (22) The labelling provisions ***also*** need to be adapted ***to new scientific evidence***. ***For example*** the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets ***have proven to be misleading*** as it | (22) The labelling provisions need to be adapted ***so that they do not mislead consumers.*** The indication of the yields for tar, nicotine and carbon monoxide on cigarette packets ***may be misread by*** |

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| makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings are more effective than text-only warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness. | ***consumers*** as it ***often*** makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings are more effective than text-only warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness. |

**Amendment 11**
**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***. |

*Justification*

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

**Amendment 12**

**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 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. | (26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets ***and outside packaging*** of tobacco products to be marked in a unique and secure way and their movements to be recorded so that these products can be tracked and traced in the Union and their compliance with this Directive can be monitored and better enforced. In addition, provision should be made for the introduction of security features that will facilitate the verification of whether or not products are authentic. ***Coherent implementation of customs legislation will strengthen customs authorities in their fight against illicit trade, in particular through technical capacity building.*** |

**Amendment 13**

**Proposal for a directive**
**Recital 28**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (28) In order to ensure independence and transparency, manufacturers of tobacco products should conclude data storage | (28) In order to ensure ***efficacy,*** independence and transparency, manufacturers of tobacco products should |

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| contracts with independent third parties, under the auspices of an external auditor. The data related to the tracking and tracing system should be kept separate from other company related data and be under the control of and accessible at all times by the competent authorities from Member States and the Commission. | conclude data storage contracts with independent third parties, under the auspices of an external auditor. The data related to the tracking and tracing system should be kept separate from other company related data and be under the control of and accessible at all times by the competent authorities from Member States and the Commission. |

**Amendment 14**

**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***, and practices such as the free distribution or swapping of tobacco products in public places for promotional purposes,*** 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. ***They should, therefore, be prohibited.*** |

*(See amendments to Article 16.)*

**Amendment 15**

**Proposal for a directive**
**Recital 31**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the developments and submit a report 5 years after the date of transposition of this Directive, in order to assess whether amendments to this Directive are necessary. | (31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the developments and submit a report 5 years after the date of transposition of this Directive, in order to assess whether amendments to this Directive are necessary. ***Children and young people must be educated, as this is the simplest and most effective way of preventing young people from starting to smoke. Consideration should also be given to creating a fund financed by the manufacturers of tobacco products, which would be used to fund anti-smoking campaigns. Member States should harmonise the legal age for purchasing tobacco products at 18.*** |

**Amendment 16**

**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 | (34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code |

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| relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. ***Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to*** the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled. | relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. ***Applying*** the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled. |

**Amendment 17**
**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*** |

*Justification*

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

**Amendment 18**
**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. |

*Justification*

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

**Amendment 19**
**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 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 | (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 measurement methods ***of yields***, ***determining uniform rules on the procedures for determining whether a tobacco product has 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, defining key elements for contracts on data storage with independent third parties, reviewing ***an exemption*** |

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| ***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. | granted to tobacco products other than cigarettes, roll-your-own tobacco and ***water-pipe*** tobacco***, adapting the substances and limit values of smokeless tobacco and laying down rules governing various aspects of new tobacco products which are significantly less harmful than traditional tobacco 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. |

*Justification*

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

**Amendment 20**

**Proposal for a directive**
**Recital 39**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (39) The Commission should monitor the developments and submit a report ***5*** years after the date of transposition of this Directive, in order to assess whether amendments to this Directive are necessary. | (39) The Commission should monitor the developments and submit a report ***3*** years after the date of transposition of this Directive, in order to assess whether amendments to this Directive are necessary***, in particular as regards packaging***. |

**Amendment 21**

**Proposal for a directive**
**Recital 41**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (41) Member States should ***remain free to*** | (41) Member States should ***be able 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***.

***adopt more stringent rules concerning tobacco*** products ***which they deem necessary to protect public health, in-so-far as such rules fall outside the scope of the provisions*** of this Directive. ***In-so-far as tobacco or related*** products ***comply*** with the ***requirements*** of this Directive***, Member States shall not prohibit or restrict the import, sale or consumption of such products***.

*Justification*

*The internal market won't benefit if Member States are allowed to take further steps regarding the aspects which fall under the scope this directive. This will lead to a patchwork of national provisions, which is not in the best interests of the internal market.*

**Amendment 22**

**Proposal for a directive**
**Recital 45**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (45) The proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), ***and*** the right to property (Article 17). The obligations imposed on manufacturers, importers and distributors of tobacco products are necessary to improve the functioning of the | (45) The proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), the right to property (Article 17***), and the right to clean air as implied by the International Covenant on Economic, Social and Cultural Rights(article 7 (b) and 12***). The |

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| internal market while ensuring a high level of health and consumer protection as set out in Articles 35 and 38 of the Charter of Fundamental Rights of the European Union. The application of this Directive should respect the EU law and relevant international obligations. | obligations imposed on manufacturers, importers and distributors of tobacco products are necessary to improve the functioning of the internal market while ensuring a high level of health and consumer protection as set out in Articles 35 and 38 of the Charter of Fundamental Rights of the European Union. The application of this Directive should respect the EU law and relevant international obligations. |

**Amendment 23**
**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; |

*Justification*

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

**Amendment 24**
**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 unambigously confirms the consumer's age in electronic form according to national requirements;*** | ***deleted*** |

*Justification*

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

**Amendment 25**

**Proposal for a directive**
**Article 2 – paragraph 1 – 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, 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***. Traditional tobacco product flavours such as menthol are not considered to be characterising flavours.*** |

*Justification*

*Menthol has been used in traditional tobacco products since the 1920's. There is no sufficient evidence that menthol has a bad influence on the smoking behaviour among youngsters.*

**Amendment 26**

**Proposal for a directive**
**Article 2 – paragraph 1 – point 8**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***(8) ‘cigarillo’ means a small type of cigar with a diameter of up to 8 mm;*** | ***deleted*** |

*Justification*

*A cigarillo is a cigar model like many other models. No separate definition is required.*

**Amendment 27**

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

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (19) ‘maximum level’ or ‘maximum yield’ means the maximum content or emission***, including 0,*** of a substance in a tobacco product measured in grams; | (19) ‘maximum level’ or ‘maximum yield’ means the maximum content or emission of a substance in a tobacco product measured in grams; |

**Amendment 28**

**Proposal for a directive**
**Article 2 – paragraph 1 – point 23**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (23) 'novel tobacco product' means a tobacco product other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use placed on the market after entry into force of this Directive; | *(Does not affect English version.)* |

*Justification*

*(Does not affect English version.)*

**Amendment 29**
**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; |

*Justification*

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

**Amendment 30**

**Proposal for a directive**
**Article 2 – paragraph 1 – point 26**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (26) ‘pipe tobacco’ means tobacco ***consumed via a combustion*** process and ***exclusively designed for the purpose of being used in a pipe***; | (26) ‘pipe tobacco’ means ***a cut or otherwise split loose or pressed*** tobacco ***which can be used without further industrial*** process and ***which is further defined in Council Directive 2011/64/EU of 21 June 2011***; |

**Amendment 31**

**Proposal for a directive**
**Article 2 – paragraph 1 – point 28**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (28) ‘roll-your-own tobacco’ means tobacco which can be used ***for making cigarettes by consumers or retail outlets***; | (28) ‘roll-your-own tobacco’ ***or 'make-your-own-tobacco'*** means ***a cut or otherwise split loose or pressed*** tobacco which can be used ***without further industrial process and which is further defined in Council Directive 2011/64/EU of 21 June 2011***; |

**Amendment 32**

**Proposal for a directive**
**Article 2 – paragraph 1 – point 30**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (30) ‘substantial change of circumstances’ means an increase of the sales volumes by product category, such as pipe tobacco, cigar, cigarillo, by at least ***10%*** in at least 10 Member States based on sales data transmitted in accordance with Article 5(4); or an increase of the prevalence level in the consumer group under 25 years of age by at least 5 percentage points in at least 10 Member States for the respective product category based on ____ [this date will be set at the moment of adoption of the Directive] Eurobarometer report or | (30) ‘substantial change of circumstances’ means an increase of the sales volumes by product category, such as pipe tobacco, cigar, cigarillo, by at least ***20%*** in at least 10 Member States based on sales data transmitted in accordance with Article 5(4); or an increase of the prevalence level in the consumer group under 25 years of age by at least 5 percentage points in at least 10 Member States for the respective product category based on ____ [this date will be set at the moment of adoption of the Directive] Eurobarometer report or |

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|---|---|
| equivalent prevalence studies; | equivalent prevalence studies; |

*Justification*

*The annual consumption of cigars and pipe tobacco in most of the Member States is very low. A 10% fluctuation in the sales volumes could happen too easily in these Member States.*

**Amendment 33**

**Proposal for a directive**
**Article 2 – paragraph 1 – point 35 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(35a) 'traditional tobacco flavour' means a tobacco flavour that has been continuously used in a Member State or part thereof at least as of 1980 and defined as such by national legislation of a Member State;*** |

*Justification*

*For the purpose of clarifying Article 6 of the proposed Directive it is necessary to provide a definition of 'traditional tobacco flavour'.*

**Amendment 34**

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

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(36a) 'reduced risk product' means any product containing tobacco which, when marketed, significantly reduces the risk of illnesses associated with the consumption of conventional tobacco products. A product used to treat addiction to tobacco consumption, including cessation, is not a reduced risk product if it has been approved as a medicinal product.*** |

**Amendment 35**

**Proposal for a directive**
**Article 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 3 | Article 3 |
| Maximum tar, nicotine, carbon monoxide and other yields | Maximum tar, nicotine, carbon monoxide and other yields |
| 1. The yield of cigarettes placed on the market or manufactured in the Member States shall not be greater than: | 1. The yield of cigarettes placed on the market or manufactured in the Member States shall not be greater than: |
| (a) 10 mg per cigarette for tar, | (a) 10 mg per cigarette for tar, |
| (b) 1 mg per cigarette for nicotine, | (b) 1 mg per cigarette for nicotine, |
| (c) 10 mg per cigarette for carbon monoxide. | (c) 10 mg per cigarette for carbon monoxide. |
| ***2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the maximum yields laid down in paragraph 1, taking into account scientific development and internationally agreed standards.*** | |
| 3. Member States shall notify the Commission of the maximum yields that they set for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. ***Taking into account internationally agreed standards, where available, and based on scientific evidence and on the yields notified by Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes that increase in an appreciable manner the toxic or addictive effect of tobacco products beyond the threshold of toxicity and addictiveness stemming from the yields of tar, nicotine and carbon monoxide fixed in paragraph 1.*** | 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. |

**Amendment 36**

**Proposal for a directive**
**Article 4**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 4 | Article 4 |
| Measurement methods | Measurement methods |
| 1. The tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide. | 1. The tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide. |
| The accuracy of the tar ***and*** nicotine indications shall be verified in accordance with ISO standard 8243. | The accuracy of the tar**,** nicotine ***and carbon monoxide*** indications shall be verified in accordance with ISO standard 8243. |
| 2. The measurement referred to in paragraph 1 shall be carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States. | 2. The measurement referred to in paragraph 1 shall be carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States. |
| Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available. | Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available. |
| 3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the methods of measurement of the tar, nicotine and carbon monoxide yields, taking into account scientific and technical developments and internationally agreed standards. | 3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the methods of measurement of the tar, nicotine and carbon monoxide yields, taking into account scientific and technical developments and ***using*** internationally agreed standards ***designed for a specific purpose and validated by the International Organisation for Standardisation***. |
| 4. Member States shall notify the Commission of the methods of measurement that they use for other emissions of cigarettes and for emissions | 4. Member States shall notify the Commission of the methods of measurement that they use for other emissions of cigarettes and for emissions |

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|---|---|
| of tobacco products other than cigarettes. Based on these ***methods***, and taking into account scientific and technical developments as well as internationally agreed standards the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt methods of measurement. | of tobacco products other than cigarettes. ***Such measurement shall be based on scientific evidence.*** Based on these ***measurements***, and taking into account scientific and technical developments as well as ***using*** internationally agreed standards ***designed for a specific purpose and validated by the International Organisation for Standardisation*** the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt methods of measurement.<br><br>***4a. The accuracy of the indications for the other emissions of other combustible tobacco products shall be verified in accordance with ISO standard 8243.*** |

**Amendment 37**

**Proposal for a directive**
**Article 5 – paragraph 1 – subparagraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields. Manufacturers or importers shall also inform the competent authorities of the concerned Member States if the composition of a product is modified affecting the information provided under this Article. Information required under this Article shall be submitted prior to the placing of the market of a new or modified tobacco product. | Member States shall require manufacturers and importers of tobacco products***, nicotine-containing products and herbal products for smoking*** to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields***, if available***. Manufacturers or importers shall also inform the competent authorities of the concerned Member States if the composition of a product is modified affecting the information provided under this Article. Information required under this Article shall be submitted prior to the placing of the market of a new or modified tobacco product. |

**Amendment 38**

**Proposal for a directive**
**Article 5 – paragraph 6 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***6a. Tobacco products other than cigarettes and roll-your-own tobacco shall be excluded from information on emissions and values until measuring methods have been developed at Community level.*** |

*Justification*

*In accordance with Recital 31 of Directive 2001/37/EC, standards and measuring methods for tobacco products other than cigarettes and roll-your-own tobacco must be developed at Community level. The Commission has been called upon to submit appropriate proposals. So far, no such methods have been developed.*

**Amendment 39**

**Proposal for a directive**
**Article 6**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 6 | Article 6 |
| Regulation of ingredients | Regulation of ingredients |
| 1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour. | 1. ***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 products with a characterising flavour. |
| | ***Exemption shall be possible for certain traditional tobacco flavours which can not be classified with the other tobacco flavours. Menthol shall be considered as traditional tobacco flavour.*** |
| 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 ***restrict or*** 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. |

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| Member States shall notify the Commission of measures taken pursuant to this paragraph. | Member States shall notify the Commission of measures taken pursuant to this paragraph. |
| 2. The Commission shall at the request of a Member State or may on its own initiative determine by means of implementing acts whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21. | 2. The Commission shall at the request of a Member State or may on its own initiative determine by means of implementing acts whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21. |
| The Commission shall ***adopt by means of 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.*** | ***2a.*** 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. |
| 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 or a combination thereof typically impart a characterising flavour when it exceeds a certain level of presence or concentration the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives or combination of additives that cause the characterising flavour. |
| 4. Member States shall prohibit the use of the following additives in tobacco products: | 4. Member States shall prohibit the use of the following additives in tobacco products: |
| (a) vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards, or | (a) vitamins and other additives that create the impression that a tobacco product has a health benefit or presents reduced health hazards, or |
| (b) caffeine and taurine and other additives and stimulant compounds that ***are associated with*** energy and vitality, or | (b) caffeine and taurine and other additives and stimulant compounds that ***have been scientifically proven to increase the level of*** energy and vitality, or |
| (c) additives having colouring properties for emissions. | (c) additives having colouring properties for emissions. |
| 5. Member States shall prohibit the use of flavourings in the components of tobacco | 5. Member States shall prohibit the use of flavourings in the components of tobacco |

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| 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. | 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.<br>***Technical measures intended to decrease specific harmful components of smoke or enhance the biodegradability of tobacco products are not affected.*** |
| 6. Member States shall ensure that provisions or conditions set out under Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate. | 6. Member States shall ensure that provisions or conditions set out under Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate. |
| 7. Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product.<br>Member States shall notify to the Commission measures taken pursuant to this paragraph. | 7. Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product.<br>Member States shall notify to the Commission measures taken pursuant to this paragraph. |
| 8. The Commission shall at the request of a Member State or may on its own initiative determine by means of an implementing act whether a tobacco product falls within the scope of paragraph 7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21 and shall be based on the latest scientific evidence. | 8. The Commission shall at the request of a Member State or may on its own initiative determine by means of an implementing act whether a tobacco product falls within the scope of paragraph 7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21 and shall be based on the latest scientific evidence. |
| 9. In case scientific evidence and the experience gained in the application of paragraphs 7 and 8 shows that a certain additive or a certain quantity thereof amplify in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives. | 9. In case scientific evidence and the experience gained in the application of paragraphs 7 and 8 shows that a certain additive or a certain quantity thereof amplify in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives. |
| 10. Tobacco products other than cigarettes, roll-your-own tobacco and ***smokeless tobacco products*** shall be exempted from | 10. Tobacco products other than cigarettes, roll-your-own tobacco and ***water-pipe tobacco*** shall be exempted from the |

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

**Amendment 40**

**Proposal for a directive**
**Article 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 7 | Article 7 |
| General provisions | General provisions |
| 1. Each unit packet of tobacco products and any outside packaging shall carry health warnings in the official language or languages of the Member State where the product is placed on the market. | 1. Each unit packet of tobacco products and any outside packaging shall carry health warnings in the official language or languages of the Member State where the product is placed on the market***, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden***. |
| 2. Health warnings shall occupy the entire surface reserved for them and they shall not be commented on, paraphrased or referred to in any form. | 2. Health warnings shall occupy the entire surface reserved for them and they shall not be commented on, paraphrased or referred to in any form. |
| 3. ***In order to ensure their graphic integrity and visibility, h***ealth 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. ***H***ealth warnings shall be irremovably printed ***and visible***, indelible and in no way hidden or interrupted, including by tax stamps, ***which shall be placed at the opening of the tobacco product package,*** price marks, tracking and tracing marks, security features or by any type of wrapper, pouch, jacket, box or other device or by the opening of the unit packet. |
| 4. Member States shall ensure that the health warnings of the main surface of the unit packet and any outside packaging are fully visible, including not being partially or totally hidden or interrupted by wrappers, pouches, jacket, boxes or other devices when tobacco products are placed on the market. | 4. Member States shall ensure that the health warnings of the main surface of the unit packet and any outside packaging are fully visible, including not being partially or totally hidden or interrupted by wrappers, pouches, jacket, boxes or other devices when tobacco products are placed on the market. |

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| 5. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets. | 5. The health warnings shall in no way hide or interrupt the tax stamps, ***which shall be placed at the opening of the tobacco product package,*** price marks, tracking and tracing marks, or security features on unit packets. |
| 6. ***Member States shall not increase the size of the health warnings including by introduction of an obligation to surround the health warnings by a border.*** The actual size of the health warnings shall be calculated in relation to the surface on which they are placed before the unit packet is opened. | 6. The actual size of the health warnings shall be calculated in relation to the surface on which they are placed before the unit packet is opened. |

**Amendment 41**

**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*** |

**Amendment 42**

**Proposal for a directive**
**Article 9**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 9 | Article 9 |
| Combined health warnings for tobacco for smoking | Combined health warnings for tobacco for smoking |
| 1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The combined health warnings shall: | 1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The combined health warnings shall: |

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| (a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library; | (a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library; |
| (b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking; | (b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking; |
| (c) cover ***75*** % of the external area of both the front and back surface of the unit packet and any outside packaging; | (c) cover ***70 %*** of the external area of both the front and back surface of the unit packet and any outside packaging; |
| (d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging; | (d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging; |
| (e) be positioned at the ***top*** edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on the packaging; | (e) be positioned at the ***bottom*** edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on the packaging; |
| ***(f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;*** | |
| (g) for unit packets of cigarettes, respect the following dimensions: | (g) for unit packets of cigarettes, respect the following dimensions: |
| (i) height: not less than ***64*** mm; | (i) height: not less than ***60*** mm; |
| (ii) width: not less than ***55*** mm. | (ii) width: not less than ***51*** mm. |
| 2. The combined health warnings shall be divided into three sets rotating on an annual basis. Member States shall ensure that each combined health warning is displayed as nearly as possible on equal numbers of each brand. | 2. The combined health warnings shall be divided into three sets rotating on an annual basis. Member States shall ensure that each combined health warning is displayed as nearly as possible on equal numbers of each brand. |
| 3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to: | 3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to: |
| (a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments; | (a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments; |
| (b) establish and adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments; | (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 |

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| | developments; |
| (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, ***taking into account linguistic specificities of each Member State;*** |
| (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. | (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. |
| | _____ |
| | **** OJ: please insert date: six months after the entry into force of this Directive.*** |

**Amendment 43**

**Proposal for a directive**
**Article 10**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 10 | Article 10 |
| Labelling of tobacco for smoking other than cigarettes and roll-your-own tobacco | Labelling of tobacco for smoking other than cigarettes and roll-your-own tobacco |
| 1. Tobacco for smoking other than cigarettes and roll-your-own tobacco shall be exempted from the obligations to carry the information message laid down in Article 8(2) and the combined health warnings in Article 9. In addition to the general warning specified in Article 8(1), each unit packet and any outside packaging of these products shall carry a text warning listed in Annex I. The general warning specified in Article 8(1) shall include a reference to the cessation services in accordance with Article 9(1)(b). | 1. Tobacco for smoking other than cigarettes and roll-your-own tobacco shall be exempted from the obligations to carry the information message laid down in Article 8(2) and the combined health warnings in Article 9. In addition to the general warning specified in Article 8(1), each unit packet and any outside packaging of these products shall carry a text warning listed in Annex I. The general warning specified in Article 8(1) shall include a reference to the cessation services in accordance with Article 9(1)(b). |
| The general warning shall be printed on the most visible surface of the unit packet and any outside packaging. The text warnings listed in Annex I shall be rotated in such a | The general warning shall be printed ***or affixed by means of irremovable stickers*** on the most visible surface of the unit packet and any outside packaging. The text |

way as to guarantee their regular appearance. These warnings shall ***be printed*** on the other most visible surface of the unit packet and any outside packaging.

warnings listed in Annex I shall be rotated in such a way as to guarantee their regular appearance. These warnings shall ***appear*** on the other most visible surface of the unit packet and any outside packaging.

2. The general warning referred to in paragraph 1 shall cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with ***three*** official languages.

2. The general warning referred to in paragraph 1 shall cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging***, with the exception of the transparent plastic wrapping commonly used in the retail trade, provided that the warning on the packaging beneath this wrapping can be seen clearly through it***. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with ***more than two*** official languages.

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

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

***3a. In the case of unit packets the most visible surface of which exceeds 75 cm2, the warnings referred to in paragraphs 2 and 3 shall cover an area of at least 22.5 cm2 on each surface. That area shall be increased to 24 cm2 for Member States with two official languages and 26.25 cm2 for Member States with more that two official languages.***

4. The general warning and the text warning referred to in paragraph 1 shall be:

4. The general warning and the text warning referred to in paragraph 1 shall be:

(a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States may determine the point size of the font, provided that the font size specified in their legislation is such as to occupy the greatest possible proportion of the area set aside for the text required;

(a) ***appear*** in black Helvetica bold type on a white background. ***The warnings may be affixed by means of stickers, provided that such stickers are irremovable.*** In order to accommodate language requirements, Member States may determine the point size of the font, provided that the font size specified in their legislation is such as to occupy the greatest possible proportion of

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| | the area set aside for the text required; |
| (b) centred in the are a in which they are required to ***be printed***, parallel to the top edge of the unit packet and any outside packaging; | (b) centred in the area in which they are required to ***appear***, parallel to the top edge of the unit packet and any outside packaging; |
| (c) surrounded by a black border not less than 3 mm and not more than 4 mm in width inside the surface reserved for the text of the warning. | (c) surrounded by a black border not less than 3 mm and not more than 4 mm in width inside the surface reserved for the text of the warning. |
| ***5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22, to withdraw the exemption laid down in paragraph 1 if there is a substantial change of circumstances as established in a Commission report.*** | |

**Amendment 44**

**Proposal for a directive**
**Article 11**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 11 | Article 11 |
| Labelling of smokeless tobacco products | Labelling of smokeless tobacco products |
| 1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning: | 1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning: |
| This tobacco product ***can damage*** your health and is addictive | This tobacco product ***damages*** your health and is addictive |
| 2. The health warning laid down in paragraph 1 shall comply with the requirementsspecified in Article 10(4). In addition, it shall: | 2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 10(4). In addition, it shall: |
| (a) be printed on the two largest surfaces of the unit packet and any outside packaging; | (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 | (b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with ***more than two*** |

languages.

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

official languages.

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

**Amendment 45**

**Proposal for a directive**
**Article 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 12 | Article 12 |
| Product description | Product description |
| 1. The labelling of a unit packet and any outside packaging and the tobacco product itself shall not include any element or feature that: | 1. The labelling of a unit packet and any outside packaging and the tobacco product itself shall not include any element or feature that: |
| (a) promotes a tobacco product by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions; | (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; |
| (b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health ***or social*** effects; | (b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health effects; |
| (c) refers to flavour, taste, any flavourings or other additives or the absence thereof; | (c) refers to flavour, taste, any flavourings or other additives or the absence thereof; |
| (d) resembles a food product. | (d) resembles a food product. |
| | ***(da) aims to reduce the effect of some harmful components of smoke or increase the biodegradability of tobacco products*** |
| 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 | 2. ***Texts***, symbols, names, trade marks, figurative or other signs, misleading colours or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves ***that may suggest that a particular tobacco product is less harmful*** |

| | |
|---|---|
| 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.*** | ***than others or that may mislead the consumer as regards the harmfulness of tobacco products shall not be used on the packaging of tobacco products***. |

**Amendment 46**

**Proposal for a directive**
**Article 13**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 13 | Article 13 |
| Appearance and content of unit packets | Appearance and content of unit packets |
| 1. A unit packet of cigarettes shall have a cuboid shape. A unit packet of roll-your-own tobacco shall have 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 ***or cuboid-like shape with chamfered edges.*** A unit packet of roll-your-own tobacco ***or make-your-own tobacco*** shall ***be packaged in a cuboid or cylindrical composite can or*** have the form of a pouch, i.e. a rectangular pocket with a flap that covers the opening. The flap of the pouch shall cover at least 70% of the front of the packet. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing at least 40 g. |
| 2. A cigarette packet can be of carton or soft material and shall not contain an opening that can be re-closed or re-sealed after the opening 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. | 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 fliptop lid. The flip-top lid of a cigarette packet shall be hinged only at the back of the packet. |
| ***3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to define more detailed rules for the shape and size of unit packets in so far as these rules are necessary to ensure the full visibility and integrity of the health warnings before the first opening, during the opening and after reclosing of the unit packet.*** | |

| | |
|---|---|
| 4. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to make either cuboid or cylindric 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. | 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. |

**Amendment 47**

**Proposal for a directive**
**Article 14**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 14 | Article 14 |
| Traceability and security features | Traceability and security features |
| 1. Member States shall ***ensure that all unit packets of tobacco products shall be marked with a unique identifier***. In order to ensure their integrity, unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or by the opening of the packet. In relation to products manufactured outside the Union the obligations laid down in this Article apply only to those destined to or placed on the Union market. | 1. ***With a view to enabling effective tracking and tracing,*** Member States shall ***require that unique, secure impossible to duplicate and non-removable identification markings (hereafter called unique identifier), 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, 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. ***In those Member States where tax stamps are applied on tobacco products the unique identifiers can be printed on the tax stamps or used together with a digital tax stamp in invisible ink***. |
| 2. The unique identifier shall allow determining: | 2. The unique identifier shall allow determining: |
| (a) the date and place of manufacturing; | (a) the date and place of manufacturing; |

| | |
|---|---|
| (b) the manufacturing facility; | (b) the manufacturing facility; |
| (c) the machine used to manufacture the products; | (c) the machine used to manufacture the products; |
| (d) the production shift or time of manufacture; | (d) the production shift or time of manufacture; |
| (e) the product ***name***; | (e) the product ***description***; |
| (f) the intended market of retail sale; | (f) the intended market of retail sale; |
| ***(g) the intended shipment route;*** | |
| h) where applicable, the importer into the Union; | h) where applicable, the importer into the Union; |
| (i) the actual shipment route from manufacturing to the first ***retail outlet***, including all warehouses used; | (i) the ***intended and*** actual shipment route***, the shipment date, shipment destination, consignee and point of departure*** from manufacturing to the first ***customer who is not affiliated with the manufacturer or importer***, including ***his warehouses and*** all ***tax*** warehouses used; |
| (j) the identity of all purchasers from manufacturing to the first retail outlet; | (j) the identity of all purchasers from manufacturing to the first retail outlet; |
| (k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet. | (k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet. |
| | ***2a. Member States shall ensure that the unique identifiers of unit packets are linked to the unique identifier on the outside packaging. Any changes in the links between unit packets and the outside packaging shall be recorded in the database mentioned in paragraph 6.*** |
| 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 last economic operator before the first retail outlet, record the entry of all unit packets ***and outside packaging*** into their possession, as well as all intermediate movements and the final exit from their possession. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging, provided that tracking and tracing of unit packets remains possible. |
| 4. Member States shall ensure that manufacturers of tobacco products provide | 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.

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, ***determined by Member States,*** allowing for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. The equipment shall be able to read and transmit the data electronically to a data storage facility pursuant to paragraph 6.

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

5. Recorded data ***has to be transmitted to a database in a timely manner. The data*** cannot be modified or deleted by any economic operator involved in the trade of tobacco products, but the economic operator that introduced the data and other economic operators directly concerned by the transaction such as the supplier or the recipient can comment on previously introduced data. The economic operator concerned shall add the correct data and a reference to the previous entry which requires rectification in their view. In exceptional circumstances and upon submission of adequate evidence, the competent authority in the Member State in which the recording took place or if the recording took place outside the Union the competent authority in the Member State of importation, can authorise the modification or deletion of data previously registered. ***The recorded data has to be kept for the period of four years from manufacturing unless any Member State or the Commission request a longer period due to an on-going investigation.***

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

6. Member States shall ***verify*** that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall be physically located on the territory of the Union**.** The suitability of the third party, in

| | |
|---|---|
| particular its independence and technical capacities, as well as the contract, shall be approved and monitored by an external auditor, who ***is proposed and paid by the tobacco manufacturer and approved*** by the Commission. Member States shall ensure full transparency and accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party on a permanent basis. ***In duly justified cases*** Member States or the Commission ***can provide*** manufacturers or importers access to this information, provided commercially sensitive information remains adequately protected in conformity with the relevant national and Union legislations. | particular its independence and technical capacities, as well as the contract, shall be approved and monitored by an external auditor, who ***shall be appointed*** by the Commission. ***The costs incurred as a result of the contract with the auditor and the database management services shall be covered by the tobacco manufacturers and importers.*** Member States shall ensure full transparency and ***online*** accessibility of the ***required*** data storage facilities for the competent authorities of the Member States, the Commission and the independent third party on a permanent basis. Member States or the Commission ***shall allow*** manufacturers or importers access to this information, provided ***with the condition that*** commercially sensitive information remains adequately protected in conformity with the relevant national and Union legislations. ***Member States shall ensure that access to a database takes place only where it is necessary for the purpose of detection or investigation of illicit trade and the database information is protected and treated confidentially. In particular, data cannot be shared with any person or organisation which is not involved in the investigation or subsequent proceedings.*** |
| 7. Member States shall ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC. | 7. Member States shall ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC. |
| 8. In addition to the unique identifier, Member States shall require that all unit packets of tobacco products which are placed on the market carry a visible, tamper proof security feature of at least 1 cm², which shall be irremovably printed or affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation. | 8. In addition to the unique ***secure and impossible-to-duplicate*** identifier, Member States shall require that all unit packets of tobacco products which are placed on the market carry a visible, tamper proof security feature of at least 1 cm², which shall be irremovably printed or affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation. |
| 9. The Commission shall be empowered to adopt delegated acts in accordance with | 9. The Commission shall be empowered ***by …****:, ***taking into account existing practices, technologies and commercial*** |

| | |
|---|---|
| Article 22: | ***practicalities as well as global standards for tracking and tracing and authentication of fast moving consumer goods and relevant requirements under the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products,*** to adopt delegated acts in accordance with Article 22: |
| (a) to define the key elements (such as duration, renewability, expertise required, confidentiality) of the contract referred to in paragraph 6, including its regular monitoring and evaluation; | (a) to define the key elements (such as duration, renewability, expertise required, confidentiality) of the contract referred to in paragraph 6, including its regular monitoring and evaluation; |
| (b) to define the technical standards to ensure that the systems used for the unique identifiers and the related functions are fully compatible with each other across the Union and | (b) to define the technical standards to ensure that the systems used for the unique identifiers and the related functions are fully compatible with each other across the Union and |
| (c) to define the technical standards for the security feature and their possible rotation ***and to adapt them to scientific, market and technical development***. | (c) to define the technical standards for the security feature and their possible rotation. |
| | ***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.*** |
| 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 ***fine-cut tobacco for the*** 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. |
| | _____ |
| | * ***OJ: please insert date: twelve months after the entry into force of this Directive.*** |

**Amendment 48**
**Proposal for a directive**
**Title 2 – chapter 3 – title**

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

*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 49**

**Proposal for a directive**
**Article 15 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Member States shall set maximum limits for toxic or carcinogenic substances present in smokeless tobacco products placed on the market. The substances and required limits are as detailed in Annex IIa.*** |

*Justification*

*This replaces a ban on oral tobacco with a product quality standard for all smokeless tobacco. Rather than banning the least hazardous smokeless tobacco products, this will have the effect of removing the most hazardous from the market, and it is therefore consistent with the health objectives of the internal market. This section reproduces the regulatory recommendations of the WHO Study Group on Tobacco Product Regulation - Report on the Scientific Basis of Tobacco Product Regulation, WHO Technical Report Series, no. 955. (2010)*

**Amendment 50**

**Proposal for a directive**
**Article 15 – paragraph 1 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the substances and limit values referred to in paragraph 1a and laid down in Annex IIa, taking into account scientific developments and internationally agreed standards, taking account of the principles of proportionality, non-discrimination and the objective of developing the internal*** |

***market with a high level of health protection.***

*Justification*

*Commission is empowered to adjust the regulatory framework – for example to include heavy metal or other carcinogens, where there is justification for it.*

**Amendment 51**

**Proposal for a directive**
**Article 16**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 16 | Article 16 |
| Cross-border distance sales of tobacco products | Cross-border distance sales of tobacco products |
| 1. Member States shall ***oblige retail outlets intending to engage in*** cross-border distance sales to consumers located in the Union ***to register with the competent authorities in the Member State where the retail outlet is established and in the Member State where the actual or potential consumer is located. Retail outlets established outside the Union have to register with the competent authorities in the Member State where the actual or potential consumer is located. All retail outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities:*** | 1. Member States shall ***prohibit*** cross-border distance sales ***of tobacco products*** to consumers located in the Union***.*** |
| ***(a) name or corporate name and permanent address of the place of activity from where the tobacco products are supplied;*** | |
| ***(b) the starting date of the activity of offering tobacco products for cross-border distance sales to the public by means of information society services;*** | |
| ***(c) the address of the website/-s used for that purpose and all relevant information*** | |

***necessary to identify the website.***

***1a. Member States shall prohibit on their territory the distribution of free or discounted tobacco products and the swapping of new, sealed packets of tobacco products for packets that have already been opened, irrespective of the channels used.***

***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.***

***3. If it is necessary in order to ensure compliance and facilitate enforcement, Member States of destination may require that the retail outlet nominates a natural person who is responsible for verifying the tobacco products before reaching the consumer comply with the national provisions adopted pursuant to this Directive in the Member State of destination.***

***4. Retail outlets engaged in distance sales shall be equipped with an age verification system, which verifies at the time of sale, that the purchasing consumer respects the minimum age foreseen under the national legislation of the Member State of destination. The retailer or nominated natural person shall report to the competent authorities a description of the details and functioning of the age verification system.***

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

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

**Amendment 52**

**Proposal for a directive**
**Article 17 – title**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Notification of novel tobacco products | Notification of novel tobacco products ***and granting of pre-marketing authorisation for reduced-risk tobacco products*** |

*Justification*

*Linked to the amendment for Article 2(1)(36a). Once the authorities have scientific evidence that some novel tobacco products carry a lower risk, effective rules will need to be laid down which ensure that consumers are properly informed. Any failure to do so would deter investment in research, development and innovation and the production and marketing of such products, which are designed to offer consumers a less harmful alternative to conventional tobacco products.*

**Amendment 53**

**Proposal for a directive**
**Article 17 – paragraph 1 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco product they intend to place on the markets of the Member States concerned. The notification shall be submitted in electronic form six months before the intended placing on the market and shall be accompanied by a detailed description of the product in question as well as information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a | 1. Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco product they intend to place on the markets of the Member States concerned ***and in respect of which they intend to make claims, based on solid scientific evidence, alleging reduced harmfulness or risk in comparison with conventional tobacco products***. The notification shall be submitted in electronic form six months before the intended placing on the market and shall be accompanied by a detailed |

| | |
|---|---|
| novel tobacco product shall also provide the competent authorities in question with: | description of the product in question as well as information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with: |

**Amendment 54**

**Proposal for a directive**
**Article 17 – paragraph 1 – point a**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| a) available scientific studies on toxicity, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions; | a) available scientific studies on toxicity, ***impact on passive smoking,*** addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions; |

**Amendment 55**

**Proposal for a directive**
**Article 17 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***1a. The Member States shall require manufacturers and importers of tobacco products to submit the information required under paragraph 1, points (a) to (c), to their competent agencies after the content and conclusions have been verified by independent scientific facilities.*** |

**Amendment 56**

**Proposal for a directive**
**Article 17 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 2. Member States shall require that manufacturers and importers of tobacco | 2. Member States shall require that manufacturers and importers of tobacco |

| | |
|---|---|
| products inform their competent authorities of any new or updated information referred to in point (a) to (c) of paragraph 1. Member States shall be entitled to require tobacco manufacturers or importers to carry out additional tests or submit additional information. Member States shall make available to the Commission all information received pursuant to this Article. Member States shall be entitled to introduce an authorisation system and charge a proportionate fee. | products inform their competent authorities of any new or updated information referred to in point (a) to (c) of paragraph 1. Member States shall be entitled to require tobacco manufacturers or importers to carry out additional tests or submit additional information. Member States shall make available to the Commission all information received pursuant to this Article. ***In connection with the placing on the market of reduced-risk tobacco products,*** Member States shall be entitled to introduce an authorisation system and charge a proportionate fee.<br><br>***Member States shall be entitled to lay down specific rules for reduced-risk products governing consumer information, packaging and labelling, ingredients and emissions and the methods used to measure tar, nicotine and carbon monoxide. Member States shall notify those rules to the Commission.*** |

*Justification*

*Linked to the amendment for Article 2(1)(36a). Once the authorities have scientific evidence that some novel tobacco products carry a lower risk, effective rules will need to be laid down which ensure that consumers are properly informed. Any failure to do so would deter investment in research, development and innovation and the production and marketing of such products, which are designed to offer consumers a less harmful alternative to conventional tobacco products.*

**Amendment 57**

**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 | 3. Novel ***and reduced-risk*** tobacco products placed on the market shall respect the requirements set out in this Directive. ***Reduced-risk tobacco products shall be covered by special provisions laid down by Member States under paragraph 2.*** The provisions applicable depend on whether the products fall under the definition of |

| | |
|---|---|
| Article 2. | smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2. |

*Justification*

*Linked to the amendment for Article 2(1)(36a). Once the authorities have scientific evidence that some novel tobacco products carry a lower risk, effective rules will need to be laid down which ensure that consumers are properly informed. Any failure to do so would deter investment in research, development and innovation and the production and marketing of such products, which are designed to offer consumers a less harmful alternative to conventional tobacco products.*

**Amendment 58**

**Proposal for a directive**
**Article 17 – paragraph 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***3a. On the basis of independent, reliable and verifiable scientific and technical data, the Commission shall, within two years of the entry into force of this Directive and in accordance with Article 22, adopt delegated acts laying down rules governing evaluation, packaging, labelling, ingredients, placing on the market, presentation and sale of, and consumer information about, new tobacco products which are significantly less harmful than traditional tobacco products.*** |

**Amendment 59**

**Proposal for a directive**
**Article 18**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Article 18 | Article 18 |
| Nicotine-containing products | Nicotine-containing products |
| 1. The following nicotine-containing | 1. The following nicotine-containing |

| | |
|---|---|
| products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC: | products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC: |
| (a) products with a nicotine level exceeding 2 mg per unit, or | (a) products with a nicotine level exceeding 2 mg per unit, or |
| (b) products with a nicotine concentration exceeding 4 mg per ml ***or*** | (b) products with a nicotine concentration exceeding 4 mg per ml**.** |
| (c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 mg of nicotine per ml. | |
| | ***1a. This Directive shall not apply to nicotine containing products authorised pursuant to Directive 2001/83/EC. Where paragraph 1 does not apply, the products may be placed on the market if they comply with this Directive.*** |
| | ***1b. Member States shall ensure that nicotine containing products comply with Union consumer protection, safety and other relevant legislation in force.*** |
| | ***1c. 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 Annex IIb as it applies to nicotine containing products and the effectiveness of those measures.*** |
| | ***1d. Member States shall introduce a ban on the use of products containing nicotine in public places.*** |
| | ***1e. Member States shall introduce a minimum age to be able to access products containing nicotine.*** |
| 2. The Commission shall ***be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC.*** | 2. The Commission shall ***by 1 April 2017, carry out a study on nicotine-containing products in consultation with relevant stakeholders and the Member States. This study will consider whether there is a need for specific legislation with regard to nicotine-containing products***. |
| 3. ***E***ach unit packet and any outside packaging of nicotine-containing products | 3. ***Subject to the provisions of Articles 5,6 and 12, e***ach unit packet and any outside |

| | |
|---|---|
| ***below the thresholds set out in paragraph 1*** shall carry the following health warning: | packaging of nicotine-containing products ***not covered by the Directive 2001/83/EC*** shall carry the following health warning: |
| This product contains nicotine and ***can damage*** your health. | This product contains nicotine and ***damages*** 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: | 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; | (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. | (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. | 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, layout, design and rotation of the health warnings. |

**Amendment 60**

**Proposal for a directive**
**Article 19 – paragraph 1 – subparagraph 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| This product can damage your health. | This product can damage your health ***and is addictive.*** |

*Justification*

*Plant products should be grouped together with tobacco products and the same rules should apply to them.*

**Amendment 61**

**Proposal for a directive**
**Article 19 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 3. The health warning shall comply with the requirements laid down in Article 10(4). It shall cover not less than 30 % of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with ***three*** official languages. | 3. The health warning shall comply with the requirements laid down in Article 10(4). It shall cover not less than 30 % of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with ***more than two*** official languages. |

**Amendment 62**

**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), ***6(2a),*** 6(3), 6(9), 6(10), 8(4), 9(3), 11(3), 13(4), 14(9), ***14(9a), 15, 17(3a),*** and 18(5) shall be conferred on the Commission for ***a*** period of ***five years*** from [Office of Publications: please insert the date of the entry into force of this Directive]. |

**Amendment 63**

**Proposal for a directive**
**Article 22 – paragraph 3**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 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 | 3. The delegation of powers referred to in Articles 4(3), 4(4), ***6(2a),*** 6(3), 6(9), 6(10), 8(4), 9(3), 11(3), 13(4), 14(9), ***14(9a), 15, 17(3a),*** and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an |

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|---|---|
| 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. | 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 64**

**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), ***6(2a),*** 6(3), 6(9), 6(10), 8(4), 9(3), 11(3), 13(4), 14(9), ***14(9a), 15, 17(3a),*** and 18(5) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council. |

**Amendment 65**

**Proposal for a directive**
**Article 23 – paragraph 1 – subparagraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| With a view to drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available. | With a view to drafting the report, the Commission shall be assisted by scientific and technical experts ***from the Member States*** in order to have all the necessary information available. |

**Amendment 66**

**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***. | 2. ***This Directive shall not affect the right of Member States to keep or introduce, in accordance with the Treaty, more stringent rules concerning the manufacture, import, sale and consumption of tobacco products which they deem necessary in order*** to protect public health***, in-so-far as such rules fall outside the scope of*** the provisions ***of*** this Directive. |

**Amendment 67**

**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 | 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. | Directive by [Publications Office, please insert the exact date: entry into force + ***24*** months] at the latest. They shall forthwith communicate to the Commission the text of those provisions. |

**Amendment 68**

**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 + ***48*** months]: |

*Justification*

*Member States should have more time to adjust to the new provisions.*

**Amendment 69**

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

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (a) ***tobacco products***; | (a) ***cigarettes and roll-your-own cigarettes***; |

**Amendment 70**
**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; |

*Justification*

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

**Amendment 71**

**Proposal for a directive**
**Article 26 – paragraph 1 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Member States may allow tobacco products other than cigarettes and roll-your-own cigarettes, 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 + 42 months).*** |

*Justification*

*According to Recital (18) of Directive 2001/37/EC, sufficiently long transitional periods should be provided in order to allow the necessary modifications in production to take place and for disposal of stocks, particularly for products other than cigarettes.*

**Amendment 72**

**Proposal for a directive**
**Annex 2 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***ANNEX IIa*** |
| | ***Maximum permissible content in smokeless tobacco, toxin per unit weight dry tobacco:*** |
| | ***NNN (N-nitrosonornicotine) plus NNK (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone): 2.0 mg/kg*** |
| | ***B(a)P (Benzo[a]Pyrene): 5.0 µg/kg*** |

*Justification*

*This table reproduces the toxicity recommendations of the WHO Study Group on Tobacco Product Regulation- Report on the Scientific Basis of Tobacco Product Regulation WHO Technical Report Series, no. 955. (2010)*

**Amendment 73**

**Proposal for a directive**
**Annex 2 b (new)**

| *Text proposed by the Commission* | *Amendment* |
| --- | --- |
| | ***ANNEX IIb*** |
| | ***EU legislation applicable to nicotine-containing products:*** |
| | ***General safety:*** |
| | ***General Product Safety Directive 2001/95/EC, in particular with regard to 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 pre-packaged 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*

## ANNEX - LIST OF SUBMISSIONS BY STAKEHOLDERS[1]

| **Organisation** |
|---|
| Action Buendnis NICHT RAUCHEN |
| Addleshaw Goddard LLP |
| Prof. Andrzej Sobczak |
| Association of the European Self-Medication Industry |
| European Association of Communications Agencies |
| Federation of European Direct and Interactive Marketing |
| Business Action to Stop Counterfeiting and Piracy |
| British American Tobacco |
| Confédération Européenne des Détaillants en Tabac |
| Deutsche Benkert GmbH & Co KG |
| Clive Bates, former director of UK-based Action on Smoking and Health |
| Confederation of European Union Cigarette Manufacturers |
| Council of European Dentists |
| European Carton Makers Association |
| European Cigar Manufacturers Association |
| Electronic Cigarette Industry Trade Association |
| European Self-Medication Industry |
| European Communities Trade Mark Association |
| European Federation of Allergy and Airways Diseases Patients' Associations |
| European Heart Network |
| E-lites (Charles Hamshaw-Thomas) |
| European Public Health Alliance |
| European Society of Cardiology |
| European Smokeless Tobacco Council ESTOC |
| European Union Cigarette Manufacturers |
| Fertin Pharma |
| European Public Health Alliance |
| Polish Chamber of Commerce |
| German Cancer Research Center |
| Gerry Stimson, Professor |
| Global Acetate Manufacturers' Association |
| International Chamber of Commerce |
| Japan Tobacco International Poland |
| Jacques Le Houezec, PhD |
| Jean-Francois ETTER – Professeur associé - Dr ès sciences |
| Krajowe Stowarzyszenie Przemysłu Tytoniowego |
| Kreab Gavin Anderson |
| MANE, a French Flavour Company/French Flavour Association (SNIAA) |
| dr Michał Kozłowski -http://esmokinginstitute.com/ |
| Mirosław Dworniczak |

[1] The list is not exhaustive

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|---|
| starychemik.wordpress.com<br>www.dworniczak.eu |
| Naczelna Rada Lekarska |
| National Brands Associations |
| dr Michał Kozłowski -http://esmokinginstitute.com/ |
| NJOY Electronic Cigarettes |
| Phillip Morris |
| Polish Confederation of Private Employers Lewiatan |
| Polish Society for Health Programmes |
| POLSKI ZWIĄZEK PLANTATORÓW TYTONIU |
| Polish tobacco farmers association |
| Smoke Free Partnership |
| Stowarzyszenie MANKO - Partnerstwo Polska Bez Dymu |
| SWM INTL |
| SCIPA Security Solutions Poland Sp. z o.o. |
| TRIERENBERG HOLDING AG |
| Zakład Szkodliwości Chemicznych i Toksykologii Genetycznej |
| Action on Smoking and Health (UK) |

## 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**<br>Date announced in plenary | ENVI<br>15.1.2013 |
| **Opinion by**<br>Date announced in plenary | IMCO<br>15.1.2013 |
| **Rapporteur**<br>Date appointed | Małgorzata Handzlik<br>23.1.2013 |
| **Discussed in committee** | 21.3.2013 24.4.2013 30.5.2013 |
| **Date adopted** | 18.6.2013 |
| **Result of final vote** | +: 23<br>–: 14<br>0: 0 |
| **Members present for the final vote** | Claudette Abela Baldacchino, Pablo Arias Echeverría, Preslav Borissov, Jorgo Chatzimarkakis, Sergio Gaetano Cofferati, Birgit Collin-Langen, Lara Comi, Anna Maria Corazza Bildt, António Fernando Correia de Campos, Christian Engström, Evelyne Gebhardt, Małgorzata Handzlik, Malcolm Harbour, Toine Manders, Franz Obermayr, Sirpa Pietikäinen, Phil Prendergast, Zuzana Roithová, Heide Rühle, Matteo Salvini, Christel Schaldemose, Andreas Schwab, Catherine Stihler, Róża Gräfin von Thun und Hohenstein, Gino Trematerra, Bernadette Vergnaud, Barbara Weiler |
| **Substitute(s) present for the final vote** | Raffaele Baldassarre, Nora Berra, Jürgen Creutzmann, María Irigoyen Pérez, Roberta Metsola, Olle Schmidt, Marc Tarabella, Sabine Verheyen |
| **Substitute(s) under Rule 187(2) present for the final vote** | Susy De Martini, Konrad Szymański |