REPORT


Committee on the Environment, Public Health and Food Safety

Rapporteur: Linda McAvan
Symbols for procedures

* Consultation procedure
*** Consent procedure
***I Ordinary legislative procedure (first reading)
***II Ordinary legislative procedure (second reading)
***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

In amendments by Parliament, amendments to draft acts are highlighted in bold italics. Highlighting in normal italics is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in bold. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION</td>
<td>5</td>
</tr>
<tr>
<td>EXPLANATORY STATEMENT</td>
<td>77</td>
</tr>
<tr>
<td>ANNEX</td>
<td>81</td>
</tr>
<tr>
<td>OPINION OF THE COMMITTEE ON INTERNATIONAL TRADE</td>
<td>83</td>
</tr>
<tr>
<td>OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY</td>
<td>115</td>
</tr>
<tr>
<td>OPINION OF THE COMMITTEE ON THE INTERNAL MARKET AND CONSUMER PROTECTION</td>
<td>159</td>
</tr>
<tr>
<td>OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT</td>
<td>219</td>
</tr>
<tr>
<td>OPINION OF THE COMMITTEE ON LEGAL AFFAIRS</td>
<td>259</td>
</tr>
<tr>
<td>OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON DELEGATED ACTS</td>
<td>302</td>
</tr>
<tr>
<td>PROCEDURE</td>
<td>320</td>
</tr>
</tbody>
</table>
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2012)0788),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0420/2012),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the reasoned opinions submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Czech Chamber of Deputies, Danish Parliament, Greek Parliament, Italian Chamber of Deputies, Italian Senate, Portuguese Parliament, Romanian Chamber of Deputies, Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,

– having regard to the opinion of the European Economic and Social Committee of 4 July 2013¹,

– having regard to the opinion of the Committee of the Regions of 3 July 2013²,

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on International Trade, the Committee on Industry, Research and Energy, the Committee on the Internal Market and Consumer Protection, the Committee on Agriculture and Rural Development and the Committee on Legal Affairs (A7-0276/2013),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

¹ Not yet published in the Official Journal.
² Not yet published in the Official Journal.
3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a directive
Recital 3 a (new)

Text proposed by the Commission

Amendment

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

Justification

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

Amendment 2

Proposal for a directive
Recital 6

Text proposed by the Commission

Amendment

(6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the whole of the Union in only a small number of production plants within the Member States and the resulting significant cross-border trade of tobacco and related products calls for legislative action at Union rather than national level to achieve the smooth operation of the internal market.

(6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the whole of the Union in only a small number of production plants within the Member States and the resulting significant cross-border trade of tobacco and related products calls for stronger legislative action at Union level to achieve the smooth operation of the internal market.
Amendment 3
Proposal for a directive
Recital 7

Text proposed by the Commission

(7) Legislative action at Union level is also necessary to implement the WHO Framework Convention on Tobacco Control (hereinafter: "FCTC") of May 2003 to which the European Union and its Member States are Parties. Of relevance are in particular its Articles 9 (regulation of the contents of tobacco products), 10 (regulation of tobacco product disclosures), 11 (packaging and labelling of tobacco products), 13 (advertising) and 15 (illicit trade in tobacco products). A set of guidelines for the implementation of FCTC provisions was adopted by consensus during various Conferences of the Parties to the FCTC with the support of the Union and the Member States.

Amendment

(7) Legislative action at Union level is also necessary to implement the landmark WHO Framework Convention on Tobacco Control ("FCTC") of May 2003. All Member States, and the European Union itself, have signed and ratified the FCTC and as a result are bound under international law by its provisions. Of particular relevance are Articles 9 (regulation of the contents of tobacco products), 10 (regulation of tobacco product disclosures), 11 (packaging and labelling of tobacco products), 13 (advertising) and 15 (illicit trade in tobacco products). A set of guidelines for the implementation of FCTC provisions was adopted by consensus during various Conferences of the Parties to the FCTC with the support of the Union and the Member States.

Justification

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

Amendment 4
Proposal for a directive
Recital 8

Text proposed by the Commission

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (hereinafter: "Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based

Amendment

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union ("Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific
on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people.

To that end, Member States should promote smoking prevention campaigns, especially in schools and through the media. In accordance with the principle of producer responsibility, manufacturers of tobacco products should be made responsible for all health costs arising as a consequence of tobacco consumption.

Amendment 5
Proposal for a directive
Recital 9 a (new)

Text proposed by the Commission

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

Justification

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

Amendment 6
Proposal for a directive
Recital 10
(10) For measuring the tar, nicotine and carbon monoxide yields of cigarettes, reference should be made to ISO standards 4387, 10315 and 8454, which are internationally recognised standards. For other emissions there are no internationally agreed standards or tests for quantifying the yields, but efforts are ongoing to develop them.

Amendment 7

Proposal for a directive
Recital 10 a (new)

Text proposed by the Commission

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

Justification

Polonium 210 is a decay product of uranium that is present in fertilizers made from uranium-rich phosphate rock. It contaminates tobacco leaves through the air via Radon 222 and through the roots via Lead 210. When burnt, Polonium 210 evaporates, and is thus inhaled by smokers. It is an alpha emitter. Alpha radiation is innocuous outside the body, but once inside the human body it is 'the most hazardous form of radiation' (The Polonium Brief, Brianna Rego, Isis, 2009).
Amendment 8

Proposal for a directive
Recital 11

Text proposed by the Commission

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

Amendment

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

Justification

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

Amendment 9

Proposal for a directive
Recital 13

Text proposed by the Commission

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

Amendment

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

Justification

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

Amendment 10

Proposal for a directive
Recital 14

Text proposed by the Commission

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

Amendment

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

Ingredients that increase addictiveness and toxicity should also be removed.

Amendment 11

Proposal for a directive
Recital 14 a (new)
(14a) In order to protect human health, an assessment should be carried out on the safety of additives for use in tobacco products. Additives should only be allowed in tobacco products if they are included in a Union list of authorised additives. That list should also indicate any conditions or restrictions on the use of allowed additives. Tobacco products containing additives not included in the Union list or used in a manner that does not comply with this Directive should not be placed on the Union market.

Amendment 12
Proposal for a directive
Recital 14 b (new)

(14b) It is important not only to consider the properties of additives as such, but also of their combustion products. Additives as well as their combustion products should not be such that they meet the criteria for classification as hazardous in accordance with Regulation EC (No) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.


Justification

Only additives that are not hazardous - as such or upon combustion - should be allowed.
Amendment 13
Proposal for a directive
Recital 15

Text proposed by the Commission

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

Amendment

(15) The likelihood of diverging regulation is further increased by concerns over tobacco products having a characterising flavour other than tobacco, which may facilitate uptake of tobacco consumption or affect consumption patterns. For example, in many countries, sales of mentholated products gradually increased even as smoking prevalence overall declined. A number of studies indicated that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people. Measures introducing unjustified differences of treatment between flavoured cigarettes (e.g. menthol and clove cigarettes) should be avoided.

Amendment 14
Proposal for a directive
Recital 16

Text proposed by the Commission

(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufactures to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives necessary for manufacturing of tobacco products should be allowed, as long as they do not result in a characterising flavour. The Commission should ensure uniform conditions for the

Amendment
deleted
implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.

**Amendment 15**

**Proposal for a directive**

**Recital 17**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(17) Certain additives are used to create the impression that tobacco products have health benefits, present reduced health hazards or increase mental alertness and physical performance. These additives should be prohibited in order to ensure uniform rules and a high level of health protection.</td>
<td>(17) Certain additives are used to create the impression that tobacco products have health benefits, present reduced health hazards or increase mental alertness and physical performance. <strong>In order to ensure uniform rules and a high level of health protection, those additives should not be approved. In addition, additives which impart a characterising flavour should not be approved. This should not result in prohibiting the use of individual additives altogether. Manufactures should, however, be required to reduce the use of an additive or of a combination of additives to such an extent that the additives no longer result in a characterising flavour. It should be possible to approve the use of additives that are essential for manufacturing of tobacco products, as long as those additives do not result in a characterising flavour and are not linked to the attractiveness of such products.</strong></td>
</tr>
</tbody>
</table>

**Amendment 16**

**Proposal for a directive**

**Recital 17 a (new)**
(17a) An increasing number of people, most of them children, suffer from asthma and various allergies. Not all causes of asthma are understood, as indicated by WHO, but it is necessary for risk factors including allergens, tobacco and chemical irritants to be prevented in order to improve people's quality of life.

Amendment 17

Proposal for a directive

Recital 18

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

Amendment 18

Proposal for a directive

Recital 18 a (new)

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

Amendment 19
Proposal for a directive
Recital 18 b (new)

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

Amendment 20
Proposal for a directive
Recital 20

Text proposed by the Commission
(20) Such disparities are liable to constitute

Amendment
(20) Such disparities are liable to constitute
a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated. Also, consumers in some Member States may be better informed about the health risks of tobacco products than in others. Without further action at Union level, the existing disparities are likely to increase in the coming years.

Amendment 21

Proposal for a directive
Recital 22

Text proposed by the Commission

(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings are more effective than text-only warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.

Amendment

(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined picture and text health warnings are more effective than text-only warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts on the field of vision on all sides of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.

Amendment 22

Proposal for a directive
Recital 23

Text proposed by the Commission

(23) In order to ensure the integrity and the

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.

Amendment 23
Proposal for a directive
Recital 23 a (new)

Text proposed by the Commission

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

Justification

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

Amendment 24

Proposal for a directive
Recital 24

Text proposed by the Commission
(24) Tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers, should be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people. The labelling of these other tobacco products should follow specific rules. The visibility of the health warnings on smokeless tobacco products needs to be ensured. Warnings should therefore be placed on the two main surfaces of smokeless tobacco product packaging.

Amendment
(24) Tobacco products for smoking, other than cigarettes, roll-your-own tobacco products and water pipe tobacco, which are mainly consumed by older consumers, should be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people. The labelling of these other tobacco products should follow specific rules. The visibility of the health warnings on smokeless tobacco products needs to be ensured. Warnings should therefore be placed on the two main surfaces of smokeless tobacco product packaging.

Amendment 25

Proposal for a directive
Recital 26

Text proposed by the Commission
(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the

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.

Amendment 26
Proposal for a directive
Recital 28

Text proposed by the Commission

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

Amendment

(28) In order to ensure independence and transparency, manufacturers of tobacco products should conclude data storage contracts with independent third parties. The suitability of such contracts should be approved and monitored by the Commission, assisted by an independent external auditor. The data related to the tracking and tracing system should be kept separate from other company related data and be under the control of and accessible at all times by the competent authorities from Member States and the Commission.
Amendment 27

Proposal for a directive
Recital 29

Text proposed by the Commission

(29) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC confirmed this prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden derogation from this prohibition. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction to the internal market of a product that is addictive, has adverse health effects and is attractive to young people.

For other smokeless tobacco products that are not produced for the mass market, a strict labelling and ingredients regulation is considered sufficient to contain market expansion beyond their traditional use.

Amendment

(29) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC confirmed this prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden derogation from this prohibition. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction to the internal market of a product that is addictive, has adverse health effects and is attractive to young people.

Amendment 28

Proposal for a directive
Recital 29 a (new)

Text proposed by the Commission

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

Amendment 29

Proposal for a directive
Recital 30

Text proposed by the Commission


Amendment

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

Amendment 30

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

Amendment 31
Proposal for a directive
Recital 30 b (new)

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

Amendment 32
Proposal for a directive
Recital 31

(31) All tobacco products have the
potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 5 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

Amendment 33

Proposal for a directive
Recital 33

*Text proposed by the Commission*

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

*Amendment*

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

Amendment 34

Proposal for a directive
Recital 34
(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. *Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework* clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

(35) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. *However, measuring nicotine delivery has proven to be difficult, as it depends on the products and how they are being used. Therefore, making all nicotine-containing products, regardless of their nicotine content, subject to Directive 2001/83/EC, while recognising the well-established use of nicotine, clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.*

Amendment 35

Proposal for a directive

Recital 35

*Text proposed by the Commission*

(35) Labelling provisions should be introduced for nicotine containing products below the threshold set out in this Directive drawing the attention of

*Amendment*

deletced
consumers to potential health risks.

Amendment 36
Proposal for a directive
Recital 35 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(35a) Member States should ensure that nicotine-containing products are not sold to persons below the age required for purchasing tobacco products or related products.</td>
<td></td>
</tr>
</tbody>
</table>

Amendment 37
Proposal for a directive
Recital 37

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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.</td>
<td>(37) In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.</td>
</tr>
</tbody>
</table>

Amendment 38
Proposal for a directive
Recital 38
(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Amendment 39

Proposal for a directive
Recital 39

Text proposed by the Commission

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

Amendment

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

amendments to this Directive are necessary, in particular as regards packaging.

Amendment 40

Proposal for a directive
Recital 39 a (new)

Text proposed by the Commission

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

Amendment 41

Proposal for a directive
Recital 40

Text proposed by the Commission

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

(40) A Member State that deems it necessary to maintain or introduce more stringent national provisions for aspects falling inside the scope of this Directive should be allowed to do so, for all products alike, insofar as such measures are compatible with the TFEU. Stricter national provisions require prior notification to, and approval from, the Commission taking into account the high level of health protection achieved through this Directive.
necessary and proportionate, not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Stricter national provisions require prior notification to, and approval from, the Commission taking into account the high level of health protection achieved through this Directive.

**Amendment 42**

**Proposal for a directive**

**Recital 42**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(42) Member States should ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.</td>
<td>(42) Member States should ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. <strong>It is essential that National data protection provisions also be taken into account.</strong></td>
</tr>
</tbody>
</table>

**Amendment 43**

**Proposal for a directive**

**Recital 45**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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</td>
<td>(45) The proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), and the right to property of <strong>trademark holders</strong> (Article</td>
</tr>
</tbody>
</table>
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.

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

Amendment 44
Proposal for a directive
Recital 45 a (new)

Text proposed by the Commission

Amendment

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

Amendment 45
Proposal for a directive
Article 1

Text proposed by the Commission

Amendment

The aim of this Directive is to approximate the laws, regulations and administrative
provisions of the Member States concerning:

(a) the ingredients and emissions of tobacco products and related reporting obligations including the maximum yields for tar, nicotine and carbon monoxide for cigarettes;

(b) the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features to ensure compliance with this Directive;

(c) the prohibition to place on the market tobacco for oral use;

(d) cross-border distance sales of tobacco products;

(e) the notification obligation for novel tobacco products;

(f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely nicotine-containing products and herbal products for smoking;

in order to facilitate the functioning of the internal market in tobacco and related products, taking as a basis a high level of health protection.

Amendment 46
Proposal for a directive
Article 2

Text proposed by the Commission
For the purposes of this Directive, the following definitions shall apply:

Amendment
For the purposes of this Directive, the following definitions shall apply:

in order to meet obligations under the WHO Framework Convention for Tobacco Control and in order to facilitate the functioning of the internal market in tobacco and related products, taking as a base a high level of health protection, especially for young people.
(1) 'addictiveness' means the pharmacological potential of a substance to cause addiction, a state which affects an individual’s ability to control behaviour typically by instilling a reward or a relief from withdrawal symptoms, or both;

(2) 'additive' means substance contained in a tobacco product, its unit packet or any outside packaging with the exception of tobacco leaves and other natural or unprocessed parts of tobacco plants;

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

(4) 'characterising flavour' means a distinguishable aroma or taste other than tobacco, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy, menthol or vanilla observable before or upon intended use of the tobacco product;

(5) 'chewing tobacco' means a smokeless tobacco product exclusively designed for the purpose of chewing;

(6) 'cigar' means a roll of tobacco consumed via a combustion process and further defined in Article 4(1) of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco;

(7) 'cigarette' means a roll of tobacco consumed via a combustion process and further defined in Article 3(1) of Council Directive 2011/64/EU;

(8) 'cigarillo' means a small type of cigar with a diameter of up to 8 mm;

(9) 'combined health warning' means a health warning provided for in this Directive and consisting of a combination of a text warning and a corresponding photograph or illustration;
(10) 'consumer' means a natural person who is acting for purposes which are outside his trade, business, craft or profession;

(11) 'cross-border distance sales' means a distance sales service where, at the time the consumer orders the product, the consumer is located in a Member State other than the Member State or the third country where the retail outlet is established; a retail outlet is deemed to be established in a Member State:

(a) in the case of a natural person - if he/she has his/her place of business in that Member State;

(b) in other cases - if it has its statutory seat, central administration or place of business, including a branch, agency or any other establishment in that Member State;

(12) 'emissions' means substances that are released when a tobacco product is used as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;

(13) 'flavouring' means an additive that imparts aroma and/or taste;

(14) 'health warning' means a warning provided for in this Directive, including text warnings, combined health warnings, general warnings and information messages;

(15) 'herbal product for smoking' means a product based on plants or herbs which contains no tobacco and is consumed via a combustion process;

(16) 'import of tobacco and related products' means the entry into the territory of the Union of such products unless the products upon their entry into the Union are placed under a customs suspensive procedure or arrangement, as well as their release from a customs suspensive procedure or arrangement;
(17) 'importer of tobacco and related products' means the owner or a person having the right of disposal over tobacco and related products that have been brought into the territory of the Union;

(18) 'ingredient' means an additive, tobacco (leaves and other natural, processed or unprocessed parts of tobacco plants including expanded and reconstituted tobacco), as well as any substance present in a finished tobacco product including paper, filter, inks, capsules and adhesives;

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

(20) 'nasal tobacco' means a smokeless tobacco product consumed via the nose;

(21) 'nicotine' means nicotinic alkaloids;

(22) 'nicotine-containing product' means a product usable for consumption by consumers via inhalation, ingestion or in other forms and to which nicotine is either added during the manufacturing process or self-administered by the user before or during consumption;

(23) 'novel tobacco product' means a tobacco product other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use placed on the market after entry into force of this Directive;

(24) 'outside packaging' means any packaging in which products are placed on the market and which include a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;

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

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

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

(20) 'nasal tobacco' means a smokeless tobacco product consumed via the nose;

(21) 'nicotine' means nicotinic alkaloids;

(22) 'nicotine-containing product' means a product usable for consumption by consumers via inhalation, ingestion or in other forms and to which nicotine is either added during the manufacturing process or self-administered by the user before or during consumption;

(23) 'novel tobacco product' means a tobacco product other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use placed on the market after entry into force of this Directive;

(24) 'outside packaging' means any packaging in which products are placed on the market and which include a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;
(24a) ‘outside transport packaging’ means any packaging, consisting of an aggregation of unit packets, in which tobacco products are transported from the manufacturer to the subsequent economic operators before being placed on the market, such as cartons, master cases and pallets;

(25) ‘place on the market’ means to make products available to consumers located in the Union, with or without payment, including by means of distance sale; in case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located;

(26) ‘pipe tobacco’ means tobacco consumed via a combustion process and exclusively designed for the purpose of being used in a pipe;

(26a) ‘water pipe tobacco’ means tobacco intended solely for use in a water pipe;

(27) ‘retail outlet’ means any outlet where tobacco products are placed on the market including by a natural person;

(28) ‘roll-your-own tobacco’ means tobacco which can be used for making cigarettes by consumers or retail outlets;

(29) ‘smokeless tobacco product’ means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;

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

(31) 'tar' means the raw anhydrous nicotine-free condensate of smoke;

(32) 'tobacco for oral use' means all products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets;

(33) 'tobacco for smoking' means a tobacco product other than a smokeless tobacco product;

(34) 'tobacco products' means products usable for consumption by consumers and consisting of, even partly, tobacco, whether genetically modified or not;

(35) 'toxicity' means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually upon repeated or continuous consumption or exposure;

(36) 'unit packet' means the smallest individual packaging of a product that is placed on the market.

Directive] Eurobarometer report or equivalent prevalence studies;

(31) 'tar' means the raw anhydrous nicotine-free condensate of smoke;

(32) 'tobacco for oral use' means all products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets;

(33) 'tobacco for smoking' means a tobacco product other than a smokeless tobacco product;

(34) 'tobacco products' means products usable for consumption by consumers and consisting of, even partly, tobacco, whether genetically modified or not;

(35) 'toxicity' means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually upon repeated or continuous consumption or exposure;

(36) 'unit packet' means the smallest individual packaging of a product that is placed on the market.

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

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

Justification

According to the Article 16 of the WHO FCTC which was ratified by the European Community 30/06/2005 conference of parties shall prohibit the sales of tobacco products to persons under the age by banning imitation tobacco products. The EU legislation shall be
adjusted to international obligations.

Amendment 47
Proposal for a directive
Article 3

**Text proposed by the Commission**

<table>
<thead>
<tr>
<th>Article 3</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum tar, nicotine, carbon monoxide and other yields</td>
<td>Maximum tar, nicotine, carbon monoxide and other yields</td>
</tr>
<tr>
<td>1. The yield of cigarettes placed on the market or manufactured in the Member States shall not be greater than:</td>
<td>1. The yield of cigarettes placed on the market or manufactured in the Member States shall not be greater than:</td>
</tr>
<tr>
<td>(a) 10 mg per cigarette for tar,</td>
<td>(a) 10 mg per cigarette for tar,</td>
</tr>
<tr>
<td>(b) 1 mg per cigarette for nicotine,</td>
<td>(b) 1 mg per cigarette for nicotine,</td>
</tr>
<tr>
<td>(c) 10 mg per cigarette for carbon monoxide.</td>
<td>(c) 10 mg per cigarette for carbon monoxide.</td>
</tr>
<tr>
<td>2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt the maximum yields laid down in paragraph 1, taking into account scientific development and internationally agreed standards.</td>
<td>2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to reduce the maximum yields laid down in paragraph 1, where necessary, in order to take into account scientific development and internationally agreed standards.</td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

3. Member States shall notify the Commission of the maximum yields that they set for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. The Commission shall adopt delegated acts in accordance with Article 22 to integrate into Union law guidelines agreed by the parties to the FCTC or WHO relating to maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes.
Amendment 48

Proposal for a directive
Article 4

Text proposed by the Commission

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

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

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

Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available.

Amendment

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

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

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

Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval, and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available.

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

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

4. Member States shall notify the Commission of the methods of measurement that they use for other emissions of tobacco products other than cigarettes. Based on these methods, and taking into account scientific and technical developments as well as internationally agreed standards the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt methods of measurement.

Amendment 49Proposal for a directive Article 5

Text proposed by the Commission

1. Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields. Manufacturers or importers shall also inform the competent authorities of the concerned Member States if the composition of a product is modified affecting the information provided under

Amendment

1. Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products by brand name and type, as well as their emissions and yields. Manufacturers or importers shall also inform the competent authorities of the concerned Member States if the composition of a product is modified affecting the information provided under

4a. The accuracy of the indications for the other emissions of other combustible tobacco products shall be verified in accordance with ISO standard 8243.
this Article. Information required under this Article shall be submitted prior to the placing of the market of a new or modified tobacco product.

The list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. The list shall indicate their status, including whether the ingredients have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as well as their classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health of consumers and taking into account, inter alia, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product. Other than for tar, nicotine and carbon monoxide and for emissions referred to in Article 4 paragraph 4, the manufacturers and importers shall indicate the measurement methods used. Member States may also require manufacturers or importers to carry out other tests as may be laid down by the competent national authorities in order to assess the effects of substances on health, taking into account, inter alia, their addictiveness and toxicity.

Other than for tar, nicotine and carbon monoxide and for emissions referred to in Article 4 paragraph 4, the manufacturers and importers shall indicate the measurement methods used. Member States may also require manufacturers or
2. Member States shall ensure the dissemination of information submitted in accordance with paragraph 1 on a dedicated website, which is available to the general public. In doing so Member States shall take due account of the need to protect information which constitutes a trade secret.

3. The Commission shall, by means of implementing acts, lay down and if necessary update the format for the submission and dissemination of the information specified in paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

4. Member States shall require manufacturers and importers to submit internal and external studies available to them on market research and preferences of various consumer groups, including young people, relating to ingredients and emissions. Member States shall also require manufacturers and importers to report the sales volume data per product, reported in sticks or kilograms, and per Member State on a yearly basis starting from the full calendar year following that of the entry into force of this Directive. Member States shall provide alternative or additional sales data, as appropriate, to ensure that information on sales volume requested under this paragraph is reliable and complete.

4a. Member States shall require manufacturers and importers to disclose their expenditure on advertising.
5. All data and information to be provided to and by Member States under this Article shall be provided in electronic form. Member States shall store the information electronically and shall ensure that the Commission has access to the information at all times. Other Member States shall have access to this information upon justified request. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

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

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

6. Fees charged by Member States for receiving, storing, handling, analysing and publishing the information submitted to them under this Article, if any, shall not exceed the cost attributable to those activities.

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

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

Justification

As per the requirements of Article 13 of the WHO FCTC. This figure is currently not available for the EU.
Amendment 50

Proposal for a directive
Article 6

Text proposed by the Commission

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

Amendment

1. Additives shall not be used in tobacco products unless they are approved in accordance with this Directive. Approved additives shall be included in the list set out in Annex [-I]. Any conditions or restrictions on use of approved additives shall also be indicated in the list. The placing on the market of tobacco products containing additives not listed in Annex [-I] or used not in compliance with any conditions or restrictions laid down in that Annex to this Directive shall be prohibited.

The following additives may not be approved:

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

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

(c) additives having colouring properties for emissions;

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

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

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

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

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

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

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

Member States shall notify the Commission of measures taken pursuant to this paragraph.

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

The Commission shall adopt by means of implementing acts uniform rules on the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in
Article 21.

3. In case the experience gained in the application of paragraphs 1 and 2 shows that a certain additive or a combination thereof typically impart a characterising flavour when it exceeds a certain level of presence or concentration the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives or combination of additives that cause the characterising flavour.

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

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

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

(c) additives having colouring properties for emissions.

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

6. Member States shall ensure that provisions or conditions set out under Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.

7. Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product.

5. The use of flavourings in the components of tobacco products such as filters, papers, packages, capsules or any technical features allowing modification of flavour or smoke intensity shall be prohibited. Filters and capsules shall not contain tobacco.
Member States shall notify to the Commission measures taken pursuant to this paragraph.

8. The Commission shall at the request of a Member State or may on its own initiative determine by means of an implementing act whether a tobacco product falls within the scope of paragraph 7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21 and shall be based on the latest scientific evidence.

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

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

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

(a) name or corporate name and permanent address of the applicant;
(b) chemical name of the additive;
(c) function of the additive and maximum
quantity to be used per cigarette;
(d) clear evidence supported by scientific data that the additive does not fall under any of the exclusion criteria listed in this Article.

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

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

10b. This Article shall be without prejudice to the application to tobacco products of the relevant provisions of Regulation (EC) No 1907/2006 or of any conditions set pursuant to that Regulation.

10c. This Article shall apply as from …*.

________________________

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

Amendment 51
Proposal for a directive
Article 7

Text proposed by the Commission

1. Each unit packet of tobacco products and any outside packaging shall carry health warnings in the official language or languages of the Member State where the product is placed on the market.
2. Health warnings shall occupy the entire

Amendment

1. Each unit packet of tobacco products and any outside packaging shall carry health warnings in the official language or languages of the Member State where the product is placed on the market.
2. Health warnings shall occupy the entire
surface reserved for them and they shall not be commented on, paraphrased or referred to in any form.

3. In order to ensure their graphic integrity and visibility, health warnings shall be irremovably printed, indelible and in no way hidden or interrupted, including by tax stamps, price marks, tracking and tracing marks, security features or by any type of wrapper, pouch, jacket, box or other device or by the opening of the unit packet. In the case of tobacco products other than cigarettes, roll-your-own, water-pipe tobacco and smokeless tobacco products health warnings may be affixed by means of stickers, provided that such stickers cannot be removed.

4. Member States shall ensure that the health warnings 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.

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

6. Member States shall not increase the size of the health warnings including by introduction of an obligation to surround the health warnings by a border. The actual size of the health warnings shall be calculated in relation to the surface on which they are placed before the unit packet is opened.

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

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

Amendment 52
Proposal for a directive
Article 8 – paragraphs 1 to 3

Text proposed by the Commission

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

Smoking kills – quit now

2. Each unit packet and any outside packaging of tobacco for smoking shall carry the following information message:

Tobacco smoke contains over 70 substances known to cause cancer

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

Amendment

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

Smoking kills – quit now

2. Each unit packet and any outside packaging of tobacco for smoking shall carry the following information message:

Tobacco smoke contains over 70 substances known to cause cancer

3. For cigarette packets the general warning and the information message shall be printed on the lateral sides of the unit packets in black Helvetica bold type on a white background. These warnings shall have a width of not less than 20 mm. For roll-your-own tobacco in pouches the information message shall be printed on the surface that becomes visible when opening the unit packet, for cylindrical containers the warnings shall be printed on the lid, and for cuboid containers the warnings shall be printed on the lateral sides. Both the general warning and the information message shall cover 50% of the surface on which they are printed.
Proposal for a directive
Article 8 – paragraph 4

_text proposed by the commission_

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

(a) to adapt the wording of the health warnings laid down in paragraphs 1 and 2 to scientific and market developments;

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

 amendment

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

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

Proposal for a directive
Article 9 – paragraphs 1 and 2

_text proposed by the commission_

Combined health warnings for tobacco for smoking

1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The combined health warnings shall:

(a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library;

(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;

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

_amendment_

Combined health warnings for tobacco for smoking

1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined picture and text health warnings. The combined health warnings shall:

(a) be comprised of a text warning listed in Annex I and a corresponding colour photograph specified in the picture library _in Annex II;

(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;

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

_Cylindrical containers shall display two_
(d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;

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

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

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

(i) height: not less than 64 mm;

(ii) width: not less than 55 mm.

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

**Amendment 55**

**Proposal for a directive**

**Article 9 – paragraph 3**

*Text proposed by the Commission*

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

(a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments;

(b) *establish and adapt the picture library referred to in point (a) of paragraph 1 of*...
**this Article** taking into account scientific and market developments;

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

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

**Amendment 56**

**Proposal for a directive**  
**Article 10 – paragraphs 1 to 4**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labelling of tobacco for smoking other than cigarettes and roll-your-own tobacco</td>
<td>Labelling of tobacco for smoking other than cigarettes, roll-your-own, and water-pipe tobacco</td>
</tr>
<tr>
<td>1. Tobacco for smoking other than cigarettes and roll-your-own tobacco shall be exempted from</td>
<td>1. Tobacco for smoking other than cigarettes, roll-your-own tobacco and water-pipe tobacco shall be exempted from</td>
</tr>
<tr>
<td>the obligations to carry the information message laid down in Article 8(2) and the combined</td>
<td>the obligations to carry the information message laid down in Article 8(2) and the combined</td>
</tr>
<tr>
<td>health warnings in Article 9. In addition to the general warning specified in Article 8(1),</td>
<td>health warnings in Article 9. In addition to the general warning specified in</td>
</tr>
<tr>
<td>each unit packet and any outside packaging of these products shall carry a text warning listed</td>
<td>Article 8(1), each unit packet and any outside packaging of these products shall</td>
</tr>
<tr>
<td>in Annex I. The general warning specified in Article 8(1) shall include a reference to the</td>
<td>carry a text warning listed in Annex I. The general warning specified in Article 8(1) shall</td>
</tr>
<tr>
<td>cessation services in accordance with Article 9(1)(b).</td>
<td>include a reference to the cessation services in accordance with Article 9(1)(b).</td>
</tr>
<tr>
<td>The general warning shall be printed on the most visible surface of the unit packet and any</td>
<td>The general warning shall be printed on the most visible surface of the unit packet and any</td>
</tr>
<tr>
<td>outside packaging. The text warnings listed in Annex I shall be rotated in such a way as to</td>
<td>outside packaging. The text warnings listed in Annex I shall be rotated in such a way as to</td>
</tr>
<tr>
<td>guarantee their regular appearance. These warnings shall be printed on the other most visible</td>
<td>guarantee their regular appearance. These warnings shall be printed on the other most visible</td>
</tr>
<tr>
<td>surface of the unit packet and any outside packaging.</td>
<td>surface of the unit packet and any outside packaging.</td>
</tr>
</tbody>
</table>
2. The general warning referred to in paragraph 1 shall cover 30% of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32% for Member States with two official languages and 35% for Member States with three official languages.

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

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

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

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

(b) centred in the area in which they are required to be printed, parallel to the top edge of the unit packet and any outside packaging;

c) surrounded by a black border not less than 3 mm and not more than 4 mm in
width inside the surface reserved for the text of the warning.

Justification

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

Amendment 57

Proposal for a directive
Article 10 – paragraph 5

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22, to withdraw the exemption laid down in paragraph 1 if there is a substantial change of circumstances as established in a Commission report to Council and the European Parliament.</td>
</tr>
</tbody>
</table>

Amendment 58

Proposal for a directive
Article 11 – paragraphs 1 to 2

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>1. Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning: This tobacco product damages your health and is addictive</td>
</tr>
<tr>
<td>2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 10(4). In addition, it shall: (a) be printed on the two largest surfaces of the unit packet and any outside packaging; (b) cover 30% of the external area of the</td>
<td>(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</td>
</tr>
</tbody>
</table>
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.

corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with more than two official languages.

Amendment 59

Proposal for a directive
Article 11 – paragraph 3

_text proposed by the Commission_

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

_amendment_

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

Amendment 60

Proposal for a directive
Article 12 – paragraph 1

_text proposed by the Commission_

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

   (a) promotes a tobacco product by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;

   (b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive

_amendment_

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

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

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

health or lifestyle effects;
(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;
(d) resembles a food or a cosmetic product.
(da) aims to reduce the effect of some harmful components of smoke or increase the biodegradability of tobacco products

Amendment 61
Proposal for a directive
Article 12 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

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

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

Justification

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

Amendment 62
Proposal for a directive
Article 12 – paragraph 2 – subparagraph 1 b (new)

Text proposed by the Commission

The cigarette paper shall include watermarks.

Justification

This is a safeguard against counterfeiting.

Amendment 63

Proposal for a directive

Article 12 – paragraph 2 a (new)

Text proposed by the Commission

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

Amendment 64

Proposal for a directive

Article 13 – paragraph 1

Text proposed by the Commission

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

Amendment

1. A unit packet of cigarettes shall contain at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing at least 40 g.
Proposed for a directive  
Article 13 – paragraphs 1 a and 2

Text proposed by the Commission

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

Amendment

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

Proposal for a directive
Article 13 – paragraph 3

Text proposed by the Commission

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.

Amendment

deleted

Proposal for a directive
Article 14

Text proposed by the Commission

1. Member States shall ensure that all unit packets of tobacco products shall be marked with a unique identifier. In order to ensure their integrity, unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or by the opening of the packet. In relation to products manufactured outside the Union the obligations laid down in this Article apply only to those destined to or placed on the Union market.

2. The unique identifier shall allow determining:
(a) the date and place of manufacturing;
(c) the machine used to manufacture the products;
(d) the production shift or time of manufacture;
(e) the product name;
(f) the intended market of retail sale;
(g) the intended shipment route;
(h) where applicable, the importer into the Union;

Amendment

1. Member States shall ensure that all unit packets and any outside transport packaging of tobacco products shall be marked with a unique identifier. In order to ensure their integrity, unique identifiers shall be secure, irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or by the opening of the packet. In relation to products manufactured outside the Union the obligations laid down in this Article apply only to those destined to or placed on the Union market.

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

2. The unique identifier shall allow determining:
(a) the date and place of manufacturing;
(c) the machine used to manufacture the products;
(d) the production shift or time of manufacture;
(e) the product description;
(f) the intended market of retail sale;
(g) the intended and actual shipment route from the place of manufacturing to the first retail outlet, including all warehouses used, the shipment date, shipment destination, consignee and point of departure;
(h) where applicable, the importer into the Union;
(i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used;

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

(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit from their possession. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging, provided that tracking and tracing of unit packets remains possible.

4. Member States shall ensure that manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies with the necessary equipment allowing for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. The equipment shall be able to read and transmit the data electronically to a data storage facility pursuant to paragraph 6.

5. Recorded data cannot be modified or deleted by any economic operator involved in the trade of tobacco products, but the economic operator that introduced the data and other economic operators directly

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

(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit and outside packets into their possession, as well as all intermediate movements and the final exit from their possession, and transmit the data electronically to a data storage facility pursuant to paragraph 6. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging,

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

4. Member States shall ensure that manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies with the necessary equipment, as determined by those Member States, allowing for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. The equipment shall be able to read and transmit the data electronically to a data storage facility pursuant to paragraph 6.

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

6. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall be physically located on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be approved and monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. Member States shall ensure full transparency and accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party on a permanent basis. In duly justified cases Member States or the Commission can provide manufacturers or importers access to this information, provided commercially sensitive information remains adequately protected in conformity with the relevant national and Union legislations.

7. Member States shall ensure that personal
data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC.

8. In addition to the unique identifier, Member States shall require that all unit packets of tobacco products which are 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. In those Member States where tax stamps are applied on tobacco products and the tax stamps applied comply with the requirements of this paragraph, no additional security feature is required.

Amendment 68

Proposal for a directive
Article 16

Text proposed by the Commission

Chapter IV: Cross-border distance sales of tobacco products

Article 16

Cross-border distance sales of tobacco products

1. Member States shall oblige retail outlets intending to engage in cross-border distance sales to consumers located in the Union to register with the competent authorities in the Member State where the retail outlet is established and in the Member State where the actual or potential consumer is located. Retail outlets established outside the Union have to register with the competent authorities in the Member State where the actual or potential consumer is located. All retail

Amendment

Chapter IV: Promotional distribution and distance sales of tobacco products

Article 16

Distance sales of tobacco products

1. Member States shall prohibit retail outlets established on their territory from engaging in cross border distance sales.
outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities:

(a) name or corporate name and permanent address of the place of activity from where the tobacco products are 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 ©vices;

(c) the address of the website/-s used for that purpose and all relevant information necessary to identify the website.

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

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

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

2. Member States which have implemented a national anti-smoking strategy may set quantitative limits on cross-border movements.
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 69

Proposal for a directive
Article 16a (new)

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

Amendment 70

Proposal for a directive
Article 17

Text proposed by the Commission

Notification of novel tobacco products

1. Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco product they intend to place on the markets of the Member States concerned. The notification shall be submitted in electronic form six months before the intended placing on the market and shall be accompanied by a detailed description of the product in question as well as information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with:

(a) available scientific studies on toxicity, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions;
(b) available studies and market research on preferences of various consumer groups, including young people and

Amendment

Notification of novel tobacco products

1. Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco product they intend to place on the markets of the Member States concerned. The notification shall be submitted in electronic form six months before the intended placing on the market and shall be accompanied by a detailed description of the product in question as well as any proposed labelling, instructions for use, details of the product’s composition, the manufacturing process and associated controls and information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with:

(a) available scientific studies on toxicity, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions;
(b) working summaries of the available studies and market research on preferences of various consumer groups, including young people and chronic heavy smokers;
(c) other available and relevant information, including a risk/benefit analysis of the product, the expected effects on cessation of tobacco consumption, the expected effects on initiation of tobacco consumption and other predicted consumer perception.

2. 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.

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment 71

Proposal for a directive
Article 18

Text proposed by the Commission

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

Amendment

1. Nicotine-containing products may only be placed on the market if they are authorised pursuant to Directive 2001/83/EC, taking into account the well-established use of nicotine.
a) products with a nicotine level exceeding 2 mg per unit, or

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

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

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

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

Amendment 72

Proposal for a directive
Article 19

\[\text{Text proposed by the Commission}\]

Herbal products for smoking
1. Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning:
This product can damage your health
2. The health warning shall be printed on the front and back external surface of the unit packet and on any outside packaging.
3. The health warning shall comply with the requirements laid down in Article 10(4). It shall cover not less than 30 % of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

\[\text{Amendment}\]

Herbal products for smoking
1. Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning:
This product can damage your health
2. The health warning shall be printed on the front and back external surface of the unit packet and on any outside packaging.
3. The health warning shall comply with the requirements laid down in Article 10(4). It shall cover not less than 30 % of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with more than two official languages.

Amendment 73

Proposal for a directive
Article 19 a (new)

\[\text{Text proposed by the Commission}\]

\[\text{Amendment}\]

\[\text{Article 19a}\]

\[\text{Imitation tobacco products}\]

\[\text{Imitation tobacco products which appeal to minors and consequently form a potential gateway to using tobacco products shall be prohibited.}\]
Justification

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

Amendment 74

Proposal for a directive
Article 20 - Paragraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive.</td>
<td>3. Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive. Any financial penalties applicable to intentional infringements shall be such as to offset the economic advantage sought through the infringement.</td>
</tr>
</tbody>
</table>

Justification

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

Amendment 75

Proposal for a directive
Article 22

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. 2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4),</td>
<td>1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. 2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4),</td>
</tr>
</tbody>
</table>
6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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

6(10a), 8(4), 9(3), 10(5), 11(3), 13(4) and 14(9) shall be conferred on the Commission for a period of five years from [Office of Publications: please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of five-year period. The delegation of power shall be tacitly extended for periods of identical duration unless the European Parliament or Council opposes such an extension not later than three months before the end of each period.

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(10a), 8(4), 9(3), 10(5), 11(3), 13(4) and 14(9) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act pursuant to Articles 3(2), 3(3), 4(3), 4(4), 6(10a), 8(4), 9(3), 10(5), 11(3), 13(4) and 14(9) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.
**Amendment 76**  
Proposal for a directive  
Article 23 – paragraph 1 – subparagraph 1

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No later than <strong>five</strong> years from the date specified in Article 25 paragraph 1, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.</td>
<td>No later than <strong>three</strong> years from the date specified in Article 25 paragraph 1, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.</td>
</tr>
</tbody>
</table>

**Amendment 77**  
Proposal for a directive  
Article 23 – paragraph 2 – subparagraph 1 – point c a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(ca)</em> evaluation of the addictive effects of those ingredients which encourage addiction;</td>
<td></td>
</tr>
</tbody>
</table>

**Justification**

*Point reinstated from current Directive 2001/37/EC*

**Amendment 78**  
Proposal for a directive  
Article 23 – paragraph 2 – subparagraph 1 – point c b (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(cb)</em> development of standardised testing methods to measure the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide;</td>
<td></td>
</tr>
</tbody>
</table>
Justification

Point reinstated from current Directive 2001/37/EC

Amendment 79

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

Text proposed by the Commission

Amendment

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

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 80

Proposal for a directive
Article 23 – paragraph 2 – subparagraph 1 – point c d (new)

Text proposed by the Commission

Amendment

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

Amendment 81

Proposal for a directive
Article 23 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

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

Justification

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

Amendment 82

Proposal for a directive

Article 24

Text proposed by the Commission

1. Member States shall not prohibit or restrict the import, sale or consumption of tobacco or related products which comply with this Directive.

2. However, a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. Such national provisions shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved

Amendment

1. Subject to paragraphs 2 and 3, Member States shall not prohibit or restrict the import, sale or consumption of tobacco or related products which comply with this Directive.

2. However, a Member State may maintain or introduce more stringent national provisions in areas covered by the Directive, insofar as such measures are compatible with the Treaty. Such national provisions shall apply equally to all products, including those imported from another Member State or a third country. They shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary
through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved.

3. This Directive shall not affect the right of Member States to maintain or introduce, in accordance with the Treaty, national provisions concerning aspects not regulated by this Directive. These national provisions must be justified by overriding reasons of public interest and be necessary and proportionate to their aim. They must not be a means of arbitrary discrimination or a disguised restriction on trade between the Member States and must not jeopardise the full application of this Directive.

Amendment 83

Proposal for a directive

Article 25 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [Publications Office, please insert the exact date: entry into force + 18 months] and in the case of Article 6 by [Publications Office, please insert the exact date: entry into force + 36 months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

Justification

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

Amendment 84
Proposal for a directive
Article 26

Text proposed by the Commission

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

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

Amendment

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

(a) tobacco products;

(b) herbal products for smoking.

Member States may allow nicotine containing products which are not in compliance with this Directive to be placed on the market until [Publications Office, please insert the exact date: entry into force + 36 months]:

Amendment 85
Proposal for a directive
Annex -I (new)

Text proposed by the Commission

Annex -I
Additives approved for use in tobacco products

Chemical name of the additive - function - maximum level permitted
Amendment 86

Proposal for a directive
Annex I

Text proposed by the Commission

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of text warnings</td>
<td>List of text warnings</td>
</tr>
<tr>
<td>(referred to in Article 9 and Article 10(1))</td>
<td>(referred to in Article 9 and Article 10(1))</td>
</tr>
<tr>
<td>(1) Smoking causes 9 out of 10 lung cancers</td>
<td>(1) Smoking causes 9 out of 10 lung cancers</td>
</tr>
<tr>
<td>(2) Smoking causes mouth and throat cancer</td>
<td>(2) Smoking causes mouth and throat cancer</td>
</tr>
<tr>
<td>(3) Smoking damages your lungs</td>
<td>(3) Smoking damages your lungs</td>
</tr>
<tr>
<td>(4) Smoking causes heart attacks</td>
<td>(4) Smoking causes heart attacks</td>
</tr>
<tr>
<td>(5) Smoking causes strokes and disability</td>
<td>(5) Smoking causes strokes and disability</td>
</tr>
<tr>
<td>(6) Smoking clogs your arteries</td>
<td>(6) Smoking clogs your arteries</td>
</tr>
<tr>
<td>(7) Smoking increases the risk of blindness</td>
<td>(7) Smoking increases the risk of blindness</td>
</tr>
<tr>
<td>(8) Smoking damages your teeth and gums</td>
<td>(8) Smoking damages your teeth and gums</td>
</tr>
<tr>
<td>(9) Smoking can kill your unborn child</td>
<td>(9) Smoking can kill your unborn child</td>
</tr>
<tr>
<td>10) Your smoke harms your children, family and friends</td>
<td>10) Your smoke harms your children, family and friends</td>
</tr>
<tr>
<td>(11) Smokers’ children are more likely to start smoking</td>
<td>(11) Smokers’ children are more likely to start smoking</td>
</tr>
<tr>
<td>(12) Quit smoking – stay alive for those close to you</td>
<td>(12) Quit smoking – stay alive for those close to you</td>
</tr>
<tr>
<td>(13) Smoking reduces fertility</td>
<td>(13) Smoking reduces fertility</td>
</tr>
<tr>
<td>(14) Smoking increases the risk of impotence</td>
<td>(14) Smoking increases the risk of impotence</td>
</tr>
<tr>
<td>(14 a) Smoking can cause cot death</td>
<td></td>
</tr>
<tr>
<td>(14 b) Smoking during pregnancy causes premature birth</td>
<td></td>
</tr>
<tr>
<td>(14 c) Passive smoking can worsen asthma or meningitis in children.</td>
<td></td>
</tr>
</tbody>
</table>
EXPLANATORY STATEMENT

It is now almost twelve years since the EU adopted the current Tobacco Products Directive. This Directive introduced a range of tobacco control measures including:

- a prohibition on terms such as “mild” or “light” which could mislead smokers into believing that one product is less harmful than others
- maximum levels for tar, nicotine and carbon monoxide content (TNCO)
- reporting requirements on ingredients
- minimum sized health warnings on all tobacco products except smokeless tobacco products (STP) which must carry a general health warning
- a common set of pictorial warnings which Member States can opt to use on packages.

The current Directive was the subject of legal challenges by tobacco companies, but the courts upheld the validity of the Directive.

Smoking and health: the challenge of deterring young smokers

Twelve years on, smoking remains the leading cause of preventable death in the EU and kills around 700,000 people per year. Measures taken over the years to cut smoking have had an impact: in the past decade the number of smokers in the EU has fallen from nearly 40% in the EU 15 in 2002 to 28% in the EU 27 in 2012.

However, prevalence rates among young people (15-25) at 29% are higher than for the population as whole. We know that children, not adults, start smoking: 70% of smokers begin before their 18th birthday, many younger still. A recent WHO survey of smoking trends among 15 year olds reveals an even more worrying trend: whereas in the period 2001-2005 smoking trends were down in the overwhelming majority of countries, in the most recent period surveyed, 2005-2010, smoking prevalence for boys was up in 14 countries and up for girls in 9 countries. The European Commission is therefore right to focus much of its attention in the new draft TPD on measures which deter young people from smoking, such as tougher health warnings and bans on packages and flavourings which can be particularly attractive to young people.

The WHO Framework Convention on Tobacco Control – a new international environment

One key international development since the last TPD has been the adoption by the EU as a whole and all its Member States individually of the World Health Organisation (WHO) Framework Convention on Tobacco Control (FCTC). This legally binding Convention which came into force in 2005 has 176 signatories and obliges parties to reduce the demand for and supply of tobacco products and to protect tobacco control policies from the influence of industry. It proposes a range of measures including guidelines on minimum health warning size, mandatory picture warnings and restrictions on packaging which enhance the attractiveness of tobacco products. Different Member States have responded with their own
proposals to implement the FCTC: 14 Member States have a minimum pack size of 20 (AT, CZ, DK, EE, FI, FR, EL, IE, LU, LT, PL, PT, RO, ES), picture warnings are used in ten Member States (BE, RO, UK, LV, FR, MT, ES, DK, IE, HU), quit messages are mandatory in 4 Member States (BE, FR, NL, SI) and voluntary in nine others (AT, DK, DE, HU, IE, LV, PL, SE, UK). These emerging differences in regulation and the need to implement the FCTC have prompted Parliament and Council to call on the Commission to revise the current TPD Directive on several occasions.

The FCTC has led other third countries to tighten up their tobacco regulation. The case of Australia adopting fully standardised (“plain”) packaging in November 2011 – and winning its court case against the tobacco companies in August 2012 is well known. New Zealand has now said it will follow suit and the UK government is consulting on the measure at present. But many other countries are ahead of the EU in terms of tobacco control legislation. Sixty three countries require picture warnings. Brazil has banned all types of flavourings and other additives, as has Canada with an exception for menthol. The USA has banned all characterising flavours except menthol. Smoking rates in Brazil at just under 15% are half those of the EU average. The rates in Canada (17%) and the USA (18.9%) are also much below the EU.

Main changes proposed in the draft Directive

**Ingredients:** Key to the thinking behind the revision of the TPD is the idea that tobacco products should look and taste like tobacco. The proposal therefore bans all what are termed “characterising flavourings” in cigarettes, roll your own (RYO) and smokeless tobacco. Examples of flavourings include chocolate, fruit flavours and menthol. A ban is also placed on other additives such as vitamins which might give the impression that a product has a health benefit or is less harmful. The proposal does not ban additives seen as essential to production of tobacco and it exempts cigars, cigarillos, pipe tobacco and water pipes from the flavourings ban as long as these continue to be mainly used by older smokers. Your rapporteur supports all these measures but is concerned about recent trends in the use of water-pipes by young people and wants the Commission to monitor this carefully.

**Labelling and packaging:** The draft law introduces a requirement for combined picture and text warnings covering 75% front and back on all cigarettes and RYO packets. The Commission does not propose fully standardised packaging as in Australia, but does leave Member States free to introduce full standardisation in national law for those parts of the packet not regulated by the Directive. The proposal also prohibits a range of features which could mislead people about the products: slim cigarettes, descriptors such as natural, organic and misleading colours. A unit pack of cigarettes would contain a minimum of 20 cigarettes. These measures would ban lipstick/perfume style cigarettes packets. A minimum of 40g size is proposed in the case of RYO tobacco pouches. Your rapporteur supports all these measures but proposes to go further in the case of cigarettes and RYO by proposing a form of standardisation which removes overt branding from packaging. This does not go as far as the Australian law which has standardised packaging for all tobacco products since it covers only cigarettes and RYO, the products most used to initiate young smokers.

This chapter also includes a series of enhanced provisions on traceability and security to
tackle illegal trade in cigarettes. Measures include a unique identifier on each packet and a system to track and trace all cigarette sales. Your rapporteur supports all these measures and has added amendments to strengthen the anti-counterfeit security, and ensure that traceability on individual packets also feature on multipacks.

**Tobacco for Oral Use**
Restrictions on the sale of oral tobacco (snus) are maintained in the new law. Your rapporteur supports this position.

**Cross border distance sales of tobacco products**
Internet sales of tobacco products are a new phenomenon and therefore not covered by the existing TPD. There seems little incentive to establish legal internet sales of cigarettes because taxes must be paid by the seller in the country of sale. Buyers cannot benefit from tax differences. This leads the Commission to conclude in its Impact Assessment that “typically, tobacco products sold on the internet do not comply with the TPD (eg health warnings and ingredients).” In addition, there are problems with age verification systems and illegal internet advertising. The FCTC calls for a ban on tobacco internet sales and nine Member States already have a ban. The Commission therefore proposes a new regulatory framework, but your rapporteur believes a ban on this business activity would be the best and clearest policy option. Your rapporteur is also concerned at companies giving away free samples of cigarettes via the internet and other channels and proposes a ban on these activities.

**Novel tobacco products**
The Commission proposes a notification system for any novel tobacco to ensure that any new products comply fully with the Directive, but gives Member States the option of introducing a prior authorisation system. Your rapporteur believes that prior authorisation should be the rule for all novel tobacco products and has tabled amendments accordingly.

**E-cigarettes**
The existing TPD does not cover nicotine containing products, but their inclusion is now proposed in the scope of the new Directive. The main development since 2001 has been the introduction onto the market of electronic or “e” cigarettes which have a growing market. There is no common approach at EU level on the regulation of e-cigarettes. At present, only 2 Member States have specific laws, but in about half of Member States nicotine is considered a medicine by function so technically e cigarettes cannot be sold unless approved as a medicine- like other smoking cessation products. In other Member States there are no specific regulations, meaning e cigarettes are covered by the General Products Safety Directive. There were nine RAPEX alerts about problems with e-cigarettes last year. E-cigarettes not authorised as medicines cannot make claims that they help smoking cessation. The USA is currently developing its own laws on e cigarette regulation under tobacco control legislation.

The Commission proposes a twin track approach to the regulation of e-cigarettes and other NCP. Products with a nicotine content over a certain level – including most e-cigarettes currently on the market - would have to be authorised as medicines. Those below the threshold would be allowed on the market with health warnings.

Tobacco control experts’ views differ about e-cigarettes. There is a general consensus on the need for better regulation but questions arise on whether e-cigarettes are a useful replacement
product for existing smokers assisting with harm reduction or simply a way to allow smokers to stay smokers by getting nicotine in smoke free areas and/or are a gateway product to attract new users to nicotine addiction and potentially to tobacco. There are also concerns that e-cigarettes could renormalize smoking. Your rapporteur has requested a study from the Parliament’s services to look at the evidence on e-cigarettes and will make proposals in this area once the study is available and after consulting colleagues and experts.

**Herbal products for smoking**

These products are not covered by the current TPD and are subject to different regulatory regimes in different countries. Herbal cigarettes are often perceived as being harmless or certainly less harmful than tobacco. However, evidence shows their use is not without risk and so the Commission proposes a labelling system for these products which your Rapporteur supports.
ANNEX

Legislative footprint

As the European Parliament's Rapporteur on the Tobacco Products Directive, Linda McAvan met with, received, or heard from representatives from the following organisations:

### EU and National Regulatory Agencies

<table>
<thead>
<tr>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Commission DG SANCO and Commissioner Borg</td>
</tr>
<tr>
<td>Irish Health Minister and Irish Permanent Representation to the EU</td>
</tr>
<tr>
<td>Lithuanian Health Minister</td>
</tr>
<tr>
<td>Czech Agricultural Minister</td>
</tr>
<tr>
<td>UK Permanent Representation to the EU and the Department for Health and the UK</td>
</tr>
<tr>
<td>Medicines and Healthcare Products Regulatory Agency</td>
</tr>
<tr>
<td>Dutch Permanent Representation to the EU</td>
</tr>
<tr>
<td>World Health Organisation</td>
</tr>
<tr>
<td>United States Food and Drugs Agency</td>
</tr>
<tr>
<td>Honduran Mission to the European Union</td>
</tr>
<tr>
<td>Committee of the Regions Rapporteur on the Tobacco Products Directive,</td>
</tr>
<tr>
<td>accompanied by the Organización Interprofesional del Tabaco de España</td>
</tr>
</tbody>
</table>

### NGOs

<table>
<thead>
<tr>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoke Free Partnership and the European Heart Network</td>
</tr>
<tr>
<td>Hosted a joint meeting with the MEP Heart Group and the MEPs Against Cancer</td>
</tr>
<tr>
<td>Group ³</td>
</tr>
<tr>
<td>UK Cancer Research</td>
</tr>
<tr>
<td>British Heart Foundation</td>
</tr>
<tr>
<td>UK Centre for Tobacco Control Studies</td>
</tr>
<tr>
<td>UK Action on Smoking &amp; Health</td>
</tr>
<tr>
<td>Smokefree Yorkshire and the Humber</td>
</tr>
</tbody>
</table>

### Industry

<table>
<thead>
<tr>
<th>Organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open meeting with the tobacco industry and upstream and downstream suppliers ⁴⁵</td>
</tr>
<tr>
<td>Open meeting with the electronic cigarette industry⁶⁷</td>
</tr>
<tr>
<td>Association of the European Self-Medication Industry</td>
</tr>
</tbody>
</table>

---


19.6.2013

OPINION OF THE COMMITTEE ON INTERNATIONAL TRADE

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


Rapporteur: Metin Kazak

AMENDMENTS

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

Amendment 1

Proposal for a directive
Recital 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,

(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. Making it mandatory to list the dangerous or potentially dangerous ingredients would enable greater transparency for the general public in terms of the harmful effects and the composition of tobacco products to be
while ensuring that appropriate account is taken of the commercial and intellectual property rights of the manufacturers of tobacco products.

guaranteed, while ensuring that appropriate account is taken of the commercial and intellectual property rights of the manufacturers of tobacco products and fulfils the Union’s international obligations contained in the WTO treaties, the provisions on Technical Barriers to Trade (TBT) and agreements on Trade-Related Intellectual Property Rights (TRIPS).

Amendment 2

Proposal for a directive
Recital 15

*Text proposed by the Commission*

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

*Amendment*

(15) The likelihood of diverging regulation is further increased by concerns over tobacco products, including smokeless tobacco products, having a *non-tobacco dominant* flavour other than tobacco or *traditional flavours such as menthol*, which may facilitate uptake of tobacco consumption or affect consumption patterns.

Amendment 3

Proposal for a directive
Recital 18

*Text proposed by the Commission*

(18) Considering the Directive’s focus on

*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.

Amendment 4

Proposal for a directive
Recital 22

(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings are more effective than text-only warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.

Amendment

(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. It is essential to carry out an independent study beforehand, in order to establish whether 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 5

Proposal for a directive
Recital 23

(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.

In case the package creates a misleading impression that the cigarettes are less harmful, health warnings must be adapted accordingly. The Commission is asked to carry out a scientific study of the real influence of these products on tobacco consumption.

Amendment 6
Proposal for a directive
Recital 26

Text proposed by the Commission

(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets of tobacco products to be marked in a unique and secure way and

(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets and any outside packaging of tobacco products to be marked in a unique
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.

and secure way and their movements to be recorded so that these products can be tracked and traced in the Union and the illegal trafficking of tobacco and tobacco products can be combated, particularly along the external borders of the Union but also from non-EU countries; and so that their compliance with this Directive can be monitored and better enforced. In addition, provision should be made for the introduction of security features for individual authentication that will facilitate the verification of whether or not products are authentic. The EU and the Member States must take and must reinforce adequate steps to combat contraband and counterfeiting by improving checks of the product supply chain and imposing penalties on criminal networks.

Amendment 7
Proposal for a directive
Recital 30

Text proposed by the Commission

(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

Amendment

(30) Cross-border distance and Internet sales of tobacco products as well as free promotional or discounted distribution of tobacco products 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, and should therefore be prohibited, in line with the implementing Guidelines of the Framework Convention on Tobacco Control (FCTC), the EU is a party to. 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

Amendment 8

Proposal for a directive

Recital 31

Text proposed by the Commission

(31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 5 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

Amendment

(31) All tobacco products have the potential to cause mortality, morbidity and disability and their sale and consumption should be contained, in particular by means of education and prevention from taking up the habit of smoking. It is therefore important to monitor developments as regards new tobacco products, how they are produced and their sales channels. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 5 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

Amendment 9

Proposal for a directive

Recital 40
Text proposed by the Commission

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

Amendment

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

Justification

The EU should respect its international commitments agreed with its trade partners.

Amendment 10

Proposal for a directive
Recital 41

Text proposed by the Commission

(41) Member States should remain free to maintain or introduce national legislations applying to all products alike for aspects falling outside the scope of this Directive, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly, Member States could, for instance,

Amendment

(41) Member States should remain free to maintain or introduce national legislations applying to domestic and imported products alike, for aspects falling outside the scope of this Directive, provided they are compatible with the Treaty and with the WTO provisions, and do not jeopardise the full application of this Directive.
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.

Accordingly, Member States could, for instance, maintain or introduce provisions providing standardisation of packaging of tobacco products *other than cigarettes and roll your own*, provided that those provisions **do not affect the full application of this Directive and** are compatible with the Treaty. **They must also be compatible with WTO obligations, in particular those set out in the Agreement on Technical Barriers to Trade (TBT), agreements on Trade-Related Intellectual Property Rights (TRIPs), and commitments undertaken in compliance with bilateral trade and investment agreements, which usually contain exceptions applying to public health. These provisions must form an instrument which will complement the fight against the counterfeiting of products concerned by** this Directive. A prior notification is required for technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on Information Society services.

**Amendment 11**

**Proposal for a directive**

**Recital 41 a (new)**

---

**Text proposed by the Commission**

(41a) Accordingly, Member States shall supplement the legal provisions of this Directive with any measures to protect the health of European citizens. Member States which benefit substantially from taxes and duties on the production and sale of tobacco might, for example, be urged to use this revenue to finance prevention and information campaigns in
the media and targeting young people and schools.

Amendment 12
Proposal for a directive
Recital 43 a (new)

Text proposed by the Commission

Amendment

(43a) This Directive should not lead to deterioration in the living conditions of people whose livelihoods depend on tobacco growing in Europe and who often live in disadvantaged areas. Given that the aim of the Directive is solely to discourage consumption of tobacco products, any decisions concerning ingredients and additives should take due account of the possible socioeconomic repercussions for groups whose livelihoods depend on tobacco growing. The European tobacco growing sector should be protected because it accounts for only a very small proportion of consumption in the EU and, at the same time, contributes to the economic stability of certain European regions where the range of alternative crops is limited. A decrease in or an end to tobacco growing in the EU would have no impact on consumption levels, but would lead to an increase in imports from third countries and a reduction in quality standards.

Justification

The growing sector is the weakest link in the manufacture chain of tobacco and therefore is necessary to protect them from unnecessary and excessive regulation.

Amendment 13
Proposal for a directive
Article 1 – paragraph 1 – point d

RR\944712EN.doc
<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(d) cross-border distance sales of tobacco products;</td>
<td>(d) the prohibition of cross-border distance sales of tobacco products;</td>
</tr>
</tbody>
</table>

**Amendment 14**

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(fa) the requirement to implement a system, outside the control of the tobacco industry, for the tracking and tracing of tobacco products, in order to secure the supply chain and assist in the detection, prevention and punishment of illicit trade;</td>
<td></td>
</tr>
</tbody>
</table>

**Amendment 15**

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2a) ‘essential additive’ means an ingredient which is indispensable for the manufacturing of a tobacco products;</td>
<td></td>
</tr>
</tbody>
</table>

**Amendment 16**

Proposal for a directive  
Article 2 – paragraph 1 – point 4

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(4) ‘characterising flavour’ means a distinguishable aroma or taste other than tobacco, resulting from an additive or combination of additives, including but</td>
<td>(4) ‘characterising flavour’ means a distinctive fruity or confectionary-like taste resulting from a flavouring or combination of flavourings, observable</td>
</tr>
</tbody>
</table>
not limited to fruit, spice, herb, alcohol, candy, menthol or vanilla observable before or upon intended use of the tobacco product; before or upon intended use of the tobacco product. For the purpose of this definition, tobacco and menthol are not considered a fruity or confectionary-like taste;

Amendment 17
Proposal for a directive
Article 2 – paragraph 1 – point 6

Text proposed by the Commission

(6) ‘cigar’ means a roll of tobacco consumed via a combustion process and further defined in Article 4(1) of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco;

Amendment

(6) ‘cigar’ or ‘cigarillo’ means a roll of tobacco consumed via a combustion process including a small type of cigar with a diameter of up to 8 mm and further defined in Article 4(1) of Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco;

Amendment 18
Proposal for a directive
Article 2 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘cigarillo’ means a small type of cigar with a diameter of up to 8 mm;

Amendment

deleted

Amendment 19
Proposal for a directive
Article 2 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘flavouring’ means an additive that imparts aroma and/or taste;

Amendment

(13) ‘flavouring’ means an additive that imparts aroma and/or taste except for
**menthol**

**Justification**

Menthol is mainly consumed by adults of an advanced age and therefore its prohibition is not consistent with the main purpose of the Directive of preventing youth from taking up smoking. Banning menthol could be inconsistent with Article 2.2 TBT agreement as there should be fewer restrictive measures to trade rather than an outright prohibition.

### Amendment 20

**Proposal for a directive**  
Article 2 – paragraph 1 – point 18

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(18) ‘ingredient’ means an additive, <em>tobacco (leaves and other natural, processed or unprocessed parts of tobacco plants including expanded and reconstituted tobacco), as well as any substance</em> present in a finished tobacco product including paper, filter, inks, capsules and adhesives;</td>
<td>(18) ‘ingredient’ means any additive present in a finished tobacco product including paper, filter, inks, capsules and adhesives;</td>
</tr>
</tbody>
</table>

### Amendment 21

**Proposal for a directive**  
Article 2 – paragraph 1 – point 18 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(18a) ‘reconstituted tobacco’ is a product which results from the enhancement of different parts of the tobacco plant from threshing and the manufacture of tobacco products, whether used as a wrap for cigars and cigarillos either as sheets or individual strands as a component of the tobacco blend for cigarettes and other tobacco products.</td>
<td>(18a) ‘reconstituted tobacco’ is a product which results from the enhancement of different parts of the tobacco plant from threshing and the manufacture of tobacco products, whether used as a wrap for cigars and cigarillos either as sheets or individual strands as a component of the tobacco blend for cigarettes and other tobacco products.</td>
</tr>
</tbody>
</table>
Amendment 22

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

Text proposed by the Commission

(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;

Amendment

(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;

Amendment 23

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

Text proposed by the Commission

(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 equivalent prevalence studies;

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 20 % in the 10 Member States with the highest volume of sales, based on sales data transmitted in accordance with Article 5(4); or an increase of the prevalence level in the consumer group under 25 years of age by at least 5 percentage points in at least 10 Member States for the respective product category based on [this date will be set at the moment of adoption of the Directive] Eurobarometer report or equivalent prevalence studies;

Amendment 24

Proposal for a directive
Article 6 – paragraph 1 – subparagraph 1
Text proposed by the Commission

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

Amendment

Member States shall prohibit the placing on the market of tobacco products with *additives that create or release a flavour which is not predominantly that of tobacco or menthol*, in accordance with the provisions of paragraph 2.

Amendment 25

Proposal for a directive
Article 8 – paragraph 3

Text proposed by the Commission

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

Amendment

3. For cigarette packets the general warning and the information message shall be printed on the lateral sides of the unit packets. For roll-your-own tobacco the information message shall be printed on the surface that becomes visible when opening the unit packet. Both the general warning and the information message shall cover 50% of the surface on which they are printed.

Amendment 26

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

Text proposed by the Commission

1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The *combined health* warnings shall:

Amendment

1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings *ensuring the right of consumers to have access to sufficient and reliable information.* The
warnings shall:

Amendment 27
Proposal for a directive
Article 9 – paragraph 1 – point c

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

Amendment
(c) cover 50% of the external area of both the front and back surface of the unit packet and any outside packaging;

Amendment 28
Proposal for a directive
Article 9 – paragraph 1 – point e

Text proposed by the Commission
(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;

Amendment
(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;

Justification

Health warnings are equally informative at the top or at the bottom of the pack; the placement at the bottom does not interfere with the opening method and therefore can be considered as less trade restrictive (Article 2.2 of the TBT agreement).

Amendment 29
Proposal for a directive
Article 9 – paragraph 1 – point g

Text proposed by the Commission
(g) for unit packets of cigarettes, respect the following dimensions:
(i) height: not less than 64 mm;

Amendment
deleted
(ii) width: not less than 55 mm.

Amendment 30
Proposal for a directive
Article 10 – paragraph 1 – subparagraph 2

Text proposed by the Commission

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

Amendment

The general warning shall be printed or affixed by means of non-removable stickers on the most visible surface of the unit packet and any outside packaging. The text warnings listed in Annex I shall be rotated in such a way as to guarantee their regular appearance. These warnings shall appear on the other most visible surface of the unit packet and any outside packaging.

Justification

The use of non-removable stickers on cigars should remain, as producers use internationally standardised packs which are customised through country specific, non-removable health warning stickers in the last stage of the production process. Banning non-removable stickers would hamper international trade.

Amendment 31
Proposal for a directive
Article 10 – paragraph 4 – point a

Text proposed by the Commission

(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;

Amendment

(a) printed in black Helvetica bold type on a white background. The general warning could be shown using self-adhesive paper provided that they cannot be removed. In order to accommodate language requirements, Member States may determine the point size of the font, provided that the point size specified in their legislation is such as to occupy the greatest possible proportion of the area set aside for the text required;
Amendment 32  
Proposal for a directive  
Article 10 – paragraph 4 – point b

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) centred in the area in which they are required to <strong>be printed</strong>, parallel to the top edge of the unit packet and any outside packaging;</td>
<td>(b) centred in the area in which they are required to <strong>appear</strong>, parallel to the top edge of the unit packet and any outside packaging;</td>
</tr>
</tbody>
</table>

Amendment 33  
Proposal for a directive  
Article 12 – paragraph 1 – point c

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;</td>
<td>deleted</td>
</tr>
</tbody>
</table>

Justification

Consumers should not be deprived of information about the product but this information must not be misleading. Less trade-restrictive alternative measures (such as banning only misleading descriptors) make this measure inconsistent with Article 2.2 of the TBT Agreement.

Amendment 34  
Proposal for a directive  
Article 12 – paragraph 2

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Prohibited elements and features may include but are not limited to <strong>texts</strong>, symbols, names, <strong>trade marks</strong>, figurative or other signs, <strong>misleading colours</strong>, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and</td>
<td>2. Prohibited elements and features may include but are not limited to symbols, names, figurative or other signs, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves.</td>
</tr>
</tbody>
</table>
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.

Amendment 35

Proposal for a directive

Article 13

Text proposed by the Commission

Amendment

Article 13 deleted

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.

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.

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.

Justification

This Article contains proposals which are technical barriers to trade without being based on any scientific evidence about its effects on smoking initiation by young people. Moreover, the opening mechanism of a pack of cigarettes does not increase or decrease the tendency to smoke.

Amendment 36

Proposal for a directive
Article 14 – paragraph 1

Text proposed by the Commission

1. Member States shall ensure that all unit packets of tobacco products shall be marked with a unique identifier. In order to ensure their integrity, unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or by the opening of the packet. In relation to products manufactured outside the Union the obligations laid down in this Article apply only to those destined to or placed on the Union market.

Amendment

1. In order to enable effective monitoring and identification, Member States shall require that unique, secure and non-removable identification markings hereafter called unique identification markings, such as codes or stamps, form part of or are affixed to 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.
Amendment 37
Proposal for a directive
Article 14 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Member States shall ensure that the unique identifiers on the packets are linked to the unique identifiers on the outside packaging. Any change made to the link between unit packets and outside packaging must be entered into the database referred to in paragraph 6.

Amendment 38
Proposal for a directive
Article 14 – paragraph 2 – point e

Text proposed by the Commission

Amendment

(e) the product name;

(c) the product name and description;

Amendment 39
Proposal for a directive
Article 14 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) the intended shipment route;

(g) the intended shipment route, the shipment date, the point of departure, the shipment destination, the sender, the consignee and the addressee;

Amendment 40
Proposal for a directive
Article 14 – paragraph 3
Text proposed by the Commission

3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit from their possession. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging, provided that tracking and tracing of unit packets remains possible.

Amendment

3. Member States shall require that track and trace technology capable of reading and transmitting data electronically to the storage facility pursuant to paragraph 6, the ownership for which is outside the control of tobacco manufacturers and their partners in the supply chain, is made available to 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. Such economic operators shall 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. In conformity with Article 14(1), this obligation shall be fulfilled by recording in aggregated form, e.g. of outside packaging, provided that tracking and tracing of unit packets remains possible.

Justification

The amendment aims to clarify that the track and trace obligation falls upon Member States and cannot be performed by or delegated to the tobacco industry. Otherwise the proposed draft, if implemented, would result in the opposite.

Amendment 41

Proposal for a directive
Article 14 – paragraph 3 a (new)

Text proposed by the Commission

3a. Member States shall ensure, in accordance with the Seoul Protocol to Eliminate Illicit Trade in Tobacco Products, that the technology used for tracking and tracing should belong to economic entities without any legal or
commercial link to the tobacco industry in the supply chain.

Amendment 42
Proposal for a directive
Article 14 – paragraph 6

Text proposed by the Commission

6. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall be physically located on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be 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.

Amendment

6. Member States shall conclude data storage contracts with a third party, which may be an agency of the Member State, and which is legally independent from the tobacco companies or their partners in the supply chain, 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. Member States shall ensure full transparency. 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 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 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.
Amendment 43

Proposal for a directive
Title 2 – chapter 3 – title

*Text proposed by the Commission*  
Amendment  

*Tobacco for oral use*  
Smokeless tobacco products

Amendment 44

Proposal for a directive
Article 15 – paragraph 1

*Text proposed by the Commission*  
Amendment

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

Justification

The EU ban on oral tobacco products is inconsistent with Article 2.2 of the WTO Agreement on Technical Barriers to Trade (TBT), since it is more trade restrictive than necessary to achieve the EU’s stated health objectives. The proposal unjustifiably discriminates between like products of different WTO Members [Articles I and III of the GATT Agreement and Article 2.1 of the TBT Agreement] and prohibits products that are less harmful than all other tobacco products allowed to be placed on sale in Europe.

Amendment 45

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

*Text proposed by the Commission*  
Amendment

1. Member States shall *oblige retail outlets intending to engage in* cross-border distance sales to consumers located in the Union to register with the competent authorities in the Member State where the retail outlet is established and in the  
1. Member States shall *prohibit* cross-border distance sales of tobacco products to consumers located in the Union as well as distribution of free or discounted tobacco products including through cross-border distance sales.
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:

Amendment 46

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

Text proposed by the Commission

Amendment

(a) name or corporate name and permanent address of the place of activity from where the tobacco products are supplied;

Amendment 47

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

Text proposed by the Commission

Amendment

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

Amendment 48

Proposal for a directive
Article 16 – paragraph 1 – point c
(c) the address of the website/-s used for that purpose and all relevant information necessary to identify the website.

Amendment 49

Proposal for a directive
Article 16 – paragraph 1 b (new)

Text proposed by the Commission

1b. It shall continue to be possible for Member States, on grounds of overriding needs relating to the protection of public health, to impose restrictions on imports of tobacco for personal use. Such restrictions shall be possible, in particular, where there is a significant difference of price between products of different geographic origins or if the health warnings are not in the official language(s) of the country where the product is purchased.

Amendment 50

Proposal for a directive
Article 16 – paragraph 1 c (new)

Text proposed by the Commission

1c. Member States shall prohibit retail outlets established on their territory from distributing free or discounted tobacco products through cross-border distance channels or through any other channel.
Amendment 51

Proposal for a directive
Article 16 – paragraph 2

Text proposed by the Commission

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.

Amendment 52

Proposal for a directive
Article 16 – paragraph 3

Text proposed by the Commission

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.

Amendment 53

Proposal for a directive
Article 16 – paragraph 4

Text proposed by the Commission

4. Retail outlets engaged in distance sales deleted
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.

Amendment 54

Proposal for a directive
Article 16 – paragraph 5

Text proposed by the Commission

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

5. deleted

Amendment 55

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

Text proposed by the Commission

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

Amendment

1. If nicotine containing products are presented as having properties for treating or preventing disease they may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:
**Justification**

Nicotine containing products such as electronic cigarettes make no claims to improve human health and should not be classified as medicinal products. Such a classification would limit their availability on the market, while more harmful tobacco products remain freely available, therefore unnecessarily restricting international trade.

**Amendment 56**

**Proposal for a directive**

**Article 24 – paragraph 2**

**Text proposed by the Commission**

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.

**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, compliant with this Directive, with the Treaty and the EU's international obligations, including WTO obligation, particularly in relation to the agreement on technical barriers to trade (TBT) and the Agreement on Trade - Related Aspects of International Property Rights (TRIPs)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.

*Justification*

*The EU has to take into account its international obligations when proposing legislation.*

**Amendment 57**

**Proposal for a directive**

**Article 26 – paragraph 1 – introductory part**

**Text proposed by the Commission**

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]:

<table>
<thead>
<tr>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 + 42 months]:</td>
</tr>
</tbody>
</table>
SHORT JUSTIFICATION

The purpose of the present proposal for a directive is to update Directive 2001/37/EC to take account of the developments in science and the market observed over the ten years since its adoption. The Commission’s proposal also responds to a number of demands made by Parliament in various resolutions adopted in 2007, 2009 and 2011, and reflects the spirit of the WHO Framework Convention on Tobacco Control which came into force in 2005, which includes among its aims the provision to consumers of appropriate information about the dangers of smoking.

The new directive sets out to ensure a higher standard of health protection and reduce tobacco use among young people. To achieve those objectives, a number of measures are proposed in relation to packaging (requiring 75% of the front and back of each packet to be taken up by a health warning), ingredients (banning products containing flavourings such as menthol), product size (banning slim cigarettes) and traceability. These measures would not apply to cigars and pipe tobacco, which would continue to be covered by the existing directive.

Your rapporteur fully endorses the public health protection objectives set out in this proposal. He also stresses that those objectives should be pursued in full compliance with the European Union’s international trade commitments and, in particular, the Agreements on Technical Barriers to Trade (TBT) and Trade-Related Aspects of International Property Rights (TRIPs). Your rapporteur believes that, if necessary, it would be appropriate to consult the Union’s partners in the TBT and TRIPs committees set up for that purpose.

On 6 and 7 March 2013, the members of the (WTO) Technical Barriers to Trade committee did in fact hold an exchange of views on the Commission’s proposal. On that occasion, tobacco-growing members of the committee expressed reservations about the proposal – which, they stated, might conflict with certain obligations under WTO, TRIPs and GATT agreements – and questioned the proportionality of the proposed measures.

The Dominican Republic – which exports 10% of its tobacco production to the European Union – believed that some provisions of the proposal for a directive contravened Article 2.2 of the WTO agreement, which stipulates that ‘technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create’, and states that such risks should be assessed on the basis of ‘scientific (...) information’.

Furthermore, provisions concerning the use of plain packaging, which does not carry a logo or any visual indication of the brand concerned, raise a number of questions regarding their compatibility with the agreements on intellectual property and trademark protection.

---

8 The members which expressed reservations were: the Dominican Republic, Nicaragua, Indonesia, Malawi, the Philippines, Honduras, Mexico, Cuba and Zambia. On the other hand, the Union was supported by Norway, Australia and New Zealand.

9 The provisions cited in the Dominican Republic document included, inter alia, the standardisation of packets, the prohibition of descriptive elements, the prohibition of slim cigarettes, mandatory plain packaging and the prohibition of aromatic ingredients.
Some countries have already introduced very strict legislation on packaging. Australia, for example, recently adopted a law making the use of plain packaging mandatory, in the hope of discouraging tobacco use by making cigarette packets less attractive and increasing the impact of health warnings.\(^{10}\)

However, Australia has already been the subject of four complaints to the WTO’s dispute settlement body.\(^ {11}\) The complainants argue that the measures taken by Australia are incompatible with a number of rules, including Article 20 of the TRIPs Agreement, which states that: ‘The use of a trademark (...) shall not be unjustifiably encumbered by special requirements, such as (...) use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings’.

In addition to the complaints brought before the WTO, the tobacco industry\(^ {12}\) has filed complaints, under the international arbitration system for investment protection, against the Australian authorities and also Uruguay, which has introduced restrictive measures on cigarette packaging.

Although your rapporteur recognises the interest, on public health grounds, of covering a significant area of every cigarette packet with a health warning, he considers that it might be useful and appropriate to allow a visual indication of the brand’s identity to be displayed in the remaining space. Moreover, introducing standard packaging without any logo or visible brand identification could increase the risk of counterfeiting, which would result in a decline in Member States’ tax revenues and increased consumption of counterfeit – and, therefore, even more dangerous – products.

Although the Commission does not specifically require the use of plain packaging, it is somewhat vague on the subject; for example, it allows Member States to introduce stricter rules concerning packets’ appearance. Moreover, in Article 12 it introduces a prohibition on ‘elements’ which ‘may include (...) texts, symbols, names, trade marks, figurative or other signs’: in other words, all the features which constitute a brand’s visual identity.

The rapporteur wishes to stress, however, that he regards the Commission proposal as a whole as relatively balanced. With regard to the details of the proposal, your rapporteur prefers to wait to hear the various opinions which will be expressed in the Committee on International Trade before making any further recommendations.

---

\(^{10}\) The Tobacco Plain Packaging Act, which was adopted by the Australian Parliament in 2011 and entered into force in December 2012.

\(^{11}\) Complaints by Ukraine (March 2012), Honduras (April 2012), the Dominican Republic (July 2012) and Cuba (May 2013).

\(^{12}\) In particular, Philip Morris International.
### PROCUREMENT

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>References</strong></td>
<td>COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)</td>
</tr>
<tr>
<td><strong>Committee responsible</strong></td>
<td>ENVI 15.1.2013</td>
</tr>
<tr>
<td><strong>Opinion by</strong></td>
<td>INTA 18.4.2013</td>
</tr>
<tr>
<td><strong>Rapporteur</strong></td>
<td>Metin Kazak 25.4.2013</td>
</tr>
<tr>
<td><strong>Discussed in committee</strong></td>
<td>27.5.2013</td>
</tr>
<tr>
<td><strong>Date adopted</strong></td>
<td>18.6.2013</td>
</tr>
</tbody>
</table>
| **Result of final vote** | +: 15  
-: 12  
0: 0 |
| **Members present for the final vote** | Maria Badia i Cutchet, David Campbell Bannerman, María Auxiliadora Correa Zamora, Christofer Fjellner, Yannick Jadot, Metin Kazak, Franziska Keller, Bernd Lange, David Martin, Vital Moreira, Paul Murphy, Cristiano Muscardini, Helmut Scholz, Peter Šťastný, Robert Sturdy, Henri Weber, Iuliu Winkler, Pawel Zalewski |
| **Substitute(s) present for the final vote** | Josef Andrés Barea, Catherine Bearder, Albert Deß, Elisabeth Köstinger, Mario Pirillo, Miloslav Ransdorf, Peter Skinner, Jarosław Leszek Wałęsa |
| **Substitute(s) under Rule 187(2) present for the final vote** | Salvador Garriga Polledo, Paul Rübig |
8.7.2013

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

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


Rapporteur: Robert Goebbels

SHORT JUSTIFICATION

The adverse effects of smoking on human health are undeniable. Tobacco may be the main risk factor for cancer. The cardiovascular toxicity of nicotine is established. According to the WHO, smoking causes five million premature deaths worldwide every year. The Commission talks of 700 000 early deaths every year in the EU alone. In 1999 the Commission put the number of smoking victims at 500 000 a year.

More than 10 years after the last Community rules on the sale of tobacco products were introduced, there has been no radical reduction in consumption. According to an EP library note, 576 billion cigarettes were consumed in the EU in 2012, which represents a drop in consumption of 100 billion over five years. Despite the near-universal ban on smoking in public places, tobacco consumption among young people and women in particular is on the rise. While fewer than 30% of Europeans remain addicted to smoking, in the 18-35 age group the figure is nearly 50%. And worse still, some 37% of adolescents aged 11 to 15 use tobacco products. Are they attracted by it being illegal?

For reasons of public health, international and national authorities are stepping up the fight against smoking. Yet nowhere is a ban on tobacco consumption being considered because that would immediately result in a huge illegal market, which would be good news for organised crime, already heavily invested in smuggling and counterfeiting.

The tobacco market is a significant sector of the economy, with nearly 50 000 jobs in production and more than 200 000 in distribution. Although European agriculture meets only 5% of the EU’s raw tobacco needs, tobacco is a source of income for nearly 90 000 farmers. The above-mentioned EP study estimates the total value of the European tobacco market in 2012 at some EUR 136.5 billion, including excise duties and tax revenues of around EUR 79 billion for the Member States, which in a way are the main beneficiaries of smoking.

In this context the question arises as to the conflict between individual freedom and social responsibility. The Commission seems to acknowledge the right of adults to smoke cigars,
cigarillos and pipe tobacco, which are subject to less strict rules than cigarettes and rolling
 tobacco, products considered to be more attractive to young people. Since the 16th century
 and Paracelsus we know that ‘everything is poison’ and that ‘only the dose makes a thing not
 a poison’. Given that all men are mortal, the dominant philosophy is that of the least risk.
 Hence the proliferation of warnings against alcohol consumption, sweets, salt, meat, industrial
 products and junk food. At the same time life expectancy is increasing throughout the EU,
 where the ultimate goal in society seems to be to die one day in good health!

 Nevertheless, the need to protect non-smokers – and your rapporteur is among those who have
 never smoked – calls for strong action to be taken by the authorities against passive smoking,
 and a policy providing effective means of quitting smoking. Prevention of smoking,
 particularly among young people, remains the priority.

 The Commission proposal seeks to tackle the appeal of smoking by multiplying and extending
 health warnings on packaging at the same time as standardising them. However, the
 Commission has not succeeded in demonstrating how the standardisation of tobacco products
 could bring about a decline in consumption, particularly among young people. Would it not
 be the case that such a blanket standardisation would play into the hands of the four major
 groups who together control 90% of the European market?

 The draft directive contains 16 articles giving the Commission the power to adopt delegated
 acts affecting, in many cases, key elements of the legislation. That seems excessive. The
 Commission intends to publish within the next five years a report on the implementation of
 the new directive, ‘accompanied by any proposals for amendments’ deemed necessary. That
 report, and the proposed amendments could be brought forward, thus avoiding a constant
 reshaping of the directive through a multiplicity of delegated acts, which are often at the limit
 of European law.

 AMENDMENTS

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

 Amendment 1
 Proposal for a directive
 Recital 6

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(6) The size of the internal market in tobacco and related products,</td>
<td>(6) The size of the internal market in</td>
</tr>
<tr>
<td>the increasing tendency of manufacturers of tobacco products to</td>
<td>tobacco and related products, the</td>
</tr>
<tr>
<td>concentrate production</td>
<td>increasing tendency of manufacturers of</td>
</tr>
<tr>
<td></td>
<td>tobacco products to concentrate production</td>
</tr>
</tbody>
</table>

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

Amendment 2

Proposal for a directive
Recital 8

Text proposed by the Commission

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (hereinafter: "Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people.

Amendment

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (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. Smoking is a current and global problem with devastating consequences, and adolescence is when most smokers start consuming tobacco.

Amendment 3

Proposal for a directive
Recital 11

Text proposed by the Commission

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

Amendment

deleted
their toxicity or addictiveness.

Amendment 4
Proposal for a directive
Recital 15

Text proposed by the Commission

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

Amendment

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

Amendment 5
Proposal for a directive
Recital 16

Text proposed by the Commission

(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufactures to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives necessary for manufacturing of tobacco products should be allowed, as long as they do not result in a

Amendment

(16) The use of additives necessary for manufacturing of tobacco products should be allowed. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.
characterising flavour. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.

Justification

Why seek to limit the choices of adult, informed consumers?

Amendment 6

Proposal for a directive
Recital 18

Text proposed by the Commission

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

Amendment

(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco and tobacco for oral use, which are mainly consumed by older consumers, should be granted an exemption from certain ingredients requirements. The Commission should carefully monitor the use of waterpipe tobacco by young people as there is increasing evidence of its use beyond the traditional, older market.

Justification

Consumption of traditional nasal and chewing tobacco is confined to very few regions of Europe and is an element in the maintenance of traditions. Moreover, nasal and chewing tobacco are mainly consumed by older persons. The same exemption should therefore apply as to cigars, cigarillos and pipe tobacco.

Amendment 7

Proposal for a directive
Recital 19
Text proposed by the Commission

(19) Disparities still exist between national provisions regarding the labelling of tobacco products, in particular with regard to the use of combined health warnings consisting of a picture and a text, information on cessation services and promotional elements in and on packets.

Amendment

(19) Disparities still exist between national provisions regarding the labelling of tobacco products, in particular with regard to the size of health warnings, information on cessation services and promotional elements in and on packets.

Amendment 8
Proposal for a directive
Recital 20

Text proposed by the Commission

(20) Such disparities are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated. Also, consumers in some Member States may be better informed about the health risks of tobacco products than in others. Without further action at Union level, the existing disparities are likely to increase in the coming years.

Amendment

(20) Such disparities are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated. Also, consumers in some Member States may be better informed about the health risks of tobacco products than in others. Without further harmonising action at Union level, the existing disparities are likely to increase in the coming years.

Amendment 9
Proposal for a directive
Recital 23

Text proposed by the Commission

(23) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimension of the warnings as well as regarding certain aspects of the appearance of the tobacco package, including the opening mechanism. The package and the products may mislead consumers, in particular young people,

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.

Amendment 10

Proposal for a directive
Recital 25

**Text proposed by the Commission**

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

**Amendment**

deleted

Amendment 11

Proposal for a directive
Recital 29

**Text proposed by the Commission**


**Amendment**

prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden derogation from this prohibition. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction to the internal market of a product that is addictive, has adverse health effects and is attractive to young people. For other smokeless tobacco products that are not produced for the mass market, a strict labelling and ingredients regulation is considered sufficient to contain market expansion beyond their traditional use.

Amendment 12

Proposal for a directive

Recital 31

Text proposed by the Commission

(31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 5 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

Amendment

(31) All tobacco products have the potential to cause mortality, morbidity and disability and their manufacture, distribution and consumption should be regulated. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 3 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

Amendment 13
Proposal for a directive  
Recital 34  

Text proposed by the Commission

(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. **A significant number of nicotine-containing** products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

Amendment

(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products. Nicotine containing products other than the tobacco containing products covered by this Directive should be regulated either under the upcoming review of the pharmaceutical package or by virtue of a specific legal instrument, once the studies currently under way have reached valid conclusions. Such an instrument may include provisions allowing the placing on the market of lower-risk nicotine containing products which can help consumers to quit smoking, provided they feature an appropriate health warning.

Amendment 14  

Proposal for a directive  
Recital 35  

Text proposed by the Commission

(35) Labelling provisions should be introduced for nicotine containing products below the threshold set out in this Directive drawing the attention of

Amendment

deleted
consumers to potential health risks.

Amendment 15
Proposal for a directive
Recital 37

Text proposed by the Commission

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

Amendment

deleted

Amendment 16
Proposal for a directive
Recital 38

Text proposed by the Commission

(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission for non-essential elements of the Directive. 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. In order to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the
certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Amendment 17
Proposal for a directive
Recital 39

Text proposed by the Commission

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

Amendment
deleted

Amendment 18
Proposal for a directive
Recital 39 a (new)

Text proposed by the Commission

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

Amendment 19
Proposal for a directive
Recital 40

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(40)</strong> <em>A Member State that deems it necessary to maintain more stringent national provisions for aspects falling inside the scope of this Directive should be allowed to do so, for all products alike, on grounds of overriding needs relating to the protection of public health. A Member State should also be allowed to introduce more stringent provisions, applying to all products alike, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health.</em> More stringent national provisions should be necessary and proportionate, not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Stricter national provisions require prior notification to, and approval from, the Commission taking into account the high level of health protection achieved through this Directive.</td>
<td></td>
</tr>
<tr>
<td><strong>(40)</strong> <em>This Directive intends to harmonise the specific rules for the manufacture, presentation and sale of tobacco products and related products, thereby ensuring that individual Member States do not introduce national legislative provisions relating to labelling and packaging requirements that go further than the Directive. If a Member State already has more stringent national provisions applying to all products alike on aspects that fall within the scope of this Directive, it should be allowed to apply these on the basis of overriding requirements relating to the protection of public health. These national provisions should, however, be necessary and proportionate, and not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Stricter national provisions require prior notification to, and approval from, the Commission taking into account the high level of health protection achieved through this Directive.</em></td>
<td></td>
</tr>
</tbody>
</table>
(41) Member States should remain free to maintain or introduce national legislations applying to all products alike for aspects falling outside the scope of this Directive, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly, Member States could, for instance, maintain or introduce provisions providing standardisation of packaging of tobacco products provided that those provisions are compatible with the Treaty, with WTO obligations and do not affect the full application of this Directive. A prior notification is required for technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on Information Society services.

Amendment 21

Proposal for a directive
Recital 42

(41) Member States should be able to adapt 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 should not prohibit or restrict the import, sale or consumption of such products.

Text proposed by the Commission

(42) Member States should ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Amendment

(42) Member States should ensure that personal data are only processed in accordance with the rules and safeguards laid down in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. National data protection provisions should also be taken into account.
Amendment 22
Proposal for a directive
Article 2 – paragraph 1 – point 2

Text proposed by the Commission

(2) 'additive' means substance contained in a tobacco product, its unit packet or any outside packaging with the exception of tobacco leaves and other natural or unprocessed parts of tobacco plants;

Amendment

(2) ‘additive’ means substance contained in a tobacco product with the exception of tobacco leaves and other natural or unprocessed parts of tobacco plants;

Amendment 23
Proposal for a directive
Article 2 – paragraph 1 – point 4

Text proposed by the Commission

(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;

Amendment

(4) 'characterising flavour' means a distinguishable aroma or taste other than tobacco, resulting from an additive or combination of additives, with the exception of menthol, including but not limited to fruit, spice, herb, alcohol, candy, or vanilla observable before or upon intended use of the tobacco product;

Amendment 24
Proposal for a directive
Article 2 – paragraph 1 – point 18

Text proposed by the Commission

(18) 'ingredient' means an additive, tobacco (leaves and other natural, processed or unprocessed parts of tobacco plants including expanded and reconstituted tobacco), as well as any substance present in a finished tobacco product including paper, filter, inks, capsules and adhesives;

Amendment

(18) ‘ingredient’ means any additive present in a finished tobacco product including paper, filter, inks, capsules and adhesives;
Amendment 25

Proposal for a directive
Article 2 – paragraph 1 – point 23 a (new)

Text proposed by the Commission

(23a) "tobacco products with lower risk" means a tobacco product that is designed and marketed to reduce the risks of smoking compared to conventional tobacco products, especially cigarettes, which is placed on the market after the entry into force of this Directive.

Amendment

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

Text proposed by the Commission

(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 equivalent prevalence studies;

deleted

Justification

In many Member States, exceptional circumstances, such as a 10% rise in sales, can occur very quickly, as consumption of cigars and pipe tobacco is very low there.
### Amendment 27

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(36a) &quot;reconstituted tobacco&quot; means the result of enhancement of different parts of the tobacco plant from threshing and the manufacture of tobacco products, whether used as a wrap for cigars and cigarillos either as sheets or individual strands as a component of the tobacco blend for cigarettes and other tobacco products.</td>
<td></td>
</tr>
</tbody>
</table>

**Justification**  
The Directive must take into consideration and define precisely all tobacco products and existing reconstitution techniques in order to implement identical rules across the internal market.

### Amendment 28

**Proposal for a directive**  
**Article 3 – paragraph 1 – introductory part**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The yield of cigarettes placed on the market or manufactured in the Member States shall not be greater than:</td>
<td></td>
</tr>
<tr>
<td>1. The yield of cigarettes placed on the market in the Member States shall not be greater than:</td>
<td></td>
</tr>
</tbody>
</table>

### Amendment 29

**Proposal for a directive**  
**Article 3 – paragraph 2**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the maximum yields</td>
<td></td>
</tr>
<tr>
<td>deleted</td>
<td></td>
</tr>
</tbody>
</table>

PE508.085v05-00  
130/320  
RR\944712EN.doc
laid down in paragraph 1, taking into account scientific development and internationally agreed standards.

Amendment 30

Proposal for a directive
Article 3 – paragraph 3

Text proposed by the Commission

Amendment

3. Member States shall notify the Commission of the maximum yields that they set for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. Taking into account internationally agreed standards, where available, and based on scientific evidence and on the yields notified by Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes that increase in an appreciable manner the toxic or addictive effect of tobacco products beyond the threshold of toxicity and addictiveness stemming from the yields of tar, nicotine and carbon monoxide fixed in paragraph 1.

Justification

Under Article 290(1) TFEU, recourse to delegated acts can only be justified in respect of non-essential elements of the directive.

Amendment 31

Proposal for a directive
Article 4 – paragraph 3
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.

Amendment 32

Proposal for a directive
Article 4 – paragraph 4

4. Member States shall notify the Commission of the methods of measurement that they use for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. Based on these methods, and taking into account scientific and technical developments as well as internationally agreed standards the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt methods of measurement.

Amendment 33

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

Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco

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.

Justification

*Clarification with the aim not to oblige manufacturers to perform costly test for emissions of parts of the products that under intended use conditions do not get burned as e.g. the filter of cigarettes.*

Amendment 34

Proposal for a directive
Article 5 – paragraph 2

*Text proposed by the Commission*

2. Member States shall ensure the dissemination of information submitted in accordance with paragraph 1 on a dedicated website, which is available to the general public. In doing so Member States shall take due account of the need to protect information which constitutes a trade secret.

*Amendment*

2. Member States shall ensure the dissemination of information submitted in accordance with paragraph 1 on a website, which is available to the general public. In doing so Member States shall take due account of the need to protect information which constitutes a trade secret.

Justification

*This amendment provides clarification that a publicly available website is sufficient for the purpose; there is no need for Member States to construct an entirely new website.*

Amendment 35

Proposal for a directive
Article 6
**Text proposed by the Commission**

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

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

Member States shall notify the Commission of measures taken pursuant to this paragraph.

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

The Commission shall adopt by means of implementing acts uniform rules on the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

3. In case the experience gained in the application of paragraphs 1 and 2 shows that a certain additive or a combination thereof typically impart a characterising flavour when it exceeds a certain level of presence or concentration the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to set maximum levels for those additives or combination of additives that

**Amendment**

1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour where it is scientifically proven that the additive concerned increases the product's harmful, toxic or addictive effect in an appreciable manner.

Member States shall not **restrict or** prohibit the use of additives which are essential for the manufacture of tobacco products.

Member States shall notify the Commission of measures taken pursuant to this paragraph.
cause the characterising flavour.

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

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

(c) additives having colouring properties for emissions.

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

6. Member States shall ensure that provisions or conditions set out under Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.

7. Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product.

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

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

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

(c) additives having colouring properties for emissions.

5. Member States shall prohibit the use of flavourings in the components of tobacco products such as filters, papers, packages, capsules or any technical features allowing modification of flavour or smoke intensity where these increase in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product. Filters and capsules shall not contain tobacco.

6. Member States shall ensure that provisions or conditions set out under Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.

7. Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product.

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.

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

Amendment 36

Proposal for a directive
Article 7 – paragraph 3

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

Justification

Health warnings on cigarette packages are already printed on packages. However, on cigar packages and other niche products, a printing on the packaging would pose a disproportionate burden on producers, which are often small and medium sized companies. There have not been any reports on health warning stickers having been removed from
packages. Therefore, the added value of printing on the packages is not evident.

**Amendment 37**  
**Proposal for a directive**  
**Article 8—paragraph 3**

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

**Amendment 38**  
**Proposal for a directive**  
**Article 8 – paragraph 4**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
</table>
| 4. The Commission shall be empowered to adopt delegated acts in accordance with Article 22:  
(a) to adapt the wording of the health warnings laid down in paragraphs 1 and 2 to scientific and market developments;  
(b) to define the position, format, layout and design of the health warnings laid down in this Article, including their font type and background colour. | deleted |

**Amendment 39**  
**Proposal for a directive**  
**Article 9 – paragraph 1 – point c**
Amendment 40

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c) cover 75 % of the external area of both the front and back surface of the unit packet and any outside packaging;</td>
<td>(c) cover 50 % of the external area of both the front and back surface of the unit packet and any outside packaging <em>with 50 % of that area providing information on smoking cessation</em>;</td>
</tr>
</tbody>
</table>

Justification

Requiring the health warnings to appear at the top edge of the unit packet and any outside packaging would make it very difficult for shopkeepers to distinguish between different manufacturers’ brands, in view of the design of news agents’ shops (and mini-supermarkets). In order to replace shop furniture, shopkeepers, whose margins are already shrinking, would have to make substantial investments. Moreover, research shows that news agents are very financially dependent on tobacco sales.

Amendment 41

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>e) be positioned <em>at the top edge of the unit packet and any outside packaging, and</em> in the same direction as any other information appearing on the packaging;</td>
<td>e) be positioned in the same direction as any other information appearing on the packaging;</td>
</tr>
</tbody>
</table>

Justification

It is not the form of packaging which creates the dependence. In an effort to ‘harmonise’ the dimensions and shape of tobacco product packaging, the Commission will end up creating a
standardised ‘market’ from which small producers will be eliminated, ultimately benefiting the four major groups that already have a 90% share of the European market.

**Amendment 42**

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(ga) for the packaging of roll-your-own tobacco and for tobacco packagings with a surface larger than 75 cm² in area, occupy at least 22.5 cm² of the surface. That area shall be increased to 24 cm² for Member States with two official languages and 26.25 cm² for Member States with three official languages.</td>
<td></td>
</tr>
</tbody>
</table>

**Amendment 43**

Proposal for a directive  
Article 9 – paragraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to: (a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments; (b) establish and adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments; (c) define the position, format, layout, design, rotation and proportions of the health warnings; (d) by way of derogation from Article 7(3), lay down the conditions under which health warnings may be broken during unit packet opening in a manner that</td>
<td></td>
</tr>
<tr>
<td>deleted</td>
<td></td>
</tr>
</tbody>
</table>
ensures the graphical integrity and visibility of the text, photographs and cessation information.

Amendment 44
Proposal for a directive
Article 10

Text proposed by the Commission

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

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

3. The text warning referred to in paragraph 1 shall cover 40 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be

Amendment

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

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

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

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

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

(b) centred in the area in which they are required to be printed, parallel to the top edge of the unit packet and any outside packaging;

(c) surrounded by a black border not less than 3 mm and not more than 4 mm in width inside the surface reserved for the text of the warning.

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 45

Proposal for a directive

Article 11 – paragraph 2 – point a

*Text proposed by the Commission*

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

*Amendment*

(a) be printed or affixed on the most visible surface of the unit packet and additionally on any outside packaging used in connection with the product, with the exception of additional fully transparent wrappers.
Justification

Especially for small and medium sized companies the burden of printing on packages with low production volumes seems disproportionate. A sticker, as it is current practice, should be allowed.

Amendment 46

Proposal for a directive
Article 11 – paragraph 3

Text proposed by the Commission

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

Amendment

deleted

Amendment 47

Proposal for a directive
Article 12

Text proposed by the Commission

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

(a) promotes a tobacco product by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;

(b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health or social effects;

(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;

(d) resembles a food product.

2. Prohibited elements and features may include but are not limited to texts,

Amendment

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;

(b) suggests that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health or social effects;

(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;

(d) resembles a food product.

2. Prohibited elements and features may include but are not limited to texts,
symbols, names, trade marks, figurative or other signs, misleading colours, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. *Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.*

Amendment 48
Proposal for a directive
Article 13

Text proposed by the Commission

Article 13

*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.

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.

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 packets.
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.

**Amendment 49**

**Proposal for a directive**  
**Article 14 – paragraph 1**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>1. Member States shall ensure that all unit packets of tobacco products shall be marked with a unique, <em>safe and impossible to duplicate</em> 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.</td>
</tr>
</tbody>
</table>

**Amendment 50**

**Proposal for a directive**  
**Article 14 – paragraph 2 – introductory part**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. The <em>unique identifier</em> shall allow determining:</td>
<td>2. The <em>identifier referred to in paragraph 1</em> shall allow determining:</td>
</tr>
</tbody>
</table>
Amendment 51
Proposal for a directive
Article 14 – paragraph 2 – point j

Text proposed by the Commission
(j) the identity of all purchasers from manufacturing to the first retail outlet;

Amendment
(j) the identity of all purchasers from manufacturing to the first customer;

Justification
The T&T system puts a significant burden on producers. Having a requirement to have even the retail outlet destination added to the information will prove nearly impossible for small producers as they rely on intermediaries. In any case, the intended product market is important to reduce illicit trade but the exact retail outlet appears not relevant. In addition, the original wording would go beyond what was agreed in the framework of the Framework Convention on Tobacco Control.

Amendment 52
Proposal for a directive
Article 14 – paragraph 2 – point k

Text proposed by the Commission
(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

Amendment
(k) the invoice, order number and payment records of all purchasers from manufacturing to the first customer.

Justification
The T&T system puts a significant burden on producers. Having a requirement to have even the retail outlet destination added to the information will prove nearly impossible for small producers as they rely on intermediaries. In any case, the intended product market is important to reduce illicit trade but the exact retail outlet appears not relevant. In addition, the original wording would go beyond what was agreed in the framework of the Framework Convention on Tobacco Control.

Amendment 53
Proposal for a directive
Article 14 – paragraph 3
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.

**Justification**

The T&T system puts a significant burden on producers. Having a requirement to have even the retail outlet destination added to the information will prove nearly impossible for small producers as they rely on intermediaries. In any case, the intended product market is important to reduce illicit trade but the exact retail outlet appears not relevant. In addition, the original wording would go beyond what was agreed in the framework of the Framework Convention on Tobacco Control.

**Amendment 54**

**Proposal for a directive**

**Article 14 – paragraph 4**

**Text proposed by the Commission**

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.

**Amendment**

4. Member States shall ensure that manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first *customer*, 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.
Justification

The T&T system puts a significant burden on producers. Having a requirement to have even the retail outlet destination added to the information will prove nearly impossible for small producers as they rely on intermediaries. In any case, the intended product market is important to reduce illicit trade but the exact retail outlet appears not relevant. In addition, the original wording would go beyond what was agreed in the framework of the Framework Convention on Tobacco Control.

Amendment 55

Proposal for a directive
Article 14 – paragraph 8

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. In addition to the <strong>unique identifier</strong>, 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.</td>
<td>8. In addition to the <strong>identifier referred to in paragraph 1</strong>, 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.</td>
</tr>
</tbody>
</table>

Amendment 56

Proposal for a directive
Article 14 – paragraph 10

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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 <strong>10</strong> years following the date referred to in paragraph 1 of Article 25.</td>
</tr>
</tbody>
</table>

Amendment 57
### Proposal for a directive
**Article 15 – paragraph 1**

**Text proposed by the Commission**

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

**Amendment**

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

### Amendment 58

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

**Text proposed by the Commission**

Notification of novel tobacco products

**Amendment**

*Market approval for and notification of novel tobacco products and less harmful products*

### Amendment 59

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

1. **Text proposed by the Commission**

   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

1. **Amendment**

   1. *Member States shall conduct a market approval system for tobacco products with a lower risk which shall be carried out for a reasonable fee.* Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco *products and for all tobacco products with a lower risk* they intend to place on the markets of the Member States concerned by *means of an application.* *This application* shall be submitted in...
in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with:

electronic form six months before the intended placing on the market and shall be accompanied by a detailed description of the product in question, all proposed labelling, conditions of use, the product composition, manufacturing and control processes as well as information on ingredients and emissions in accordance with Article 5. The manufacturers and importers applying for a marketing authorization for tobacco products with a lower risk shall also provide the competent authorities in question with:

Amendment 60

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

Text proposed by the Commission

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

Amendment

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

Amendment 61

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

Text proposed by the Commission

(b) available studies and market research on preferences of various consumer groups, including young people and

Amendment

(b) available studies and market research on the perception and use of the product, including labelling by consumers as well as on the preferences of various consumer groups, especially young people and
Article 17 – paragraph 2

Text proposed by the Commission

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.*

Amendment

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.

The new market authorisation procedure in the Member States shall stipulate the following:

1. scientific risk assessment,
2. empirical standards regarding evidence of health risks,
3. reduction of harmful substances in smoke,
4. compliance with the provisions of points (a) to (c) of paragraph 1,
5. Post-marketing surveillance.

Requirements in respect of labelling, text health warnings, product description, packaging, measuring, including methods for measuring tar, nicotine and carbon monoxide, as well as the additional ingredients used in reduced-risk tobacco products, shall also be included among the conditions for market authorisation in the Member States.

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 and notify it of the authorisation procedure.

Justification

These amendments facilitate the marketing of tobacco products which are less hazardous than conventional tobacco products and the supply of information regarding their benefits, in so far as this is authorized by the Member State governments.

Amendment 63

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission
3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment
3. Lower-risk tobacco products placed on the market shall respect the requirements set out in this Directive. Because of the various risk-reducing properties of these tobacco products, it is necessary to adjust accordingly the measuring methods referred to in Article 4, content regulation referred to in Article 6 and labelling and packaging referred to in Articles 7, 8, 9, 10, 12 and 13. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment 64

Proposal for a directive
Title III, title

Text proposed by the Commission
NON TOBACCO PRODUCTS deleted

Amendment
Proposal for a directive

Article 18

Text proposed by the Commission

Amendment

Article 18

Nicotine-containing products

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

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

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

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

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the external area of the corresponding surface of the unit packet.
and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

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

Amendment 66
Proposal for a directive
Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the

Amendment

2. The power to adopt delegated acts referred to in Articles 6(9) and 14(9) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment 67
Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the

Amendment

3. The delegation of powers referred to in Articles 6(9) and 14(9) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of
European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment 68
Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

5. A delegated act pursuant to Articles 6(9) and 14(9) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Justification

See 'Short Justification'.

Amendment 69
Proposal for a directive
Article 23 – paragraph 1 – subparagraph 1

Text proposed by the Commission

No later than five years from the date specified in Article 25 paragraph 1, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.

Amendment

No later than three years from the date specified in Article 25 paragraph 1, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.
Amendment 70
Proposal for a directive
Article 23 – paragraph 3 a (new)

Text proposed by the Commission

3a. Prior to the publication of the report, accompanied by any proposals for amendments to this Directive, the Commission may only use the powers hereby conferred on it in the case of the adaptation of the Directive to new scientific evidence.

Justification
To avoid excessively frequent legislative changes, forcing the Member States to constantly adapt their legislation, the Commission is required only to use the powers conferred on it in cases of absolute necessity, backed by clear scientific evidence.

Amendment 71
Proposal for a directive
Article 24 – paragraph 2

Text proposed by the Commission

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

Amendment

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.
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.

Amendment 72

Proposal for a directive
Article 24 – paragraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. This Directive shall not affect the right of Member States to maintain or introduce, in accordance with the Treaty, national provisions concerning aspects not regulated by this Directive. These national provisions must be justified by overriding reasons of public interest and be necessary and proportionate to their aim. They must not be a means of arbitrary discrimination or a disguised restriction on trade between the Member States and must not jeopardise the full application of this Directive.</td>
<td>deleted</td>
</tr>
</tbody>
</table>

Amendment 73

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) tobacco products;</td>
<td>(a) cigarettes and roll-your-own tobacco;</td>
</tr>
</tbody>
</table>

Amendment 74

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); deleted

Amendment 75

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 tobacco, 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]:
## 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 | ENVI 15.1.2013 |
| Opinion by | ITRE 15.1.2013 |
| Rapporteur | Robert Goebbels 6.3.2013 |
| Discussed in committee | 25.4.2013 |
| Date adopted | 20.6.2013 |
| Result of final vote | +: 37  
| | −: 10  
| | 0: 3 |
| Substitute(s) present for the final vote | Ioan Enciu, Françoise Grossetête, Andrzej Grzyb, Cristina Gutiérrez-Cortines, Roger Helmer, Jolanta Emilia Hibner, Gunnar Hökmark, Bernd Lange |
| Substitute(s) under Rule 187(2) present for the final vote | Josefa Andrés Barea, Jerzy Buzek, Bas Eickhout, Philippe Lamberts |
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


Rapporteur: Małgorzata Handzlik

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**

PE508.085v05-00 160/320 RR:944712EN.doc
Proposal for a directive

Citation 1

Text proposed by the Commission

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Amendment

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

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (hereinafter: "Treaty"), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people.

Amendment

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (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

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

Amendment

(11) In relation to the fixing of maximum yields, it might be necessary and appropriate at a later date to adapt the yields fixed or to fix maximum thresholds for emissions, taking into consideration scientific development and internationally agreed standards to assess their toxicity or addictiveness.

Amendment 4
Proposal for a directive
Recital 12

Text proposed by the Commission

(12) In order to exercise their regulatory function, Member States and the Commission require comprehensive information on ingredients and emissions to assess the attractiveness, addictiveness and toxicity of tobacco products and the risks to health associated with the consumption of such products. To this end, the existing reporting obligations for ingredients and emissions should be reinforced. This is consistent with the obligation placed on the Union to ensure a high level of protection for human health.

Amendment

(12) In order to exercise their regulatory function, Member States and the Commission require comprehensive information on ingredients and emissions to assess the attractiveness, addictiveness and toxicity of tobacco products and the risks to health associated with the consumption of such products. To this end, the existing reporting obligations for ingredients and emissions should be reinforced, 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
(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.

*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**

(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.

*Amendment*

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

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

**Amendment 7**

**Proposal for a directive**

**Recital 15**

*Text proposed by the Commission*

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

*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

(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufactures to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives necessary for manufacturing of tobacco products should be allowed, as long as they do not result in a characterising flavour. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.

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

(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

Amendment

deleted
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.

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

(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings are more effective than text-only warnings. In this light combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the packet surface. A minimum size should be set for all health warnings to ensure their visibility and effectiveness.

Amendment

(22) The labelling provisions 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 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

(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

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.

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

(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

Amendment

(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets and outside packaging of tobacco products to be marked in a unique and secure way and their movements to be
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. 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
(28) In order to ensure independence and transparency, manufacturers of tobacco products should conclude data storage contracts with independent third parties, under the auspices of an external auditor. The data related to the tracking and tracing system should be kept separate from other company related data and be under the control of and accessible at all times by the competent authorities from Member States and the Commission.

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

Amendment 14
Proposal for a directive
Recital 30

Text proposed by the Commission
(30) Cross-border distance sales of tobacco facilitate access to tobacco products of young people and risk to undermine compliance with the requirements provided

Amendment
(30) Cross-border distance sales of tobacco, and practices such as the free distribution or swapping of tobacco products in public places for promotional

(See amendments to Article 16.)

Amendment 15

Proposal for a directive
Recital 31

Text proposed by the Commission

(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

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. *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*

(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. **Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.**

*Amendment*

(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. 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.**
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

(35) Labelling provisions should be introduced for nicotine containing products below the threshold set out in this Directive drawing the attention of consumers to potential health risks.

Amendment

deleted

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

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

Amendment

(37) In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting 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

(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Amendment

(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting 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 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.

PE508.085v05-00 172/320 RR:944712EN.doc
Amendment 20
Proposal for a directive
Recital 39

(Text proposed by the Commission)

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

(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)

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

(41) Member States should be able to 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.
Information Society services.

Justification

The internal market won't benefit if Member States are allowed to take further steps regarding the aspects which fall under the scope of 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

(45) The proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), and the right to property (Article 17). The obligations imposed on manufacturers, importers and distributors of tobacco products are necessary to improve the functioning of the internal market while ensuring a high level of health and consumer protection as set out in Articles 35 and 38 of the Charter of Fundamental Rights of the European Union. The application of this Directive should respect the EU law and relevant international obligations.

Amendment

(45) The proposal affects several fundamental rights as laid down in the Charter of Fundamental Rights of the European Union, notably the protection of personal data (Article 8), the freedom of expression and information (Article 11), freedom of economic operators to conduct business (Article 16), 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 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
### Amendment 24

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(d) cross-border distance sales of tobacco products;</td>
<td>(d) the prohibition of cross-border distance sales of tobacco products;</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(3) ‘age verification system’ means a computing system that unambiguously confirms the consumer's age in electronic form according to national requirements;</td>
<td>deleted</td>
</tr>
</tbody>
</table>

**Justification**

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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;</td>
<td>(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.</td>
</tr>
</tbody>
</table>
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

(8) ‘cigarillo’ means a small type of cigar with a diameter of up to 8 mm;

Amendment
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

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

Amendment

(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

(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

Amendment

(Does not affect English version.)
use placed on the market after entry into force of this Directive;

**Justification**

*Does not affect English version.*

**Amendment 29**
**Proposal for a directive**
**Article 2 – paragraph 1 – point 25**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(25) ‘place on the market’ means <strong>to make products available to consumers located</strong> in the Union, with or without payment, including by means of distance sale; <strong>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</strong>;</td>
<td>(25) ‘place on the market’ means <strong>any supply of products for distribution, consumption or use</strong> in the Union, with or without payment including by means of distance sale;</td>
</tr>
</tbody>
</table>

**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**

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

**Amendment 31**
**Proposal for a directive**
Article 2 – paragraph 1 – point 28

Text proposed by the Commission

(28) ‘roll-your-own tobacco’ means tobacco which can be used for making cigarettes by consumers or retail outlets;

Amendment

(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

(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 equivalent prevalence studies;

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 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 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)
(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)

(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

Article 3
Maximum tar, nicotine, carbon monoxide and other yields

Article 3
Maximum tar, nicotine, carbon monoxide and other yields
1. The yield of cigarettes placed on the market or manufactured in the Member States shall not be greater than:
(a) 10 mg per cigarette for tar,
(b) 1 mg per cigarette for nicotine,
(c) 10 mg per cigarette for carbon monoxide.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the maximum yields laid down in paragraph 1, taking into account scientific development and internationally agreed standards.

3. Member States shall notify the Commission of the maximum yields that they set for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. Taking into account internationally agreed standards, where available, and based on scientific evidence and on the yields notified by Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes that increase in an appreciable manner the toxic or addictive effect of tobacco products beyond the threshold of toxicity and addictiveness stemming from the yields of tar, nicotine and carbon monoxide fixed in paragraph 1.

Amendment 36
Proposal for a directive
Article 4

Text proposed by the Commission

Amendment

Article 4
Measurement methods

Article 4
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.

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

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

Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and update it whenever any change is made. The Commission shall make the list of approved laboratories as indicated by Member States publicly available.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the methods of measurement of the tar, nicotine and carbon monoxide yields, taking into account scientific and technical developments and internationally agreed standards.

4. Member States shall notify the Commission of the methods of measurement that they use for other emissions of 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.

4. Member States shall notify the Commission of the methods of measurement that they use for other emissions 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.
Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt methods of measurement.

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
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.

Amendment
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
6a. Tobacco products other than

Amendment
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

Article 6
Regulation of ingredients
1. Member States shall prohibit the placing on the market of tobacco products with a characterising 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 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

Amendment

Article 6
Regulation of ingredients
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 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.

Member States shall notify the Commission of measures taken pursuant to this paragraph.

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

The Commission shall adopt by means of implementing acts uniform rules on the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

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.

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

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

(c) additives having colouring properties for emissions.

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

7. Member States shall, based on scientific evidence, prohibit the placing on the market of tobacco products with additives in quantities that increase in an appreciable manner at the stage of consumption the toxic or addictive effect of a tobacco product.

Member States shall notify to the Commission measures taken pursuant to this paragraph.

8. The Commission shall at the request of a Member State or may on its own initiative determine by means of an implementing act whether a tobacco product falls within the scope of paragraph 7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21 and shall be based on the latest scientific evidence.

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

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

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

Article 7

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.

Amendment

Article 7

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, 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, health warnings shall be irremovably printed, indelible and in no way hidden or interrupted, including by tax stamps, price marks, tracking and tracing marks, security features or by any type of wrapper, pouch, jacket, box or other device or by the opening of the unit packet.

3. Health warnings shall be irremovably printed 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.

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

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.
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.

Amendment 41

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(b)</em> to define the position, format, layout and design of the health warnings laid down in this Article, including their font type and background colour.</td>
<td>deleted</td>
</tr>
</tbody>
</table>

Amendment 42

Proposal for a directive
Article 9

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 9 Combined health warnings for tobacco for smoking 1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The combined health warnings shall: (a) be comprised of a text warning listed in Annex I and a corresponding colour</td>
<td>Article 9 Combined health warnings for tobacco for smoking 1. Each unit packet and any outside packaging of tobacco for smoking shall carry combined health warnings. The combined health warnings shall: (a) be comprised of a text warning listed in Annex I and a corresponding colour</td>
</tr>
</tbody>
</table>
photograph specified in the picture library;
(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;
(c) cover 75 % of the external area of both the front and back surface of the unit packet and any outside packaging;
(d) show the same text warning and corresponding colour photograph on both sides of the unit packets and any outside packaging;
(e) be positioned at the top edge of the unit packet and any outside packaging, and in the same direction as any other information appearing on the packaging;
(f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to paragraph 3;
(g) for unit packets of cigarettes, respect the following dimensions:
(i) height: not less than 64 mm;
(ii) width: not less than 55 mm.
2. The combined health warnings shall be divided into three sets rotating on an annual basis. Member States shall ensure that each combined health warning is displayed as nearly as possible on equal numbers of each brand.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:
(a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments;
(b) establish and adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments;

(g) for unit packets of cigarettes, respect the following dimensions:
(i) height: not less than 60 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.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to:
(a) adapt the text warnings listed in Annex I to this Directive taking into account scientific and technical developments;
(b) establish by ...* and if necessary thereafter adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments;
(c) define the position, format, layout, design, rotation and proportions of the health warnings;

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

(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

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).

The general warning shall be printed on the most visible surface of the unit packet and any outside packaging. The text warnings listed in Annex I shall be rotated in such a way of rogation from Article 7(3), lay down the conditions under which health warnings may be broken during unit packet opening in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.

Amendment

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).

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.

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

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

4. The general warning and the text warning referred to in paragraph 1 shall be:
(a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States may determine the point size of the font, provided that the font size specified in their legislation is such as to occupy the greatest possible proportion of

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, 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 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 than two official languages.

4. The general warning and the text warning referred to in paragraph 1 shall be:
(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
the area set aside for the text required;

(b) centred in the area in which they are required to **be printed**, parallel to the top edge of the unit packet and any outside packaging;

(c) surrounded by a black border not less than 3 mm and not more than 4 mm in width inside the surface reserved for the text of the warning.

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*

Article 11

Labelling of smokeless tobacco products

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

2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 10(4). In addition, it shall:

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35

*Amendment*

Article 11

Labelling of smokeless tobacco products

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

This tobacco product **damages** your health and is addictive

2. The health warning laid down in paragraph 1 shall comply with the requirements specified in Article 10(4). In addition, it shall:

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35
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

Article 12
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:

(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;

(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;

(d) resembles a food product.

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

Amendment

Article 12
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:

(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 effects;

(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;

(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. Texts, symbols, names, trade marks, figurative or other signs, misleading colours or other additional material such as adhesive labels, stickers, onserts, scratch-
other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.

offs and sleeves that may suggest that a particular tobacco product is less harmful 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

Article 13
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.

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.

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

Amendment

Article 13
Appearance and content of unit packets
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.
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.

Amendment 47

Proposal for a directive
Article 14

Text proposed by the Commission

Article 14

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.

Amendment

Article 14

Traceability and security features

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
2. The unique identifier shall allow determining:
(a) the date and place of manufacturing;
(b) the manufacturing facility;
(c) the machine used to manufacture the products;
(d) the production shift or time of manufacture;
(e) the product name;
(f) the intended market of retail sale;
(g) the intended shipment route;

h) where applicable, the importer into the Union;
(i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used;

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

(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

with a digital tax stamp in invisible ink.

2. The unique identifier shall allow determining:
(a) the date and place of manufacturing;
(b) the manufacturing facility;
(c) the machine used to manufacture the products;
(d) the production shift or time of manufacture;
(e) the product description;
(f) the intended market of retail sale;

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

(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

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

4. Member States shall ensure that manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies with the necessary equipment allowing for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. The equipment shall be able to read and transmit the data electronically to a data storage facility pursuant to paragraph 6.

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

6. Member States shall ensure that manufacturers and importers of tobacco by recording in aggregated form, e.g. of outside packaging, provided that tracking and tracing of unit packets remains possible.

4. Member States shall ensure that manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies with the necessary equipment, 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 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 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.

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

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 **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.

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
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 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;

(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.

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.

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 by …*, taking into account existing practices, technologies and commercial 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;

(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.

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 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)
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

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-

Article 16

Cross-border distance sales of tobacco products

1. Member States shall prohibit cross-border distance sales of tobacco products to consumers located in the Union.
border distance sales shall submit at least the following information to the competent authorities:

(a) name or corporate name and permanent address of the place of activity from where the tobacco products are 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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification of novel tobacco products</td>
<td>Notification of novel tobacco products and granting of pre-marketing authorisation for reduced-risk tobacco products</td>
</tr>
</tbody>
</table>

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
1. Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco product they intend to place on the markets of the Member States concerned. The notification shall be submitted in electronic form six months before the intended placing on the market and shall be accompanied by a detailed description of the product in question as well as information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with:

- available scientific studies on toxicity, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions;
- impact on passive smoking, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions;

**Amendments**

**Amendment 54**

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

**Text proposed by the Commission**

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

**Amendment**

- 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

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

Proposal for a directive
Article 17 – paragraph 2

Text proposed by the Commission

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.

Amendment

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. 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.

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**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.</td>
<td>3. Novel <strong>and reduced-risk</strong> tobacco products placed on the market shall respect the requirements set out in this Directive. <strong>Reduced-risk tobacco products shall be covered by special provisions laid down by Member States under paragraph 2.</strong> The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.</td>
</tr>
</tbody>
</table>

### 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)**
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

Article 18

Nicotine-containing products

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

(a) products with a nicotine level exceeding 2 mg per unit, or
(b) products with a nicotine concentration exceeding 4 mg per ml or
(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 mg of nicotine per ml.

Amendment

Article 18

Nicotine-containing products

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

(a) products with a nicotine level exceeding 2 mg per unit, or
(b) products with a nicotine concentration exceeding 4 mg per ml.

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.

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35
% for Member States with three official languages.

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

Amendment 60
Proposal for a directive
Article 19 – paragraph 1 – subparagraph 1

Text proposed by the Commission
This product can damage your health.

Amendment
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
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.

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 more than two official languages.
Amendment 62

Proposal for a directive
Article 22 – paragraph 2

*Text proposed by the Commission*

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an *indeterminate* period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

*Amendment*

2. The power to adopt delegated acts referred to in Articles 4(3), 4(4), 6(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*

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

*Amendment*

3. The delegation of powers referred to in Articles 4(3), 4(4), 6(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 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
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, 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

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.

Amendment

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

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

Amendment

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
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.

Amendment 67
Proposal for a directive
Article 25 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [Publications Office, please insert the exact date: entry into force + 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
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]:

**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**

(a) tobacco products;

**Amendment**

(a) cigarettes and roll-your-own cigarettes;

**Amendment 70**

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

**Text proposed by the Commission**

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

**Amendment**

(b) nicotine containing products;

**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**

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)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANNEX IIa</td>
<td></td>
</tr>
<tr>
<td>Maximum permissible content in smokeless tobacco, toxin per unit weight dry tobacco:</td>
<td></td>
</tr>
<tr>
<td>NNN (N-nitrosornicotine) plus NNK (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone): 2.0 mg/kg</td>
<td></td>
</tr>
<tr>
<td>B(a)P (Benzo[a]Pyrene): 5.0 µg/kg</td>
<td></td>
</tr>
</tbody>
</table>

Justification


Amendment 73

Proposal for a directive
Annex 2 b (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANNEX IIb</td>
<td></td>
</tr>
<tr>
<td>EU legislation applicable to nicotine-</td>
<td></td>
</tr>
</tbody>
</table>

RR\944712EN.doc 213/320 PE508.085v05-00
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


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

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

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

---

13 The list is not exhaustive
| Miroslaw Dworniczak                      |
| starychemik.wordpress.com               |
| www.dworniczak.eu                      |
| Naczelnia Rada Lekarska                 |
| National Brands Associations            |
| dr Michal Kozlowski -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                  |
| Zaklad Szkodliwosci Chemicznych i Toksykologii Genetycznej |
| Action on Smoking and Health (UK)       |
## PROCEDURE

<table>
<thead>
<tr>
<th>Title</th>
<th>Approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products</th>
</tr>
</thead>
<tbody>
<tr>
<td>References</td>
<td>COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)</td>
</tr>
<tr>
<td>Committee responsible</td>
<td>ENVI 15.1.2013</td>
</tr>
<tr>
<td>Opinion by</td>
<td>IMCO 15.1.2013</td>
</tr>
<tr>
<td>Rapporteur</td>
<td>Małgorzata Handzlik 23.1.2013</td>
</tr>
<tr>
<td>Discussed in committee</td>
<td>21.3.2013 24.4.2013 30.5.2013</td>
</tr>
<tr>
<td>Date adopted</td>
<td>18.6.2013</td>
</tr>
</tbody>
</table>
| Result of final vote | +: 23  
–: 14  
0: 0 |
| 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 |
27.6.2013

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

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


Rapporteur: Csaba Sándor Tabajdi

SHORT JUSTIFICATION

The rapporteur welcomes the Commission's proposal for a new tobacco products Directive and fully endorses the promotion of the well-being of people and supports a better protection of public health. It also emphasises the importance of considering all aspects of tobacco manufacturing, presentation and sale, especially preserving agricultural jobs along the tobacco value chain in order to have a balanced legal framework. The rapporteur underlines that the proposed text shall be adjusted to the international trade commitments of the WTO and legally binding of obligations of the WHO Framework Convention on Tobacco Control (FCTC) adopted by the European Communities.

The rapporteur underlines the importance of measures, which will considerably and genuinely decrease tobacco consumption and prevent youngsters from taking up smoking, but do not lead to the decline of the European tobacco growing sector, i.e. through the replacement of European tobacco by cheaper and uncontrolled tobacco from third countries, and increased illegal trafficking of tobacco products along the EU’s external borders.

Tobacco causes almost 700 000 deaths every year in the Union. The Commission focuses in its proposal on preventing people, in particular youngsters, from taking up the habit of smoking, since 70 % of smokers start consuming tobacco before the age of eighteen. Furthermore, tobacco is a labour-intensive agricultural product that provides 400 000 full-time and seasonal jobs around Europe, mainly in socially deprived regions with few or no labour alternatives. Data by economic stakeholders show that 96 % of tobacco farms are family farms with a cultivation area between 0,5 and 3 hectares.

The European Parliament has addressed the lack of relations between tobacco growing and smoking several times. Also, the European Commission acknowledges in its evaluation report
that there is no direct link between tobacco cultivation and smoking rates.

The most powerful tool to prevent young people from taking up smoking is education, and prevention programmes. The most recent representative survey reveals that within the past ten years, there has been a continuous decline in the consumption of tobacco due to various prevention programmes e.g. in Federal Republic of Germany. Therefore the rapporteur strongly advises that a European Smoking Prevention Fund be set up to finance programmes assisting citizens to quit smoking, prevent citizens to take up smoking, and inform citizens about the harmful health effects of smoking.

The rapporteur believes that citizens do not receive proper information about the harmful effects of smoking. Therefore, bearing in mind the protection of consumers, better labelling should be introduced, such as indication of different levels of harmfulness of tobacco products. This must not mislead consumers, as all tobacco products are harmful.

In numerous Member States men and women with lower levels of education and in difficult social circumstances smoke drastically more: e.g. in Hungary 45 % of men and 26 % of women who dropped out of education after elementary school men are smoking. 32 % of men and 22 % of women that finished their studies in high school are smoking. At the same time, only 20 % of men and 18 % of women with university degrees are smoking. Therefore the Directive should consider social aspects as well when regulating tobacco products.

The rapporteur is concerned that the scope of the delegated acts in the proposed by the Commission is too broad and could lead to an institutional imbalance between the Parliament and Council as legislators and the Commission.

Article 3 of the proposed new TPD empowers the Commission and the member states to modify the maximum yields on tar, nicotine, carbon monoxide or other emissions; a decision to dramatically reduce the nicotine yield can discriminate Burley tobacco producers.

Article 6 of the proposal allows member states and the Commission to decide which flavour or concentration of ingredients can be considered as imparting a characterizing flavour; they can also decide to prohibit placing on the market tobacco products with additives “based on scientific evidence”. In order to clarify the situation on additives the rapporteur wants a positive or a negative list of additives which are essential for the manufacture of tobacco products and which result in a product with a characterising flavour to be set up.

By allowing the cross-border purchase of tobacco products, including online, the proposal creates a special danger on young generations. The adoption of the proposal might imply an easier access to tobacco products for youngsters under the age of eighteen. Therefore, in order to prevent youngsters from taking up the habit of smoking the rapporteur proposes to ban internet sales of tobacco products. Some member states already apply the aforementioned good practice.

In order to achieve the pivotal objective of the TFEU – to promote well-being of citizens – the rapporteur deems that in the spirit of subsidiarity, Member States that already introduced anti-tobacco provisions beyond the Commission proposal, shall sustain their respective systems.
AMENDMENTS

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

Amendment 1

Proposal for a directive
Recital 6

Text proposed by the Commission

(6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the whole of the Union in only a small number of production plants within the Member States and the resulting significant cross-border trade of tobacco and related products calls for legislative action at Union rather than national level to achieve the smooth operation of the internal market.

Amendment

(6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the whole of the Union in only a small number of production plants within the Member States and the resulting significant cross-border trade of tobacco and related products calls for stronger legislative action at Union level to achieve the smooth operation of the internal market.

Amendment 2

Proposal for a directive
Recital 6 a (new)

Text proposed by the Commission

(6a) The European Union should pay particular attention to tobacco production in less-favoured areas, especially in the outermost regions where it is frequently associated with specific geographical and socio-economic characteristics, and the Union should allow the Member States concerned to implement specific measures to ensure continued production in these
Amendment 3
Proposal for a directive
Recital 8

**Text proposed by the Commission**

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (hereinafter: ‘Treaty’), a high level of health protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco, health protection should be given high importance, in particular to reduce smoking prevalence among young people.

**Amendment**

(8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (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. The most powerful tools to prevent young people from taking up smoking are education, information and prevention campaigns and programmes to help citizens who wish to give up smoking. Those tools continue to play an essential role. Therefore a European Smoking Prevention Fund should be set up in order to finance programmes assisting citizens to quit smoking, preventing citizens to take up smoking, and informing citizens about the harmful health effects of smoking.

Amendment 4
Proposal for a directive
Recital 11

**Text proposed by the Commission**

(11) In relation to the fixing of maximum yields, it might be necessary and appropriate at a later date to adapt the

**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.

(yields fixed or to fix maximum thresholds for emissions, taking into consideration scientific developments, progress and knowledge and internationally agreed standards when assessing their toxicity or addictiveness.

**Amendment 5**
Proposal for a directive
Recital 13

*Text proposed by the Commission*

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

**Amendment**

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

**Amendment 6**
Proposal for a directive
Recital 15

*Text proposed by the Commission*

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

**Amendment**
deleted
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.

Justification

There is no independent research showing that the addition of menthol either increases smoking or encourages people to have ‘a first cigarette’. Only three Member States have a high level of consumption of mentholated cigarettes.

Amendment 7

Proposal for a directive
Recital 15 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(15a) Reliable research shows that the level of tobacco growing in the EU is not linked to the number of EU citizens who smoke. At the same time, a majority of the tobacco grown in the EU comes from very small family farms, which find it very difficult to switch to a different production model. EU farmers should therefore have the opportunity to market the tobacco they produce for the needs of European consumers, while ensuring that the highest quality raw materials are used and complying with the standards on ingredients laid down in this Directive, without discriminating against tobacco varieties grown in unfavourable climatic conditions. In addition, Member States should take action to retrain tobacco farmers in order for them move into other agricultural sectors, particularly through the use of funds available under</td>
<td></td>
</tr>
</tbody>
</table>
Amendment 8
Proposal for a directive
Recital 16

Text proposed by the Commission
(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufacturers to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives necessary for manufacturing of tobacco products should be allowed, as long as they do not result in a characterising flavour. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.

Amendment
deleted

Amendment 9
Proposal for a directive
Recital 22

Text proposed by the Commission
(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others.

Amendment
(22) The labelling provisions also need to be adapted to new scientific evidence. For example the indication of the yields for tar, nicotine and carbon monoxide on cigarette packets have proven to be misleading as it makes consumers believe that certain cigarettes are less harmful than others.
Evidence also suggests that large combined 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 10**

**Proposal for a directive**

**Recital 23**

*Text proposed by the Commission*

(23) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimension of the warnings as well as regarding certain aspects of the appearance of the tobacco package, including the opening mechanism. The package and the products may mislead consumers, in particular young people, suggesting that products are less harmful. For instance, this is the case with certain texts or features, such as ‘low-tar’, ‘light’, ‘ultra-light’, ‘mild’, ‘natural’, ‘organic’, ‘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.**

*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’, names, pictures, and figurative or other signs.
Recital 24

Text proposed by the Commission

(24) Tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers, should be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people. The labelling of these other tobacco products should follow specific rules. The visibility of the health warnings on smokeless tobacco products needs to be ensured. Warnings should therefore be placed on the two main surfaces of smokeless tobacco product packaging.

Amendment

Amendment

(24) Tobacco products for smoking, other than cigarettes and roll-your-own tobacco products should be granted an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns in relation to young people. The labelling of these other tobacco products should follow specific rules. The visibility of the health warnings on smokeless tobacco products needs to be ensured. Warnings should therefore be placed on the two main surfaces of smokeless tobacco product packaging.

Amendment 12
Proposal for a directive
Recital 26

Text proposed by the Commission

(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets of tobacco products to be marked in a unique and secure way and their movements to be recorded so that these products can be tracked and traced in the Union and their compliance with this Directive can be monitored and better enforced. In addition, provision should be

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 order to restrain illegal
made for the introduction of security features that will facilitate the verification of whether or not products are authentic. The trafficking of tobacco products especially along the external borders of the Union. In addition, provision should be made for the introduction of security features that will facilitate the verification of whether or not products are authentic. The Commission and Member States should also ensure that any measures adopted in application of this Directive do not lead indirectly to an increase in the illicit trade in tobacco products.

Amendment 13

Proposal for a directive
Recital 30

**Text proposed by the Commission**


**Amendment**

(30) Cross-border distance sales including internet sales of tobacco, and practices such as the free distribution or bartering 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.
Amendment 14
Proposal for a directive
Recital 31

Text proposed by the Commission
(31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 5 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

Amendment
(31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained by means of education and prevention from taking up the habit of smoking. It is therefore important to monitor developments as regards novel tobacco products. A notification obligation for novel tobacco products should be put on manufacturers and importers, without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the development and submit a report 5 years after the transposition deadline of this Directive, in order to assess whether amendments to this Directive are necessary.

Amendment 15
Proposal for a directive
Recital 37

Text proposed by the Commission
(37) In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting, the determination of products with characterising flavours or with increased levels of toxicity and addictiveness and the methodology for determining whether a tobacco product has characterising flavour, implementing powers should be conferred on the Commission. Those powers should be

Amendment
(37) In order to ensure uniform conditions for the implementation of this Directive, in particular concerning the format of ingredients reporting, increased levels of toxicity and addictiveness, the Commission may lay down, by means of implementing acts and in accordance with the procedure referred to in Article 21, the methodology for determining increased levels of toxicity and addictiveness of

Amendment 16

Proposal for a directive
Recital 38

Text proposed by the Commission

(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.
Amendment 17

Proposal for a directive
Recital 40

Text proposed by the Commission

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

Amendment

(40) In order to improve the functioning of the internal market, a Member State shall not be allowed to introduce more stringent national provisions, applying to all products falling within the scope of this Directive.

Amendment 18

Proposal for a directive
Recital 40 a (new)

Text proposed by the Commission

(40a) A Member State that deems it necessary to maintain and/or introduce national and/or regional provisions geared to preserving traditional tobacco plantations, for justified reasons relating to the socio-economic dependence of local communities, should be allowed to do so.
Amendment 19
Proposal for a directive
Recital 41

Text proposed by the Commission

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

Amendment

(41) With respect for current international market rules, and in order to improve the functioning of the internal market, Member States, when they maintain or introduce more stringent national provisions in areas outside the scope of this Directive, shall not prohibit or place restrictions on the import, sale and consumption of tobacco and related products that comply with this Directive.

Amendment 20
Proposal for a directive
Recital 43 a (new)

Text proposed by the Commission

(43a) This Directive should not lead to a deterioration in the living conditions of people whose livelihoods depend on tobacco growing in Europe and who often live in disadvantaged areas. Given that the aim of the Directive is solely to discourage consumption of tobacco products, any
decisions concerning ingredients and additives should take due account of the possible socioeconomic repercussions for groups whose livelihoods depend on tobacco growing. The European tobacco growing sector should be protected because it accounts for only a very small proportion of consumption in the EU and, at the same time, contributes to the economic stability of certain European regions where the range of alternative crops is limited. A decrease in or an end to tobacco growing in the EU would have no impact on consumption levels, but would lead to an increase in imports from third countries and a reduction in quality standards.

Amendment 21
Proposal for a directive
Article 2 – paragraph 1 – point 4

Text proposed by the Commission

(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;

Amendment

(4) ‘characterising flavour’ means a distinguishable aroma or taste other than tobacco or menthol, resulting from an additive or combination of additives, including but not limited to fruit, spice, herb, alcohol, candy or vanilla observable before or upon intended use of the tobacco product;

Amendment 22
Proposal for a directive
Article 2 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘flavouring’ means an additive that imparts aroma and/or taste;

Amendment

(13) ‘flavouring’ means an additive that imparts aroma and/or taste but is not essential to the process of manufacturing
the tobacco product.

**Amendment 23**  
Proposal for a directive  
Article 2 – paragraph 1 – point 18  

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(18) ‘ingredient’ means an additive, tobacco (leaves and other natural, processed or unprocessed parts of tobacco plants including expanded and reconstituted tobacco), as well as any substance present in a finished tobacco product including paper, filter, inks, capsules and adhesives;</td>
<td>(18) ‘ingredient’ means an additive, as well as any substance present in a finished tobacco product including paper, filter, inks, capsules and adhesives;</td>
</tr>
</tbody>
</table>

**Justification**

Tobacco leaves should not be considered as an ingredient since they are a constituent of the product and not an added part. The current TPD (2001/37/EC) does not include tobacco as an ingredient.

**Amendment 24**  
Proposal for a directive  
Article 2 – paragraph 1 point 18 a (new)  

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(18a) 'natural constituent' means tobacco (leaves and other natural, processed or unprocessed parts of tobacco plants including expanded and reconstituted tobacco);</td>
<td></td>
</tr>
</tbody>
</table>

**Amendment 25**  
Proposal for a directive  
Article 2 – paragraph 1 – point 19  

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(19) 'maximum level' or 'maximum yield' means the maximum content or emission,</td>
<td>(19) ‘maximum level’ means the maximum content of a substance in a tobacco product</td>
</tr>
</tbody>
</table>
including 0, of a substance in a tobacco product measured in grams;

Amendment 26
Proposal for a directive
Article 2 – paragraph 1 – point 34

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(34) 'tobacco products' means products usable for consumption by consumers and consisting of, even partly, tobacco, whether genetically modified or not;</td>
<td>(34) 'tobacco products' means products usable for consumption by consumers and consisting of, even partly, tobacco;</td>
</tr>
</tbody>
</table>

Amendment 27
Proposal for a directive
Article 2 – paragraph 1 – point 36 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(36a) 'imitation tobacco products' means sweets, snacks, toys or any other objects in the form of tobacco products which may appeal to minors. These products shall be prohibited.</td>
<td></td>
</tr>
</tbody>
</table>

Justification

According to the Article 16 of the WHO FCTC which was ratified by the European Community 30/06/2005 conference of parties shall prohibit the sales of tobacco products to persons under the age by banning imitation tobacco products. The EU legislation shall be adjusted to international obligations.

Amendment 28
Proposal for a directive
Article 3 – paragraph 2

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. The Commission shall be empowered to</td>
<td>2. The Commission may submit proposals</td>
</tr>
</tbody>
</table>
to adopt the maximum yields laid down in paragraph 1, based on sound and undisputed scientific evidence and internationally agreed standards.

**Amendment 29**

Proposal for a directive

Article 3 – paragraph 3

*Text proposed by the Commission*

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.

*Amendment*

3. Member States shall notify the Commission of the maximum yields that they set for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. Taking into account internationally agreed standards based on sound and undisputed scientific evidence and on the yields notified by Member States, the Commission may put forward proposals to 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.

**Amendment 30**

Proposal for a directive

Article 4 – paragraph 3

*Text proposed by the Commission*

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt the methods of measurement of the tar, nicotine and

*Amendment*

3. The Commission may submit proposals to adapt the maximum yields referred to in paragraph 1, taking into account scientific developments and internationally agreed
carbon monoxide yields, taking into account scientific and technical developments and internationally agreed standards.

Justification

The purpose of this amendment is to ensure that the Commission and Member States cannot change the maximum yields of tar, nicotine, carbon monoxide and other emissions by means of delegated acts independently of Parliament. Any substantial changes to these yields could affect the tobacco growing sector. This is particularly true of nicotine, which is a major component of Burley.

Amendment 31

Proposal for a directive
Article 4 – paragraph 4

Text proposed by the Commission
4. Member States shall notify the Commission of the methods of measurement that they use for other emissions of cigarettes and for emissions of tobacco products other than cigarettes. Based on these methods, and taking into account scientific and technical developments as well as internationally agreed standards the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adopt and adapt methods of measurement.

Amendment
deleted

Amendment 32

Proposal for a directive
Article 6 – paragraph -1 (new)

Text proposed by the Commission
-1. The Commission may establish a negative list of additives which are not essential for the manufacture of tobacco products and which result in a product
 Amendment 33
Proposal for a directive
Article 6 – paragraph 1 – subparagraph 1

1. Member States shall prohibit the placing on the market of tobacco products with a characterising flavour. The traditional use of menthol should be exempted from this provision.

Amendment

1. Member States shall prohibit the placing on the market of tobacco products with additives that create or release a flavour which is not predominantly that of tobacco or menthol.

Amendment 34
Proposal for a directive
Article 6 – paragraph 1 – subparagraph 2

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

Amendment

Member States shall not prohibit the use of sugar and other additives which are essential for the manufacture of tobacco products, particularly those which improve the quality of tobacco grown in unfavourable climatic conditions and less favoured areas.

Amendment 35
Proposal for a directive
Article 6 – paragraph 2

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

The Commission shall adopt by means of implementing acts uniform rules on the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21. An independent panel shall be used to assist in the decision making.

Amendment 36
Proposal for a directive
Article 6 – paragraph 3

Text proposed by the Commission

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.

Amendment 37
Proposal for a directive
Article 6 – paragraph 4 – point c

Text proposed by the Commission

(c) additives having colouring properties for emissions.

Amendment

(c) additives having colouring properties for emissions unless they have no effect on consumer health;
Amendment 38
Proposal for a directive
Article 6 – paragraph 4 – point c a (new)

Text proposed by the Commission

(\textit{ca}) additives resulting in a product with a characterising flavour.

Amendment

Amendment 39
Proposal for a directive
Article 6 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Amendment 40
Proposal for a directive
Article 6 – paragraph 7 – subparagraph 1 a (new)

Text proposed by the Commission

\textit{However, Member States shall not, on that basis, prohibit the placing on the market of tobacco products containing menthol solely on the basis of their menthol content.}

Amendment

Amendment 41
Proposal for a directive
Article 6 – paragraph 9

Text proposed by the Commission

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

Amendment 42

Proposal for a directive
Article 8 – paragraph 3

Text proposed by the Commission

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

Amendment 43

Proposal for a directive
Article 8 – paragraph 4 – introductory part

Text proposed by the Commission

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

Amendment

4. The Commission shall be empowered to
Article 22:  

make proposals:

Amendment 44

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 45

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

Text proposed by the Commission

Amendment

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 ensuring consumers’ right to have access to proper information. The combined health warnings shall:

Amendment 46

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

Text proposed by the Commission

Amendment

(c) cover 75 % of the external area of both the front and back surface of the unit packet and any outside packaging; (c) cover 50 % of the external area of both the front and back surface of the unit packet and any outside packaging;
Amendment 47
Proposal for a directive
Article 9 – paragraph 1 – point e

Text proposed by the Commission

(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;

Amendment

(e) be positioned at the bottom edge of the unit packet and any outside packaging

Amendment 48
Proposal for a directive
Article 9 – paragraph 1 – point g

Text proposed by the Commission

(g) for unit packets of cigarettes, respect the following dimensions:
(i) height: not less than 64 mm;
(ii) width: not less than 55 mm.

Amendment

deleted

Amendment 49
Proposal for a directive
Article 9 – paragraph 3 – introductory part

Text proposed by the Commission

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

Amendment

3. The Commission shall be empowered to make proposals to:

Amendment 50
Proposal for a directive
Article 9 – paragraph 3 – point c
(c) define the position, format, layout, design, rotation and proportions of the health warnings;

Amendment 51
Proposal for a directive
Article 9 – paragraph 3 – point d

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

Amendment 52
Proposal for a directive
Article 10 – paragraph 2

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.

Amendment 53
Proposal for a directive
Article 10 – paragraph 5

Text proposed by the Commission

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

Amendment 54

Proposal for a directive
Article 11 – paragraph 2 – point b

Text proposed by the Commission

(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.

Amendment 55

Proposal for a directive
Article 11 – paragraph 3

Text proposed by the Commission

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

Amendment 56
Article 12 – paragraph 1 – point c

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

Amendment
deleted

Amendment 57

Proposal for a directive
Article 12 – paragraph 2

Text proposed by the Commission
2. Prohibited elements and features may include but are not limited to texts, symbols, names, trade marks, figurative or other signs, misleading colours, inserts or other additional material such as adhesive labels, stickers, onserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.

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

Justification
Banning ‘slim’ cigarettes would have negative economic consequences and entail losses disproportionate to any health benefits.

Amendment 58

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

Text proposed by the Commission
2a. The variety of tobacco used to manufacture the product and/or its country of origin may be indicated on the unit packet.

Amendment
**Amendment 59**

**Proposal for a directive**
**Article 13 – paragraph 1**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>deleted</td>
</tr>
</tbody>
</table>

**Amendment 60**

**Proposal for a directive**
**Article 13 – paragraph 2**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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, <strong>other than the flip-top lid. The flip-top lid of a cigarette packet shall be hinged only at the back of the packet.</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

**Amendment 61**

**Proposal for a directive**
**Article 13 – paragraph 3**

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

Amendment 62
Proposal for a directive
Article 13 – paragraph 4

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>deleted</td>
</tr>
</tbody>
</table>

Amendment 63
Proposal for a directive
Article 14 – paragraph 10

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>10. Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the application of paragraph 1 to 8 during a period of 10 years following the date referred to in paragraph 1 of Article 25.</td>
</tr>
</tbody>
</table>

Justification
See Article 8(3) of the Protocol to Eliminate Illicit Trade in Tobacco Products (protocol to the FCTC).
Amendment 64

Proposal for a directive
Article 15 – paragraph 1

Text proposed by the Commission

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

**Amendment**

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

Amendment 65

Proposal for a directive
Article 16 – title

Text proposed by the Commission

*Cross-border distance* sales of tobacco products

**Amendment**

*Internet* sales of tobacco products

**Justification**

*It is difficult to enforce age restrictions on tobacco sales over the internet. Moreover there are problems with illegal internet advertising and non-compliance with the existing legislation (e.g. health warnings). It encourages young people to smoke and gives them an easier access to tobacco products. All internet sales, not only cross-border, should therefore be prohibited. Nine Member States have already done it. An EU ban would therefore harmonize the rules and facilitate the enforcement.*

Amendment 66

Proposal for a directive
Article 16

Text proposed by the Commission

1. Member States shall *oblige retail outlets intending to engage in cross-border distance sales to consumers located in the*

**Amendment**

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

a) name or corporate name and permanent address of the place of activity from where the tobacco products are 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.

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.

Justification

It is difficult to enforce age restrictions on tobacco sales over the internet. Moreover there are problems with illegal internet advertising and non-compliance with the existing legislation (e.g. health warnings). It encourages young people to smoke and gives them an easier access to tobacco products. All internet sales, not only cross-border, should therefore be prohibited. Nine Member States have already done it. An EU ban would therefore harmonize the rules and facilitate the enforcement.

Amendment 67

Proposal for a directive
Article 16 – paragraph 1a (new)

Text proposed by the Commission

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.
Justification

Promotional schemes in which free packets of cigarettes are handed out or new packets are swapped for packets that have already been opened are targeted at young people and thus indefensible.

Amendment 68

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

Text proposed by the Commission

1. Member States shall require that manufacturers and importers of tobacco products notify the competent authorities of Member States of any novel tobacco product they intend to place on the markets of the Member States concerned. The notification shall be submitted in electronic form six months before the intended placing on the market and shall be accompanied by a detailed description of the product in question as well as information on ingredients and emissions in accordance with Article 5. The manufacturers and importers notifying a novel tobacco product shall also provide the competent authorities in question with:

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 which they intend to place on the markets of the Member States concerned and which, on the basis of substantial scientific evidence, they intend to make the subject of a claim that it is less harmful, or constitutes a lower risk, than 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 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 69

Proposal for a directive
Article 18

Text proposed by the Commission

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

Amendment

Nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.
(a) products with a nicotine level exceeding 2 mg per unit, or

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

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

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine-containing products pursuant to Directive 2001/83/EC.

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10 (4). In addition, it shall:

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

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

With the exception of tobacco products – nicotine-containing products – regardless of nicotine quantity – should be classified as pharmaceuticals. Article 18 of the Commission proposal does not promote ensuring high level health protection and violates Article 168 (7) of the TFEU. Article 18, as proposed by the Commission, represents a step back when compared to the legal provisions in place in certain Member States.

Amendment 70

Proposal for a directive
Article 19 – paragraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>

Amendment 71

Proposal for a directive
Article 22 – paragraph 2

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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].</td>
<td>2. The power to adopt delegated acts referred to in Articles 6(10) and 14(9), shall be conferred on the Commission for a period of five years from [Office of Publications: please insert the date of the entry into force of this Directive].</td>
</tr>
</tbody>
</table>
Amendment 72
Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of powers referred to in Articles 6(10) and 14(9) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment 73
Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

5. A delegated act pursuant to Articles 6(10) and 14(9) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.
Amendment 74

Proposal for a directive
Article 23 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission

In the report, the Commission shall indicate in particular the features which should be reviewed or developed in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, and shall pay special heed to:

Amendment

In the report, the Commission shall indicate in particular the features which should be reviewed or developed in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, and shall pay special heed to:

Amendment 75

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

Text proposed by the Commission

(c a) the impact on production and employment in the tobacco sector, paying particular attention to small and medium-sized farmers;

Amendment

(c a) the impact on production and employment in the tobacco sector, paying particular attention to small and medium-sized farmers;

Amendment 76

Proposal for a directive
Article 23 – paragraph 2 – subparagraph 1 – point c b (new)

Text proposed by the Commission

(c b) the potential impact on European tobacco growing of the Directive.

Amendment

(c b) the potential impact on European tobacco growing of the Directive.
Text proposed by the Commission

1. Member States shall not prohibit or restrict the import, sale or consumption of tobacco or related products which comply with this Directive.

Amendment

1. Member States shall not prohibit or restrict the import, sale or consumption of tobacco or related products which comply with this Directive. At the same time, measures must be taken to restrict the import of tobacco products, including from third countries, which do not comply with this Directive.
## PROCEDURE

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

**References**  
COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)

**Committee responsible**  
Date announced in plenary  
ENVI  
15.1.2013

**Opinion by**  
Date announced in plenary  
AGRI  
7.2.2013

**Rapporteur**  
Date appointed  
Csaba Sándor Tabajdi  
5.3.2013

**Discussed in committee**  
25.4.2013

**Date adopted**  
19.6.2013

**Result of final vote**  
+ 36  
− 4  
0 2

**Members present for the final vote**  

**Substitute(s) present for the final vote**  
Luís Paulo Alves, Margrete Auken, Maria Auxiliadora Correa Zamora, Marian Hurkin, Sandra Kalniete, Maria do Céu Patrão Neves, Valdemar Tomaševski, Jacek Włosowicz, Milan Zver

**Substitute(s) under Rule 187(2) present for the final vote**  
Fiona Hall
25.6.2013

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS

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


Rapporteur: Klaus-Heiner Lehne

SHORT JUSTIFICATION

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

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

The Commission bases its proposal on Article 114(1) TFEU. This provision allows approximation measures aimed at improving the conditions for the establishment and functioning of the internal market. The measures must “genuinely have that object, actually contributing to the elimination of obstacles to the free movement of goods or to the freedom to provide services, or to the removal of distortions of competition”. ¹⁴ Some of the measures proposed by the Commission, however, do not aim at improving the conditions of the internal market, but have as their only objective the protection of public health.

For example, it is difficult to see how the proposed (de facto) ban on menthol and on slim cigarettes could improve the functioning of the internal market. It is true that even prohibitions may, in certain circumstances, be regarded as harmonising measures, but this is

¹⁴ Case C-491/01, British American Tobacco (Investments) and Imperial Tobacco, paragraph 60.
only the case where "there are obstacles to trade or it is likely that such obstacles will emerge in future." Currently, however, not a single Member State has banned slim cigarettes or menthol or is even considering it. Thus, the ban will neither remove nor prevent the emergence of obstacles to fundamental freedoms.

As reflected in the recitals of the Commission’s proposal, the true aim of these measures is the achievement of a higher level of health protection. It is feared that menthol and slim cigarettes might be particularly attractive to young people. While the protection of health is of the utmost importance, it is up to the Member States and not the European Union to take measures in that regard. Article 168(5) TFEU explicitly excludes any harmonisation regarding measures "having as their direct objective the protection of public health regarding tobacco". The Commission can only take a high level of health protection as a basis pursuant to Article 114(3) TFEU if the requirements of Article 114(1) TFEU are fulfilled. Otherwise, the European Union could circumvent the clear division of competences resulting from Article 168(5) TFEU.

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

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

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

---

15 Case C-210/03, Swedish Match, paragraphs 30, 33.
16 There is also no obligation to ban menthol only because other flavours are banned. The Commission’s proposal makes reference to a decision of a WTO Appellate Body (WTO Appellate Body, AB-2012-1, United States – Measures Affecting the Production and Sale of Clove Cigarettes (DS406)). This decision, however, only said that menthol and clove cigarettes were, under the specific circumstances of the case, “like products” and that they could not be treated differently. The WTO Appellate Body did not reason that the US could not distinguish between menthol and other characteristic flavours such as fruit and candy flavours.
17 See e.g. recital 15: “A number of studies indicated that mentholated tobacco products can facilitate inhalation as well as smoking uptake among young people.” and recital 23: “A recent study has also shown that smokers of slim cigarettes were more likely to believe that their own brand might be less harmful. This should be addressed.”
18 See C-491/01, British American Tobacco (Investments) and Imperial Tobacco, paragraph 62.
19 Case C-491/01, British American Tobacco (Investments) and Imperial Tobacco, paragraph 132.
their other functions such as its advertising function. This would also not be in accordance with national constitutional law as well as international treaties such as the TRIPS Agreement.

Bearing in mind the impact on intellectual property rights, it is more than surprising that the Commission did not even consider less restrictive measures such as smaller health warnings. Taking into account the importance of intellectual property rights and legitimate health objectives, it is suggested that health warnings should cover 50% of the front and back surface. This would also be in line with the FCTC, the implementation of which is one of the aims of the Commission's proposal. Pursuant to Article 11(1) of the FCTC, health warnings describing the harmful effects of tobacco use "should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas".

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

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

---

20 See for example the judgment of the German Federal Constitutional Court, BVerGE 95, 173, paragraph 70.
21 See e.g. Article 8.1 and 20 TRIPS. Contrary to what is sometimes asserted, the decision of the Australian High Court of 15 August 2012 regarding the compatibility of the so-called plain packaging rules with the Australian Constitution does not in any way suggest that plain packaging or similar measures would be in accordance with European law. Pursuant to section 51 of the Australian Constitution, a law violates the Australian Constitution if it deprives a person or company from its property and provides the Australian government with some proprietary benefit from that property. The plain packaging requirement was upheld because the Australia had not “acquired” the property. However, the Court found that plain packaging does indeed “deprive” tobacco manufacturers of their property. Under Article 17 of the Charter and thus EU law, an “acquisition” of property is no precondition for a breach of the right to property – a deprivation is sufficient. Therefore, if anything, the judgment of the Australian High Court speaks against the admissibility of similar measures under EU law.
22 Relying on the strict jurisprudence of the CJEU, several national courts have already held that e-cigarettes cannot be qualified as a medicinal product by function under the Medicinal Products Directive, see e.g. Oberverwaltungsgericht Nordrhein-Westfalen, 24 April 2012, 16 L 2043/11.
23 Article 18 also lacks a valid legal base as it is in no way aimed at improving the conditions for the establishment and functioning of the internal market. Pursuant to the Commission, the provision will allow NCP to move freely across borders as they would benefit from the mutual recognition procedure under the Medicinal Products Directive.
Finally, the Commission’s proposal contains a large number of provisions delegating powers to the Commission. However, pursuant to Article 290 TFEU, a delegation of powers is only possible with regard to non-essential elements of the legislative proposal. Some of the proposed provisions providing for delegated acts do not fulfill this requirement. For example, Article 3(2) in conjunction with Article 2(19) would grant the Commission to set the maximum yield of nicotine for cigarettes placed on the market to 0, effectively prohibiting cigarettes for good.

**AMENDMENTS**

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

**Amendment 1**

Proposal for a directive
Recital 6

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>(6) The size of the internal market in tobacco and related products, the increasing tendency of manufacturers of tobacco products to concentrate production for the whole of the Union in only a small number of production plants within the Member States and the resulting significant cross-border trade of tobacco and related products calls for legislative action at Union rather than national level to achieve the smooth operation of the internal market.</em></td>
<td>deleted</td>
</tr>
</tbody>
</table>

Products Directive (Impact Assessment, page 8). However, this is already the case without Article 18, as any NCP which qualifies as a medicinal product is already now subject to the Medicinal Products Directive. The only effect Article 18 has is that it prohibits the placing on the market of NCP that are not authorised pursuant to the Medicinal Products Directive.
Amendment 2

Proposal for a directive
Recital 11

*Text proposed by the Commission*

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

*Amendment*

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

Amendment 3

Proposal for a directive
Recital 14

*Text proposed by the Commission*

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

*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.
palatability, create the impression that the tobacco products have health benefits, are associated with energy and vitality or have colouring properties.

Amendment 4
Proposal for a directive
Recital 15

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

Amendment
(15) The likelihood of diverging regulation is further increased by concerns over tobacco products, including smokeless tobacco products, having a characterising flavour other than tobacco and traditional flavours such as menthol, which may facilitate uptake of tobacco consumption or affect consumption patterns.

Amendment 5
Proposal for a directive
Recital 16

Text proposed by the Commission
(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufactures to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives

Amendment
(16) The prohibition of tobacco products with characterising flavours does not prohibit the use of individual additives altogether, but obliges the manufactures to reduce the additive or the combination of additives to such an extent that the additives no longer result in a characterising flavour. The use of additives
necessary for manufacturing of tobacco products should be allowed, as long as they do not result in a characterising flavour. The Commission should ensure uniform conditions for the implementation of the provision on characterising flavour. Independent panels should be used by the Member States and by the Commission to assist in such decision making. The application of this Directive should not discriminate between different tobacco varieties.

Amendment 6

Proposal for a directive
Recital 23

Text proposed by the Commission

(23) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimension of the warnings as well as regarding certain aspects of the appearance of the tobacco package, including the opening mechanism. The package and the products may mislead consumers, in particular young people, suggesting that products are less harmful. For instance, this is the case with certain texts or features, such as 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', '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.

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' or 'organic'.
Amendment 7
Proposal for a directive
Recital 25

Text proposed by the Commission

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

Amendment

deleted

Amendment 8
Proposal for a directive
Recital 26

Text proposed by the Commission

(26) Considerable volumes of illicit products, which do not comply with the requirements laid down in Directive 2001/37/EC, are placed on the market and indications are that these volumes might increase. Such products undermine the free circulation of compliant products and the protection provided for by tobacco control legislations. In addition, the FCTC obliges the Union to fight against illicit products, as part of a comprehensive tobacco control policy. Provision should thus be made for unit packets of tobacco products to be marked in a unique and secure way and their movements to be recorded so that these products can be tracked and traced in the Union and their compliance with this Directive can be monitored and better enforced. In addition, provision should be made for the introduction of security features that will facilitate the verification 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 of tobacco products to be marked in a unique and secure way and their movements to be recorded so that these products can be tracked and traced in the Union and their compliance with this Directive can be monitored and better enforced.
Amendment 9
Proposal for a directive
Recital 27

Text proposed by the Commission

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

Amendment

(27) An interoperable tracking and tracing system should be developed. For an initial period only cigarettes and roll-your-own tobacco should be subjected to the tracking and tracing system. This would allow producers of other tobacco products to benefit from the experiences gained in the meantime.

Amendment 10
Proposal for a directive
Recital 29

Text proposed by the Commission

(29) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC confirmed this prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden derogation from this prohibition. The prohibition of the sale of oral tobacco should be maintained in order to prevent the introduction to the internal market of a product that is addictive, has adverse health effects and is attractive to young people. For other smokeless tobacco products that are not produced for the mass market, a strict labelling and ingredients regulation is considered sufficient to contain market

Amendment

(29) Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products and the prohibition of the marketing of certain types of tobacco for oral use prohibited the sale in the Member States of certain types of tobacco for oral use. Directive 2001/37/EC confirmed this prohibition. Article 151 of the Act of Accession of Austria, Finland and Sweden grants the Kingdom of Sweden derogation from this prohibition. Upholding the ban on tobacco products for oral use should however not affect historically traditional tobacco products for oral use, which may be allowed by individual Member States. For other smokeless tobacco products that are not produced for the mass market, a strict labelling and ingredients regulation is considered sufficient to contain market.
regulation is considered sufficient to contain market expansion beyond their traditional use. 

Amendment 11

Proposal for a directive
Recital 30 a (new)

*Text proposed by the Commission*

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

Amendment 12

Proposal for a directive
Recital 33

*Text proposed by the Commission*

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

Amendment 13

Proposal for a directive
Recital 34
(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by Directive 2001/83/EC are fulfilled.

Amendment 14

Proposal for a directive
Recital 35

(35) Labelling provisions should be introduced for nicotine containing products below the threshold set out in this Directive drawing the attention of consumers to potential health risks.

Amendment

deleted
Amendment 15

Proposal for a directive
Recital 35 a (new)

Text proposed by the Commission

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

Amendment

Amendment 16

Proposal for a directive
Recital 38

Text proposed by the Commission

(38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products and reviewing the nicotine levels for nicotine containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.
consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Amendment 17

Proposal for a directive
Recital 40

Text proposed by the Commission

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

Amendment 18

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

Amendment 19
Proposal for a directive
Article 2 – paragraph 1 – point 3

(3) ‘age verification system’ means a computing system that unambiguously confirms the consumer’s age in electronic form according to national requirements; it can also mean a physical verification system in form accordant to national requirements, that unambiguously confirms the consumer age in situations other than direct purchase for example by the usage of vending machines;
Amendment 20

Proposal for a directive
Article 2 – point 4

Text proposed by the Commission

(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;

Amendment

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

Justification

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

Amendment 21

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

Text proposed by the Commission

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

Amendment

deleted

Amendment 22

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

Text proposed by the Commission

(25) ‘place on the market’ means to make products available to consumers located in

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;

Amendment 23
Proposal for a directive
Article 2 – paragraph 1 – point 36 a (new)

Text proposed by the Commission

Amendment

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

Amendment 24
Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission

Amendment

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the maximum yields laid down in paragraph 1, taking into account scientific development and internationally agreed standards.

deleted

Justification

The establishment of maximum yields for tar, nicotine and carbon monoxide is an essential element of the proposed directive. Consequently, it should be subject to the ordinary legislative procedure.
Amendment 25

Proposal for a directive
Article 3 – paragraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

Justification

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

Amendment 26

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
</table>
| Member States shall prohibit the placing on the market of tobacco products with a characterising flavour. | Member States shall prohibit the placing on the market of tobacco products with a characterising flavour, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden, where it
was unequivocally proved by scientific studies that the additive increases toxicity of the products or facilitate addiction.

**Justification**

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

**Amendment 27**

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

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

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

**Amendment 28**

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

*Text proposed by the Commission*  
*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.*

*Amendment*  
deleted

**Justification**

*The decision whether a tobacco product falls within the scope of paragraph 1 and is therefore to be prohibited is not a decision for the Commission, but for the legislator to make.*
Amendment 29
Proposal for a directive
Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission
The Commission shall adopt by means of implementing acts uniform rules on the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Amendment
deleted

Amendment 30
Proposal for a directive
Article 6 – paragraph 3

Text proposed by the Commission
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.

Amendment
deleted

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

Amendment 31
Proposal for a directive
Article 6 – paragraph 5
Text proposed by the Commission

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

Amendment

5. Member States shall prohibit the use of **characterising** flavourings in the components of tobacco products such as filters, papers, packages, capsules or any technical features allowing modification of flavour or smoke intensity, **where it was proved by scientific studies that the additive increases toxicity of the products or facilitate addiction**. Filters and capsules shall not contain tobacco.

Amendment 32

Proposal for a directive
Article 6 – paragraph 9

Text proposed by the Commission

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

Amendment

delete

Justification

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

Amendment 33

Proposal for a directive
Article 6 – paragraph 10
10. Tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco products shall be exempted from the prohibitions laid down in paragraphs 1 and 5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to withdraw this exemption if there is a substantial change of circumstances as established in a Commission report.

**Amendment 34**

**Proposal for a directive**

**Article 8 – paragraph 3**

**Text proposed by the Commission**

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

**Amendment**

3. For cigarette packets the general warning and the information message shall be printed on the lateral sides of the unit packets. For roll-your-own tobacco the information message shall be printed on the surface that becomes visible when opening the unit packet. Both the general warning and the information message shall cover 50% of the surface on which they are printed.

**Justification**

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

**Amendment 35**

**Proposal for a directive**

**Article 8 – paragraph 4 – point b**
Text proposed by the Commission

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

Amendment

deleted

Justification

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

Amendment 36

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

Text proposed by the Commission

(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking;

(b) include smoking cessation information such as phone numbers, e-mail addresses and/or Internet sites designed to inform consumers about the programmes available to support those who want to stop smoking; those platforms designed to inform consumers about the programmes available to support those who want to stop smoking should play active role in promoting knowledge on the severe effects of smoking among children and youth as those most at risk of becoming dependent on tobacco;

Amendment 37

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

Text proposed by the Commission

(c) cover 75 % of the external area of both the front and back surface of the unit

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

Amendment 38
Proposal for a directive
Article 9 – paragraph 1 – point e

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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;</td>
<td>(e) be positioned in the same direction as any other information appearing on the packaging;</td>
</tr>
</tbody>
</table>

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

Amendment 39
Proposal for a directive
Article 9 – paragraph 1 – point g – introductory part

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(g) for unit packets of cigarettes, respect the following dimensions:</td>
<td>deleted</td>
</tr>
</tbody>
</table>

Justification
The prescription of a minimum size for health warnings effectively leads to a minimum size of packs. This reduces consumer choice and may infringe intellectual property rights. With a view to the uncertain potential benefits of a minimum size of packs the measure is not in accordance with the principle of proportionality.
Amendment 40

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

Text proposed by the Commission

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

Amendment 41

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

Text proposed by the Commission

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

Amendment 42

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

Text proposed by the Commission

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

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

Amendment 43

Proposal for a directive
Article 10 – paragraph 5

Text proposed by the Commission

5. The Commission shall be empowered to deleted
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.

Justification

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

Amendment 44

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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;</td>
<td>(a) promotes a tobacco product by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, in particular by suggesting that a particular tobacco product is less harmful than others unless independent scientific evidence substantiates a significantly reduced health risk, or has vitalising, energetic, healing, rejuvenating, natural, organic or otherwise positive health effects;</td>
</tr>
</tbody>
</table>

Justification

Product description must not be misleading.

Amendment 45

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c) refers to flavour, taste, any flavourings or other additives or the absence thereof;</td>
<td>deleted</td>
</tr>
</tbody>
</table>

RR\944712EN.doc 283/320 PE508.085v05-00
Justification

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

Amendment 46

Proposal for a directive
Article 12 – paragraph 2

Text proposed by the Commission

2. Prohibited elements and features may include but are not limited to texts, symbols, names, trade marks, figurative or other signs, misleading colours, inserts or other additional material such as adhesive labels, stickers, inserts, scratch-offs and sleeves or relate to the shape of the tobacco product itself. Cigarettes with a diameter of less than 7.5 mm shall be deemed to be misleading.

Amendment

deleted

Justification

The provision relating to prohibited items and features is likely to lead to legal uncertainty and should therefore be deleted. Article 12(1) provides sufficient guidance as it clearly prohibits any product description which is misleading. The proposed de facto ban of cigarettes with a diameter of less than 7.5 mm lacks any legal base and was not even subject to a proper impact assessment by the Commission. In addition, this measure would violate the intellectual property rights of manufacturers.

Amendment 47

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The length of one side of the bottom of a unit packet of cigarettes placed on the market shall be at least double that of its adjacent sides. A unit packet of any other
that covers the opening. The flap of the pouch shall cover at least 70% of the front of the packet. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing at least 40 g.

Amendment 48

Proposal for a directive
Article 13 – paragraph 2

Text proposed by the Commission

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

Amendment 49

Proposal for a directive
Article 13 – paragraph 3

Text proposed by the Commission

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.

Amendment 50

Proposal for a directive
Article 13 – paragraph 4
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 51

Proposal for a directive
Article 14 – paragraph 1

**Text proposed by the Commission**

1. Member States shall ensure that all unit packets of tobacco products shall be marked with a unique identifier. In order to ensure their integrity, unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or by the opening of the packet. In relation to products manufactured outside the Union the obligations laid down in this Article apply only to those destined to or placed on the Union market.

**Amendment**

1. For the purposes of effective tracking and tracing, Member States shall require that unique, secure and non-removable identification markings hereafter called unique identification markings, such as codes or stamps, are affixed to or form part of all unit packets and packages and any outside packaging of cigarettes. In order to ensure their integrity, unique identifiers shall be irremovably printed/affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or by the opening of the packet. In relation to products manufactured outside the Union the obligations laid down in this Article apply only to those destined to or placed on the Union market.

Amendment 52

Proposal for a directive
Article 14 – paragraph 2 – point e
Text proposed by the Commission Amendment

(e) the product name;

(e) the product description;

Justification

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

Amendment 53

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

Text proposed by the Commission Amendment

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

(i) the shipment date, the shipment destination, point of departure and consignee;

Amendment 54

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

Text proposed by the Commission Amendment

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

(j) the identity of any known subsequent purchaser;

Amendment 55

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

Text proposed by the Commission Amendment

(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

(k) the invoice, order number and payment records of the first customer who is not affiliated with the manufacturer.
Amendment 56

Proposal for a directive
Article 14 – paragraph 3

Text proposed by the Commission

3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the last economic operator before the first retail outlet, record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit from their possession. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging, provided that tracking and tracing of unit packets remains possible.

Amendment

3. Member States shall ensure that all economic operators involved in the trade of tobacco products from the manufacturer to the first client (buyer), record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit from their possession. This obligation can be fulfilled by recording in aggregated form, e.g. of outside packaging, provided that tracking and tracing of unit packets remains possible.

Justification

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

Amendment 57

Proposal for a directive
Article 14 – paragraph 4

Text proposed by the Commission

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,

Amendment

4. Member States shall ensure that manufacturers of tobacco products provide all economic operators involved in the trade of tobacco products from the manufacturer to the first customer who is not affiliated with the manufacturer, with the necessary equipment allowing for the recording of the tobacco products purchased, sold to the first customer who is not affiliated with the manufacturer, stored, transported or
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. otherwise handled. The equipment shall be able to read and transmit the data electronically to a data storage facility pursuant to paragraph 6.

Amendment 58

Proposal for a directive
Article 14 – paragraph 6

Text proposed by the Commission

6. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall be physically located on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be approved and monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. Member States shall ensure full transparency and accessibility of the data storage facilities for the competent authorities of the Member States, the Commission and the independent third party on a permanent basis. In duly justified cases Member States or the Commission can provide manufacturers or importers access to this information, provided commercially sensitive information remains adequately protected in conformity with the relevant national and Union legislations.

Amendment

6. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party, which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall be physically located and accessible on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the 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.

Justification

Currently, all genuine cigarettes in the EU are already tracked by the big manufacturers, based on Agreements concluded with the Commission and each Member State. Tracking the cigarettes all the way and knowing the intended shipment route after the first sale is technically impossible, that is why it is not provided by the WHO FCTC Protocol.

Description
of the security tamper should focus on reliability not on size, colour or other features. Holograms, for instance, do not provide security (they can be easily counterfeit and create the appearance of authenticity).

Amendment 59

Proposal for a directive
Article 14 – paragraph 8

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 $1\text{ cm}^2$, 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.</td>
<td>8. In addition to the unique identifier, Member States shall require that all unit packets of tobacco products which are placed on the market carry a visible, tamper proof security feature, which shall be irremovably printed or affixed, indelible and in no way hidden or interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation.</td>
</tr>
</tbody>
</table>

Justification

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

Amendment 60

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c) to define the technical standards for the security feature and their possible rotation and to adapt them to scientific, market and technical development.</td>
<td>deleted</td>
</tr>
</tbody>
</table>

PE508.085v05-00  290/320  RR\944712EN.doc
### Amendment 61

**Proposal for a directive**  
**Article 14 – paragraph 10**

<table>
<thead>
<tr>
<th><strong>Text proposed by the Commission</strong></th>
<th><strong>Amendment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>10. Tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the application of paragraph 1 to 8 during a period of 10 years following the date referred to in paragraph 1 of Article 25.</td>
</tr>
</tbody>
</table>

### Amendment 62

**Proposal for a directive**  
**Article 15 – paragraph 1**

<table>
<thead>
<tr>
<th><strong>Text proposed by the Commission</strong></th>
<th><strong>Amendment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.</td>
<td>Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden. <em>This ban should, however, not affect traditional tobacco products for oral use, which may be allowed by individual Member States on cultural or historical grounds.</em></td>
</tr>
</tbody>
</table>

### Amendment 63

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

<table>
<thead>
<tr>
<th><strong>Text proposed by the Commission</strong></th>
<th><strong>Amendment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2a. In connection with the marketing of reduced-harm tobacco products, Member States shall introduce an authorisation system and charge a proportionate fee. They shall also specify rules applicable to the scientific assessment of risk and the</td>
<td></td>
</tr>
</tbody>
</table>
type of evidence to be presented, including, but not only, clinical and non-clinical information and other available studies examining how consumers use and perceive the product. Member States may diverge from the requirements laid down by this Directive in relation to authorised reduced-harm products in order to illustrate their less harmful nature.

Amendment 64
Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment

3. Novel tobacco products placed on the market shall respect the requirements set out in this Directive, unless otherwise authorised as provided for in paragraph 2 of this Article. The provisions applicable depend on whether the products fall under the definition of smokeless tobacco product in point (29) of Article 2 or tobacco for smoking in point (33) of Article 2.

Amendment 65
Proposal for a directive
Article 18

Text proposed by the Commission

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

(a) products with a nicotine level

Amendment

1. Nicotine-containing products that are presented as having properties for treating or preventing disease in human beings, other than through any message specified in paragraph 3, may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.
exceeding 2 mg per unit, or
(b) products with a nicotine concentration exceeding 4 mg per ml or
(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.

1 a. This Directive shall not apply to nicotine-containing products authorised pursuant to Directive 2001/83/EC.
1 b. For nicotine-containing products where paragraph 1 does not apply, the products may be placed on the market if they comply with this Directive
1 c. Member States shall ensure that nicotine containing products comply with European Union consumer protection, safety and other relevant legislation in force
1 d. No later than 12 months from entry into force of this Directive, each Member State shall provide the Commission with a report on the measures it has taken to implement and enforce the legislation set out in [new] Annex IV as it applies to nicotine containing products and the effectiveness of those measures.
1 e. Member States shall ensure that nicotine-containing products are not sold to persons below the national legal age for purchasing tobacco products.

2. The Commission shall be empowered to 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 in regard to nicotine-containing products.

3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:
3. Each unit packet and any outside packaging of nicotine-containing products which do not fall under the scope of Directive 2001/83/EC shall carry the
This product contains nicotine **and can** damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:

(a) be printed on the two largest surfaces of the unit packet and any outside packaging;

(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

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

**Justification**

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

**Amendment 66**

**Proposal for a directive**

**Article 20 – paragraph 3**

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

**Amendment 67**

**Proposal for a directive**  
**Article 22 – paragraph 2**

**Text proposed by the Commission**

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

**Amendment**

2. The power to adopt delegated acts referred to in Articles 4(3), 4(4), 8(4), 9(3), 11(3) and 14(9) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

**Justification**

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

**Amendment 68**

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

**Text proposed by the Commission**

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of

**Amendment**

3. The delegation of powers referred to in Articles 4(3), 4(4), 8(4), 9(3), 11(3) and 14(9) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
any delegated acts already in force.

**Amendment 69**

**Proposal for a directive**
**Article 22 – paragraph 5**

*Text proposed by the Commission*

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

*Amendment*

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

**Amendment 70**

**Proposal for a directive**
**Article 23 – paragraph 1 a (new)**

*Text proposed by the Commission*

1a. No later than 2 years from the date specified in Article 25 paragraph 1, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the economic and social consequences of the application of this Directive.

*Amendment*
Amendment 71

Proposal for a directive
Article 24 – paragraph 2

Text proposed by the Commission

| 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. |

Amendment

| deleted |

Justification

The procedure foreseen in Article 24(2) of the proposal is not in accordance with the TFEU. The procedure foreseen by the Commission matches the one foreseen in Article 114(5) and (6) TFEU which is explicitly only applicable to measures relating to the protection of the environment or the working environment.
Amendment 72

Proposal for a directive
Article 25 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [Publications Office, please insert the exact date: entry into force + 36 months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

Amendment 73

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

Text proposed by the Commission

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

Amendment

(b) nicotine containing products;

Amendment 74

Proposal for a directive
Annex I a (new)

Text proposed by the Commission

ANNEX I a
EU legislation applicable to nicotine-containing products:
General safety:
General Product Safety Directive 2001/95/EC
The RAPEX system - notification and alerts of dangerous products
Packaging and labelling:

Amendment


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

Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU (where appropriate)
Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU

Batteries Directive 2006/66/EC

Weights and measures:
Making-up by weight or by volume of certain prepackaged products - Directive 76/211/EEC
Nominal Quantities for Prepacked Products Directive 2007/45/EC

Commercial practice
Distance Selling Directive 97/7/EC
Directive on Electronic Commerce 2000/31/EC
Misleading and Comparative Advertising Directive 2006/114/EC

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

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>References</strong></td>
<td>COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)</td>
</tr>
<tr>
<td><strong>Committee responsible</strong></td>
<td>ENVI 15.1.2013</td>
</tr>
<tr>
<td><strong>Date announced in plenary</strong></td>
<td>ENVI 15.1.2013</td>
</tr>
<tr>
<td><strong>Opinion by</strong></td>
<td>JURI 15.1.2013</td>
</tr>
<tr>
<td><strong>Date announced in plenary</strong></td>
<td>JURI 15.1.2013</td>
</tr>
<tr>
<td><strong>Rapporteur</strong></td>
<td>Klaus-Heiner Lehne 22.1.2013</td>
</tr>
<tr>
<td><strong>Date appointed</strong></td>
<td>Klaus-Heiner Lehne 22.1.2013</td>
</tr>
<tr>
<td><strong>Discussed in committee</strong></td>
<td>24.4.2013 30.5.2013 19.6.2013</td>
</tr>
<tr>
<td><strong>Date adopted</strong></td>
<td>20.6.2013</td>
</tr>
</tbody>
</table>
| **Result of final vote** | +: 14  
-: 6  
0: 4 |
| **Substitute(s) present for the final vote** | Sergio Gaetano Cofferati, Eva Lichtenberger, Angelika Niebler, Axel Voss |
| **Substitute(s) under Rule 187(2) present for the final vote** | Frédérique Ries, Nikolaos Salavrakos, Jacek Włosowicz |
OPINION OF THE COMMITTEE ON LEGAL AFFAIRS ON DELEGATED ACTS

Mr Matthias Groote
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS


Dear Mr Chair,

The Committee on Legal Affairs decided on 6 June 2013, pursuant to Rule 37a(3), to consider a number of questions concerning the use of delegated and implementing acts in the above proposal.

The committee considered the above questions at its meeting of 20 June 2013.

At its meeting of 9 July 2013 the Committee on Legal Affairs adopted the following opinion unanimously.

Yours sincerely,

Klaus-Heiner Lehne

I - Background


24 The following were present: Raffaele Baldassarre (Vice-Chair), Luigi Berlinguer, Sebastian Valentin Bodu (Vice-Chair), Piotr Borys, Françoise Castex (Vice-Chair), Christian Engström, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Klaus-Heiner Lehne (Chair), Jörg Leichtfried (pursuant to Rule 187(2)), Eva Lichtenberger, Antonio López-Istúriz White, Jiří Maštálka, Bernhard Rapkay, Rebecca Taylor, Alexandra Thein, Axel Voss, Cecilia Wikström, Tadeusz Zwiefka, Anna Záborská (pursuant to Rule 187(2)).
concerning the manufacture, presentation and sale of tobacco products.

The aim of the Proposal is to approximate the laws, regulations and administrative provisions of the Member States within five policy areas:

Smokeless tobacco products and extension of the product scope (i.e. nicotine containing products and herbal products for smoking);

1. Packaging and labeling;
2. Ingredients/additives;
3. Cross-border distance sales; and
4. Traceability and security features.

Whereas the 2001 directive only provided for implementing powers to the Commission when it came to measures concerning illustration of health consequences and adaptation to scientific and technical progress of measurement methods, the majority of the areas for which the Commission is suggesting delegated or implementing acts in the current proposal were governed by the following Article (emphasis added):

*Article 11*

*Report*

*No later than 31 December 2004, and every two years thereafter, the Commission shall submit to the European Parliament, the Council and the Economic and Social Committee a report on the application of this Directive.*

*With a view to drafting the report referred to in the first paragraph, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available.*

*On submission of the first report, the Commission shall indicate in particular the features which should be reviewed or developed in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, and shall pay special heed to:*

— subsequent reduction of the maximum yields laid down in Article 3(1),
— possible links between these yields,
— improvements in health warnings, in terms of size, position and wording,
— new scientific and technical information regarding labelling and the printing on cigarette packets of photographs or other illustrations to depict and explain the health consequences of smoking,
— methodologies for more realistically assessing and regulating toxic exposure and harm,
— evaluation of the addictive effects of those ingredients which encourage
addiction,
— evaluation of tobacco products which may have the potential to reduce harm,
— development of standardised testing methods to measure the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide,
— toxicological data to be required from manufacturers on ingredients and the manner in which they should be tested in order to allow public health authorities to assess their use,
— development of standards concerning products other than cigarettes, in particular rolling tobacco.

The report shall also examine the links between the labelling requirements laid down in Article 5 and consumer behaviour. That report shall be accompanied by any proposals for amendments to this Directive which the Commission deems necessary to adapt it to developments in the field of tobacco products, to the extent necessary for the establishment and operation of the internal market, and to take into account any new development based on scientific facts and developments on internationally agreed product standards.

II - Background to delegated and implementing acts

Please see Section II of the enclosed Opinion of the Committee on Legal Affairs of 27 April 2012 to the Committee on Agriculture concerning the regulation amending Regulation (EC) No 834/2007 on organic production and labelling of organic products, and the working document drawn up in the context of the follow-up on the delegation of legislative powers and the control by Member States of the Commission's exercise of implementing powers (rapporteur: József Szájer), which provide for an extensive background to both delegated and implementing acts.

III - Parliament's position on the delegation of legislative power

The demarcation between delegated and implementing acts has been the subject of some controversy in a number of legislative procedures following the entry into force of the Lisbon Treaty. The Council has insisted on the use of implementing acts in order better to influence the preparatory phase of such acts through the experts from the Member States sitting in the relevant committees provided for in the Implementing Acts Regulation. In the preparation of delegated acts there is no formal role for national experts. Furthermore, the role, influence and prerogatives of Parliament are far greater when it comes to delegated acts, with the possibility of objecting to a proposed delegated act and revoking a delegation being the strongest tools in its possession. When it comes to implementing acts, the powers of Parliament are limited to a right of scrutiny, and the Commission may adopt a proposed implementing act notwithstanding any objection from Parliament.

The choice of the correct instrument has significant consequences not only for the possibility of Parliament to exercise its right of control or scrutiny, but also for the validity of the legal act itself. The President of the Commission, in a letter to the President of Parliament, has
stressed that the delineation between implementing and delegated acts is not a matter of political choice, and that the starting point of any analysis therefore must be the legal criteria established in Articles 290 and 291 TFEU. The Commission has therefore sought clarification from the Court of Justice on the delineation issue in a case where it considered that the wrong kind of act had been chosen.

In order to establish a horizontal political position on the issue of delegated acts to protect Parliament's prerogatives and avoid further risk of legal challenges and the risk of annulment of legislative acts with an incorrect choice of delegated or implementing acts, the Conference of Presidents endorsed in 2012 the following 4-step approach with a view to ensuring that Parliament is capable of exercising to the full the powers conferred on it by the Lisbon Treaty:

1. Choice of the right instrument;
2. Strengthening the Member States' role in the preparatory phase of delegated acts;
3. Inclusion in the basic act ("codecision");
4. Adoption of Parliament's position without a first reading agreement.

As a last step, where delegated acts could not be included in a particular file, although it had been established that they should, this approach calls for refusing to submit the file to the plenary as such, and that further horizontal negotiations with the Council would then be required.

IV - Analysis

In the absence of any case law from the Court of Justice on the question of the demarcation between delegated and implementing acts, the starting point for any analysis must be the wording of the Treaty itself. Article 290 TFEU only permits a delegation of legislative power for the adoption of "non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act" (emphasis added).

To examine whether those criteria are fulfilled here, it is necessary to examine the nature of the power in question on a case-by-case basis. Please see the Annex.

V - Conclusion and recommendation

---

25 Letter of 3 February 2012 from President Barroso to President Schulz.
26 On 19 September 2012, the Commission brought an action to the Court of Justice against the Parliament and the Council seeking to annul an article in the Biocidal Products Regulation which provides for the adoption of measures establishing the fees payable to the European Chemicals Agency (ECHA) by an implementing act rather than by a delegated act. The Commission argues that since the article in question seeks to supplement certain non-essential elements of the legislative act, and with regard to the nature of the delegation and the purpose of the act to be adopted under those powers, such an act ought therefore to be adopted in accordance with the procedure laid down in Article 290 TFEU and not the procedures laid down in Article 291 TFEU. Case C-427/12, Commission v European Parliament and Council of the European Union.
27 Political guidelines on a horizontal approach within Parliament on dealing with delegated acts (Letter of 19 April 2012 from the Chair of the CCC to the President of Parliament).
In light of the foregoing reasoning, the Committee on Legal Affairs should take the view that with the exception of the proposed provisions on delegated acts in Paragraphs 3 and 4 of Article 4 and Points (b) and (c) of Article 14(9) of the proposal concerning methods of measurement, none of the suggested provisions on delegated acts should be accepted by Parliament.

All other suggested provisions providing for the adoption of delegated acts should be deleted and the substantive content included in the basic act. In certain cases, delegated acts could be used to make determinations or implementing acts to provide uniform implementing conditions, but only where the criteria are further specified in the basic act. Alternatively, the Commission could be required to draw up a report within a certain time-span to the co-legislators, with possible accompanying proposals for amending legislative acts, as in the 2001 Directive.

The model recitals and articles from the Common Understanding and the Implementing Acts Regulation seem to have been respected. The current wording of Recital 37 does not however correspond to what the Commission is suggesting in Article 6(2) of the proposal.

In view of the political guidance endorsed by the Conference of Presidents, the Committee on Legal Affairs therefore calls on the Committee on the Environment, Public Health and Food Security to take these recommendations into consideration when drawing up its report. If the Council takes a position contrary to these recommendations and favours delegated or implementing acts where the criteria therefore are not met, the Committee should inform the Council that the file will not be submitted to the plenary as such, and if the Council still persists, the Committee should recommend the adoption of Parliament's position without a first reading agreement.
## Annex - Provisions containing delegated and implementing acts

<table>
<thead>
<tr>
<th>Article</th>
<th>Relevant text</th>
<th>Objectives, content and scope</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recital 37</td>
<td>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.</td>
<td>This statement is contrary to the own-initiative determinations which are suggested in Article 6(2) below concerning characterising flavour. The recital only mentions methodology. A recital justifying the choice of the examination procedure seems to be missing.</td>
<td>This recital corresponds to the correct template, but fails to state correctly what the Commission intends to do in Article 6(2). It must be adapted to the determinations below. A recital on either advisory or examination procedure should be added.</td>
</tr>
<tr>
<td>Recital 38</td>
<td>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</td>
<td>The stated objective only covers &quot;keep up with technical, scientific and international developments&quot;, whereas the majority of the provisions on delegated acts suggested below do not pertain to this objective, but rather to the too vague and broad objective of making the Directive &quot;fully operational&quot;.</td>
<td>The objective of making the Directive &quot;fully operational&quot; must be deleted, and the objectives of the delegation should be adapted to the determinations below. The content and scope</td>
</tr>
</tbody>
</table>
| Article 3  
| Maximum tar, nicotine, carbon monoxide and other yields |
|---|---|---|
| 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. | In view of the public health aim, the question of level of harmful substances touches upon essential elements. The scope of potential prohibition is unlimited. | Delete, not appropriate to delegate. Should be specified in the basic act. |
| 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 Parliament would effectively be left out of setting the level of harmful substances, which touches upon essential elements. The scope of potential prohibition is unlimited. | | Delete, not appropriate to delegate. Should be specified in the basic act. |

The standard recital in the Common Understanding does not include the words "in particular" when it comes to setting out the content and the scope. Important aspects are therefore left out.

The sentence on expert consultations is not included in the standard recital in the Common Understanding.

The sentence on expert consultations should be deleted, unless Parliament experts are explicitly mentioned.

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.

The standard recital in the Common Understanding does not include the words "in particular" when it comes to setting out the content and the scope. Important aspects are therefore left out.

The sentence on expert consultations is not included in the standard recital in the Common Understanding.
<table>
<thead>
<tr>
<th>Article 4</th>
<th>Measurement methods</th>
<th>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.</th>
<th>The purpose here is to adapt methods of measurement, which are only incidental to the obligation, which is contained in Article 3, and therefore constitute non-essential elements. Since those methods will apply equally to all manufacturers, the delegated acts will be of general application, and the Commission would be best placed to supplement or amend those elements. The word &quot;adapt&quot; should however not be used.</th>
<th>Delegated acts ok, but &quot;supplement or amend&quot; should be used rather than &quot;adapt&quot;.</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Member States shall notify the Commission of the methods of measurement that they use for other...</td>
<td>Same as for Article 4(3) above. Best practice from the Member...</td>
<td>Delegated acts ok, but &quot;supplement or amend&quot;...</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
emissions of cigarettes and for emissions of tobacco products other than cigarettes. Based on these methods, and taking into account scientific and technical developments as well as internationally agreed standards the Commission shall be empowered to adopt **delegated acts** in accordance with Article 22 to adopt and adapt methods of measurement.

<p>| Article 5 Reporting of ingredients and emissions | 3. The Commission shall, by means of <strong>implementing acts</strong>, lay down and if necessary update the format for the submission and dissemination of the information specified in paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21. | This is a question of providing uniform conditions for implementation. | Implementing acts ok. |
| Article 6 Regulation of ingredients | 2. The Commission shall at the request of a Member State or may on its own initiative determine by means of <strong>implementing acts</strong> 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 <strong>implementing acts</strong> 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. | This proposed text has nothing to do with uniform conditions for implementation. The Commission is rather giving itself an unlimited margin for appreciation. The wording is furthermore imprecise and touches upon essential elements. | Delete, not appropriate to use implementing acts. More detailed criteria should be specified in the basic act, and determinations could be made through delegated acts (see also JURI opinion on organic products). |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>to in Article 21.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>The Commission is giving itself an unlimited margin for appreciation concerning essential elements.</td>
<td>Delete, not appropriate to delegate. Better to set a date for a review by the Commission with a report to the co-legislators, possibly accompanied by proposals for amending legislative acts.</td>
</tr>
<tr>
<td>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.</td>
<td>Imprecise, could touch upon essential elements.</td>
<td>Delete, the obligation in Paragraph 7 is already clear.</td>
</tr>
<tr>
<td>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</td>
<td>The Commission is giving itself an unlimited margin for appreciation concerning essential elements.</td>
<td>Delete, not appropriate to delegate. Either specify in basic act or provide for future report with possible accompanying legislative proposals.</td>
</tr>
<tr>
<td>Article 8</td>
<td>Text warnings for tobacco for smoking</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------------------------</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>The Commission shall be empowered to adopt <strong>delegated acts</strong> in accordance with Article 22:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(a) to adapt the wording of the health warnings laid down in paragraphs 1 and 2 to scientific and market developments;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Article 9</th>
<th>Combined health warnings for tobacco for smoking</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>The Commission shall be empowered to adopt <strong>delegated acts</strong> in accordance with Article 22 to:</td>
</tr>
<tr>
<td></td>
<td>(a) adapt the text warnings listed in Annex I to this</td>
</tr>
</tbody>
</table>

|          | The wording of the warning text, which is proposed to be specified in the basic act, clearly touches upon essential elements. |
|          | Delete, not possible to delegate. |

|          | The Commission is giving itself an unlimited margin for appreciation concerning essential elements. |
|          | Delete, not appropriate to delegate. Either specify in basic act or provide for future report with possible accompanying legislative proposals. |

|          | The Commission is giving itself an unlimited margin for appreciation concerning essential elements. |
|          | Delete, not possible to delegate. |

|          | The wording of the warning text, which is proposed to be specified in the basic act, clearly touches upon essential elements. |
|          | Delete, not possible to delegate. |

|          | The wording of the warning text, which is proposed to be specified in the basic act, clearly touches upon essential elements. |
|          | Delete, not possible to delegate. |

|          | The wording of the warning text, which is proposed to be specified in the basic act, clearly touches upon essential elements. |
|          | Delete, not possible to delegate. |

<p>|          | The wording of the warning text, which is proposed to be specified in the basic act, clearly touches upon essential elements. |
|          | Delete, not possible to delegate. |</p>
<table>
<thead>
<tr>
<th>Smiling</th>
<th>Directive taking into account scientific and technical developments;</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)</td>
<td>Establish and adapt the picture library referred to in point (a) of paragraph 1 of this Article taking into account scientific and market developments;</td>
</tr>
<tr>
<td></td>
<td>The warning pictures clearly touch upon essential elements. Delete, not possible to delegate.</td>
</tr>
<tr>
<td>(c)</td>
<td>Define the position, format, layout, design, rotation and proportions of the health warnings;</td>
</tr>
<tr>
<td></td>
<td>The positioning of health warning is proposed to be specified in the basic act. The content of this point should be governed by the Directive itself.</td>
</tr>
<tr>
<td>(d)</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>The positioning of health warning is proposed to be specified in the basic act. The content of this point should be governed by the Directive itself.</td>
</tr>
</tbody>
</table>

**Article 10 Labelling of tobacco for smoking other than cigarettes and roll-your-own tobacco**

<p>| 5. | The Commission shall be empowered to adopt <strong>delegated acts</strong> 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. |
|    | The Commission can not be given the power to withdraw an exception, unless the criteria have been sufficiently specified. Here, the Commission is giving itself an unlimited margin for appreciation concerning essential elements. Delete, not possible to delegate. |
| Article 11 Labelling of smokeless tobacco products | 3. The Commission shall be empowered to adopt <strong>delegated acts</strong> in accordance with Article 22 to adapt the requirements in paragraphs 1 and 2 taking into account scientific and market developments. | The wording of the warning text, which is proposed to be specified in the basic act, clearly touches upon essential elements. | Delete, not possible to delegate. |
| Article 13 Appearance and content of unit packets | 3. The Commission shall be empowered to adopt <strong>delegated acts</strong> 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. | The Commission is giving itself an unlimited margin for appreciation concerning essential elements, in particular by the wording &quot;define more detailed rules&quot;. This is a rather a question of providing uniform conditions for implementation, based on criteria set in the basic act. | Delete, not possible to delegate. Alternatively implementing acts if further specified criteria in the basic act. |
| 4. The Commission shall be empowered to adopt <strong>delegated acts</strong> in accordance with Article 22 to make either cuboid or cylindrical 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. | The Commission is giving itself an unlimited margin for appreciation concerning essential elements, in particular by the wording &quot;make ... mandatory&quot;. This is a rather a question of providing uniform conditions for implementation, based on criteria set in the basic act. | Delete, not possible to delegate. Alternatively implementing acts if further specified criteria in the basic act. |
| Article 14 Traceability and | 9. The Commission shall be empowered to adopt <strong>delegated acts</strong> in accordance with Article 22: | The Commission is giving itself an unlimited margin for | Delete, not possible to delegate. Alternatively |
| security features | (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; appreciation concerning essential elements, in particular by the wording &quot;define the key elements&quot;. This is a rather a question of providing uniform conditions for implementation, based on criteria set in the basic act. implementing acts if further specified criteria in the basic act. | (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 These issues constitute non-essential elements of the proposal. Delegated acts ok. | (c) to define the technical standards for the security feature and their possible rotation and to adapt them to scientific, market and technical development. These issues concern non-essential elements of the proposal. Delegated acts ok. |
| Article 18 Nicotine-containing products | 2. The Commission shall be empowered to adopt <strong>delegated acts</strong> 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. In view of the public health aim, the question of level of harmful substances touches upon essential elements. The scope of potential prohibition is unlimited. Delete, not appropriate to delegate. Should be specified in the basic act. | 5. The Commission shall be empowered to adopt The wording of the warning text, Delete, not appropriate |</p>
<table>
<thead>
<tr>
<th><strong>delegated acts</strong> in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.</th>
<th>which is proposed to be specified in the basic act, clearly touches upon essential elements.</th>
<th>to delegate.</th>
</tr>
</thead>
</table>
| **Article 21 Committee procedure** | 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.  
   2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.  
   3. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request. | Parliament could take the position that the advisory procedure in Article 4 of Regulation (EU) No 182/2011 should be used instead of the examination procedure in Article 5.  
   The majority of committee members required in Paragraph 3 could be changed. | This article corresponds to the correct template.  
Parliament is free to change the procedure and required majority. |
| **Article 22 Exercise of the delegation** | 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.  
   2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) | Parliament could opt for a set duration in Paragraph 3, for instance a number of years, coupled with reporting requirements (option 2 in the Common Understanding). | The Article corresponds to the model Article in the Common Understanding, but it should be adapted to the determinations above. |
shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act pursuant to Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not

The objection period in Paragraph 5 is the standard 2+2 months, which Parliament is free to make longer or shorter.

Parliament is free to change the timeframes.
| object. That period shall be extended by two months at the initiative of the European Parliament or of the Council. |
|---|---|---|

EN
## PROCEDURE

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>Approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>References</strong></td>
<td>COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)</td>
</tr>
<tr>
<td><strong>Date submitted to Parliament</strong></td>
<td>19.12.2012</td>
</tr>
<tr>
<td><strong>Committee responsible</strong></td>
<td>ENVI (Date announced in plenary: 15.1.2013)</td>
</tr>
<tr>
<td><strong>Committee(s) asked for opinion(s)</strong></td>
<td>INTA (Date announced in plenary: 18.4.2013), ITRE (Date: 15.1.2013), IMCO (Date: 15.1.2013), AGRI (Date: 7.2.2013)</td>
</tr>
<tr>
<td><strong>Rapporteur(s)</strong></td>
<td>Linda McAvan (Date appointed: 23.1.2013)</td>
</tr>
<tr>
<td><strong>Discussed in committee</strong></td>
<td>21.3.2013, 24.4.2013, 30.5.2013</td>
</tr>
<tr>
<td><strong>Date adopted</strong></td>
<td>10.7.2013</td>
</tr>
<tr>
<td><strong>Result of final vote</strong></td>
<td>+: 51, -: 12, 0: 8</td>
</tr>
<tr>
<td><strong>Substitute(s) present for the final vote</strong></td>
<td>Christofer Fjellner, Gaston Franco, Julie Girling, Jutta Haug, Georgios Koumoutsakos, James Nicholson, Michèle Rivasi, Christel Schaldemose, Renate Sommer, Bart Staes, Marianne Thyssen, Marita Ulvskog, Kathleen Van Brempt</td>
</tr>
<tr>
<td><strong>Substitute(s) under Rule 187(2) present for the final vote</strong></td>
<td>Philip Claeys</td>
</tr>
<tr>
<td><strong>Date tabled</strong></td>
<td>24.7.2013</td>
</tr>
</tbody>
</table>