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*Committee on International Trade*

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**2012/0366(COD)**

19.6.2013

## **OPINION**

of the Committee on International Trade

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

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

Rapporteur: Metin Kazak

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## 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*

(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. ***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 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 3**

**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 4**

**Proposal for a directive  
Recital 22**

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*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*

(18) Considering the Directive's focus on young people, tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco **other than nasal 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.

*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. ***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**

*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***

*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’. ***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***

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.*

*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 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) 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 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 Directive 97/7/EC of the European Parliament and the Council of 20 May 1997 on the protection of consumers in respect of distance contracts, which will be replaced by Directive 2011/83/EU of the European Parliament and the Council of 25 October 2011 on consumer rights, as of 13 June 2014.

*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 be replaced by Directive 2011/83/EU of the European Parliament and the Council of 25 October 2011 on consumer rights, as of 13 June 2014.

## 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

*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. 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.

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, maintain or introduce provisions providing standardisation of packaging of tobacco products provided that those provisions are compatible with the Treaty, **with WTO obligations and do not affect the full application of** this Directive. A prior notification is required for technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on Information Society services.

##### *Amendment*

(41) Member States should remain free to maintain or introduce national legislations applying to **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. 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*

*Amendment*

*(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**

*Text proposed by the Commission*

*Amendment*

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

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

**Amendment 14**

**Proposal for a directive**

**Article 1 – paragraph 1 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

***(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;*

## **Amendment 15**

### **Proposal for a directive**

#### **Article 2 – paragraph 1 – point 2 a (new)**

*Text proposed by the Commission*

*Amendment*

*(2a) ‘essential additive’ means an ingredient which is indispensable for the manufacturing of a tobacco products;*

## **Amendment 16**

### **Proposal for a directive**

#### **Article 2 – paragraph 1 – point 4**

*Text proposed by the Commission*

*Amendment*

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

(4) ‘characterising flavour’ means a *distinctive fruity or confectionary-like* taste resulting from *a flavouring* or combination of *flavourings, observable 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*

*Amendment*

(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 ;

(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*

*Amendment*

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

**deleted**

**Amendment 19**

**Proposal for a directive  
Article 2 – paragraph 1 – point 13**

*Text proposed by the Commission*

*Amendment*

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

(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

*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 21

### Proposal for a directive

#### Article 2 – paragraph 1 – point 18 a (new)

*Text proposed by the Commission*

*Amendment*

**(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.**

## 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**

*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;

*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 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**

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*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 28**

**Proposal for a directive**

**Article 9 – paragraph 1 – point e**

*Text proposed by the Commission*

*Amendment*

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

(e) be positioned 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*

*Amendment*

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

**deleted**

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

**(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 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 32**

**Proposal for a directive  
Article 10 – paragraph 4 – point b**

*Text proposed by the Commission*

*Amendment*

(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;

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

### **Amendment 33**

#### **Proposal for a directive**

#### **Article 12 – paragraph 1 – point c**

*Text proposed by the Commission*

*Amendment*

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

#### *Justification*

*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**

*Text proposed by the Commission*

*Amendment*

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

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 .

## **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 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.*

*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;

(e) 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*

*Amendment*

3. Member States shall **ensure that** all economic operators involved in the trade of tobacco products from the manufacturer to

3. Member States shall **require that track and trace technology capable of reading and transmitting data electronically to the**

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.

*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*

*Amendment*

***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 on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden.***

***deleted***

#### *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 Member State where the actual or potential consumer is*** located. ***Retail outlets established outside the Union have to register with the competent authorities***

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.

*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;* **deleted**

#### **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;* **deleted**

#### **Amendment 48**

##### **Proposal for a directive Article 16 – paragraph 1 – point c**

*Text proposed by the Commission*

*Amendment*

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

**Amendment 49**

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

*Text proposed by the Commission*

*Amendment*

***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*

*Amendment*

***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*

*Amendment*

***2. The competent authorities of the***

***deleted***

*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*

*Amendment*

*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.*

*deleted*

## **Amendment 53**

### **Proposal for a directive Article 16 – paragraph 4**

*Text proposed by the Commission*

*Amendment*

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

*deleted*

*details and functioning of the age verification system.*

#### **Amendment 54**

##### **Proposal for a directive Article 16 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

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

**deleted**

#### **Amendment 55**

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

*Text proposed by the Commission*

*Amendment*

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

**1. 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]:

*Amendment*

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + **42** months]:

## 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<sup>1</sup>.

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'<sup>2</sup>.

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.

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<sup>1</sup> 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.

<sup>2</sup> 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<sup>1</sup>.

However, Australia has already been the subject of four complaints to the WTO's dispute settlement body<sup>2</sup>. 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<sup>3</sup> 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.

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<sup>1</sup> The Tobacco Plain Packaging Act, which was adopted by the Australian Parliament in 2011 and entered into force in December 2012.

<sup>2</sup> Complaints by Ukraine (March 2012), Honduras (April 2012), the Dominican Republic (July 2012) and Cuba (May 2013).

<sup>3</sup> In particular, Philip Morris International.

## PROCEDURE

|   |   |
|---|---|
| <b>Title</b>  | Approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products   |
| <b>References</b>   | COM(2012)0788 – C7-0420/2012 – 2012/0366(COD)   |
| <b>Committee responsible</b><br>Date announced in plenary         | ENVI<br>15.1.2013   |
| <b>Opinion by</b><br>Date announced in plenary                    | INTA<br>18.4.2013   |
| <b>Rapporteur</b><br>Date appointed                               | Metin Kazak<br>25.4.2013  |
| <b>Discussed in committee</b>                                     | 27.5.2013   |
| <b>Date adopted</b>   | 18.6.2013   |
| <b>Result of final vote</b>                                       | +: 15<br>-: 12<br>0: 0  |
| <b>Members present for the final vote</b>                         | 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, Cristiana Muscardini, Helmut Scholz, Peter Šťastný, Robert Sturdy, Henri Weber, Iuliu Winkler, Paweł Zalewski |
| <b>Substitute(s) present for the final vote</b>                   | Josefa Andrés Barea, Catherine Bearder, Albert Deß, Elisabeth Köstinger, Mario Pirillo, Miloslav Ransdorf, Peter Skinner, Jarosław Leszek Wałęsa  |
| <b>Substitute(s) under Rule 187(2) present for the final vote</b> | Salvador Garriga Polledo, Paul Rübig  |