



EUROPEAN PARLIAMENT

2009 - 2014

Committee on the Environment, Public Health and Food Safety

2012/0366(COD)

10.4.2013

*****|**

DRAFT REPORT

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))

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

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION.....	5
EXPLANATORY STATEMENT.....	42
ANNEX.....	46

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, Italian Senate, Swedish Parliament, Greek Parliament, Italian Chamber of Deputies, Portuguese Parliament, Romanian Chamber of Deputies, Danish 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 Committee¹,
 - having regard to the opinion of the Committee of the Regions²,
 - 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 Industry, Research and Energy, the Committee on the Internal Market and Consumer Protection and the Committee on Agriculture and Rural Development (A7-0000/2013),
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;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.

² OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.

Amendment 1

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 (hereinafter: "FCTC") of May 2003. **All Member States and the European Union itself have signed and ratified the Convention and as a result are bound under international law by the provisions of the FCTC**. 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.

Or. en

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 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

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.

their toxicity or addictiveness.

Or. en

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 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

(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. ***The Commission should carefully monitor the use of water-pipe tobacco by young people as there is increasing evidence of their use beyond the traditional, older market;***

Or. en

Justification

The use of shishas in bars and nightclubs is becoming increasingly popular and users are not always aware that these water-pipes normally contain tobacco. Eurobarometer shows that young people and students report higher use of water-pipes than other groups.

Amendment 4

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 of the packet surface.

Or. en

Justification

self explanatory

Amendment 5

Proposal for a directive Recital 22 a (new)

Text proposed by the Commission

Amendment

22 a. Where combined health warnings are used, the rest of the tobacco package should be standardised and free from any branding, in order to maximise the impact of the health warning. Evidence shows that standardised packaging is particularly effective in dissuading young people from starting to smoke.

Justification

Standardised "plain" packaging is anything but plain - most of the packet is covered with large graphic health warnings, and in Australia the background is a dark, drab brown. Four Member States are at varying stages of considering standard packs (UK, BE, FI and FR). Fully standardising packaging is the most effective way of removing obstacles to trade on the single market. It is also the best option in terms of health protection: it increases the impact of health warnings amongst those who have not yet started to smoke, and is proven to be effective at discouraging young people in particular from starting

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) A minimum size should be set for all health warnings to ensure their visibility and effectiveness, and the opening mechanism of the package should not detract from the health warnings in any way. The package and the products may mislead consumers, in particular young people, ***by*** 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 7

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 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.

Or. en

Justification

As per the requirements of the WHO Protocol to Eliminate Illicit Trade in Tobacco Products, there should also be unique identifiers on any outside packaging (i.e. pallets, master cases and cartons etc). The unique identifiers on the outside packaging and on the inside unit packages should be linked, so that authorities know what is inside a pallet, master case or carton

Amendment 8

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 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.

Or. en

Justification

The Commission's impact assessment finds that cross-border internet sales are mainly motivated by 1) offering lower prices for illicit/counterfeit products or 2) illegally exploiting the differences in national tax regimes. This leads to a distortion of competition, with traditional retailers - particularly those based in Member States with high taxation - having to compete with lower prices from (mainly) illegal internet retailers

Amendment 9

Proposal for a directive Recital 30 a (new)

Text proposed by the Commission

Amendment

30 a. Free distribution of tobacco products still occurs in several Member States, via online retail outlets and in public places. Given its targeting of young people and its potential to recruit new smokers, this practice should be prohibited

Or. en

Justification

Free promotional distribution of cigarettes in night-clubs and on beaches etc is targeted at young people and is indefensible.

Amendment 10

Proposal for a directive Recital 31

Text proposed by the Commission

Amendment

(31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to ***monitor developments as regards*** novel tobacco products. ***A notification*** obligation for novel tobacco products should be put on manufacturers and importers, ***without prejudice to the power of the Member States to ban or to authorise them. The Commission should monitor the 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.***

(31) All tobacco products have the potential to cause mortality, morbidity and disability and their consumption should be contained. It is therefore important to ***pre-authorise any*** novel tobacco products. ***An obligation to apply for a marketing authorisation*** for novel tobacco products should be put on manufacturers and importers.

Justification

Tobacco products are extremely harmful to public health and should not be allowed on the market without being pre-authorized by public authorities.

Amendment 11**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, 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

The details about whether and how to set up independant testing panels for determining if a tobacco product has a characterising flavour would be more appropriately decided via delegated acts rather than implementing acts.

Amendment 12**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,

Amendment

(38) In order to make this Directive fully operational and to keep up with technical,

scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission, in particular in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or attractiveness, the use of health warnings, unique identifiers and security features in the labelling and packaging, defining key elements for contracts on data storage with independent third parties, reviewing certain exemptions granted to tobacco products other than cigarettes, roll-your-own tobacco and smokeless tobacco 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.

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 methodology for determining whether a tobacco product has characterising flavour***, 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.

Or. en

Justification

see AM to recital 37

Amendment 13

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 **domestic and imported** 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 **domestic and imported** 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.

Or. en

Justification

To clarify that Member States have the freedom to maintain or introduce stricter national rules in areas covered by this Directive, as long as these are appropriately justified and approved. These stricter rules should also apply to imported products.

Amendment 14

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 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 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.

Or. en

Justification

To clarify that Member States have the freedom to maintain or introduce stricter national rules also in areas not covered by this Directive, as long as these are appropriately justified. These stricter rules should also apply to imported products.

Amendment 15

Proposal for a directive Article 1 - point d

Text proposed by the Commission

(d) cross-border distance sales of tobacco

Amendment

(d) **the prohibition of** cross-border distance

products;

sales of tobacco products;

Or. en

Justification

See justification to article 16.

Amendment 16

**Proposal for a directive
Article 1 - point e**

Text proposed by the Commission

Amendment

(e) the **notification** obligation for novel tobacco products;

(e) the **pre-market authorisation** obligation for novel tobacco products;

Or. en

Justification

See justification to article 17.

Amendment 17

**Proposal for a directive
Article 1 - paragraph 1 - subparagraph 2**

Text proposed by the Commission

Amendment

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.

in order to **meet commitments 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**,

Or. en

Justification

The aim of the Directive is to harmonize laws to improve the functioning of the internal

market. But in choosing the direction of harmonization, the decisive factor has been guaranteeing a high level of public health protection, particularly for young people - and implementing internationally agreed standards.

Amendment 18

Proposal for a directive Article 3 - paragraph 2

Text proposed by the Commission

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.

Amendment

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, taking into account scientific development and internationally agreed standards.

Or. en

Justification

The Commission should only need to reduce TNCO yields in the future, in line with the direction of international standards.

Amendment 19

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

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 **reduce** maximum yields for other emissions of cigarettes and for emissions of tobacco products other than cigarettes

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.

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.

Or. en

Justification

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

Amendment 20

Proposal for a directive Article 4 - paragraph 1

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.

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.

Or. en

Justification

This international standard is already used to measure the accuracy of carbon monoxide indications.

Amendment 21

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.

Or. en

Justification

Some Member States already have dedicated websites on tobacco control. This amendment clarifies that they do not need to set up a whole new website.

Amendment 22

Proposal for a directive Article 5 - paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Member States shall require manufacturers and importers to disclose their expenditure on advertising, promotion and sponsorship per Member State, on a yearly basis starting from the full calendar year following that of the entry into force of this Directive.

Or. en

Justification

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

Amendment 23

Proposal for a directive Article 5 - paragraph 5 a (new)

Text proposed by the Commission

Amendment

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.

Or. en

Justification

It will be the first time that much of this information is made available to regulators. It would be useful for an analysis to be made in case there are possible lessons to be drawn for future tobacco control policies.

Amendment 24

Proposal for a directive Article 5 - paragraph 6

Text proposed by the Commission

Amendment

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.**

6. **Proportionate fees** may be charged by Member States for receiving, storing, handling, analysing and publishing the information submitted to them under this Article.

Or. en

Justification

The fees requirement here should be consistent with the requirements in article 17.

Amendment 25

Proposal for a directive

Article 6 - paragraph 2 - subparagraph 1

Text proposed by the Commission

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.

Amendment

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, **and is therefore to be prohibited across the single market.** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Or. en

Justification

To clarify that by adopting an implementing act, the Commission extends the prohibition of a particular product to the rest of the single market.

Amendment 26

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

The Commission shall adopt by means of **delegated** acts **detailed criteria and** procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those **delegated** acts shall be adopted in accordance with the procedure referred to in **Article 22**.

Or. en

Justification

The details about whether and how to set up independent testing panels for determining if a tobacco product has a characterising flavour would be more appropriately decided via

delegated acts rather than implementing acts.

Amendment 27

Proposal for a directive Article 6 - paragraph 7

Text proposed by the Commission

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.

Amendment

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

Or. en

Justification

Self-explanatory

Amendment 28

Proposal for a directive Article 6 - paragraph 8

Text proposed by the Commission

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.

Amendment

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 ***and is therefore to be prohibited across the single market.*** 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.

Or. en

Justification

To clarify that by adopting an implementing act, the Commission extends the prohibition of a particular product to the rest of the single market.

Amendment 29

**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

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 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.

Or. en

Justification

Self-explanatory.

Amendment 30

**Proposal for a directive
Article 7 - paragraph 4**

Text proposed by the Commission

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.***

Amendment

4. Member States shall ensure that the health warnings of the main surface of the unit packet and any outside packaging are fully visible, ***and shall adopt the necessary rules to prevent the placing on the market of any type of wrapper, pouch, jacket, box or other device which partially or entirely hides or interrupts the health warnings.***

Justification

Measures should be taken to ensure that the health warnings are clearly visible to the public.

Amendment 31

Proposal for a directive

Article 9 - paragraph 1 - point a

Text proposed by the Commission

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

Amendment

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

Justification

to correct a drafting omission

Amendment 32

Proposal for a directive

Article 9 - paragraph 2

Text proposed by the Commission

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

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 ***available for use in any one year*** is displayed as nearly as possible on equal numbers of each brand.

Justification

to clarify that each of the fourteen combined health warnings available for use in a particular

year should appear as equally as possible on each cigarette and RYO brand.

Amendment 33

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

2. A cigarette packet **shall** be **made** 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.

Or. en

Justification

self-explanatory

Amendment 34

Proposal for a directive Article 13 - paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. All outer surfaces of the unit packet and any outside packaging of cigarettes and roll-your-own tobacco not governed by the provisions of this Directive shall be standardised in the following way:

a) not contain any trade mark or any other mark, apart from the brand name and any variant name for the tobacco products;

b) the brand name, and any variant name shall:

i) not appear more than once on any one surface

ii) appear horizontally below, and in the

same orientation as, the combined health warning, in the centre of the space remaining on the front and back surfaces of the unit packet and any outside packaging;

iii) comply with any more detailed rules set out in paragraph 3;

Or. en

Justification

Standardised "plain" packaging is anything but plain - most of the packet is covered with large graphic health warnings, and in Australia the background is a dark, drab brown. Four Member States are at varying stages of considering standard packs (UK, BE, FI and FR). Fully standardising packaging is the most effective way of removing obstacles to trade on the single market. It is also the best option in terms of health protection: it increases the impact of health warnings amongst those who have not yet started to smoke, and is proven to be effective at discouraging young people in particular from starting.

Amendment 35

**Proposal for a directive
Article 13 - paragraph 2 b (new)**

Text proposed by the Commission

Amendment

2b. No trade mark or any other mark may appear on the tobacco product itself

Or. en

Justification

Branding or other designs (e.g. floral decoration) should not be allowed on individual cigarettes.

Amendment 36

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

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to define more detailed rules for the shape, size **and background colour** of unit packets, ***as well as the font type and size to be used for the brand name, and any variant name.***

Or. en

Justification

Standardised "plain" packaging is anything but plain - most of the packet is covered with large graphic health warnings, and in Australia the background is a dark, drab brown. Four Member States are at varying stages of considering standard packs (UK, BE, FI and FR). Fully standardising packaging is the most effective way of removing obstacles to trade on the single market. It is also the best option in terms of health protection: it increases the impact of health warnings amongst those who have not yet started to smoke, and is proven to be effective at discouraging young people in particular from starting.

Amendment 37

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

Amendment

1. Member States shall ensure that all unit packets ***and any outside packaging*** 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

apply only to those destined to or placed on the Union market.

obligations laid down in this Article apply only to those destined to or placed on the Union market.

Or. en

Justification

As per the requirements on the "WHO Protocol to Eliminate Illicit Trade in Tobacco Products", there should also be unique identifiers on any outside packaging (i.e. pallets, master cases and cartons etc). The unique identifiers on the outside packaging and on the inside unit packages should be linked, so that authorities know what is inside a pallet, master case or carton. Any repackaging should be recorded.

Amendment 38

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 of unit packets are linked to the unique identifier on the outside packaging. Any changes in links between unit packs and the outside packaging shall be recorded in the database mentioned in paragraph 6.

Or. en

Justification

As per the requirements on the "WHO Protocol to Eliminate Illicit Trade in Tobacco Products", there should also be unique identifiers on any outside packaging (i.e. pallets, master cases and cartons etc). The unique identifiers on the outside packaging and on the inside unit packages should be linked, so that authorities know what is inside a pallet, master case or carton. Any repackaging should be recorded.

Amendment 39

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 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, **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, provided that tracking and tracing of unit packets remains possible.

Or. en

Justification

As per the requirements on the "WHO Protocol to Eliminate Illicit Trade in Tobacco Products", there should also be unique identifiers on any outside packaging (i.e. pallets, master cases and cartons etc). The unique identifiers on the outside packaging and on the inside unit packages should be linked, so that authorities know what is inside a pallet, master case or carton. Any repackaging should be recorded.

Amendment 40

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

Amendment

6. Member States shall ensure that manufacturers and importers of tobacco products conclude data storage contracts with an independent third party which shall host the data storage facility for data relating to the manufacturer and importer concerned. The data storage facility shall

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

be physically located on the territory of the Union. ***The independent third party shall be free from commercial and other vested interests of the tobacco industry and other related industries.*** The suitability of the third party, in particular its independence and technical capacities, as well as the contract, shall be approved and monitored ***by the Commission, assisted*** by an ***independent*** external auditor, who is 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.

Or. en

Justification

To ensure a firewall between the data storage organisation and the tobacco industry, and to ensure the full independence of the former, extra safeguards should be put in place.

Amendment 41

Proposal for a directive Article 14 - paragraph 8

Text proposed by the Commission

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

Amendment

8. In addition to the unique identifier, Member States shall require that all unit packets of tobacco products which are placed on the market carry a visible, ***and invisible***, tamper proof security feature of at least 1 cm², which shall be irremovably printed or affixed, indelible and in no way

interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation.

hidden or interrupted in any form, including through tax stamps and price marks, or other elements mandated by legislation.

Or. en

Justification

Invisible security features would make it more difficult to counterfeit products. However, given that invisible features could only be verified by officials, the security feature should have both visible and invisible elements, similar to the systems used on cigarettes in the UK, Turkey, Brazil and Malaysia.

Amendment 42

Proposal for a directive Article 16 - paragraph 1

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 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;

Amendment

1. Member States shall ***prohibit*** retail outlets ***established on their territory from engaging in cross border distance sales.***

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

Or. en

Justification

There is very little legal cross-border internet sale of tobacco products, and so, typically, tobacco products sold on the internet do not comply with the provisions of TPD. The Commission's impact assessment finds that cross border internet sales are mainly motivated by 1) offering lower prices for illicit/counterfeited products or 2) illegally exploiting the differences in national tax regimes. This leads to a distortion of competition, with traditional retailers - particularly those based in Member States with high taxation - having to compete with lower prices from (mainly) illegal internet retailers

Amendment 43

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

Text proposed by the Commission

Amendment

1a. 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.

Or. en

Justification

Free promotional distribution of cigarettes in night-clubs and on beaches etc is targeted at young people and is indefensible.

Amendment 44

**Proposal for a directive
Article 16 - paragraph 2**

Text proposed by the Commission

Amendment

2. The competent authorities of the Member States shall publish the complete

Deleted

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.

Or. en

Justification

There is very little legal cross-border internet sale of tobacco products, and so, typically, tobacco products sold on the internet do not comply with the provisions of TPD. The Commission's impact assessment finds that cross border internet sales are mainly motivated by 1) offering lower prices for illicit/counterfeited products or 2) illegally exploiting the differences in national tax regimes. This leads to a distortion of competition, with traditional retailers - particularly those based in Member States with high taxation - having to compete with lower prices from (mainly) illegal internet retailers

Amendment 45

**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

Or. en

Justification

There is very little legal cross-border internet sale of tobacco products, and so, typically, tobacco products sold on the internet do not comply with the provisions of TPD. The

Commission's impact assessment finds that cross border internet sales are mainly motivated by 1) offering lower prices for illicit/counterfeited products or 2) illegally exploiting the differences in national tax regimes. This leads to a distortion of competition, with traditional retailers - particularly those based in Member States with high taxation - having to compete with lower prices from (mainly) illegal internet retailers

Amendment 46

Proposal for a directive Article 16 - paragraph 4

Text proposed by the Commission

Amendment

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

Deleted

Or. en

Justification

There is very little legal cross-border internet sale of tobacco products, and so, typically, tobacco products sold on the internet do not comply with the provisions of TPD. The Commission's impact assessment finds that cross border internet sales are mainly motivated by 1) offering lower prices for illicit/counterfeited products or 2) illegally exploiting the differences in national tax regimes. This leads to a distortion of competition, with traditional retailers - particularly those based in Member States with high taxation - having to compete with lower prices from (mainly) illegal internet retailers

Amendment 47

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

Deleted

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.

Or. en

Justification

There is very little legal cross-border internet sale of tobacco products, and so, typically, tobacco products sold on the internet do not comply with the provisions of TPD. The Commission's impact assessment finds that cross border internet sales are mainly motivated by 1) offering lower prices for illicit/counterfeited products or 2) illegally exploiting the differences in national tax regimes. This leads to a distortion of competition, with traditional retailers - particularly those based in Member States with high taxation - having to compete with lower prices from (mainly) illegal internet retailers

Amendment 48

**Proposal for a directive
Article 17 - Title**

Text proposed by the Commission

Amendment

Notification of novel tobacco products

Pre-market authorisation of novel tobacco products

Or. en

Justification

Regulators should be able to prevent the marketing of future novel tobacco products, if necessary.

Amendment 49

Proposal for a directive Article 17 - Paragraph -1 a (new)

Text proposed by the Commission

Amendment

-1 a. Member States shall pre-authorise the placing on the market of any novel tobacco product. For this purpose, Member States shall introduce an authorisation system and charge a proportionate fee.

Or. en

Justification

Regulators should be able to prevent the marketing of future novel tobacco products, if necessary.

Amendment 50

Proposal for a directive Article 17 - Paragraph 1

Text proposed by the Commission

Amendment

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

1. Member States shall require that manufacturers and importers of tobacco products ***submit an application*** to the competent authorities of Member States ***for*** any novel tobacco product they intend to place on the markets of the Member States concerned. The ***application*** shall be submitted in electronic form and shall ***contain*** 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 ***applying for marketing authorisation for*** a novel tobacco product shall also provide the competent authorities in question with:

Or. en

Justification

Regulators should be able to prevent the marketing of future novel tobacco products, if necessary.

Amendment 51

**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. After the placing on the market, 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.

Or. en

Justification

Regulators should be able to prevent the marketing of future novel tobacco products, if necessary.

Amendment 52

**Proposal for a directive
Article 20 - Paragraph 3**

Text proposed by the Commission

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.

Amendment

3. Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced.

The penalties provided for shall be effective, proportionate and dissuasive.

The penalties provided for shall be effective, proportionate and dissuasive.
Any financial penalties applicable to intentional infringements shall offset the economic advantage sought through the infringement.

Or. en

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 53

**Proposal for a directive
Article 23 - Paragraph 2 - point b**

Text proposed by the Commission

(b) market developments in novel tobacco products considering, inter alia, ***notifications received*** under Article 17;

Amendment

(b) market developments in novel tobacco products considering, inter alia, ***authorisations made*** under Article 17;

Or. en

Justification

See justification to article 17

Amendment 54

**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

Amendment

2. However, a Member State may maintain more stringent national provisions 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

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.

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 apply to all products alike, 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 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.

Or. en

Justification

To clarify that where Member States decide to maintain or introduce stricter national rules, these rules should also apply to imported products.

Amendment 55

Proposal for a directive Article 24 - Paragraph 3

Text proposed by the Commission

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

Amendment

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 ***shall***

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.

apply to all products alike, including those imported from another Member State or a third country, 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.

Or. en

Justification

To clarify that where Member States decide to maintain or introduce stricter national rules, these rules should also apply to imported products.

Amendment 56

Proposal for a directive
Article 26 - point a

Text proposed by the Commission

Amendment

(a) tobacco products;

Deleted

Or. en

Justification

Self-explanatory

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

NGOs
Smoke Free Partnership and the European Heart Network
Hosted a joint meeting with the MEP Heart Group and the MEPs Against Cancer Group ¹ .
UK Cancer Research
British Heart Foundation
UK Centre for Tobacco Control Studies
UK Action on Smoking & Health
Smokefree Yorkshire and the Humber

Industry
Open meeting with the tobacco industry and upstream and downstream suppliers ^{2 3} .
Open meeting with the electronic cigarette industry ^{4 5} .
Association of the European Self-Medication Industry

¹ Participant list and meeting record available <http://www.mepheartgroup.eu/meetings-activities/item/52-the-battle-against-tobacco-cancer-and-heart-disease.html>

² Participant list available <http://www.europarl.europa.eu/document/activities/cont/201303/20130320ATT63555/20130320ATT63555EN.pdf>

³ record of the meeting available <http://www.europarl.europa.eu/committees/en/envi/events.html?id=other#menuzone>

⁴ Participant list available <http://www.europarl.europa.eu/document/activities/cont/201303/20130320ATT63557/20130320ATT63557EN.pdf>

⁵ and record of the meeting available <http://www.europarl.europa.eu/committees/en/envi/events.html?id=other#menuzone>