



EUROPEAN PARLIAMENT

2009 - 2014

Committee on Legal Affairs

03/06/2013

AMENDMENTS 1 - 29

Klaus-Heiner Lehne

Approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

Proposal for a directive COM(2012)0788 - C7-0420/2012 – 2012/0366(COD)

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Proposal for a directive COM(2012)0788 - C7-0420/2012 – 2012/0366(COD)

Amendment 1

Rebecca Taylor

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 avoided³⁶.

Amendment

(15) The likelihood of diverging regulation is further increased by concerns over tobacco products, including smokeless tobacco products, having a characterising flavour other than tobacco, which may ***make tobacco products more palatable, and therefore*** 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 avoided³⁶.

Or. en

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Amendment 2

Rebecca Taylor

Proposal for a directive

Recital 30 a (new)

Text proposed by the Commission

Amendment

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

Or. en

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Amendment 3

Rebecca Taylor

Proposal for a directive

Recital 34

Text proposed by the Commission

(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use⁴² provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products. ***A significant number of nicotine-containing products were already authorised under this regulatory regime. The authorisation takes into account the nicotine content of the product in question. Subjecting all nicotine-containing products, whose nicotine content equals or exceeds the content of a nicotine containing product previously authorised under Directive 2001/83/EC, to the same legal framework clarifies the legal situation, levels out differences between national legislations, ensures equal treatment of all nicotine containing products usable for smoking cessation purposes and creates incentives for research and innovation in smoking cessation. This should be without prejudice to the application of Directive 2001/83/EC to other products covered by this Directive if the conditions set by***

Amendment

(34) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use provides a legal framework to assess the quality, safety and efficacy of medicinal products including nicotine containing products ***which claim to have properties beneficial to human health. A significant number of nicotine-containing products presenting such claims have already been authorised under this regulatory regime. Member States are obliged to ensure nicotine containing products which do not fall under Directive 2001/83/EC and which are placed on the common market comply with the appropriate legislation listed in [new] Annex IV.***

Directive 2001/83/EC are fulfilled.

Or. en

Justification

Clarifies that a 'two track' approach should be taken regarding nicotine containing products. Those which do not fall under Directive 2001/83/EC have to comply with the broad range of consumer and product safety legislation listed in [new] Annex IV.

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Amendment 4

Rebecca Taylor

Proposal for a directive

Recital 35

Text proposed by the Commission

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

Amendment

(35) Labelling provisions should be introduced for nicotine containing products ***falling outside of the scope of Directive 2001/83/EC*** drawing the attention of consumers to potential health risks, ***and Member States should be obliged to ensure that national age restrictions for buying nicotine containing products are kept in line with those for the sale of tobacco products.***

Or. en

Justification

A level playing field between age restrictions for the sale of nicotine-containing products and tobacco products should be maintained, so as to discourage minors from taking up either product for the first time.

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Proposal for a directive COM(2012)0788 - C7-0420/2012 – 2012/0366(COD)

Amendment 5

Rebecca Taylor

Proposal for a directive

Article 6 – paragraph 5

Text proposed by the Commission

5. Les États membres interdisent l'utilisation de substances aromatiques dans les composants des produits du tabac tels que les filtres, le papier, le conditionnement et les recharges, ainsi que de tout dispositif technique permettant de modifier l'arôme ou l'intensité de la **combustion**. Les filtres et recharges ne doivent pas contenir de tabac.

Amendment

5. Les États membres interdisent l'utilisation de substances aromatiques dans les composants des produits du tabac tels que les filtres, le papier, le conditionnement et les recharges, ainsi que de tout dispositif technique permettant de modifier l'arôme ou l'intensité de la **fumée**. Les filtres et recharges ne doivent pas contenir de tabac.

Or. fr

Justification

For linguistic consistency reasons it is necessary to change the French text from "intensité de la combustion" to "intensité de la fumée" to reflect the English version. Intensity of combustion and intensity of smoke are not the same things.

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Proposal for a directive COM(2012)0788 - C7-0420/2012 – 2012/0366(COD)

Amendment 6

Rebecca Taylor

Proposal for a directive

Article 6 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

Needed for compliance with Article 2, paragraph 1, point 4, and the rest of the proposal, which systematically associates 'flavour' with the adjective 'characterising' in order to improve legal clarity.

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Amendment 7

Rebecca Taylor

Proposal for a directive

Article 9 – paragraph 1 – point c

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

The implementing guidelines of the WHO FCTC call for warnings covering more than 50% of the surface of packaging, and go as far as to say warnings should "aim to cover as much of the principal display areas as possible". Several EU countries already have health warnings covering well over 50% of the surface of packaging and minimum harmonisation should aim to strengthen provisions in this area.

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Amendment 8

Rebecca Taylor

Proposal for a directive

Article 9 – paragraph 1 – point g – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

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Amendment 9

Rebecca Taylor

Proposal for a directive

Article 9 – paragraph 1 – point g – point i

Text proposed by the Commission

Amendment

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

(i) height: 64 mm;

Or. en

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Amendment 10

Rebecca Taylor

Proposal for a directive

Article 9 – paragraph 1 – point g – point ii

Text proposed by the Commission

Amendment

(ii) width: *not less than* 55 mm.

(ii) width: 55 mm.

Or. en

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Amendment 11

Rebecca Taylor

Proposal for a directive

Article 12 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

(a) promotes a tobacco product by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, ***in particular by suggesting that a particular tobacco product is less harmful than others or has vitalising, energetic, healing, rejuvenating, natural or otherwise positive health effects.***

Or. en

Justification

Tobacco products should not be allowed to be promoted in a way that attempts directly or indirectly to suggest they are less harmful to health or have any positive health effects. The concept of “social effects” is deleted as this is legally vague and could be interpreted a myriad of different ways.

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Amendment 13

Rebecca Taylor

Proposal for a directive

Article 13 – paragraph 1

Text proposed by the Commission

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

Amendment

1. A unit packet of cigarettes shall have a cuboid shape **and include at least 20 cigarettes**. A unit packet of **any other** tobacco **for smoking shall be packaged in a cuboid or cylindrical composite can or have the form of a pouch i.e. rectangular packet with a flap that covers the opening, and shall contain tobacco weighing at least 40g.**

Or. en

Justification

The original Proposal does not take into account the requirement for the composite can for specific uses of fine-cut loose tobacco i.e. 'make-your-own' cigarettes & pipes. The goal of this revision is to make the uptake of smoking much less attractive to young people, but the composite can is usually purchased by older adults and owing to its weight and volume is less financially affordable for young people. No internal market or public health goal will be achieved by prohibiting their use.

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Amendment 14

Rebecca Taylor

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 can be of carton or soft material and shall contain an opening that can be ***in the form of a*** flip-top lid. The flip-top lid of a cigarette packet shall be hinged only at the back of the packet..

Or. en

Justification

This would allow for resealable inner security features, such as inner liners, which can help in combating counterfeiting, but would not hinder in any way the visibility and integrity of the health warnings on the pack.

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Amendment 15

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. ***Nicotine-containing products that are presented as having properties for treating or preventing disease in human beings, other than through any message specified in paragraph 3,*** may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC

Or. en

Justification

This makes a medicines marketing authorisation mandatory if a health claim is made using strictly the definition in the medicines directive: ‘presented as having properties for treating or presenting disease’ is quoted from the first part of the medicines directive definition of a medicine 2001/83/EC Article 1.2(a)

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Amendment 16

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. This Directive shall not apply to nicotine containing products authorised pursuant to Directive 2001/83/EC.

Or. en

Justification

Makes it clear that provisions of the directive do not apply to NCPs regulated as medicines.

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Amendment 17

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1 b. For nicotine-containing products where paragraph 1 does not apply, the products may be placed on the market if they comply with this Directive

Or. en

Justification

Ensures that the TPD applies to all other NCPs, and limits the application of medicines regulation to those vendors making health claims consistent with the medicines regulation definition. It rules out member states classifying NCPs as medicines under Article 1.2(b) of 2001/83/EC – the ‘functional’ definition based on changes to physiology – an approach that has been repeatedly struck down in courts in several Member States.

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Amendment 18

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

1 c. Member states shall ensure that nicotine containing products comply with European Union consumer protection, safety and other relevant legislation in force.

Or. en

Justification

Member states should apply the body of existing consumer and safety legislation to nicotine containing products.

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Amendment 19

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 d (new)

Text proposed by the Commission

Amendment

1 d. No later than 12 months from entry into force of this Directive, each Member State shall provide the Commission with a report on the measures it has taken to implement and enforce the legislation set out in [new] Annex IV as it applies to nicotine containing products and the effectiveness of those measures.

Or. en

Justification

The requirement to report will mean a more systematic approach is taken, and will provide data for a future Commission review of the regulatory framework for NCPs. .

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Amendment 20

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 e (new)

Text proposed by the Commission

Amendment

1 e. Member States shall ensure that nicotine-containing products are not sold to persons below the national legal age for purchasing tobacco products.

Or. en

Justification

A level playing field in the age sale requirements between nicotine-containing products and tobacco products should be maintained, so as to prevent young people from buying NCPs.

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Amendment 21

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 f (new)

Text proposed by the Commission

Amendment

1 f. Where appropriate, Member States may impose marketing restrictions on nicotine-containing products similar to those which apply to the marketing of tobacco products.

Or. en

Justification

Member States should be able to apply certain restrictions to the marketing of nicotine containing products, so as to prevent for example manufacturers from using marketing techniques aimed at minors such as advertising near schools, or promoting their products in a way which glamorises them, thus indirectly appealing to minors.

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Amendment 22

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 – point a

Text proposed by the Commission

Amendment

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

deleted

Or. en

Justification

Thresholds make no sense as the products above and below still need to be regulated appropriately – the distinction between whether medicines regulation or consumer regulation is applied rests on whether a therapeutic health claim is made, not on an arbitrary threshold.

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Amendment 23

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

deleted

Or. en

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Amendment 25

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The Commission shall, ***by 1 April 2017, carry out a study on nicotine-containing products in consultation with relevant stakeholders and the Member States. This study will consider whether there is a need for specific legislation in regard to nicotine-containing products.***

Or. en

Justification

Nicotine containing products are potentially a huge market and can play a key role in public health as a less harmful alternative to cigarettes. It is important that regulation is designed with care and is legally robust – not to be excessively burdensome or too general to capture any specific risks arising from the products. There are currently too many unanswered questions in relation to NCPs, hence the need for further study including by the Commission.

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Proposal for a directive COM(2012)0788 - C7-0420/2012 – 2012/0366(COD)

Amendment 26

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 3 – subparagraph 1 – introductory part

Text proposed by the Commission

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

Amendment

Each unit packet and any outside packaging of nicotine-containing products ***which do not fall under the scope of Directive 2001/83/EC*** shall carry the following health warning:

Or. en

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Amendment 27

Rebecca Taylor

Proposal for a directive

Article 18 – paragraph 3 – subparagraph 1 – subparagraph 1

Text proposed by the Commission

This product contains nicotine ***and can*** damage your health.

Amendment

This product contains nicotine ***which is addictive and may*** damage your health.

Or. en

Justification

Consumers should be informed of the addictive characteristics of nicotine, and that such an addiction may be detrimental to health. While the effects of nicotine on the human body are well established, and for the most part do not pose serious risks to health, the effect of long-term use of nicotine-containing products cannot currently be confirmed, so caution is needed.

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Amendment 28

Rebecca Taylor

Proposal for a directive

Article 26 – paragraph 1 – point b

Text proposed by the Commission

(b) nicotine containing products *below the threshold set out in Article 18(1)*;

Amendment

(b) nicotine containing products;

Or. en

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Amendment 29

Rebecca Taylor

Proposal for a directive

Annex 2 a (new)

Text proposed by the Commission

Amendment

ANNEX IV

EU legislation applicable to nicotine-containing products:

General safety:

***General Product Safety Directive
2001/95/EC***

The RAPEX system - notification and alerts of dangerous products

Packaging and labelling:

***Dangerous Substances Directive
67/548/EEC***

***Dangerous Preparations Directive
99/45/EC***

Classification, Labelling and Packaging of Substances and Mixtures - the CLP Regulation 1272/2008 applies from 2015.

Chemical safety:

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) 1907/2006

Electrical safety:

Low Voltage Directive 2006/95/EC

*Electro-Magnetic Compatibility Directive
2004/108/EC*

*Restriction of Hazardous Substances
(RoHS) Directive 2011/65/EU (where
appropriate)*

*Waste Electrical and Electronic
Equipment (WEEE) Directive
2012/19/EU*

Batteries Directive 2006/66/EC

Weights and measures:

*Making-up by weight or by volume of
certain prepackaged products - Directive
76/211/EEC*

*Nominal Quantities for Prepacked
Products Directive 2007/45/EC*

Commercial practice

Distance Selling Directive 97/7/EC

*Directive on Electronic Commerce
2000/31/EC*

*Misleading and Comparative Advertising
Directive 2006/114/EC*

*Unfair Commercial Practices Directive
2005/29/EC*

Or. en

Justification

Member states should apply the body of existing consumer and safety regulation to nicotine containing products. The requirement to report will mean a more systematic approach is taken, and will form the basis of a Commission review to be completed by April 2017.