



EUROPEAN PARLIAMENT

2009 - 2014

Committee on the Environment, Public Health and Food Safety

2012/0366(COD)

14.5.2013

AMENDMENTS 1234 - 1360

Draft report

Linda McAvan

(PE508.085v03-00)

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

Proposal for a directive

(COM(2012)0788 – C7-0420/2012 – 2012/0366(COD))

AM\935765EN.doc

PE510.722v01-00

EN

United in diversity

EN

Amendment 1234
Françoise Grossetête

Proposal for a directive
Article 18 – paragraph 4

Text proposed by the Commission

Amendment

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

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

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

Or. fr

Amendment 1235
Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive
Article 18 – paragraph 4

Text proposed by the Commission

Amendment

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

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

b) cover 30 % of the external area of the corresponding surface of the unit packet

and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.

Or. pl

Amendment 1236
Erik Bánki

Proposal for a directive
Article 18 – paragraph 4

Text proposed by the Commission

Amendment

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

deleted

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

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

Or. en

Justification

The regulatory concept of this article is not supported. With the exception of tobacco products – nicotine-containing products – regardless of nicotine quantity – should be classified as pharmaceuticals. Article 18 of the draft does not promote ensuring high level health protection and violates Article 168, Paragraph (7) of the Treaty on the Functioning of the European Union. Article 18 represents a stepback when compared to the Hungarian regulations in force, therefore it is unacceptable in the current form.

Amendment 1237

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive

Article 18 – paragraph 4

Text proposed by the Commission

Amendment

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

deleted

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

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

Or. it

Amendment 1238

Daniël van der Stoep

Proposal for a directive

Article 18 – paragraph 4 – point b

Text proposed by the Commission

Amendment

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

(b) cover **15** % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to **17** % for Member States with two official languages and **20** % for Member States with three official languages.

Or. nl

Amendment 1239
Frédérique Ries, Corinne Lepage

Proposal for a directive
Article 18 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The Commission shall request an opinion from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) within 24 months of the entry into force of the Directive in order to obtain reliable scientific and toxicological information on whether or not the main ingredients of electronic cigarettes are harmful and on possible prudential measures to be taken in respect of this tobacco-related product;

Or. fr

Justification

A comprehensive safety report on the various types of electronic cigarettes currently available on the market (which often fall outside the scope of any legislation) should be drawn up by the Commission and its scientific committees as soon as possible.

Amendment 1240
Françoise Grossetête

Proposal for a directive
Article 18 – paragraph 5

Text proposed by the Commission

Amendment

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

deleted

Or. fr

Amendment 1241
Gaston Franco

Proposal for a directive
Article 18 – paragraph 5

Text proposed by the Commission

Amendment

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

Or. en

Justification

All decisions in this directive are highly political decisions. Any changes have to be made with ordinary legislative procedure.

Amendment 1242
Milan Cabrnoch

Proposal for a directive
Article 18 – paragraph 5

Text proposed by the Commission

Amendment

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

Or. cs

Amendment 1243

Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

**Proposal for a directive
Article 18 – paragraph 5**

Text proposed by the Commission

Amendment

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

Or. pl

Amendment 1244

Ewald Stadler

**Proposal for a directive
Article 18 – paragraph 5**

Text proposed by the Commission

Amendment

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

Or. de

Amendment 1245

Erik Bánki

**Proposal for a directive
Article 18 – paragraph 5**

Text proposed by the Commission

Amendment

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

Or. en

Justification

The regulatory concept of this article is not supported. With the exception of tobacco products – nicotine-containing products – regardless of nicotine quantity – should be classified as pharmaceuticals. Article 18 of the draft does not promote ensuring high level health protection and violates Article 168, Paragraph (7) of the Treaty on the Functioning of the European Union. Article 18 represents a stepback when compared to the Hungarian regulations in force, therefore it is unacceptable in the current form.

Amendment 1246

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive

Article 18 – paragraph 5

Text proposed by the Commission

Amendment

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

Or. it

Amendment 1247
Renate Sommer

Proposal for a directive
Article 18 – paragraph 5

Text proposed by the Commission

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

Amendment

5. The Commission shall, ***within 5 years of the transposition of the Directive into the national law of all EU Member States, submit a report on the application of further provisions of the Directive on nicotine-containing products. In it the Commission shall examine*** scientific and ***technical*** developments ***in the field of nicotine-containing products with regard to consumer behaviour and product categories.***

The Commission shall, where appropriate, add a legislative proposal to the report setting out rules on product safety, advertising for nicotine-containing products and provisions on the position, format, layout, design and rotation of the health warnings.

Or. de

Amendment 1248
Martin Callanan

Proposal for a directive
Article 18 – paragraph 5

Text proposed by the Commission

Amendment

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

5. The Commission shall, ***by 1 January 2017, carry out a study on nicotine containing products in consultation with the relevant stakeholders and the Member States. This study will include a comprehensive safety evaluation, a risk assessment and a cost-benefit analysis, and will present a variety of potential legislative options.***

Or. en

Justification

Electronic cigarettes are not a medicinal product as they make no claim to improve human health or to prevent disease. Moreover, although they vaporise nicotine, they are also not a tobacco product. Consequently they do not belong in either medicinal or tobacco product legislation. This amendment calls for a study to present legislative options appropriate to these new products.

Amendment 1249
Holger Krahmer

Proposal for a directive
Article 18 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. No later than two years from the date specified in Article 25 paragraph 1, the Commission shall submit to the European Parliament, the Council and the Economic and Social Committee a report on whether to propose further legislation on the placing on the market of nicotine containing products not authorised pursuant to Directive 2001/83/EC.

In the report, the Commission shall indicate in particular the features which should be considered in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and

standards on products, paying special attention to:

(a) standards for the manufacture and supply of nicotine containing products;

(b) the appropriate minimum age of sale and purchase for nicotine containing products;

(c) consumer information requirements;

(d) advertising and communication in line with the harm reduction potential of the products, including the use of science based product claims;

(e) the need to ensure availability of nicotine containing products to consumers of tobacco products.

With a view to drafting the report the Commission, assisted by scientific and technical experts, shall analyse usage and consumption patterns of nicotine containing products.

Or. xm

Justification

Products whose risks have been minimised, such as e-cigarettes, can replace traditional tobacco products and help to reduce the adverse impact of tobacco consumption on health overall. Legal regulation is needed, but the requirement of licensing pursuant to the Directive relating to medicinal products for human use does not accord with current scientific knowledge and should be reconsidered.

Amendment 1250

Linda McAvan, Karl-Heinz Florenz

Proposal for a directive

Article 18 a (new)

Text proposed by the Commission

Amendment

Article 18 a

Nicotine-containing products

1. Nicotine-containing products may only be placed on the market if they are

authorised pursuant to:

(a) Directive 2001/83/EC, or

(b) The simplified procedure as set out in paragraph 2 and 3.

Simplified procedure

2. Under the simplified procedure, Member States shall require manufacturers and importers of nicotine-containing products to submit an application for a marketing authorisation, which shall contain the following:

(a) Evidence that the product is manufactured in accordance with the principles and guidelines of Good Manufacturing Practice;

(b) A detailed description of the product in question, including all ingredients and quantities thereof, as well as information on emissions;

(c) A Risk-Management Plan, including a system for monitoring and recording any adverse reactions;

Member States shall be entitled to charge a fee for processing the application. They may also require manufacturers or importers to carry out additional tests or submit additional information. Each Member State shall take due account of authorisations previously granted by another Member State.

3. For products authorised under the simplified procedure, Member States shall ensure that the following conditions are fulfilled:

(a) the product is clearly labelled with the nicotine content, instructions for use, instructions for reporting adverse reactions, and details of the manufacturer;

(b) each unit packet and any outside packaging shall carry the following health warning:

This products is intended for use by existing smokers aged 18 or over as an alternative to tobacco cigarettes. It contains nicotine which is a highly addictive substance. Consult your doctor if you are pregnant, breast feeding, allergic to nicotine or propylene glycol, or have high blood pressure

(c) flavourings shall not be allowed;

(d) the sale of the product shall be restricted in line with the legal age for sale of tobacco products in the relevant Member State;

(e) the products shall be available to be sold outside pharmacies;

(f) advertising and promotion shall be appropriately regulated;

4. Member States shall monitor the development of the nicotine-containing products market, including any progress made in harm reduction, as well as any evidence of gateway use amongst young people. Based on the evidence, the Commission shall report back to the European Parliament and the Council 5 years after the transposition date of this Directive. The report shall assess whether amendments to this Directive are necessary.

Or. en

Justification

There is evidence that e-cigarettes may help with harm reduction strategies, and so they should be allowed to compete more freely with cigarettes - in terms of where they are sold etc. However products should still comply with appropriate safety and quality standards. The option of a simplified authorisation procedure takes elements from medicines regulation as well as tobacco regulation. We should proceed cautiously, given the lack of data, especially on long-term effects. There is a need for further monitoring, and the regulatory regime for NCPs should be reviewed in five years time.

Amendment 1251
Riikka Manner

PE510.722v01-00

14/76

AM935765EN.doc

Proposal for a directive
Article 19 – title

Text proposed by the Commission

Amendment

Herbal products for smoking

Tobacco substitutes

Or. en

Justification

The title of article 19 is too narrow, it should be extended to cover also tobacco substitutes (e.g. nicotine-free cartridges used in e-cigarettes and herbal cigarettes), because they also damage health.

Amendment 1252
Riikka Manner

Proposal for a directive
Article 19 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

Each unit packet and any outside packaging of ***herbal products*** for smoking shall carry the following health warning:

Each unit packet and any outside packaging of ***tobacco substitutes*** for smoking shall carry the following health warning:

Or. en

Amendment 1253
Sari Essayah

Proposal for a directive
Article 19 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warning:

Each unit packet and any outside packaging of herbal products for smoking ***or nicotine-free products intended for vaporising or smoking*** shall carry the following health warning:

Or. fi

Amendment 1254
Georgios Koumoutsakos

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

Text proposed by the Commission

Amendment

This product *can damage* your health

This product *damages* your health

Or. el

Amendment 1255
Frédérique Ries

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

Text proposed by the Commission

Amendment

This product can damage your health

This *natural* product can damage your health

Or. fr

Justification

Health warnings should reflect the true nature of the product in question and describe it as fully as possible.

Amendment 1256
Riikka Manner

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

Text proposed by the Commission

Amendment

This product *can damage* your health

This product *damages* your health

Or. en

Amendment 1257

Karl-Heinz Florenz, Peter Liese, Thomas Ulmer, Richard Seeber, Sophie Auconie, Elena Oana Antonescu

Proposal for a directive

Article 19 – paragraph 1 – subparagraph 1

Text proposed by the Commission

This product *can damage* your health.

Amendment

This product *damages* your health.

Or. de

Amendment 1258

Milan Cabrnoch

Proposal for a directive

Article 19 – paragraph 2

Text proposed by the Commission

2. The health warning shall be printed on the front *and* back external surface of the unit packet and on any outside packaging.

Amendment

2. The health warning shall be printed on the front, *bottom or* back external surface of the unit packet and on any outside packaging.

Or. cs

Amendment 1259

Daniël van der Stoep

Proposal for a directive

Article 19 – paragraph 3

Text proposed by the Commission

3. The health warning shall comply with the requirements laid down in Article 10(4). It shall cover not less than **30 %** of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to **32 %**

Amendment

3. The health warning shall comply with the requirements laid down in Article 10(4). It shall cover not less than **15 %** of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to **17 %**

for Member States with two official languages and **35 %** for Member States with three official languages.

for Member States with two official languages and **20 %** for Member States with three official languages.

Or. nl

Amendment 1260
Ewald Stadler

Proposal for a directive
Article 19 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The health warning shall comply with the requirements laid down in Article 10(4). It shall cover not less than **15 %** of the area of the corresponding surface of the unit packet and of any outside packaging. That proportion shall be increased to **18 %** for Member States with two official languages and **20 %** for Member States with three official languages.

Or. de

Amendment 1261
Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive
Article 19 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Amendment 1262
Esther de Lange

Proposal for a directive
Article 19 a (new)

Text proposed by the Commission

Amendment

Article 19 a

Imitation tobacco products

The placing on the market of imitation tobacco products shall be prohibited.

Or. en

Amendment 1263
Gerben-Jan Gerbrandy

Proposal for a directive
Article 19 a (new)

Text proposed by the Commission

Amendment

Article 19 a

Imitation tobacco products

1. Imitation tobacco products which can appeal to minors and form a potential gateway to using tobacco products shall be prohibited.

Or. en

Justification

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

Amendment 1264

Róża Gräfin von Thun und Hohenstein, Bogusław Sonik, Czesław Adam Siekierski

Proposal for a directive

Article 20 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The negative economical and social consequences of the implementation of this Directive shall be counteracted by appropriate measures and financial support in the framework of the EU budget.

Or. en

Amendment 1265

Gaston Franco

Proposal for a directive

Article 22

Text proposed by the Commission

Amendment

Article 22

deleted

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) may be revoked at any time by the European Parliament or

by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

Or. en

Justification

All decisions in this directive are highly political decisions. Any changes have to be made with ordinary legislative procedure.

Amendment 1266
Ewald Stadler

Proposal for a directive
Article 22 – paragraph 1

Text proposed by the Commission

Amendment

1. The power to adopt delegated acts is

1. The power to adopt delegated acts is

conferred on the Commission subject to the conditions laid down in this Article.

conferred on the Commission subject to the conditions laid down in this Article.

Delegated acts may only be adopted in cases in which this Directive expressly provides for such a delegation.

Or. de

Justification

It seems inefficient to enumerate each and every delegation provided for in this Directive in the following paragraphs.

Amendment 1267

Anna Rosbach

Proposal for a directive

Article 22 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. When preparing delegated acts the Commission shall ensure proper consultation at both Member State and Union level adhering to Article 4 paragraph 7, and Article 5 paragraph 3 of the WHO Framework Convention on Tobacco Control (FCTC).

Or. en

Justification

This amendment was inspired by a letter from The Standing Committee of European Doctors (CPME)

Amendment 1268

Georgios Koumoutsakos

Proposal for a directive

Article 22 – paragraph 2

Text proposed by the Commission

Amendment

2. The power to adopt delegated acts

2. The power to adopt delegated acts

PE510.722v01-00

22/76

AM\935765EN.doc

referred to in Articles **3(2), 3(3), 4(3), 4(4), 6(3), 6(9)**, 6(10), 8(4), **9(3)**, 10(5), 11(3), **13(3), 13(4), 14(9)**, 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

referred to in Articles **6(10)**, 8(4), 10(5), 11(3), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. el

Justification

The deleted provisions are essential elements of the legislative act. Any amendment to these provisions should therefore be subject to the usual legislative procedure.

Amendment 1269

Ewald Stadler

Proposal for a directive

Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts ***referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5)*** shall be conferred on the Commission for ***an indeterminate period of time*** from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts shall be conferred on the Commission for ***a period of two years*** from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. de

Justification

In order to increase parliamentary control, the duration of the delegation must be limited. Two years seems appropriate because Parliament must also be able to exercise some control over the Commission within a parliamentary term.

Amendment 1270

Martin Callanan

Proposal for a directive

Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles **3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5)** shall be conferred on the Commission for **an indeterminate** period of **time from [Office of Publications: please insert the date of the entry into force of this Directive]**.

Amendment

2. The power to adopt delegated acts referred to in Articles 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 11(3), 13(3), 13(4), **and 14(9)** shall be conferred on the Commission for **a period of 5 years from (...). (Publications Office is to fill in the date of entry into force of this amending Act). The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of five-year period. The delegation of power shall be tacitly extended for periods of identical duration unless the European Parliament or Council opposes such an extension not later than 3 months before the end of each period.**

Or. en

Justification

Consistent with the European Parliament's standard wording on delegated acts.

Amendment 1271

Karl-Heinz Florenz, Thomas Ulmer

Proposal for a directive

Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), **6(9), 6(10)**, 8(4), 9(3), 10(5), 11(3), 13(3), **13(4)**, 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(**4**), 8(4), 9(3), 10(5), 11(3), 13(3), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. de

Justification

Follow-up amendment: technical adjustment due to the amendments to Articles 6 and 13 of the Commission proposal.

Amendment 1272

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), **13(3), 13(4), 14(9), 18(2) and 18(5)** shall be conferred on the Commission for ***an indeterminate*** period of ***time*** from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3a), 4(3), 4(4) ***and 4(4a), 6(2)***, 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3) ***and*** 14(9) shall be conferred on the Commission for ***a*** period of ***five years*** from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. it

Amendment 1273

Paolo Bartolozzi, Elisabetta Gardini, Sergio Berlato, Salvatore Tatarella, Giovanni La Via, Roberta Angelilli

Proposal for a directive Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for ***an indeterminate*** period of ***time*** from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for ***a*** period of ***three years*** from [Office of Publications: please insert the date of the entry into force of this Directive]. the date of the entry into force of this Directive].

Amendment 1274

María Auxiliadora Correa Zamora, Esther Herranz García

Proposal for a directive

Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles **3(2), 3(3), 4(3)**, 4(4), **6(3), 6(9), 6(10)**, 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts referred to in Articles, 4(4), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. en

Justification

Coherence with previous amendments

Amendment 1275

Eleni Theocharous

Proposal for a directive

Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles **3(2), 3(3)**, 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts referred to in Articles 4(3), 4(4), 6(3),

6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an

indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. en

Amendment 1276
Sergej Kozlík

Proposal for a directive
Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles **3(2)**, **3(3)**, 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts referred to in Articles 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. en

Amendment 1277
Cristian Silviu Buşoi

Proposal for a directive
Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles **3(2)**, **3(3)**, 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts referred to in Articles 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. en

Justification

In line with deletion of delegated acts in previous amendments.

Amendment 1278

Milan Cabrnoch

Proposal for a directive

Article 22 – paragraph 2

Text proposed by the Commission

2. The power to adopt delegated acts referred to in Articles **3(2)**, **3(3)**, 4(3), 4(4), 6(3), 6(9), 6(10), **8(4)**, 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Amendment

2. The power to adopt delegated acts referred to in Articles 4(3), 4(4), 6(3), 6(9), 6(10), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5) shall be conferred on the Commission for an indeterminate period of time from [Office of Publications: please insert the date of the entry into force of this Directive].

Or. cs

Amendment 1279

Jaroslav Kalinowski

Proposal for a directive

Article 22 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. Delegated acts issued on the basis of Article 8(4) and Article 9(3)(a)–(c) provide for a transition period of at least 24 months, during which smoking tobacco packaging featuring health warnings set out in this Directive, as well as in the delegated act announced on the basis of the authorisations contained in the above provisions, may be used in parallel.

Or. pl

Justification

The production and distribution cycle, from printing the packages to their sale by the retailer, lasts from 18 to 24 months, and in the event that significant changes are made to the appearance of the packaging – up to 36 months. In this connection, in order to prevent unnecessary losses linked to the need to withdraw cigarettes from the market, there should be provision for a transition period during which packages with the ‘old’ health warnings would remain in circulation in parallel with those featuring the newly introduced warnings. This would facilitate the smooth transition between packaging designs.

Amendment 1280

Ewald Stadler

Proposal for a directive

Article 22 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. de

Amendment 1281

Martin Callanan

Proposal for a directive

Article 22 – paragraph 3

Text proposed by the Commission

3. *The delegation of powers referred to in* Articles *3(2), 3(3), 4(3), 4(4), 6(3), 6(9),*

Amendment

3. Articles 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 11(3), 13(3), 13(4), *and* 14(9)

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

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

Or. en

Amendment 1282

María Auxiliadora Correa Zamora, Esther Herranz García

Proposal for a directive

Article 22 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

Coherence with previous amendments

Amendment 1283

Karl-Heinz Florenz, Thomas Ulmer

Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. de

Justification

Follow-up amendment: technical adjustment due to the amendments to Articles 6 and 13 of the Commission proposal.

Amendment 1284

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission

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

Amendment

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

European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. it

Amendment 1285
Cristian Silviu Buşoi

Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

In line with deletion of delegated acts by previous amendments.

Amendment 1286
Eleni Theocharous

Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission

3. The delegation of powers referred to in Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9),

Amendment

3. The delegation of powers referred to in Articles 4(3), 4(4), 6(3), 6(9), 6(10), 8(4),

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

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

Or. en

Amendment 1287

Milan Cabrnoch

Proposal for a directive

Article 22 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. cs

Amendment 1288

Sergej Kozlík

Proposal for a directive

Article 22 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1289

Ewald Stadler

Proposal for a directive

Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. de

Amendment 1290
Jaroslav Kalinowski

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. pl

Justification

The removed provisions concern the Commission's power to issue delegated acts, which should be regulated by the basic act or the examination procedure on the basis of Article 291 of the TFEU.

Amendment 1291
Martin Callanan

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

5. A delegated act pursuant to Articles **3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), 13(3), 13(4), 14(9), 18(2) and 18(5)** shall enter into force only if no objection has been expressed either by the European Parliament or the Council

Amendment

5. A delegated act pursuant to Articles 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 11(3), 13(3), 13(4), **and** 14(9) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period

within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Or. en

Amendment 1292

María Auxiliadora Correa Zamora, Esther Herranz García

Proposal for a directive

Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

Coherence with previous amendments

Amendment 1293

Karl-Heinz Florenz, Thomas Ulmer

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. de

Justification

Follow-up amendment: technical adjustment due to the amendments to Articles 6 and 13 of the Commission proposal.

Amendment 1294

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

5. A delegated act pursuant to Articles 3(2), 3(3), 4(3), 4(4), 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3), **13(3), 13(4)**, 14(9), **18(2) and 18(5)** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European

Amendment

5. A delegated act pursuant to Articles 3(2), 3(3a), 4(3), 4(4), **4(4a), 6(2)**, 6(3), 6(9), 6(10), 8(4), 9(3), 10(5), 11(3) **and** 14(9) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the

Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Or. it

Amendment 1295
Milan Cabrnoch

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. cs

Amendment 1296
Sergej Kozlík

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1297
Eleni Theocharous

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1298
Cristian Silviu Buşoi

Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

In line with deletion of delegated acts by previous amendments.

Amendment 1299
Paul Nuttall, Godfrey Bloom

Proposal for a directive
Article 23

Text proposed by the Commission

Article 23

Report

1.

No later than five years from the date specified in Article 25 paragraph 1, the

Amendment

deleted

Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive.

With a view to drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information available.

2.

In the report, the Commission shall indicate in particular the features which should be reviewed or developed in the light of developments in scientific and technical knowledge, including the development of internationally agreed rules and standards on products, and shall pay special heed to:

(a) the experience gained with respect to the design of package surfaces not governed by this Directive taking into account national, international, legal, economic and scientific developments;

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

(c) market developments which amount to a substantial change of circumstances.

The Member States shall provide the Commission with assistance and all available information for carrying out the assessment and preparing the report.

3. The report shall be accompanied by any proposals for amendments to this Directive which the Commission deems necessary to adapt it to developments in the field of tobacco and related products, to the extent necessary for the operation of the internal market, and to take into account any new developments based on scientific facts and developments on internationally agreed product standards.

Or. en

Amendment 1300

Róża Gräfin von Thun und Hohenstein, Bogusław Sonik, Czesław Adam Siekierski

Proposal for a directive

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. No later than 2 years from the date specified in Article 25 paragraph 1, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the economic and social consequences of the application of this Directive

Or. en

Amendment 1301

Milan Cabrnoch

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

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

b) market developments in novel tobacco products considering, inter alia, notifications received under Article 17, ***with particular reference to evaluating the potential advantages of less harmful new categories of tobacco products and the decreased risk of smoking-associated diseases;***

Or. cs

Amendment 1302

Christel Schaldemose, Dan Jørgensen

Proposal for a directive

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

Text proposed by the Commission

Amendment

(ca) methodologies for more realistically assessing and regulating toxic exposure and harm;

Or. da

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 1303

María Auxiliadora Correa Zamora, Esther Herranz García

Proposal for a directive

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

Text proposed by the Commission

Amendment

(ca) The Directive's potential impact on European tobacco cultivation.

Or. es

Amendment 1304

Christel Schaldemose, Dan Jørgensen

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c b (new)

Text proposed by the Commission

Amendment

(cb) evaluation of the addictive effects of those ingredients which encourage addiction;

Or. da

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 1305

Christel Schaldemose, Dan Jørgensen

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c c (new)

Text proposed by the Commission

Amendment

(cc) evaluation of tobacco products which may have the potential to reduce harm;

Or. da

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 1306

Christel Schaldemose, Dan Jørgensen

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c d (new)

Text proposed by the Commission

Amendment

(cd) development of standardised testing methods to measure the yields of constituents in cigarette smoke other than tar, nicotine and carbon monoxide;

Or. da

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 1307

Christel Schaldemose, Dan Jørgensen

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c e (new)

Text proposed by the Commission

Amendment

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

Or. da

Justification

Point reinstated from current Directive 2001/37/EC

Amendment 1308

Christel Schaldemose, Dan Jørgensen

Proposal for a directive

Article 23 – paragraph 2 – subparagraph 1 – point c f (new)

Text proposed by the Commission

Amendment

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

Or. da

Amendment 1309

Carl Schlyter

Proposal for a directive

Article 23 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Member States shall report every two years to the Commission on the enforcement of the measures taken pursuant to Council Recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control , in particular with regard to age limits set in national

legislation, as well as their plans to increase the age limit to achieve the goal of a "smoke-free generation".

Or. en

Justification

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

Amendment 1310

Martin Callanan

Proposal for a directive

Article 24 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 1311

Holger Krahmer

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***

Amendment

2. ***This Directive shall not affect the right of Member States, in accordance with the Treaty, to maintain or introduce more stringent provisions with respect to tobacco products which they deem***

the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. Such national provisions shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved.

necessary to protect public health, provided these provisions do not fall within the scope of the provisions of this Directive.

Or. de

Amendment 1312
Martin Callanan

Proposal for a directive
Article 24 – paragraph 2

Text proposed by the Commission

2. *However*, a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, *on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the*

Amendment

2. A Member State may *adopt or* maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, *insofar as such provisions are compatible with the Treaty.*

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.

Or. en

Justification

It is crucial for public health reasons that Member States retain the ability to go further domestically on tobacco control measures if they so wish and that Member States are not restricted in their ambitions on tobacco control where it is proportionate and compatible with EU law. Furthermore, there is a strong argument that Member States should not be forced to consider regressive action following the adoption of the revised Directive.

Amendment 1313 **Georgios Koumoutsakos**

Proposal for a directive **Article 24 – paragraph 2**

Text proposed by the Commission

2. However, *a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the*

Amendment

2. However, *this Directive shall not affect the right of Member States to introduce more stringent provisions, provided these provisions are justified by the need to protect public health, in accordance with the principle of subsidiarity. Such national provisions shall be notified to the Commission together with the grounds for*

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.

maintaining or introducing them.

Or. el

Justification

The aim of the Directive is to harmonise the market in tobacco products rather than to fragment it. It must also be emphasised that public health protection falls within the competence of Member States.

Amendment 1314 Milan Cabrnoch

Proposal for a directive Article 24 – paragraph 2

Text proposed by the Commission

2. However, a Member State may maintain more stringent national provisions, applicable to **all products alike**, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of

Amendment

2. However, a Member State may maintain more stringent national provisions, applicable to **products manufactured and sold in the Member State concerned**, 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

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.

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. ***Without prejudice to Directive 98/84/EC***, 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.

Or. cs

Amendment 1315
Frédérique Ries

Proposal for a directive
Article 24 – paragraph 2

Text proposed by the Commission

2. However, a Member State **may** maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State **may** also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. Such national provisions shall be notified to the Commission together with the grounds for

Amendment

2. However, a Member State **shall have the right to** 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.

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.

A Member State *shall* also *have the right to* 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.

Or. fr

Justification

Member States should be able to maintain more stringent national provisions, applicable to all products, in areas covered by the Directive, where there are compelling public health grounds for doing so.

Amendment 1316

Martina Anderson, Kartika Tamara Liotard

Proposal for a directive

Article 24 – paragraph 2

Text proposed by the Commission

2. However, a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. Such national provisions shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved.

Amendment

2. However, a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. ***Provisions recommending retailers of tobacco products to not display them at the point of sale are considered suitable measures to safeguard public health.*** A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. Such national provisions shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved.

Or. en

Justification

All measures which discourage the sale of tobacco related products, including those

provisions which recommend appropriate concealment from display of those products in the authorised shops, have been undertaken to protect public health.

Amendment 1317

Renate Sommer

Proposal for a directive

Article 24 – paragraph 2

Text proposed by the Commission

2. However, a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. Such national provisions shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved.

Amendment

2. In the absence of a decision by the Commission within this period the national provisions shall be deemed to be approved. However, a Member State may maintain more stringent national provisions, applicable to all products alike, in areas covered by the Directive, on grounds of overriding needs relating to the protection of public health. A Member State may also introduce more stringent provisions, on grounds relating to the specific situation of this Member State and provided the provisions are justified by the need to protect public health. Such national provisions shall be notified to the Commission together with the grounds for maintaining or introducing them. The Commission shall, within six months from the date of receiving the notification, approve or reject the provisions after having verified, taking into account the high level of health protection achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim ***and to the requirements and principles of the single market*** 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. de

Amendment 1318
Holger Krahmer

Proposal for a directive
Article 24 – paragraph 3

Text proposed by the Commission

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 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.

deleted

Or. de

Amendment 1319
Martin Callanan

Proposal for a directive
Article 24 – paragraph 3

Text proposed by the Commission

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 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***

3. This Directive shall not affect the right of Member States to maintain or introduce, ***insofar as they are compatible with*** the Treaty, national provisions concerning aspects not regulated by this Directive.

this Directive.

Or. en

Justification

The deleted text is redundant given the application of the Treaty.

Amendment 1320
Ewald Stadler

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 not be a means of arbitrary discrimination or a disguised restriction on trade between the Member States ***and must not jeopardise the full application of this Directive.***

Amendment

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

Or. de

Justification

The last phrase is redundant, because the Directive must in any case be transposed according to the provisions of the Treaty.

Amendment 1321
Ewald Stadler

Proposal for a directive
Article 24 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. This Directive shall under no circumstances affect the right of Member States to adopt more stringent rules, provided they are essential for the protection of public health and do not go excessively beyond the standards set in, or fall outside the scope of, this Directive.

Or. de

Justification

Excessive deviations would be a gross violation of the principle of legal certainty and deflect from, rather than promote, the intended purpose of this Directive.

Amendment 1322
Milan Cabrnoch

Proposal for a directive
Article 25 – paragraph 1

Text proposed by the Commission

Amendment

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

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [Publications Office, please insert the exact date: entry into force + **24** months] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

Or. cs

Amendment 1323
Karl-Heinz Florenz, Thomas Ulmer

Proposal for a directive
Article 25 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. de

Justification

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

Amendment 1324
Paul Nuttall, Godfrey Bloom

Proposal for a directive
Article 26

Text proposed by the Commission

Article 26

Transitional provision

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

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

Amendment

deleted

Amendment 1325
Milan Cabrnoch

Proposal for a directive
Article 26 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. cs

Amendment 1326
Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive
Article 26 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. pl

Justification

Member States should be provided with an appropriate amount of time to adapt to the changes ensuing from the Directive's provisions, especially since these changes will have different effects on different Member States.

Amendment 1327
Renate Sommer

Proposal for a directive
Article 26 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until [**24 months after transposition into national law**]:

Or. de

Amendment 1328
Timothy Kirkhope

Proposal for a directive
Article 26 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market until [Publications Office, please insert the exact date: entry into force + **42** months **to allow for necessary changes in the production and packaging process and for the disposal of existing stocks**]:

Or. en

Amendment 1329
Linda McAvan, Karl-Heinz Florenz

Proposal for a directive
Article 26 – paragraph 1 – introductory part

Text proposed by the Commission

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market

Amendment

Member States may allow the following products, which are not in compliance with this Directive, to be placed on the market

until [Publications Office, please insert the exact date: entry into force + **24** months]:

until [Publications Office, please insert the exact date: entry into force + **36** months]:

Or. en

Amendment 1330

Glenis Willmott, Andrés Perelló Rodríguez, Kartika Tamara Liotard, Carl Schlyter, Catherine Stihler, Antonia Parvanova

Proposal for a directive

Article 26 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Member States may allow nicotine containing products which are not in compliance with this Directive to be placed on the market until [Publications Office, please insert the exact date: entry into force + 48 months]:

Or. en

Justification

It is important that nicotine containing products have enough time to be authorised as pharmaceuticals, to avoid a time period where these products are removed from the market entirely.

Amendment 1331

Holger Krahmer

Proposal for a directive

Article 26 – paragraph 1 – point a

Text proposed by the Commission

Amendment

a) tobacco ***products***;

a) ***cigarettes and roll-your-own*** tobacco;

Or. de

Amendment 1332

Glenis Willmott, Andrés Perelló Rodríguez, Kartika Tamara Liotard, Carl Schlyter, Catherine Stihler, Antonia Parvanova

Proposal for a directive

Article 26 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

Or. en

Justification

It is important that nicotine containing products have enough time to be authorised as pharmaceuticals, to avoid a time period where these products are removed from the market entirely.

Amendment 1333

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive

Article 26 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

(b) nicotine containing products;

Or. en

Amendment 1334

Linda McAvan, Karl-Heinz Florenz

Proposal for a directive

Article 26 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

(b) nicotine containing products;

Amendment 1335

Jolanta Emilia Hibner, Małgorzata Handzlik, Bogusław Sonik

Proposal for a directive

Article 26 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

b) nicotine containing products;

Or. pl

Amendment 1336

Holger Krahmer

Proposal for a directive

Article 26 – paragraph 1 – point c

Text proposed by the Commission

Amendment

c) herbal products for smoking.

c) herbal products for smoking.

Member States may allow tobacco products other than cigarettes and roll-you-own tobacco that do not comply with the provisions of this Directive until [Date of entry into force + 42 months].

Or. de

Justification

Pursuant to recital (18) of Directive 2001/37/EC, sufficiently long transitional periods should be granted to allow the necessary modifications in production and the selling-of existing stocks to take place. This is particularly important in relation to small and medium-sized enterprises and tobacco plantations affected by this Directive.

Amendment 1337

Glenis Willmott, Kartika Tamara Liotard, Carl Schlyter, Nessa Childers, Catherine Stihler, Antonia Parvanova, Kathleen Van Brempt

Proposal for a directive

Annex 1 a (new)

Text proposed by the Commission

Amendment

Annex -I

Additives approved for use in tobacco products

Chemical name of the additive - function - maximum level permitted

Or. en

Justification

The positive list of additives that can be used in tobacco products should be inserted as a new Annex to the Directive.

Amendment 1338

Daniël van der Stoep

Proposal for a directive

Annex 1 – point 1

Text proposed by the Commission

Amendment

(1) Smoking causes 9 out of 10 lung cancers

deleted

Or. nl

Amendment 1339

Daniël van der Stoep

Proposal for a directive

Annex 1 – point 2

Text proposed by the Commission

Amendment

(2) Smoking causes mouth and throat cancer

deleted

Or. nl

Amendment 1340
Frédérique Ries

Proposal for a directive
Annex 1 – point 2 a (new)

Text proposed by the Commission

Amendment

(2 a) Smoking causes bladder cancer

Or. en

Justification

Bladder cancer is alarmingly common in the EU (fourth most common cancer in men and fourteenth in women, according to the IARC) and tobacco smoking represents the first risk factor for bladder cancer. A number of countries (including Australia, Canada and New Zealand) already use this health warning to raise awareness on the causal link between smoking and bladder cancer.

Amendment 1341
Daniël van der Stoep

Proposal for a directive
Annex 1 – point 4

Text proposed by the Commission

Amendment

(4) Smoking causes heart attacks

deleted

Or. nl

Amendment 1342
Daniël van der Stoep

Proposal for a directive
Annex 1 – point 5

Text proposed by the Commission

Amendment

(5) Smoking causes strokes and disability

deleted

Or. nl

Amendment 1343

Françoise Grossetête, Frédérique Ries, Karl-Heinz Florenz

Proposal for a directive

Annex 1 – point 6 a (new)

Text proposed by the Commission

Amendment

(6a) Smoking causes cancer of the bladder

Or. fr

Justification

This type of cancer poses a more serious health risk than people realise. Smoking is the cause of 50 % of bladder cancer cases in men and a third of such cases in women. Whilst until now men have been more likely to develop this form of cancer, there has been a significant increase in the numbers of women suffering from cancer of the bladder owing to the rise in the number of women smokers.

Amendment 1344

Daniël van der Stoep

Proposal for a directive

Annex 1 – point 7

Text proposed by the Commission

Amendment

(7) Smoking increases the risk of blindness

deleted

Or. nl

Amendment 1345

Daniël van der Stoep

Proposal for a directive

Annex 1 – point 8

Text proposed by the Commission

Amendment

(8) Smoking damages your teeth and gums

deleted

Amendment 1346
Daniël van der Stoep

Proposal for a directive
Annex 1 – point 9

Text proposed by the Commission

Amendment

(9) Smoking can kill your unborn child **deleted**

Amendment 1347
Andrés Perelló Rodríguez

Proposal for a directive
Annex 1 – point 10

Text proposed by the Commission

Amendment

10) Your smoke **harms** your children,
family and friends

10) Your smoke **shortens the life of** your
children, family and friends; **do not expose**
them to it

Amendment 1348
Daniël van der Stoep

Proposal for a directive
Annex 1 – point 11

Text proposed by the Commission

Amendment

(11) Smokers' children are more likely to
start smoking **deleted**

Amendment 1349
Daniël van der Stoep

Proposal for a directive
Annex 1 – point 12

Text proposed by the Commission

Amendment

(12) *Quit smoking – stay alive for those close to you* ***deleted***

Or. nl

Amendment 1350
Daniël van der Stoep

Proposal for a directive
Annex 1 – point 13

Text proposed by the Commission

Amendment

(13) *Smoking reduces fertility* ***deleted***

Or. nl

Amendment 1351
Daniël van der Stoep

Proposal for a directive
Annex 1 – point 14

Text proposed by the Commission

Amendment

(14) *Smoking increases the risk of impotence* ***deleted***

Or. nl

Amendment 1352
Peter Liese, Angelika Niebler, Gaston Franco, Radvilė Morkūnaitė-Mikulėnienė, Anne Delvaux, Karl-Heinz Florenz, Jolanta Emilia Hibner, Renate Sommer, Alojz Peterle, Richard Seeber, Françoise Grossetête, Esther de Lange, Marianne Thyssen, Miroslav Mikolášik, Elena Oana Antonescu, Christa Klauß

**Proposal for a directive
Annex 1 – point 14 a (new)**

Text proposed by the Commission

Amendment

***(14 a) Smoking in presence of children
can cause sudden infant death***

Or. en

Justification

There should be a new text warning to protect children and unborn child from health threats caused by smoking.

Amendment 1353

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

**Proposal for a directive
Annex 1 – point 14 a (new)**

Text proposed by the Commission

Amendment

***(14 a) This product contains nicotine and
is damaging to your health.***

*(Amendment linked to the amendment on
Title 1a (new) of Annex I.)*

Or. it

See amendments to Article 18.

Amendment 1354

Peter Liese, Angelika Niebler, Gaston Franco, Radvilė Morkūnaitė-Mikulėnienė, Anne Delvaux, Karl-Heinz Florenz, Renate Sommer, Jolanta Emilia Hibner, Alojz Peterle, Richard Seeber, Françoise Grossetête, Esther de Lange, Marianne Thyssen, Sophie Auconie, Miroslav Mikolášik, Elena Oana Antonescu, Christa Klauß

**Proposal for a directive
Annex 1 – point 14 b (new)**

Text proposed by the Commission

Amendment

(14 b) Smoking during pregnancy causes

premature birth

Or. en

Justification

There should be a new text warning to protect children and unborn child from health threats caused by smoking.

Amendment 1355

Peter Liese, Angelika Niebler, Gaston Franco, Radvilė Morkūnaitė-Mikulėnienė, Anne Delvaux, Karl-Heinz Florenz, Renate Sommer, Alojz Peterle, Jolanta Emilia Hibner, Richard Seeber, Esther de Lange, Marianne Thyssen, Sophie Auconie, Miroslav Mikolášik, Elena Oana Antonescu, Christa Klauß, Anna Rosbach

Proposal for a directive

Annex 1 – point 14 c (new)

Text proposed by the Commission

Amendment

(14 c) Children that are forced to smoke passive are more vulnerable to asthma and meningitis

Or. en

Justification

There should be a new text warning to protect children and unborn child from health threats caused by smoking.

Amendment 1356

Giancarlo Scottà, Oreste Rossi, Matteo Salvini, Francesco Enrico Speroni, Claudio Morganti, Lorenzo Fontana

Proposal for a directive

Annex 1 – heading 1 a (new)

Text proposed by the Commission

Amendment

List of the text warnings referred to in Article 18

Or. it

See amendments to Article 18.

Amendment 1357
Frédérique Ries, Corinne Lepage

Proposal for a directive
Annex 1 a (new)

Text proposed by the Commission

Amendment

Annex I a new

List of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.

Constituent

Acetaldehyde

Acetamide

Acetone

Acrolein

Acrylamide

Acrylonitrile

Aflatoxin B1

4-Aminobiphenyl

1-Aminonaphthalene

2-Aminonaphthalene

Ammonia

Anabasine

o-Anisidine

Arsenic

A- α -C (2-Amino-9H-pyrido[2,3-b]indole)

Benz[a]anthracene

Benz[j]aceanthrylene

Benzene

Benzo[b]fluoranthene

Benzo[k]fluoranthene

Benzo[b]furan

Benzo[a]pyrene

Benzo[c]phenanthrene
Beryllium
1,3-Butadiene
Cadmium
Caffeic acid
Carbon monoxide
Catechol
Chlorinated dioxins/furans
Chromium
Chrysene
Cobalt
Coumarin
Cresols (o-, m-, and p-cresol)
Crotonaldehyde
Cyclopenta[c,d]pyrene
Dibenz[a,h]anthracene
Dibenzo[a,e]pyrene
Dibenzo[a,h]pyrene
Dibenzo[a,i]pyrene
Dibenzo[a,l]pyrene
2,6-Dimethylaniline
Ethyl carbamate (urethane)
Ethylbenzene
Ethylene oxide
Formaldehyde
Furan
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole)
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]imidazole)
Hydrazine
Hydrogen cyanide
Indeno[1,2,3-cd]pyrene
IQ (2-Amino-3-methylimidazo[4,5-

flquinoline)
Isoprene
Lead
MeA- α -C (2-Amino-3-methyl)-9H-pyrido[2,3-b]indole)
Mercury
Methyl ethyl ketone
5-Methylchrysene
4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)
Naphthalene
Nickel
Nicotine
Nitrobenzene
Nitromethane
2-Nitropropane
N-Nitrosodiethanolamine (NDELA)
N-Nitrosodiethylamine
N-Nitrosodimethylamine (NDMA)
N-Nitrosomethylethylamine
N-Nitrosomorpholine (NMOR)
N-Nitrosornicotine (NNN)
N-Nitrosopiperidine (NPIP)
N-Nitrosopyrrolidine (NPYR)
N-Nitrososarcosine (NSAR)
Nornicotine
Phenol
PhIP (2-Amino-1-methyl-6-phenylimidazo[4,5-b]pyridine)
Polonium-210
Propionaldehyde
Propylene oxide
Quinoline
Selenium

Styrene
o-Toluidine
Toluene
Trp-P-1 (3-Amino-1,4-dimethyl-5H-pyrido[4,3-b]indole)
Trp-P-2 (1-Methyl-3-amino-5H-pyrido[4,3-b]indole)
Uranium-235
Uranium-238
Vinyl acetate
Vinyl chloride

Or. en

Justification

It is important to set up in a new annex a list of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke, the same as the one established in 2009 by the FDA in the Family Smoking Prevention and Tobacco Control Act .

Amendment 1358
Frédérique Ries, Corinne Lepage

Proposal for a directive
Annex 1 b (new)

Text proposed by the Commission

Amendment

<i>Table 1 - HPHCs in Cigarette Smoke</i>	<i>Table 2 - HPHCs in Smokeless Tobacco</i>	<i>Table 3 - HPHCs in Roll-your-own Tobacco</i>
<i>Acetaldehyde</i>	<i>Acetaldehyde</i>	<i>Ammonia</i>
<i>Acrolein</i>	<i>Arsenic</i>	<i>Arsenic</i>
<i>Acrylonitrile</i>	<i>Benzo[a]pyrene</i>	<i>Cadmium</i>
<i>4-Aminobiphenyl</i>	<i>Cadmium</i>	<i>Nicotine</i>
<i>1-Aminonaphthalene</i>	<i>Crotonaldehyde</i>	<i>NNK*</i>

<i>2-Aminonaphthalene</i>	<i>Formaldehyde</i>	<i>NNN**</i>
<i>Ammonia</i>	<i>Nicotine</i>	
<i>Benzene</i>	<i>NNK*</i>	
<i>Benzo[a]pyrene</i>	<i>NNN**</i>	
<i>1,3-Butadiene</i>		
<i>Carbon monoxide</i>		
<i>Crotonaldehyde</i>		
<i>Formaldehyde</i>		
<i>Isoprene</i>		
<i>Nicotine</i>		
<i>NNK*</i>		
<i>NNN**</i>		
<i>Toluene</i>		

** 4-(methylnitrosamino)-
1-(3-pyridyl)-1-butanone*

*** N-nitrosonornicotine*

Or. en

Justification

Linked with the amendment to the Article 5-paragraph 1-subparagraph 1. It is important to establish a short list of the most common hazardous substances identified by tobacco product type, similar to the American law ("Tobacco Control Act"). This new Annex provides a basis to begin the study of regulated tobacco products pending submission of information for all Harmful and Potentially Harmful Constituents within the transposition deadline of Article 25.

Amendment 1359

Christian Engström, Chris Davies, Christofer Fjellner

Proposal for a directive

Annex 2 a (new)

Text proposed by the Commission

Amendment

ANNEX III

***Maximum permissible content in
smokeless tobacco, toxin per unit weight***

dry tobacco:

NNN (N-nitrosornicotine) plus NNK (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone): 2.0 mg/kg

B(a)P (Benzo[a]Pyrene): 5.0 µg/kg

Or. en

Justification

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

Amendment 1360

Christian Engström, Chris Davies, Christofer Fjellner, Rebecca Taylor

Proposal for a directive

Annex 2 b (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