Info post: EU legislative proposals for nicotine containing products (e-cigarettes)

written by Clive Bates | 30 November 2013

Updated 20 December 2013. This post provides nine texts following the development of the TPD provisions for nicotine containing products – for information and without comment:

1. The Commission Proposal for Article 18 on Nicotine Containing Products, 19 December 2012.

2. The Council General Approach for Article 18 – an informal agreement between representatives of the member states, 21 June 2013.

3. The European Parliament's amendment 170 for Article 18, 8 October 2013.

4. The Commission's 'suggested text' from a 'non-paper' leaked to the Nicotine Science and Policy website undated but approximately 22 November 2013 (secret).

5. An update to the Commission's suggested text published on 29 November 2013 (secret).

6. A further update Presidency / Commission text 6 December 2013 (secret).

7. A newly modified version of the Presidency / Commission negotiating text 10 December 2013 (secret)

8. Negotiating text 12 December 2013 (secret) – note PDF only

9. Text agreed by trilogue process and subsequently approved by COREPER 17 December (secret) – here

1. Article 18 Commission Proposal (19 December 2012)

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

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

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

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

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

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

“This product contains nicotine and can damage your health”.

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

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

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

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

[**note**: almost all e-cigarettes would be covered by paragraph 1 alone]

2. Article 18 Council General Approach (21 June 2013)

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

(a) products with a nicotine level equal to or exceeding 1 mg per unit, or

(b) products with a nicotine concentration equal to or exceeding 2 mg per ml

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

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

This product contains nicotine which is an addictive substance and can damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 8(4). In addition, it shall:

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

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

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the wording of the health warning in paragraphs 3 based on scientific and market developments.

5a. The provisions of paragraphs (3) to (5) of this article shall be without prejudice to the application of Directive 2001/83/EC.

6. Nicotine-containing products referred to in Article 18(1) and which are placed on the market before [entry into force + 24 months], may continue to be marketed until [entry into force + 36 months]

3. European Parliament Amendment 170 to Article 18 at first reading (8 October 2013)

1. Nicotine-containing products may only be placed on the market in accordance with the notification procedure set out in Article 17 of this Directive.

Member States shall ensure that nicotine-containing products comply with all relevant Union legislation, and in particular with Directive 2001/95/EC on general product safety.

2. Nicotine-containing products that are presented as having properties for treating or preventing disease may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC.

3. As regards nicotine-containing products to be placed on the market in accordance with paragraph 1, Member States shall ensure that:

(a) nicotine-containing products with a nicotine level exceeding 30 mg/ml are not placed on the market;

(b) manufacturers and importers of nicotine-containing products submit to the competent authorities a list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof, as well as any changes. Member States shall then ensure the dissemination of this information on a website with due regard to the protection of trade secrets. Manufacturers and importers shall also report to the authorities about national sales volumes by brand name and type;

(c) nicotine-containing products with additives listed in Article 6(4) are not placed on the market;

(d) the unit packet of nicotine-containing products includes a leaflet with instructions for use, including that the reference that the product is not recommended for use by non-smokers, contra-indications, warnings for specific risk groups, reporting of adverse reactions, place of manufacture and contact details of the manufacturer or importer;

(e) each unit packet and any outside packaging of nicotine-containing products carry the following health warning:

"This product is intended for use by existing smokers. It contains nicotine which is a highly addictive substance";

(f) the sale of the product is restricted in line with the legal age for sale of tobacco products in the relevant Member State; in any case it should not be allowed under the age of 18;

(g) the products are available to be sold outside pharmacies;

(h) flavourings are allowed in the products;

(i) the limitations on advertising, sponsorship, audiovisual commercial communication and product placement for tobacco products as set out in Directive 2003/33/EC and Directive 2010/13/EC shall apply to nicotine-containing products;

(j) cross-border distance sales of nicotine-containing products are regulated in accordance with Article 16;

(k) tobacco trademarks, brand names and symbols are not used on nicotine-containing products.

4. The health warning referred to in paragraph 3(e) shall comply with the requirements specified in Article 10.

5. Member States shall monitor the development of the nicotine-containing products market, including any evidence of gateway use among young people and report their findings to the Commission. Based on the evidence submitted as well

as scientific studies the Commission shall submit a report to the European Parliament and the Council on nicotine-containing products five years after entry into force of this Directive. The report shall assess if amendments to this Directive or any further legislation are necessary.

4. Commission 'suggested text' for Article 18 from trilogue process (~22 November 2013) – secret

[Scope]

1. Electronic cigarettes are a tobacco related product. They can be placed on the market as a tobacco related product if they comply with the relevant provisions of this Directive and all other relevant Union legislation.

Electronic cigarettes can be classified as medicinal product by presentation pursuant to first subparagraph 2a of Art. 1(2) of Directive 2001/83/EC if they are presented as having properties for treating or preventing disease in human beings. They cannot be classified as a medicinal product by function pursuant to the second subparagraph 2b of Article 1(2) of Directive 2001/83/EC.

[Notification]

2. Manufacturers and importers of electronic cigarettes shall notify the products with the competent authorities of the Member States in which the product is intended to be placed on the market. The notification shall be submitted in electronic form 6 months before the intended placing on the market. For electronic cigarettes already placed on the market on the date referred to in paragraph 1 of Article 25, the notification shall be submitted within 6 months of that date. A new notification shall be submitted for each substantial modification of the product.

The notification shall include at least the following information:

a. name and contact details of the manufacturer and, if applicable, the importer into the EU;

b. list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof;

c. toxicological data available to the manufacturer or importer regarding these ingredients;

d. information on nicotine dosing when used under reasonable and foreseeable conditions; and

e. description of the components of the electronic cigarette.

Proportionate fees may be charged by Member States for receiving, storing, handling and analysing the information submitted to them.

[Safety and quality]

3. Member States shall require manufacturers and importers of electronic cigarettes to bear full responsibility for the quality and safety of electronic cigarettes placed on the market when used under reasonable and foreseeable conditions.

Member States shall require that manufacturers and importers of electronic cigarettes to establish and comply at least with the following manufacturing requirements:

a) design and manufacture in accordance with the safety requirement set out in this article;

b) procedures in place for series production to remain in conformity with the safety requirement;

c) a safety assessment prior to placing on the market, with information on the composition of the product, microbiological quality, impurities and traces, toxicological profiles, and adverse effects;

d) a legal or natural contact person within the European Union.

Member States shall require manufacturers and importers of electronic cigarettes to ensure that electronic cigarettes deliver the nicotine doses uniformly and consistently.

Member States shall ensure that electronic cigarettes with refillable cartridges or tanks are not placed on the market. Only single use cartridges can be placed on the market.

[Restrictions/limitations and information to consumers]

4. Member States shall require manufacturers and importers to ensure that:

a) Electronic cigarettes do not contain nicotine in excess of 20 mg/ml and 10 mg/unit;

b) Electronic cigarettes with additives listed in paragraph 4 of Article 6 are not placed on the market;

c) Only flavours which are authorized for use in nicotine replacement therapies can be used in electronic cigarettes, unless such a flavour is particularly attractive to young people and non-smokers;

d) Only ingredients of high purity and free from contaminants are used in the manufacture of the liquid for electronic cigarettes;

e) Unit packets of electronic cigarettes include a leaflet with information instructions for use, including a reference that the product is not recommended for use by young people and non-smokers, contra-indications, warnings for specific risk groups, information on possible adverse effects, and contact details of the manufacturer or importer;

f) Unit packets and any outside packaging of electronic cigarettes:

i. include a list of all ingredients contained in the product in descending order, and an indication of nicotine content and delivery per dose;

ii. do not include elements or features referred to in Article 12, with the exception of paragraph 1(a) of Article 12 concerning the nicotine content;

iii. do not use tobacco trademarks, brand names and symbols;

iv. carry the following health warning:

“This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers.”

g) the health warnings shall comply with the provisions in paragraph 2 of Article 11.

5. Member States shall ensure that:

a) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of electronic cigarettes and for publications which are printed and published in third countries, where those publications are not principally intended for the European Union market;

b) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes which are prohibited pursuant to Art. 18 par. 5, lit. a) are prohibited in information society services as defined in Article 1(2) of Directive 98/34/EC;

c) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the radio;

d) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes is prohibited;

e) any form of public or private contribution to any event, activity or individual with the aim or direct or indirect effect of promoting electronic cigarettes and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;

f) audiovisual commercial communications falling under Directive 2010/13/EU are prohibited for electronic cigarettes;

g) cross-border distance sales of electronic cigarettes are regulated in accordance with Article 16.

[Reporting and monitoring obligation]

6. Member States shall require manufacturers and importers of electronic cigarettes to submit to competent authorities on an annual basis comprehensive data on sales volumes, by brand name and type, as well as information on preferences of various consumer groups, including young people, non-smokers

and main types of current users, as well as the mode of sale of the products. They shall also submit executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the development of the electronic cigarette market, including any evidence of gateway use among young people.

7. Member States shall ensure the dissemination of information received pursuant to paragraph 2 on a website with due regard to the protection of trade secrets.

Member States shall make available, upon request, all information received pursuant to this Article to the Commission and other Member States. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

8. Member States shall require that manufacturers, importers or distributers establish and maintain a system to collect information about all suspected adverse effects. If an operator considers or has reason to believe that electronic cigarettes, which are in its possession and are intended to be placed on the market, are not of good safety or quality or is otherwise not in conformity with this Directive, the operator shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, as appropriate. In such a case the operators shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available, giving details, in particular, of the risk to health and safety and of any corrective action taken, and of the results of such corrective action. Member States may also request additional information from the operators, for example on safety and quality aspects or any adverse effects.

[Re delegated acts]

9. The Commission shall also be empowered to adopt delegated acts to adapt the wording of the health warning in paragraph 4 (f) iv.

The Commission shall adopt by means of implementing acts a common notification format pursuant to paragraph 2.

Amendments to other articles

Article 2

[definition of Electronic cigarettes]

Electronic cigarette means a product, or any components thereof including cartridges and the device without cartridge, that can be used for consumption of nicotine containing vapour via a mouth piece.

Article 20

[on cooperation of competent authorities]

The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the proper application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive uniformly.

Article 21a new

[on designation of competent authorities and change title into "Committee procedure and competent authorities"]

Member States shall designate the competent authorities within the period of 3 months after the transposition pursuant to Article 25. Member States shall, without delay, inform the Commission about the identity of the competent authorities responsible for enforcement of obligations provided for in this Directive. The Commission shall publish that information in the Official Journal of the European Communities.

Article 23

[to add in paragraph 2]

market developments in electronic cigarettes considering, inter alia, information received under Article 18

Recitals

a) Electronic cigarettes are a tobacco related product and should be regulated within this Directive. They simulate smoking behaviour and are increasingly used and marketed to young people and non-smokers. Diverging legislation exists in Member States to regulate these products requiring action at Union level to improve the functioning of the internal market. Other nicotine containing products are not covered by the provisions of this Directive. Electronic cigarettes which are presented as having properties for treating or preventing disease in human beings should not fall under this Directive. They can only be placed on the market if duly authorised under Directive 2001/83/EC. For electronic cigarettes that fall under this Directive, the definition of medicinal products according to Article 1.2.b of Directive 2001/83/EC does not apply. This clarifies the legal situation of this product in the light of Article 2.2 of Directive2001/83/EC.

b) Refillable cartridges or electronic cigarettes with refillable tanks are considered to pose a risk to public health. Such products would for example allow for a circumvention of the flavour regulation, they would increase the risk of contamination and they would lead to the wider availability of larger quantities of nicotine containing liquids, which can be a risk to inexperienced users or children.

c) Given the risk that electronic cigarettes can develop into a gateway to normal cigarettes, and considering that they mimic and normalise the action of smoking, Member States should lay down age limits for their sale to consumers and their use, and shall ensure that their labelling displays sufficient and appropriate information on safe use, in order to protect human health and safety.

d) Responsibility for ensuring that electronic cigarettes comply with the essential safety requirements should rest with manufacturers. If manufacturers are not established in the European Union, the natural or legal person who imports electronic cigarettes into the European Union should bear the responsibility.

e) Disparities existing between national practices on electronic cigarettes advertising and sponsorship impede the free movement of goods and the freedom to provide services and create an appreciable risk of distortions to competition. Without further action at Union level, the existing disparities are likely to increase in the coming years, considering also the growing market for electronic

cigarettes. European legislature should therefore approximate national legislation on the advertising and sponsoring of electronic cigarettes. Article 114(3) of the Treaty on the Functioning of the European Union requires the Commission, in its proposals for the establishment and functioning of the internal market concerning health, to take as a base a high level of protection. In this light, restrictions on the advertising of electronic cigarettes is intended to protect public health by regulating the promotion of these products, which can develop into a gateway to normal cigarettes, and which mimic and normalise the action of smoking. This Directive does not harmonise rules on domestic sales arrangements or advertising, nor does it introduce an age limit for electronic cigarettes. Member States are free to regulate such matters in their own domain.

f) Brand names have the potential to attract consumers and maintain their brand loyalty. The strength of tobacco brands names could lead to attracting people – especially young people – to buy and use electronic cigarettes marketed under the same brand. Moreover the use of tobacco trademarks, brand names and symbols for electronic cigarettes could indirectly promote smoking, facilitate the shift of users from one category to the other. It could also undermine national legislation limiting the advertising for tobacco products. Therefore the use of tobacco trademarks, brand names and symbols for electronic cigarettes is prohibited under this Directive.

5.Updated Commission / Presidency 'suggested text' proposal (29 November 2013) – secret

Comment: A new version of this text with minor amendments was produced on 29 November (recitals and other articles) remain unchanged. Additions are in bold and deletions show with strikethrough.

[Scope]

1. Electronic cigarettes are a tobacco related product. They can be placed on the market as a tobacco related product if they comply with the relevant provisions of this Directive and all other relevant Union legislation.

[Notification]

2. Manufacturers and importers of electronic cigarettes shall notify the products with the competent authorities of the Member States in which the product is intended to be placed on the market. The notification shall be submitted in electronic form 6 months before the intended placing on the market. For electronic cigarettes already placed on the market on the date referred to in paragraph 1 of Article 25, the notification shall be submitted within 6 months of that date. A new notification shall be submitted for each substantial modification of the product.

The notification shall include ~~at least~~ the following information:

1. name and contact details of the manufacturer, **a responsible legal or natural person within the European Union,** and, if applicable, the importer into the European Union;
2. list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof;
3. toxicological data ~~available to the manufacturer or importer~~ regarding these ingredients **and their emissions**;
4. information on nicotine dosing when used under reasonable and foreseeable conditions; and
5. description of the components of the electronic cigarette.

Where Member States consider that data are incomplete, they are entitled to request the completion of such data.

Proportionate fees may be charged by Member States for receiving, storing, handling and analysing the information submitted to them.

[Safety and quality]

3. Member States shall require manufacturers and importers of electronic cigarettes to bear full responsibility for the quality and safety of electronic cigarettes placed on the market and when used under reasonable and foreseeable conditions.

Member States shall require manufacturers and importers of electronic cigarettes to establish and comply ~~at least~~ with the following manufacturing requirements:

a) to design and manufacture in accordance with the ~~safety~~requirements set out

in this article;

b) to have procedures in place for series production **to ensure** ~~to remain in~~ conformity with the safety requirements **set out in this article;**

c) **to undertake and have available for the competent authorities,** a safety assessment of **electronic cigarettes**, ~~prior to placing on the market,~~ with information on the **chemical** composition of the **liquid** ~~product~~, microbiological quality, impurities and traces, toxicological profile **including when heated, mechanics, electronics** and adverse effects;

Member States shall require manufacturers and importers of electronic cigarettes to ensure that electronic cigarettes deliver the nicotine doses uniformly and consistently.

Member States shall ensure that electronic cigarettes with refillable cartridges or tanks are not placed on the market. Only single use cartridges can be placed on the market.

Member States shall require manufacturers and importers to ensure that only electronic cigarettes are placed on the market that cannot be operated or opened by children.

[Content restrictions/limitations]

4. Member States shall require manufacturers and importers to ensure that:

a) Electronic cigarettes do not contain nicotine in excess of 20 mg/ml and 10 mg/unit;

b) Electronic cigarettes with additives listed in paragraph 4 of Article 6 are not placed on the market;

c) Only flavours which are authorized for use in nicotine replacement therapies can be used in electronic cigarettes, unless such a flavour is particularly attractive to young people and non-smokers;

d) Only ingredients of high purity and free from contaminants are used in the manufacture of the liquid for electronic cigarettes;

4. new

[Packaging and labelling, consumer information]

a) Unit packets of electronic cigarettes include a leaflet with information instructions for use, including a reference that the product is not recommended for use by young people and non-smokers, contra-indications, warnings for specific risk groups, information on possible adverse effects, **on addictiveness and toxicity**, and contact details of the manufacturer or importer **and a legal or natural contact person within the European Union**;

b) Unit packets and any outside packaging of electronic cigarettes

i. include a list of all ingredients contained in the product in descending order, and an indication of nicotine content and delivery per dose;

ii. do not include elements or features referred to in Article 12, with the exception of paragraph 1(a) of Article 12 concerning the nicotine content

iii. do not use tobacco trademarks, brand names and symbols;

iv. carry the following health warning

"This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers."

c) the health warnings shall comply with the provisions in paragraph 2 of Article 11.

[Advertising, promotion and cross-border distance sales]

5. Member States shall ensure that:

a) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of electronic cigarettes and for publications which are printed and published in third countries, where those publications are not principally intended for the European Union market;

b) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes which are prohibited pursuant to Art. 18 par. 5, lit. a) are prohibited in information society services as defined in Article 1(2) of

Directive 98/34/EC;

c) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the radio;

d) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes is prohibited;

e) any form of public or private contribution to any event, activity or individual with the aim or direct or indirect effect of promoting electronic cigarettes and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;

f) audiovisual commercial communications falling under Directive 2010/13/EU are prohibited for electronic cigarettes;

g) cross-border distance sales of electronic cigarettes are regulated in accordance with Article 16.

[Reporting and monitoring obligation]

6. Member States shall require manufacturers and importers of electronic cigarettes to submit to competent authorities on an annual basis comprehensive data on sales volumes, by brand name and type, as well as information on preferences of various consumer groups, including young people, non-smokers and main types of current users, as well as the mode of sale of the products. They shall also submit executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the development of the electronic cigarette market, including any evidence of gateway use among young people.

[Disclosure and information exchange]

7. Member States shall ensure the dissemination of information received pursuant to paragraph 2 on a website with due regard to the protection of trade secrets.

Member States shall make available, upon request, all information received pursuant to this Article to the Commission and other Member States. Member States and the Commission shall ensure that trade secrets and other confidential

information are treated in a confidential manner.

[Market surveillance]

8. Member States shall require that manufacturers, importers or distributers establish and maintain a system to collect information about all suspected adverse effects. If any of these operators considers or has reason to believe that electronic cigarettes, which are in its possession and are intended to be placed on the market, are not of good safety or quality or is otherwise not in conformity with this Directive, the operator shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, as appropriate. In such a case the operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available, giving details, in particular, of the risk to health and safety and of any corrective action taken, and of the results of such corrective action. Member States may also request additional information from the operator, for example on safety and quality aspects or any adverse effects.

[Re delegated acts]

9. The Commission shall also be empowered to adopt delegated acts to adapt the wording of the health warning in paragraph 4 (f) iv.

The Commission shall adopt by means of implementing acts a common notification format pursuant to paragraph 2

6. Presidency / Commission suggested text 6 December 2013 – secret

[Scope]

1. Electronic cigarettes **may be placed on the market if they comply with the relevant provisions of this Directive and with all other relevant Union legislation.**

This Directive is not applicable to products which are subject to an authorisation requirement under Directive 2001/83/EC

[Notification]

2. Manufacturers and importers of electronic cigarettes shall notify the products with the competent authorities of the Member States in which the product is intended to be placed on the market. The notification shall be submitted in electronic form 6 months before the intended placing on the market. For electronic cigarettes already placed on the market on the date referred to in paragraph 1 of Article 25, the notification shall be submitted within 6 months of that date. A new notification shall be submitted for each substantial modification of the product.

The notification shall include the following information:

a) name and contact details of the manufacturer, **a responsible legal or natural person within the European Union,** and, if applicable, the importer into the European Union;

b) list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof;

c) toxicological data regarding these ingredients **and their emissions, including when heated, referring in particular to their effects on health of consumers and taking into account, *inter alia*, any addictive effect**;

d) information on nicotine dosing when used under reasonable and foreseeable conditions; and

e) description of the components of the electronic cigarette.

Where Member States consider that data are incomplete, they are entitled to request the completion of such data.

Proportionate fees may be charged by Member States for receiving, storing, handling and analysing the information submitted to them.

[Obligations of manufactures and importers]

3. Member States shall require manufacturers and importers of electronic cigarettes to bear full responsibility for the quality and safety of electronic cigarettes placed on the market and when used under reasonable and foreseeable

conditions.

Member States shall require manufacturers and importers of electronic cigarettes to establish and comply with the following requirements:

a) to design and manufacture in accordance with the ~~safety~~ requirements set out in this article;

b) to have procedures in place for series production **to ensure** ~~to remain in~~ conformity with the requirements **set out in this article;**

c) **to undertake and have available for the competent authorities,** a safety assessment of **electronic cigarettes**, ~~prior to placing on the market,~~ with information on the **chemical** composition of the **liquid** microbiological quality, impurities and traces, toxicological profile **including when heated, mechanics, electronics** and adverse effects;

[Product related requirements]

4. Member States shall require manufacturers and importers to ensure that:

a) Electronic cigarettes do not contain nicotine in excess of **[**20 mg/ml and 10 mg/unit**]**;

b) Electronic cigarettes with additives listed in paragraph 4 of Article 6 are not placed on the market;

c) Only ingredients of high purity and free from contaminants are used in the manufacture of the liquid for electronic cigarettes;

d) Only ingredients of high purity and free from contaminants are used in the manufacture of the liquid for electronic cigarettes **that do not have toxic properties in heated or unheated form with the exception of nicotine**;

e) electronic cigarettes deliver the nicotine doses uniformly and consistently;

f) electronic cigarettes with refillable cartridges or tanks are not placed on the market; ~~and only non re-fillable cartridges are placed on the market~~.

g) **that only electronic cigarettes are placed on the market that cannot be operated or opened by children.**

[Packaging and labelling, consumer information]

h) Unit packets of electronic cigarettes include a leaflet with information instructions for use, including a reference that the product is not recommended for use by young people and non-smokers, contra-indications, warnings for specific risk groups, information on possible adverse effects, **on addictiveness and toxicity**, and contact details of the manufacturer or importer **and a legal or natural contact person within the European Union**;

i) Unit packets and any outside packaging of electronic cigarettes

i. include a list of all ingredients contained in the product in descending order, and an indication of nicotine content and delivery per dose;

ii. do not include elements or features referred to in Article 12, with the exception of paragraph 1(a) of Article 12 concerning the nicotine content;

iii. do not use tobacco trademarks, brand names and symbols;

iv. carry **one of** the following health warning:

This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers.

or

"This product contains nicotine which is a highly addictive substance."

Member States shall determine which of these health warnings are used.

j) the health warnings shall comply with the provisions in paragraph 2 of Article 11.

[Advertising, promotion and cross-border distance sales]

5. Member States shall ensure that:

a) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of electronic cigarettes and for publications which are

printed and published in third countries, where those publications are not principally intended for the European Union market;

b) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes which are prohibited pursuant to Art. 18 par. 5, lit. a) are prohibited in information society services as defined in Article 1(2) of Directive 98/34/EC;

c) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the radio;

d) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes is prohibited;

e) any form of public or private contribution to any event, activity or individual with the aim or direct or indirect effect of promoting electronic cigarettes and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;

f) audiovisual commercial communications falling under Directive 2010/13/EU are prohibited for electronic cigarettes;

g) cross-border distance sales of electronic cigarettes are regulated in accordance with Article 16.

[Reporting and monitoring obligation]

6. Member States shall require manufacturers and importers of electronic cigarettes to submit to competent authorities on an annual basis comprehensive data on sales volumes, by brand name and type, as well as information on preferences of various consumer groups, including young people, non-smokers and main types of current users, as well as the mode of sale of the products. They shall also submit executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the development of the electronic cigarette market, including any evidence of gateway use among young people.

[Disclosure and information exchange]

7. Member States shall ensure the dissemination of information received pursuant to paragraph 2 on a website with due regard to the protection of trade secrets.

Member States shall make available, upon request, all information received pursuant to this Article to the Commission and other Member States. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

[Market surveillance]

8. Member States shall require that manufacturers, importers or distributers establish and maintain a system to collect information about all suspected adverse effects. If any of these operators considers or has reason to believe that electronic cigarettes, which are in its possession and are intended to be placed on the market, are not of good safety or quality or is otherwise not in conformity with this Directive, the operator shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, as appropriate. In such a case the operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available, giving details, in particular, of the risk to health and safety and of any corrective action taken, and of the results of such corrective action. Member States may also request additional information from the operator, for example on safety and quality aspects or any adverse effects.

[Re delegated acts]

9. The Commission shall also be empowered to adopt delegated acts to adapt the wording of the health warning in paragraph 4**(j)**. **When adapting that health warning, the Commission shall ensure that it is factual.**

The Commission shall adopt by means of implementing acts a common notification format pursuant to paragraph 2.

Citations

Having regards to the Treaty on the Functioning of the European Union, and in particular Articles 53(**1**), 62* and 114 thereof,

* *Addition of the Articles 53(1) and 62 TFEU is related to the legal basis for the Directive 2003/33/EC on advertising and sponsorship of tobacco products.*

Recitals

(a) **Electronic cigarettes appear to allow certain consumers to switch away or reduce tobacco consumption to consumption of this new product.These products should be regulated within this Directive, unless they are subject to Directive 2001/83/EC. Electronic cigarettes simulate smoking behaviour. From a public health perspective they are a concern if they are increasingly used and marketed to young people and non-smokers. Diverging legislation exists in Member States to regulate these products requiring action at Union level to improve the functioning of the internal market. Other nicotine containing products are not covered by the provisions of this Directive.**

(b) Refillable cartridges or electronic cigarettes with refillable tanks are considered to pose a risk to public health. Such products would increase the risk of contamination and they would lead to the wider availability of larger quantities of nicotine containing liquids, which can be a risk to inexperienced users or children **and can lead to poisoning or abuse**.

(c) Given the risk that electronic cigarettes can develop into a gateway to **nicotine addiction and ultimately traditional tobacco consumption**, and considering that they mimic and normalise the action of smoking, Member States should **consider** laying down age limits for their sale to consumers and their use, and shall ensure that their labelling displays sufficient and appropriate information on safe use, in order to protect human health and safety.

(d) Responsibility for ensuring that electronic cigarettes comply with the essential ~~safety~~ requirements should rest with manufacturers. If manufacturers are not established in the European Union, the natural or legal person who imports electronic cigarettes into the European Union should bear the responsibility.

(e) Disparities existing between national practices on electronic cigarettes advertising and sponsorship impede the free movement of goods and the freedom to provide services and create an appreciable risk of distortions to competition. Without further action at Union level, the existing disparities are likely to increase in the coming years, considering also the growing market for electronic cigarettes.**Therefore, it is necessary to approximate the national rules on**

advertising and sponsoring of electronic cigarettes, taking as a base a high level of health protection. Electronic cigarettes can develop into a gateway to normal cigarettes, as they mimic and normalise the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising of electronic cigarettes.

~~(f)~~ **This Directive does not harmonise all aspects of electronic cigarettes, and leaves for example the regulation of flavours in electronic cigarettes to the Member States. Member States may consider allowing flavours in electronic cigarettes which they authorise for nicotine replacement therapies, bearing in mind that some flavours may develop toxic properties when heated.** ~~**Member States are encouraged to take measures in this area to limit the appeal of electronic cigarettes to young people and non-smokers.**~~

(g) This Directive does not harmonise rules on **smoke-free environment, or on** domestic sales arrangements or advertising, nor does it introduce an age limit for electronic cigarettes. Member States are free to regulate such matters in their own domain.

(h) Brand names have the potential to attract consumers and maintain their brand loyalty. The strength of tobacco brands names could lead to attracting people – especially young people – to buy and use electronic cigarettes marketed under the same brand. Moreover the use of tobacco trademarks, brand names and symbols for electronic cigarettes could indirectly promote smoking **and encourage parallel use of traditional cigarettes and electronic cigarettes**.**Their use** could also undermine national legislation limiting the advertising for tobacco products. Therefore the use of tobacco trademarks, brand names and symbols for electronic cigarettes is prohibited under this Directive.

Articles

Article 2

[definition of Electronic cigarettes]

Electronic cigarette means a product, or any components thereof including cartridges and the device without cartridge, that can be used for consumption of nicotine containing vapour via a mouth piece.

Article 20

[on cooperation of competent authorities]

The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the proper application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive uniformly.

Article 21a new

[on designation of competent authorities and change title into "Committee procedure and competent authorities"]

Member States shall designate the competent authorities within the period of 3 months after the transposition pursuant to Article 25. Member States shall, without delay, inform the Commission about the identity of the competent authorities responsible for enforcement of obligations provided for in this Directive. The Commission shall publish that information in the Official Journal of the European Communities.

Article 23

[to add new point (g) inArticle 23, paragraph 2]

(g) market developments in electronic cigarettes considering, inter alia, information received

under Article 18, **including uptake by young people and non-smokers and impacts on cessation efforts;**

7. Updated negotiating text 10 December 2013 – secret

[Scope]

1. **The Member States shall ensure that** electronic cigarettes ~~**may be**~~ **are placed on the market under this Directive only if they comply with the**

relevant provisions thereof ~~of this Directive~~ and with all other relevant Union legislation.

This Directive does not apply ~~is not applicable~~ to products ~~which~~ that are subjet to an authorisation requirement under Directive 2001/83/EC

[Notification]

2. Manufacturers and importers of electronic cigarettes shall notify the products with the competent authorities of the Member States in which the product is intended to be placed on the market. The notification shall be submitted in electronic form 6 months before the intended placing on the market. For electronic cigarettes already placed on the market on the date referred to in paragraph 1 of Article 25, the notification shall be submitted within 6 months of that date. A new notification shall be submitted for each substantial modification of the product.

The notification shall ~~include~~ **contain** the following information:

a. name and contact details of the manufacturer, **a responsible legal or natural person within the European Union,** and, if applicable, the importer into the European Union;

b.list of all ingredients contained in and emissions resulting from the use of the product, by brand name and type, including quantities thereof;

c. toxicological data regarding these ingredients **and their emissions, including when heated, referring in particular to their effects on health of consumers when inhaled and taking into account, *inter alia*, any addictive effect**;

d. information on nicotine dosing when used under reasonable and foreseeable conditions;

e. description of the components of the electronic cigarette;

f. confirmation that the requirements of paragraph 3 letters (a) to (c) are respected.

Where Member States consider that data are incomplete, they are entitled

to request the completion of such data.

Proportionate fees may be charged by Member States for receiving, storing, handling and analysing the information submitted to them.

[Obligations of manufactures and importers]

3. Member States shall require manufacturers and importers of electronic cigarettes to bear full responsibility for the quality and safety of electronic cigarettes placed on the market, ~~and~~ when used under reasonable and foreseeable conditions.

Member States shall require manufacturers and importers of electronic cigarettes ~~to establish~~ and comply with the following requirements:

a) to design and manufacture in accordance with the requirements set out in this article;

b) to have procedures in place for series production **to ensure** conformity with the requirements **set out in this article;**

c) **to undertake and have available for the competent authorities,** a safety assessment of **electronic cigarettes** with information on the **chemical** composition of the **liquid** microbiological quality, impurities and traces, toxicological profile **including when heated, mechanics, electronics** and adverse effects.

[Product related requirements]

4. Member States shall require manufacturers and importers to ensure that:

a) electronic cigarettes do not contain nicotine in excess of **[**20 mg/ml and 10 mg/unit**]**;

b) electronic cigarettes with additives listed in paragraph 4 of Article 6 are not placed on the market;

c) only ingredients of high purity and free from contaminants are used in the manufacture of the liquid for electronic cigarettes;

d) only ingredients **are used** ~~of high purity and free from contaminants are used~~

~~in the manufacture of the liquid for electronic cigarettes~~ **that do not have toxic properties in heated or unheated form with the exception of nicotine**;

e) electronic cigarettes deliver the nicotine doses ~~uniformly and~~ consistently;

f) electronic cigarettes with refillable cartridges or tanks are not placed on the market; ~~and only non re-fillable cartridges are placed on the market.~~

~~g)~~ **electronic cigarettes are childproof;** ~~**that only electronic cigarettes are placed on the market that cannot be operated or opened by children.**~~

[Packaging and labelling, consumer information]

5. Member States shall require manufacturers and importers to ensure that:

(a) unit packets of electronic cigarettes include a leaflet with information instructions for use, including a reference that the product is not recommended for use by young people and non-smokers, contra-indications, warnings for specific risk groups, information on possible adverse effects, **on addictiveness and toxicity**, and contact details of the manufacturer or importer **and a legal or natural contact person within the European Union**;

(b) unit packets and any outside packaging of electronic cigarettes:

i. include a list of all ingredients contained in the product in descending order, and an indication of nicotine content and delivery per dose;
ii. do not include elements or features referred to in Article 12, with the exception of paragraph 1(a) of Article 12 concerning the nicotine content;
~~do not use tobacco trademarks, brand names and symbols~~;
iii. carry **one of** the following health warning:

This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers.

or

"This product contains nicotine which is a highly addictive substance."

Member States shall determine which of these health warnings are used.

(c) the health warnings shall comply with the provisions in paragraph 2 of Article 11.

[Advertising, promotion and cross-border distance sales]

6. Member States shall ensure that:

a) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of electronic cigarettes and for publications which are printed and published in third countries, where those publications are not principally intended for the European Union market;

b) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes which are prohibited pursuant to Art. 18 par. 5, lit. a) are prohibited in information society services as defined in Article 1(2) of Directive 98/34/EC;

c) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes are prohibited in the radio;

d) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes is prohibited;

e) any form of public or private contribution to any event, activity or individual with the aim or direct or indirect effect of promoting electronic cigarettes and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;

f) audiovisual commercial communications falling under Directive 2010/13/EU are prohibited for electronic cigarettes;

g) cross-border distance sales of electronic cigarettes are regulated in accordance with Article 16.

[Reporting and monitoring obligation]

7. Member States shall require manufacturers and importers of electronic cigarettes to submit to competent authorities on an annual basis comprehensive

data on sales volumes, by brand name and type, as well as information on preferences of various consumer groups, including young people, non-smokers and main types of current users, as well as the mode of sale of the products. They shall also submit executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the development of the electronic cigarette market, including any evidence of gateway use among young people.

[Disclosure and information exchange]

8. Member States shall ensure the dissemination of information received pursuant to paragraph 2 on a website with due regard to the protection of trade secrets.

Member States shall make available, upon request, all information received pursuant to this Article to the Commission and other Member States. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

[Market surveillance]

9. Member States shall require that manufacturers, importers or distributers establish and maintain a system to collect information about all suspected adverse effects. If any of these operators considers or has reason to believe that electronic cigarettes, which are in its possession and are intended to be placed on the market, are not of good safety or quality or is otherwise not in conformity with this Directive, the operator shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, as appropriate. In such a case the operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available, giving details, in particular, of the risk to health and safety and of any corrective action taken, and of the results of such corrective action. Member States may also request additional information from the operator, for example on safety and quality aspects or any adverse effects.

[Delegated acts]

10. The Commission shall ~~also~~ be empowered to adopt delegated acts **in accordance with Article 22** to adapt the wording of the health warning in

paragraph 4**(j)**. **When adapting that health warning, the Commission shall ensure that it is factual.**

11. The Commission shall adopt by means of implementing acts a common notification format pursuant to paragraph 2.

These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Recitals

(a) **Electronic cigarettes may ~~appear to~~ allow certain consumers partially or completely reduce tobacco consumption. ~~to switch away or reduce tobacco consumption to consumption of this new product.~~ These products should be regulated within this Directive, unless they are subject to Directive 2001/83/EC. ~~Electronic cigarettes simulate smoking behaviour. From a public health perspective they are a concern if they are increasingly used and marketed to young people and non-smokers.~~**

Diverging legislation and practices including on safety requirements exist in Member States .as regards ~~to regulate~~ these products requiring action at Union level to improve the functioning of the internal market. Harmonization measures in this respect should take into account that, from a public health perspective, electronic cigarettes are a concern if they are used and marketed to young people and non-smokers. They also simulate smoking behaviour and normalise the action of smoking. ~~Other nicotine containing products are not covered by the provisions of this Directive.~~

(b) **In order to allow Member States to exercise their functions of surveillance and control, manufacturers and importers of electronic cigarettes should be required to notify their products before the intended placing of the market.**

(c) Responsibility for ensuring that electronic cigarettes comply with the essential requirements should rest with manufacturers. If manufacturers are not established in the European Union, the natural or legal person who imports electronic cigarettes into the European Union should bear the responsibility.

(d) **Only electronic cigarettes whose nicotine content does not exceed 20 mg/ml and 10 mg/unit should be allowed under this Directive, as this level is comparable to the dose of nicotine derived from a standard cigarette during the same duration of smoking.**

(e) **Only electronic cigarettes that deliver the nicotine doses consistently should be allowed under this Directive. Consistent delivery of the nicotine doses under normal use is necessary for health, safety and quality purposes including to avoid the risk of accidental consumption of high doses.**

(f) **Electronic cigarettes may create a risk when used by children. Therefore, it is necessary to ensure that electronic cigarettes are childproof including child-proof labelling, design and fastenings.**

(g) Refillable cartridges or electronic cigarettes with refillable tanks are considered to pose a risk to public health. Such products would increase the risk of contamination and they would lead to the wider availability of larger quantities of nicotine containing liquids, which can be a risk to inexperienced users or children **and can lead to poisoning or abuse**.

(h) Given the risk that electronic cigarettes can develop into a gateway to **nicotine addiction and ultimately traditional tobacco consumption**, and considering that they mimic and normalise the action of smoking, ~~Member States should **consider** laying down age limits for their sale to consumers and their use, and shall ensure that their labelling displays sufficient and appropriate information on safe use, in order to protect human health and safety~~ **their labelling and packaging should display sufficient and appropriate information on safe use, in order to protect human health and safety, carry appropriate health warning and should not include any misleading element or feature.**

(i) Disparities existing between national **legislations and** practices on electronic cigarettes advertising and sponsorship impede the free movement of goods and the freedom to provide services and create an appreciable risk of distortions to competition. Without further action at Union level, the existing disparities are likely to increase in the coming years, considering also the growing market for electronic cigarettes.**Therefore, it is necessary to**

approximate the national rules on advertising and sponsoring of electronic cigarettes, taking as a base a high level of health protection. Electronic cigarettes can develop into a gateway to ~~normal cigarettes~~ nicotine addiction and ultimately traditional tobacco consumption , as they mimic and normalise the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising of electronic cigarettes.

(j) **In order to exercise their regulatory function, Member States and the Commission require comprehensive information on market developments in electronic cigarettes. To this end reporting obligations on sales volumes, preference of various consumers groups and mode of sales of electronic cigarettes should be put on manufacturers and importers of these products. The transparency of this information should be ensured for the general public with due regard for trade secrets.**

~~**This Directive does not harmonise all aspects of electronic cigarettes, and leaves for example the regulation of flavours in electronic cigarettes to the Member States. Member States may consider allowing flavours in electronic cigarettes which they authorise for nicotine replacement therapies, bearing in mind that some flavours may develop toxic properties when heated.**~~

(k) **In order to ensure appropriate market surveillance by Member States, it is necessary that manufacturers, importers and distributors have an appropriate system for monitoring, recording and imforming the competent authorities about suspected adverse effects, so that appropriate action can be taken.**

(l) **This Directive does not harmonise all aspects of electronic cigarettes, and leaves for example the regulation of flavours in electronic cigarettes to the Member States. It may be useful for Member States to consider allowing flavours in electronic cigarettes. However, they should be mindful of the potential attractiveness for young people and non smokers.** Moreover, this Directive does not harmonise rules on **smoke-free environment, or on** domestic sales arrangements or advertising, **use of tobacco trademarks, brand names and symbols for electronic cigarettes**, nor does it introduce an age limit for electronic cigarettes. **In any case, the**

presentation and advertising of electronic cigarettes should not be used to promote tobacco consumption or give rise to confusion with tobacco products. Member States are free to regulate such matters in their own domain **and are encouraged to do so.**

~~Brand names have the potential to attract consumers and maintain their brand loyalty. The strength of tobacco brands names could lead to attracting people – especially young people – to buy and use electronic cigarettes marketed under the same brand. Moreover the use of tobacco trademarks, brand names and symbols for electronic cigarettes could indirectly promote smoking~~ **and encourage parallel use of traditional cigarettes and electronic cigarettes**~~.~~**Their use** ~~could also undermine national legislation limiting the advertising for tobacco products. Therefore the use of tobacco trademarks, brand names and symbols for electronic cigarettes is prohibited under this Directive.~~

Amendments to other articles

Article 2

[definition of Electronic cigarettes]

Electronic cigarette means a product, or any components thereof including cartridges and the device without cartridge, that can be used for consumption of nicotine-containing vapour via a mouth piece.

Article 20

[on cooperation of competent authorities]

The competent authorities of the Member States shall cooperate with each other and with the Commission to ensure the proper application and due enforcement of this Directive and shall transmit to each other all information necessary with a view to applying this Directive uniformly.

Article 21a new

[on designation of competent authorities and change title into "Committee procedure and competent authorities"]

Member States shall designate the competent authorities **responsible for the**

implementation and enforcement of obligations provided for in this Directive within the period of 3 months after the transposition pursuant to Article 25. Member States shall, without delay, inform the Commission about the identity of the**se** ~~competent authorities responsible for enforcement of obligations provided for in this Directive~~. The Commission shall publish that information in the Official Journal of the European Communities.

Article 23

[to add new point (g) inArticle 23, paragraph 2]

(g) market developments in electronic cigarettes considering, inter alia, information received

under Article 18, **including uptake by young people and non-smokers and impacts on cessation efforts;**

8. Negotiating text for COREPER meeting 13 December 2013 (secret)

New negotiating text 12 December 2013 (secret) for 13 December COREPER (Council) meeting – note PDF only

9. Text agreed by trilogue process and subsequently approved by COREPER 17 December 2013 (secret)

See here in a separate posting.