

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 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~~ **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 distributors 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 informing 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 ~~these 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) in Article 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;**