COUNCIL OF THE EUROPEAN UNION

Brussels, 12 December 2013

17506/13
ADD 2

Interinstitutional file:
2012/0366 (COD)

LIMITE

SAN
MI
COMPET
FISC
CODEC

ADVANCED COPY !

NOTE

from:	Presidency
to:	Permanent Representatives Committee (Part I)
No. Cion prop.:	18068/12 SAN 377 MI 850 FISC 206 CODEC 3117
No. prev. doc.:	17373/13 ADD 2 SAN 505 MI 1126 FISC 250 CODEC 2836
Subject:	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 (First reading) (Legislative deliberation) - *Preparation for the informal trilogue*

Following the discussion at Coreper on 11 December 2013 and the forth trilogue concerning the above proposal, the Delegations will find attached the Presidency proposal for wording of Article 18, which, if agreed by Coreper, can be presented to the last trilogue on 16 December 2013.

ANNEX

ARTICLE 18

EP text	**Suggested text for Article 18**
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	*[Scope]* 1. **The Member States shall ensure that** electronic cigarettes ***and refill containers*** **are** ***only*** **placed on the market if they comply with the relevant provisions** ***of this Directive*** **and with all other relevant Union legislation.** **This Directive does not apply ~~is not applicable~~ to products that are subjet to an authorisation requirement under Directive 2001/83/EC** ***or to the requirements set out in Directive 93/42/EEC.*** *[Notification]* 2. Manufacturers and importers of electronic cigarettes ***and refill containers*** 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~~ ***products*** 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, ***depending on whether the product is an electronic cigarette or a refill container,*** ~~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;

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	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 ***and delivery to blood stream*** when used under ***normal or*** reasonably ~~and~~ foreseeable conditions; e. description of the components of the electronic cigarette; ***f. description of the production process including series production and declaration that the production process ensures conformity with the requirements in this article;*** ***g. declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.*** **~~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:~~

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	~~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~~. ***~~3~~***. Member States shall ~~require manufacturers and importers to~~ ensure that: ***a) Nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml or in single use cartridges to be used in rechargeable electronic cigarettes or in disposable electronic cigarettes;*** b) ~~electronic cigarettes~~***~~the liquid~~*** do***es*** not contain nicotine in excess of 20 mg/ml***~~and 10 mg/unit~~***; c) ~~electronic cigarettes with~~***the liquid does not contain*** additives listed in paragraph 4 of Article 6 ~~are not placed on the market~~; d) only ~~ingredients~~ ***substances*** of high purity and free from contaminants are used in the manufacture of the liquid ~~for electronic cigarettes~~; e) only ~~ingredients~~ ***substances*** **are used *in the liquid* that *are* ~~do~~ not ~~have~~ toxic ~~properties~~ in heated or unheated form with the exception of nicotine**; f) electronic cigarettes deliver the nicotine doses ~~uniformly and~~consistently; ~~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 *and refill containers* are childproof; ~~that only electronic cigarettes are placed on the market that cannot be operated or opened by children~~.** *h) **electronic cigarettes and the refill containers are protected against breakage and leakage.*** *[Packaging and labelling, consumer information]*

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	~~5~~. **4. Member States shall require manufacturers and importers to ensure that:** (a) unit packets of electronic cigarettes ***and refill containers*** include a leaflet with information instructions for use ***and storage***, 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 ***and refill containers:*** i. include a list of all ingredients contained in the product in descending order, and an indication of nicotine content and delivery per dose ***and a recommendation to keep out of reach of children;*** 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. carry **one of** the following health warnings: *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.~~ 5. Member States shall ensure that: a) commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes ***and refill containers*** are prohibited ***in information society services as defined in Article 1(2) of Directive 98/48/EC,*** in the press and other printed publications, with the exception of publications that are intended exclusively for professionals in the trade of ***the***

further legislation are necessary.	***products*** ~~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;~~commercial communications with the aim or direct or indirect effect of promoting electronic cigarettes ***and refill containers*** are prohibited in the radio; c) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes ***and refill containers*** is prohibited; d) 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 refill containers*** and involving or taking place in several Member States or otherwise having cross-border effects is prohibited; e) audiovisual commercial communications falling under Directive 2010/13/EU are prohibited for electronic cigarettes ***and refill containers***; f) cross-border distance sales of electronic cigarettes ***and refill containers*** are regulated in accordance with Article 16. *[Reporting and monitoring obligation]* ~~7~~.6. Member States shall require manufacturers and importers of electronic cigarettes ***and refill containers*** 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 ***as well as the market for refill containers***, including any evidence of gateway use among young people and non-smokers. *[Disclosure and information exchange]*

	~~8~~.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]* ~~9~~.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 ***or refill containers***, 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. *[Standard safeguard clause]* (here copied from cosmetics legislation) ***In the case of products meeting the requirements of this Article, where a competent authority ascertains or has reasonable grounds for concerns that an electronic cigarette or a refill container could present a serious risk to human health, it shall take all appropriate measures and shall immediately communicate to the Commission and the competent authorities of other Member States the measures taken and any supporting data. The Commission shall determine, as soon as possible, whether the provisional measure is justified following whenever possible appropriate consultations. The Commission shall inform the Member State concerned, which will ensure appropriate follow-up.***

	[Delegated acts] ~~10~~.9. 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~~. 10.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.**

Related provisions to Art 18 – to be added

	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 *and refill containers*** ~~**may appear to allow certain consumers partially or completely reduce tobacco consumption.These products**~~ **should be regulated within this Directive, unless they are *due to their presentation or function* subject to Directive 2001/83/EEC.** **Diverging legislation and practices including on safety requirements exist in Member States as regards these products requiring action at Union level to improve the functioning of the internal market. *A high level of public health should be taken into account when regulating these products.*** ~~**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**~~. **In order to allow Member States to exercise their functions of surveillance and control, manufacturers and importers of electronic cigarettes *and refill containers* should be required to notify their products before the intended placing of the market.**

	(b)	Responsibility for ensuring that ***the products*** ~~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.
	(c)	~~**Only electronic cigarettes whose**~~ **Nicotine** ***containing liquid should only be allowed under this Directive where the nicotine concentration*** **does not exceed 20 mg/ml.** ~~**and 10 mg/unit should be allowed under this Directive, as**~~ **This level is** ***considered satisfactory for an average smoker that wants to reduce tobacco consumption with the assistance of an electronic cigarette.*** ~~**comparable to the dose of nicotine derived from a standard cigarette during the same duration of smoking.**~~
	(d)	**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.**
	(e)	**Electronic cigarettes** ***and refill containers*** **may create a risk when they are** ***in the hands of*** **children. Therefore, it is necessary to ensure that** ***these products*** ~~**electronic cigarettes**~~ **are childproof including child-proof labelling, design,** ~~**and**~~ **fastenings** ***and opening mechanism*****.**
	(f)	~~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**~~~~.~~ ***Given that nicotine is a toxic substance and considering the potential risks also to those for whom the product is not intended, nicotine-containing liquid should be placed on the market in electronic cigarettes or in refill containers with a fixed maximum volume***

	that meets certain safety and quality requirements.
	(g) ~~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,~~ ***T*****he labelling and packaging *of these products* should display sufficient and appropriate information on safe use, in order to protect human health and safety, *should* carry appropriate health warnings and should not include any misleading elements or features.**
	(h) 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 ***and refill containers***.**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 *and refill containers*.**
	(i) **In order to exercise their regulatory function, Member States and the Commission require comprehensive information on market developments in electronic cigarettes *and refill containers*. 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.**~~ (j) **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. A safeguard clause is warranted allowing Member States to act against serious risks to public health.** (k) **This Directive does not harmonise all aspects of electronic cigarettes *or refill containers*, 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 *the products* ~~electronic cigarettes~~. However, they should be mindful of the potential attractiveness for young people and non smokers. *Such prohibitions of flavours would need to be justified and notified according to Directive 98/34/EC.*** (l) Moreover, this Directive does not harmonise rules on **smoke-free environment, or on** domestic sales arrangements or advertising, ***brand stretching*** ~~**use of tobacco trademarks, brand names and symbols for electronic cigarettes**~~, nor does it introduce an age limit for electronic cigarettes ***or refill containers***. **In any case, the presentation and advertising of ~~electronic cigarettes~~ *the products* 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.** **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. ***Electronic cigarettes can be disposable, refillable by means of a refill container or rechargeable with single use cartridges.*** ***Refill containers shall mean a receptacle that contains a nicotine-containing liquid which can be used to refill an electronic cigarette.*** 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**. 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 ***and refill containers*** considering, inter alia, information received under Article 18, **including uptake by young people and non-smokers and impacts on**

	cessation efforts ***as well as measures taken by Member States regarding flavours. In addition, suspected adverse effects resulting from use of electronic cigarettes with refillable cartridges or tanks, in particular for inexperienced users or children, as well as potential risk of contamination shall be considered.***