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CORRIGENDUM TO NOTE

from: Presidency
to: Permanent Representative Committee (Part I)

No. Cion prop.: 18068/12 SAN 377 MI 850 FISC 206 CODEC 3117
No. prev. doc.: 17506/13 SAN 514 MI 1144 COMPET 913 FISC 252 CODEC 2887

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)
- *Analysis of the final compromise text with view to an agreement*

Recital 30 of the document 17727/13 INIT shall read:

(30) Cross-border distance sales of tobacco can facilitate access to tobacco products that do not comply with the rules set out in this Directive. There is also the increased risk of access to tobacco products by young people. Consequently, there is a risk that tobacco control legislation will be undermined. Therefore Member States may prohibit cross-border distance sales. Where cross-border distances sales are not prohibited, common rules on the registration of retail outlets engaging in such sales are necessary to ensure the effectiveness of the provisions of this Directive. Member States should, in accordance with Article 4(3) TEU cooperate with each other in order to facilitate the implementation of this Directive, in particular with respect to measures taken regarding cross-border distance sales of tobacco products.

Recitals (e), (f) and (m) related to Article 18 of the document 17727/13 INIT shall read:

- (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 are child- and tamper proof including child-proof labelling, design, fastenings and opening mechanism.
- (f) 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 that meets certain safety and quality requirements. **It is important to ensure that electronic cigarettes do not break or leak during use and refill.**
- (m) In the context of an emerging market on electronic cigarettes, it is possible that, although conforming to the provisions of this Directive, a given electronic cigarette or refill container, or a type of electronic cigarettes or refill containers, placed on the market could pose an unforeseen risk to human health. It is therefore advisable to provide for a procedure intended to address this risk, which should include the possibility for a Member State to adopt provisional appropriate measures. Such provisional measures could involve the prohibition on the placing on the market of a given electronic cigarette or refill container, or of a type of electronic cigarettes or refill containers. In this context, the Commission should be empowered to adopt delegated acts in order to prohibit a given electronic cigarette or refill container, or a type of electronic cigarettes or refill containers, when at least three Member States have prohibited these products on justified grounds and it is necessary to extend this prohibition to all the Member States in order to ensure the smooth functioning of the internal market for compliant products not presenting the same safety concerns. **The Commission should report on the potential risks associated with refillable electronic cigarettes at the latest at the date of the entry into force of this Directive.**

Recitals 37, 38 and 39 of the document 17727/13 INIT shall read:

- (37) In order to ensure uniform conditions for the implementation of this Directive concerning *the establishment and update of the priority list of ingredients ~~for enhanced-re-enforced reporting~~*, the format of ingredients reporting, the determination of products with characterising flavours or with increased levels of toxicity, addictiveness *or CMR properties*, the methodology for determining whether a tobacco product has characterising flavour, *the technical standards for the unique identifiers and security features and the technical specifications for the design, ~~and~~ layout and shape of health warnings and their precise positioning for roll-your-own tobacco in pouches, and the common notification format and the technical standards of the refill mechanisms for electronic cigarettes and refill containers*, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011¹.
- (38) In order to make this Directive fully operational and to keep up with technical, scientific and international developments in tobacco manufacture, consumption and regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of adopting and adapting maximum yields for emissions and their measurement methods, setting maximum levels for ingredients that increase toxicity, addictiveness or *attractiveness, the establishing and adapting of the picture library and adapting the health warnings and reviewing certain exemptions granted to tobacco products other than cigarettes and roll-your-own tobacco, defining key elements of the data storage contracts to be concluded in the context of the tracking and tracing system and adapting the health warnings and extending Member States' measures concerning a given electronic cigarette or refill container or a type thereof.* products and reviewing the nicotine levels for nicotine-containing products. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

¹ OJ L 55, 28.2.2011, p. 13-18.

(39) The Commission should monitor the developments and submit a report 5 years after the date of transposition of this *Directive*, **and, when necessary every 5 years thereafter**, in order to assess whether amendments to this Directive are necessary. ***The report should include, information on the package surfaces not governed by this Directive, market developments in novel tobacco products, market developments that amount to a substantial change of circumstance, market development and consumer perception of slim cigarettes, of waterpipe tobacco and of electronic cigarettes and refill containers.***

Article 8, paragraph 6 of the document 17727/13 INIT shall read:

6. *The Commission shall, by means of implementing acts, determine the precise positioning of the general warning and information message ~~health warning~~ on roll-your-own tobacco in pouches, in light of the various shapes of pouches.*
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21.

Article 14, paragraph 10 of the document 17727/13 INIT shall read:

10. *Paragraph 1 to 7 shall apply to cigarettes and roll-your-own tobacco 3 years following the date referred to in paragraph 1 of Article 25 and to tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the application of paragraphs 1 to 7 during a ~~period of~~ 8 years following the date referred to in paragraph 1 of Article 25.*

Article 18, paragraph 1, second subparagraph of the document 17727/13 INIT shall read:

This Directive does not apply to **electronic cigarettes and refill containers** products that are subject to an authorisation requirement under Directive 2001/83/EC **or to the requirements set out in Directive 93/42/EEC.**

Article 18, paragraph 2, letter e. of the document 17727/13 INIT shall read:

e. description of the components of the ~~electronic cigarette~~ product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;

Article 18, paragraph 3, letter d) of the document 17727/13 INIT shall read:

- d) only ingredients of high purity and free from contaminants are used in the manufacture of the liquid; *substances other than the ingredients referred to in paragraph 2(b) are only present in trace levels, if they are technically unavoidable during manufacture;*

Article 18, paragraph 10 (new) of the document 17727/13 INIT, shall read:

10. *In the case of products meeting the requirements of this Article, where a competent authority ascertains or has reasonable grounds for concerns that a given electronic cigarette or a refill container, or a type of electronic cigarettes or refill containers, could present a serious risk to human health, it may take appropriate provisional 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 of its assessment, in order for the Member State to which will ensure appropriate follow-up.*

Where, in the application of the first subparagraph of this paragraph, a given type of electronic cigarette or refill container, or a type of electronic cigarettes or refill containers has been banned on justified ground by at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 22 to extend such a ban to all Member States, if that measure is justified and proportionate.

Article 26, letters (b) and (c) of the document 17727/13 INIT shall read:

- (b) *electronic cigarettes or refill containers manufactured or released for free circulation before [Publications Office, please insert the exact date: entry into force + 30 months];* ~~nicotine-containing products below the threshold set out in Article 18(1);~~
- (c) herbal products for smoking *manufactured or released for free circulation before [Publications Office, please insert the exact date: entry into force + 24 months];*