



Notification Number : 2019/0280/EE (Estonia)

## Draft amending the Tobacco Act

Date received : 14/06/2019

End of Standstill : 16/09/2019 (16/12/2019) (withdrawn)

### Message

Message 002

Communication from the Commission - TRIS/(2019) 01620

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2019/0280/EE

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidējimai nepradedami - Nem nyitja meg a késéseket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201901620.EN)

1. MSG 002 IND 2019 0280 EE EN 14-06-2019 EE NOTIF

2. EE

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4. 2019/0280/EE - X00M

5. Draft amending the Tobacco Act

6. Tobacco and tobacco products

7. DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

8. The draft proposes amending the Estonian Tobacco Act (hereafter “the Tobacco Act”) by creating a new category of tobacco products: “heated tobacco products”. The Tobacco Act is supplemented by rules relating to heated tobacco products.

The draft puts an end to the legal uncertainty regarding heated products on the Estonian market. Currently, it is possible to market heated products in Estonia as products for smoking. The handling of smokeless tobacco products is restricted in Estonia (see § 24 of the Tobacco Act). Heated products are novel tobacco products, which by nature are between



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  
Single Market Enforcement  
Notification of Regulatory Barriers

traditional smoking and classic smokeless tobacco products and, therefore, it is appropriate to regulate heated tobacco products separately.

A heated tobacco product is a novel tobacco product, which is consumed without a tobacco burning process and by using an accessory to heat the tobacco. The heated tobacco product category includes only those tobacco products that are novel tobacco products within the meaning of the Tobacco Directive and Tobacco Act.

The draft foresees that a heated tobacco product cannot have a characterising flavour and the ingredients of a heated tobacco product must be without flavours. The purpose of the amendment is to introduce common rules for the contents of heated tobacco products, cigarettes, smoking tobacco for rolling cigarettes, as well as electronic cigarettes.

According to the draft, the use of stickers—as for other tobacco products—extends equally to heated tobacco products.

The draft establishes a health warning for heated tobacco products. The wording of § 131(1) and (2) is based on Article 12(1) and (2) of the Tobacco Directive. The wording of point 1 of § 131(3) is based on the second sentence of Article 12(2) and point b of Article 9(4) of the Tobacco Directive. The wording of points 2 and 3 of § 131(3) is based on points a and b of Article 12(2) of the Tobacco Directive.

According to the draft, similar restrictions, in terms of the consumption of tobacco products, are extended to heated tobacco products—consumption by people under the age of 18 is prohibited, a list of locations where their consumption is prohibited or restricted is extended to heated tobacco products.

9. The creation of a category of heated tobacco products is necessary to prevent a lack of legal clarity in the classification of such novel tobacco products. Heated tobacco products constitute tobacco products, which by nature are between traditional smoking and classic smokeless tobacco products, because these products are heated by using a heating accessory and do not combust or produce smoke. However, their use does involve gas, which has a disturbing smell and can cause health risks.

The draft foresees that a heated tobacco product cannot have a characterising flavour and the ingredients of a heated tobacco product must be without flavours. The purpose of the amendment is to introduce common rules for the contents of heated tobacco products, cigarettes, smoking tobacco for rolling cigarettes, as well as electronic cigarettes. According to § 8(5) of the Tobacco Act, cigarettes and smoking tobacco for rolling cigarettes cannot have a characterising flavour. A characterising flavour is a clearly noticeable taste or smell other than that of tobacco, resulting from an additive or a combination of additives and which is noticeable before or during the consumption of the cigarette or smoking tobacco. According to § 8(6) of the Tobacco Act, the ingredients of cigarettes and smoking tobacco for rolling cigarettes—such as filters, papers, packaging and capsules—cannot be flavoured. The use of any technical feature allowing modification of the taste or smell of the tobacco product or its smoke intensity is prohibited. According to point 5 of § 81(2) of the Tobacco Act, the liquid of an electronic cigarette cannot be flavoured, except if it is that of tobacco.

The draft amendment upholds the principles and aims of the Tobacco Directive. According to point 8 of the preamble of the Tobacco Directive, a high level of health protection should be taken as a base for legislative proposals and, in particular, any new developments based on scientific facts should be taken into account. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco on human health, health protection should be given high importance, in particular, to reduce smoking prevalence among young people. Point 15 of the preamble states that the FCTC guidelines in relation to the regulation of the contents of tobacco products and regulation of tobacco product disclosures call in particular for the removal of ingredients that increase palatability, create the impression that tobacco products have health benefits, are associated with energy and vitality or have colouring properties. Point 18 of the preamble states that certain additives are used to create the impression that tobacco products have health benefits, present reduced health risks or increase mental alertness and physical performance. These additives, as well as additives that have CMR properties in unburnt form, should be prohibited in order to ensure uniform rules throughout the Union and a high level of protection of human health. Additives that increase addictiveness and toxicity should also be prohibited. Point 34 of the preamble states that it is important to monitor developments as



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  
Single Market Enforcement  
Notification of Regulatory Barriers

regards novel tobacco products. Manufacturers and importers should be obliged to submit a notification of novel tobacco products, without prejudice to the power of the Member States to ban or authorise such novel products. Thus, it is for a Member State to decide whether to allow, prohibit or restrict the sale of novel tobacco products in a particular Member State.

According to Article 7(1) and (7) of the Tobacco Directive, Member States shall prohibit the placing on the market of tobacco products with a characterising flavour, as well as tobacco products containing flavourings in any of their components. According to Article 7(12) of the Tobacco Directive, tobacco products other than cigarettes and roll-your-own tobacco shall be exempted from the prohibitions laid down in paragraphs 1 and 7. The Commission may adopt delegated acts to withdraw that exemption for a particular product category. In view of the principles and aims listed in the preamble of the Tobacco Directive, as well as based on the wording of Article 7(2), it is uncertain whether the exemption also applies to novel tobacco products. If it would also apply to novel tobacco products, it would result in an unjustified difference of treatment of different tobacco products (tobacco products for smoking as well as smokeless and heated tobacco products) and related products (including electronic cigarettes).

In addition to the above, point 54 of the preamble and Article 24(3) of the Tobacco Directive state that a Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through the Tobacco Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months of the date of receiving the notification provided for in Article 24(3) of the Tobacco Directive, approve or reject the national provisions after having verified, taking into account the high level of protection of human health achieved through the Tobacco Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within the period of six months, the national provisions shall be deemed to be approved.

Estonia has based its regulation of tobacco products and related products on the aims of the Tobacco Directive, including the aim to ensure a high level of health protection, and prohibited flavourings in cigarettes and smoking tobacco for rolling cigarettes, as well as in electronic cigarettes. The decision was made, having regard to the following circumstances: 1) during thermal treatment, chemical compounds—which are harmful to health—are formed as a result of the disintegration process of the flavourings; 2) the flavourings may contribute to a nicotine overdose; 3) the flavourings are particularly attractive to young people, lower the perception of risk in terms of the health risks involved with the product, and help attract new consumers among non-smokers, especially among young people; 4) the use of flavourings in alternative tobacco products may encourage the consumption of standard cigarettes later on and inhibit the reduction of smoking prevalence.

The research so far has covered mainly the flavourings of electronic cigarettes; very little research has been done on heated products due to their novelty. Given that both electronic cigarettes as well as heated products entail heating of substances and use of similar flavourings, it may be assumed that flavourings in the composition of heated products may pose a similar risk as in the composition of electronic cigarettes. Unless the contrary is proven, it is appropriate to prohibit the use of flavourings in heated products for risk prevention purposes. It is also appropriate given the principle of equal treatment—there are no arguments for treating heated products more leniently than electronic cigarettes, as there is no proof that they are safer for health.

10. Reference(s) to basic text(s): Tobacco Act  
Estonia's Notification 2016/648/EE.

The basic texts were forwarded with an earlier notification: 2014/253/EE: 2016/648/EE

11. No

12. -



EUROPEAN COMMISSION  
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs  
Single Market Enforcement  
Notification of Regulatory Barriers

13. No

14. No

15. Yes

16. TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft is neither a sanitary nor a phytosanitary measure.

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European Commission

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