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and Foreign Trade
9, rue du Palais de Justice
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Subject: **Notification No 2024/0660/LU**

'Draft Law amending the amended Law of 11 August 2006 on tobacco control'

Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535 of 9 September 2015



Within the framework of the notification procedure laid down in Directive (EU) 2015/1535 ⁽¹⁾, the Luxembourgish authorities notified to the Commission on 9 December 2024 the Draft Law amending the amended Law of 11 August 2006 on tobacco control (hereinafter referred to as the 'notified draft').

According to the notification message, the aim of the notified draft is to regulate the manufacture and marketing of nicotine pouches as these products, like tobacco products, may have adverse health effects and should be treated in the same way from a legal perspective. Thus, the draft law proposes to establish a similar regime for nicotine pouches as that for tobacco products, making them subject to the same restrictions and obligations. The notified draft also introduces further changes related to tobacco products.

It is noted that the notified draft is largely similar to the draft law submitted in the context of notification 2024/0444/LU on 5 August 2024. The Commission provided comments on 5 November 2024, after which the Luxembourgish authorities withdrew their notification on 4 December 2024.

¹ () Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

As the notified draft in the present notification is largely similar to the draft law of the previous notification 2024/0444/LU and since the Commission's comments have not been addressed, the Commission would like to reiterate the same comments, as follows below.

Definition of nicotine

Article 2(40) of the Law on tobacco control ⁽²⁾, as amended by the notified draft, defines 'nicotine' as meaning "*nicotinic alkaloids and nicotine salts*".

The Commission would like to draw the attention of the Luxembourgish authorities to the fact that this definition deviates from Article 2(19) of Directive 2014/40/EU of the European Parliament and of the Council ⁽³⁾, which defines 'nicotine' as meaning "*nicotinic alkaloids*".

This difference risks creating the false impression that nicotine salts are not considered nicotinic alkaloids and would not be covered by the definition of 'nicotine' in Directive 2014/40/EU. The Commission therefore invites the Luxembourgish authorities to ensure that the provision of Article 2(40) of the Law on tobacco control, as amended by the notified draft, is in line with the definition of 'nicotine' laid down in Article 2(19) of Directive 2014/40/EU.

Reporting obligation

Article 3a(4) of the Law on tobacco control, as provided for in the notified draft provides the following:

"(4) By no later than eighteen months after the inclusion of an additive on the priority list drawn up in accordance with the implementing decision provided for in Article 6 of Directive 2014/40/EU of 3 April 2014, manufacturers and importers shall submit to the Directorate the in-depth studies they have carried out on this additive".

The Commission notes that according to Article 6(4), second subparagraph of Directive 2014/40/EU, "[m]anufacturers or importers shall submit these reports to the Commission and a copy thereof to the competent authorities of those Member States where a tobacco product containing this additive is placed on the market [...]".

The Commission therefore invites the Luxembourgish authorities to clarify in the notified draft that manufacturers and importers shall submit the relevant reports not only to the national Directorate but also to the Commission and the Member States where a tobacco product containing this additive is placed on the market.

Health warnings on vending machines

Article 3b(3) of the Law on tobacco control, as amended by the notified draft, provides that "[a]utomatic devices for distributing tobacco and tobacco products, as provided for in Article 9(3), shall also bear the health warnings provided for in Article 4(1). Graphic

² () Law of 11 August 2006 on tobacco control, Base text for the present Notification.

³ () Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 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 and repealing Directive 2001/37/EC, OJ L 127, 29.4.2014, p. 1.

representations on vending machines for tobacco and tobacco products other than health warnings are prohibited.’.

The Commission understands that the cited provision of the notified draft is intended to transpose the provision of Article 8(8) of Directive 2014/40/EU ⁽⁴⁾ regarding tobacco products distributed via vending machines. In this regard the Commission invites the Luxembourgish authorities to ensure that the cited provision of the notified draft will be interpreted and applied in line with the interpretation of Article 8(8) of Directive 2014/40/EU provided by the Court of Justice of the European Union in its judgments in Cases C-370/20 Pro Rauchfrei ⁽⁵⁾ and C-356/22 Pro Rauchfrei-II ⁽⁶⁾.

Health warnings on novel tobacco products

Article 4(1) of the Law on tobacco control, as amended by the notified draft provides the following:

‘Each unit packet and any outer packaging of cigarettes, roll-your-own tobacco and waterpipe tobacco, nicotine sachets, novel tobacco products and novel nicotine products must have a general warning, an information message and combined health warnings. Each unit packet and any outer packaging of a tobacco product for smoking other than cigarettes, roll-your-own tobacco and, waterpipe tobacco, nicotine sachets, novel tobacco products and novel nicotine products must have a general warning and a specific warning message’.

Under Article 11(1) of Directive 2014/40/EU, as amended by Delegated Directive (EU) 2022/2100 ⁽⁷⁾, Member States are allowed to exempt tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products from the obligations to carry the information message laid down in Article 9(2) of that Directive and the combined health warnings laid down in Article 10 of that Directive. In that event, and in addition to the general warning provided for Article 9(1) of that Directive, each unit packet and any outside packaging of such products must carry one of the text warnings listed in Annex I to that Directive. The general warning must include a reference to the cessation services referred to in Article 10(1), point (b), of that Directive.

Article 19(4) of Directive 2014/40/EU lays down the following in relation to novel tobacco products:

“Novel tobacco products placed on the market shall respect the requirements of this Directive. Which of the provisions of this Directive apply to novel tobacco products depends on whether those products fall under the definition of a smokeless tobacco product or of a tobacco product for smoking.”

The Commission would like to remind the Luxembourgish authorities that Article 11 of Directive 2014/40/EU only applies to tobacco products for smoking. With regard to the

⁴ ()Article 8(8) of Directive 2014/40/EU provides that images of unit packets and any outside packaging targeting consumers in the Union shall comply with the provisions of Chapter II of Title II of that Directive on labelling and packaging.

⁵ ()ECLI:EU:C:2021:988.

⁶ ()ECLI:EU:C:2023:173.

⁷ ()Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products, OJ L 283, 3.11.2022, p. 4.

rules on the labelling of novel tobacco products, and in accordance with Article 19(4) of Directive 2014/40/EU, it must be ensured that the applicable provisions depend on whether novel tobacco products fall under the definition of a smokeless tobacco product⁽⁸⁾ or of a tobacco product for smoking⁽⁹⁾. While several provisions apply to tobacco products in general, certain provisions only apply to tobacco products for smoking⁽¹⁰⁾ or to smokeless tobacco products.⁽¹¹⁾ In the light of this, the Luxembourgish authorities must ensure that this difference is respected.

The Commission highlights that the notified draft neither includes a general clarification, in accordance with Article 19(4) of Directive 2014/40/EU, that novel tobacco products placed on the market shall respect the requirements of Directive 2014/40/EU, nor indicates which of the provisions of the Law on tobacco control apply only to novel tobacco products for smoking or to novel tobacco products that are not for smoking (i.e. smokeless tobacco products).

The Commission therefore invites the Luxembourgish authorities to: a) ensure compliance with Article 19(4) of Directive 2014/40/EU; and to b) clarify which provisions of Article 4(1) of the Law on tobacco control, as amended by the notified draft, only apply to novel tobacco products for smoking and which of them only apply to novel tobacco products that are not for smoking (i.e. smokeless tobacco products).

Heated tobacco products

The Commission notes that the notified draft includes provisions which appear to be intended to transpose Delegated Directive (EU) 2022/2100.

In this context, the second subparagraph of Article 7(3) of the Law on tobacco control, as amended by the notified draft provides that tobacco products other than cigarettes, heated tobacco products and roll-your-own tobacco are exempt from the prohibitions in points (a) and (h) of that Article, namely the prohibition to contain a particular characterising flavour and the prohibition to contain flavours in any of their components, such as filters, paper, packets and capsules, or any technical device for altering the smell or taste of the tobacco products concerned or their burning intensity, respectively.

The Commission notes that the provision of point (b) of the first subparagraph of Article 7(3) of the Law on tobacco control, as amended by the notified draft, provides for the prohibition for tobacco products to contain any technical device for altering the smell or taste of tobacco products, or their burning intensity. Whereas the same provision seems to be included as part of point (h) of that subparagraph, point (b) would still apply to tobacco products other than cigarettes, heated tobacco products and roll-your-own tobacco as it is not mentioned among the provisions to be covered by the exemption in the second subparagraph of the same Article. This would appear to be in conflict with point (h) of Article 7(3) of the notified draft and would not be in line with Article 7(12) of Directive 2014/40/EU, read in conjunction with Article 7(7) of that Directive, insofar

⁸ ()See definition in Article 2(5) of Directive 2014/40/EU, which defines ‘smokeless tobacco product’ as ‘a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use’.

⁹ ()See definition in Article 2(9) of Directive 2014/40/EU, which defines ‘tobacco products for smoking’ as ‘tobacco products other than a smokeless tobacco product’.

¹⁰ ()See Articles 9 to 11 of Directive 2014/40/EU.

¹¹ ()See Article 12 of Directive 2014/40/EU.

as it would also apply to tobacco products covered by the exemption resulting from those provisions of Directive 2014/40/EU. The Commission therefore invites the authorities to clarify that tobacco products other than cigarettes, roll-your-own tobacco and heated tobacco products are also exempted from the prohibition for tobacco products to contain any technical device for altering the smell or taste of tobacco products, or their burning intensity, which is established under point (b) of the provision of the notified draft concerned.

General remark on the transposition of Delegated Directive (EU) 2022/2100 into the Luxembourgish legal order

The Commission finally notes that the present assessment of the notified draft is without prejudice to the examination of the national measures in the course of the compliance assessment of the transposition of Delegated Directive (EU) 2022/2100. In this regard, the Commission takes the opportunity to remind the Luxembourgish authorities, that whilst the notified draft includes provisions which appear to be intended to transpose part of Directive (EU) 2022/2100, Luxembourg has yet to notify to the Commission the full transposition of Directive (EU) 2022/2100 into its national legal order. The Commission takes the opportunity to remind the Luxembourgish authorities of their obligation to notify their transposition measures.

The Luxembourgish authorities are invited to take into account the above-mentioned comments.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.



For the Commission

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