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Subject: **Notification No 2025/0055/PL**

On the draft Act amending the Act on protection of health against the consequences of consumption of tobacco and tobacco products

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



On 27 January 2025, within the framework of the notification procedure laid down in Directive (EU) 2015/1535¹, the Polish authorities notified to the Commission the **Draft Act amending the Act on protection of health against the consequences of consumption of tobacco and tobacco products** (hereinafter ‘the notified draft’).

According to the notification message, the notified draft aims to regulate nicotine-free liquids intended for use in electronic cigarettes.

The examination of the notified draft has prompted the Commission to issue the following comments.

1) Electronic cigarettes and health warnings

Article 1(1)(b) of the notified draft amends the definition of ‘electronic cigarette’ laid down in Article 2(20) of the basic act² as follows:

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 (codification), OJ L 241, 17.9.2015, p. 1.

² Act on protection of health against the consequences of consumption of tobacco and tobacco products.

‘electronic cigarette – a product that can be used for consumption of nicotine-containing vapour or nicotine-free vapour via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank; electronic cigarettes can be disposable or refillable by means of a refill container or a tank, or rechargeable with single-use cartridges’

The definition differs from the relevant definition established in Article 2(16) of Directive 2014/40/EU³, insofar as it covers the consumption of nicotine-free vapour via a mouthpiece.

In addition, the notified draft in Article 1(7) introduces Article 11c(7a) in the basic act, which reads as follows:

‘7a. The packaging [...] of electronic cigarettes that can only be used for consumption of nicotine-free vapour, and of refill containers with nicotine-free liquid, shall carry the following health warning:

“Product harmful to health”.’

The products regulated under the provision of Article 11c(7a) of the notified draft are electronic cigarettes that can only be used for the consumption of nicotine-free vapour and refill containers with nicotine-free liquid and therefore fall outside the scope of Directive 2014/40/EU.

However, it cannot be ruled out that certain electronic cigarettes (notably the refillable and rechargeable ones) which can be used for the consumption of nicotine-free vapour can also be used for the consumption of nicotine-containing vapour. Insofar as such products meet the definition of electronic cigarettes under Directive 2014/40/EU, they should comply with the requirement to carry a health warning, as set in Article 20(4)(b) (iii) of Directive 2014/40/EU.

The Commission invites the Polish authorities to ensure that the definition of ‘electronic cigarettes’ in the notified draft will not interfere with the requirements applicable to electronic cigarettes under Directive 2014/40/EU as defined in Article 2(16) of that Directive. In particular, the Commission invites the Polish authorities to ensure that the implementation of the notified draft will not allow to circumvent compliance with Article 20(4)(b)(iii) of Directive 2014/40/EU as regards the requirement that unit packets and any outside packaging of electronic cigarettes as defined in Article 2(16) of Directive 2014/40/EU, must bear a health warning on nicotine content.

2) Definition of refill containers

Article 1(1)(a) of the notified draft amends the definition of ‘refill containers’ laid down in Article 2(18) of the basic act as follows:

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.

‘refill container – a receptacle that contains a nicotine-containing liquid, which can be used for refilling an electronic cigarette, or a receptacle that contains a nicotine-free liquid that is intended to be used in electronic cigarettes’.

This definition deviates from the definition of ‘refill containers’ under Directive 2014/40/EU, which in Article 2(17) states that ‘refill container’ means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette. In the notified draft, the term ‘refill containers’ does not only refer to refill containers with nicotine, but also to refill containers without nicotine.

To ensure legal certainty, the Commission invites the Polish authorities to ensure that the definition of ‘refill containers’ will not create confusion as to the scope of application of the relevant requirements for tobacco and related products under Directive 2014/40/EU.

3) Definition of related products

Article 1(1)(b) of the notified draft amends the definition of ‘related products’ laid down in Article 2(21) of the basic act as follows:

‘related product – an electronic cigarette, a refill container, a herbal product for smoking, and a nicotine pouch’.

The Commission notes that while Directive 2014/40/EU does not include a definition of ‘related products’, it is clear from its Article 1(f), which sets out the scope of application of the Directive and from Title III of the Directive, that the term refers to ‘related products’ as covering electronic cigarettes and refill containers, and herbal products for smoking.

It follows that the definition of ‘related products’ in the notified draft is broader than what the same term covers under the Directive. In the notified draft ‘related products’ do not only refer to (nicotine-containing) electronic cigarettes, refill containers and herbal products for smoking, but also to nicotine-free electronic cigarettes and nicotine pouches.

To ensure legal certainty, the Commission invites the Polish authorities to ensure that the definition of ‘related products’ in the notified draft will not create confusion as to the scope of application of the relevant requirements for tobacco and related products under Directive 2014/40/EU.

4) The use of EU-CEG

Article 1(9) of the notified draft introduces Article 11ha to the basic act, on the information that the manufacturer or importer of nicotine pouches needs to submit to the national competent authorities. Article 11ha(7) of the basic act, as introduced by the notified draft provides that ‘the format for the submission and making available of information on nicotine pouches is laid down in Commission Implementing Decision (EU) 2015/2186’.

The Commission notes that the information that manufacturers and importers need to provide for tobacco products and e-cigarettes and refill containers in the EU-CEG is set out in Commission Implementing Decision (EU) 2015/2186⁴ establishing a format for the submission and making available of information on tobacco products, and in Commission Implementing Decision (EU) 2015/2183⁵ establishing a common format for the notification of electronic cigarettes and refill containers.

Article 1 of Implementing Decision (EU) 2015/2186 establishes the scope of the Decision and provides that the Decision establishes a common format for the reporting and making available of information on ingredients and emissions of tobacco products and on sales volumes. Similarly, Article 1 of Implementing Decision (EU) 2015/2183 provides that this Decision establishes a common format for the notification of information on electronic cigarettes and refill containers. The tools set up in Implementing Decision (EU) 2015/2186 could also facilitate the submission of information on herbal products for smoking pursuant to Article 22 of Directive 2014/40/EU.

The Commission stresses that nicotine pouches do not fall within the scope of the above Implementing Decisions. Should the Polish authorities wish to use EU-CEG for the storage of information concerning these products, they should take due regard of the following elements:

- (i) all information encoded in the EU-CEG system is visible to the Commission;
- (ii) the Commission cannot be held liable for access, loss or damage of that information;
- (iii) the Polish authorities must ensure that the reporting of information related to these products, does not impact on and/or interfere (i.e. does not create confusion) with the reporting of information for the products required by Directive 2014/40/EU and the above Implementing Decisions.

Hence, the Commission would like to invite the Polish authorities to explain how the relevant provision in Article 1(9) of the notified draft, introducing Article 11ha(7) to the basic act, will be implemented in practice so that it would be ensured that the reporting of information related to products which do not fall within the scope of the above two Implementing Decisions, does not impact on and/or interfere (i.e. does not create confusion) with the reporting of information that is required by Directive 2014/40/EU and those decisions.

The Polish authorities are invited to take these comments into account.

⁴ Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products, OJ L 312, 27.11.2015, p. 5.

⁵ Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers, OJ L 309, 26.11.2015, p. 15.

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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