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Subject: **Notification 2023/488/HU**

Government Decree amending Government Decree No 39/2013 of 14 February 2013 on the production, placing on the market and control of tobacco products, on combined warnings, and the detailed provisions on the application of healthcare penalties (Draft)

Delivery of a detailed opinion pursuant to Article 6(2) of Directive (EU) 2015/1535 of 9 September 2015

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

Sir,

Within the framework of the notification procedure laid down in Directive (EU) 2015/1535([1]), the Hungarian authorities notified to the Commission on 7 August 2023 the **"Government Decree amending Government Decree No 39/2013 of 14 February 2013 on the production, placing on the market and control of tobacco products, on combined warnings, and the detailed provisions on the application of healthcare penalties (Draft)"** (hereafter "the notified draft").

According to the notification message, the purpose of the notified draft is to regulate the ingredients, the packaging, consumption and control of consumption of products that pose a serious health risk to consumers and those in their vicinity, taking into account the trends in smoking, the evolution of consumption patterns and the emergence of new

[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.

recreational products with dangerous amounts of nicotine, which can cause serious poisoning and death.

As regards nicotine pouches, the notified draft would thus complete the rules on ingredients, the maximum allowed quantities of nicotine, additives, packaging, labelling, information provision on harmful effects as well as the rules on the mandatory use of child locks. The amendments in the notified draft also concern the numerical adjustment of the list of prohibited additives, the inclusion of cannabidiol (CBD) among prohibited additives, and the regulation of the composition of herbal products for smoking and electronic devices imitating smoking.

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

1. DETAILED OPINION

By Section 6(1) of the notified draft, Section 19/B(1)(b) of Government Decree No 39/2013 of 14 February 2013 on the production, placing on the market and control of tobacco products, on combined warnings, and the detailed provisions on the application of healthcare penalties (hereinafter "the Decree") would be amended to read as follows:

"'(b) nicotine-containing liquids or liquids containing nicotine in any form, used in electronic cigarettes or refill containers, may be placed on the market in the form of:

(ba) refill containers with a capacity not exceeding 10 ml,

(bb) disposable electronic cigarettes or single-use cartridges with a capacity not exceeding 2 ml, both specially designed for this purpose,'".

Under Article 20(3)(a) of Directive 2014/40/EU 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 ([2]), Member States are required to ensure that:

"(a) nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml".

Article 2(16) of Directive 2014/40/EU defines 'electronic cigarette' as follows:

"'electronic cigarette' means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, 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 and a tank, or rechargeable with single use cartridges".

Recital 38 of Directive 2014/40/EU explains that:

[2]() 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.

“In order to limit the risks associated with nicotine, maximum sizes for refill containers, tanks and cartridges should be set.”

It follows that, insofar as Section 19/B(1)(b) of the Decree as amended by Section 6(1) of the notified draft, which sets out the maximum sizes as referred to in Article 20(3)(a) of Directive 2014/40/EU, does not set out a maximum size for tanks, that provision of the notified draft is incompatible with the said provision of the Directive.

By Section 6(2) of the notified draft, Section 19/B(5) of the Decree would be amended to read as follows:

“‘(5) The two largest surfaces of unit packets and multipacks of electronic cigarettes and refill containers, which are pre-filled with nicotine-containing refill liquid, shall bear the following health warning in a way that occupies at least 30 % of each surface: ‘This product contains nicotine which is harmful to your health and leads to addiction.’”

Under Article 20(4)(b)(iii) of Directive 2014/40/EU, Member States are required to ensure that:

“(b) unit packets and any outside packaging of electronic cigarettes and refill containers: […]”

“(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 is to be used”.

The Commission fully shares the objectives of the notified draft relating to a high level of protection of human health, especially for young people, which are also those of Directive 2014/40/EU in accordance with its Article 1. Nevertheless, the Commission notes that Article 20(4)(b)(iii) of that Directive harmonises the wording of the health warnings to be carried by unit packets and any outside packaging of electronic cigarettes and refill containers. As the wording of the health warning to be introduced into Section 19/B(5) of the Decree by Section 6(2) of the notified draft deviates from that harmonised wording, that provision may create obstacles to the free movement of the products concerned within the internal market. It follows that Section 19/B(5) of the Decree as amended by Section 6(2) of the notified draft is incompatible with Article 20(4)(b)(iii) of Directive 2014/40/EU.

For the reasons stated above, the Commission delivers a detailed opinion as provided for in Article 6(2) of Directive (EU) 2015/1535 to the effect that:

- Section 19/B(1)(b) of Government Decree No 39/2013 of 14 February 2013 on the production, placing on the market and control of tobacco products, on combined warnings, and the detailed provisions on the application of healthcare penalties as amended by Section 6(1) of the notified draft is incompatible with Article 20(3)(a) of Directive 2014/40/EU; and

- Section 19/B(5) of Government Decree No 39/2013 of 14 February 2013 on the production, placing on the market and control of tobacco products, on combined warnings, and the detailed provisions on the application of healthcare penalties as amended by Section 6(2) of the notified draft is incompatible with Article 20(4)(b)(iii) of Directive 2014/40/EU.

The Commission would remind the Hungarian authorities that under the terms of Article 6(2) of Directive (EU) 2015/1535, the delivery of a detailed opinion obliges the Member State that has drawn up the draft technical regulation concerned to postpone its adoption for six months from the date of its notification.

This standstill period therefore comes to an end on 7 February 2024.

The Commission further draws the attention of the Hungarian authorities to the fact that under the above-mentioned provision the Member State that is the addressee of a detailed opinion is obliged to report to the Commission on the action that it proposes to take on such detailed opinion.

The Commission furthermore invites the Hungarian authorities to communicate to it on adoption the definitive text of the draft technical regulation concerned, in accordance with Article 5(3) of Directive (EU) 2015/1535.

Should the Hungarian authorities not comply with the obligations provided in Directive (EU) 2015/1535 or should the text of the draft technical regulation under consideration be adopted without account being taken of the above-mentioned objections, or be otherwise in breach of EU law, the Commission may commence proceedings pursuant to Article 258 of the Treaty on the Functioning of the European Union.

2. COMMENTS

Unit packets of roll-your-own tobacco

Section 15/A(ca) of the Decree as amended by Section 2(2) of the notified draft provides that:

“The unit packet, […] in the case of smoking tobacco […] is a rectangular or upright sachet containing smoking tobacco […]”.

Insofar as the provision of Section 15/A(ca) of the Decree as amended by Section 2(2) of the notified draft applies to roll-your-own tobacco as defined in Article 2(3) of Directive 2014/40/EU and does not refer to forms of unit packets other than that of a *“rectangular or upright sachet”*, the Hungarian authorities are invited to clarify that provision of the notified draft so as to ensure that it complies with the second sentence of Article 14(1) of Directive 2014/40/EU. According to that provision, unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch.

Herbal products for smoking

Section 18/C of the Decree of which the text is replaced by Section 5 of the notified draft contains provisions applicable to herbal products for smoking.

Under Article 22(2) of Directive 2014/40/EU, Member States are required to ensure that the information on the composition of herbal products for smoking submitted in accordance with paragraph 1 of that Article is made publicly available on a website.

The Commission notes that Section 18/C of the Decree as amended by Section 5 of the notified draft does not appear to contain any provision to transpose into the Hungarian legislation the obligation laid down in Article 22(2) of Directive 2014/40/EU. This is in contrast to the Decree of which a consolidated version has been submitted by the Hungarian authorities with the notification and of which Section 18/C(6) appears to transpose the said obligation.

The Hungarian authorities are therefore invited to clarify Section 18/C of the Decree as amended by Section 5 of the notified draft so as to ensure compliance with Article 22(2) of Directive 2014/40/EU.

Prohibited additives

A number of provisions of the notified draft refer to Annex 4 of the Decree as regards additives prohibited in the products referred to in those provisions ([3]). Annex 1 to the notified draft, as referred to in Section 10 thereof, replaces Annex 4 to the Decree which contains the list of prohibited additives. The Commission also notes that the Decree refers to Annex 4 in a number of its other provisions, including its Section 4(1) and (2) which prohibit the added prohibited additives as set out in Annex 4 in tobacco products and the placing on the market of tobacco products containing those additives ([4]).

Article 7 of Directive 2014/40/EU lays down obligations for the Member States in relation to the regulation of ingredients of tobacco products. In particular, under paragraph 6 of that Article, Member States are required to prohibit the placing on the market of tobacco products containing the following additives:

"(a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;

(b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

(c) additives having colouring properties for emissions;

(d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and

(e) additives that have CMR properties in unburnt form."

Under Article 20(3)(c) of Directive 2014/40/EU, Member States are required to ensure that the nicotine-containing liquid for electronic cigarettes and refill containers does not contain additives listed in Article 7(6) of that Directive.

[3]() Section 18/C(1)(a) of the Decree as amended by Section 5 of the notified draft (herbal products for smoking), Section 19/C(1)(ca) of the Decree as amended by Section 7 of the notified draft (nicotine-free liquid for electronic devices imitating smoking and nicotine-free refill containers) and Section 19/G(1)(aa) of the Decree as amended by Section 8 of the notified draft (nicotine-containing smoking substitutes).
[4]() Section 19/B(1)(da) of the Decree prohibits those additives in nicotine-containing liquid for electronic cigarettes and refill containers.

The Commission recalls its comments on notification 2015/529/HU by which earlier amendments to the Decree, including a previous version of Annex 4 thereto, were notified to the Commission. In line with those comments, the Commission invites the Hungarian authorities to ensure that, insofar as Annex 4 to the Decree as amended by Annex 1 to the notified draft prohibits additives that are not specifically referred to in Article 7 of Directive 2014/40/EU, such prohibition is nonetheless based on the application of that Directive, in particular, on more generally expressed provisions contained in Article 7 of that Directive. The Hungarian authorities are also invited to ensure that the prohibition of additives under the Hungarian legislation extends to all the additives prohibited by Article 7(6) of Directive 2014/40/EU with a particular view to the fact that, for tobacco products, Section 4 of the Decree, whilst referring to Annex 4, does not appear to refer to the specific categories of additives mentioned in that Article.

The Commission invites the Hungarian authorities to take into account the above comments.

The Commission furthermore invites the Hungarian authorities to communicate to it on adoption the definitive text of the draft technical regulation concerned, in accordance with Article 5(3) of Directive (EU) 2015/1535.

Yours faithfully,

For the Commission

Thierry Breton
Member of the Commission