



EUROPEAN COMMISSION

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

Message 201

Communication from the Commission - TRIS/(2024) 0821

Directive (EU) 2015/1535

Notification: 2023/0488/HU

Forwarding of the response of the Member State notifying a draft (Hungary) to of European Commission.

MSG: 20240821.EN

1. MSG 201 IND 2023 0488 HU EN 08-02-2024 25-03-2024 HU ANSWER 08-02-2024

2. Hungary

3A. Európai Unió Ügyek Minisztériuma
EU Jogi Megfelelésvizsgáló Főosztály - Műszaki Notifikációs Központ
H-1054 Budapest, Báthory u. 10.
E-mail: technicalnotification@eum.gov.hu

3B. Belügyminisztérium
Nemzetközi és Európai Unió Jogi Osztály
H-1051 Budapest V. József Attila utca 2-4.
E-mail: judit.vera.acs@bm.gov.hu

4. 2023/0488/HU - X60M - Tobacco

5.

6. Responses to the Commission's detailed opinion

1. Containers with nicotine-containing liquid

In its detailed opinion, the Commission explains that Section 19/B(1)(b) of Government Decree No 39/2013 of 14 February 2013, as amended by Section 6(1) of the draft notified under notification number 2023/488/HU, which specifies the maximum permissible sizes referred to in Article 20(3)(a) of Directive 2014/40/EU, does not set a maximum permissible size for nicotine-containing containers. In this regard, the said provision of the notified draft is not compatible with the referred provision of the Directive.

We would like to inform the Commission that we agree with their detailed opinion. Accordingly, the following text has been added to the draft to govern the containers' maximum capacity.

“(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, cartridges or containers of a capacity not exceeding 2 ml.”

2. Health warnings



EUROPEAN COMMISSION

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

In its detailed opinion, the Commission explains that the text of the health warning which is to be inserted in Section 19/B(5) of Government Decree No 39/2013 of 14 February 2013, as amended by Section 6(2) of the draft notified under number 2023/488/HU, differs from the harmonised wording and this provision may impede the free movement of the concerned products within the internal market. It follows from this that Section 19/B(5) of the Decree, which was amended by Section 6(2) of the notified draft, is incompatible with Article 20(4)(b)(iii) of Directive 2014/40/EU.

We would like to inform the Commission that we agree with their detailed opinion. We refrain from amending Section 19/B(5) of Government Decree No 39/2013 of 14 February 2013, therefore the text of the health warnings will remain as follows:

“This product contains nicotine, which is a highly addictive substance.”

Replies to the Commission’s comments

1. Unit packets of roll-your-own tobacco

In its comments, the Commission explains that the provision in Section 15/A(ca) of Government Decree No 39/2013 of 14 February 2013, as amended by Section 2(2) of the draft notified under number 2023/488/HU, does not comply with the second sentence of Article 14(1) of Directive 2014/40/EU, since the legislation does not permit the marketing of cylindrical units of packaging.

We appreciate the Commission’s observations in this respect. At the same time, we would like to inform the Commission that we do not intend to make changes to the wording. Already at the time of transposing the so-called TPD II directive, Hungary notified Government Decree No 39/2013 of 14 February 2013 as a legislation which, in its wording, lays down restrictions for unit packets of smoking tobacco, in terms of size and shape. In our view, Hungary could do so, inter alia, on the basis of Article 24(2) of the TPD; and this practice has been in place for many years – and is accepted by everyone. In this context, it should be stressed that in Hungary, in comparison to the EU average, smoking tobacco had been consumed in significantly high quantities earlier as well, and such products used to be marketed in huge bags and large cylindrical ‘buckets’, which – due to their size and colourful appearance – did not only encourage consumption, but also had the power to attract people’s attention. The Hungarian legislature therefore first restricted the shape and size of the available-for-sale unit packets (30-50 grams), and later introduced a plain package for these unit packets. Accordingly, any change towards the permissibility of cylindrical boxes would be understood as an explicit step backwards when observed from a public health point of view in Hungary.

2. Herbal products for smoking

In its comments, the Commission explains that Section 18/C of Government Decree No 39/2013 of 14 February 2013, as amended by Section 5 of the draft notified under notification number 2023/488/HU, does not contain any provision that would transpose into Hungarian law the obligation laid down in Article 22(2) of Directive 2014/40/EU, which stipulates that information (on the composition of herbal products for smoking) in accordance with Article 22(1) of Directive 2014/40/EU shall be made available on a website.

We agree with the Commission’s comments. Section 18/C of the draft is, thus, amended with the addition of a new paragraph, so that the information provided about the composition of the above-mentioned herbal products for smoking becomes available to the public via a website.

“(6) The information provided about the ingredients used in the manufacture of herbal products for smoking, their quantity and changes thereto are made public via the NNGYK (National Public Health and Pharmaceutical Center) website. Throughout the publication process, trade secrets designated by the economic operator shall be protected.”



EUROPEAN COMMISSION

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

3. Prohibited additives

In its comments, the Commission explains that Annex 1, which is mentioned in Section 10 of the draft notified under notification number 2023/488/HU and which replaces Annex 4 of Government Decree No 39/2013 of 14 February 2013, does not comply with Article 20(3)(c) of Directive 2014/40/EU, which requires Member States to ensure that the nicotine-containing liquids used in electronic cigarettes and refill containers do not contain additives listed in Article 7(6) of the Directive.

We agree with the Commission's comments. Accordingly, Section 4 of Government Decree No 39/2013 of 14 February 2013 has been reformulated so that

- as a general prohibition, the text covers all the additives prohibited by Article 7(6) of Directive 2014/40/EU;
- the legislation also lays down that the use of additives specified in Annex 4 is prohibited, without prejudice to the general prohibitions;
- since they are specifically mentioned in Article 7 of the Directive and are specified in the new paragraph 1 of Section 4 of Government Decree No 39/2013 of 14 February 2013, caffeine and taurine have been deleted from Annex 4, thus creating consistency between the general and the special provisions.

"Section 4(1) Tobacco products may not contain any added prohibited additives and foreign substances. In particular, tobacco products may not contain:

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

(2) Without prejudice to paragraph 1, it shall be prohibited to place on the market and make available tobacco products which contain an additive listed in Annex 4."

European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu