Message 303

Communication from the Commission - TRIS/(2023) 00965
Directive (EU) 2015/1535
Notification: 2023/0019/CZ

Observations from the Commission (article 5, paragraph 2, of Directive (EU) 2015/1535). These observations do not have the effect of extending the standstill period.

Observaciones - připomínky - Bemärkninger - Bemerkungen - Märkused - Παρατηρήσεις - Comments - Observations - Osservazioni - Piezīmes - Komentarai - Megjegyzések - Kummenti - Opmerkingen - Uwagi - Observacoes - Komentáre- Pripombe - Huomautuksia - Synpunkter - Коментари - Comentarii.

Sin plazo de statu quo - Doba pozastavení prací se neaplikuje - Ingen status quo frist - Keine Stillhaltefrist - Ooteaeg ei ole kohaldatav - Δεν υπάρχει statu quo - Standstill period does not apply - Pas de délai de statu quo - Termine di status quo non previsto - Bezdarbības periods netiek piemērots - Atidėjimo periodas netaikomas - A halasztási időszak nem alkalmazandó - Il-perijodu ta' waqfien ma japplikax - Geen status quo-periode - Okres odroczenia nie ma zastosowania - Prazo do statu quo não previsto - Perióda pozastavenia neplatí - Obdobje mirovanja ne velja - Ei status quon määräaikaa - Ingen tidfrist för status quo - Не се прилага период на прекъсване - Perioada de stagnare nu se aplică.

(MSG: 202300965.EN)
1. MSG 303 IND 2023 0019 CZ EN 20-04-2023 05-04-2023 COM 5.2 20-04-2023

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2023/0019/CZ - C00C

5. article 5, paragraph 2, of Directive (EU) 2015/1535

6. Within the framework of the notification procedure laid down by Directive (EU) 2015/1535 , the Czech authorities notified to the Commission on 19 January 2023 the draft Decree on tobacco-free nicotine pouches (hereinafter, 'the notified draft').

According to the notification message, the notified draft aims to set out requirements for nicotine pouches without tobacco. In particular, it lays down requirements related to the composition, appearance, quality and characteristics. It also provides for labelling requirements, including prohibited elements and features, and requirements on the manner, deadlines and scope of the notification obligation.

The examination of the notified draft has prompted the Commission to deliver the following comments pursuant to Article 5 (2) of Directive (EU) 2015/1535.

COMMENTS

(i) References to the EU legal framework applicable to food

The Commission notes that certain provisions of the notified draft seem to extend the application of certain provisions of EU food law to the placing on the market of nicotine pouches.

In particular, Section 2(2) of the notified draft states that only additives listed in Annex II, Part B to Regulation (EC) No 1333/2008 on food additives may be used as additives in nicotine pouches, whereas Section 2(3)(a) provides that vitamins, minerals or other ingredients that give the impression that they are beneficial to health or present a reduced health risk shall not be added to nicotine pouches as separate substances. The provision cross-refers to Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods .

Section 2(6) of the notified draft provides that a nicotine pouch dose consists of, inter alia, edible or inedible packaging safe for human health in accordance with the requirements of Article 3(1) of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, and the requirements of Article 4(a) and (e) in the part concerning the composition requirements of Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, and the requirements of national legislation on hygiene requirements for products intended to come into contact with food and meals.

Finally, Section 4(4) of the notified draft states that the packaging of the unit packet and the outer packaging of a nicotine pouch bear information pursuant to Article 9(1)(c) of Regulation (EU) No 1169/2011 on the provision of food information to consumers .

The Commission also notes that Section 3(1) on the appearance and properties of nicotine pouches provides, inter alia, that the unit packet itself and any outer packaging of the nicotine pouch must not resemble food, whereas Section 5(5)(c) states that the labelling of the unit packet itself and of any outer packaging of the nicotine pouch must not contain any element or feature that resembles a food.

The Commission notes that in the absence of a definition of nicotine pouches in the notified draft, it is not clear whether the references to the above-quoted EU legal acts indicate that nicotine pouches are to be considered as food.

In this regard, the Commission notes that according to Article 2 of Regulation (EC) No 178/2002, "«food» (or «foodstuff») means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans" (first paragraph) and "shall not include (…) (f) tobacco and tobacco products(…)" and reminds the Czech authorities about the need to ensure compliance of the products regulated under the notified draft with this definition.

The Commission invites the authorities to ensure that the provisions of the notified draft do not equate nicotine pouches with 'food' as defined in Regulation (EC) No 178/2002 above and do not imply that procedures applicable to food would apply to nicotine pouches (for example notification obligations under the Rapid Alert System for Food and Feed (RASFF) are not relevant for such products).

(ii) Use of EU-CEG system

Sections 6 and 7 of the notified draft foresee the use of the EU Common Entry Gate (hereinafter 'EU-CEG') for the notification of certain information related to nicotine pouches.

The Commission notes that the information manufacturers and importers need to provide for tobacco products and e-cigarettes in the EU-CEG is set out in Commission Implementing Decision (EU) 2015/2186 establishing a format for the submission and making available of information on tobacco products and Commission Implementing Decision (EU) 2015/2183 establishing a common format for the notification of electronic cigarettes and refill containers .

Since nicotine pouches do not fall within the scope of the above decisions, the Commission is not in the position to provide any specific support for such reporting. Hence the Commission would like to invite the Czech authorities to explain what kind of guidance they would provide to operators in order to ensure compliance of nicotine pouches'

reporting under the EU-CEG validation.

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

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.

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