



EUROPEAN COMMISSION

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

Message 103

Communication from the Commission - TRIS/(2023) 2228

Directive (EU) 2015/1535

Notification: 2023/0215/B

Forwarding of the observations of a Member State (Czechia) (article 5, paragraph 2, of Directive (EU) 2015/1535). These observations do not have the effect of extending the standstill period.

Sensitive - Sensible - Sensibel - Känslig - Arkaluonteinen - Følsomme - Gevoelig - чувствителна - Sensibil - Konfidencialu - Sensitīvs - Tundlik - Citlivé - Zaupen - Povjerljivo - ευαίσθητες - Sensible - Sensibile - Sensível - Citlivý - Érzékeny - Wrażliwy - Sensitiv - íogair

Document handled in the framework of 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.

This document is only releasable to staff of the European Commission and Member States' public administrations with an established need-to-know basis in the framework of Directive (EU) 2015/1535.

In case you are the holder of this document without having the established need-to-know basis, as indicated above, inform the author, originator or sender immediately and return it securely unread. Failure to do so shall be considered a breach of security, which may give rise to disciplinary or legal action.

MSG: 20232228.EN

1. MSG 103 IND 2023 0215 B EN 26-10-2023 24-07-2023 CZ COMMS 5.2 26-10-2023

2. Czechia

3A. Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
Biskupský dvůr 1148/5
110 00 Praha 1
tel: 221 802 212
e-mail: eu9834@unmz.cz

3B. Ministerstvo průmyslu a obchodu
oddělení 51120
Na Františku 32
110 15 Praha 1

4. 2023/0215/B - X00M - GOODS AND MISCELLANEOUS PRODUCTS

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

6. On 25/04/2023, a Belgian notification was published in the TRIS database concerning the draft Royal Decree of XXX on the manufacture and placing on the market of tobacco and herbal products intended for smoking (hereinafter the 'Draft Regulation').



EUROPEAN COMMISSION

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

The main objective of the Draft Regulation is the transposition of Commission Delegated Directive 2022/2100 of 29 June 2022 (hereinafter the 'CD Directive') amending Directive 2014/40/EU of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (the 'TPD') as regards the abolition of certain exemptions for heated tobacco products.

I.

The Czech Republic considers that the proposed wording of Article 2(15) of the Draft Regulation does not contain a complete definition of heated tobacco products (hereinafter 'HTP'), as contained in Article 1(1) (and also in point 4 of the preamble) of the CD Directive, and further considers that Article 11(1) of the Draft Regulation, as a consequence, unduly considers all HTP to be tobacco products for smoking, which makes the Draft Regulation liable to create an unjustified obstacle to the free movement of goods within the meaning of Article 34 of the Treaty on the Functioning of the European Union.

II.

Under Article 24(1) of the TPD, 'Member States may not, by reason of discretion relating to the aspects covered by this Directive, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive, subject to paragraphs 2 and 3 of this Article'. Point 53 of the preamble to the TPD provides that tobacco products 'which comply with that directive should benefit from the free movement of goods'. Article 19(4) of the TPD stipulates that 'New tobacco products placed on the market shall comply with the requirements of this Directive. Which provisions of this Directive apply to novel tobacco products depends on whether these products are covered by the definition of smokeless tobacco product or the definition of tobacco product for smoking.' The CD Directive defines HTP in Article 1(1) (and also in point 4 of the preamble) as 'a new tobacco product which is heated to produce emissions containing nicotine and other chemicals, which is then inhaled by the user (users) and which, depending on its characteristics, is a smokeless tobacco product or smoking tobacco.'

The Draft Regulation should transpose the definition of HTP in full and not only the first part of the wording, since the application of the same health warnings for tobacco products (hereafter 'health warnings') to products that do not burn and emit smoke and thus have different toxicological profiles from tobacco products intended for smoking could be misleading for consumers. The incomplete definition in Article 2(15) of the Draft Regulation means that all HTP (whether they are smokeless tobacco products or smoking tobacco products due to their characteristics) must be accompanied by an information message in accordance with Article 9(2) and a combined health warning according to Article 10 of the TPD. The CD Directive implies, in the way it conceives and works with the above-mentioned concepts, that the laws of the Member States must distinguish between the rules on the labelling of HTP that are smokeless tobacco products (health products focus on nicotine as a substance consumers need to be warned about) and those that are classified as smoking tobacco products (health warnings focus on smoke and other substances related to health effects), whereas smokeless tobacco products are to be labelled in accordance with Article 12 of the TPD.

III.

In view of the above, the Czech Republic therefore considers that the Draft Regulation contains provisions that may create disproportionate barriers to the free movement of goods and significantly distort the business environment in the internal market and may be contrary to the Kingdom of Belgium's obligations under EU law, since the deletion of the second part of the definition of HTP, as set out in the CD Directive, provides the opportunity to impose the same health warning obligations on all heated tobacco products, regardless of their characteristics. In addition, the Draft Regulation should make clear that the combined health warnings and information as well as all other labelling requirements set out in Articles 9 and 10 of the TPD apply only to heated tobacco products, in the case of smoking tobacco products, and that the labelling requirements laid down in Article 12 of the TPD apply to HTP that are smokeless tobacco products.



EUROPEAN COMMISSION

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

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