



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/(2024) 0358

Directive (EU) 2015/1535

Notification: 2023/0636/SI

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.

MSG: 20240358.EN

1. MSG 103 IND 2023 0636 SI EN 13-02-2024 12-02-2024 CZ COMMS 5.2 13-02-2024

2. Czechia

3A. Úřad pro technickou normalizaci, metrologii a státní zkušebnictví  
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3B. Ministerstvo průmyslu a obchodu  
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4. 2023/0636/SI - X60M - Tobacco

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

6. Czech Republic's comment on notification 2023/0636/SI

On 10 November 2023, a Slovenian notification of a draft act (hereinafter the 'draft legislation') amending the Act on the restriction of the use of tobacco and related products (hereinafter the 'national Act') was published in the TRIS database.

The main objective of the draft Act 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 (hereinafter the 'TPD') as regards the abolition of certain exemptions for heated tobacco products.

I.

We believe that this draft legislation can create new barriers to the free movement of goods within the meaning of Article 34 TFEU and disproportionately interfere with the rights of tobacco producers in the EU internal market.

II.

The proposed amendment, in Article 2, which supplements Article 3 of the current national Act, in particular points 12 and 23, extends the definitions of e-cigarettes and cartridges to include nicotine-free products. Furthermore, the



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proposed amendment provides for the definition of herbal products intended for smoking in points 25 and 50, including the heating process.

Electronic cigarettes and herbal products for smoking have their own Chapter III in the Tobacco Products Directive (Articles 20-22), which deals, *inter alia*, with the regulation of nicotine content. It therefore follows that, for the application of those provisions, an electronic cigarette should contain at least a minimum quantity of nicotine in order to be classified as an electronic cigarette pursuant to the Tobacco Products Directive. This is because Article 20(3) provides, for example, that Member States are to ensure that liquid containing nicotine is placed on the market only in specific containers and does not contain nicotine in quantities greater than 20 mg/ml. Or, for example, Article 20(4)(iii) provides that any packaging of electronic cigarettes shall bear a statement that 'This product contains nicotine, which is a highly addictive substance. It is not recommended for use by non-smokers'. It is also apparent from individual recitals of the preamble to the Tobacco Products Directive (in particular 37, 41 and 43) that the increased requirements laid down in the Directive reflect the fact that e-cigarettes may lead to increased consumption and nicotine dependence. The Czech Republic therefore believes that the amendments of the individual points of Article 26(3) of the national Act contained in Article 10 of the draft legislation thus subject e-cigarettes not containing nicotine to unjustified requirements that are anticipated in the Tobacco Directive only for e-cigarettes containing nicotine. In addition, pursuant to Article 19 of the draft legislation, the draft legislation imposes stiff penalties for non-compliance with the obligations laid down by Article 19 of the draft legislation by amending Article 42(1)(17) of the national Act.

According to the draft legislation, an herbal product intended for smoking is a 'product based on plants, herbs or fruits and that contains no tobacco and that can be used through a heating or combustion process'. It should be noted that the transposed Delegated Directive no longer exempts heated tobacco products from the prohibitions laid down in Article 7(1) and (7). Thus, Member States may not exempt heated tobacco products within the meaning of Article 7(12) from the obligation to have the information communication provided for in Article 9(2) and the combined health warnings provided for in Article 10. However, Article 2(15) of the Tobacco Products Directive clearly sets out the definition of an herbal product as a product based on plants, herbs or fruits that contains no tobacco and that can be consumed via a combustion process. The proposed amendment in the draft legislation should therefore not impose new obligations on herbal products intended for heating beyond the definition of the herbal product in the Tobacco Products Directive, which, in Articles 21 and 22, imposes obligations only on herbal products intended for smoking within the meaning of Article 2(15) that can be consumed via a combustion process.

III.

Furthermore, by adding paragraph 8 to the national Act, the draft legislation provides that liquids used in e-cigarettes must not contain any flavours other than tobacco or menthol, and these permitted flavours will be specified by the Slovenian Ministry of Health within three months of the Act's entry into force. It should be noted that the draft text of Article 10 of the draft legislation amending Article 26(3) of the current national Act can be considered disproportionate as it goes beyond what is necessary to achieve the given objective.

The Czech Republic believes that the stated objective of the draft Act to limit the use of e-cigarettes by juveniles, based on the precautionary principle in the area of public health, can be achieved by means of more appropriate and less restrictive measures than the proposed regulation, such as a ban on flavours imitating sweets or the introduction of higher fines in the case of the sale of e-cigarettes to minors. It should be noted that the proposed regulation of flavours is resorting to more restrictive legislation than is usual in other EU Member States. Account must also be taken of the intention of the legislator, as expressed, for example, in Recital 16 of the Tobacco Products Directive, which states that measures that introduce unjustified differences in the treatment of different types of flavoured cigarettes should be avoided and that products with a characteristic flavour with a higher volume of sales should be taken off the market over a longer period of time in order to give customers sufficient time to switch to other products.

IV.

Therefore, in light of the above, the Czech Republic considers that the draft legislation contains provisions that may



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create disproportionate barriers to the free movement of goods and significantly distort the business environment in the internal market and are thus contrary to Slovenia's obligations under EU law.

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European Commission

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