



EUROPEAN COMMISSION

Brussels, 1.2.2024  
C(2024) 755 final

Ms Tanja Fajon  
Minister of Foreign Affairs  
Prešernova cesta 25  
SI-1000 Ljubljana

Subject: **Notification No 2023/0636/SI – ‘Draft Act amending the Act on Restriction of the Use of Tobacco and Related Products’.**

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

Dear Madam,

## **1. THE NOTIFICATION**

Within the framework of the notification procedure laid down in Directive (EU) 2015/1535, the Slovenian authorities notified to the Commission on 10 November 2023 the Draft Act amending the Act on Restriction of the Use of Tobacco and Related Products, (hereinafter, ‘the notified draft’).

According to the notification, the notified draft aims to introduce a restriction on flavourings in electronic cigarettes and their refill fluids or fillers, with a view to reducing their attractiveness and protecting individuals, especially children and adolescents. The notified draft further complements the definition of electronic cigarettes and containers containing refill fluids by also covering nicotine-free products. Finally, in the definition of herbal products for smoking, a reference to “heating process” is added to the existing reference to “combustion process” in order to cover new herbal products on the market.

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

## **2. COMMENTS**

### **DEFINITIONS**

From the outset, the Commission notes that the notified draft modifies several definitions of the Act on Restriction of the Use of Tobacco and Related Products’, and that those new definitions differ from the relevant definitions established in Directive 2014/40/EU.

To ensure legal clarity, the Slovenian authorities are invited not to diverge from the definitions established under the Directive.

In particular, Article 2 of the notified draft amends Article 3, point 25, of the national legislation which now reads as follows:

*‘25. Related products are electronic cigarettes, including refill containers, herbal products for smoking, **novel tobacco products** and **novel nicotine products**. Related products **include accessories or devices for their use**, without which the related products cannot be used’.*

The Commission notes that, whilst Directive 2014/40/EU does not explicitly define ‘related products’, it is clear from Article 1(f) and Title III of the Directive that the term refers to electronic cigarettes and refill containers, as well as herbal products for smoking. Article 1(f) provides that *“the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, and herbal products for smoking”*. In Title III of the Directive, Article 20 concerns electronic cigarettes and refill containers, while Articles 21 and 22 concern herbal products for smoking.

It follows that the definition of ‘related products’ in the notified draft is broader than what the same term in Directive 2014/40/EU covers. In the notified draft ‘related products’ do not only refer to electronic cigarettes, refill containers and herbal products for smoking, but also to novel tobacco products and novel nicotine products, including their accessories or devices for their use. To ensure legal certainty, the Commission invites the Slovenian authorities to ensure that the definition of ‘related products’ will not create confusion as to the scope of application and the relevant requirements for tobacco and related products under Directive 2014/40/EU.

In addition, the Commission notes that Article 2 of the notified draft amends Article 3, point 50, of the Act on Restriction of the Use of Tobacco and Related Products as follows:

*"50. Herbal smoking product means a product based on plants, herbs or fruit, not containing tobacco, where the use of which involves a **heating or combustion process**."*

The Commission notes that the way ‘herbal products for smoking’ are defined in the notified draft risks being confusing because this definition deviates from the definition in Article 2(15) of Directive 2014/40/EU. That provision defines a ‘herbal product for smoking’ as *“a product based on plants, herbs or fruits which contains no tobacco and that can be consumed **via a combustion process**”*. If the herbal product in question is heated, but cannot be consumed via a combustion process, it is not a herbal product *for smoking*. <sup>(1)</sup>

#### **HEALTH WARNINGS**

Article 10 of the notified draft amends Article 26(5)(2) of the Act on Restriction of the Use of Tobacco and Related Products which reads as follows:

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<sup>1)</sup> Compare also the distinction between a “smokeless tobacco product” within the meaning of Article 2(5) of Directive 2014/40/EU and a “tobacco product for smoking” within the meaning of Article 2(9) of Directive 2014/40/EU.

*‘2. regardless of the preceding point, they [the products] do not contain elements or characteristics referred to in Article 17 of this Act, except in the first indent of the paragraph 1 regarding information on nicotine content and information relating to the taste or smell of tobacco or menthol, and **in the case of nicotine content**, they state the following health warning that meets the requirements of the Article 16(2) and (3) of this Act:*

*“This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers.”.’, in c*

Under Article 20(4)(b)(iii) of Directive 2014/40/EU, Member States are required to ensure that unit packets and any outside packaging of electronic cigarettes and refill containers 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 notes that the wording of the provision of the notified draft (“in the case of nicotine content”) seems to imply that non-disposable electronic cigarettes (i.e., refillable or rechargeable electronic cigarettes), that can be used with both nicotine and non-nicotine liquid, could be excluded from the obligation to bear the health warning on their packaging in accordance with Article 20(4)(b)(iii) of the Directive, in cases where the non-disposable electronic cigarettes’ device is marketed empty.

In light of this, the Commission invites the Slovenian authorities to ensure that the notified draft complies with Article 20(4)(b)(iii) of Directive 2014/40/EU as regards the requirement that unit packets and any outside packaging of electronic cigarettes and refill containers must bear a health warning on nicotine content.

### **TERM ‘polnilo’**

Further, the Commission services would like to note that the notified draft uses the term ‘polnilo’ interchangeably as ‘cartridge’ and ‘other substance’. The same term is used in the Slovenian version of Directive 2014/40/EU to refer to the term ‘cartridge’. To ensure legal certainty and to avoid any confusion between the terms used in the notified draft and the terms used in the Directive, the Commission services encourage the Slovenian authorities to reflect on the possibility to use another term for ‘other substance’ to distinguish it from ‘cartridge’, which has a different meaning.

Finally, the Commission notes that the present assessment on the notified draft is without prejudice to the examination of the national measure in the course of the compliance assessment of the transposition of Delegated Directive (EU) 2022/2100.

The Commission invites the Slovenian authorities to take the above comments into consideration.

Yours faithfully,

For the Commission

Sandra GALLINA  
Directorate-General for Health and  
Food Safety