



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2023/0636/SI (Slovenia)

Draft Act amending the Act on Restriction of the Use of Tobacco and Related Products

Date received : 10/11/2023

End of Standstill : 13/02/2024 (closed)

Message

Message 001

Communication from the Commission - TRIS/(2023) 3148

Directive (EU) 2015/1535

Notification: 2023/0636/SI

Notification of a draft text from a Member State

Notification – Notification – Notifizierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéset - Non fa decorrere la mora - Atidējimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ il-perijodi ta' dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20233148.EN

1. MSG 001 IND 2023 0636 SI EN 10-11-2023 SI NOTIF

2. Slovenia

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4. 2023/0636/SI - X60M - Tobacco

5. Draft Act amending the Act on Restriction of the Use of Tobacco and Related Products

6. Tobacco and related products

7.



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8. The draft Act in Article 3 of the Act on Restriction of the Use of Tobacco and Related Products (hereinafter 'ZOUTPI') supplements the definitions of electronic cigarettes and refill containers, so that they also refer to products that do not contain nicotine. All requirements of the Directive and ZOUTPI (Article 26) also apply to nicotine-free electronic cigarettes and to nicotine-free refill containers.

Article 3 of the ZOUTPI also supplements the definition of herbal product for smoking, so that, in addition to the combustion process, it also includes the heating process.

Article 26(3) of the ZOUTPI provides that the liquid or any other filler with or without nicotine used in electronic cigarettes or refillable containers may not contain any flavourings other than the taste or smell of tobacco or menthol. Flavourings or substances that will be allowed in electronic cigarettes and refill containers shall be determined by the minister responsible for health by means of rules to be adopted within three months of the entry into force of the act.

9. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (hereinafter 'Directive') leaves responsibility for the adoption of rules on flavourings in electronic cigarettes to the Member States. Therefore, the draft act introduces the restriction of flavourings in electronic cigarettes and their liquids, or refillable containers. Following the example of Denmark and Estonia, all flavourings, except the taste or smell of tobacco or menthol, will be banned. By limiting flavourings in electronic cigarettes, we want to reduce their appeal and protect everyone, especially children and adolescents, from accessing electronic cigarettes, thus also protecting their health, which may be endangered by inhaling harmful substances in the aerosol of electronic cigarettes. Flavourings are one of the key factors in product selection and most adolescents start using a product that contains flavourings. These also reduce the perception of harmfulness and increase the willingness to try the product, making the aerosol more pleasant to inhale or the product more pleasant to use, which makes it easier to start and continue using it. More and more research shows that among adolescents who otherwise do not smoke, the use of an electronic cigarette significantly increases the probability (up to four times) that they will also start smoking regular cigarettes. Flavourings make electronic cigarettes wrongly perceived as less harmful than traditional cigarettes or even as harmless, which also applies to the perception of adults. Flavourings can have severe adverse health effects, in particular on respiratory health.

The data shows that the percentage of electronic cigarette users in Slovenia among adolescents is significant and much higher than among adults. The periodic monitoring of data for Slovenia from the International survey Health Behaviour in School-aged Children (HBSC), which is based on a nationally representative sample of pupils aged 11, 13 and 15, found that the use of electronic cigarettes among those 15-year-olds who answered that they currently use electronic cigarettes increased from 1 % in 2014 to 17 % in 2022. Among adults (18-74 years), a 2022 PANDA survey showed that 7 % of adults used electronic cigarettes at the time of the survey, which is much less than among 15-year-olds. Preliminary HBSC data for 2022 shows that even among 11-year-olds, 3.6 % of 11-year-olds have used electronic cigarettes at some point in their lives, and 2.2 % of 11-year-olds used electronic cigarettes at the time of the survey.

The use of electronic cigarettes is associated with an increased risk of cardiovascular diseases, respiratory diseases and also cancer. In addition to mouth and throat irritation, cough, nausea, headache and nicotine addiction, short-term health effects include epileptic seizures and lung damage. In 2019, several thousand people in the USA, mainly young people, suffered from acute lung injuries related to the use of electronic cigarettes, with numerous deaths and severe respiratory health consequences.

In addition to restricting flavourings, we are expanding the definition of electronic cigarettes and refillable liquid containers to now include products that do not contain nicotine. The amended definition is necessary in order to equally treat the electronic cigarettes and liquids or refill containers with and without nicotine (for example, as regards the official notification that must be submitted six months before the intended placing on the market, their volume, the prohibition of the addition of vitamins, the ensuring that these products cannot be used by children and other provisions prescribed by the Directive for electronic cigarettes and nicotine refill containers). The aforementioned change is



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necessary due to the increasing use of electronic cigarettes among children and adolescents and the increasing use of liquids or fillers that do not contain nicotine, but contain various flavourings, which are later mixed with the nicotine filler or liquid.

In addition to the combustion process, a heating process is added to the definition of herbal products for smoking, as more and more new herbal products appear on the market that do not include a combustion process, but are only heated and thus do not fall within the definition introduced by the Directive for herbal products for smoking and are consequently not subject to the restrictions from the Directive and the ZOUTPI (UL RS, Nos 9/17 and 29/17). If we do not include the heating process in the definition, there will be more and more unregulated herbal products on the market that are heated and otherwise do not contain tobacco, but are impregnated with nicotine or contain cannabis and will not be subject to e.g. the prohibition of sales to minors and all other prohibitions that already apply to tobacco products and herbal products involving a combustion process. With this measure, we want to protect especially children and adolescents from using new products and from becoming addicted to the nicotine that is added to these products.

With the aforementioned measures, we will take an important step towards realizing the long-term vision of the Strategy for a Tobacco-Free Slovenia, namely that Slovenia will be a tobacco-free society in 2040. This means that the proportion of the population aged 15 and over who will use tobacco, related products and other nicotine products not registered as nicotine replacement therapy will not exceed 5 %. We want to contribute to better people's health and the sustainability of the healthcare system in the future.

10. References to basic texts

11. No

12.

13. No

14. No

15. No

16.

TBT aspects:

The draft has significant impact on international trade

SPS aspects: No

European Commission

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