



EUROPEAN COMMISSION

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

Message 201

Communication from the Commission - TRIS/(2024) 1013

Directive (EU) 2015/1535

Notification: 2023/0636/SI

Forwarding of the response of the Member State notifying a draft (Slovenia) to comments (5.2) of Czechia.

MSG: 20241013.EN

1. MSG 201 IND 2023 0636 SI EN 13-02-2024 15-04-2024 SI ANSWER 13-02-2024

2. Slovenia

3A. SIST - Slovenski inštitut za standardizacijo, Kontaktna točka, Ulica Gledališča BTC 2, SI - 1000 Ljubljana, tel: 01/478 3065, e-mail: contact@sist.si

3B. Ministrstvo za zdravje, Direktorat za javno zdravje, Štefanova ulica 5, SI - 1000 Ljubljana, tel: 386 1 478 6854, e-mail: natasa.blazko@gov.si

4. 2023/0636/SI - X60M - Tobacco

5.

6. Subject: Reply of the Republic of Slovenia on the comments of the Czech Republic to the notification of the Draft Act amending the Act on Restriction of the Use of Tobacco and Related Products

Connection: Letter No 20240358.EN

Thank you for the comments submitted by the Czech Republic in the context of the notification procedure under Article 5(2) of Directive (EU) 2015/1535.

The comments refer to the extension of certain terms in Directive 2014/40/EU, such as electronic cigarettes, refill containers, herbal products for smoking and related new obligations, and to the restriction of flavourings in electronic cigarettes, which, according to the Czech Republic, could create new barriers to the free movement of goods and could disproportionately interfere with producers' rights in the EU internal market.

Below we provide answers to the comments.

With regard to the Czech Republic's finding that the notified draft extends some of the terms of Directive 2014/40/EU, we would like to clarify that the amendment to the Act (EPA 1145-IX), which was adopted on 28 March 2024 by the National Assembly, these definitions of terms have been amended. The terms 'nicotine-free electronic cigarette', 'nicotine-free refill container' and 'heated herbal product' are redefined in order to avoid confusion, which obligations apply to products defined by Directive 2014/40/EU and which for products regulated at national level.

We have accordingly amended the provision relating to health warnings on the packaging of electronic cigarettes and refill containers, so that it is now clear that the indication of the health warning on the nicotine content is always required, except for nicotine-free electronic cigarettes and nicotine-free refill containers. It is also clearer that certain obligations on electronic cigarettes apply only to those products containing nicotine.

Some obligations, which have so far only applied to electronic cigarettes and nicotine-containing liquids, will now also



EUROPEAN COMMISSION

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

apply to nicotine-free liquids:

- manufacturers and importers of electronic cigarettes and nicotine-free liquids will be required to provide information on the list of all ingredients, toxicological data on the ingredients, a description of all components of the product, a description of the manufacturing process in an official communication to the NLZOH six months before placing it on the market,
- a nicotine-free liquid may also be placed on the market in refill packages with a capacity not exceeding 10 ml, as has been the case so far only for nicotine-containing products. In nicotine-free electronic cigarettes, the maximum refill volume will be 2 ml,
- the nicotine-free liquid must not contain vitamins or other additives that give the impression of health benefits or reduced health risks, nor caffeine, taurine or other stimulants,
- nicotine-free electronic cigarettes and nicotine-free refill containers will also need to be protected against tampering, fracturing and leaking, including a mechanism to prevent opening or use by young children,
- packets of nicotine-free electronic cigarettes and their refills will have to contain a list of all ingredients.

The change is necessary due to the increasing use of electronic cigarettes among children and adolescents and the increasing use of liquids or refills that do not contain nicotine but contain various flavourings and other substances that are subsequently mixed with the nicotine refill or liquid. This has rendered the legislation deflected or ineffective.

With regard the definition of the term 'herbal product for smoking', we would like to clarify that the adopted amendment act does not extend this definition any further, but adds a new definition of the term 'heated herbal product', namely a product based on plants, herbs or fruit, not containing tobacco, which undergoes a heating process. Heated herbal products, like herbal products for smoking, will be subject to the article of Directive 2014/40/EU concerning the reporting of their ingredients.

At the same time, we would like to inform you that, as part of the process of adopting legislation in the National Assembly, the menthol flavour was removed through amendments, and thus nicotine or non-nicotine liquid in electronic cigarettes, nicotine-free electronic cigarettes and nicotine-free refill containers can only contain tobacco flavour.

Despite the fact that the restriction of flavourings in electronic cigarettes and refill containers may constitute obstacles to the free movement of goods and interfere with the rights of manufacturers of these products, we consider the measure to be necessary in Slovenia, as the percentage of users of electronic cigarettes among adolescents is 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 10 % in 2018 and to 17 % in 2022. Among adults (18-74 years), there are far fewer users of electronic cigarettes than among adolescents. We recorded 2 % of current users in 2020 and 7 % of current electronic cigarette users in 2022. In 2022, as much as 4 % of 11-year-olds reported having tried electronic cigarettes and 2 % of 11-year-olds reported current use. Even from the school environment, we are getting more and more warnings from principals and other school workers that the use of electronic cigarettes is detected already in the lower grades of elementary school.

When using electronic cigarettes, the individual is exposed to significant amounts of potentially harmful substances, irritants and carcinogens (formaldehyde, acetaldehyde, acrolein, carbonyl compounds, tobacco-specific nitrosamines, volatile organic compounds and phenols, free radicals and reactive oxygen compounds, small particles, metals, etc.). One of the key ingredients is nicotine, which is highly addictive and has adverse effects on the cardiovascular system, lung function and development, and brain function in adolescents. Children and adolescents, however, are very susceptible to nicotine addiction - more than adults. The younger an individual is when they start using nicotine, the more likely they are to become addicted and the more addicted they will be. Nicotine in adolescents also increases the risk of addiction to other psychoactive substances.

Adolescence is a crucial period for the development of the brain, which is still developing until about 25 years of age. Exposure to nicotine during intense brain development can interfere with the development of brain networks that control attention, learning, and susceptibility to addiction. It can lead to irreversible adverse effects on cognitive (thinking)



EUROPEAN COMMISSION

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

abilities, disturbances in working memory, disturbances in attention, mood and perception of sound, and increased irritability or anxiety, as well as an increase in the risk of using other drugs, including illicit drugs.

Flavourings reduce the perception of harmfulness, 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. Inhaling any substance can be dangerous. Flavourings that can be safe when ingested can have severe adverse health effects if inhaled. An example is vitamin E, which can be ingested, but if inhaled can cause severe lung damage or even death. Inhalation of butter flavourings (diacetyl and acetyl propionyl) can cause bronchitis, asthma and the severe lung disease bronchiolitis obliterans. Cinnamaldehyde, the cinnamon flavouring found in electronic cigarettes with various flavours such as tobacco, sweet or fruity, has cytotoxic and genotoxic effects, as well as harmful effects on the respiratory tract, even at low doses. Saccharides, which are used for sweet flavours, break down when heated into harmful substances, namely furans and aldehydes.

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 nicotine poisoning, seizures and acute chemical damage to the lungs. In 2019, around 2,800 people, mainly young people, were diagnosed with acute lung injuries associated with the use of electronic cigarettes in the United States, with 68 deaths, and the survivors often suffered severe respiratory health consequences.

Slovenia joins seven EU Member States that have introduced a ban on flavourings in electronic cigarettes. A ban on flavourings, with the exception of tobacco, has been introduced by Finland, Hungary, the Netherlands, Lithuania and Latvia. All flavourings except tobacco and menthol are also prohibited by Denmark and Estonia.

The amendment act also provides a transitional period for economic operators in Slovenia, as electronic cigarettes, nicotine-free electronic cigarettes, refill containers and nicotine-free refill containers with flavourings can be placed on the market for another 12 months from the entry into force of the Act, i.e. until 24 April 2025.

By limiting attractive fruit, sweet and herbal flavourings, we want to reduce the attractiveness and use of electronic cigarettes, thus protecting the health of children and adolescents and all other users who inhale harmful substances in the aerosol of electronic cigarettes. We follow the guarantee of constitutional rights to a healthy living environment, healthcare and children's rights.

Yours faithfully,

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