



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/(2025) 2917

Directive (EU) 2015/1535

Notification: 2025/0548/CZ

Forwarding of the response of the Member State notifying a draft (Czechia) to request for supplementary information (INFOSUP) of European Commission.

MSG: 20252917.EN

1. MSG 201 IND 2025 0548 CZ EN 01-10-2025 14-10-2025 CZ ANSWER 01-10-2025

2. Czechia

3A. Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
Biskupský dvůr 1148/5
110 00 Praha 1
tel: 221 802 216
e-mail: eu9834@unmz.cz

3B. Ministerstvo zdravotnictví České republiky,
Palackého náměstí 4,
128 01 Praha 2
tel.: +420 224 971 111

4. 2025/0548/CZ - X60M - Tobacco

5.

6. Notification 2025/548/CZ – Request for additional information

Within the framework of the notification procedure laid down by Directive (EU) 2015/1535, the Czech authorities, invoking the urgency procedure established in that Directive, notified to the Commission on 30 September 2025 the draft amending Decree No 37/2017 on electronic cigarettes, refill containers and herbal products for smoking (hereinafter the 'Notified Draft').

Article I(12) of the Notified Draft, read in conjunction with the existing provisions of Decree No 37/2017 submitted by the Czech authorities with the notification, provides that containers of liquid for electronic cigarettes may not contain cannabinoids or derivatives thereof.

According to the notification message, this amendment responds to the fact that in the last eight days in the Czech Republic, new synthetic cannabinoids have led to intoxication requiring the hospitalisation of nine young people.

In order for the Commission services to be able to complete their assessment under the relevant provisions of EU law, we request the Czech authorities to respond to the following request for additional information:

1. What types of cannabinoids and derivatives thereof can be legally added to electronic cigarettes or refill containers under the Czech legislation currently in force, i.e. prior to the entry into force of the amendment foreseen in the Notified Draft, and under what conditions? In their response, the Czech authorities are requested to take into account any



EUROPEAN COMMISSION

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

legislation relating to the legal status of the substances concerned in the Czech Republic, i.e. not only Decree No 37/2017 or other legislation relating to electronic cigarettes, tobacco or other related products.

- Any, as long as they are not included in one of the lists in the annexes to Government Regulation No 463/2013 on schedules of addictive substances, as amended, or Government Regulation No 11/2025 on the list of scheduled psychoactive substances pursuant to Act No 167/1998 on addictive substances and amending certain other acts, as amended. Emerging cannabinoid derivatives that are not yet on any of the above lists may be legally sold in e-cigarette refill containers.

2. In particular, are cannabinoids illegal, regardless of any THC threshold and regardless of whether they are consumed through vapour or other means?

- Cannabinoids are generally not prohibited as a generic group of substances in the Czech Republic. However, certain specific cannabinoids are included in the lists in the annexes to Government Regulation No 463/2013 on schedules of addictive substances, as amended, or Government Regulation No 11/2025 on the list of scheduled psychoactive substances, and are therefore prohibited, or their use is restricted to very limited medical or scientific purposes.

3. Does Article 1(12)(g) of the Notified Draft Decree amending Decree No 37/2017 specifically relate to synthetic cannabinoids, or to all cannabinoids?

- This subparagraph pertains to all cannabinoids, i.e. in addition to emerging derivatives, also substances such as cannabidiol.

4. Are the health risks referred to in the notification message in this regard caused by substances that are legally on the Czech market or illegal substances?

- The health risks mentioned in the notification are caused by substances that are legally on the Czech market, as they are not yet included in any 'banned' list, i.e. they are not included in Government Regulation No 463/2013 or Government Regulation No 11/2025.

5. Has the Czech Republic notified these medical incidents to the Early Warning System of the European Union Drugs Agency (EUDA)?

- Yes.

Psychoactive substances in the Czech Republic, if considered potentially risky, are included in one of the lists of addictive substances (Government Regulation No 463/2013) if their dangerous properties are proven, or classified psychoactive substances (Government Regulation No 11/2025) if they pose a potential risk to public health or society. There is no generic classification according to chemical structure. For this reason, as soon as a new psychoactive substance appears – cannabinoid derivatives are very popular at present – it is necessary to amend some of the above-mentioned government regulations, which takes at least two months, by which time these substances very often quickly spread on the market, in many cases in the form of refills for electric cigarettes. Furthermore, it is not possible to place electronic cigarettes on the market that contain substances that are otherwise presented as being beneficial to health, which may also affect substances falling under the cannabinoids group, in this case cannabidiol. However, due to the lack of an overview of substances that are 'beneficial to health', this requirement is difficult to enforce at the national level, particularly due to the lack of data and the fact that it is difficult to prove whether cannabinoids are natural or synthetic. For that reason, a more detailed list of prohibited substances in e-cigarette cartridges has been adopted in the draft legislation. The only way to effectively protect public health is to prohibit cannabinoids on a generic level, so that the prohibition includes all cannabinoids, both natural and synthetic.

6. The Commission bodies would welcome clarifications regarding Point 20, § 4(3) of the Notified Draft measure, which stipulates that:



EUROPEAN COMMISSION

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

'A refillable electronic cigarette may not contain more than three tanks or cartridges'

'An electronic cigarette that can be refilled may not contain more than three containers or cartridge inserts'.

In particular, could the Czech authorities please clarify the intended scope of this restriction? Does this pertain to devices with multiple tanks, i.e. products designed with more than one tank or cartridge insert, which are part of a single e-cigarette? Or does it pertain to the number of refills/cartridges supplied in the package, such as a set of three cartridges placed on the market together with the device? This clarification would assist the Commission bodies in assessing the compatibility of the measure with Articles 2(16) and 20(3)(a) of Directive 2014/40/EU.

- Yes, this provision pertains to devices with multiple tanks or cartridges that are part of a single electronic cigarette. However, the same paragraph of the provision also stipulates a restriction in accordance with Article 20(3)(a) of the Directive, stating that 'The capacity of the tank of a refillable electronic cigarette for refilling with nicotine-containing refill liquid must not exceed 2 ml.'. This means that electronic cigarettes with up to three tanks or cartridges may be sold, provided that none of the tanks or cartridges exceeds a volume of 2 ml. At the same time, electronic cigarettes containing or capable of containing multiple tanks or cartridges must not allow the simultaneous use of the content of different tanks or cartridges. The draft is also in line with Article 2(16), as when using an electronic cigarette, the user can only use one cartridge with a volume of 2 ml at a time.

The Czech authorities are kindly invited to reply as soon as possible and by no later than 10 October 2025.

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