Message 201

Communication from the Commission - TRIS/(2025) 2406

Directive (EU) 2015/1535

Notification: 2025/0191/CZ

Forwarding of the response of the Member State notifying a draft (Czechia) to of European Commission.

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1. MSG 201 IND 2025 0191 CZ EN 03-10-2025 03-09-2025 CZ ANSWER 03-10-2025

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4. 2025/0191/CZ - C00C - CHEMICALS

5.

6. Reply to the European Commission’s detailed opinion on notification 2025/0191/CZ – Draft Decree on psychomodulatory substances

Introduction

The European Commission has sent the Czech Republic its detailed opinion and comments on the draft Decree on psychomodulatory substances, notified on 2 April 2025 in the framework of the notification procedure under Directive (EU) 2015/1535. The Czech Republic takes the liberty to respond to the detailed opinion and individual comments of the European Commission and at the same time to present the legal argumentation supporting the compatibility of the national legislation with European law.

A) Response to the detailed opinion

Following the notified proposal 2025/0093/CZ, the Czech Republic decided to exclude hemp with a THC content of up to 1% and related extracts and tinctures from the draft Decree.

B) Responses to individual comments from the European Commission

a) Herbal products for smoking

In its opinion, the European Commission draws attention to the definition of herbal smoking product within the meaning of Article 2(15) of Directive 2014/40/EU on tobacco and related products.

Czech legislation explicitly prohibits placing on the market herbal products for smoking containing psychomodulatory substances. This prohibition is laid down in § 12j(6) of Act No 110/1997 on foodstuffs and tobacco products, as amended. This measure therefore excludes the possibility that psychomodulatory substances, including kratom and its extract, could be marketed as herbal products intended for smoking and thus be subject to the regime of Directive 2014/40/EU.

The Czech Republic therefore notes that the current national legal framework effectively prevents any legal conflict with the EU legislation on herbal products for smoking. At the same time, we would point out that Czech legislation prohibits the placing on the market or making available for marketing of psychomodulatory substances containing tobacco, nicotine, nicotine salts, narcotic drugs and psychotropic substances or other psychomodulatory substances (§ 33f(6)(e) of Act No 167/1998 on addictive substances, as amended). Psychomodulatory substances are therefore not covered by the part of EU legislation or Directive 2014/40/EU concerning products containing tobacco or nicotine. If products containing psychomodulatory substances that meet the definition of a herbal product for smoking appear on the market , the seller would commit an offence and these products would have to be taken off the market.

b) Novel foods

In its opinion, the European Commission draws attention to the possible classification of psychomodulatory substances as food under Article 2 of Regulation (EC) No 178/2002, with a potential impact on the obligations under Regulation (EU) 2015/2283 on novel foods.

§ 2(1)(l) of Act No 167/1998 on addictive substances defines psychomodulatory substances as ‘new psychoactive substances and other substances with psychoactive effect that do not pose a serious risk to public health or a risk of severe social impacts on individuals and society and are listed in the Government Regulation on the Schedule of psychomodulatory substances and products thereof’. Under Council Framework Decision 2004/757/JHA, as amended by Directive (EU) 2017/2103, new psychoactive substances are defined as substances that are not covered by international drug control conventions, such as the Single Convention on Narcotic Drugs of 1961 or the Convention on Psychotropic Substances of 1971, but that may pose health or social risks equivalent to those posed by the substances covered by those conventions. Since 2017, new psychoactive substances pursuant to Directive (EU) 2017/2103 have been explicitly included in the definition of a drug. In turn, Article 1b of Council Framework Decision 2004/757/JHA allows Member States to regulate new psychoactive substances by means of such national control measures as they deem appropriate.

In its opinion in the context of notification 2024/0265/CZ regarding the draft Act itself (later Act No 321/2024), the European Commission has recognised the possibility of introducing a new category of 'psychomodulatory substances', which falls under the broader concept of 'new psychoactive substances'. The European Commission has therefore confirmed that Member States may, on the basis of Article 1b of Council Framework Decision 2004/757/JHA, adopt national control measures in accordance with their national policies and needs and that the Czech Republic may therefore introduce the category of psychomodulatory substances as products of their kind as proposed.

§ 10(1)(h) of Act No 110/1997 on foodstuffs and tobacco products, as amended, clearly prohibits the addition of psychomodulatory substances to foodstuffs. If products containing a psychomodulatory substance were to appear on the market, for example in the form of baked goods, confectionery or energy drinks, the seller would be guilty of an offence and these products would have to be taken off the market. Furthermore, § 33g(2) of Act No 167/1998 prohibits the export of psychomodulatory substances outside the territory of the Czech Republic. Thus, within its legal system, the Czech Republic designates psychomodulating substances as a category of products of its kind regulated under the regime for new psychoactive substances on the basis of Article 1b of Council Framework Decision 2004/757/JHA, which may be distributed and marketed only in the Czech Republic.

c) Good manufacturing practice

In its comments, the Commission stresses the need to avoid confusion about the manufacturing standards for psychomodulatory substances, so that they are not confused with medicinal products.

Czech legislation clearly distinguishes between psychomodulatory substances and medicinal products within the meaning of Directive 2001/83/EC. The use of the term 'good manufacturing practice' in the context of psychomodulatory substances is intended solely to ensure the safety and quality of these products, not to implicitly classify them as medicinal products. The Czech legislation on psychomodulatory substances makes no reference in any of its parts to national or European pharmaceutical legislation.

It is therefore quite clear that the standards of good manufacturing practice for psychomodulatory substances are specifically defined exclusively for psychomodulatory substances and are not requirements applied to medicinal products. There is therefore no doubt that the two categories of products are subject to different legal regimes and that there is no confusion among consumers or others as to the different nature of the two categories of products.

Conclusion
The Czech Republic is ready to continue a constructive dialogue with the European Commission, to share its experience with the implementation of the regulation of psychomodulatory substances and to contribute to the European debate on a modern and effective approach to the regulation of psychoactive substances.

The maximum quantity of a psychomodulatory substance in a unit packet, the list of active substances and their maximum quantity in a unit packet, and the maximum concentration of active substances in a psychomodulatory substance

Psychomodulatory substance Maximum amount of psychomodulatory substance per unit pack Active substance Maximum amount of active substance per unit pack Maximum concentration of active substance in % by weight of the psychomodulatory substance

Kratom 50 g Mitragynine 1250 mg 2.5
7-hydroxymitragynine 50 mg 0.1

Kratom extract 10 g or 10 ml Mitragynine 1250 mg 12.5
7-hydroxymitragynine 50 mg 0.5

Annex 2 to Decree No .../2025

Names, forms and subtypes of psychomodulatory substances and their characteristic appearance and properties

Psychomodulatory substance Name Form Subtype Characteristic appearance and properties

Kratom Kratom Powder Green Finely crushed or ground mixture of dried leaves of the plant Mitragyna speciosa predominantly green in colour.
White Finely crushed or ground mixture of dried leaves of the plant Mitragyna speciosa predominantly white in colour.
Yellow Finely crushed or ground mixture of dried leaves of the plant Mitragyna speciosa predominantly yellow in colour.
Red Finely crushed or ground mixture of dried leaves of the plant Mitragyna speciosa predominantly red in colour.
Brown Finely crushed or ground mixture of dried leaves of the plant Mitragyna speciosa predominantly brown in colour.
Gold Finely crushed or ground mixture of dried leaves of the plant Mitragyna speciosa predominantly golden in colour.

Kratom extract Kratom Extract

Concentrated powder Powdery substance made from the psychomodulatory substance Kratom.
Alcohol tincture Liquid substance containing an alcohol-based solvent, made from the psychomodulatory substance Kratom.
Oil tincture Liquid substance containing an oil-based solvent, made from the psychomodulatory substance Kratom.
Fat paste Paste-like substance containing a fat- or oil-based solvent, made from the psychomodulatory substance Kratom.
Paste Paste-like substance containing other than a fat- or oil-based solvent, made from the psychomodulatory substance Kratom.
Jelly Semi-solid substance containing a jelly-based solvent, made from the psychomodulatory substance Kratom.
Pastille Semi-solid to solid substance containing a solvent, made from the psychomodulatory substance Kratom.

Annex 4 to Decree No .../2025

Text of the consumer information notice

The text of the information notice for the psychomodulatory substance Kratom and the psychomodulatory substance Kratom extract reads as follows:
'This product has psychoactive effects. This product is not a food. This product is not a medicinal product and has not been clinically tested. If you are unsure whether this product is suitable for you, consult your physician.

Effects:

At the recommended dosage, this product has stimulating effects. If the recommended dosage is exceeded, this product has sedative effects.

The use of this product may affect alertness, movement coordination, speech coordination, balance, sensory perception, pain perception, sleep, mood, and immune system function.

Prolonged use of high doses may lead to addiction. This product should not be used every day; there should be a three-day break between each use. Long-term effects on human health have not been sufficiently documented, especially for uses other than oral use of the dried plant itself.

Warning:

Do not use this product while, immediately before, or within eight hours before driving a motor vehicle or performing activities requiring increased attention, concentration, or motor coordination. If you feel under the influence of this product, do not drive or engage in such activities even after this period.

This product is not intended for persons under 18 years of age. Do not use this product in combination with other psychoactive substances, alcohol, nicotine, medicines, or during pregnancy or breastfeeding, or if you suffer from mental health illness or physical illness involving impaired kidney, liver, heart, or vascular function.

There have been reports of suspected kratom poisoning and subsequent death.

Use in accordance with the instructions for use. Do not exceed the recommended daily dose. Keep out of reach of persons under 18 years of age.'.

Annex 5 to Decree No .../2025

Maximum permitted single doses and maximum permitted daily doses of the active substance

Psychomodulatory substance Active substance Maximum permitted single dose of active substance Maximum permitted daily dose of active substance

Kratom

Kratom extract
Mitragynine 125 mg 375 mg
7-hydroxymitragynine 5 mg 15 mg

1) The values given in the table are intended for oral administration, i.e. administration involving the swallowing of the substance, where absorption occurs predominantly in the lower parts of the digestive tract and not exclusively or almost exclusively in the oral cavity.

2) If the method of use indicated in the product’s instructions for use includes administration other than oral, the permitted single dose and the permitted daily dose must not exceed 30% of the value indicated in the table.

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