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**Subject: Notification 2025/0093/CZ**

**Draft Government Regulation on the list of psychomodulatory substances**

**Delivery of a detailed opinion pursuant to Article 6(2) of Directive (EU) 2015/1535 of 9 September 2015**

Sir,

Within the framework of the notification procedure laid down by Directive (EU) 2015/1535 <sup>(1)</sup>, the Czech authorities notified to the Commission on 25 February 2025 the “Draft Government Regulation on the list of psychomodulatory substances” (hereinafter ‘the notified draft’), which schedules in this group four new substances (kratom, kratom extract, Hemp/Cannabis up to 1% tetrahydrocannabinol (THC), and Hemp/Cannabis extract and tincture up to 1% THC).

Czechia defined this new category of psychomodulatory substances in § 2(1) of Act No 167/1998 on addictive substances and amending certain other acts, as amended from 1 January 2025. This amending Act was already subject to Notification 2024/0265/CZ and introduced a new category of substances with psychoactive effect, namely psychomodulatory substances. The Act provides a regulatory framework for substances which – contrary to the International Drug Control Conventions - Czechia does not consider as drugs and which cannot be considered as “food” under EU law due to their psychoactive effect. It introduces stricter rules on the way in which these substances can be placed on the market, including by prohibiting advertising of these substances and sales through vending machines and outside of specialised shops, the sale of these substances to persons under the age of 18, children’s access to specialised stores where

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<sup>1</sup>) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, (OJ L 241, 17.9.2015, p. 1).

the substances are sold, and the sale on school premises and other listed places, as well as strict restrictions to selling online. The Commission had made comments on this notification pursuant to Article 5(2) of Directive (EU) 2015/1535, with regard to the interaction between the notified draft and Council Framework Decision 2004/757/JHA <sup>(2)</sup> on illicit drug trafficking (hereinafter ‘Framework Decision 2004/757’). It stated that while the Czech authorities were in principle free to decide to introduce the new category of psychomodulatory substances, which can be placed on the market under strict rules, the addition of any substances already scheduled as drugs under the International Drug Control Conventions and under Framework Decision 2004/757 was incompatible with such legal frameworks.

Czechia explained how it would take these comments into account in the subsequent preparation of the Government Regulation on the list of psychomodulatory substances now being subject to notification.

In a meeting of 30 January 2025, following presentations by Czechia of its new legislation on psychomodulatory substances to other Member States, Czechia and the Commission again exchanged views on the list of psychomodulatory substances under preparation.

Examination of the notified draft prompted the Commission to issue the following detailed opinion.

The measure envisaged does not comply with EU secondary legislation.

Including Cannabis up to 1% THC, and Cannabis extract and tincture up to 1% THC in the Czech list of psychomodulatory substances would allow for the placing on the market – under conditions – of drugs for human consumption in Czechia. However, under Article 2 of Framework Decision 2004/757 each Member State shall take the necessary measures to ensure that the sale, distribution, offering and other intentional conduct related to drugs when committed without right is punishable.

Drugs are defined in Article 1(1)(a) of Framework Decision 2004/757 as ‘a substance covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances’.

Article 1(1)(j) of the Single Convention defines ‘drug’ as ‘any of the substances in Schedules I and II, whether natural or synthetic’. Schedule I of the Single Convention lists ‘cannabis and cannabis resin and extracts and tinctures of cannabis’. The definition of ‘cannabis’ set out in Article 1(1)(b) of the Single Convention refers to: ‘the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated’.

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<sup>2</sup>) Council Framework Decision 2004/757/JHA () of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, [http://data.europa.eu/eli/dec\\_framw/2004/757/2022-08-18](http://data.europa.eu/eli/dec_framw/2004/757/2022-08-18)

According to the Explanatory memorandum to the notified draft, the psychomodulatory substances newly scheduled by Czechia are, besides kratom and kratom extract, which are currently not listed in any Schedule of the Single Convention,

- Cannabis up to 1% THC as ‘the flowering or fruiting top of a cannabis plant (Cannabis) or the aerial part of a cannabis plant, which includes a top containing the sum of substances of the tetrahydrocannabinol group and their acids up to a maximum of 1% of the content of the substance, intended for human consumption or for processing for human consumption [...]. It should be noted that these are products that are offered for human consumption and are also produced and manufactured for this purpose, and therefore do not fall under the treatment defined [for] industrial hemp’ (for which exceptions exist under the International Drug Control Conventions);
- Cannabis extract and tincture up to 1% THC as ‘an extract or tincture obtained from cannabis with up to 1% THC, containing a total of substances from the tetrahydrocannabinol group and their acids at a level of 1% of the substance content, intended for human consumption or for processing for human consumption [...]’. These had been formerly exempted from the Czech definition of addictive substances.

Other than the exceptions for industrial, horticultural, medical and scientific purposes, which do not apply to the current case, the Single Convention does not contain any exception to the coverage of Cannabis or Cannabis extract and tincture as defined therein. It does not distinguish between certain thresholds of THC in Cannabis or Cannabis extract and tincture.

The judgment of the Court of Justice of the European Union of 19 November 2020 in Case C-663/18, B S and C A, which excluded Cannabidiol (CBD) from the qualification as a ‘drug’ since it does not contain a psychoactive ingredient in the current state of scientific knowledge, is not relevant as Cannabis up to 1% THC and Cannabis extract and tincture up to 1% THC indeed do contain such a psychoactive ingredient. CBD is not scheduled in any of the International Drug Control Conventions, while THC is scheduled in Schedule I of the 1971 Convention on Psychotropic Substances.

Therefore, the addition of Cannabis up to 1% THC and Cannabis extract and tincture up to 1% THC to the list of psychomodulatory substances by the notified draft means that an illicit drug is – under conditions – allowed to be sold for the purpose of human consumption. This does not comply with Framework Decision 2004/757, which requires Member States to make trafficking in drugs a criminal offence.

The Commission invites the Czech authorities to take the detailed opinion into account in order to ensure that the national legislation is adopted and applied in conformity with the applicable Union and international law.

The Commission reminds the Czech authorities that they shall report to the Commission on the action they propose to take on such a detailed opinion in accordance with Article 6(2) of Directive (EU) 2015/1535.

The Commission services are open to a close cooperation and discussion with the Czech authorities on possible solutions to the identified issues in full respect with Union law.

However, if the Czech authorities fail to comply with the obligations laid down in Directive (EU) 2015/1535 or if the text of the notified draft under consideration is adopted without taking account of the objections raised or is otherwise contrary to Union law, the Commission reserves the right to initiate proceedings against Czechia in accordance with Article 258 of the TFEU.

Yours faithfully,

For the Commission

Stéphane Séjourné  
Executive Vice-President