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Subject: Notification 2023/230/CZ

**Draft Government Regulation amending Government Regulation
No 463/2013 Coll. on lists of addictive substances, as amended**

**Delivery of comments pursuant to Article 5(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 ⁽¹⁾, invoking the urgency procedure provided for by Article 6(7) of that Directive, the Czech authorities notified to the Commission on 10 May 2023 the “Draft Government Regulation amending Government Regulation No 463/2013 Coll. on lists of addictive substances, as amended” (hereinafter ‘the notified draft’).

The notified draft introduces new substances as “narcotic” and “psychotropic” substances in Annexes 3 and 4 to Government Regulation No 463/2013 Coll.

Article I, point 7, of the notified draft reads:

“In the table in Annex 4, a new row is inserted in the column headed ‘International non-proprietary name (INN) in Czech’ with the word ‘hexedron’, in which the word ‘Hexahydrocannabinol’ appears in the column headed ‘International non-proprietary name (INN)’, the column ‘Other international non-proprietary name or common name’ appears with the abbreviation ‘HHC’, in the column headed ‘Chemical name according

¹() 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).

to IUPAC', the word '(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,9,10,10a-hexahydrobenzo[c]chromen-1-ol' shall appear and in the column 'Note' the words 'Except for HHC if contained in a plant of technical hemp, technical hemp, hemp extract and tincture and technical hemp preparation in quantities below 0.3 %.'".

Article I, point 10, of the notified draft reads:

"In the table in Annex 4, a new line is inserted in the column headed 'International non-proprietary name (INN) in Czech' with the word 'Tetrahydrocannabinol' in the column headed 'International non-proprietary name (INN)', with the word 'Tetrahydrocannabiphinol' in the column headed 'Other international non-proprietary name or common name', the abbreviation 'THCP', in the column headed 'Chemical name according to IUPAC', the word '(6aR,10aR)-3-heptyl-6,6,9-trimethyl-6a,7,8,10a-tetrahydrobenzo[c]chromen-1-ol' is indicated and in the column 'Note' the words 'Except for THCP when present in a plant of technical hemp, technical hemp, hemp extract and tincture and technical hemp preparation in quantities below 0.3 %.'".

Examination of the notified draft has prompted the Commission to issue the following comments.

With regard to the 'authorised limit' of 0.3% of HHC and THCP in 'a plant of technical hemp, technical hemp, hemp extract and tincture and technical hemp preparation', the Commission would like to remind the Czech authorities that extracts and tinctures of cannabis are drugs under Council Framework Decision 2004/757/JHA ⁽²⁾ and the international drug control conventions.

In its judgment of 19 November 2020 in Case C-663/18, *Criminal proceedings against B S and C A [Commercialisation du cannabidiol (CBD)]*, the Court of Justice of the European Union (CJEU) excluded Cannabidiol (CBD) from the qualification as a drug due to the absence of psychoactive effects. HHC and THCP are both psychoactive drugs. Therefore, the reasoning of the CJEU in the afore-mentioned judgment cannot apply to them. HHC was first identified in Europe in August 2022 and is monitored intensively as a new psychoactive substance by the EU Early Warning System (EWS). THCP is not (yet) monitored by the EU EWS. However, internationally recognised studies have found THCP to be 33 times more active than THC, and *in vivo* (mice) tests further supported the psychoactivity of THC-P ⁽³⁾.

Therefore, the 0.3% limit set by the Czechia in the notified draft, without considering the effect of the substance and the route of administration (i.e., if a product is eaten or applied topically) is not justified. The Commission considers that unavoidable trace levels of both substances could be tolerated, similarly to what was established regarding THC levels authorised as contaminants in hemp seeds and hemp seed oil (which are

²⁾ 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, OJ L 335, 11.11.2004, p. 8–11.

³⁾ Citti, C., Linciano, P., Russo, F. *et al.* A novel phytocannabinoid isolated from *Cannabis sativa* L. with an *in vivo* cannabimimetic activity higher than Δ^9 -tetrahydrocannabinol: Δ^9 -Tetrahydrocannabiphinol. *Sci Rep* 9, 20335 (2019). <https://doi.org/10.1038/s41598-019-56785-1>

much lower than 0.3%). Also in that regard, the psychoactivity of the substances concerned – HHC and THCP – as well as the route of administration need to be a key consideration.

The Commission invites the Czech authorities to take the above comments into account.

The Commission furthermore reminds the Czech authorities that once the definitive text has been adopted, they are required to communicate it to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.



For the Commission

Thierry Breton
Member of the Commission