Message 301

Communication from the Commission - TRIS/(2024) 3448

Directive (EU) 2015/1535

Notification: 2024/0691/CZ

Request for supplementary information from the Commission.

Request for supplementary information - Demande d'informations complémentaires - Žádost o doplňující informace - Ersuchen um ergänzende Informationen - Искане за допълнителна информация - Žádost o dodatečné informace - Anmodning om supplerende oplysninger - Αίτηση συμπληρωματικών πληροφοριών - Solicitud de información complementaria - Lisateabe edastamise palve – Lisätietopyyntö - Zahtjev za dodatne informacije - Kiegészítő információ kérése - Domanda di informazioni complementari - Prašymas pateikti papildomos informacijos - Papildu informācijas pieprasījums - Talba għal tagħrif addizzjonali - Verzoek om aanvullende inlichtingen - Prośba o uzupełnienie informacji - Pedido de informações complementares - Solicitare de informații suplimentare - Žiadosť o ďalšie informácie - Zahteva za dodatne informacije - Begäran om kompletterande upplysningar - Iarraidh ar fhaisnéis fhorlíontach

MSG: 20243448.EN

1. MSG 301 IND 2024 0691 CZ EN 19-12-2024 COM INFOSUP COM

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2024/0691/CZ - C00C - CHEMICALS

5.

6. Within the framework of the notification procedure under Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, authorities of the Czech Republic notified to the Commission on 17 December 2024, the draft Proposal for a Government Regulation on the list of classified psychoactive substances (hereinafter “the notified draft”).
The draft government regulation includes 9 semisynthetic cannabinoids and 123 other new psychoactive substances.
The notified draft intends to include the semisynthetic cannabinoids (HHC, THCP, HHCP, HHCH, HHCB, THCH, THCB, THC-C8, HHC-C8 and their esters) in the new list of included psychoactive substances. These substances were included in the list of addictive substances this year, with a time limit until 31 December 2024, due to the negotiation of amendments to Act No 167/1998 on addictive substances, as amended, and other related acts (the ‘Amendment to the Act’), which now provides for two additional lists to be established by government regulation, namely the list of classified psychoactive substances and the list of psychomodulating substances, which will serve as a more adequate instrument to regulate some of these substances. In view of the fact that this amendment to the Act is already in force on 1 January 2025, it is possible to re-list those substances.
Another objective of the draft government regulation is the inclusion of new 123 psychoactive substances in the list of classified psychoactive substances in order to allow for their further investigation and risk assessment in accordance with Section 33k of the Act.
In order to allow the Commission services to complete their analysis under the relevant provisions of EU law, the Czech authorities are kindly invited to reply to the following request for supplementary information:
- Please inform and clarify, how the Czech Republic took into account the comments of the European Commission raised withing the notification 2024/278/CZ.
The Commission would like to remind that also concerning the implementation of the now notified draft measure under

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

2024/691/CZ Czechia needs to comply with the comments made with regard to previous notifications in this context. The Commission in particular refers to its comments made with regard to notification 2024/278/CZ, which are replicated below. These mainly concern a limit of 0.3% of THC authorised by Czechia for THCB and THCH, an authorised limit which is still included in the now notified draft measure.
With regard to the 'authorised limit' of 0.3% of THCB and THCH 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 extract and tincture of cannabis are drugs under Council Framework Decision 2004/757/JHA and the international drug control conventions. In Case C-663/18, the Court reasoned to exclude CBD from the drug qualification due to absence of psychoactive effect. THCB and THCH are both psychoactive, therefore the court's reasoning cannot apply to them.

Therefore, the 0.3% limit proposed by Czechia, 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. We consider that unavoidable trace levels of both substances could be tolerated, similarly to what was done regarding THC levels authorized as contaminants in hemp seeds and hemp seed oil (which are much lower than 0.3). Here again, the psychoactivity of the substances concerned – THCB and THCH – as well as the route of administration need to be a key consideration.
Given the timing of the notification, the Czech authorities are kindly invited to reply as soon as possible in order for the Commission services to examine the measure and its urgency.

****

Mary Veronica Tovsak Pleterski
Director
European Commission

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