

Directorate-General for Health & Food Safety

Update on the discussion on possible
maximum levels for delta-9-
tetrahydrocannabinol (Δ^9 -THC) in food

EFSA scientific opinion

- EFSA scientific opinion adopted on 5 June 2015 on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. The CONTAM Panel reviewed all the available evidence from studies on toxicity in experimental animals and adverse effects in humans.

EFSA scientific opinion

- The CONTAM Panel derived an acute reference dose (ARfD) of 1 μg Δ^9 -THC/kg b.w.
- The exposure estimates related to exposure from food of animal origin (in particular milk) are at most 3 % and 13 % the ARfD, in adults and toddlers, respectively
- The presence of Δ^9 -THC in food of animal origin is not of an immediate health concern
- However exposure to Δ^9 -THC from the consumption of hem (seed) derived food could be much more significant. However there were only limited occurrence data available on the presence of Δ^9 -THC in hemp derived food, not enabling to perform a reliable exposure assessment.

Commission Recommendation

- To address the lack of occurrence data, Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of Δ^9 -tetrahydrocannabinol, its precursors and other cannabinoids in food (food of animal origin/**hemp derived food**) was adopted

→ EFSA report on exposure (see further)

Comments from stakeholders on the ARfD established by EFSA

- The European Industrial Hemp Association (EIHA) introduced a request to revise the ARfD in particular as regards the chosen lowest-observed adverse-effect level (LOAEL) and the used uncertainty factor.
- The CONTAM Panel discussed at its 100th meeting (24-26 September 2019) in detail the information received. Minutes available at:
https://www.efsa.europa.eu/sites/default/files/event/190924-m_0.pdf

Comments from stakeholders on the ARfD established by EFSA

- *The EIHA stated that a single dose of 2.5 mg/day identified as the LOAEL in the CONTAM Panel opinion is questionable and that the uncertainty factors (UFs) applied were excessive, i.e. a total UF of 30, based on extrapolation of a NOAEL from the LOAEL (3) and interindividual differences (10). The EIHA proposed an ARfD of 7 µg Δ9-THC/kg bw based on a total dose of 5 mg/day (2 x 2.5 mg/day) and a UF of 10 for interindividual differences.*
- *Following discussion on this issue, the CONTAM Panel agreed that 2.5 mg/day should still be considered as the LOAEL, as adverse effects on the central nervous system were observed in the human studies used in the 2015 assessment even following a single dose and therefore the application of an UF of 3 for extrapolation from LOAEL to NOAEL, as well as an UF of 10 for interindividual differences, are appropriate.*
- **In conclusion, the CONTAM Panel confirmed that the ARfD of 1 µg Δ9-THC/kg bw, derived in the 2015 CONTAM Panel assessment, should be retained**

Comments from stakeholders on the ARfD established by EFSA

- In case new relevant toxicity studies would become available in the future, the Commission would ask EFSA to assess these studies and to update if necessary its risk assessment, including the ARfD.

EFSA report January 2020

- EFSA report on “Acute human exposure assessment to Δ^9 -THC”
- Occurrence data for Total- Δ^9 -THC (588 samples in total) were used for this assessment up to the highest reliable percentile for each food category. The EFSA ARfD of 1 $\mu\text{g}/\text{kg}$ bw was exceeded in the adult high consumers of most considered hemp and hemp-containing products.

EFSA report January 2020

- The use of proxies for the consumption of hemp and hemp-containing products, the limited number of occurrence data and the analytical limitations in the quantification of $\Delta 9$ -THC represent the most important sources of uncertainty.
- Overall, exposure estimates presented in this report are expected to represent an overestimation of acute exposure to $\Delta 9$ -THC in the EU.

Follow-up discussions

- Possible maximum levels for total $\Delta 9$ -THC considered for hemp seed and hemp seed derived products.
- Levels to be set to ensure a high level of human health protection and that are achievable by applying good practices (according to the ALARA principle : « As Low As Reasonably Achievable »)
- Occurrence data as used for the EFSA report also used for the discussion on maximum levels



European
Commission

Possible maximum levels submitted to targeted stakeholder consultation for comments (September 2020)

Food	Possible Maximum level for THC (*) mg/kg
Hemp seeds	3.0
Ground hemp seeds (hemp seed powder), (partially) defatted hemp seed (press cake) (hemp seed flour), hemp seed bran	3.0
Hemp seed oil	7.5

(*) the maximum level refers to the sum of Δ^9 -tetrahydrocannabinol (Δ^9 -THC) and Δ^9 -tetrahydrocannabinolic acid (Δ^9 -THCA)

Current status of the discussions and outlook

- Comments received from EIHA, COPA-COGECA, EHPM and FSE
- Consideration of comments (ongoing)
- Discussion on sampling and analytical aspects (ongoing)
- Outlook

**Thank you for
your
attention !**