



THC as a contaminant in hemp-derived products for food and feed

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THC as contaminant in food

EFSA opinion



EFSA scientific opinion 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 derived an **acute reference dose (ARfD) of 1 µg Δ9-THC/kg b.w.**

The exposure estimates in the 2015 EFSA opinion related to the presence of Δ9-THC in milk, and were calculated to be at 3 % and 13 % the ARfD, in adults and toddlers, respectively.

→ The presence of Δ9-THC in food of animal origin is not of an immediate health concern

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EFSA opinion



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

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EFSA opinion



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.

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EFSA opinion



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Comments from stakeholders on the ARfD established by EFSA

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

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.

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Commission Recommendation



However, exposure to Δ 9-THC from the consumption of hem (seed) derived food could be much more significant. However there were at that time only limited occurrence data available on the presence of Δ 9-THC in hemp derived food, not enabling to perform a reliable exposure assessment.

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)

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Human exposure report



EFSA report on acute exposure published in January 2020.

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.

The use of proxies for the consumption, 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, the exposure estimates are expected to be an overestimation of acute exposure to $\Delta 9$ -THC in the EU.

THC as contaminant in food

Maximum levels



Commission Regulation (EU) 2022/1393 of 11/08/2022 amending Reg. (EC) No 1881/2006 as regards maximum levels of delta-9-tetrahydrocannabinol (Δ 9-THC) in hemp seeds and products derived therefrom

FOOD	MAXIMUM LEVELS (mg/kg) (*)
Hemp seeds	3,0
Ground hemp seeds, (partially) defatted hemp seed and other hemp seed derived/processed products (**) with the exception of hemp seed oil	3,0
Hemp seed oil	7,5

(*) the maximum level refers to the sum of delta-9-tetrahydrocannabinol (Δ 9-THC) and delta-9-tetrahydrocannabinolic acid (Δ 9-THCA), expressed as Δ 9-THC. A factor of 0,877 is therefore applied to the level of Δ 9-THCA in case it is analysed separately

(**) hemp seed derived/processed products are products derived/processed exclusively from hemp seeds

THC as contaminant in food

Maximum levels



Measurement uncertainty

A consignment is considered as non-compliant if analytical result, corrected for recovery exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty

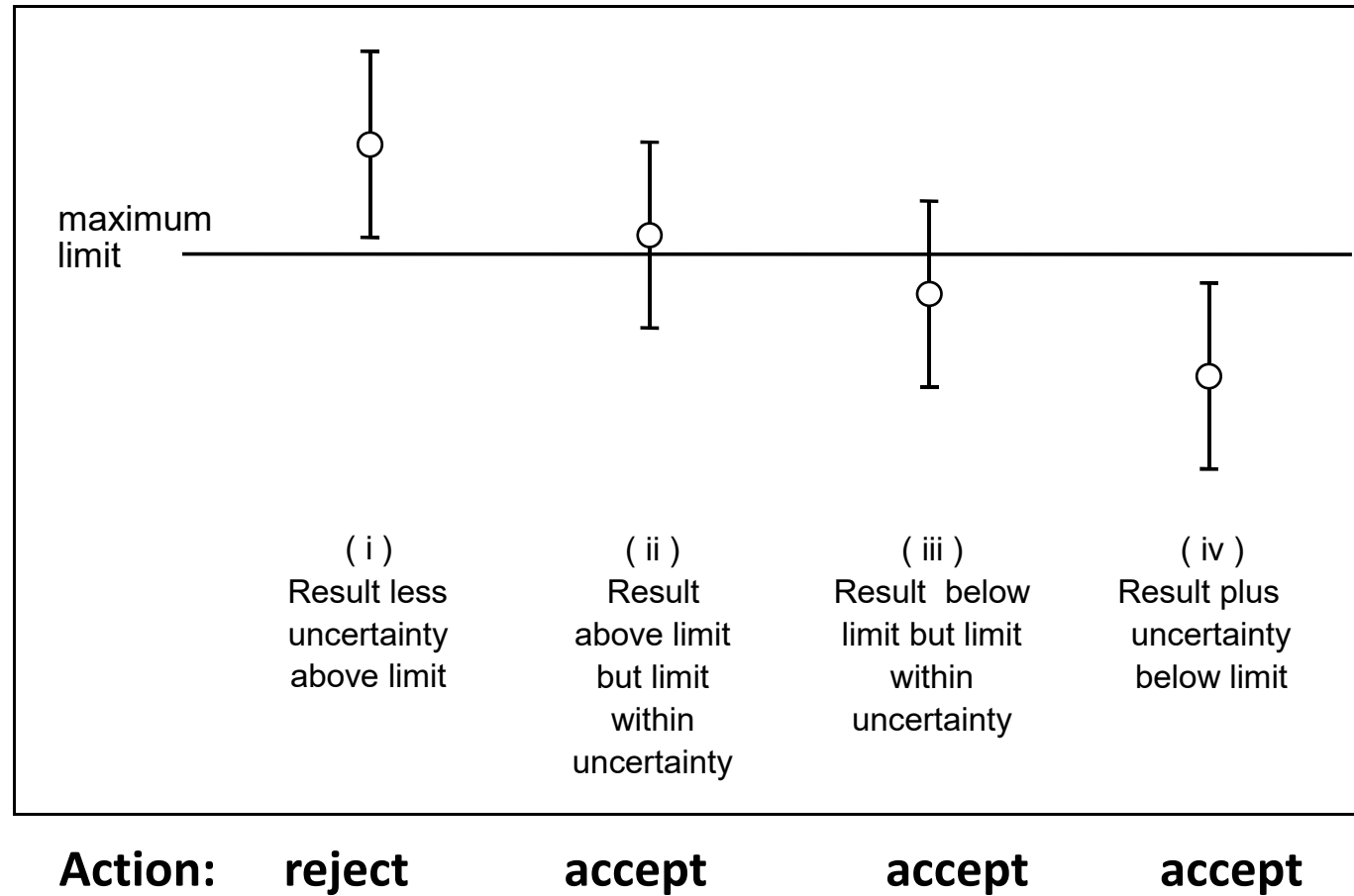
Interpretation of the measurement of uncertainty when considering compliance with a statutory limit, where the circle is the analytical result (next slide)

THC as contaminant in food

Maximum levels



Measurement uncertainty



Feed materials in catalogue



[Commission Regulation \(EU\) 2022/1104](#) of 1 July 2022 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials

Hemp seed	Seeds from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014
Hemp expeller	Product of oil manufacture obtained by pressing hemp seeds from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014
Hemp seed oil	Oil obtained by pressing of hemp seeds from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014
Hemp flour	Flour ground from stems from hemp from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014
Hemp fibre	Product obtained during the mechanical processing of hemp stems from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014

Feed materials in catalogue



Forage meal; [green meal]	Product obtained by drying and milling and in some cases compacting forage plants (*)
Blossoms(*), dried	All parts of dried blossoms of consumable plants and their fractions
Leaves (*), dried	Dried leaves of consumable plants and their fractions
Products from the processing of plants	Products obtained from freezing or drying whole plants (*) or their parts
Powder cellulose	Product obtained by decomposition, separation of lignin and further cleaning as cellulose from vegetable fibre (*) of untreated wood and which is modified by mechanical processing only. Neutral detergent fibre (NDF) minimum 87%

(*) **With the exception of *Cannabis sativa L.***

THC as contaminant in feed



Maximum levels for Δ^9 -THC in feed – Under discussion

Undesirable substance	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
“6. Delta-9-tetrahydrocannabinol (Δ^9 -THC) (*)	Feed materials	
	- hemp seed	3.0
	- hemp expeller	3.0
	- hemp seed oil	7.5
	- hemp flour	7.5
	- hemp fibre	7.5
	Complete feed	0.5

(*) the maximum level refers to the sum of delta-9-tetrahydrocannabinol (Δ^9 -THC) and delta-9-tetrahydrocannabinolic acid (Δ^9 -THCA), expressed as Δ^9 -THC. Therefore, a factor of 0.877 is applied to the level of Δ^9 -THCA and the maximum level refers to the sum of Δ^9 -THC + 0.877 Δ^9 -THCA.

Outlook regulations in feed and food related to THC

- Request to EFSA as regards the toxicity of $\Delta 8$ -THC for future regulation in feed and food
- Establishment of maximum levels for other hemp food derived foods
- Restrictions on the use in hemp in feed



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**Thank you for
your attention !**