Background

In this guide

In this guide

This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

Previous evaluations

EFSA

6. In their 2011 opinion, EFSA's Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) evaluated the safety of hemp (*Cannabis* genus) derived feed for animals and the potential distribution of psychoactive metabolites, majorly 11-hydroxy- Δ⁹-THC (11-OH-THC), to different tissues and organs of animals, fat and target tissue. Transfer rates of 11-OH-TCH to milk were estimated to be 0.15%. A Provisional Maximum Tolerable Daily Intake (PMTDI) of 0.0004 mg/kg bw was derived from single and repeated dose studies in human volunteers that showed multiple psychotropic effects observed at a lowest observed adverse effect levels (LOAEL) of 0.04 mg/kg body weight and applying an uncertainty factor of 100 (FEEDAP, 2011).

7. Exposure calculations showed both adult and children had exceedances in the PMTDI which occurred via consumption of milk from animals fed whole hemp plant material. However, exposure to milk from hemp seed-derived fed animals was below the PMTDI. The Panel recommended a maximum THC content of 10 mg/kg in hemp seed-derived feed materials, in reference to the Δ^9-THC compound only.

8. In its 2015 scientific opinion, the EFSA CONTAM Panel evaluated the risks to human health from the presence of Δ^9-THC in milk and other animal-derived foods, particularly when animals are fed hemp seed-derived feed. From reported human data in the literature, the Panel identified a LOAEL of 2.5 mg/day (0.036 mg/kg bw) for Δ^9-THC, primarily due to central nervous system effects. An Acute Reference Dose (ARfD) of 1 µg/kg body weight (bw) was established after applying the uncertainty factor (UF) of 30. Exposure estimates showed that high consumers of milk and dairy products were below this threshold, 3% of the ARfD for adults and 13% for toddlers, and therefore unlikely to pose a health concern.

9. The opinion also discussed Δ^8-THC. From the limited literature, it was noted that concentrations in *Cannabis sativa* preparations were typically very low and did not significantly contribute to the psychoactive effects associated with Δ^9-THC. This reinforced the focus on Δ^9-THC as the primary compound of concern in food safety and there is limited contribution from Δ^8-THC within the assessments related to hemp-fed animals.

10. The EFSA Scientific Report (2020) provided an assessment of acute human exposure to Δ^9-THC through hemp and hemp containing food products. The report found that high adult consumers of most hemp-based products exceeded the ARfD, of 1 µg/kg bw, under both lower bound and upper bound exposure scenarios. The report focused exclusively on Δ^9-THC and did not include any discussion of Δ^8-THC.

US FDA

11. The FDA memoranda from 2021 and 2024 concluded that Δ^8-THC is not Generally Recognised as Safe (GRAS) for use in food. The FDA cited concerns about its potential adverse effects on multiple systems including the nervous, respiratory, reproductive, and endocrine systems as well as risks to neurodevelopment in individuals exposed during pregnancy. In 2024, the FDA reaffirmed this position, stating that new literature up to October 2023 did not

change their original safety concerns. As a result, Δ^8-THC remains not approved for inclusion in food products.

FDA Reported Cases

12. The Secretariat have included the following FDA reports of adverse events in addition to information within the EFSA opinion for Members interest.

13. The FDA received 104 reports of adverse events in patients who consumed Δ^8-THC products between December 1, 2020, and February 28, 2022 (Ou *et al.*, 2021). Of these 104 adverse event reports:

i) 77% involved adults, 8% involved paediatric patients less than 18 years of age, and 15% did not report age.

ii) 55% required intervention (e.g., evaluation by emergency medical services) or hospital admission.

iii) 66% described adverse events after ingestion of Δ^8-THC -containing food products (e.g., brownies, gummies).

14. Adverse events included, but were not limited to: hallucinations, vomiting, tremor, anxiety, dizziness, confusion, and loss of consciousness.

15. National poison control centres received 2,362 exposure cases of Δ^8-THC products between January 1, 2021 (i.e., date that Δ^8-THC product code was added to database), and February 28, 2022. Of the 2,362 exposure cases:

i) 58% involved adults, 41% involved paediatric patients less than 18 years of age, and 1% did not report age.

ii) 40% involved unintentional exposure to Δ^8-THC and 82% of these unintentional exposures affected paediatric patients.

iii) 70% required health care facility evaluation, of which 8% resulted in admission to a critical care unit; 45% of patients requiring health care facility evaluation were paediatric patients.

iv) One paediatric case was coded with a medical outcome of death.

2025 Joint ACNFP and COT position paper Δ^9-THC paper summary

16. The Secretariat have included the Joint position paper from the (ACNFP) & (COT) on establishing a Safe Upper Limit for delta-9-tetrahydrocannabinol (Δ9-THC) and its precursor as contaminants of hemp-derived products including CBD novel foods summary for information to Members.

17. In July 2025, the ACNFP and COT published a joint position paper on establishing a Safe Upper Limit for Δ^9-THC and its precursor as contaminants of hemp-derived products including cannabidiol (CBD) novel foods.

18. The Committee conducted a risk assessment on CBD and other minor cannabinoids, including Δ^9-THC as an accidental contaminant, in hemp (*Cannabis sativa Linnaeus)* after concerns were raised on physiological and psychoactive effects cause by the isomers (ACNFP and COT, 2025).

19. An oral safe upper limit of 1 µg Δ9-THC/kg bw/day (as the sum of Δ^9-THC and the precursor Δ^9-THC A) was established, with consumer protected at intake at or below this value. This was established after considering that 100% of Δ^9-THCA could be converted to Δ^9-THC if heated. Considerations of EFSA scientific opinion (EFSA, 2015) and Advisory Council on the Misuse of Drugs (ACMD) were used when considering a safe upper limit.