EFSA Draft opinion on $\Delta^{\text{8}}\text{-THC}$ – Derivation of a Health Based Guidance Value $\Delta^{\text{8}}\text{-}$ THC

Establishing a HBGV

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65. In the 2025 EFSA opinion on Δ^8 -THC, it was established that the ARfD of 1 μ g Δ^9 -THC/kg bw set by CONTAM Panel (CONTAM, 2015) is still valid. No revaluation of Δ^9 -THC was carried out in this opinion. It was deemed suitable, that due to the similarities between the MOA and effects between Δ^9 -THC and Δ^8 -THC, the ARfD derived for Δ^9 -THC can be considered applicable as a combined group ARfD for both compounds. Therefore, exposure would be calculated as a sum of Δ^9 -THC and Δ^8 -THC.

Occurrence in food

Δ^8 -THC occurrence in food

66. The Panel extracted data from EFSA Scientific Data Warehouse, from 2014 – 2024, included 1,914 analytical results on Δ^8 -THC in food reported by 7

European 2035 countries. Following cleaning of duplications with literature reporting and misreporting, this resulted in a dataset of 1,671 samples/analytical results on Δ^8 -THC from 18 FoodEx2 (Level1) food categories. 93% of the samples collected were censored and specifically in the category's hemp infusion leaves, hemp seed oil, and hemp seeds, 96%-99% of the samples were censored.

- 67. The LODs and limits of quantification (LOQs), considering the different method types, food categories (at FoodEx2 Level 1) were presented in Annex A1 in the EFSA opinion on Δ^8 -THC.
- 68. The highest reported concentration (P95) was found in the category 'Sugar and similar, confectionery and water-based sweet desserts' at $39,100\,\mu\text{g/kg}$. This was followed by 'Products for nonstandard diets, food imitates and food supplements,' ranging from 24,000 to $75,000\,\mu\text{g/kg}$, and 'Grains and grain-based products', with levels between 350 and $1,000\,\mu\text{g/kg}$.

Cooccurrence with other cannabinoids

- 69. The panel evaluated further data using occurrence data of Δ^8 -THC with other cannabinoids in hemp derive. Selecting CBD data resulted in a further 986 result and Δ^9 -THC a further 1145 results. The Panel chose to only evaluate samples with a reliable analysis of LC-MS based methods.
- 70. Within this data set, Δ^9 -THC was commonly detected alone, while Δ^8 -THC alone appeared in only a few samples. Both cannabinoids were found together in 96 samples, with the Δ^8/Δ^9 ratio ranging widely from 0.009 to 17.7 (average 1.37, SD 2.28). Literature suggests that naturally occurring Δ^8 -THC typically has a ratio below 1, whereas many EFSA samples showed ratios above 1.
- 71. The Panel made observations that the reported values could indicate the possible addition of semi-synthetic Δ^8 -THC, formation during processing, storage, or addition of a natural Δ^8 -THC into the samples. This is most likely possible in product containing hemp extracts (CBD oils) which inherently have higher concentrations of cannabinoids.
- 72. Very few publications report Δ^8 -THC occurrence in hemp food products. Δ^8 -THC was largely undetected in hemp food products across multiple studies, with only a few samples showing trace levels (0.02 -10 mg/kg). Most findings confirmed its absence even when Δ^9 -THC was present, and the highest concentration reported in food (675 mg/kg) was still below levels found in products intentionally fortified with semi-synthetic Δ^8 -THC for drug use.

Uncertainties in occurrence analysis

- 73. The Panel acknowledged major uncertainties in the data concerning Δ^8 -THC and its co-occurrence with Δ^9 -THC. Significant uncertainties had arisen from the analytical methods used to detect plant cannabinoids. Although the applicable standards required a relative standard deviation under reproducibility conditions of 25%, corresponding to a measurement uncertainty of 50%, older datasets or those generated by less experienced laboratories may not have met these criteria. This likely led to less reliable concentration estimates. Additionally, analytical artefacts affecting Δ^8 -THC quantification may have caused either underestimation or overestimation of its levels.
- 74. Another source of uncertainty was the wide range of reported LOQs, which spanned from 2 to 10,000 μ g/kg depending on the analytical method and food category. Higher LOQs had an impact on upper bound (UB) exposure estimates, particularly in food categories where cannabinoids were more likely to be present.
- 75. While some products explicitly recorded the presence of CBN and/or CBD extracts, it was possible that other food samples also contained such extracts without disclosure.
- 76. Finally, a large proportion of left-censored data had resulted in substantial differences between lower bound (LB) and UB estimates across several food categories. This discrepancy was especially relevant for products such as hemp seed oils and food supplements, where the occurrence of Δ^8 -THC was more likely.