

Advice 25-2017 of the Scientific Committee of the FASFC on tetrahydrocannabinol (THC) in food of animal origin: hazard quotation and action thresholds**Background & Terms of reference**

Tetrahydrocannabinol (THC or "total" Δ 9-THC) refers to the sum of delta-9-tetrahydrocannabinol (Δ 9-THC) and its precursors. Δ 9-THC is an important, psychoactive ingredient of the hemp plant *Cannabis sativa*. In fresh vegetable material of *C. sativa*, up to 90% of the "total" Δ 9-THC is present in the form of the non-psychoactive precursor delta-9-tetrahydrocannabinolic acid (Δ 9-THCA). Under certain external conditions (e.g. high temperature) Δ 9-THCA is decarboxylated to the active form Δ 9-THC. Literature regarding Δ 9-THC does not always clearly indicate whether the data reported as 'THC' or 'total THC' refer to Δ 9-THC or to the sum of Δ 9-THC, its precursors and/or other relevant cannabinoids in the hemp plant.

Only *C. sativa* varieties with a low THC content (< 0.2%), i.e. the non-hallucinogenic variants which are also referred to as kemp or industrial hemp, are allowed to be cultivated in Europe. The big difference between cannabis (marijuana) and industrial hemp or kemp is the THC content. Whereas total THC content of kemp is limited to 0.2%, total THC content of cannabis varies between 3 and 15%. (For clarity, "kemp" is used in this opinion to indicate that the scientific opinion concerns THC-poor hemp varieties.)

Kemp has a wide range of applications, including as a food source for humans and animals. For the moment, the cultivation of kemp, as well as its processing in food and feed, seems relatively limited in Europe. Moreover, few data are available about the presence of Δ 9-THC in food or feed. Therefore, Recommendation (EU) 2016/2115 asks the Member States to monitor the presence of Δ 9-THC, its precursors and other cannabinoids in foodstuffs.

Currently, a number of foods derived from kemp are already allowed on the Belgian market based on a specific derogation. Hereto maximum Δ 9-THC levels are applied: 10 mg/kg for kemp seed oil, 5 mg/kg for kempseed and kempseed meal, 0.2 mg/kg for all other vegetable foods and alcoholic beverages, and 0.04 mg/kg for non-alcoholic beverages (e.g. soft drinks). For food of animal origin, no maximum levels have been determined.

It is in this context that the Scientific Committee has been asked to provide advice on (i) a quotation regarding the public health hazard of Δ 9-THC, and on (ii) possible action thresholds for Δ 9-THC in food of animal origin in order to provide the FASFC with a scientific basis to preserve safety of the food chain.

Methodology

The scientific opinion is based on a risk assessment by means of information available in the scientific literature combined with expert opinion.

Results

Δ 9-THC probably has hormone disrupting properties and is psychoactive. In oral human exposure studies, an increased heart rate and central nervous system effects, including mood swings, analgesia and sedation, were observed already at low Δ 9-THC levels and shortly after ingestion. Based on these adverse effects on the central nervous system, EFSA (2015) established an acute reference dose (ARfD) of 1 μ g Δ 9-THC/kg body weight (bw). According to EFSA the establishment of a tolerable daily intake (TDI) was not necessary. Based on the

evaluation of the dose-response relationship in subchronic and chronic oral exposure studies with rats, the benchmark dose corresponding to a benchmark response of 10% (BMDL10) was found to be 700 times higher than the ARfD. This implies that ensuring an exposure below the ARfD would also protect against possible effects of Δ 9-THC after repeated exposure.

Within the FASFC a quotation is attributed to the severity of the adverse health effects, ranging from a quotation 1 ("not or little serious") to quotation 4 ("very serious") in the context of official controls. Based on the possible health effects and the relatively low ARfD value of 1 μ g Δ 9-THC/kg bw, the Committee proposes to allocate a quotation 3 ("serious") to the severity of the adverse effects of Δ 9-THC.

Based on the highest P97.5 consumption value reported for the Belgian population (i.e. children between 2.5 and 6.5 years old and persons older than 15 years) in the EFSA Comprehensive European Food Consumption Database and the ARfD of 1 μ g Δ 9-THC/kg bw, the Committee proposes following action thresholds with respect to the Δ 9-THC level in food of animal origin:

Food group	Proposed action thresholds	
	mg/kg	μ g/kg
Meat & meat products	0,04	40
Milk & dairy products	0,01	10
Egg & egg products	0,80	800
Fish & other seafood	0,20	200

As it may be assumed that the prevalence of THC in foods is very low, a highly targeted sampling is recommended (for instance, sampling of foodstuffs from animals fed with kemp-derived feed, bio- and regional products with a focus on HIGH-FAT products or products with e.g. kemp seed added as herbs). It is appropriate -if possible- to analyse besides Δ 9-THC, Δ 9-THCA and other cannabinoids, particular those that are known to be psychoactive, and those that have the potential to interact with Δ 9-THC, as is also indicated in Recommendation (EU) 2016/2115. Given the recent toxicological reference value (ARfD), it is additionally recommended to re-evaluate the maximum Δ 9-THC levels currently used in Belgium for granting derogations to specific, kemp-containing or kemp-derived products.

Conclusions

The risk of Δ 9-THC can be considered to be low at the moment. The Committee proposes to apply a quotation 3 with respect to the public health hazard or the adverse effects of Δ 9-THC. To provide the FASFC with a scientific basis with a view to preserving safety of the food chain, the Committee proposes action thresholds between 0.01 and 0.80 mg Δ 9-THC/kg in food of animal origin.

The full text is available on this website in dutch and in french.