# EIHA contribution on maximum levels for THC in food

Hemp has been a **traditional food source** for thousands of years and all parts of the plant, except stems, have been consumed, both in Europe and abroad. In the pre-industrial era, hemp oil was one the most consumed vegetable oils in the human diet. Modern food business operators have been producing and trading hemp food in our continent for decades: as recorded in a survey requested by the Commission in 1997, multiples tonnes of hemp food were already present on the market at that time[1].
Furthermore, hempseeds are particularly rich in **high-quality proteins** and have a **unique essential fatty acid spectrum**. A shift in consumers' trends towards healthy diets led to a **strong increase of hemp food demand**, resulting in a significant development of the supply chains.

Cannabinoids are natural constituents of the plant Cannabis sativa L. and its raw materials (i. e. seeds, leaves) derived therefrom, and not to be regarded as contaminants.
For the residual contents of **natural constituents** to be limited in food we propose the term **"residual natural constituents"**. By this we define the residual level that shows in hemp food after certain (industrial) processing measures.
Food derived from hemp contains traces of a cannabinoid which is the psychoactive substance **tetrahydrocannabinol** (delta9-THC), and which remains in the food even after the most careful cleaning processing, being a residual natural constituent of hemp.

Hemp, hempseeds and food products are:

- **traditional**, because they have a thousand of years of history as food in Europe;
- **innovative**, because they were just rediscovered in the last decades;
- **healthy**, because of their unsaturated fatty acids content, a perfectly balanced ratio of the fatty acids Omega-3 and Omega-6, the content in easy digestible proteins as well as vitamins and trace elements;
- **safe**, because all hemp food products are derived from **industrial hemp with very low THC levels (from EU certified hemp varieties)**.

At the EU level, the Health Based Guidance Value (HBGV) **for THC intake from food recommended by EFSA is outdated and unnecessary strict**. Based on a biased consideration of past studies, the assessment led to an unnecessary strict and obsolete result (TDI/ARfD of 0.001 mg/kg bw). The difference is particularly striking if compared to the HBGV's of our international competitors, like Canada (0.014 mg/kg bw), Switzerland (0.007 mg/kg bw) or Australia and New Zealand (0.006 mg/kg bw). Indeed, the guidance value for THC recommended by EFSA, upon which the Council will most probably base its decision on THC limits in food, is based on wrong conclusions of studies and data in many respects.
In particular, **we would like to highlight the following biases** of the EFSA guidance on THC:

- The LOAEL of 2.5 mg of delta9-THC, defined by EFSA and BfR for effects on the central nervous system, is derived from only a few clinical studies or trials, respectively, results of which are not conclusive. The whole ensemble of clinical and observational **studies on THC shows that the LOAEL is to be at least set at 5 mg per day and adult**.

[1] Hempseeds: ca 200 tonnes; Hempseed oil: ca 33,000 litres; Hemp ready made products (snacks, flour, muesli, bread, bakery & pasta): ca 55 tonnes; Drinks with hemp flowers/leaves: ca 115,000 litres; Snacks with hemp flowers ca 2 tonnes

- The overall **uncertainty factor (or safety factor) of around 36** applied to the LOAEL for deriving a **Health Based Guidance Value (HBGV) for THC is set much too high** for such a substance of relatively low acute toxicity, compared to other substances (toxins) of concern in food or consumer products such as alcohol, caffeine, nicotine, glycoalkaloids (e. g. solanine) or morphine (from poppy seeds). There is no scientific evidence that sub-psychoactive levels of THC on foods have any significant effects on human health. During the last 50 years, the threshold amount of THC that is required for psychoactivity has been carefully studied in humans and is quite well known by now. Aside from the mild psychoactivity effect in most humans when taken orally 5 mg of THC or more, there are no other physiological or psychological effects that can be ascribed to low amounts of THC that are below the psychoactive threshold. Hence, the Acute Reference Dose (ARfD) **or HBGV of 1 µg/kg bw**, proposed by EFSA in 2015, is unnecessarily low and not justified from a modern scientific viewpoint.
- The **health authority for Australia and New Zealand (FSANZ)** has derived a dose of 5 mg THC per day as LOAEL in a re-examination (2011) of its careful risk assessment of THC in food. On this basis a **HBGV of 6 µg/kg bw** was derived for THC.
- The **Swiss Federal Office of Public Health (SFOPH)** had derived a **HBGV of 7 µg/kg bw** on the basis of various studies, also using a LOAEL of 5 mg/d of THC per adult person.
- **Croatia** is also an EU country with an up-to-date HBGV at the higher level.

**Based on scientific studies and on experience, a HBGV of delta9-THC may reach up to 7 µg/kg bw (or 490 µg per day and adult).**

On these grounds, **the DRAFT values for maximum levels for THC in food suggested by the European Commission** (Working Group "Agricultural Contaminants") in the context of a stakeholder consultation **are unnecessarily low, not supported by scientific evidence and unacceptable.**

Considering all the above and the "**Scientific Discourse on Lowest Observed Adverse Effect Level (LOAEL) and Acute Reference Dose (ARfD) of delta9-THC and their impacts on thresholds for hemp food"** (Annex) the EIHA request for thresholds is:

| **Food** | **Maximum level for THC (*) mg/kg** | **Alternatively: Guidance value for THC (*) mg/kg** |
|---|---|---|
| Hemp seeds | 10 | 10 |
| Ground hemp seeds (hemp seed powder), (partially) defatted hemp seed (press cake) (hemp seed flour), hemp seed bran | 10 | 10 |
| Hemp seed oil | 20 | 10 |

(*) the maximum level and the guidance value refer to the sum of Δ9-tetrahydrocannabinol (Δ9-THC) and Δ9-tetrahydrocannabinolic acid (Δ9-THCA)

Based on **appropriate consumption data** for hemp containing food, correspondingly **higher guidance values for THC in food (raw material, see table above) and ready-to-eat food products and food supplements** are derived (see table below):

**Table 1:** New EIHA proposal resulting in a daily total THC uptake of 500.55 µg

| Food categories | EIHA Guidance value for total THC [µg/kg] | Average Consumption Pattern [g/day/person] | Total THC uptake/day/person (consumption * guidance value = uptake) [µg] | Current Guidance values (Germany – BfR) [µg/kg] |
|---|---|---|---|---|
| Edible oils | 10 000 | 2.93 | 29.30 | 5 000 |
| 'High Volume' foods: Protein (e.g. Tofu, hemp based dairy alternatives) | 1 000 | 183.87 | 183.87 | 150 |
| 'High Volume' foods: Carbohydrates (Bread, Baked Goods, Pasta, Breakfast Cereal) | 1 000 | 230 | 230 | 150 |
| 'Low Volume' foods (Protein Shakes, Sweets) | 1 000 | 27.01 | 27.01 | 150 |
| | | [ml/day/person] | | |
| Alcoholic beverages (Beer, Wine, Spirits) | 20 | 180.61 | 3.61 | 5 |
| Non-heated Non-alcoholic beverages (Soft Drinks, Fruit Juices) | 20 | 120.03 | 2.40 | 5 |
| Heated Non-alcoholic beverages (Tea, Infusions) | 80 | 304.47 | 24.36 | 5 |
| Total THC daily uptake | | | 500.55 | |

**Table 2:** List of new total-THC-reference values (green box) for hemp ingredients derived from EIHA proposal on ready-to-eat products, selected recipes and consumption patterns; together with guidance values and limits for listed countries.

| Ingredients | EIHA proposal 2017 Total THC [µg/kg] | THC Guidelines | THC limits[4] | | |
|---|---|---|---|---|---|
| | | Germany – BfR [µg/kg] (total THC) 2000 | Switzerland [µg/kg] 2016 | Canada [µg/kg] 1998 | Australia and New Zealand [µg/kg] 2017 |
| Hemp Seeds Whole or Hulled | 10 000 | – | 10 000 | 10 000 | 5 000 |
| Hemp Seed Oil (Edible oil) | 10 000 | 5 000 | 20 000 | 10 000 | 10 000 |
| Processed Press Cake (Protein powders, Flour) | 10 000 | – | – | 10 000 | 5 000 |

Tables 1 and 2: Proposals for THC guidance values in food (from EIHA Position Paper, 2017, www.eiha.org)

**Addendum:**

For food supplements, an allowable maximum daily intake of 490 µg of total-THC is proposed.

The proposed guidance values are not to be meant as legally binding limits, whereas maximum limits are understood as proposals for legally binding values.

In this context, total THC is the sum of delta9-THC and delta-9-tetrahydrocannabinol carboxylic acid (THCA) as determined by analysis and **normalized by calculation to delta9-THC**. THCA, the natural form of THC that is produced by the hemp plant, is not orally active and cannot enter the central nervous system by consuming hemp foods. For this reason, it would not be reasonable to establish legally binding food THC limits according to the total THC with the constituents THC plus THCA that occur in hemp foods as natural constituents. However, the above guidance values are proposed as **total-THC values for practical reasons** and **could be accepted by industry only on these grounds:** comparability with historical values, easier analytical measurement, and possible (part-)decarboxylation of the corresponding acid on prolonged exposure to elevated temperatures.

However, when it came to fixing **legally binding limits for THC**, we could **only accept maximum limits for delta9-THC** (without the corresponding acid THCA), if there were a **validated analytical method** in place (preferentially some type of High Performance Liquid Chromatography) which would separate these two chemical compounds and allow their separate quantitative measurement. This analytical method should be binding for all Member State authorities.

As such a legally binding analytical method was also possible to establish for the measurement of total-THC (by Gas Chromatography) in the hemp field samples (see CDR 2017/1155, Annex I) this should also be possible for a state-of-the-art analytical method for quantification of the psychoactive constituent delta9-THC in food and feed.

**Questions and Remarks on the EU COM Proposal, which need to be discussed and considered in in the further course of the consultation:**

1. Why are the proposed limits set for total-THC? (Total-THC as sum of delta9-THC and the non-psychotropic delta9-THCA). Total-THC includes THCA and because of that the proposed limits are much too low. They have to be doubled at least, if not tripled. For example, it will be practically impossible to comply with the limit for whole (unpeeled) hemp seeds. There is no risk assessment at all by EFSA on THCA as a natural constituent of hemp food, and there is no HBGV for delta9-THCA. The EFSA risk assessment was for delta9-THC (acid-free) only. The reason is quite simple: EFSA's Scientific Opinion (2015) could only refer to delta9-THC because all the studies used for EFSA's derivation of the ARfD of delta9-THC (1 µg/kg bw*d) had been performed with Marinol or pure delta9-THC (INN: Dronabinol, acid-free). Thus, scientifically based limits can be given for delta9-THC (acid-free) only, not for total-THC.

2. How is the sum of delta9-THC and delta9-THCA defined by the EU COM? Will delta9-THCA be normalized to delta9-THC?

3. Are there official, validated analytical methods in place for all European authorities and national laboratories for quantitative determination of THC and THCA, including

analytical LOQ (Limit of Quantification)? Since there is no standard analytical method for governments in the EU to follow for the analysis of ppm amounts of THC and THCA in foods, such minimal levels must not be set too low, because it will be impossible for such low levels to be analysed with accuracy and precision throughout the EU by a wide variety of methods that do not follow one specific procedure. In other words, we need higher levels to allow some tolerance and room for human error in the results.

4. Why is this proposal not in line with Commission Recommendation 2016/2115 on the monitoring of the presence of delta9-THC, its precursors and other cannabinoids in food?

5. Are there no maximum levels given for other foodstuff because for the latter it is intended to apply Article 2 of Reg (EC) 1881/2006 using a dilution factor for calculation of the (lower) max. limit in the food containing (a) hemp seed (derivative)?
   If this procedure were meant, it would not be acceptable at all in the context of the proposed extremely low THC limits in the EU COM Agri proposal. (see Reg (EC) 1881/2006 Art. 2, para 3. on compound foodstuff). On this point, EIHA requests detailed explanation what is meant by application of Art. 2 of the Regulation.