

Cannabinoids – Determination in Food and Novel Food

Top webinar questions

Questions of the attendees, asked during the webinar:

“Cannabinoids – Determination in Food and Novel Food”

Some facts about Cannabis sativa L.

- Cannabis sativa L. is a very old cultivated plant
 - It is used for paper production since 2nd millennium B.C.
 - **Cannabinoids** (> 100 substances known so far): **naturally occurring compounds** found in the Cannabis sativa plant
 - All plant parts except seeds contain cannabinoids
 - There are 2 sorts of Cannabis sativa L.. A **drug hemp** and a **fibre hemp** (legal in EU if <0.2% THC)
 - **It's glandular hairs**
 - On the entire surface of the plant except seeds and roots
 - Secrete a resin (resin consists of 80-90% cannabinoids, the rest is made up of essential oils, phenols, terpenes, waxes)
 - Cannabinoid content correlates with the number of glandular hairs
 - Cannabis sativa L. gains significance in food production
 - **Hemp seeds** contain **all 8 essential amino acids** in ideal proportions for human nutrition
 - **Hemp oil** has the highest content of unsaturated fatty acids of all vegetable oils.
 - **Increasingly products** which contain **highly concentrated the cannabinoid cannabidiol (CBD)** are offered in internet shops and special stores.
 - **Health benefits** are promoted for cannabidiol.
 - **CBD extracts**, any products to which they are added, as well as synthetically obtained cannabinoids are considered **Novel Foods**
 - 50 Novel Food applications were under review by the European Commission in December 2020
 - Hemp seeds, hemp leaves as feed
 - Transfer to food of animal origin
- A recording of the webinar can be found at:
- <https://www.institut-kirchhoff.de/en/areas-of-work/food/>

1. I produce chocolate with hemp seeds, do you provide analysis for this and which regulatory demands do I have to comply with?

Yes, we provide analysis for this matrix. Our method used for the analysis of hemp seeds can be used for many food matrices. The clean-up process is based on the QuEChERS approach in pesticide analysis, especially modified for samples containing high amounts of fat. When customers send us matrices we have not analyzed so far, we perform validation studies and enhance the scope of our method promptly.

Hemp seeds are not defined as narcotics if fibre hemp is used.

contamination of the seeds has to be avoided to achieve a low THC content (evaluation according ALARA-principle (a slow as reasonably achievable)

THC-content may not be above ARfD (= unsuitable for consumption) or even LOAEL (= harmful).

2. I want to sell hemp oil to Europe, do I have special regulations there?

2 cases: oil from hemp seeds and CBD oil
oil from hemp seeds

can be sold as food if fibre hemp is used
contamination of the seeds has to be avoided to achieve a low THC content (evaluation according ALARA-principle (a slow as reasonably achievable)

THC-content may not be above ARfD (= unsuitable for consumption) or even LOAEL (= harmful)

CBD oil

extracts from flowers and leaves are not marketable, because classified as narcotic
isolated or synthetic CBD is classified as novel food (application for approval necessary); if THC is detectable classification as drug by most food inspection offices.

3. You mentioned that THC acid can be transformed into THC. May this happen for CBD as well? At which temperatures does this occur? Is this relevant during production?

Yes, CBD acid is transformed into CBD at higher temperatures as well. At temperatures below 80°C decarboxylation processes are very slow, but at higher temperatures the transformation happens very quickly. In a solution, for example, CBDA is transformed into CBD completely within several days at 80°C, within approx. 1 hour at 110°C and within 10 minutes at 130°C. At higher temperatures, however, CBD is not the only product. Several other products are also formed. Of course, these reactions are also relevant during production if high temperatures are applied.

4. Which EU act of law makes CBD approved in foods? Perhaps you think about hemp oil, seeds, flour which are just the food. If any other CBD preparation is approved pls let us know the legal basis.

In 2020 the European Court of Justice decided that CBD is not considered to be a narcotic drug. So as long as you have a product containing isolated or synthetic CBD it is not classified as a drug. Extracts from flowers and leaves would be classified as drugs. Furthermore THC must not be detectable.

BUT Very important: You need approval as Novel Food, because CBD had not been used for human consumption before 1997. Currently none of the CBD products is finally approved in the European Union.

Hemp oil and seeds are legal because hemp seeds are excluded from the drug definition.

5. Can we identify the presence of pesticides in Cannabinoids oils?

Yes, we can provide pesticide analysis in cannabinoid oils. Feel free to contact us after this webinar.

6. For hemp seed oil and hemp seed there are BfR requirements from 2018, but actually they advise to use the EFSA ARfD for max. THC content in products. What do you think ?

In its Opinion No. 006/2021, BfR (Federal Institute for Risk Assessment) recommends that the toxicological assessment of hemp-containing foodstuffs should be carried out on the basis of the acute reference dose (ARfD) derived by the EFSA in 2015. For each product to be evaluated, BfR recommends that it should be assessed on a case-by-case basis whether the ARfD might be exceeded. The analyzed THC contents and the estimated consumption quantity are used for the determination. Information on the latter is provided, for example, by the EFSA Comprehensive European Food Consumption Database.

The BfR already came to the conclusion in 2018 that the BgVV guideline values from 2000 no longer correspond to the scientific state of the art.

Because of our participation in the §64 LFGB working group "Plant Toxins" at the BVL, we are in contact with numerous institutions of official food monitoring. The general consensus is that the BgVV guideline values are no longer used in the evaluation of THC contents in food and that the toxicological evaluation is carried out on the basis of the ARfD value.

7. What are the consequences for a lab if you possess CBD-containing products with an illegal amount of THC?

We would inform our customer, discuss the next steps and proceed in agreement with our customer.

8. Does the amount of THC have an impact on the evaluation? Or is it just crucial to detect THC, regardless of the amount detected?

The food control authorities usually classify CBD products as narcotic as soon as delta-9-THC is detectable. The level of the Delta-9-THC is not relevant for this classification.

The situation is different with foods based on hemp seeds. Here, the THC content is relevant for the assessment, as it depends on this content whether the food is classified as unsuitable for consumption or harmful to health.

9. Legal qualification of cosmetics

Concerning the use of cannabis and extracts thereof in cosmetic products, reference should be made to Article 14 para 1. lit. a in conjunction with Annex 2 No. 306 of Regulation (EC) No. 1223/2009. In the list of substances prohibited in cosmetic products, natural and synthetic anesthetics are mentioned. Schedule I of the UN Single Convention on Narcotic Drugs (ESK 1961) lists Cannabis, Cannabis resin, extracts and tinctures of Cannabis. Placing a product containing Cannabis, Cannabis resin, extract or tincture on the market is thus not permitted..

10. Can you analyze / quantify Cannabinoids in raw materials? Or even in plants before preparing the final products?

Yes, we can analyse raw materials. We perform for example analysis of Hemp seeds or hemp oil. If you target raw materials for food production please contact us and we can discuss your options.

11. Please tell me where I find the most CBD? In the seed or in the flower? What about the whole plant? Is it useful for feed?

Hemp seeds contain only minor amounts of cannabinoids compared to the flowers. It should be noted that in the unprocessed plant material cannabidiol is predominantly present as cannabidiolic acid and is only converted into cannabidiol through processing (heating, decarboxylation). The same applies to delta-9-THC/delta-9-THC acid.

According to Commission Regulation (EU) 2017/1017 hemp seed (controlled seeds of varieties of *Cannabis sativa* L. with a maximum tetrahydrocannabinol content according to Regulation (EC) No 1782/2003), hemp expeller and hemp oil are currently approved as feed materials. Other parts of hemp or the whole plant are currently not approved as feed materials. According to article 3 (1) of Regulation (EC) No 1831/2003 no feed additives may be placed on the market unless an authorization has been granted for them.

13. Would you consider a product marketed as "Infusion of cannabis sativa flowers", as novel food or as drug, if the analytical result doesn't show the presence of THC but only CBD?

According to Article 1b) of the United Nations Single Convention on Narcotic Drugs, 1961, Cannabis flowers are not classified as drugs if the resin has been extracted. So if the resin has been extracted and THC cannot be detected in the product the product can be classified as novel food.

13. Where is use of hemp oil and hemp seeds regulated?

For each product the crucial question is if the product is food or narcotic. Not food (according to Article 2 g, Regulation (EU) 178/2002) are narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971. According to Article 1 j) Single Convention on Narcotic Drugs of 1961 means "drug" any of the substances in Schedules I and II, whether natural or synthetic (here: "Cannabis and cannabis resin and extracts and tinctures of cannabis"). Article 1 b defines "Cannabis" as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted". So hemp seeds and oil made from hemp seeds are excluded from the drug definition.

Currently there are no specific limits for THC in food, but the ARfD (Acute Reference Dose) of 1 µg/kg body weight / day and the LOAEL (Lowest observed adverse effect level) of 2.5 µg/day. Both toxicological values have been published by the EFSA (European Food Safety Authority). Limits for THC contents in oil from seeds and other food containing hemp seeds are currently discussed.

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