

Frequently asked questions about the health risks of foods containing hemp

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Hemp in noodles and energy drinks - as an ingredient in numerous foods, hemp has experienced substantial hype in recent years. People have been utilizing the fibres of this crop for centuries, among other things, for the production of ropes, textiles and paper. Parts of the hemp plant (e.g., the leaves and flowers, or extracts made thereof) are used as remedy, but also as narcotic drug.

The seeds of the hemp plant are rich in valuable amino and fatty acids, similar to linseeds. However, the leaves and flowers contain so-called cannabinoids. Some of them can influence the psyche. They are also referred to as psychoactive substances. Contact with parts of plants containing cannabinoids, for example during the harvest, can result in contamination of the seeds.

The best-known cannabinoids include tetrahydrocannabinol (THC) and cannabidiol (CBD). THC, in particular, has a psychoactive effect. Exposure calculations carried out by the BfR indicate that consumption of hemp tea, or hemp seed oil with high THC concentration, may result in exceedance of the acute reference dose (ARfD) for THC established by the European Food Safety Authority (EFSA). Children in particular have an increased risk of consuming excessive amounts of THC due to their low bodyweight. Even small amounts of the psychoactive substance can affect the central nervous system and the cardiovascular system. As a result, mood swings and fatigue can occur, among other things.

CBD-containing products are said to have health-promoting effects, but most of them have not yet been scientifically proven. They are primarily offered as dietary supplements. According to the current state of knowledge, CBD is not psychoactive. But it exerts a pharmacological action. CBD products may also become contaminated with THC.

When placing products containing hemp on the market, the relevant laws governing narcotic drugs, medicinal products and foods must be observed.

In the following, the BfR has put together a FAQ on the subject of “foods containing hemp”.

Hemp - what is it?

Hemp (*cannabis*) is a plant genus of the hemp family (Cannabaceae). The species *Cannabis sativa* L. is usually cultivated in Europe.

What is hemp used for?

Hemp is one of the oldest cultivated plants and agricultural crops. Various preparations of the plant have been used as remedy, but also as narcotic drug, since ancient times. Industry mainly utilizes hemp to obtain fibres, for example to manufacture textiles. In the 20th century, the industrial importance of hemp as a useful crop declined, but cultivation is currently rising again.

The number of hemp-containing foods in retail has increased in recent years. These primarily include products that contain hemp seeds as an ingredient. But there are also teas that are made on the basis of hemp leaves or hemp flowers.

In the European Union (EU), hemp seeds - in the form of hemp oil, hemp flour or press cakes resulting from oil extraction - as well as hemp fibres from certain types of hemp, approved for this purpose, are used as animal feed.

Which hemp-containing foods are on the market?

The range of hemp-containing foods on the market has grown in recent years. Hemp seeds are most often used as the main ingredient. For example, there are:

- Edible oil derived from hemp seeds
- Foods that contain the oil as an ingredient
- Foods that contain hemp seeds or the protein powder derived from hemp seeds (e.g., muesli bars, pasta)
- Dietary supplements that contain protein powder made mainly from hemp seeds.

In addition, there are also foods that contain other parts of the hemp plant, e.g.:

- Teas made from hemp leaves and/or hemp flowers
- Other foods that contain extracts from the leaves and / or flowers (e.g., energy drinks)
- Food supplements that contain extracts from the leaves and/or flowers of the hemp plant.

Important: Products containing hemp can generally only be marketed as food, if they are not classified as narcotic drugs or medicinal products and the food itself is deemed as being safe (see also the questions “Do hemp-containing foods fall under the Narcotic Drugs Act?” and “Is it true that a maximum content of 0.2 % THC applies to hemp?”).

Do foods containing hemp fall under the Narcotic Drugs Act?

Cannabis (marijuana, plants and parts of plants belonging to the genus *Cannabis*), cannabis resin (hashish, the secreted resin from plants belonging to the genus *Cannabis*), THC and other tetrahydrocannabinols are listed as narcotic drugs in the Narcotic Drugs Act (BtMG). Exceptions to this are, amongst others, the hemp seeds - provided that they are not intended for unauthorised cultivation - as they do not contain any THC as an ingredient. Accordingly, foods made from the seeds are generally not subject to the Narcotic Drugs Act.

The situation may be different for products that contain leaves and/or flowers of industrial hemp, since plant parts other than the seeds are only exempted from the Narcotic Drugs Act under very specific conditions. The legal situation here is very complex. In individual cases, such products can be deemed by the competent authorities as being narcotic drugs under certain circumstances. The Federal Opium Agency at the Federal Institute for Drugs and Medical Devices (BfArM) provides legally binding information on questions relating to narcotics law: https://www.bfarm.de/DE/Bundesopiumstelle/_node.html

What ingredients does hemp contain?

So far, over 560 different substances have been identified in the hemp plant. The seeds have a high content of fatty oil (25-35 %) and protein (20-25 %) and provide all essential amino and fatty acids. The fatty acid profile - comparable to nuts, linseeds or chia seeds - has a high proportion of unsaturated fatty acids and is therefore considered valuable from a nutritional perspective.

With the exception of the seeds and roots, the entire hemp plant has glandular hairs that produce a resin that consists of around 80-90 % cannabinoids. To date, over 120 different cannabinoids have been identified; they also include the common cannabinoids THC and CBD. Cannabinoids are not found in the seeds as ingredients due to the lack of glandular hairs. It

is assumed that the THC levels measured in hemp seeds and the foods made from them (including hemp protein, hemp seed oil) represent a contamination caused by contact with THC-containing parts of plants during the harvest or processing.

Which ingredients of the hemp plant cause intoxication?

The cannabinoid THC is primarily held responsible for the psychoactive effects of cannabis products. THC has a perception-altering effect. THC is a natural component of hemp. It is formed there in the glandular hairs located on the leaves, leaf veins and inflorescences of the plant. A particularly large number of glandular hairs can be found in the area of the inflorescences, especially in female plants. The hemp seeds, on the other hand, have no glandular hairs and therefore do not contain any THC as an ingredient. However, contact with parts of plants containing THC, for example during the harvest, can result in contamination of the seeds. How much THC a hemp plant contains also depends on the varieties. In the varieties allowed for industrial hemp cultivation in Germany, the amount of THC is currently set at a maximum of 0.2 %.

The hemp plant contains a mixture of THC and THC carboxylic acid (THCA), a biosynthetic precursor of THC, which itself has no psychoactive effect. According to a publication by Jung *et al.* cited by the European Food Safety Authority (EFSA), around 90 % of the total of THC and THCA should be in the form of THCA in fresh plant material. This statement is made in the publication by Jung *et al.* but not supported by experimental evidence. Experimental studies by other authors have shown that although THCA is dominant in most cases, the exact ratio between THCA and THC can vary widely. When exposed to heat, THC carboxylic acid can convert into THC. Because certain analytical methods can only determine the sum of THC and THC carboxylic acid, this sum is also referred to as total THC.

In addition to THC, other cannabinoids found in smaller quantities in the hemp plant also have psychoactive properties. The cannabinoid CBD, which occurs in higher quantities in industrial hemp, however, does not possess a psychoactive effect with regard to the effects described for THC, since CBD has only an extremely low affinity for the cannabinoid receptors.

What is the difference between industrial hemp varieties and “narcotic hemp” or “medicinal hemp”?

Industrial hemp (industrial hemp, fibre hemp) is the term used to describe hemp varieties that have only low levels of the cannabinoid THC compared to narcotic or medicinal hemp. With certain exceptions, industrial hemp is also subject to the regulations of the Narcotic Drugs Act. The cultivation of industrial hemp is permitted in the EU under strict conditions. However, only certified varieties that are listed in the EU Common Catalogue of varieties of agricultural plant species are allowed to be cultivated. In Germany, the cultivation of industrial hemp is monitored by the Federal Office for Agriculture and Food (BLE). Currently, according to the legal regulations, the varieties approved for industrial hemp cultivation in Germany must not exceed a THC concentration of 0.2 % based on the dry matter. Further information is available under the following link: https://www.ble.de/DE/Themen/Landwirtschaft/Nutzhanf/nutzhanf_node.html

What health risks do foods containing hemp pose?

According to Article 14 of Regulation (EC) No. 178/2002, food shall be deemed to be safe. This also applies to foods containing hemp. The responsibility for this lies primarily with the food business operators.

With regard to a possible health risk, the focus in the case of foods containing hemp is the psychoactive ingredient THC. It is known from animal studies on chronic toxicity that the long-term intake of THC can mediate various undesirable effects. These include the suppression of the body's own immune system (immunosuppressive effect) as well as negative effects on fertility. However, these effects were only observed at higher intake levels. For the risk assessment of foods containing hemp, the psychoactive effects that occur even with lower intake are in the foreground.

In 2015, the European Food Safety Authority (EFSA) assessed the health risks that can arise from foods containing hemp. Accordingly, an effect on the central nervous system and the cardiovascular system is to be expected in humans after ingestion of smaller amounts of THC. This can lead to mood swings and fatigue, for example. These effects have already been observed at an intake of 2.5 milligrams per person (corresponding to approximately 0.036 milligrams per kilogram of bodyweight assuming a bodyweight of 70 kilograms) - both after single and repeated intake. This dose was therefore regarded as the "lowest observed adverse effect level" (LOAEL). On this basis, the EFSA established an acute reference dose (ARfD) of 0.001 milligrams of THC per kilogram of body weight. The ARfD indicates the estimated maximum intake of THC that can be consumed in the course of one day - either during one meal or during several meals - without a detectable health risk.

Is it true that particularly strict standards were applied in the assessment process of THC?

The procedure for the toxicological assessment of THC by the EFSA and the BfR followed the established guidelines. In a first step, the most sensitive toxicologically relevant endpoint was identified on the basis of the available studies. A dose of 2.5 milligrams per person was regarded as the "lowest dose with observed adverse effects" (LOAEL).

In a further step, an acute reference dose (ARfD) was derived using the LOAEL as a reference point and an extrapolation factor of 30. Following international standards, an extrapolation factor is made up of a factor of three for extrapolating from the LOAEL to the "highest dose at which no adverse effects are observed" (NOAEL, No observed adverse effect level) and a factor of 10 for taking into account the different sensitivities among the population. The derived ARfD is intended to ensure that sensitive individuals in the population are also adequately protected. The size of the extrapolation factors used corresponds to the international standards for toxicological assessments.

Which foods can cause particularly high intake levels of THC?

The BfR does not currently have any representative data on the consumption quantities of foods containing hemp, therefore, a reliable exposure assessment has not yet been possible.

However, exposure calculations performed by the BfR indicate that the consumption of hemp tea, as well as hemp seed oil with high tetrahydrocannabinol (THC) levels, may result in exceedance of the acute reference dose (ARfD) for THC derived by EFSA. Children, in particular, possess an elevated risk of consuming excessive amounts of THC due to their low bodyweight.

Hemp seeds do not naturally contain cannabinoids. In the course of extraction and processing, however, hemp seeds may be contaminated with cannabinoids (contamination). The concentrations can generally be kept low through suitable conditions during the harvest and further processing. Accordingly, most hemp seed oils have such low THC concentrations that they can be regarded as harmless from a toxicological standpoint.

In the case of hemp tea and other hemp products containing hemp leaves and possibly hemp flowers, however, THC is not a contaminant, but an ingredient. The THC level is subject to large fluctuations depending on the hemp varieties as well as various environmental factors. From the BfR's point of view, it is therefore doubtful whether the levels in these foods can be reliably reduced.

So-called CBD oils primarily contain the cannabinoid cannabidiol (CBD). CBD does not have a psychoactive effect with regard to the effects described for THC, since CBD has only an extremely low affinity for the cannabinoid receptors. In particular, CBD oils made from hemp extracts can also contain THC. There is currently no reliable information about THC levels in CBD oils. It should be pointed out that the Federal Office of Consumer Protection and Food Safety (BVL), which is responsible for risk management, states that it "[...] is currently not aware of any case where cannabidiol (CBD) in food, including food supplements, would be legally marketable within the European Union

Are there any maximum levels for THC in foods?

There are currently no uniform maximum levels for THC in foods within the EU. The introduction of EU maximum levels for hemp seeds and products made from them such as hemp seed oil is currently being discussed at EU level. In Germany, the former Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV) published guidance values for maximum THC concentrations in various food groups in 2000. These were 0.005 milligrams per kilogram for non-alcoholic and alcoholic beverages, 5 milligrams per kilogram for edible oils and 0.150 milligrams per kilogram for all other foods and were related to ready-to-eat foods. From BfR's point of view, based on the current state of knowledge, these guidance values are no longer suitable, in all cases, to ensure an adequate level of protection, since the ARfD can be exceeded, especially for oils, even if the guidance values are adhered to. An additional difficulty is the fact that the group "all other foods" currently includes a large number of different hemp-containing foods that were not on the market when the guidance values were established in 2000 and therefore could not be taken into account, which is why the relevance of this guidance value is also questionable.

Even without legally stipulated maximum levels, foods containing hemp may not be placed on the market with arbitrarily high THC concentrations. Rather, foods containing hemp must comply with the general provisions of food law under Regulation (EC) No. 178/2002. Products containing hemp can generally only be marketed as food, if they are not classified as narcotic drugs or medicinal products and the food itself is deemed as being safe (see also the questions "Do hemp-containing foods fall under the Narcotic Drugs Act?" and "Is it true that a maximum level of 0.2 % THC applies to hemp?"). It is the responsibility of the food business operator to check compliance with legal requirements before marketing.

Is it true that a maximum level of 0.2 % THC applies to hemp?

The cited content of 0.2 % for THC is primarily relevant for the narcotics classification of herbal raw materials. Since hemp plants with higher concentrations generally fall under the Narcotic Drugs Act, such parts of the plant can usually not be used as food. It should be noted that even hemp plants with lower concentrations can be viewed as narcotics if, for example, abuse of the products in question for the purpose of intoxication cannot be ruled out. However, the value of 0.2 % is not suitable for the toxicological assessment of food. There are currently no uniform maximum THC levels for foods in the EU. However, EFSA has established an acute reference dose (ARfD) for food. This indicates the estimated maximum amount of THC that can be consumed in the course of one day - either during one meal or during several meals - without detectable health risk.

The following example illustrates why a maximum level of 0.2% THC in raw plant material is not suitable for the assessment of food:

THC levels in foods containing hemp should not lead to intake levels above the ARfD of 0.001 milligrams of THC per kilogram of bodyweight. The consumption of only 1000 milligrams of a food with a THC content of 0.2% leads to an intake of 2 milligrams of THC. For an adult with a body weight of 70 kilograms, this would correspond to about 30 times the ARfD being exceeded (~0.03 milligrams per kilogram of bodyweight). In the case of children or people with a lower bodyweight or in the case of higher consumption quantities, this excess would be even higher.

On what basis can foods containing hemp be assessed toxicologically?

The BfR recommends that toxicological assessment of foods containing hemp be performed on the basis of the acute reference dose (ARfD) for THC of 0.001 milligrams/kilogram bodyweight established by EFSA. The ARfD indicates the estimated maximum intake of THC that can be consumed in the course of one day - either during one meal or during several meals - without a detectable health risk. From BfR's point of view, each product should be evaluated on a case-by-case basis to assess whether the ARfD may be exceeded.

The measured THC levels and the estimated consumption are used for the determination. Information on the estimated consumption quantities is available from EFSA in the form of the "EFSA Comprehensive European Food Consumption Database" or from consumption studies. In the case of dietary supplements, the recommended daily intake can be used, which is legally required for dietary supplements.

Why does the BfR recommend that THC carboxylic acid be taken into account in the assessment?

The acute reference dose (ARfD) was derived on the basis of studies with pure THC. The precursor substance THC carboxylic acid, on the other hand, has no psychoactive properties. From a toxicological point of view, it still makes sense to use total THC - i.e., the sum of THC and THC carboxylic acid - for the toxicological assessment, provided that the measured values relate to the starting products. This procedure is also intended for the assessment of maximum levels that is currently being discussed at European level.

Heat treatment during further food processing cannot be excluded for the majority of the available raw material containing hemp, e.g., the roasting of hemp seeds or the use of hemp seed oil for frying. As a result of the heating, the THC carboxylic acid contained in the raw material may have been partially or completely converted into THC in the ready-to-eat food. It therefore seems appropriate to use the total content of THC and THC-carboxylic acid determined in the raw material for assessments and relate it directly to the ARfD.

From the BfR's point of view, however, this approach should be derogated from, if in individual cases it is not expected that a particular product will undergo further thermal treatment. This would be the case with dietary supplements in the form of capsules or tablets. Only the measured THC content should be used for comparison with the ARfD.

Do different ingredients of the hemp plant influence each other?

Findings are repeatedly discussed in the literature, which suggest other ingredients of the hemp plant may weaken the undesirable effects of THC. However, the relevant data situation is contradictory. From a toxicological point of view, THC that occurs naturally in foods containing hemp cannot be assessed differently from the isolated or synthetically produced pure substance based on the current state of knowledge.

Is it possible for a drug test to return a positive result after consuming foods containing hemp?

There is currently no reliable answer to this question. In the literature, it is described that positive results in forensic tests are in principle possible after consumption of food containing hemp. The BfR therefore referred to this fact in its opinion from 2018. The positive results were usually obtained after consuming products with a relatively high THC levels. The consumption of contaminated products with low levels generally did not lead to positive results. Information on this issue can be found, for example, in a review by Lachenmeier *et al.* (Foods Containing Hemp - An Update, 2019).

If, for example, the acute reference dose (ARfD) for THC of 0.001 milligrams per kilogram of bodyweight is not exceeded when consuming slightly contaminated products, positive findings in forensic tests are rather unlikely. However, the exact concentrations of THC or its metabolic products in various body fluids can be influenced by a large number of factors. With prolonged consumption, the substances can also accumulate in the body. For this reason, it is currently not possible to conclusively assess the exact intake quantities from which positive findings can occur in forensic tests.

Many products containing CBD can be found in stores. What does this have to do with hemp?

The abbreviation CBD describes the substance cannabidiol. It is a cannabinoid that is primarily obtained from industrial hemp. In contrast to THC, CBD is considered a non-psychoactive cannabinoid, which is why it is not listed as a narcotic drug in the Narcotic Drugs Act (BtMG). Among the general public, CBD is attributed to a multitude of supposed health-promoting effects. The substance is therefore currently a popular ingredient in numerous products, e.g., also in foods including food supplements. Most of the effects advertised as being positive for health have not yet been scientifically proven. It should be pointed out that the Federal Office of Consumer Protection and Food Safety (BVL), which is responsible for risk management, states that it “[...] is currently not aware of any case where cannabidiol (CBD) in food, including food supplements, would be legally marketable within the European Union.”

It is known that CBD possesses pharmacological activity. In Germany, the substance is listed in the Ordinance on Prescription-Only Medicinal Products as a prescription medicinal product. There is now an approved medicinal product with CBD in the EU, which can be used to treat certain rare forms of epilepsy in children.

Do foods with CBD represent no health concern?

The data available on potential health risks due to the presence of CBD in foods are currently still limited. However, it is already known from the use of CBD as a medicinal product that CBD can cause undesirable effects, at least at higher intake levels. These include, for example, a sedative effect and liver dysfunction. According to the current state of knowledge, there is also a potential for interaction with various other medicinal products. This means that taking CBD at the same time can impair or increase the effects of other medicinal products. Whether these effects are also relevant at low intake levels that no longer have a pharmacological effect and can therefore be considered for the food sector cannot yet be assessed.

EFSA is currently examining applications for approval of certain foods containing CBD under the Novel Food Regulation (EU) 2015/2283. The results are not yet available.

Are dietary supplements containing CBD legally marketable in Germany?

The classification of products and the assessment of their marketability in individual cases is one of the tasks of the state authorities in Germany that are responsible for food monitoring. The Federal Office of Consumer Protection and Food Safety (BVL) responsible for risk management “[...] is [however] currently not aware of any case where cannabidiol (CBD) in food, including food supplements, would be legally marketable within the European Union. From the point of view of the BVL, either an application for approval of a medicinal product or an application for approval of a novel food must be submitted for products containing CBD before they can be placed on the market. As part of this procedure, the safety of the product must be proven by the applicant.” Source: https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/13_FAQ/FAQ_Hanf_THC_CBD/FAQ_Cannabidiol_node.html

Are products containing hemp considered as novel foods?

Foods are considered to be novel according to the Novel Food Regulation (EU) 2015/2283 if they had not yet been consumed to a significant degree by humans in the EU before 15 May 1997 and are assigned to certain food categories specified in this regulation. Then, they require an authorisation, under which the safety of the novel food is evaluated by EFSA.

The so-called novel food catalogue of the European Commission regards extracts of the hemp plant (*Cannabis sativa* L.) and CBD as novel foods. These require approval in accordance with Regulation (EU) 2015/2283. As part of this process, EFSA is currently evaluating the safety of CBD as a food. Results are not yet available.

Additional Information:

- <https://www.bzfe.de/lebensmittel/trendlebensmittel/hanf/>
- https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/04_AntragstellerUnternehmen/05_NovelFood/Im_novelFood_node.html
- https://www.bvl.bund.de/SharedDocs/FAQ/DE/02_Unternehmer/01_Lebensmittel/03_FAQ_Hanf_THC_CBD/03_FAQ_Cannabidiol_CBD.html

Is there a difference between foods containing hemp and medicinal products containing hemp?

In principle, the ingredients of foods, which also include food supplements, must not have any pharmacological effects, i.e., properties for healing or alleviating diseases. If a product has such an effect, these products fall under the Medicinal Products Act and require approval as a medicinal product before they can be placed on the market. This is to ensure the effectiveness and safety of the medical products and prevent misuse. The Federal Institute for Drugs and Medical Devices (BfArM) is responsible in this case.