Volksgezondheid
Veiligheid van de Voedselketen
Leefmilieu

Federal Agency
for the Safety
of the Food Chain

Questions and answers on the use of hemp (Cannabis sativa L.) and cannabinoids (such as cannabidiol) as or in foods

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1. Is there a difference between cannabis and hemp?

The two are the same plant species *Cannabis sativa* L. Hemp refers to the varieties of *Cannabis sativa* which have a generally lower THC content: the THC content of the inflorescence does not exceed 0.3%. While the total THC content for growing hemp[1] is limited to 0.3% (or 3000 mg/kg), the total THC content of other varieties of cannabis (weed, marijuana) varies between 3 and 15%. By way of comparison, the limit for THC for the consumption of safe foods is around 1,000 times lower! (see question 5)

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2. What does THC mean?

THC (delta-9-tetrahydrocannabinol) is a substance belonging to the group of cannabinoids and is a psychoactive component of the plant *Cannabis sativa*. The psychoactive properties of THC mean that it has an impact on human consciousness and can be addictive.

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3. Is there a safe threshold for THC?

The European risk assessment conducted by EFSA in 2020 lays down an acute reference dose of 1 microgram of THC per kilogram of body weight per day. If this dose is not exceeded, there is no risk.

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4. What does CBD mean?

CBD (cannabidiol) is one of several cannabinoids found in *Cannabis sativa*. Unlike THC, it does not have any psychoactive properties and is not addictive.

Nevertheless, using CBD in foods (including food supplements) is prohibited (see Question 7). Moreover, it has not been proven that CBD is safe as a food or food supplement.

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5. Are there European harmonised limits for THC in hemp seeds and derivative foods?

Maximum levels for THC in hemp seeds and derivative foods are laid down by Regulation (EU) 2023/915. A limit of 3.0 mg/kg of 'THC equivalents'[2] is imposed for hemp seed, and 7.5 mg/kg for hemp seed oil. For

[1] More information on the restrictions on growing hemp can be obtained from the regional authorities responsible for agriculture.

[2] THC equivalents are defined as the sum of THC and delta-9-tetrahydrocannabinolic acid (Δ9-THCA) expressed as THC (=Δ9-THC + 0.877 × Δ9-THCA). This is because Δ9-THCA can be converted to THC when food is processed.

compound foods, the THC equivalent limit is recalculated based on the amount of hemp seed and/or hemp seed oil present in this product (Article 3 of Regulation (EU) 2023/915).

These maximum levels have applied since 1 January 2023. Products that are not in compliance with the maximum levels cannot be placed on the market. There is a transitional measure for products that were previously placed on the market lawfully, so that these products can remain on the market until the date of minimum durability.

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6. Which products derived from Cannabis sativa L. are NOT considered novel foods?

The term 'novel food' covers new foods and ingredients that were not used for human consumption to a significant degree in the European Union prior to May 1997. Novel foods can only be placed on the market if they are authorised in advance at the European level. Without EU approval, it is prohibited to use novel foods for human consumption.

Currently, hemp seed and some derivatives thereof (e.g., hemp seed oil, ground seed, (partially) defatted hemp seed, the seed press cake or so-called hemp seed protein) have a proven history of significant consumption as a food prior to 15 May 1997 in the European Union.

In addition, there is also a known history of using hemp leaves for herbal infusions. Nevertheless, although these water-based infusions are no longer considered a novel food, placing them on the market is still prohibited in Belgium (see question 7).

More information on novel foods can be found at https://www.health.belgium.be/nl/voeding/voedselveiligheid/nieuwe-voedingsmiddelen/wat-een-nieuw-voedingsmiddel.

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7. Which products derived from Cannabis sativa L. can NOT be used in foods?

The whole plant, the leaves as such (other than use in herbal infusions) and their preparations (e.g., the pressing of these plant parts, the powder of the leaves, all types of extracts of CBD or other cannabinoids, etc.) cannot be used in foods. Indeed, no significant history of consumption of the leaves as such or extracts of CBD as a food ingredient has been demonstrated to date. They are therefore considered novel foods and are prohibited on that basis.

The flowers of *Cannabis sativa L.* do not meet the definition of food (General Food Law EU 178/2002), as they are on the list of psychotropic substances (International Convention). Using the flowers in food is

therefore prohibited on that basis. Pressing of the whole plant is also prohibited on this basis, as the flowers are part of it.

Extracts of cannabinoids from *Cannabis sativa*, which have psychotropic properties (such as a THC extract), cannot be added to foods either, as they do not meet the definition of 'food'. However, THC is also naturally present in hemp seeds, for example, which do have a known history of consumption as a food). The maximum permissible content of THC in these cases is regulated within the framework of the legislation on contaminants (see question 5).

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8. Can foods based on *Cannabis sativa* be placed on the market?

Cannabis sativa L. is on list 1 of "Dangerous plants" of the Royal Decree of 31 August 2021 on the production of and trade in foodstuffs composed of or containing plants or plant preparations. It is therefore, a priori, prohibited to place foods containing *Cannabis sativa* L., plant parts thereof, or preparations based on *Cannabis sativa* L, on the market. This prohibition also applies to the hemp variety (see question 1) the THC content of which is less than or equal to 0.3%. While the total THC content for growing hemp is limited to 0.3%, the limit for safe use in food is much lower (see question 5). However, derogations can be obtained from the prohibition on placing foods derived from Cannabis sativa L on the market (see question 9).

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9. Can derogations be obtained from the prohibition on placing foods derived from *Cannabis sativa* L on the market?

Article 3 §2 of the Royal Decree of 31 August 2021 stipulates that derogations may be granted under specific conditions for the use of plants, in List 1, in or as foods. Among other things, a toxicological and analytical dossier must demonstrate that the plant preparations no longer contain the toxic properties or substances of the plant from which the plant preparations were obtained.

Derogations can only be granted for the plant parts and/or preparations derived therefrom if it has been demonstrated that they were used in foods to a significant degree in the European Union prior to 15 May 1997. If there is no such history of consumption, these parts of hemp and/or preparations derived therefrom are considered novel foods and are prohibited (see also questions 6, 7 and 10). More information on novel foods can be found on the website: What is a novel food | FPS Public Health (belgium.be).

Currently, there is a consensus within the EU that as regards *Cannabis sativa* L., the following plant parts/preparations are NOT considered novel foods:

- Seed: hemp seeds, ground hemp seeds, (partially) defatted hemp seeds and some other hemp seed derivatives such as hemp seed oil

- Infusions of hemp leaves (100% water and to consume as such)

It is therefore only for these plant parts and/or preparations derived therefrom that derogations from the prohibition imposed by the Royal Decree on Plants (31.08.2021) can be granted.

(a) Hemp seeds and foods derived therefrom:

From 1 January 2023, European harmonised limits have applied for THC in hemp seeds and food derived therefrom (see question 5).

Pursuant to Article 3 §2 of the RD of 31 August 2021 and the general opinion of the Advisory Committee for Plant Preparations of 25 April 2023, the use of hemp seeds and foods derived therefrom is authorised provided that the limits for THC equivalents imposed by Regulation (EU) 2023/915 are observed. In its opinion, the Committee also recommends that compliance with the imposed limits be demonstrated by analysis for each batch of hemp seed or hemp seed oil.

Moreover, for food supplements and fortified foods composed of hemp seeds or products derived or processed from hemp seeds, the notification dossier must contain at least one certificate of analysis.

As such, since 1 January 2023, it has no longer been necessary to request a derogation for the use of hemp seeds and food products derived therefrom. It must always be possible to demonstrate compliance with European harmonised standards (EU 2023/915) (see question 5)

(b) Infusions of hemp leaves: with 100% water to consume as such

As regards using the leaves for infusions, there are currently no European harmonised standards for THC equivalents.

However, in 2016, the Advisory Committee for Plant Preparations issued an opinion stating that the use of the leaves of *Cannabis sativa* for infusions cannot be permitted, even if they come from varieties with low THC content. Indeed, it cannot be sufficiently guaranteed that the acute reference value for THC established by EFSA (1 µg per kg body weight per day) is respected. Furthermore, misuse of these leaves cannot be ruled out.

Based on this opinion, **placing the leaves of *Cannabis sativa* on the market for use in infusions remains prohibited**, both as/in food and in food supplements. This will continue to be the case until European harmonised standards are laid down for the safe use of the leaves.

(c) Other foods based on *Cannabis sativa* L.:

The use of foods in which other plant parts/other preparations of *Cannabis sativa* are present are considered novel foods. Consequently, use thereof is prohibited and no derogations from the prohibition imposed by the Royal Decree on Plants (31.08.2021) can be granted.

For more information, you can always contact apf.sup@health.fgov.be.

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10. Is CBD permitted in or as food?

No, CBD and CBD extracts may not be placed on the market in any form as a food or food supplement, even if they come from cannabis plants with a THC content not exceeding the 0.3% limit. Indeed, CBD is regarded as a novel food, since there is no evidence of significant consumption as a food in the European Union prior to 15 May 1997. Novel foods require prior authorisation to be placed on the market in the European Union.

This novel food status - and consequently the prohibition - applies both to the extract as such (of the whole plant or from plant parts such as the stem, leaves or flowers) and to products to which this extract is added as an ingredient (such as diluted in hemp seed oil or other edible oils). This novel food status applies to all possible types of extracts (alcoholic, CO_2 critical extraction or obtained by any other process). The level of dilution in the final product (e.g., hemp seed oil with added CBD) does not affect the novel food status.

The novel food status applies throughout the European Union: see 'cannabinoids', 'Cannabis sativa L.' in the European catalogue https://ec.europa.eu/food/safety/novel_food/catalogue_en.

Synthetically obtained cannabidiol or other cannabinoids (CBG or cannabigerol, HHC or hexahydrocannabinol) are also considered as novel foods to the extent that they are not deemed to be narcotics or medicines.

The European Food Safety Authority (EFSA) is responsible for assessing different dossiers based on synthetically obtained or naturally sourced CBD. In the context of this assessment process, it reported in June 2022 that **there are still too many uncertainties regarding the potential dangers of consuming CBD as a food ingredient. EFSA highlights the insufficient data on the effect of CBD on the liver, gastrointestinal tract, endocrine system, nervous system and on people's psychological well-being.** The data gaps need filling before the evaluations of these dossiers can go ahead Without this evaluation, it is impossible to make a decision on any authorisation for placing products containing CBD on the market. Taking into account the state of play, the authorisation of CBD in foods is not envisaged in the short term.

As such, placing products containing CBD on the market for consumption (whether or not this use is clearly stated on the packaging) is illegal.

More information on novel foods can be found at https://www.health.belgium.be/nl/voeding/voedselveiligheid/nieuwe-voedingsmiddelen/wat-een-nieuw-voedingsmiddel.

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11. Do hemp seed oil and CBD oil mean the same thing?

No. Pure hemp seed oil produced by a simple pressing of the seeds is not considered a novel food. The product can be placed on the market under the conditions stated in questions 5 and 9.

CBD oil refers to an oil that contains CBD. It is often an oil (for example, hemp seed oil or another edible oil) to which CBD or a CBD extract has been added. CBD oil is considered an unauthorised novel food (see questions 8 and 9) and cannot be placed on the market in the European Union (including via e-commerce).

More information on novel foods can be found at https://www.health.belgium.be/nl/voeding/voedselveiligheid/nieuwe-voedingsmiddelen/wat-een-nieuw-voedingsmiddel.

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12. Is it permitted to place herbal tea based on the leaves of hemp on the market?

No. Using the leaves to prepare infusions is still prohibited in Belgium. This prohibition will remain in place until European harmonised standards are laid down for the safe use of leaves. (see also question 9).

*

13. Is it permitted to place herbal tea made from the hemp flowers (*Cannabis sativa L.*) on the market?

No. The flowers cannot be used as food. The flowers of *Cannabis sativa L.* do not meet the definition of food (General Food Law EU 178/2002), as they are on the list of psychotropic substances (International Convention).

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14. Can *Cannabis sativa* be used as a source material for the production of a flavouring preparation (aroma)?

No. To date, there is no known use of cannabis as a source material for the production of a flavouring preparation within the meaning of the 'flavourings' Regulation (EC) No. 1334/2008. *Indeed, Cannabis sativa*

L. does not appear in any reference works, such as *Fenaroli's handbook on flavor ingredients* (George A. Burdock) or the Council of Europe publication 'Natural sources of flavourings' (3 volumes).

If no evidence can be provided that there is a history of safe use as a flavouring, a preliminary safety assessment of the flavouring preparation by the European Food Authority (EFSA) is necessary. Therefore, until proven otherwise, cannabis-based flavouring preparations are illegal.

Based on the European flavourings Regulation (EC) No. 1334/2008, flavouring preparations can only be obtained by certain suitable processes and/or from certain source materials, and must not present a health hazard. The annex of source materials is not currently complete in the legislation. In the meantime, reference works or other valid evidence of a history of use must be used as the basis, and it must be possible for an operator of a food company to produce such evidence.

More information on aromas and flavouring preparations can be found on the next page:

https://www.health.belgium.be/nl/voeding/specifieke-toegevoegde-stoffen/aromas/wat-een-aroma

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15. What can you do as a consumer if you have doubts that the product was lawfully placed on the market?

For food supplements, consumers can always check whether the product in question can be found in the list of notified products (products notified or updated less than 5 years ago).

If a consumer has doubts as to whether a particular product has been lawfully placed on the market, they can contact the FASFC hotline (FASFC - Consumer hotline (favv-afsca.be)).

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16. What are the conditions for using cannabis in products other than food?

Foodstuffs are distinguished from other consumer products (cosmetics, e-cigarettes, etc.) by the fact that they are REASONABLY intended to be consumed (ingested) based on how they are presented (usage instructions, composition, resemblance to other foods, etc.). ANY possible confusion with other consumer products or any form of misleading information must be avoided. A single product cannot fall under two different regulatory categories.

For example: Labels such as "this is not a food product" or "not intended for consumption" are not sufficient to automatically exclude a product from being classified as a foodstuff, if it can be reasonably determined, based on its intended use and/or presentation, that it is meant for consumption. The product's composition can also be a determining factor. For example, a product that looks like candy, is made of typical candy ingredients, but also contains CBD, and is labeled "not intended for consumption," will still be classified as

a foodstuff under food law. The overall presentation and composition of the product are considered when determining its classification. The operator is and remains responsible for placing safe products and foodstuffs on the market.

If there is uncertainty regarding whether a product should be classified as a medicinal product or a foodstuff, the classification as a medicinal product generally takes precedence. This is especially the case when the product is claimed to prevent, treat, or cure diseases, or is presented as causing significant physiological changes, which are reserved for medicinal products[3]. A product may thus be considered a medicinal product based on its function and/or its presentation.

If there is uncertainty or possible confusion regarding whether a product should be classified as a foodstuff or a cosmetic, the classification as a foodstuff takes precedence (precautionary principle), as it cannot be ruled out that the product is exclusively intended for external use. Therefore, any product that could potentially be consumed or ingested cannot be classified solely as a cosmetic.

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More information?

***For questions relating to medicines**, please contact* info.medicines@fagg.be

A question and answer list is available at
https://www.famhp.be/en/human_use/particular_products/specially_reglemented_substances/narcotics_psychotropics/frequently

***For questions related to cosmetics**, you can contact* apf.cos@health.fgov.be

***For questions related to e-cigarettes**, you can contact* apf.food@health.fgov.be

For questions related to novel foods, you can contact novelfood@health.fgov.be (FPS Public Health, Food Chain Safety and Environment)

For questions related to notifications or derogations, you can contact apf.sup@health.fgov.be (FPS Public Health, Food Chain Safety and Environment)

For questions related to the inspection, you can contact your local control unit (LCU):

[3] Royal Decree of 17 April 1980 concerning advertising for foodstuffs (consumers) and the Law of 25 March 1964 relating to medicinal products (transposition of Directive 2001/83/EC as amended by Directive 2004/27/EC).

https://www.favv-afsca.be/professionelen/contact/Ice (Federal Agency for the Safety of the Food Chain)

Disclaimer

This question and answer list is based on Regulation (EU) 2015/2283 on novel foods and the Royal Decree of 31 August 2021 on the production and trade in foodstuffs made of plants or plant preparations or which contain them.

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