



Questions & answers on the use of hemp (cannabis sativa L.) and cannabinoids (such as cannabidiol) as or within foodstuffs

Version January 2023









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1. Is there a difference between cannabis and hemp?

It is the same plant, *Cannabis sativa* L. "Hemp" refers to varieties of *Cannabis sativa* with a low THC content (< 0.2%). While the total THC content of hemp does not exceed 0.2%, that of other cannabis varieties (weed, marijuana) varies between 3 and 15%.

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2. What is THC?

THC (delta-9-tetrahydrocannabinol) is a substance belonging to the group of cannabinoids and is the psychoactive component of the plant *Cannabis sativa*. The psychoactive properties of THC imply that it has an effect on the psychological state and that it is likely to cause dependence.

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3. Is there a safe threshold for THC?

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

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4. What is meant by CBD?

CBD (Cannabidiol) is one of the different cannabinoids found in *Cannabis sativa* plants. Unlike THC, CBD has no psychoactive properties and is not addictive. Nevertheless, the use of CBD in food (including food supplements) is forbidden (see question 9).

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5. Are there European harmonized limits for THC in hemp seeds and foods derived from them?

Maximum levels for THC in hemp seeds and derived foods are laid down in Regulation (EU) 2022/1393 amending Regulation (EC) No 1881/2006. A limit of 3.0 mg/kg of 'THC equivalents' has been set for hemp seed, and 7.5 mg/kg for hemp seed oil. These maximum levels apply from **1 January 2023**. Products that do not comply with the maximum levels shall not be placed on the market. A transitional measure applies to products that have been lawfully placed on the market before; so that they can remain on the market until their minimum durability date.

6. Can Cannabis sativa based foodstuffs be marketed?

Cannabis sativa L. is included in List 1 ("Dangerous plants") of the Royal Decree of 31 August 2021 on the manufacture of and trade in foodstuffs composed of or containing plants or plant preparations. It is

¹ THC-equivalents are defined as the sum of THC and delta-9-tetrahydrocannabinolic acid (Δ 9-THCA), expressed as THC (= Δ 9-THC + 0,877 x Δ 9-THCA). This is because Δ 9-THCA can be converted to THC during food processing.





therefore prohibited to produce and place on the market foodstuffss that contain *Cannabis sativa* L., parts of that plant, or preparations from *Cannabis sativa* L.

These provisions also apply to hemp (see question 1) with a THC content of 0.2% or less.

Although products with a THC content of less than 0.2% do not fall under the law on narcotics, the limit for safe use in food is much lower (see question 5).

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7. Can derogations be obtained from the ban on marketing food products based on *Cannabis sativa* L

Article 3 §2 of the <u>Royal Decree of 31 August 2021</u> provides that derogations may be granted under specific conditions for the use of plants, mentioned in List 1, in or as foodstuffs. 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.

(a) Hemp seeds and products derived therefrom

Since January, 1st 2023, European harmonised limits for THC in hemp seeds and derived foodstuffs apply (see question 5).

Based on Article 3 §2 of the RD of 31 August 2021 and the general opinion of the Plant Commission of 4 April 2022, the use of hemp seeds and foodstuffs derived therefrom is authorised **under the condition** that, for each lot of hemp seed or derived product used, compliance with the standards for THC equivalents of the European Regulation on contaminants in food can be demonstrated via a certificate of analysis. Certificates of analysis should be presented in case of a control.

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

From 1 January 2023, no individual lot-by-lot derogations must be requested for the use of hemp seeds and food products derived therefrom.

(b) Other foodstuffs based on Cannabis sativa L.

For foods based on *Cannabis sativa* L. that do not fall within the scope of the Regulation on contaminants, an individual derogation may be granted in accordance with the provisions of Article 3 §2 of the Royal Decree of 31 August 2021 on the basis of advice from the Advisory Commission on Plant Preparations. When applying for a derogation, a toxicological and analytical dossier must demonstrate that the plant preparation no longer contains the toxic properties or substances of the plant from which the plant preparation was obtained.





Derogations can only be granted for hemp parts or preparations for which a significant history of consumption in food in the European Union before 15 May 1997 has been demonstrated. In the absence of such a history of consumption, these parts and preparations are considered novel foods and are prohibited (see questions 7 and 8).

You can find more information (in French or Dutch) on novel foods at https://www.health.belgium.be/fr/alimentation/securite-alimentaire/nouveaux-aliments/quest-ce-quunnouvel-aliment (select language).

The use of certain plant parts of *Cannabis sativa* L. may still pose a health risk due to the presence of other cannabinoids even when the THC content is very low. This applies e.g. to the use of infusion/herbal tea from leaves, stems and flowers of *Cannabis sativa* L.

Due to the health risks associated with the presence of other cannabinoids and possible abuses, no derogation will be granted for the consumption of *Cannabis sativa* L. leaves, stems and flowers in the form of infusion or herbal tea, even if a history of consumption could be demonstrated, and even when the THC content is very low

For more information, you can contact us at apf.sup@health.belgium.be.

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8. Which Cannabis sativa L. based products are NOT considered as novel foods?

Currently, there is only a demonstrated and recognized history of significant consumption as a foodstuff in the European Union before 15 May 1997 for hemp seeds and some of their derivatives (e.g. hemp seed oil, ground seeds, defatted seeds, seed cake, hemp seed protein). A derogation (see question 7) can therefore only be granted for these ingredients.

For the whole plant, the leaves and the flowers and their preparations (press of these plant parts, extracts, CBD, ...), a history of significant consumption has not been demonstrated as a food ingredient. They are therefore considered as novel foods, remain prohibited and no derogation can therefore be granted to them (see question 7).

You can find more information (in French or Dutch) on novel foods at https://www.health.belgium.be/fr/alimentation/securite-alimentaire/nouveaux-aliments/quest-ce-quunnouvel-aliment (select language).

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9. Is CBD allowed as or in foodstuffs?

No, CBD and CBD extracts cannot be marketed in any form as food or as a food supplement, even if it comes from a cannabis plant with a THC content of no more than 0.2%. CBD is considered a "novel food" because there is no evidence of its significant consumption in the European Union before 15 May 1997. Novel foods





must be subject to prior authorisation under Regulation (EU) 2015/2283 in order to be placed on the European market.

This novel food status – and as a consequence the prohibition – apply to both the extract itself and to the products to which it is added as an ingredient (such as hemp seed oil), and are independent of the type of extract (alcoholic extract, critical CO_2 extraction or via another process). Synthetic CBD is also considered as a novel food. The degree of dilution in the final product (hemp oil with the addition of CBD extract) has no influence on the novel food status.

The novel food status applies to the whole of the European Union (see https://ec.europa.eu/food/safety/novel_food/catalogue_en).

You can find more information (in French or Dutch) on novel foods at https://www.health.belgium.be/fr/alimentation/securite-alimentaire/nouveaux-aliments/quest-ce-quunnouvel-aliment (select language).

The European Food Safety Authority (EFSA) is currently evaluating several authorisation applications relating to CBD. As part of this evaluation process, it <u>communicated in June 2022</u> that there is still too much uncertainty regarding the potential dangers associated with the consumption of CBD. EFSA notes the lack of data on the potential adverse effects of CBD on the liver, gastrointestinal tract, endocrine system, nervous system and psychological well-being. In the absence of this data, the evaluation of the applications cannot be continued. However, without this assessment, it is impossible to decide on a possible authorisation for the marketing of products containing CBD.

The placing on the market of products containing CBD intended to be ingested (whether or not this use is clearly mentioned on the packaging) is therefore illegal.

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

No. Pure hemp seed oil produced by simply pressing the seeds is not considered novel food. The product can be placed on the market under the conditions listed in questions 5 and 6.

"CBD oil" means an oil containing CBD. This is often oil (e. g. hemp seed) to which CBD has been added. CBD oil is considered an unauthorised novel food (see question 8 and 9) and therefore cannot be marketed in the European Union (nor via the Internet).

You can find more information (in French or Dutch) on novel foods at the following link: https://www.health.belgium.be/fr/alimentation/securite-alimentaire/nouveaux-aliments/quest-ce-quunnouvel-aliment (select language).

*





11. Can we make herbal teas from flowers or cannabis leaves?

No. Due to the health risks associated with the presence of other cannabinoids and possible abuses, no derogation will be granted for the use of *Cannabis sativa* leaves and flowers in the form of infusion or tea, even when the THC content is very low. For more information on this subject, see question 6. Furthermore, those parts are regarded as novel foods and are therefore prohibited.

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

No. There is no known history of use of *Cannabis sativa* L. as source material for the production of a flavouring preparation as defined in the Flavouring regulation (EU) No 1334/2008. *Cannabis sativa* L. is not mentioned in any reference book on flavourings, such as Fenaroli's handbook on flavor ingredients (George A. Burdock) or the publications of the Council of Europe 'natural sources of flavourings' (3 volumes).

In case no evidence can be provided of a safe history of use as flavouring, a pre-market evaluation of the flavouring preparation by the European Food Safety Authority (EFSA) is required. Until proof of the contrary, flavourings based on Cannabis sativa L. are illegal.

On the basis of the Flavouring Regulation (EU) No 1334/2008 flavouring preparations may only be obtained by specific appropriate processes and/or from certain source materials and they may not raise safety concern for human health. The annex with source of materials of the legislation is not yet completed. In the meantime, reference books can be used as a basis or the food business operator should be able to provide other valid proofs of a history of use.

More information on flavouring and flavouring preparations can be found on following page:

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

https://www.health.belgium.be/fr/alimentation/substances-specifiques-ajoutees/aromes/quest-ce-quunarome

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13. As a consumer, what can you do if you have doubt 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 <u>list of notified products</u> (products notified or updated less than five years ago).

In case of doubt as to whether a particular product was lawfully placed on the market, the FASFC contact point can be contacted (AFSCA - Point de contact pour les consommateurs (favv-afsca.be)).

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14. What are the conditions for using cannabis in products other than foodstuffs? For questions about medicines, you can contact: info.medicines@fagg.be.

A FAQ in French and Dutch) is available at the following link:

https://www.afmps.be/fr/humain/produits particuliers/subst specialement reglementees/stupefiants et psychotropes/fag cannabis.

For questions regarding cosmetics, you can contact: apf.cos@health.fgov.be.

For questions regarding e-cigarettes, you can contact: apf.food@health.fgov.be

More information?

<u>apf.food@health.fgov.be</u> (Federal Public Service Health, Food Chain Safety and Environment) S3.pccb@favv-afsca.be (Federal Agency for the Safety of the Food Chain)

Disclaimer

This FAQ is based on Regulation (EU) 2015/2283 on novel foods and the Royal Decree of 31 August 2021 on the manufacture of and trade in foodstuffs composed of or containing plants or plant preparations.

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