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INFORMATION

From: To:	General Secretariat of the Council Delegations
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Subject:	Working Party on Agricultural Products on 5 November 2026 - Commission presentation on food and feed safety legislation of hemp-derived products

Food and feed safety legislation of hemp-derived products



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The views expressed are purely those of the speaker and may not in any circumstances be regarded as stating an official position of the European Commission

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NOVEL FOOD

Health and Food Safety

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- ✓ Novel Food Regulation (NFR) – Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods
- ✓ 'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories

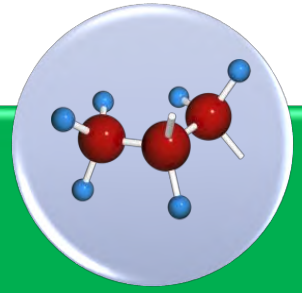
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Novel Food Categories



New production process



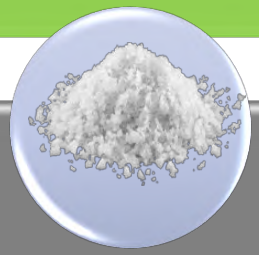
New or modified molecular structure



Micro-organisms, fungi, algae



From plants or their parts



Mineral origin



From animals or their parts



cell or tissue cultures derived from animals/ plants/fungi/ algae



Engineered nanomaterials

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EU legislation and hemp-derived foods

➢ Reg. 178/2002 (GFL). Food: "*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*", except (amongst others):

- ✓'medicinal products' within the meaning of the Medicinal Products Directive 2001/83/EC;
- ✓ 'narcotic or psychotropic substances' within the meaning of the 1961 and 1971 UN Conventions.

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EU legislation and hemp-derived foods

- Where products qualify as 'food', they are subject to the EU acquis applicable to food. Those acts seek to ensure:
  - ✓The effective functioning of the internal market; and
  - ✓The safety of food to guarantee a high level of protection of human life and consumers' interests.
- This acquis includes rules on **novel foods**, **contaminants**, food labelling, food supplements, etc.

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EU legislation and hemp-derived foods

- Hemp seeds, hemp seed oil, ground hemp seeds, (partially) defatted hemp seeds and other hemp seed-derived food for which a history of consumption has been demonstrated are not novel.
- A history of consumption in the EU has also been demonstrated for the water infusion of hemp leaves (when not accompanied by the flowering and fruiting tops) consumed as such or as part of herbal infusions. Such use(s) is(are) therefore not novel. Only varieties of *Cannabis sativa* L. listed in the EU's Common Catalogue of Varieties of Agricultural Plant Species (referred to as hemp) may be used for water infusion of hemp leaves.

CBD

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- ✓ From Jan 2019 on, all Member States considered that no history of consumption was demonstrated for food containing *Cannabis sativa* L. extracts (e.g. cannabidiol) and that these should thus be considered as 'novel', regardless of the levels of CBD in the source material.
- ✓ This position was entered into the Novel Food Status Catalogue, a non-binding instrument that lists the status of various food products as regards their 'novel' status.

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EU legislation and hemp-derived foods

- CBD and other products derived from the hemp plant as 'foods': it must be carefully considered whether the concerned products can qualify as 'food' or if they qualify as 'medicinal products' or 'narcotic or psychotropic substances.

  - ✓ As regards CBD, the Court of Justice of the European Union concluded that CBD should not be considered as 'drug' in so far as it does not have psychotropic effect (C-663/18):

"since CBD does not contain a psychoactive ingredient in the current state of scientific knowledge […]*, it would be contrary to the purpose and general spirit of the Single Convention to include it under the definition of 'drugs' within the meaning of that convention as a cannabis extract."*

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EU legislation and hemp-derived foods

The Commission considers that:

- CBD and other non-psychoactive cannabinoids extracted from any part of the hemp plant may be qualified as food, provided that also the other conditions regarding the definition of food in the General Food Law (Regulation (EC) No 178/2002) are met.
- The same is valid for 'synthetic' CBD, which is not extracted from the plant.
- PAFF meeting-27 Feb 2023. Statement on CBD. It is a NF. Endorsed by MS.

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CBD: Currently submitted under two NF categories

(i) food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;

…..

(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species …..

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Overview of CBD applications

- Over 190 CBD applications received by EC.
- Majority of applications submitted during the period 2019-2021.
- UK FSA. CBD is allowed to remain on the market if a valid applications are submitted by 31 March 2021 (It was misunderstood that the UK rule could also be applicable in the EU).
- Only 18 CBD dossiers are under European Food Safety Authority Risk assessment.
- To date, here has been no authorisation of CBD, of any other cannabinoids, nor of products containing either CBD and/or other cannabinoids derived from the *Cannabis sativa* L. plant under the NFR.

EFSA – ASSESSMENT OF CBD

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Previous authorisations

CBD is not authorized as Novel Food. Exposure to THC should not exceed the Acute Reference Dose of 1 μg/kg bw per day (70 μg day in adults) set by EFSA CONTAM Panel.

Recent publications

- In 2022 EFSA published a Statement identifying data gaps and uncertainties for the evaluation of Cannabidiol.
- An update of this statement was published for public consultation on 09/09/2025.

EFSA ASSESSMENT OF CBD
PREVIOUS STATEMENT (JUNE 2022)

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OUTCOME IN A NUTSHELL

DATA GAPS:

- Liver
- Neurological, psychiatric and psychologic effects
- Endocrine and reproductive system
- Gastrointestinal tract
- Pharmacokinetic
- Presence of small particles

DATA REQUESTED:

- Human clinical trial
- Extended One-Generation Reproductive Toxicity Study (OECD TG 443)
- Data on presence of small particles

EFSA ASSESSMENT OF CBD
CONCLUSION OF THE UPDATE OF THE STATEMENT

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PUBLISHED FOR **PUBLIC CONSULTATION ON 09/09/2025**

- The new literature published since the EFSA CBD Statement (EFSA NDA Panel, 2022) is not sufficient to address the data gaps and uncertainties previously identified.
- Uncertainties remain regarding the effects of long-term consumption of CBD on liver, reproductive and immune systems, as well as on neurological function and kinetic behaviour.
- Data gaps related to neuronal development are of particular concern, especially considering that this process continues in humans between 18 and 25 years of age. Additionally, CBD interacts with drug metabolising enzymes, indicating a potential for interactions with medicinal drugs.
- Taking all of the above into account, the safety of CBD as a novel food cannot be established for doses exceeding 0.0275 mg/kg body weight per day, which corresponds to 2 mg/day for a 70 kg adult, until the relevant safety data become available.
- This provisional value applies exclusively to CBD formulations with a purity greater than 95%, consumed as food supplements, that do not involve exposure to small particles, including nanoparticles, and for which genotoxicity has been ruled out.
- The safety of CBD use in individuals under 25, pregnant or lactating women, and those on concurrent medications, cannot be established.

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FOOD CONTAMINANTS

Health and Food Safety

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Council Regulation 315/93

Regulatory framework for contaminants in food:

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

(this Regulation does not apply to contaminants which are the subject of more specific Union rules, such as pesticide residues, veterinary drug residues, …)

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Regulation 315/93 Provisions

- General provision:
  - **food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market**
- Good practice:
  - **Contaminant levels shall be kept as low as can reasonably be achieved following good practices at all stages (ALARA)**

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Regulation 315/93 Provisions

When necessary for protecting public health maximum levels shall established for specific contaminants --> Procedure for setting maximum levels. This can also include a reference to the sampling and analysis methods to be used.

Obligatory consultation of the European Food Safety Authority(EFSA) Panel on contaminants in the food chain before provisions having effect upon public health shall be adopted.

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Regulating contaminants in EU

- Outcome of the EFSA risk assessment on the health risks related to the presence of a certain contaminant in food is the basis for regulatory measures .
- Presence of contaminant in food is to a certain extent unavoidable.
- Maximum levels as a possible risk management measure to be established following the As Low As Reasonable Achievable (ALARA) principle applying good practices along the production and distribution chain.
- Maximum levels are established in Commission Regulation (EU) 2023/915 on maximum levels for certain contaminants in food

Contaminants for which maximum levels have been established - Regulation (EU) 2023/915

- **Mycotoxins**: aflatoxins, ochratoxin A, patulin, Fusarium-toxins (zearalenone, fumonisins, deoxynivalenol, T-2 and HT-2 toxin), ergot sclerotia, ergot alkaloids, citrinin
- **(Heavy) metals**: lead, cadmium, mercury, inorganic tin, inorganic arsenic, nickel
- **Other environmental contaminants**: dioxins, dioxin-like PCBs, PAH, non-dioxin-like PCBs, PFAS
- **Processing/industrial contaminants:** 3-MCPD, inorganic tin, PAH, 3- MCPD esters and glycidyl esters, furan…(acrylamide: no ML –benchmark levels)
- **Inherent plant toxins**: erucic acid, opium alkaloids, pyrrolizidine alkaloids, tropane alkaloids, hydrocyanic acid, **Δ-9-THC**,
- Nitrates, melamine, perchlorate

EFSA assessment of Delta-9-THC

In 2015, EFSA adopted a scientific opinion on the risks to human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin . THC, more precisely Δ9-THC, is the most relevant constituent of the hemp plant *Cannabis sativa*. The Authority established an acute reference dose (ARfD) of 1 µg Δ9-THC/kg body weight (bw).

In order to obtain more data on the presence of Δ9-THC and other relevant non-psycho-active precursors in hemp-derived foods and foods containing hemp or hemp-derived ingredients, Commission Recommendation (EU) 2016/2115 was adopted.

On 7 January 2020, the Authority published a scientific report assessing acute human exposure to Δ9-THC, taking into account the occurrence data generated through Recommendation (EU) 2016/2115. The ARfD of 1 µg/kg bw was exceeded in certain acute exposure estimates. Although the exposure estimates are expected to overestimate acute exposure to Δ9-THC in the Union, the exposure to Δ9-THC is a potential health concern.

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Maximum levels of Δ9-THC - Commission Regulation (EU) 2022/1393 of 11 August 2022 (consolidated /integrated in Commission Regulation (EU) 2023/915)

Food	ML for THC (*) mg/kg
Hemp seeds	3.0
Ground hemp seeds, (partially) defatted hemp seed and other hemp seed derived/processed products (**) with the exception of hemp seed oil	3.0
Hemp seed oil	7.5

(*) the maximum level refers to the sum of delta-9-tetrahydrocannabinol (Δ9-THC) and delta-9-tetrahydrocannabinolic acid (Δ9-THCA), expressed as Δ9-THC. A factor of 0,877 is therefore applied to the level of Δ9-THCA in case it is analysed separately

(**) hemp seed derived/processed products are products derived/processed exclusively from hemp seeds

ML - Delta-9-THC in hemp leaves for infusion – under finalisation

- An **ML of 40 mg/kg of Δ9-THC in hemp leaves for infusion**
  - Requirement to label clearly that the hemp leaves are destined for infusion only
  - The hemp leaves for infusion are not allowed to be used to prepare beverages for infants and young children.
  - The ML should apply without prejudice to more restrictive national rules (i.e. bans) in certain Member States on the placing of the market of THC containing plants/plant parts

- **An ML of 0,02 mg/kg of Δ9-THC in hemp beverages ready to drink** placed on the market for the final consumer

Delta-8 THC

- Scientific opinion of 9 October 2025 on the derivation of a health-based guidance value for **delta 8-tetrahydrocannabinol (Δ8-THC)** and its occurrence in food

- **Main conclusion :**
  In this Opinion no new evaluation of Δ9-THC was performed. An ARfD of 1 µg Δ9-THC/kg b.w has been previously set by CONTAM Panel on (EFSA CONTAM Panel, 2015). Given the similarity in the effects and mode of action between Δ8-THC and Δ9-THC**, the ARfD derived for Δ9-THC can be considered applicable as a group ARfD for for the sum of Δ^8- and Δ^9 THC.**

- Regulatory follow-up still to be decided

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FEED

Feed materials and contaminants (undesirable substances)

European Commission

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Feed materials

In accordance with Article 24 of Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, **a Catalogue of feed materials** was established by Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials.

Pursuant to that Regulation, the Catalogue is not an exhaustive list of feed materials, however the name of a feed material listed in the Catalogue may be used only for a feed material complying with the requirements of the entry concerned.

PUBLIC

Feed materials

The only hemp derived feed materials currently listed in the Catalogue of feed materials are hemp seed, hemp expeller, hemp seed oil, hemp flour and hemp fibre, which are derived from hemp seeds and stems and therefore considered safe for use in animal nutrition.

PUBLIC

Commission Regulation (EU) 2022/1104 of 1 July 2022 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials

Hemp seed	**Seeds** from varieties of *Cannabis sativa* L. with a tetrahydrocannabinol content < 0.2% (to be updated to 0,3 %) according to the quantification method established in Regulation (EU) No 639/2014 (to be updated to Commission Delegated Regulation (EU) 2022/126)
Hemp expeller	Product of oil manufacture obtained by pressing **hemp seeds** from varieties of *Cannabis sativa* L. with a tetrahydrocannabinol content < 0.2% (to be updated to 0,3 %) according to the quantification method established in Regulation (EU) No 639/2014 (to be updated to Commission Delegated Regulation (EU) 2022/126)

European Commission

PUBLIC

Commission Regulation (EU) 2022/1104 of 1 July 2022 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials

Hemp seed oil	Oil obtained by pressing of **hemp seeds** from varieties of *Cannabis sativa* L. with a tetrahydrocannabinol content < 0.2% (to be updated to 0,3 %) according to the quantification method established in Regulation (EU) No 639/2014 ((to be updated to Commission Delegated Regulation (EU) 2022/126)

PUBLIC

Commission Regulation (EU) 2022/1104 of 1 July 2022 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials

Hemp flour	Flour ground from **stems from hemp** from varieties of *Cannabis sativa* L. with a tetrahydrocannabinol content < 0.2% (to be updated to 0,3 %) according to the quantification method established in Regulation (EU) No 639/2014 (to be updated to Commission Delegated Regulation (EU) 2022/126)
Hemp fibre	Product obtained during the mechanical processing of **hemp stems** from varieties of *Cannabis sativa* L. with a tetrahydrocannabinol content < 0.2% (to be updated to 0,3 %) according to the quantification method established in Regulation (EU) No 639/2014 (to be updated to Commission Delegated Regulation (EU) 2022/126)

Commission Regulation (EU) 2022/1104 on the Catalogue of feed materials

Forage meal; [green meal]	Product obtained by drying and milling and in some cases compacting forage plants (*)
Blossoms(*), dried	All parts of dried blossoms of consumable plants and their fractions
Leaves (*), dried	Dried leaves of consumable plants and their fractions
Products from the processing of plants	Products obtained from freezing or drying whole plants (*) or their parts
Powder cellulose	Product obtained by decomposition, separation of lignin and further cleaning as cellulose from vegetable fibre (*) of untreated wood and which is modified by mechanical processing only. Neutral detergent fibre (NDF) minimum 87%

(*) With the exception of *Cannabis sativa L.*

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Use of other hemp-derived feed materials in animal feed

Regulation (EC) No 767/2009 on the placing on the market and use of feed provides for a list of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited.

In 2011, the European Food Safety Authority adopted a scientific opinion on the safety of hemp for use as animal feed . In its opinion, the Authority concluded that the use of whole hemp plant-derived feed materials in animal nutrition is, due to the THC content, not safe for the consumer of milk produced by animals fed with those feed materials

Given that the content of tetrahydrocannabinol (THC) differs on the part of the plant that is considered, discussions are currently ongoing to possibly restrict/prohibit the use of certain parts of the hemp plant (*Cannabis* sp.) (such as flowering tops) for the production of feed materials for animal nutrition.

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Use of CBD in feed

The use of cannabidiol (CBD) in feed requires a pre-market authorisation of CBD as feed additive in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition and currently CBD is not authorised as feed additive.

PUBLIC

Contaminants/undesirable substances in feed - Regulatory approach

- Maximum levels for feed materials and compound feed in Directive 2002/32/EC on undesirable substances in feed
- Commission establishes/modifies maximum and/or action levels (12 % moisture content)
- Obligatory consultation of the European Food Safety Authority (EFSA) Panel on contaminants in the feed/food chain before provisions having effect upon public health or animal health or the environment

PUBLIC

Maximum levels for delta-9-THC in feed

- Already in 2011, EFSA in its scientific opinion on the safety of hemp concluded that the use in feed of hemp-derived feed materials should be restricted due to the presence of Δ9-tetrahydrocannabinol (Δ9-THC) to ensure a high level of human health protection.
- Maximum levels for Δ9-THC for certain hemp-derived products intended for human consumption are established by Commission Regulation (EU) 2023/915.
- As these maximum levels are achievable by applying good practices regardless of whether these hemp-derived products are destined for food or feed, it is appropriate to establish corresponding maximum levels for relevant feed materials (those listed in the Catalogue of feed materials) and complete feed.

PUBLIC

Amendment to Directive 2002/32/EC - Maximum levels for Δ9-THC in feed – Under finalisation

Undesirable substance	**Products intended for animal feed**	**Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %**
"6. Delta-9-tetrahydrocannabinol (Δ^9-THC) (*)	Feed materials - hemp seed - hemp expeller - hemp seed oil - hemp flour - hemp fibre Complete feed	 3.0 3.0 7.5 7.5 7.5 0.5

(*) the maximum level refers to the sum of delta-9-tetrahydrocannabinol (Δ^9-THC) and delta-9-tetrahydrocannabinolic acid (Δ^9-THCA), expressed as Δ^9-THC. Therefore, a factor of 0.877 is applied to the level of Δ^9-THCA and the maximum level refers to the sum of Δ^9-THC + 0.877 Δ^9-THCA.

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European Commission, DG Health and Food Safety website

https://food.ec.europa.eu/food-safety_en