



CDG Arable crops - Cotton, Flax and Hemp sectors

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CBD as novel food and THC as a contaminant in hemp-derived products

European Commission,
DG Health and Food Safety (SANTE)

Unit E2 'Food processing technologies and novel foods'

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

EU legislation and hemp-derived foods

➤ 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;
- ✓ ‘narcotic or psychotropic substances’ within the meaning of the 1961 and 1971 UN Conventions.

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."

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.

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.

Scope of the NF Regulation



It does not apply to

- (a) **genetically modified foods** falling within the scope of Regulation (EC) No 1829/2003;
- (b) **foods** when and in so far as they are used as:
 - (i) *food enzymes* falling within the scope of Regulation (EC) No 1332/2008;
 - (ii) *food additives* falling within the scope of Regulation (EC) No 1333/2008;
 - (iii) *food flavourings* falling within the scope of Regulation (EC) No 1334/2008;
 - (iv) *extraction solvents* used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC.

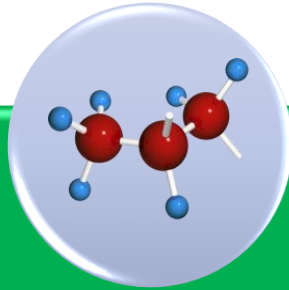
Definition and categories



Definition: Food not used for human consumption to a significant degree before 15 May 1997 and that falls under at least one of the 10 listed categories



New production process



New or modified molecular structure



Micro-organisms, fungi, algae



From plants or their parts



Of mineral origin



From animals or their parts



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



Engineered nanomaterials

Determination of the NF status: Consultation

- Art 4(1) NFR: food business operators shall verify whether or not the food, which they intend to place on the EU market, qualifies as a novel food
- Art 4(2) NFR: If FBOs are still unsure about a food as novel, they shall consult the competent authorities of the EU country where they first intend to place the food on the market. Commission Implementing Regulation (EU) 2018/456
- List of MS CA: https://ec.europa.eu/food/safety/novel-food/consultation-process-novel-food-status_en
- **To date, no request under Article 4 has been submitted to MS ref CBD extracted from hemp as a complex mixture.**

Publication of consultation process



To date, 68 NF status published

CBD isolate (purity > 98%)	Novel when used as or in foods.	View document { EN ... }	Category 3.2 (a)(iv)
Celastrus orbiculatus Thunb. - fruit	Novel when used as or in foods.	View document { EN ... }	Category 3(2)(a(iv))
Chlamydomonas reinhardtii dried biomass powder	Novel when used as or in foods.	View document { EN ... }	Category 3.2 (a)(ii)
Chrysanthemum morifolium Ramat. - plant	Novel when used as or in foods.	View document { EN ... }	Category 3(2)(a(iv))
Coix lacryma-jobi L. – seeds	Not novel in food supplements.	View document { EN ... }	
Cold pressed Nigella sativa seed oil	Not novel when used as or in foods.	View document { EN ... }	
Coprinus comatus dehydrated mycelium powder	Novel when used as or in foods.	View document { EN ... }	Category 3.2 (a)(ii)
Curcumin, extract complex from the root of Curcuma longa L.	Novel when used as or in foods.	View document { EN ... }	Article 3(2)(a(iv))

Novel Food Catalogue



The Novel Food Catalogue is a non-exhaustive and non-binding database which aims to document Member States' discussions on the 'novel' character of specific products, namely on whether they were used for human consumption to a significant degree within the Union before 15 May 1997 or not. The Catalogue presents the outcome of discussions within the Working Group on Novel Foods.

It can give an indication to food business operators about the position taken by Member States on certain products. However, **it does not replace the applicable procedures laid down in the applicable legislation**, including Regulation (EU) 2015/2283 and Regulation (EU) 2017/2470.

CBD: Currently submitted under two 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

CBD and the Novel Food Regulation

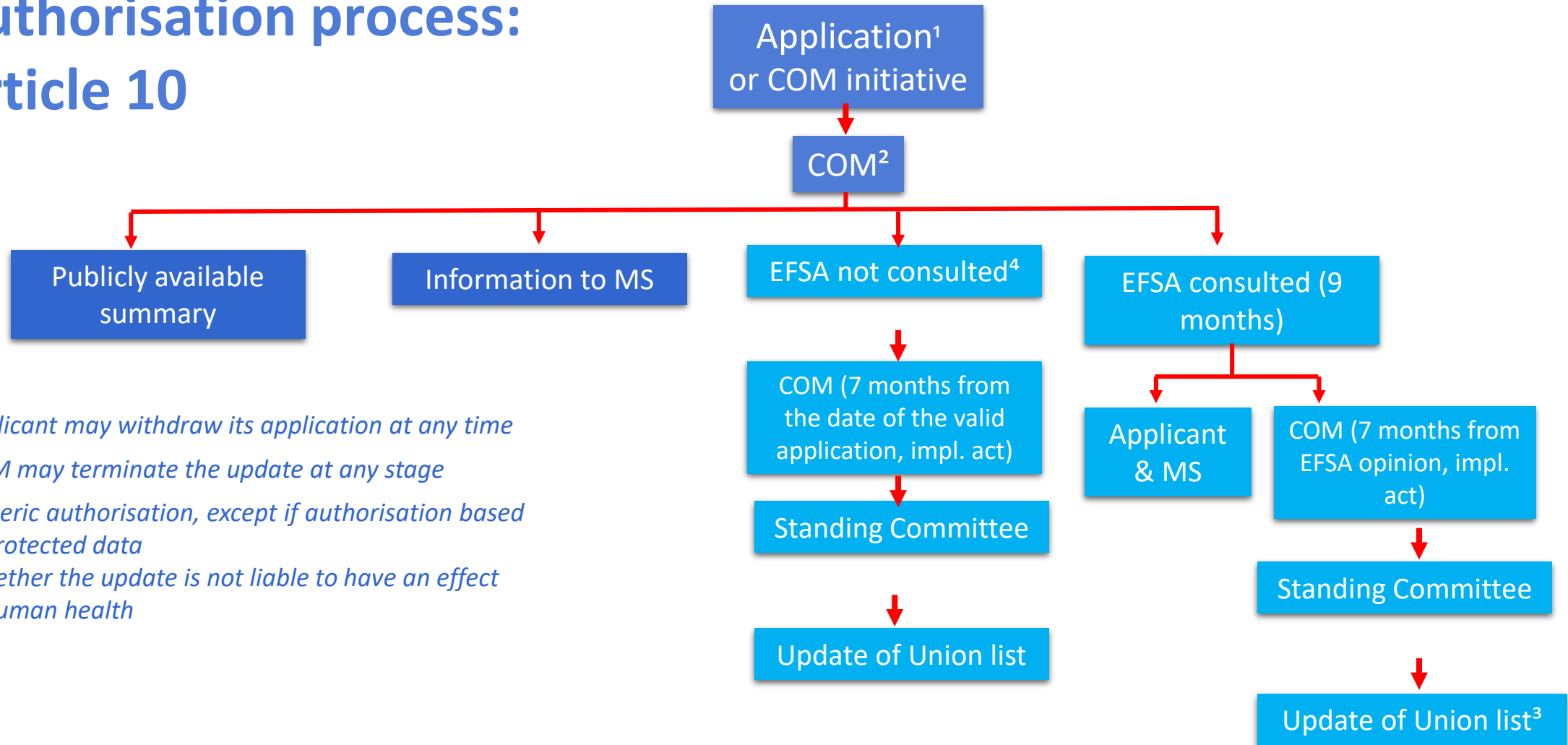


- ✓ Prior to Jan 2019, the NFC was amended twice as regards hemp and hemp-derived products.
- ✓ Extraction solvents used in the production of foods are subject to Directive 2009/32/EC. While extraction solvents are not in the scope of the Novel Food Regulation, foods resulting from processes involving extraction solvents may qualify as novel foods, regardless of the nature of the solvents used.
- ✓ Since 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.



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Authorisation process: Article 10



¹Applicant may withdraw its application at any time

²COM may terminate the update at any stage

³Generic authorisation, except if authorisation based on protected data

⁴Whether the update is not liable to have an effect on human health

EFSA Novel Food Guidance (2016)



- Administrative data
- Introduction
- Identity of the novel food
- Production process
- Compositional data
- Specifications
- History of use of the novel food and of its source
- Proposed uses and use levels and anticipated intake
- Absorption, distribution, metabolism, and excretion

- Nutritional information
- Toxicological information
- Allergenicity
- Concluding remarks
- Annexes, References

EFSA shall consider the following:

- ✓ whether the Novel Food in question is **safe**
- ✓ whether the composition of the food and the conditions of its use **do not pose a safety risk** to human health in the Union
- ✓ whether the normal consumption of the NF/TF would be **nutritionally disadvantageous** for the consumer

CBD and the Novel Food Regulation



From 1 Jan 2018 to 26 March 2021 - FSCAP	N*
CBD applications (extracted from hemp plant)	108
Synthetic CBD applications	6
Total	114
From 27 March 2021 - ESFC	
CBD applications (extracted from hemp plant)	43
Synthetic CBD applications	0
Total	43



State of CBD applications	N*
Validity Check by EC	88
Suitability/Completeness Check by EFSA	8
EFSA risk assessment	18

State of CBD applications	N*
Validity Check by EC	38
Suitability/Completeness Check by EFSA	5
EFSA risk assessment	0

THC as contaminant in food



EFSA scientific opinion 2015 on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin.

The CONTAM Panel derived an **acute reference dose (ARfD) of 1 µg Δ9-THC/kg b.w.**

The exposure estimates in the 2015 EFSA opinion related to the presence of Δ9-THC in milk, and were calculated to be at 3 % and 13 % the ARfD, in adults and toddlers, respectively..

THC as contaminant in food



Commission Recommendation (EU) 2016/2115 of 1 December 2016 on the monitoring of the presence of Δ 9-tetrahydrocannabinol, its precursors and other cannabinoids in food (food of animal origin/hemp derived food)

EFSA report on acute exposure published in January 2020.

The EFSA ARfD of 1 $\mu\text{g}/\text{kg}$ bw was exceeded in the adult high consumers of most considered hemp and hemp-containing products.

The use of proxies for the consumption, the limited number of occurrence data and the analytical limitations in the quantification of Δ 9-THC represent the most important sources of uncertainty. Overall, the exposure estimates are expected to be an overestimation of acute exposure to Δ 9-THC in the EU.

THC as contaminant in food



Maximum levels for Δ 9-THC in food - adoption procedure ongoing Foreseen entry into application: 1 January 2023

FOOD	MAXIMUM LEVELS (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 (Δ 9-THC) and delta-9-tetrahydrocannabinolic acid (Δ 9-THCA), expressed as Δ 9-THC. A factor of 0,877 is therefore applied to the level of Δ 9-THCA in case it is analysed separately

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

Hemp entries in feed catalogue (updated)

Hemp seed	Seeds from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014
Hemp expeller	Product of oil manufacture obtained by pressing hemp seeds from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014
Hemp seed oil	Oil obtained by pressing of hemp seeds from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014
Hemp flour	Flour ground from stems from hemp from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014
Hemp fibre	Product obtained during the mechanical processing of hemp stems from varieties of <i>Cannabis sativa</i> L. with a tetrahydrocannabinol content < 0.2% according to the quantification method established in Regulation (EU) No 639/2014

Feed materials in catalogue



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.*

THC as contaminant in feed



Maximum levels for Δ^9 -THC in feed – Under discussion

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	3.0
	- hemp expeller	3.0
	- hemp seed oil	7.5
	- hemp flour	20
	- hemp fibre	20
	Complete feed	1.0

(*) 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.



European Commission, DG Health and Food Safety website
https://ec.europa.eu/food/food/novel-food_en

Functional mailbox: SANTE-NOVELFOODS@ec.europa.eu