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CANNABIDIOL (CBD) AND HEMP: NOVEL FOOD STATUS IN THE EU

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Background

In November 2015, the European Parliament and the Council of the European Union adopted a new regulation on novel food, Regulation (EU) 2015/2283, with the intent of making the novel food authorization process more efficient while ensuring high standards of food safety for consumers. This new Regulation came into force on 1 January 2018. It amended Regulation (EU) No 1169/2011, and repealed and replaced prior regulations Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 which were in place until 31 December 2017. [1]

The main purposes of the new Regulation include:

- To ensure human health and consumer interests are protected
- To optimize the function of the internal food market
- To review and update the 1997 novel foods legislation to include current technological and scientific developments in the food industry
- To make the novel food authorization process more efficient
- To ensure foods that are new to the EU market undergo a thorough pre-market authorization and safety evaluation process

What is the definition of novel food under the new Regulation?

The definition of novel food has not changed from the previous regulations. Novel food is defined as "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 the Member States to the Union", and falls under at least one of ten specified food categories detailed in Article 3 of the Regulation. [2]

According to the European Commission:

> *'Novel Food' can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside of the EU.*
>
> *Examples of Novel Food include new sources of vitamin K (menaquinone) or extracts from existing food (Antarctic Krill oil rich in phospholipids from Euphausia superba), agricultural products from third countries (chia seeds, noni fruit juice), or food derived from new production processes (UV-treated food (milk, bread, mushrooms and yeast).*

The underlying principles underpinning Novel Food in the European Union are that Novel Foods must be:

- *Safe for consumers*
- *Properly labelled, so as not to mislead consumers*
- *If novel food is intended to replace another food, it must not differ in a way that the consumption of the Novel Food would be nutritionally disadvantageous for the consumer.*

Pre-market authorization of Novel Foods on the basis of an evaluation in line with the above principles is necessary. [3]

What are examples of guidance from food regulators regarding hemp and CBD as novel foods?

Guidance from food regulators in Denmark:

Denmark released a guidance document on regulations for food containing cannabidiol (CBD) in October 2018. In it, authorities state that:

> *Rules for marketing in Denmark food, including food supplements, containing the active substance cannabidiol (CBD) from the hemp plant (Cannabis sativa L.)…must generally comply with food legislation including Regulation 2015/2283 on novel food, which says that food which have not been used for human consumption to a significant degree in the Union before 15 May 1997 shall be subject to risk assessment and authorization prior to the placing on the market, and Article 14 of the Food Regulation according to which food must not be unsafe.* [2]

Denmark's guidance document specifies that hemp seeds and products derived from hemp seed including hemp flour, protein powder and oil are not considered novel foods as long as they are produced from "the hemp plant (*Cannabis sativa* L.) listed in the Community catalogue of plant varieties, which are free of or contain low levels of tetrahydrocannabinol (THC)". It goes on to state that as there is no evidence that other parts of the hemp plant, including flowers, leaves and extract from different plant parts, were being consumed as food prior to 15 May 1997, and therefore these are considered to be novel food. However, it also states that if new information is provided by a Member State confirming that the flowers, leaves and extracts of hemp were commonly considered as a significant food source, and were marketed as food prior to 15 May 1997, the EU Novel Food Catalogue will need to be updated to include the parts of the hemp plant that do not fall under the novel foods regulation. [2]

Guidance from food regulators in Ireland:

The Food Safety Authority of Ireland's CBD Oils and Hemp Oils – Legal Status FAQ web page states that:

> *If the CBD oil is extracted using particular extraction methods, like using solvents or supercritical CO_2 extraction, you cannot sell it in the EU (unlike CBD oil extracted simply by pressing e.g. cold pressing). It is important that you know how the CBD oil has been extracted.* …
>
> *Generally speaking, hemp oil obtained by cold-pressing the seeds or other parts of the hemp plant does not require authorization. This is because hemp oil was consumed in the EU to a significant degree before 1997 (see entry for Cannabis sativa L in the EU Novel Food Catalogue).*
>
> *If, however, the CBD/hemp oil is subjected to certain forms of extraction or purification techniques, then a novel food authorization may be required, as there may be an accompanying increase in undesirable constituents. A typical example is hemp oil subjected to supercritical CO_2 extraction.*
> …
>
> *A number of products with names such as hemp oil, hemp seed oil, cannabidiol oil, CBD oil or CBD hemp oil recently entered the Irish market. These products are derived from the hemp plant (Cannabis sativa). They are typically marketed as food supplements (or dietary supplements) in liquid or capsule form. Oil is obtained from the hemp plant by cold-pressing the seeds or other parts of the hemp plant. This oil naturally contains low levels of cannabidiol (CBD), a non-psychoactive compound. CBD can also be chemically extracted from hemp to produce products with a higher CBD content.* [4]

What are the main features of the new Regulation?

The new Regulation includes improvements put in place to facilitate the addition of new foods to the EU market, while maintaining superior safety for consumers. [5]

The European Commission describes some of the updates to the new Regulation as follows:

1. ***Expanded categories of Novel Foods:*** *The Novel Food definition describes the various situations of foods originating from plants, animals, microorganisms, cell cultures, minerals, etc., specific categories of foods (insects, vitamins, minerals, food supplements, etc.), foods resulting from production processes and practices, and state of the art technologies (e.g. intentionally modified or new molecular structure, nanomaterials), which were not produced or used before 1997 and thus may be considered to be as novel foods.*

2. ***Generic authorizations of Novel Foods:*** *Under the new Regulation, all authorizations (new and old) are generic as opposed to the applicant-specific, restricted novel food authorizations under the old Novel Food regime. This means that any food business operator can place an authorized Novel Food on the European Union market, provided the authorized conditions of use, labelling requirements, and specifications are respected.*
3. ***Establishment of a Union list of authorized Novel Foods:*** *This is a positive list containing all authorized novel foods. Novel Foods which will be authorized in the future will be added to the Union list by means of Commission Implementing Regulations. Once a novel food is added to the Union list, then it is automatically considered as being authorized and it can be placed in the European Union market.*
4. ***A simplified, centralized authorization procedure*** *managed by the European Commission using an online application submission system.*
5. ***Centralized, safety evaluation of the Novel Foods*** *will be carried out by the European Food Safety Authority (EFSA). The European Commission consults EFSA on the applications and bases its authorization decisions on the outcome of the EFSA's evaluation.*
6. ***Efficiency and transparency*** *will be improved by establishing deadlines for the safety evaluation and authorization procedure, thus reducing the overall time spent on approvals.*
7. ***A faster and structured notification*** *system* ***for traditional foods from third countries*** *on the basis of a history of safe food use. To facilitate the marketing of traditional foods from countries outside the EU, which are considered novel foods in the EU, the new Regulation introduces a simplified assessment procedure for foods new to the EU. If the safety of the traditional food in question can be established on the basis of evidence of a history of consumption in the third country, and there are no safety concerns raised by the EU countries or EFSA, the traditional food will be allowed to be placed on the European Union market.*
8. ***Promotion of innovation*** *by granting an individual authorization for five years based on protected data. Data protection provisions are included in the new Regulation. That means that an applicant may be granted an individual authorization for placing on the market of a novel food. This is based on newly developed scientific evidence and proprietary data and is limited in time to 5 years.* [5]

Who is responsible for determining the novel food status for a food product?

According to Article 4 of the new Regulation, food business operators are responsible for verifying whether or not the food they would like to place on the EU market is considered a novel food. If the food business operator is still unsure of the novel food status of the food after consulting all the available information (including the new Regulation (EU) 2015/2283, the Union List of Novel Foods, and the EU Novel Food Catalogue), the food business operator should check the status of their food with the authorities in the Member State in which they plan to place the food on the market first.

How does a food business operator consult a Member State to clarify novel food status?

The process for consulting a Member State to clarify novel food status is governed by the Commission Implementing Regulation (EU) 2018/456, and the contact list of the authorities responsible for the consultation process of novel food status can be found here.

The general steps are as follows:

1. Identify the Member State in which the food will be marketed first, or choose one of the Member States if more than one will be marketed at the same time.
2. Submit a consultation request electronically to the Member State. Per Article 4 of Regulation (EU) 2018/456, the consultation request should include a cover letter, a technical dossier, supporting documentation, and explanatory note clarifying the purpose of the submitted documentation.
3. Once received by the Member State, the Member State will confirm whether the consultation request contains all the pertinent information to make it a valid request, and will communicate status promptly to the food business operator. NOTE: The Member State may request additional information which would need to be provided within the timeframe specified by the Member State.
4. Once all the required information is received, the Member State will provide novel food status on the food item within 4 months of the date the consultation request was deemed valid. NOTE: The Member State may request additional information which would need to be provided within a mutually agreed timeframe. If justified, the Member State may extend the time to confirmation of status by a maximum of 4 months.

5. Once the Member State forms a conclusion on the novel food status of the food, the Member State shall notify the food business operator, the other Member States and the European Commission of the decision, with accompanying justification. Per Article 7 of Regulation (EU) 2018/456, the following information must be included in the notification: (i) the name and description of the food concerned, (ii) a statement indicating whether the food concerned is novel, not novel or not novel only in food supplements (iii) justification for the decision, (iv) where the food is a novel food, the food category under which it falls in accordance with Article 3(2) of Regulation (EU) 2015/2283.
6. To conclude the process, the European Commission must add the details concerning the novel food status of the food item to the European Commission public website in a timely fashion.

When can a novel food be placed on the EU market?

A novel food can only be placed on the EU market once it has successfully gone through the authorization process, and the European Commission has added it to the Union List of Novel Foods. [6]

What is the Union List of Novel Foods?

The Union List of Novel Foods is a reference list of all authorized novel foods that can be placed on the market in the EU. It is kept up to date by the European Commission, and is governed by the Commission Implementing Regulation (EU) 2017/1023 in accordance with the new Regulation.

What is the procedure for authorization of a novel food?

Under the new Regulation, the authorisation procedure is centralized. The European Commission (EC) and the European Food Safety Authority (EFSA) work together to assess and authorize novel foods for human consumption. Details regarding the procedure for authorisation of a novel food can be found in Articles 10-13 of the new Regulation.

The general steps are as follows:

1. The process begins with the applicant submitting an online application for novel food authorization to the EC (Figure 1). The application must contain details specified in Article 10 of the new Regulation. EFSA has prepared the Guidance on the preparation and presentation of an application for authorization of a novel food in the context of Regulation (EU) 2015/2283 and the Administrative guidance on the submission of applications for authorization of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283 documents to assist applicants with preparing and submitting their application.
2. Upon receipt of the application, the EC makes it available for the Member States and prepares a summary of the application for public access.
3. Upon review of the application, if the EC believes that the novel food may have an affect on human health then the European Commission will request that EFSA carry out a safety risk assessment, and will forward the application to them for this purpose. EFSA will provide its input to the EC within nine months from the date of the receipt of the application from the EC.
4. Within seven months from the date that EFSA provides its input to the EC, the EC will provide the Standing Committee on Plants, Animals, Food and Feed (the PAFF Committee) a draft implementing act authorizing the addition of the novel food to the Union List of Novel Foods.
5. Once the act is approved by the PAFF Committee, and is adopted and published by the EC, the novel food can be placed on the EU market.

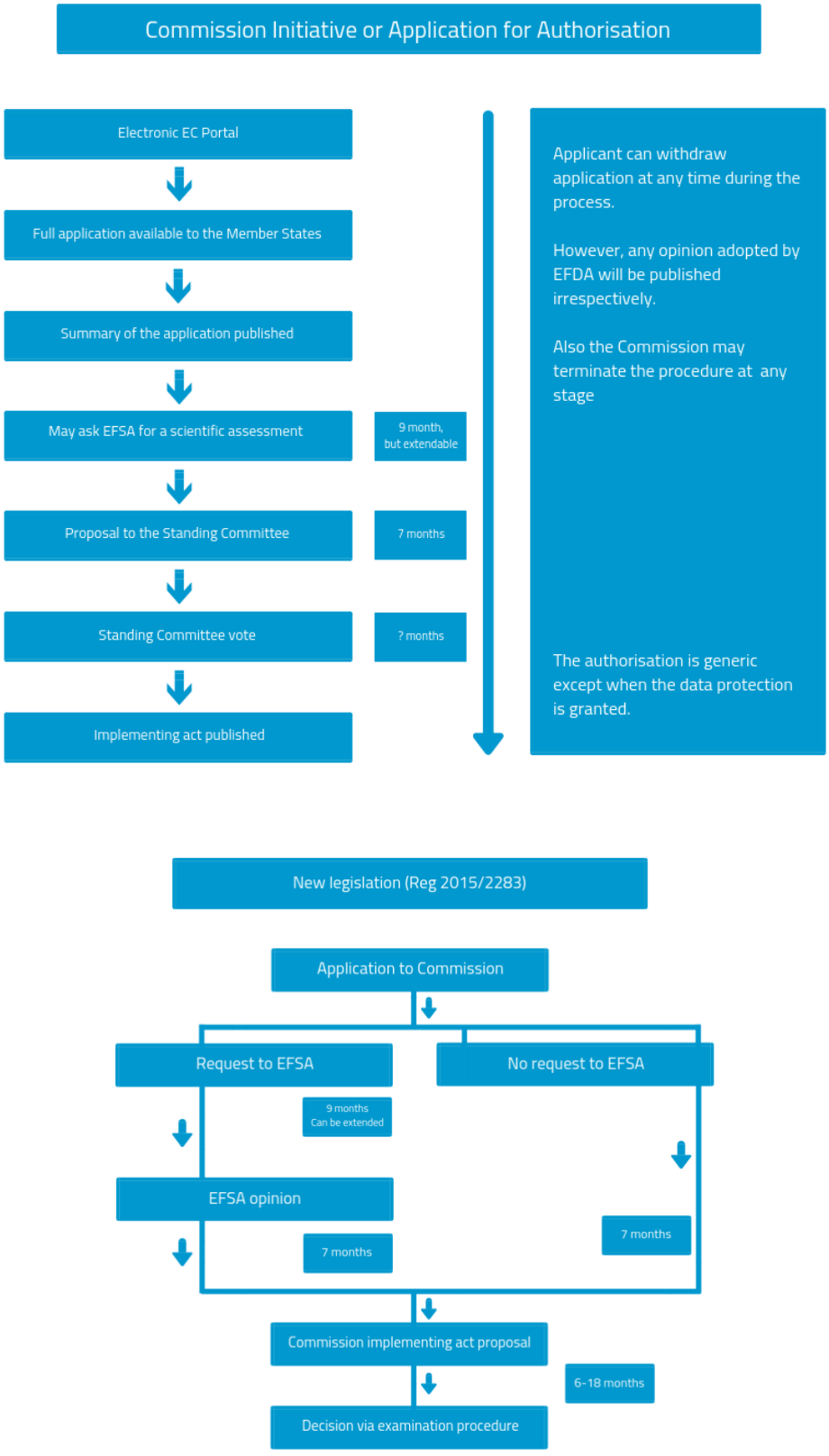

Figure 1: Process for authorization of a novel food per Regulation 2015/2283

What is addressed in a risk assessment of a novel food?

Generally speaking, when assessing the safety of a novel food, EFSA considers the following:

1) *whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;*
2) *whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the Union;*
3) *a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer* [7]

What should be included in the application for novel food authorization?

In accordance with Article 10 of the new Regulation, the Commission Implementing Regulation (EU) 2017/2469 provides details on the administrative, technical and scientific requirements to include in an application for novel food authorization.

EFSA has prepared the Guidance on the preparation and presentation of an application for authorization of a novel food in the context of Regulation (EU) 2015/2283 and the Administrative guidance on the submission of applications for authorization of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283 documents to assist applicants with preparing and submitting their application.

The European Commission or EFSA may request additional information from the applicant for the purposes of risk assessment or risk management if applicable. [2]

The application for the authorization of a novel food must contain extensive safety data and (toxicological) studies supporting the safety of the novel food.

In alphabetical order:

- *Additional information.*
  - *Is there any information that the product concerned is used within the Union as medicinal product in accordance with Directive 2001/83/EC1?*
  - *Is there any other information which would assist in determining the novel food status?*
- *Analysis method(s).*
  - *Where appropriate.*

- *Biological or toxicological study.*
    - *The applicant shall clarify whether the test material conforms to the proposed or existing specification.*
    - *Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration.*
        - *For each study.*
- *Conditions of intended use and for specific labelling requirements*
    - *How is the food intended to be used?*
    - *Type of product(s) in which the food is intended to be used.*
    - *Level / concentration (or range of levels) in the product(s) in which the food is intended to be used.*
        - *Which do not mislead the consumer or verifiable justification why those elements are not necessary.*
            - *A proposal.*
- *Consultations on availability in the Union.*
    - *Have other food business operators or food business operator federations been consulted?*
    - *Is the food currently available on the market within the Union?*
- *Copy of the documentation on the procedure and strategy followed when gathering the data.*
- *Date of submission of the dossier.*
- *Description of the production process(es).*
- *Description of the safety evaluation strategy and the corresponding toxicological testing strategy.*
    - *Shall justify the inclusion or exclusion of specific studies or information.*
- *Detailed composition of the novel food.*
- *Detailed description of the food.*
- *Detailed list of documents annexed to the dossier.*
    - *Including references to titles, volumes and pages.*
- *Dossier*
    - *Dossier submitted in support of an application for the authorization of a novel food shall enable a comprehensive risk assessment of the novel food.*
- *Extracts.*
    - *Any further details of the source material for the extract.*
    - *Specification of the extract.*
    - *If extracted from a food source, will the intake of any extract components in the new food be higher than the intake of these components from the original food source?*
    - *Is the structure or composition of the food affecting its nutritional value, metabolism or level of undesirable substances because of the process by which the food has been prepared?*
    - *Is the food produced from a source that, in itself, is not normally consumed as part of the diet?*
- *For chemical substances: CAS number(s) (if this has been attributed); chemical name(s) according to IUPAC nomenclature rules; synonyms, trade name, common name, where*

applicable; molecular and structural formulae; specification about purity/concentration.

- *For organisms (microorganisms, fungi, algae, plants, animals): taxonomic name (full Latin name with author name); synonyms, other names, where applicable; specification of which part of the organism the use for human consumption before 15 May 1997 within the Union refers to.*
- *Further characterization of the food and/or source of the food (where relevant).*
- *History of human consumption of the food within the Union before 15 May 1997:*
    - *to what extent was the food consumed to a significant degree throughout the Union.*
    - *to what extent was the food consumed to a significant degree in one Member State.*
    - *Food consumed only regionally/on a small local scale in the Union.*
    - *Was the food available before 15 May 1997 in the Union as an ingredient designed for specific target population (e.g. food for a special medical purpose)?*
- *Information and explanations substantiating the existence of the applicant's right of reference to the proprietary scientific evidence or scientific data in accordance with Article 26 of Regulation (EU) 2015/2283.*
    - *That information shall be included in a separate folder.*
- *List of the parts of the dossier to be treated as confidential and verifiable justification in accordance with Article 23 of Regulation (EU) 2015/2283 and the rules set out in Annex II to this Regulation.*
    - *Where the production process contains confidential data, a non-confidential summary of the production process shall be provided.*
- *Name and address of the applicant.*
- *Name of the novel food.*
- *Name, address and contact details of the person responsible for the dossier authorized to communicate on behalf of the applicant with the Commission.*
- *Name(s) of the manufacturer(s) of the novel food, if different than the applicant's, address and contact details.*
- *Overall conclusion on the safety of the proposed uses of the novel food.*
    - *The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.*
- *Production process: detailed description of the production process. Include a flow process chart to describe the production process.*
- *Proposed category of the novel food in accordance with Article 3 (2) (a) of Regulation (EU) 2015/2283.*
- *Raw data for the individual studies, published and unpublished, undertaken by the applicant, or on their behalf, to support their application.*
    - *This information includes data used to generate the conclusions of the individual studies and results of examinations.*
    - *On request.*
- *Safety data.*
    - *Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups.*

- *Scientific evidence demonstrating that the novel food does not pose a safety risk to human health.*
- *Table of contents of the dossier.*

What is the EU Novel Food Catalogue?

The EU Novel Food Catalogue is an informal tool on the European Commission website. It is a searchable catalogue that lists plant and animal products and other substances that are subject to the new novel food Regulation. Along with a description of the food product, it also provides information on novel food status of the product (Figure 2).

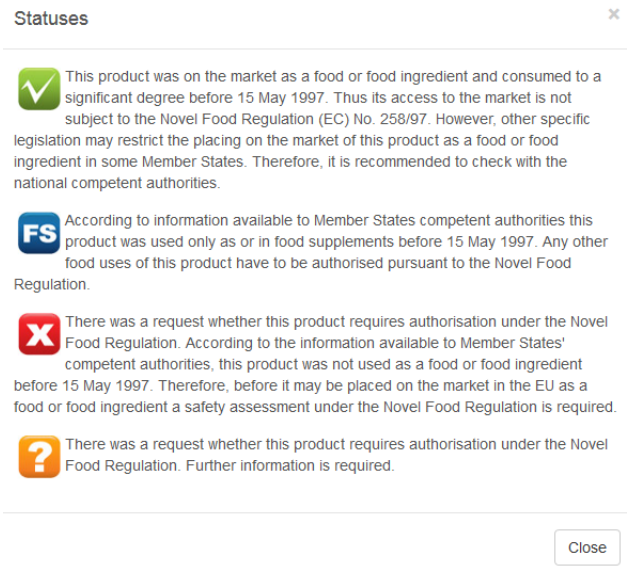

Figure 2: Screen shot of EU Novel Food Catalog status definitions

For example, According to the EU Novel Food Catalog, food and food ingredients from hemp (*Cannabis sativa* L.) that contains less than 0.2% tetrahydrocannabidiol (THC) and is registered in the Common Catalogue of Varieties of Agricultural Plant Species are not considered novel foods. However, it is recommended to check with authorities in specific Member States of the EU, as national legislation may restrict certain products from being sold in their country.

The current status for hemp (*Cannabis sativa* L.) indicates "This product was on the market as a food or food ingredient and consumed to a significant degree before 15 May 1997. Thus its access to the market is not subject to the Novel Food Regulation (EC) No. 258/97. However, other specific legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities." (Figure 3).

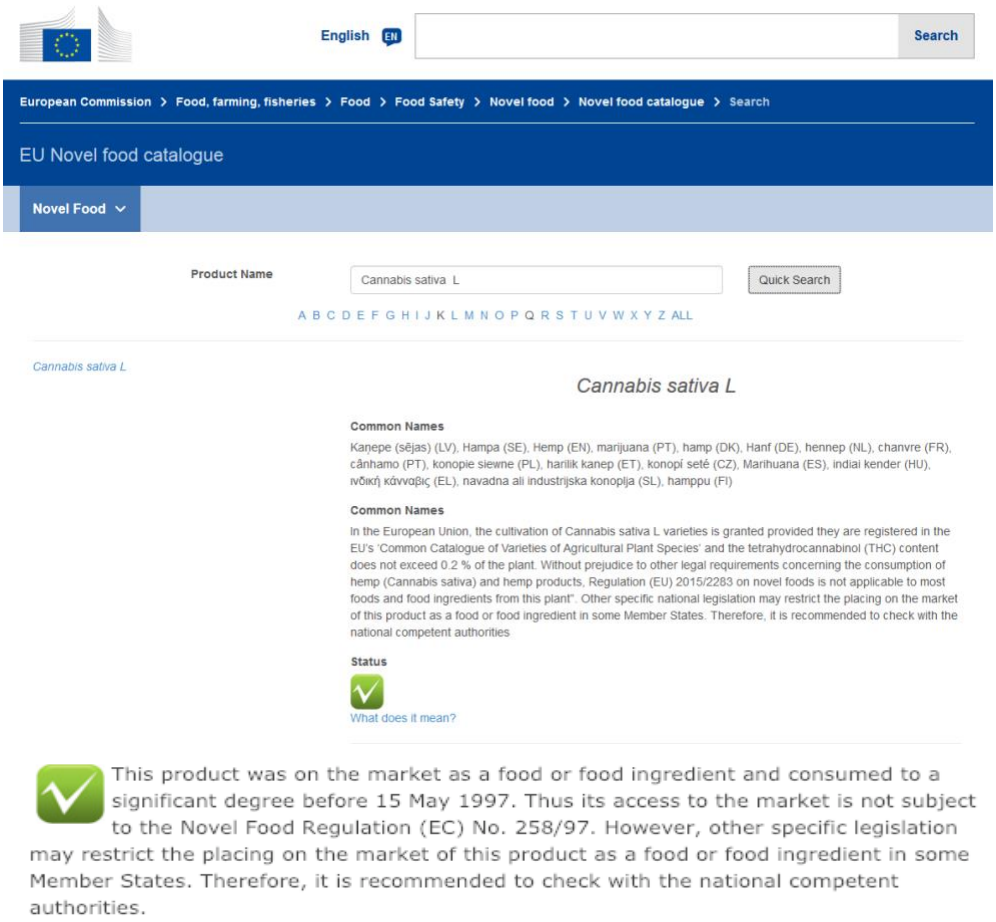

Figure 3: Screen shot of EU Novel Food Catalogue information on *Cannabis sativa* L.

With respect to cannabidiol (CBD), the EU Novel Food Catalog states that "Extracts of Cannabis sativa L in which cannabidiol (CBD) levels are higher than the CBD levels in the source Cannabis sativa L are novel in food. Cannabidiol (CBD) is one of the cannabinoids in Cannabis sativa plant. In the European Union, the cultivation of Cannabis sativa L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant."

The current status of Cannabidiol indicates "There was a request whether this product requires authorization under the Novel Food Regulation. According to the information available to Member States' competent authorities, this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required." (Figure 4)

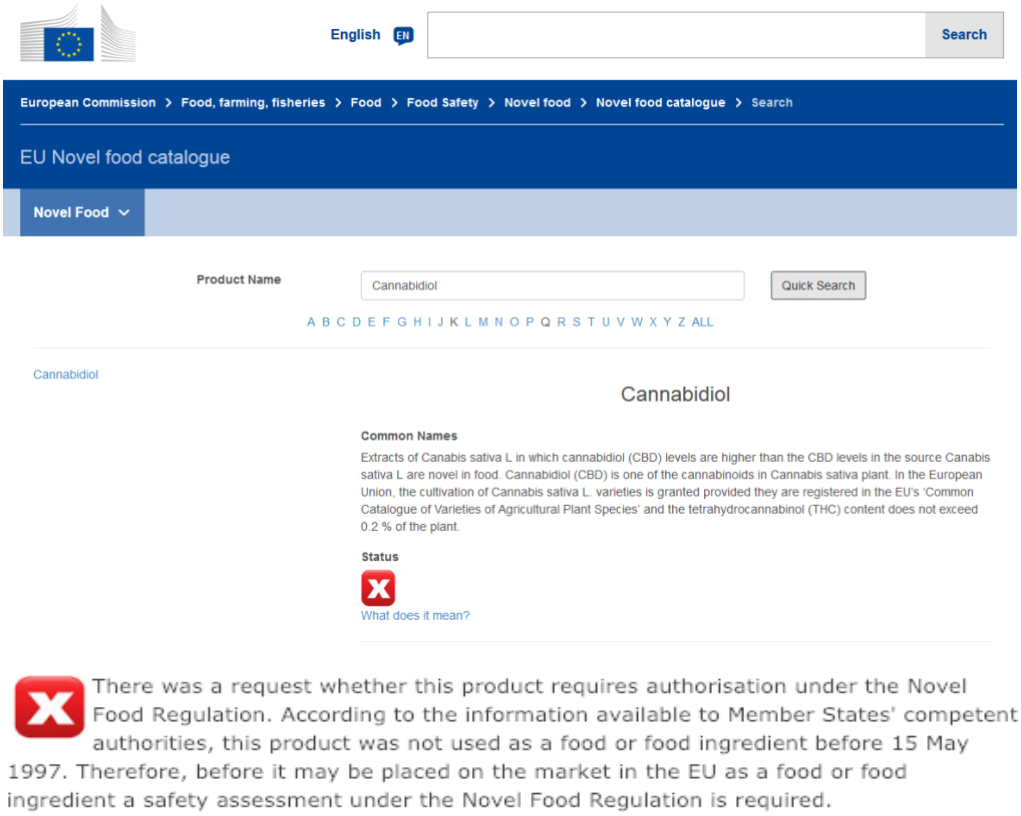

Figure 4: Screen shot of EU Novel Food Catalogue information on Cannabidiol

How is my business protected?

Per Article 23 of the new Regulation, applicants may request to have certain information in their application for novel food authorization to be treated confidentially to protect their competitive position. Applicants can indicate the specific parts of information they wish to remain confidential and provide substantiation for their request for consideration by the European Commission.

According to the new Regulation, the following information cannot remain confidential:

- *the name and address of the applicant,*
- *the name and description of the novel food,*
- *the proposed conditions of use of the novel food,*
- *a summary of the studies submitted by the applicant,*
- *the results of the studies carried out to demonstrate the safety of the food;*
- *where appropriate, the analysis method(s),*
- *any prohibition or restriction imposed in respect of the food by a third country.* [2]

Also, per Article 26 of the new Regulation, there is a possibility for applicants to receive 5-year exclusivity based on proprietary protection, provided that the following conditions are met:

- *the newly developed scientific evidence or scientific data was designated as proprietary by the applicant at the time the first application was made,*
- *the applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made and*
- *the novel food could not have been assessed and authorized without the applicant's proprietary scientific evidence or data.* [2]

The data protection provisions were put in place to help protect the interests of companies producing new, innovative products. Innovation in the food sector can help create new job and growth opportunities, and fortify the competitiveness of the EU food industry. [8]

What might happen if an unauthorized product is found on the EU market?

When talking about whole plant extracts, a "Grey Zone" will remain for some time (at least until 2Q 2019). In regards to CBD, moving forward, companies operating in the "Grey Zone" will slowly be excluded from the whole EU market once particular products are banned. The new novel food Regulation will help national regulators find and ban products that have no novel food authorization and/or are not extracted from varieties of hemp from the Common Catalogue of Varieties of Agricultural Plant Species .

Also, Member States will implement rules and impose penalties applicable to infringements of the provisions of the new Regulation, and will take all necessary measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive.

How are existing products on the market handled?

If lawfully marketed in the EU after 15 May 1997, existing products can remain on the market as long as an application for novel food authorization is submitted to the European Commission before 1 January 2019.

Have any applications for novel food authorization been submitted for CBD products?

Currently, only one application can be found on the European Commission - Summary of ongoing applications web page.

Products details per the European Commission summary are as follows:

Summary of the dossier: *(-)-trans-cannabidiol*

Applicant: *Cannabis Pharma, s.r.o., Masarykova 1595/54, 415 01 the Czech Republic*
This is an application for authorization to place on the market (-)-trans-cannabidiol (CBD) as a novel food in food supplements in the European Union (EU) intended for the adult population and excluding pregnant and lactating women.

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorization of a Novel Food in the Context of Regulation (EU) 2015/2283.

Cannabidiol (CBD) is to be obtained through a series of purification steps from Cannabis sativa L. plants. C. sativa is one of the first cultural crops used in many applications including food (seed oil), fibers for ropes, twines and coarse textiles and woody core for animal bedding.

Hemp seed oil has been traditionally consumed as food. It has a delicate flavor and distinctive nutty taste. It contains high concentration of poly-unsaturated fatty acids and rare omega 3 and omega 6 acids present such as gamma-linolenic and stearidonic acid, and certain phytosterols. Hemp seed and its oil is a high source of Vitamin E. Hemp seed and seed cake is a high source of vitamins and minerals: thiamin, vitamin B6, folate, iron, phosphorus, magnesium, zinc, copper and manganese.

The application contains publicly available safety and toxicological information and toxicity reviews, which include acute and long terms toxicity studies in animals, and tolerance studies in humans. The overall data package as submitted aims to support the safety of cannabidiol as a novel food in food supplements for adults with a daily intake of up to 130 mg or 1.86 mg/kg body weight. As an additional precautionary measure, the food supplements containing cannabidiol will be limited to the adult population and will exclude pregnant and lactating women. [9]

Recommendations

CBD and hemp extract producers should apply for novel food authorizations for their products. Authorized novel food products will have a great comparative advantage to the many unauthorized products.

In the future, there will be many summaries comparing these products (including those by ICCI). This means that all the product information will be shared publicly and those without novel food authorization will become targets of inspections by national regulators.

Future Considerations

No further regulatory changes are anticipated for novel foods at the EU level.

There is a possibility (and ICCI will support it at a national and EU level) for some kind of further guidance from the European Commission or its affiliates. We do not expect this guidance earlier than 2020 due to administrative procedures in the EU institutions and time needed for adequate data collection.

The only expected legislative change will be the approach towards extracts. The question remains as to whether or not extracts of cannabis are a novel food.

References

[1] European Food Safety Authority https://www.efsa.europa.eu/en/topics/topic/novel-food
[2] EUR – Lex Regulation (EU) 2015/2283 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283
[3] European Commission https://ec.europa.eu/food/safety/novel_food_en
[4] Food Safety Authority of Ireland https://www.fsai.ie/faq/cbd_oils_and_hemp_oils_legal_status.html
[5] European Commission https://ec.europa.eu/food/safety/novel_food/legislation_en
[6] European Commission https://ec.europa.eu/food/safety/novel_food/authorisations_en
[7] European Food Safety Authority https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4594
[8] European Commission https://ec.europa.eu/food/sites/food/files/safety/docs/fs_novel-food_leg_q-n-a-new-regulation-nf_en.pdf
[9] European Commission https://ec.europa.eu/food/safety/novel_food/authorisations/summary-ongoing-applications-and-notifications_en