All you need to know about

the EIHA Novel Food Consortium

Definition of 'Novel Food'

The first Novel Food regulation was introduced in 1997 by Regulation (EU) 258/97 with the aim of establishing a food safety mechanism to control newly developed, synthetic or genetically produced food. An updated version of the regulation came into force on 1st January 2018 (Regulation (EU) 2015/2283).

According to art. 3, **'novel food' is**:

> ***"any food that was not used for human consumption to a significant degree within the Union before 15 May 1997".***

If a food is considered novel, it must be authorised by the EU Commission and undergo a pre-market safety assessment by the European Food Safety Authority (EFSA), before it can be legally marketed in the EU.

The **Novel Food Catalogue** serves as a non-legally binding orientation on whether a product (of animal and plant origin, as well as other substances) will need an authorisation under the Novel Food Regulation. The Novel Food Catalogue reflects the opinion of the Member States.

Cannabis in the Novel Food regulation

Until the end of 2018, extracts of cannabidiol were considered novel **only if the levels of cannabidiol were *"higher than the CBD levels in the source Cannabis sativa L.".***

The **Standing Committee** already **decided in December 1997** and the **Commission confirmed** to the European hemp industry in writing in the beginning of 1998 **literally**:

> *"it was decided that foods containing parts of the hemp plant do not fall under the scope of the regulations EC 258/97" and also "that hemp flowers … are considered to be food ingredients" (e. g. used for the production of beer-like beverages)".*

Obviously, hemp flowers and leaves being parts of the hemp plant, were not considered to be Novel Food.

However, **in January 2019**, Member States' representatives updated the Catalogue entries for "Cannabis sativa L." and "Cannabinoids". These updates are demonstrably incorrect, based on logic and historical facts, as EIHA repeatedly explained to Member States and the European Commission.

- The new entry for **"Cannabis sativa L." does not mention hemp leaves and flowers**. From this alone, it is obvious that the latest changes, which seem to be hastily written, concerning the entries in the Novel Food catalogue are not correct. Moreover, the **traditionally produced hemp extracts are also missing**, although extraction is considered as a traditional and conventional method of food processing.
- In the new entry for **"Cannabinoids" extracts with a naturally occurring level of cannabinoids are now excluded**, although they were mentioned in the previous entry formulation. Such products were already on the market and consumed before 1997 to a significant degree.

Extraction in the EU legislation

CBD extracts can be aqueous extracts (e. g. "for beer-like beverages"), extracts by pressing, extracts based on fat extraction ("defatted hemp seed") or extracts produced by traditional extraction agents.

Since 2009, the EU directive 2009/32/EC clearly states that traditional extraction agents, such as ethanol (alcohol) or CO2 (carbon dioxide), must be permitted by Member States in the production of foodstuffs or food ingredients.

In simple terms, this means that when a food or food ingredient is processed through a traditional method of extraction by means of the extraction agents listed and authorised in the Directive, it remains a food or food ingredient and is not a "novel food" product (cf. Art. 2(1), 2nd subparagraph of the Directive).

The **subsequent** update of the Novel Food Regulation (2015/2283) **can therefore**, taking into account this already existing Directive 2009/32/EC, only mean **novel** extraction agents and "**new** extracts", but **not extracts obtained and produced by the traditional extraction agents already regulated**.

EIHA's position

EIHA has already shared substantial evidences with the European Commission proving that hemp flowers, leaves and extracts have been consumed as food for centuries and that the so-called "low-THC" varieties, defined as industrial hemp, have always contained cannabidiol (CBD). Particularly in these industrial hemp varieties - including those that were already listed in the EU catalogue of varieties long before 1997 - the respective content of CBD in relation to THC is very high compared to "high-THC" cannabis varieties.

The position conveyed by EIHA has always been consistent and aligned to the following: ***Hemp leaves and flowers as well as such hemp extracts from industrial hemp, with the natural content of cannabinoids, (i.e. those that are not enriched with isolated CBD) are traditional foods and do not fall under the scope of the Novel Food Regulation.***

This position is perfectly in line with the Novel Food Catalogue entries' formulations in place until January 2019,

EIHA's actions

- **EIHA is further on collecting evidences** all around Europe to prove irrevocably and undeniably the ancient culinary tradition and consumption as food of industrial hemp. The complete collection of evidences will **soon be submitted to the EU Commission through a Member State**, activating the procedures established in **article 4** of the Novel Food regulation.
- **EIHA will continue supporting its members in their relations with national authorities and in the courts,** in cases where undifferentiated distribution bans are imposed on basis of the false entries Novel Food catalogue. These efforts are therefore still necessary for the time being.

EIHA Novel Food Consortium

Because of the situation described above **a legal and planning security for the European hemp industry** and for **the trade of CBD-related products** can only be achieved by approval as Novel Food. EIHA intends to secure a fair market for its members who farm, process and trade with CBD related products – **a constant, reliable and EU wide regulated common market status.**

The **main tasks for EIHA** are to **finally** achieve **a legal and planning security** for the European hemp industry and its CBD market, including a **level playing field** for all European companies and global players, as well as to **avoid free rider effects** by entities that are not willing to contribute.

EIHA's Board proposed to its members during the General Assembly of June 2019 to create a Novel Food Consortium, with the aim of submitting a joint Novel Food application and share the costs. EIHA estimates that an individual company registering a single product under Novel Food guidelines need to invest between €350,000 and €500,000. The EIHA Novel Food Consortium will have the advantage of reducing the costs per company to an affordable level. These fees will increase over time. The founding members will have a preferential partnership rate. Based on the latest assessment it is estimated that the consortium **will invest up to €3,5 million for financing all relevant and unprecedented toxicological studies on CBD and THC**.
The **steps already taken by EIHA** prior to the creation of the NF Consortium include:

- The hiring of a service provider (ChemSafe);
- The designation of a task force whose members were strictly appointed based on their expertise.

The toxicological studies

The ingredients tested will cover a whole range of cannabinoids containing ingredients (so called: isolate, gold, regular and raw). Therefore, the application will secure all food products using these ingredients.

ChemSafe will carry out the toxicological studies in GLP laboratories and follow a standard study plan according to OECD criteria. Once confirmed by ChemSafe, the testing will be conducted on the product considered to be the "worst toxicological case" among the four products to be submitted as Novel Foods. The "worst toxicological case" will be selected on the basis of the analytical profile of each product.
The duration of the project is estimated between 24 and 36 months (by then, the applications should be approved under the Novel Food rules).

EIHA projects GmbH

A **corporation** under German law **was founded** (EIHA projects GmbH), which collects the special contributions to finance this project, orders, organizes and finances the toxicological studies of the chosen laboratories and acquires all rights for the distribution of the approved products based on the data protection granted under the Novel Food Regulation. **EIHA projects GmbH** will manage these rights and transfer them to the members.

A parallel application for the UK market

In order to ensure that its members will be covered across the whole European market, EIHA will submit two NF applications: one to the UK Food Safety Authority (FSA) for the British market, and the other to EFSA for the EU market. With regards to the UK, EIHA held a meeting on the 12 March with the FSA to discuss the specifications of the submission. The FSA clarified that the deadline of 31.03.2021 to submit a valid NF application was set for currently existing food operators, who are already selling CBD on the market, and are willing to stay on the UK. By "fully validated application" the FSA means the applications that were submitted to the EU Commission (DG SANTE), checked for its completion and forwarded to EFSA for the risk assessment.

If during the risk assessment (to be carried out after 31.03.2021) EFSA wishes to request additional data or studies, this will not stop the food operator from selling CBD as the application will already be validated.
Moreover, the FSA stated that all applications submitted before 31.12.2020 are to be submitted to the EU Commission, whereas, as of 01.01.2021, applications should be submitted to the FSA as the FSA will adopt its own process for validating applications similar to currently used by the EU Commission. In order to respect the deadline established by the FSA, the EIHA Consortium will shortly submit a NF application based only on existing studies. The toxicological studies will be launched in August 2020.

Explanatory notes on the fee schedule for the EIHA Novel Food joint submission

During the EIHA GM held on June 2019 it was agreed that the special contribution for participation in the Joint Novel Food Application should be mandatory for all EIHA members working with CBD relevant raw materials or products. Secondly it was decided that in principle all partners of the Joint Application should be members of EIHA. This decision was reconfirmed at the AGM in November 2019. EIHA's strategic goal is to represent a large part of the industry, by speaking on behalf of the highest possible number of members, at the political sphere and authorities. Only a strong industrial association encompassing a wide array of members will achieve the necessary improvements that the hemp industry needs.

In this context, the special contribution was specified and devised by a fee structure for participation in the joint application and finally confirmed during the GM in June 2020. It is now important to attract as many partners as possible, including new EIHA members. This will ensure an even and fair allocation of the enormous costs of this project, especially with regards to the comprehensive and unprecedented toxicological studies on CBD and THC. Free-rider effects are to be considered and ruled out as far as possible.

Therefore, companies must be taken into account with their worldwide consolidated turnover in the CBD-related area, whether they are or will become members of EIHA with only one (European) subsidiary, or whether they are members with the holding company and have other subsidiaries in the CBD area.

Furthermore, EIHA projects GmbH, which acquires and administers all rights under the NF Regulation, will only grant permission to distribute the trademarks of a project partner, whereby a transfer of rights by the partners to other companies or their trademarks is excluded.

This also means that partners who sell white or private label products cannot pass on the rights to their customers and these customers must also become project partners and

members of EIHA in order to legally distribute products approved under the Novel Food Regulation with the consent of EIHA. This principle also applies if the label identifies a producer who is independent of the trademark owner and this producer is already a partner of the joint application. The EIHA membership fees and the partner fees for the EIHA projects GmbH that these distribution and/or brand companies will pay will be based on the hemp and/or CBD-related turnover, and not on their total turnover.

For internal strategic reasons some companies may not always be eligible for EIHA membership or partnership in the Joint Application. Because of this, the creation of a licensing possibility, which is permitted under the system of the NF Regulation, was envisaged. This system will be further explained, although it is clear that licensing will be more expensive than becoming a project partner.

The cost of the partner fee will also increase over time to encourage early partnership in this project and to reward partners who have been involved and financially committed to this project from the beginning.

The project has a chance to succeed only if a sufficiently large number of partners support the joint application from the very beginning. Hence, in the interest of the entire project, EIHA calls on potential members and interested parties to become partners now and not to rely on a licensing option after the successful completion of the approval procedure. After approval by the EU Commission, EIHA will be able to seek injunctive relief from providers of non-approved CBD products, which will be used where appropriate.

The details of the granting of consent, the amount of the special contribution and the other conditions for participation in the joint application, in particular for companies not yet active in the CBD area, are set out in the GM decision of 6/15/2020, in the Fee Structure resolution and the project contract with EIHA projects GmbH.

Why should companies join us?

By becoming a Regular Member of EIHA you automatically and mandatorily join the Consortium, as we need to combine our forces in order to offer a united solution to a common challenge facing the entire hemp industry. Being part of the Consortium means that following a positive outcome of the novel food application, **your company's products will be allowed to be marketed in the EU with an exclusivity on the study that will last 5 years**.

If you join EIHA and the joint application later than by 15th August 2020 the costs to participate in the consortium will be higher!

The moment to become a member of the EIHA is now! Just follow the link below!

https://eiha.org/membership-application/