EIHA
European Industrial Hemp Association

EIHA PRESS NOTES:

Status of Hemp Extracts in Europe

Contents

Brussels – May 2019

Introduction: Changes to the Novel Food Catalog

In this press note, EIHA and its members, want to provide a clear and factual overview of the current legislative framework.

To clarify: We are talking about "hemp" (Cannabis sativa L.), which is authorized under the EU's Common Catalogue of Varieties of Agricultural Plant species (Reg. 1308/2013). Commonly hemp is known for its historic use as food and its use for rope, textiles and paper.

Most foods and food ingredients from the hemp plant were exempt from the scope of "Novel Food" Regulation (EC) No 258/97.

Without further industry consultation, the wording of the NF catalogue was changed in January 2019. According to the newly phrased "entry", which is not a legally-binding document for Member States:

- Only seed derived products are considered food,
- Leaves and flowers are now considered not explicitly exempt from the scope of Novel Food (Regulation (EU) 2015/2283) which has moved them from previously foods into a 'grey zone', and
- A new entry, called Cannabinoids, was created which now states that all hemp extracts are novel food.

What does it mean?

It means that this change in wording has turned the whole previously legitimate hemp extract and hemp (leaves/infructescense/flowers) supply into an industry that is now 'novel' and is required to apply for marketing authorisation prior to placing its products onto the market. This would be a long and very expensive process placing the entire EU hemp industry at risk. In addition, it is wholly unnecessary, illogical and illicit considering that:

a) the hemp industry received written confirmation from the EU in 1998 that hemp flowers/leaves are permitted for food use, and

b) hemp has been in the human food chain for millennia and it is disingenuous to argue that leaves and flowers in food are novel.

How are hemp extracts made?

Swedish advertising for hemp extract (undated)

The word extract derives from latin "extrahere" (draw out, remove), it means any method that uses a (solid, liquid or gaseous) extraction agent (= can be simply physical pressure) to remove one or several components from a substance mixture (of solid, liquid or gaseous substances). In Europe today there are four main extraction methods to obtain hemp extracts (including CBD).

1. Cold pressing: The simplest extract from hemp fruiting tops is hempseed oil which has been in human consumption for millennia.
2. Ethanol extraction: Using alcohol to whole fruiting tops (infructescense) and leaves. Ethanol extractions for botanicals have been used for centuries.
3. CO2 extraction: Using supercritical carbon dioxide to whole fruiting tops (infructescences) and leaves. **CO2** extraction alongside ethanol extractions are permitted for food use under Attachment I of Directive 2009/32/EC.
4. Fat extraction: Can easily be used for home-made preparations. (See, e.g. tortellini recipe, shown as Exhibit 1.

Nowadays, complementary EU approved food methods such as distillation exist to "purify" hemp extracts thus obtaining a final product less "contaminated" by presence of trace amounts of natural THC residues.

Indeed, extracts can be left raw or decarboxylated and added to consumer products without further processing. Extracts are usually winterized in order to remove plant waxes or can be further distilled/rectified in order to remove unwanted elements such as chlorophyll.

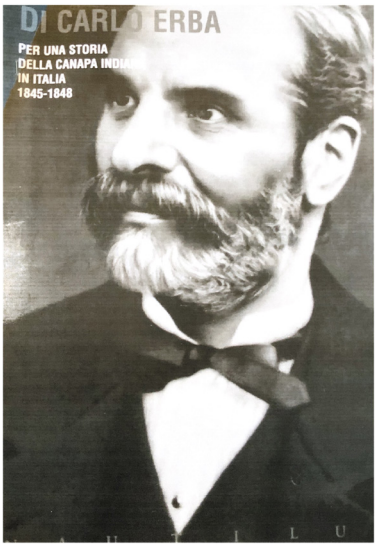
In hemp, the natural ratio of CBD:THC is approx. 20:1 – 25:1.

What can you extract from the plant?

Following any of the above four methods mentioned, you can obtain hemp extracts rich (but not unnaturally enriched) in CBD and other health supporting compounds. CBD is one of the 144 cannabinoids present in the hemp plant (mainly in the green parts of the plant). Consumers are buying CBD mainly for its health maintaining and supporting (promoting) properties.

The EU legal context

The legislation which covers the so-called NF products in Europe is Regulation (EU) 2015/2283. The purpose of the regulation is two-fold: protect the effective functioning of the Single Market and to provide a high level of protection of human health and consumer interests. The regulation also outlines the process for placing Novel Food on the market.



Di Carlo Erba, whose studies on hemp extract were published between 1945-1948

When Food Business Operators (FBOs) place a product on the market the safety of the products is their responsibility. Hemp foods, as all regular food products, are not subject to any authority licensing obligation or authority licensing options at European or national level.

Many FBOs in Europe voluntarily comply with "marketability certificates" issued by private institutions that guarantee an appropriate safety level (ISO 22000, HACCP, BRC, etc.) for European consumers. This includes correct labelling of products and clear instructions for use. Great effort is placed by FBOs to provide consumers with the highest quality products to avoid any negative consequence in term of image for the entire thriving sector.

According to EU law, novel food means a food which was not used for human consumption to a significant degree in the EU before 15 May 1997. EIHA states clearly and has provided evidence that hemp leaves, flowers and hemp extracts are NOT Novel Food as they have been consumed prior to this date to significant degree. It would be disingenuous to argue that hemp flowers, leaves, infructescence and their extracts are novel. Hemp leaves, flowers and extracts which contain health promoting cannabinoids were part of the human diet for centuries, more likely millennia.

What is the Novel Food Catalogue?

The Novel Food Catalogue lists products of animal and plant origin and other substances subject to the Novel Food Regulation, based on information provided by the EU Member States. It is a non-exhaustive list and serves as orientation on whether a product will need an authorisation under the Novel Food Regulation. EU countries may restrict the marketing of a product through specific legislation.

In some cases, it shows information on the history of use of food supplements and ingredients used exclusively in food supplements in the EU countries. If foods and/or food ingredients were used exclusively in food supplements, new uses in other foods require authorisation under the Novel Food Regulation.

Who advises on the Novel Food Catalogue?

Representatives coming from Member States that operate within the so called PAFF Standing Committee (Plants, Animals, Feed and Food).

The aim of this Standing Committee is to deliver opinions to inform the Commission's work on measures that it is planning. The Commission consults the relevant committee depending on the policy area: food & feed safety, animal health & welfare and plant health. Committee members are national experts who represent EU governments and public authorities. The PAFF Committee plays a key role in ensuring that Union measures on food and feed safety, animal health & welfare as well as plant health are practical and effective. It delivers opinions on draft measures that the Commission intends to adopt.

Recent action by Member States and Commission

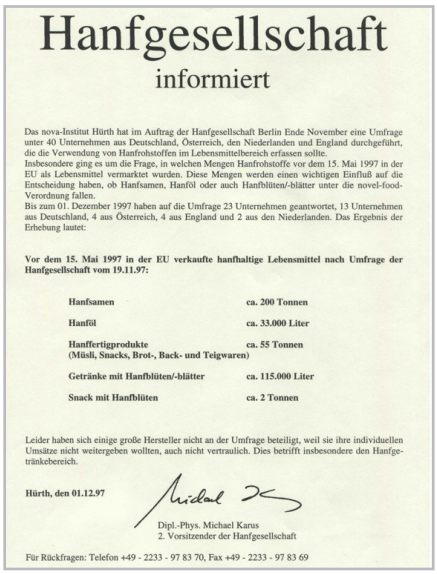
On the 20 January 2019 the previous entries for "Cannabis sativa L." and for "Cannabidiol" were both rephrased.

When the NF directive (Regulation (EC) 258/97) became implemented in 1997, the Commission requested the hemp industry provide evidence of consumption which was collated by Hanfgesellschaft and submitted to the Commission for their consideration. In responses from February and March 1998, the Commission confirmed in letters to two FBOs that "hemp flowers … are considered to be food ingredients" and that "foods containing parts of the hemp plant do not fall under the scope of the Regulation (EC) 258/97" and a thriving hemp industry has since developed.

Below is an analysis of the various entries relating to Cannabis Sativa L (hemp), Cannabidiol (CBD) and the recent addition of a new category, Cannabinoids.

1st version from 1998 till 2017	**2nd version** from 2017 to end of 2018	**3rd version** 20/01/2019
Only one entry for Cannabis sativa L. (no entry for CBD or Cannabinoids) NF regulation is not applicable to MOST foods and food ingredients of this plant This entry reflected the PAFF decision of 1997 and was valid until …	One additional entry: Cannabidiol (CBD) Extracts of Cannabis sativa L. in which CBD levels are higher than the CBD level naturally present in the source Cannabis sativa L. are novel Based on this definition, the hemp industry, made huge investments in the sector	Both entries were changed: Cannabis sativa L. and CBD √ Only seeds products and seed oil is now considered traditional (no NF application needed) X Food products made from leaves, flowers and all extracts containing cannabinoids are now considered as NF

EIHA actions and summary



Hanfgesellschaft

informiert

Das nova-Institut Hürth hat im Auftrag der Hanfgesellschaft Berlin Ende November eine Umfrage unter 40 Unternehmen aus Deutschland, Österreich, den Niederlanden und England durchgeführt, die die Verwendung von Hanfrohstoffen im Lebensmittelbereich erfassen sollte.
Insbesondere ging es um die Frage, in welchen Mengen Hanfrohstoffe vor dem 15. Mai 1997 in der EU als Lebensmittel vermarktet wurden. Diese Mengen werden einen wichtigen Einfluß auf die Entscheidung haben, ob Hanfsamen, Hanföl oder auch Hanfblüten/-blätter unter die novel-food-Verordnung fallen.
Bis zum 01. Dezember 1997 haben auf die Umfrage 23 Unternehmen geantwortet, 13 Unternehmen aus Deutschland, 4 aus Österreich, 4 aus England und 2 aus den Niederlanden. Das Ergebnis der Erhebung lautet:

Vor dem 15. Mai 1997 in der EU verkaufte hanfhaltige Lebensmittel nach Umfrage der Hanfgesellschaft vom 19.11.97:

Hanfsamen	**ca. 200 Tonnen**
Hanföl	**ca. 33.000 Liter**
Hanffertigprodukte (Müsli, Snacks, Brot-, Back- und Teigwaren)	**ca. 55 Tonnen**
Getränke mit Hanfblüten/-blätter	**ca. 115.000 Liter**
Snack mit Hanfblüten	**ca. 2 Tonnen**

Leider haben sich einige große Hersteller nicht an der Umfrage beteiligt, weil sie ihre individuellen Umsätze nicht weitergeben wollten, auch nicht vertraulich. Dies betrifft insbesondere den Hanfgetränkebereich.

Hürth, den 01.12.97

Dipl.-Phys. Michael Karus
2. Vorsitzender der Hanfgesellschaft

Für Rückfragen: Telefon +49 - 2233 - 97 83 70, Fax +49 - 2233 - 97 83 69

In response to the change of catalogue entry, EIHA was invited to present its position during the last PAFF Working Group on 12 March in Brussels. On this occasion, EIHA delivered to the Commission and Member States consistent, relevant and accurate evidence proving that hemp leaves/flowers were consumed to a significant degree prior to May 1997.

It is important to mention that due to the 'war on drugs' hemp was almost entirely eradicated during the 20th century and only slowly re-emerged in the mid-1980s. Therefore the evidence provided mostly refers to historical references found between the 12th-19th century.

There is considerable information which shows the recognised importance of hemp as an agicultural crop europe-wide. Products from hemp included rope, clothing, paper and construction materials in addition to food (seed oil & leaves/infructescence). Interestingly, the World's oldest cookbook 'De Honesta Voluptate' lists a recipe for a 'health drink' which is an almost identical recipe of how to make a modern day hemp extract food supplement. Whilst flowers were used from tortellini in Italy to soup in monasteries and 'edible grasses' (vegetables) in the Baltic states.

Hempseed oil and hemp seeds were a staple food for centuries. Prior to modern cleaning and separation technologies (e. g. air separation, colour sorting, de-hulling) the raw material to make hempseed oil would have included the whole seed with shell, infructescence and bracts which both were naturally covered in cannabinoids which people consumed as part of their regular diet.

Cannabinoids are mostly contained in a sticky resin produced by the plant to naturally protect its fruits from UV beams and insects. In the past, up until the beginning of the 20th century, when mechanical threshers were introduced, seeds were obtained in the process of manual threshing with flails. It was therefore practically impossible to separate (or isolate) cannabinoids from the rest of the parts of the plant that were largely consumed in human diet. The most used methods to separate flowers from impurity (chaff and tailings) were using a shovel with a short shaft combined with natural wind. Needless to say, this method was primitive and inefficient, yet the poorest peasants continued to use it as late as inter-war period in the early 20th century (Medical Properties of hemp and its application in medicine, Poland).

Therefore we can deduce beyond a reasonable doubt that in the past people were regularly consuming high quantity of cannabinoids naturally as part of their diet.

It is documented that medieval monks used hemp in dishes, including a hemp soup

At this point it becomes important to consider our body's endocannabinoid system. Humans have an important physiological system whose primary role is homeostasis, meaning balance. Whilst our body produces its own cannabinoids, so called endo-cannabinoids, we have traditionally consumed so called phyto-cannabinoids (plant based) to maintain and support our body's vital endocannabinoid system.

Moreover, Cannabinoids are known to occur in several plant species besides Cannabis. According to CB Receptor Ligands from Plants, the plants that contain Cannabinoids are: coneflower (echinacea), oxeye (Heliopsis helianthoides), black pepper (Piper nigrum), cacao tree (Theobroma cacao), truffles and many others.

What the changes mean for the hemp industry?

According to the catalogue, all food/food supplements products containing hemp leaves/infructescence (tea, snacks, muesli etc) or containing hemp extracts now need to obtain a pre-marketing authorisation in order to being placed on the market. These authorisations are costly in terms of time as an authorisation process takes two years plus and significant amounts of money (300.000+ Euro per product). Only large operators and corporations will be able to afford the authorisation process. This way, Small and Medium Enterprises which mainly composed the EU market today, will be naturally left out of the market and alongside, this could potentially destroy the entire rapidly emerging and thriving European hemp industry.

If Europe will not allow FBOs to fully exploit the plant as a direct consequence the EU hemp sector will collapse in favour of other markets, such as US, Canada, Switzerland and China.

EIHA in cooperation with EU institutions are planning next steps to be further developed with the aim to restore a regulation able to fulfil both scopes (art 1 point 2 of the NF regulation): protect the consumers and guarantee a smooth functioning of the internal market.

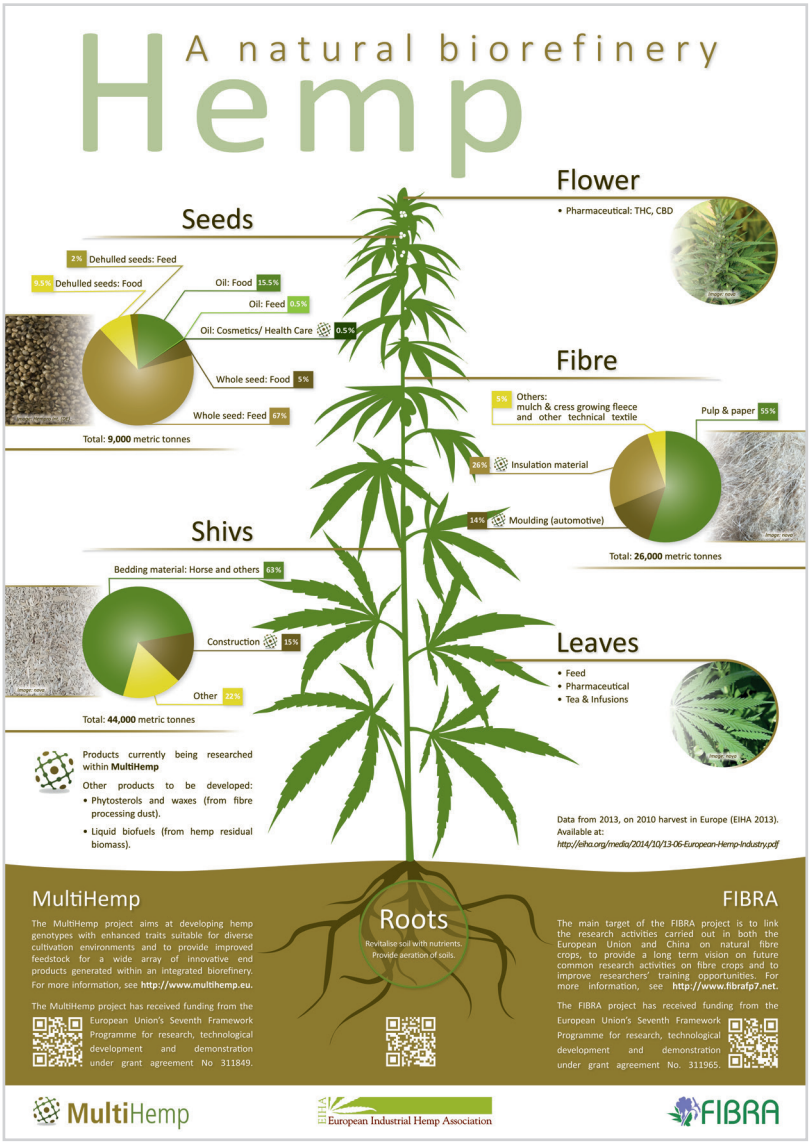
What else is at stake?

Hemp is emerging as one of the most rapidly growing agricultural and industrial markets that has emerged for decades

10,000+ applications including bioplastics, construction, high protein foods and beverages, food supplements, textiles, paper products, composites, biofuel, graphene substitutes

Major environmental benefits

- Carbon sequestration, enhanced biodiversity, land reclamation and phytoremediation, environmentally responsible industrial and consumer products
- Profitable cash crop for farmers when permitted to utilise the whole plant
- Plus multi-billion euro downstream markets



Key environmental benefits

Hemp protects the environment
Hemp can be grown without the use of herbicides, pesticides or fungicides. Hemp is in the top 5 out of 23 crops for biodiversity friendliness, performing better than all major crops such as wheat, maize or rapeseed.

Excellent carbon sequestration
One hectare of industrial hemp can absorb 15 tonnes of CO_2 per hectare. In comparison, agricultural land use emits approx. 3t CO_2 per hectare. Hemp's rapid growth also makes it one of the fastest CO_2-to-biomass conversion tools available, more efficient than agro-forestry.

Restores soil health
Hemp is a valuable preceding crop in rotations. After cultivation the soil is left in optimum condition.

Plethora of opportunities for environmentally responsible products

Hemp contains around 65-70% cellulose (wood contains around 40%, flax 65-75%, and cotton up to 90%); Hemp represents a sustainable and carbon negative source of plasticizing material.

Making one tonne of steel emits 1.46 tonnes of CO_2 and 198kg of CO_2 is emitted to make one tonne of reinforced concrete. One square metre of timber framed, hemp-lime wall, after allowing for the energy cost of transporting and assembling the materials actually stores 35.5kg of CO_2.

Body panels and chassis components in cars made from hemp are lighter weight than steel or metal which improves fuel consumption. Every bit of plastic, carpeting and upholstery in a car can be made of hemp.

For hemp to be a viable cash crop for our farmers and processors, they need to be empowered to utilise the entire plant.

The new Novel Food classification threatens the entire nascent environmentally friendly European hemp industry and we seek your support to raise awareness.

EIHA Position

Leaves and flowers	• Are Traditional Food • Considered as traditional ingredients for food and food supplements
Hemp extracts with traditional extraction methods	• Are Traditional Food • Considered as traditional ingredients for food and food supplements
Naturally occured cannabinoids in the whole plant extracts	• Are Traditional Food • Considered as traditional ingredients for food and food supplements
Isolated Cannabinoids	• Are Novel Food • Need authorisations to be placed on the EU market
Genetic Modified plants	• Are Novel Food • Need authorisations to be placed on the EU market

+

For consumers safety EIHA proposes a **maximum daily intake of CBD equivalent at 160 mg** (for average adults) for food supplements and **20 mg** in foods.