EIHA European Industrial Hemp Association

Cannabis sativa L. as a traditional food source





16 October 2018

Novel Foods Working Group, Brussels, Belgium

Mark Reinders - President of EIHA
Boris Bañas - Board Member
Bernhard Beitzke - Advisory Board
Catherine Wilson - Advisory Board

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PART 1

Introduction to the EIHA

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EIHA – European Industrial Hemp Association

- The EIHA has been around for over 18 years and has a membership that extends across 25 EU member states, plus 11 additional countries including Australia, Canada, China, India, New Zealand, Russia, Thailand, Turkey, Ukraine, USA.
- Founded in 2000 informally, and formally est. in 2005
- EIHA represents the whole value chain; farmers, most major processors, manufacturers, brand owners, importers and all hemp related sectors.

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EIHA Memberships and International Collaborations

- The ASTM D37 Committee on Cannabis
- the "Expert Group on Bio-based Products" of the European Commission,
- the biomass supply Thematic Working Group of the "Bioeconomy Panel" of the European Commission,
- the Standing Committee on Agricultural Research (SCAR), working group "Sustainable Bioresources for a Growing Bioeconomy".

- InterChanvre, France
- Hemp Industries Association (HIA), USA
- Canadian Hemp Trade Alliance (CHTA), Canada
- International Hemp Building Association (IHBA), Ireland
- British Hemp Association (BHA), UK

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Mark Reinders, HempFlax B.V., (NL), President of the EIHA

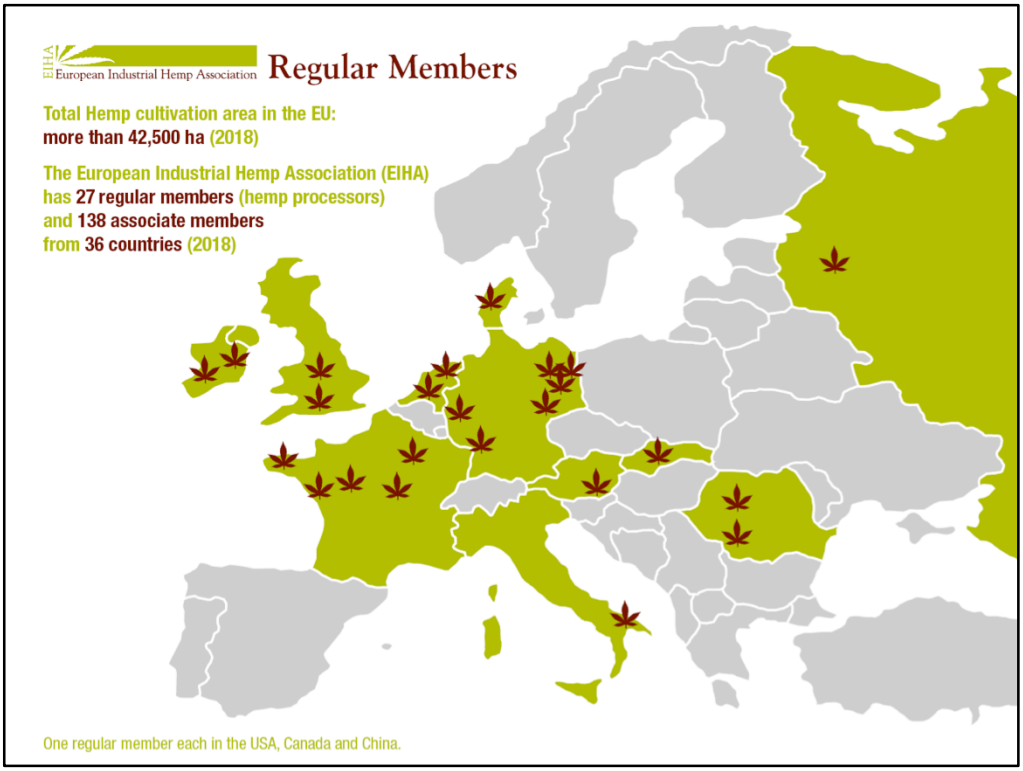


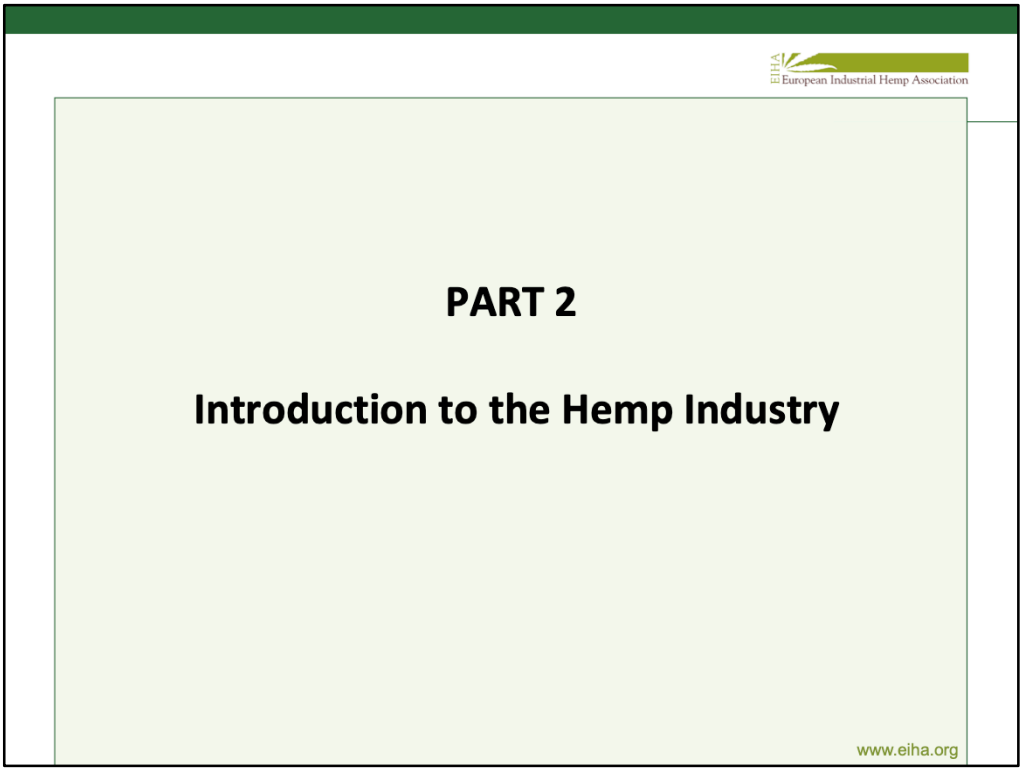
	***Bernd Frank*** *BaFa Neu GmbH (DE),* ***Treasurer***			***Philippe Heusele*** *InterChanvre (FR),* ***Deputy President***
Rachele Invernizzi South Hemp Tecno srl (IT)	**Boris Bañas** The Hemp Cooperative (SK)	**Daniel Kruse** HEMPRO INT. GmbH & Co. KG (DE)	**Daniela Sfrija** CANAH INT. SRL (RO)	**Michael Carus** nova-Institut GmbH (DE) Managing Director
				

Advisory Board:

Catherine Wilson
Tony Reeves
Bernhard Beitzke
Hanka Gabrilova

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EIHA
European Industrial Hemp Association
Regular Members
Total Hemp cultivation area in the EU:
more than 42,500 ha (2018)
The European Industrial Hemp Association (EIHA)
has 27 regular members (hemp processors)
and 138 associate members
from 36 countries (2018)
One regular member each in the USA, Canada and China.

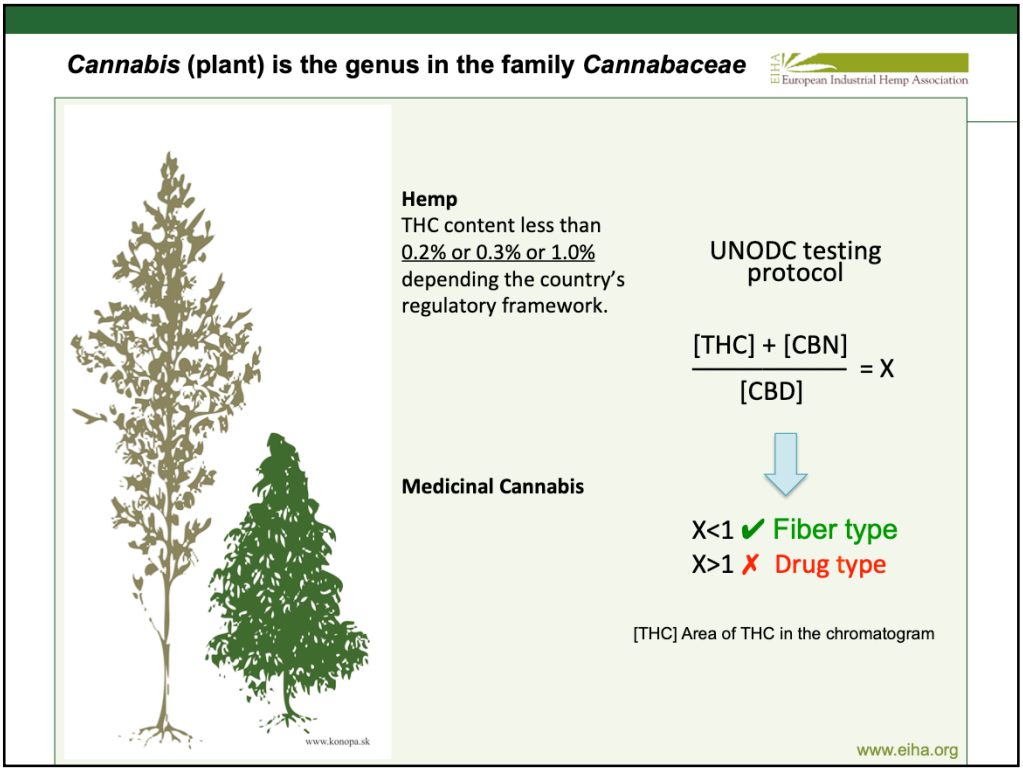


In the following three minutes, I will elaborate on the three main reasons why extracts of industrial hemp are traditional, rather than novel food.

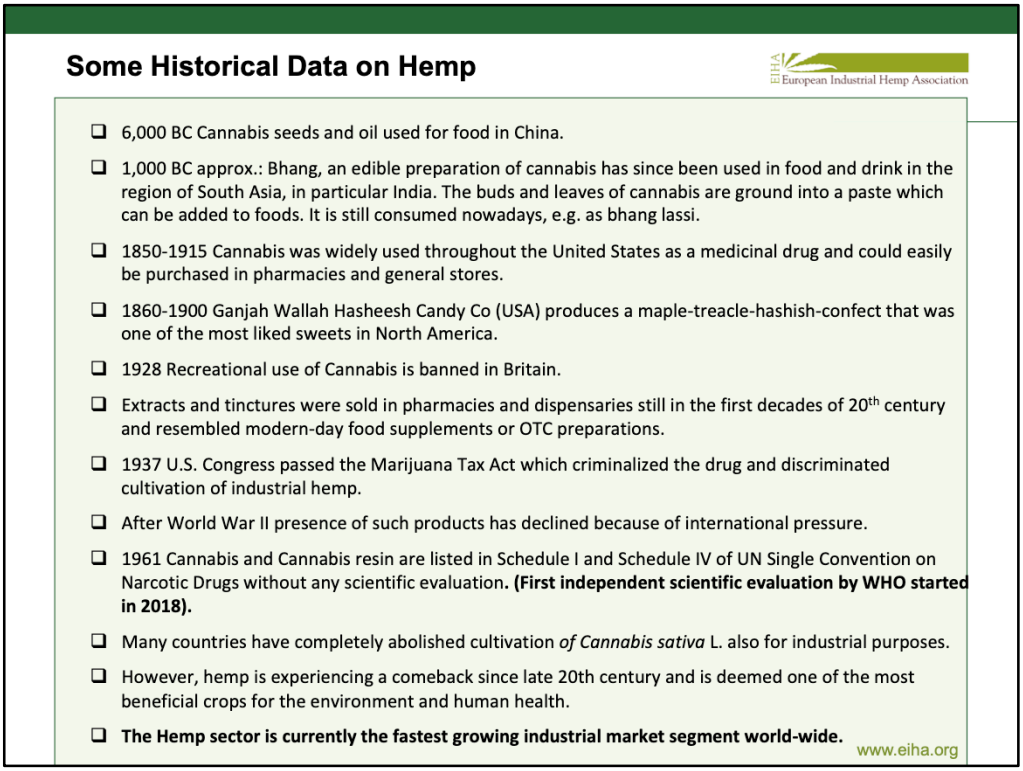
One: Hemp is a different type of genus *Cannabis* species from those used in medicinal or recreational applications.

Two: If we understand emergence of agriculture to be connected with the development of species *Homo Sapiens*, then genus *Cannabis* has been humankind's true companion ever since.

Three: Cannabidiol has been proven safe by WHO experts on drug dependence and has been a major driver behind unprecedented expansion of hemp cultivation areas worldwide.



Our first argument is that while botanical taxonomies may collide, the United Nations Office on Drug and Crime sets clear rules how to distinguish between a "drug type" and a "fiber type" cannabis plants by a formula where *Cannabidiol* is a denominator. In practice, countries rather mention maximum Tetrahydrocannabinol content in hemp. In general, the EU limit is 0.2% in upper third of the plant, while 0.3% applies in Canada, USA, Czechia and Austria and 1.0% THC applies in Switzerland and Australia for hemp.



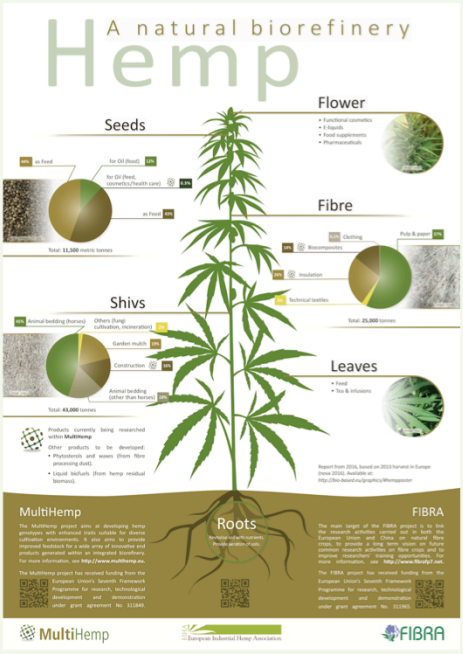
Concerning our second argument:

Hemp is a true biorefinery: providing renewable and carbon-neutral, sometimes even carbon-nagative intermediates. Examples are fiber for insulation, for plastic composites and fine papers, woody core for hemp concrete and animal bedding, seeds and foliage for foods and whole plant for feed silage.

With a widespread use of hemp in European area since middle-ages, it would be extremely bold to argue that most parts of the hemp plant had not been used as food or in food. Hemp extracts and tinctures were indeed made and sold in products which would be called nowadays “supplements” up to 80 years ago.

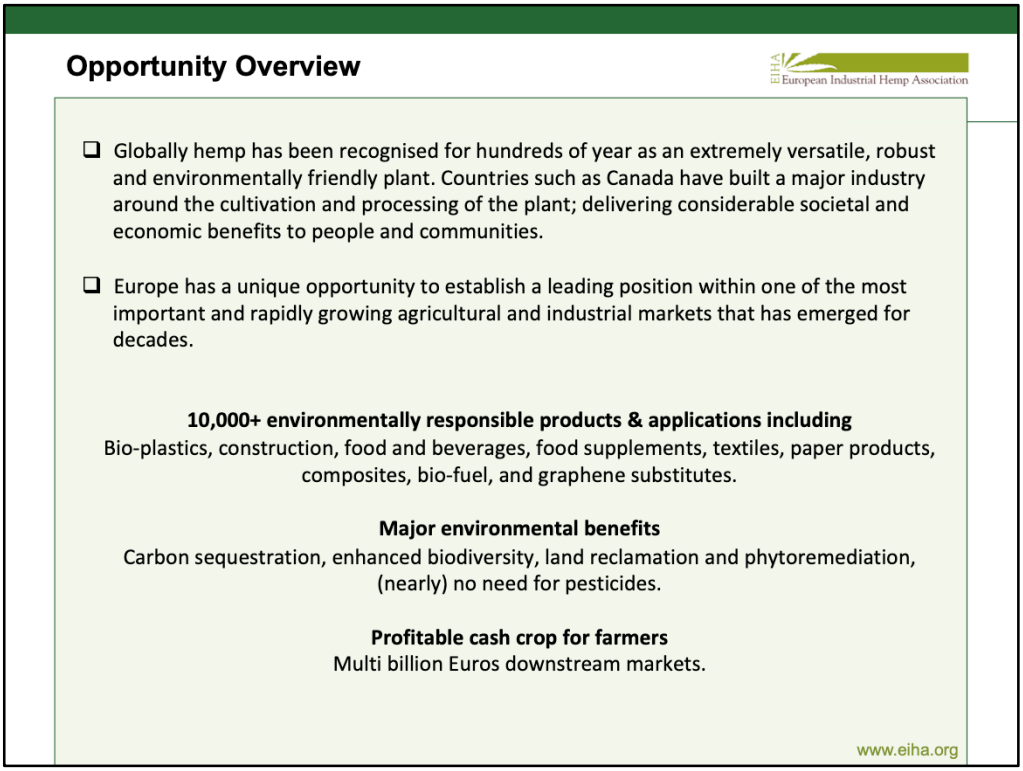
Hemp is a most useful plant

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"The production of Hemp is ***carbon negative***, which means it absorbs more carbon from the atmosphere during its growth than is emitted by the equipment used to harvest, process and transport it."

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Hemp was called a Billion Dollar Crop in 1930's already. However, severe discrimination in the second half of the 20th century happened when many countries applied international anti-drug conventions in the unnecessarily strict way to hemp.

Hemp has almost disappeared from our daily life and from our kitchen cabinets. Luckily, countries like France and Lithuania, with highest acreage in Europe, have been a leading example of its ongoing use. Other evidence is at hand proving use of hemp green parts in applications such as beer brewing and teas which we will show later.

Environment and Agriculture

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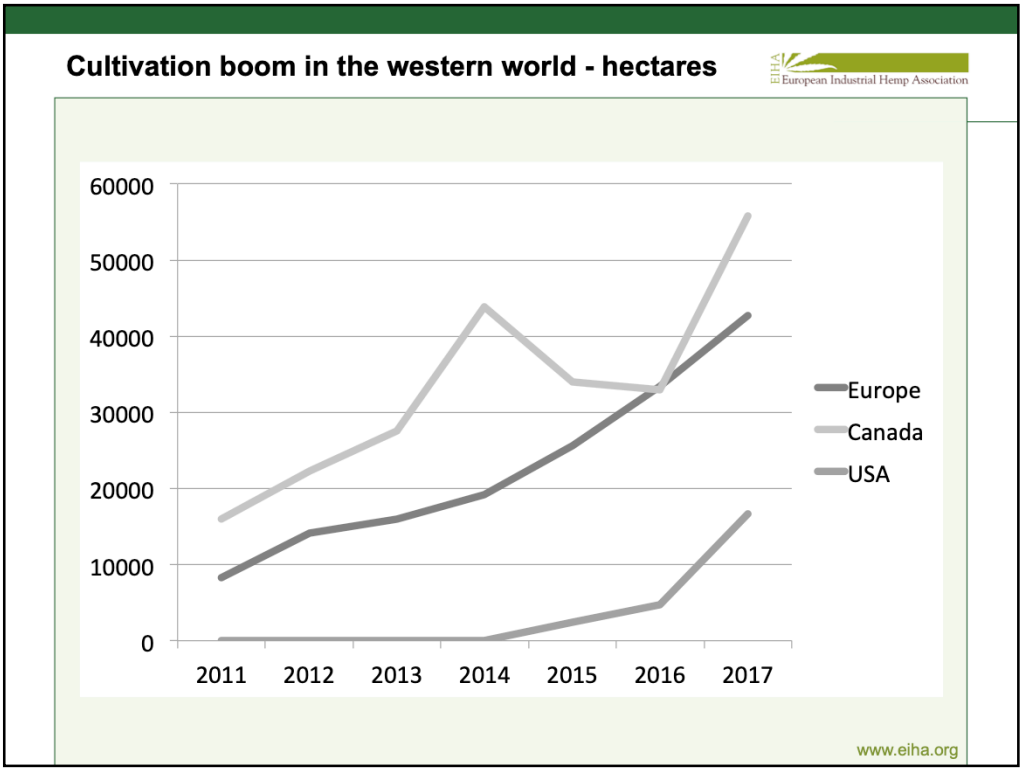
- **Protects the environment**: Hemp can be grown without the use of herbicides, pesticides or fungicides. Hemp is suitable for cultivation near surface water. Hemp is in the top 5 out of 23 crops for biodiversity friendliness, performing better than all major crops such as wheat, maize or rapeseed (Montford and Small, 1999)
- **Excellent carbon sequestration**: One hectare of industrial hemp can absorb 15 tonnes of CO2 per hectare. Hemp's rapid growth makes it one of the fastest CO2-to-biomass conversion tools available, more efficient than agro-forestry.
- **Restores soil health**: Due to its vigorous growth, hemp is known to be a pioneer plant that can be used for land reclamation and indeed phytoremediation; 'cleaning' land polluted by heavy metals. Hemp is a valuable preceding crop in rotations. After cultivation the soil is left in optimum condition

The EU Reform of Common Agricultural Policy (CAP) provides a historic opportunity to re-establish large scale hemp farming as it meets all environmental criteria and will be a valuable cash crop to European farmers.

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Last but not least, our third approach shows that CBD-containing extracts actually promote individual as well as public health and welfare. The safety profile will be discussed by Dr. Bernhard Beitzke, Catherine Wilson will demonstrate a plethora of evidence of traditional usage of ready-to-eat products with CBD concentrations considered natural within EU perspective. In conclusion, we will present our regulatory guidance proposal for hemp extracts containing Cannabidiol on the traditional food market.



Unprecedented demand makes hemp one of the most rapidly growing market segment this century.

This can be demonstrated by increase in cultivation areas in the western world, however small compared to other agricultural commodities.

Hemp foods are recognized as health promoting. General consumer patterns have shifted towards a healthier diet whilst at the same time people wanting more environmentally friendly products.

This provides an excellent opportunity to reinstate hemp in good faith acknowledging its traditional use.

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PART 3

Hemp CBD Extracts are a Traditional Food

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Hemp CBD Extracts are a Traditional Food

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- Extracts and tinctures were sold in pharmacies still in the first decades of 20th century and resembled modern-day food supplements or OTC preparations.
- [redacted] (Germany) have produced hemp extracts since 1994, also for the use in food.
- Hemp flowers and hemp extracts have been used for brewing "hemp beers" since 1996. e.g. Cannabia® has been sold since 1996 by [redacted], and [redacted] AG produced a hemp beer since 1996 with high demand from the very beginning.
- Letter of the European Commission, dated 03.02.1998, to [redacted], confirms "that hemp flowers used for the production of beer-like beverages are considered to be food ingredients and not additives since they are used in the same manner as hop flowers. Secondly it was decided that foods containing parts of the hemp plant do not fall under the scope of the Regulation (EC) 258/97."
- Letter of the European Commission to [redacted], dated 03.03.1998, confirming that the Standing Committee on Food agreed on 18.12.1997 that "food containing parts of the hemp plant do not fall under Regulation (EC) No. 258/97 ..... on Novel Food and Novel Food Ingredients."
- Letter of National Institute of Public Health to [redacted] s.r.o. dated August 12, 2015 *"Cannabis sativa* belongs to the category of traditional plant constituents of food supplements."

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Historical Use of Botanical Hemp / Extract as Food (1)

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The [redacted] website (www.[redacted]) states under "History" that hemp and hemp extracts have been produced since 1994 and the hemp extract has been used in food stuffs.



History

[redacted] *Natural Products has tested itself in in the production of 100% natural aromas and essential oils since 1989. After extensive work and successful handling of different natural products, the company decided to spend time on the most valuable, but untested raw material: hemp. Since 1994 we have produced and distributed hemp products at our manufactory. Cannabis is unique effective, rich and easy to grow. From beginning we have focused on the production of high quality hemp oil and hemp extract to use in foodstuff. The long-term experiences while handling this raw material distinguish our company and our first-class products.*

Since 1996 we have been concerned intensively with the difficult cultivation and the production of hemp. For almost 20 years we were allowed to implement the harvest of hemp for fiber as well as the distribution of officially certificated hemp seeds for farmers. Thereby, the legal gaining of hemp extract have always been top priority on a contractual basis. We exclusively produce the extract as a flavor and use it in our precious products.

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Historical Use of Botanical Hemp / Extract as Food (2)

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The entry on Cannabis sativa in the EU Novel Food catalogue still in Jan 2017 states "....Leaves are added to soups in southeast Asia."

Bhang (buds and leaves) ground into a paste have been added to drinks and foods since 1,000 BC.

"This product was on the market as a food or food ingredient and consumed to a significant degree before 15 May 1997....."

The Hemp plant contains CBD, CBDA, traces of other cannabinoids including THC and this proves that cannabinoid-containing parts of the hemp plant have been used as a traditional food.

Cannabis sativa

Common Names

Kaņepe (sējas) (LV), Hampa (SE), Hemp (EN), marijuana (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), harilik kanep (ET), konopí seté (CZ), Marihuana (ES), indiai kender (HU), ινδική κάνναβις (EL), navadna ali industrijska konoplja (SL hamppu (FI)

Common Names

Without prejudice to other legal requirements concerning the consumption of hemp (*Cannabis sativa*) and hemp products, Regulation (EC) No 258/97 is not applicable to most foods and food ingredients from this plant.

It is an annual herb, usually erect belonging to the Cannabaceae Family. Native to Central Asia and long cultivated in Asia, Europe and China. It´s a multiple-use plant, furnishing fiber, oil, medicine and narcotics. Fibers are best produced from male plants. Leaves are added to soups southeast Asia. Most varieties contain cannabinol and cannabinin. **See also Cannabidiol**

Status



What does it mean?

Historical Use of Botanical Hemp / Extract as Food (3)

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Lachenmeier (2004, 2005) mentions in his publication that hemp leaves and hemp flowers have been and are used for teas in Germany and other European countries, and that the **food character** (not recreational purpose) **prevails**.

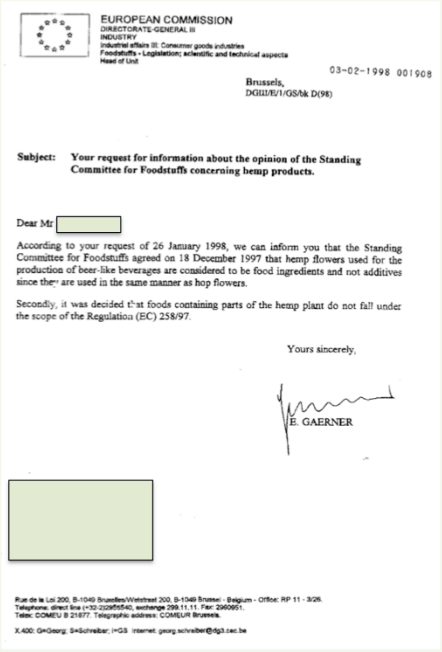
Official use of hemp leaves for making teas can also be demonstrated on a case of Slovak Republic below:

SLOVAKIA - DECREE 09/2015 Z.z. of Ministry of Agriculture and Rural Development of Slovak Republic, of December 4, 2015, on spices, table salt, dehydrated food, soup preparations and on aromas
contains item konopa siata - *Cannabis sativa* L. - **leaf**, seed
in Annex III, Table 1:
LIST OF PLANTS AND THEIR PARTS SUITABLE FOR PRODUCTION OF TEAS
without recommending any restrictions on the amount [of herb] used.

Lachenmeier, D.W., Walch, S.G. Current Status of THC in German Hemp Food Products, J. Ind. Hemp 10(2) 2005, 5-17.
Lachenmeier, D.W., Kroener, L., Musshoof, F., Madea, B.: Determination of cannabinoids in hemp food products by use of headspace solid-phase microextraction and gas chromatography-mass spectrometry, Anal. Bioanal. Chem. (2004), 378, 183-189.

Historical Use of Botanical Hemp / Extract as Food (4)

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EUROPEAN COMMISSION
DIRECTORATE-GENERAL III
INDUSTRY
Industrial affairs III: Consumer goods industries
Foodstuffs - Legislation; scientific and technical aspects
Head of Unit

03-02-1998 001908

Brussels,
DGIII/E/1/GS/bk D(98)

Subject: **Your request for information about the opinion of the Standing Committee for Foodstuffs concerning hemp products.**

Dear Mr [redacted]

According to your request of 26 January 1998, we can inform you that the Standing Committee for Foodstuffs agreed on 18 December 1997 that hemp flowers used for the production of beer-like beverages are considered to be food ingredients and not additives since they are used in the same manner as hop flowers.

Secondly, it was decided that foods containing parts of the hemp plant do not fall under the scope of the Regulation (EC) 258/97.

Yours sincerely,

E. GAERNER

[redacted]

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: RP 11 - 3/26.
Telephone: direct line (+32-2)295[illegible], exchange 299.11.11. Fax: 2960951.
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

X.400: G=Georg; S=Schreiber; I=GS internet: georg.schreiber@dg3.cec.be

Use of hemp flowers **and** CO_2 hemp plant extracts since 1996 for brewing "hemp beers" may be demonstrated by, for example, Cannabia® which has been marketed since 1996 by [redacted], and which was also sold in kegs.
The first Swiss hemp beer was brewed by Brewery [redacted] since 1996 and the demand was high from the very beginning.

In this context the letter of European Commission, dated 03.02.1998, to Mr [redacted]) is important "that hemp flowers used for the production of beer-like beverages are considered to be food ingredients and not additives since they are used in the same manner as hop flowers."
While cannabinoids cannot be extracted well into water, it is to be expected that a certain part of cannabinoids is extracted into a 4-8% alcoholic brew.

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Historical Use of Botanical Hemp / Extract as Food (5)

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EUROPÄISCHE KOMMISSION
GENERALDIREKTION III
INDUSTRIE
Gewerbliche Wirtschaft III: Verbrauchsgüterindustrie
Nahrungsmittel - Rechtsvorschriften; wissenschaftliche und technische Aspekte

Brüssel, den 03-03-1998 304243
DG III/E1 AK/ak D(98)

Betrifft: **Ihre Anfrage bezüglich Pflanzenteile von *Cannabis sativa***

Bezug: **Ihre Telefaxnachricht vom 16. Februar 1998**

Sehr geehrter Herr [redacted]

bezüglich Ihrer o.a. Anfrage kann ich Ihnen mitteilen, daß der Ständige Lebensmittelausschuß sich am 18. Dezember mit der Frage der Verwendung von Hanf in Lebensmitteln befaßt hat. Es wurde Übereinkunft erzielt , daß Lebensmittel, die Teile der Hanfpflanze enthalten, nicht unter die Verordnung (EG) Nr. 258/97 des Europäischen Parlaments und des Rates über neuartige Lebensmittel und neuartige Lebensmittelzutaten fallen.

Mit freundlichen Grüßen

E. Gaerner
Abteilungsleiter

[redacted]

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgien - Büro: RP11 3/57.
Telefon: Durchwahl: (+32-2)2953126. Zentrale 299.11.11. Telefax: 2960951.
Fernschreiber: COMEU B 21877. Telegrammadresse: COMEUR Brüssel.

continued:
"Secondly it was decided that foods containing parts of the hemp plant do not fall under the scope of the Regulation (EC) 258/97."

Letter of the European Commission to Mr [redacted], dated 03.03.1998, saying the Standing Committee on Food agreed on 18.12.1997 that food containing parts of the hemp plant do not fall under Regulation (EC) No. 258/97 ..... on Novel Food and Novel Food Ingredients."

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Historical Use of Botanical Hemp / Extract as Food (6)

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STATE HEALTH INSTITUTE
Šrobárova 48
Praha 10
100 42

Your letter of:
Day: 12 May 2015,
Our Sign:

Date: 12 August 2015

Subject: **TECHNICAL EXPERTISE** on health safety of preparations

SUBJECT OF REQUEST:

You have requested us to give an expert's opinion on health safety of the following preparations:

TECHNICAL EXPERTISE:
Based on the submitted documentation, the main ingredient of the preparations is the extract of hemp (Cannabis Sativa). Cannabis sativa belongs to the category of traditional plant constituents of food supplements. Your preparations contain the extract of this constituent made by common physical and chemical methods, as described in your manufacturing technology. According to the description of manufacturing technology, it is an extract of Cannabis sativa which does not contain THC, and may contain, among others, a constituent named cannabidiol – CBD. In case it is proven that it is not a cannabis sativa extract containing a mixture of the extracted substances, but pure cannabidiol CBD, it will be necessary to assess this constituent as a potential food ingredient of a new type and its introduction into the market is subject to EU Regulation No 258/1997.

SUMMARY:

To summarise, **we classify the preparations as food supplements** supposing that the constituent called "cannabis sativa bud extract" **does not contain THC and it is not pure cannabidiol (CBD).**
The health claims in the text of the label must be corrected in compliance with the applicable legislation, namely with EU Regulation No 432/2012.

National Institute of Public Health Czech Republic

Letter to . ref. dated 12/08/2015

"Based on the submitted documentation, **the main ingredient** of the preparations **is the extract of hemp** (*Cannabis sativa*)."

"Cannabis sativa **belongs** to the category of **traditional** plant constituents of **food supplements. "**

"…it will be **necessary** to assess **[pure cannabidiol]** as a **potential novel food** ingredient in accordance with Regulation EC/258/1997".

"we classify preparation **as food supplements".**

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PART 4

Safety Profile of CBD and Hemp Extracts

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Summary – Safety of Use

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Confidential – Unpublished Data

- "There are **no** case reports of **abuse** or **dependence** relating to the use of pure CBD."
  "**No** public **health problems** have been associated with CBD use."
  (Excerpts from a letter of WHO Director General to Secretary-General of the United Nations, July 23, 2018)

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Toxicity profile of CBD - Details

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- "CBD exhibits very low toxicity in humans and other species…" Rosenkrantz et al.(1981) showed that an oral dose 20-50 times larger than the intravenous route [212 mg/kg b.w. rhesus monkeys] is required to initiate severe intoxication. "CBD does not cause relevant CNS alterations."
  (Scuderi, C. et al., Cannabidiol in Medicine: A Review of its Therapeutic Potential in CNS Disorders, Phytother. Res. 23, 597-602 (2009))

- "Chronic intake and high doses of up to 1500 mg Cannabidiol per day are well tolerated."
  (Votes of the BfArM Expert Committee, 75th Meeting, 19.01.2016; and cit. ref in Bergamaschi et al.: Safety and Side Effects of Cannabidiol, a Cannabis sativa Constituent, Current Drug Safety, 2011, 6)

Confidential – Unpublished Data

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Hemp Seeds and Oil - Safety of Use

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"Hemp seeds possess an extremely high nutritional value due to a high content of unsaturated fatty acids (about 80% of fatty acids) and proteins (about 25%). **It is not to be ruled out that other minor components, such as terpenes and cannabinoids, could contribute to the surprising beneficial effects of hemp seeds."**

- WHO Expert Committee on Drug Dependence Pre-Review, Extracts and tinctures of cannabis, Section 1: Chemistry, WHO, 2018 page 21

"Hemp seed oils are widely sold for human food and, depending on national regulatory, appropriate label with chemical composition should be reported."

- WHO Expert Committee on Drug Dependence Pre-Review, Extracts and tinctures of cannabis, Section 1: Chemistry, WHO, 2018 page 23.

"Hemp seed oils are unlikely to have any significant toxicity and are accepted as foods and animal feed in many countries around the world with strict caps on low concentrations of Δ9-THC (e.g. 10 µg of Δ9-THC/gram of hemp seeds (10 ppm))"

-WHO Expert Committee on Drug Dependence Pre-Review, Extracts and tinctures of cannabis, Section 3: Toxicology, WHO, 2018, page 8.

"Hemp seed oil contains traces of CBD and CBDA as well, the ratio of which may be used to determine the freshness of the oil."

Citti et al., Analysis of Cannabinoids in commercial hemp seed oils and decarboxylation kinetics studies of cannabidiolic acid (CBDA), J. Pharm. Biomed. Anal. 149 (2018) 532-40.

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WHO on CBD and Extracts

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"There are **no** case reports of **abuse** or **dependence** relating to the use of pure CBD. **No** public **health** problems have been associated with CBD use."

"CBD has been found to be generally **well tolerated** with a **good safety profile**. Adverse effects of CBD include loss of appetite, diarrhoea, and fatigue."

"The [Expert] Committee [on Drug Dependence] recommended that preparations considered to be **pure CBD should not be scheduled**."

"The Committee noted that the category "**extract** and tinctures of cannabis" encompasses a variety of very diverse formulations with varying ratios of cannabis components, in particular THC, and with or **without psychoactive properties**."

-Excerpts from a letter of WHO Director General to Secretary-General of the United Nations, July 23, 2018

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Clarifying Confusions in WHO Reviews

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Extract of *cannabis*	*Cannabis sativa, ext. (Hemp Extract)*	*Cannabidiol*	Hempseed/ Hemp oil	Hemp Essential oil
CAS-No.: 6465-30-1	CAS-No.: 89958-21-4	CAS-No.: 13956-29-1	CAS-No.: 8016-24-8	CAS-No.: none partic.
HS Code: N/A	HS Code: 1302.19	HS Code: 2907.29	HS Code: 1515.90	HS Code: 3301.90
IDS Code: NC008	IDS Code: **N/A**	IDS Code: **N/A**	IDS Code: **N/A**	IDS Code: **N/A**

For Extract of *Cannabis* WHO uses a much too broad definition, that comprises the whole plant *Cannabis sativa*. For instance, it is to be noted that CAS-No. 89958-21-4 is not the CAS-No. of Cannabis extract but it is the CAS-No. of "Cannabis sativa, ext.", as listed in the European Inventory of Chemicals: https://echa.europa.eu/de/information-on-chemicals/ec-inventory

Therefore, this CAS-No. is that of an extract from the whole plant *Cannabis sativa*, and not from *cannabis* as such.

Extract of *cannabis* itself has CAS-No 6465-30-1. The International Narcotics Control Board (INCB) acknowledges it in its last version of the "yellow" List of Narcotic Drugs under International Control (see July 2017 edition): under the entry IDS Code NC008, *Cannabis* ("the flowering or fruiting tops of the cannabis plant (resin not extracted)") is listed together with the CAS-No.
6465-30-1. This is what the WHO should have used!

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PART 5

Proposal on Regulatory Framework for CBD-containing Extracts

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Why are Hemp CBD Extracts Beneficial to Health ?

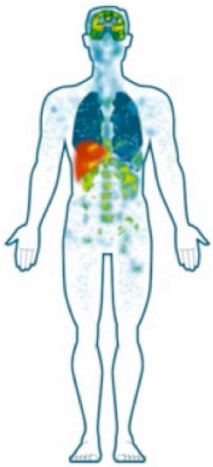
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Perhaps the most important botanical food in recent decades.

- Cannabidiol or CBD was first isolated by a team of chemists at the University of Illinois back in 1940 (Adams).
- Its structure was elucidated in 1963 (Mechoulam et al.).
- CBD is the most abundant cannabinoid present in industrial hemp and is non-psychotropic and non-intoxicating, neither is CBDA.

Hemp CBD extracts provide important substances* with physiological effect to our body, attributes could potentially include:

- contribute to the protection of cells from oxidative stress (as for example, Vitamin C , Vitamin E or Olive Oil Polyphenols) *(see Hampson et al. Proc. Natl. Acad. Sci. USA, 95, 8268-73, 1988)*
- contribute to the normal functioning of the nervous system
- contributes to the normal function of the immune system



*Cannabinoids, (poly)unsaturated fatty acids (as triglycerides), terpenes, bioflavonoids, phytosterols, chlorophyll (w/o limitation, depending on process of preparation, inter alia)

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Finding Recommended Daily Intake for Food Use

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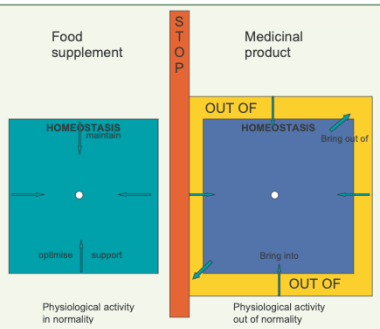
Apply Homeostasis approach:

Food Supplements		**Medicinal Products**
Maintain	vs	Restore
Support	vs	Correct
Optimize	vs	Modify

Apply proper recommended daily intake:

Based on the available high quality clinical studies the minimum dosage to induce a well defined therapeutic effect on a well defined pathology is then derived. This is called the minimum therapeutic dosage. In case of new clinical evidence, it is possible that this dosage has to be reviewed. To fix the maximum amount for food supplements, from the minimal therapeutic dosage one goes down 10% due to analytical uncertainties plus an extra 10% (minimum) to make the distance. Whenever the observed effect change is strong with small dosage changes, an extra % is brought in to increase the distance with the minimal therapeutic dosage. However, this has to be done carefully as to avoid the product has no longer any physiological effect which then should come in conflict with the requirements of the Food Supplement directive.

- Homeostasis..., Public Health Commitee, Council of Europe, 07.02.2008



Minimum therapeutic dose of CBD
= **200 mg / day**
Minus 10% analytical uncertainties
= 180 mg / day
Minus 10% to make the distance =

= 180 mg / day =

= maximum daily intake of "CBD equivalent" in food / supplements for an average adult

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Preparation: Extraction Methods

EIHA European Industrial Hemp Association

Hemp extracts are prepared by using extraction solvents allowed for food.

Attachment I of **Directive 2009/32/EC gives us a clear understanding** on extraction solvents used in the production of foodstuffs and which solvents may be used in processing foods:

Propane
Butane
Ethyl acetate
Ethanol
Carbon dioxide
Acetone
Nitrous oxide

- **Therefore solvent extraction processes (including CO_2) are approved for food stuffs.**
- **The use of Ethanol or Carbon dioxide was already allowed for all uses before 1997 under Council Directive 88/344 EEC.**
- **The solvent extraction process is a traditional food preparation process.**

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Extract Preparation: Processing

EIHA European Industrial Hemp Association

Traditional food preparation processes are used for hemp extracts.

After *extraction* of plant matter a further removal of unwanted residuals such as waxes may be done by *Refrigeration/Freezing*, and removal of other contaminants may be done by *Distillation/rectification* which are considered traditional food preparation processes as per **Annex II** of **Regulation (EC) No. 1334/2008**.

ANNEX II

List of traditional food preparation processes

Chopping	Coating
Heating, cooking, baking, frying (up to 240 °C at atmospheric pressure) and pressure cooking (up to 120 °C)	Cooling
Cutting	Distillation/rectification
Drying	Emulsification
Evaporation	Extraction, incl. solvent extraction in accordance with Directive 88/344/EEC
Fermentation	Filtration
Grinding	
Infusion	Maceration
Microbiological processes	Mixing
Peeling	Percolation
Pressing	Refrigeration/Freezing
Roasting/Grilling	Squeezing
Steeping	

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EIHA's Three-tier Regulatory Proposal

EIHA European Industrial Hemp Association

Scientific literature shows that pharmacological activity for a wide variety of effects of CBD in clinical studies is not observed under approx. 200 mg oral/d for an average adult.

(Devinsky et al., 2014, dos Santos et al., 2014, Food Standards Australia P1042; Friedman et al., 2015; Hill et al., 2012, Iffland et al., 2016; Schubart et al., 2013)

Proposed use of *Cannabidiol* and/or CBD-rich hemp extracts based on **daily oral dose of CBD equivalent** for an average adult.

Daily dose per average adult	Proposed use
Over 200 mg	As active ingredient in medicinal products with or without prescription.
Between 20 – 160 mg	Should be freely available as food supplements (such as valerian or hop pills, silymarin, glucosamine or Gingko Biloba). Extract to be standardised to CBD content.
Less than 20 mg	Should be allowed in food products without any restrictions.

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What levels of CBD do hemp and extracts contain?

EIHA European Industrial Hemp Association

- Total-CBD-content in raw biomass of EU-registered varieties is between **1 and 5 %** depending the variety and climate. This is the **naturally occurring level** of total CBD. This has been obviously used traditionally for hemp beer brewing, teas, etc.
- In preparing an extract, this level is, of course, increased by loss of insoluble plant matter.
- This raw extract is usually not sold to the consumer (it is an isolated intermediate).
- This intermediate is optionally purified by traditional food preparation processes and then diluted with some edible oil to get it standardised to a max. 5 % CBD formulation
  (See for example traditional extract from [redacted] which was a CO_2-extract with CBD and CBDA in it since 1994).
- Such an diluted extract with up to 5% total-CBD may be sold as food ingredient or food supplement with all necessary labelling and consumer information as required by Regulation (EU) No 1169/2011 or Directive 2002/46/EC, respectively.

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What about the Daily Dose of CBD ?

EIHA European Industrial Hemp Association

Based on a 5% extract dilution, a person would need to take 30 drops to consume 50 mg of CBD.

That would equal approximately one full standard-size dropper (pipette) of a 10 ml bottle.

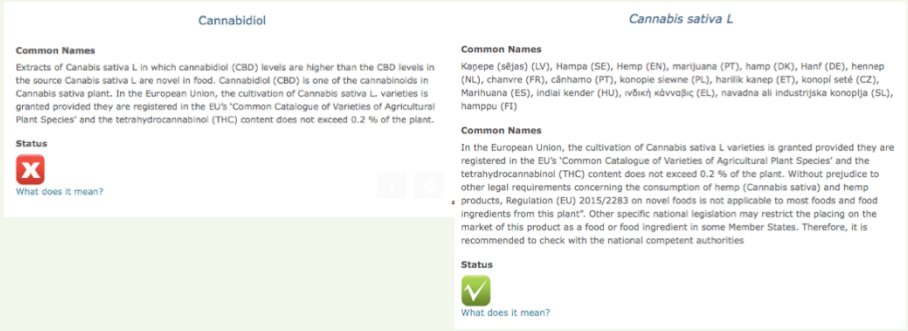
% w/w CBD in Tincture Oil	1ml = 30 drops
5%	50 mg
10%	100 mg
15%	150 mg

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Novel Food Catalogue – Cannabidiol and Cannabis sativa L

Current status (of entries) on 16 October 2018



Cannabidiol

Common Names

Extracts of Canabis sativa L in which cannabidiol (CBD) levels are higher than the CBD levels in the source Canabis 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.

Status

What does it mean?

Cannabis sativa L

Common Names

Kaņepe (sējas) (LV), Hampa (SE), Hemp (EN), marijuana (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), harilik kanep (ET), konopí seté (CZ), Marihuana (ES), indiai kender (HU), ινδική κάνναβις (EL), navadna ali industrijska konoplja (SL), hamppu (FI)

Common Names

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. Without prejudice to other legal requirements concerning the consumption of hemp (Cannabis sativa) and hemp products, Regulation (EU) 2015/2283 on novel foods is not applicable to most foods and food ingredients from this plant". Other specific national 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

Status

What does it mean?

The naturally occurring level of total CBD in the source Cannabis sativa L. (EU-registered varieties) is between 1 and 5 % depending the variety and climate.

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Guidance for definition of a CBD Level in Food

EIHA European Industrial Hemp Association

EIHA hereby asks the European Commission to recognise that

green parts of the hemp plant

and hemp extracts and their tinctures

with up to 5% CBD

are traditional food in EU.

EIHA would also like to make available our
extensive stakeholder knowledge and scientific expertise
in the development of an operational framework that satisfies both
industry and compliance & regulatory requirements.

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EIHA European Industrial Hemp Association

Thank you !

Questions & Answers

Expert Panel and area of expertise:

Mark Reinders, President – Farming & Retail
Boris Banas, Board – Extraction Processes
Dr. rer.nat. Bernhard Beitzke, Advisory Board – Chemist / Biochemist
Catherine Wilson, Advisory Board – Retail & Compliance

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