

Annex C

I would like to request links to articles/studies/papers you have used to make your determination that cannabidiol is a novel food. Also what evidence was submitted to yourselves by 3rd parties that showed evidence of historical use.

Email 1

Title: Supporting information for botanical hemp extracts (CBD)

Dear **[Section 40]**,

on behalf to **[Section 40]** my colleague **[Section 40]** and I had a meeting with you in March this year about CBD and botanical hemp extracts.

We have now heard from a colleague that the FSA and EFSA are looking into CBD and botanical hemp extracts and would like to provide some supporting information you mentioned at the time which would be helpful.

1. Where botanical hemp extracts available before 1997

We can provide a copy listed in the pharmacopeia of the 19th century showing hemp and cannabis extraction methods. Whilst it can be argued that the pharmacopeia refers to medicinal products, this would not be relevant, as there was no medication as such as nearly all remedies were botanical extractions which some now fall into the category of food stuffs including supplements.

2. CO₂ extraction process used for botanical extracts before 1997

We can confirm that CO₂ extraction has been widely used in the food industry prior to 1997 and have below listed a selection of reports on botanical extractions for your information.

Supercritical CO₂ extraction of essential oils and cuticular waxes from peppermint leaves

- First published: September 1996

Link: [http://onlinelibrary.wiley.com/doi/10.1002/\(SICI\)1097-4660\(199609\)67:1%3C21::AID-JCTB522%3E3.0.CO;2-0/full](http://onlinelibrary.wiley.com/doi/10.1002/(SICI)1097-4660(199609)67:1%3C21::AID-JCTB522%3E3.0.CO;2-0/full)

Properties and processing of corn oils obtained by extraction with supercritical carbon dioxide

Received: 15 April 1984

Links: <https://link.springer.com/article/10.1007%2F02540815?LI=true>

Extraction of Ginger Oil with Supercritical Carbon Dioxide: Experiments and Modeling

Publication Date (Web): February 8, 1996

Copyright © 1996 American Chemical Society

Link: <http://pubs.acs.org/doi/abs/10.1021/ie950357p>

Extraction of essential oils with carbon dioxide

- First published: September 1993

Link: <http://onlinelibrary.wiley.com/doi/10.1002/ffj.2730080502/full>

Caffeine extraction rates from coffee beans with supercritical carbon dioxide

- First published: May 1992

Link: <http://onlinelibrary.wiley.com/doi/10.1002/aic.690380513/abstract>

Supercritical Carbon Dioxide Extraction of Vanilla

Article · March 1991

Link:

https://www.researchgate.net/publication/244361014_Supercritical_Carbon_Dioxide_Extraction_of_Vanilla

We hope this information is helpful and I would welcome the opportunity for a brief telephone conversation about the above. When would be convenient?

Also, **[Section 40]** will contact you separately about hemp foods and recent **[Section 40]** efforts.

Kind regards,

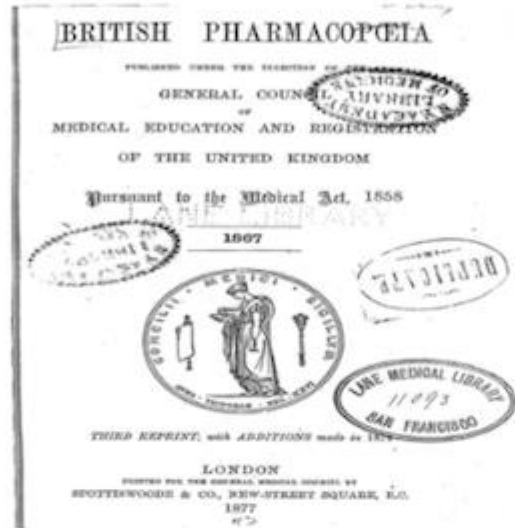
[Section 40]

Attachment 1: British Pharmacopeia 1867

British Pharmacopœia of 1867

YESTERDAY - PUBLIC

Historic: "MEDICAL EDUCATION AND REGISTRATION OF THE UNITED KINGDOM"
released by The Cannabis Re-Education Team P2P



68

BRITISH PHARMACOPŒIA.

CANNABIS INDICA.
INDIAN HEMP.

The dried flowering tops of the female plants of *Cannabis sativa*, *Lin.*, *Hemp*, *Berg v. Schmidt*, *Off. Gmelin*, plate six, b. For medicinal use that which is grown in India, and from which the resin has not been removed, is alone to be employed.

Character.—Tops consisting of one or more alternate branches, bearing the remains of the flowers and smaller leaves and a few ripe fruits, pressed together in masses which are about two inches long, harsh, of a dusky green colour and a characteristic odour.

Preparations.

Extractum Cannabis Indicæ.

Tinctura Cannabis Indicæ. { 25 grains of extract in 1 fluid ounce, nearly

CANTHARIS.

CANTHARIDES.

Cantharis vesicatoria, *De Geer*, *Hist. des Insectes*. The Beetle, dried; collected chiefly in Hungary.

Character and Test.—From eight to ten lines long, furnished with two wing-covers of a shining metallic-green colour, under which are two membranous transparent wings; odour strong and disagreeable; powder greyish-brown, containing shining green particles. Free from mites.

Preparations.

Acetum Cantharidis	2 ounces to 1 pint
Charta Epipepatica	
Emplastrum Callosificans	1 part in 24, nearly
— Cantharidis	1 part in 3
Liquor Epipepaticus	1 ounce to 3½ fluid ounces
Tinctura Cantharidis	5½ grains to 1 fluid ounce
Unguentum Cantharidis	1 part to 7, nearly

Attachment 2: British Pharmacopœia 1867 Recipes

EXTRACTUM CALUMBÆ.
EXTRACT OF CALUMBA.

Take of
 Calumba Root, cut small 1 pound
 Distilled Water 4 pints
 Macerate the calumba with two pints of the water for twelve hours, strain and press. Macerate again with the same quantity of water, strain and press as before. Mix and filter the liquors, and evaporate them by the heat of a water-bath until the extract is of a suitable consistence for forming pills.
 Dose.—2 to 10 grains.

EXTRACTUM CANNABIS INDICÆ.
EXTRACT OF INDIAN HEMP.

Take of
 Indian Hemp, in coarse powder 1 pound
 Rectified Spirit 4 pints
 Macerate the hemp in the spirit for seven days, and press out the tincture. Distil off the greater part of the spirit and evaporate what remains by a water-bath to the consistence of a soft extract.
 Dose.— $\frac{1}{2}$ to 1 grain.
 Preparation.—Tinctura Cannabis Indicæ, 1 ounce to 1 pint.

EXTRACTUM CINCHONÆ FLAVÆ
LIQUIDUM.

LIQUID EXTRACT OF YELLOW-CINCHONA.

Take of
 Yellow-Cinchona Bark, in coarse powder } 1 pound
 Distilled Water a sufficiency
 Rectified Spirit 1 fluid ounce

TINCTURA CANNABIS INDICÆ.
TINCTURE OF INDIAN HEMP.

Take of
 Extract of Indian Hemp 1 ounce
 Rectified Spirit 1 pint
 Dissolve the extract of hemp in the spirit.
 Dose.—2 to 20 minims.

TINCTURA CANTHARIDIS.
TINCTURE OF CANTHARIDES.

Take of
 Cantharides, in coarse powder $\frac{1}{2}$ ounce
 Proof Spirit 1 pint
 Macerate for seven days in a closed vessel, with occasional agitation, strain, press, filter, and add sufficient proof spirit to make one pint.
 Dose.—2 to 20 minims.

TINCTURA CAPSICI.
TINCTURE OF CAPSICUM.

Take of
 Capsicum Fruit, bruised $\frac{1}{2}$ ounce
 Rectified Spirit 1 pint
 Macerate the capsicum for forty-eight hours in fifteen fluid ounces of the spirit, in a closed vessel, agitating occasionally; then transfer to a percolator, and when the fluid ceases to pass, continue the percolation with the remaining five ounces of spirit. Afterwards subject the contents of the percolator to pressure, filter the product, mix the liquors, and add sufficient rectified spirit to make one pint.
 Dose.—10 to 20 minims.

Email 2

Title: Re: Supporting information for botanical hemp extracts (CBD)

Dear **[Section 40]**,

thank you for your email and information. May we suggest meeting? Please send us some suitable dates and we look forward to meeting you and your team again.

Best wishes,

[Section 40]

On Wed, Oct 25, 2017 at 6:20 PM, **[Section 40]** wrote:

Dear **[Section 40]**

Thank you for getting in touch. Your email is very timely as we are trying to engage with hemp industry organisations both to provide an update on the recent discussions and to help inform our thinking on the issue of extracts of hemp in particular those with higher levels of CBD.

The situation with CBD products is similar to other foods where particular products have been available for a long time but, more recently, changes in extraction methods or the selective concentration of particular components result in a new food that has different properties and therefore falls within the scope of the regulation. For example, this has happened with green tea versus highly refined extracts containing more Epigallocatechin gallate. The key challenge at the moment is around better understanding of products which fall within the scope of food law (rather than other legal frameworks) and a discussion about which products are consistent with the established history of consumption for products from *Cannabis sativa*, and those which are not.

At EU level there is starting to be a greater discussion on which products are consistent with the established history of consumption and which are not and should be considered novel. We are keen to ensure that the discussion of which foods should be subject to the novel foods regulation is one informed by information on the products that were available as foods prior to 1997. The recent discussion at EU level focused on whether the use of particular techniques is indicative of a more selective extraction process compared to those used in respect of products available before 1997, making the resulting products novel. We would be grateful to receive any information the industry may have on techniques such as CO₂ extraction being used in producing extracts of *Cannabis Sativa* for food used prior to 1997, which would help better inform decisions around which products are subject to the novel foods regulation.

We think the next stage of the discussion will be around the level of concentration of key components such as CBD that would constitute a new product. Once more, if the industry has any information on the level of CBD in different types of product and whether these products were marketed before 1997 this would be very helpful. To put this issue in context you may wish to have a look at the EU guidance on deciding [history of consumption](#) which will explain the approach used and the types of evidence that are most useful in demonstrating this.

We will, of course, keep you updated on the discussions. Any information the industry can share on the types of products that have been produced from *Cannabis sativa* prior to 1997 will ensure a more informed position on which products should be considered under the novel foods regulation.

Best wishes

[Section 40]

Radiological and Novel Food Policy

Food Standards Agency

Aviation House, [125 Kingsway, London, WC2B 6NH](#)

www.food.gov.uk

Phone **[Section 40]**

Email 3

Title: Re: Co2 extraction used for Hemp by Dupetit since 1994

Dear **[Section 40]**,

14.00 hours is confirmed.

Look forward to meeting you next week.

Best regards,

[Section 40]

On Wed, Nov 22, 2017 at 3:43 PM, **[Section 40]** wrote:

Dear **[Section 40]**

Thank you for responding. Looking at the availability of rooms in Aviation House it would be preferred that we meet between 14.00 and 15.00 on Thursday 30 November. Would this still be suitable for you both?

Kind regards

[Section 40]

Radiological and Novel Food Policy

Food Standards Agency

Aviation House, [125 Kingsway, London, WC2B 6NH](#)

www.food.gov.uk

Phone [Section 40]

From: [Section 40]

Sent: Tuesday, November 21, 2017 8:58 AM

To: [Section 40]

Cc: [Section 40]

Subject: Re: Co2 extraction used for Hemp by Dupetit since 1994

Dear [Section 40],

thank you for coming back to us and finding the time to meet. We would prefer the 30th November please. Due to the distance getting to London would it also be possible to hold the meeting ideally at 1pm, but we could both get there from 12.15.

Kind regards,

[Section 40]

On Mon, Nov 20, 2017 at 2:03 PM, [Section 40] wrote:

Dear [Section 40]

Thank you for sharing the information on CO₂ extraction which I look forward to considering in detail. I can only apologise for the delay in responding to your suggestion of a meeting. We are currently experience a very high workload associated with the new regulation that comes into force in January.

In terms of possible dates would you have any availability on the morning of the 28th November, or the 30 November or 15th December for a hour and half meeting? Please let me know if any of these dates would be suitable so I can make the necessary arrangements.

As explained on the phone while the Agency has an interest in THC contamination of foods this is a Home Office lead as a result of the interaction with the Misuse of Drugs Act. On this basis I don't think it would be possible to cover this issue at our meeting. However, we have flagged your concerns with the relevant team at FSA so that they aware and can discuss this further with the Home Office as appropriate.

I look forward to hearing from you on a possible date for our meeting.

kind regards

[Section 40]

Radiological and Novel Food Policy

Food Standards Agency

Aviation House, [125 Kingsway, London, WC2B 6NH](https://www.gov.uk/government/offices/food-standards-agency)

www.food.gov.uk

Phone [Section 40]

From: [Section 40]

Sent: Wednesday, November 8, 2017 2:29:09 PM

To: [Section 40]

Cc: [Section 40]

Subject: Co2 extraction used for Hemp by Dupetit since 1994

Dear [Section 40],

thank you for our telephone conversation last week.

You mentioned whether we can give supporting information that Co2 extraction was used for Hemp prior to 1997. Dupetit company have used CO2 extraction for hemp since 1996 for Cannabia® which is a hemp-beer drink. It is internationally sold with exports to over 16 countries. Here is a link to their website:

<http://www.dupetit.eu/>



[dupetit Natural Products](#)

www.dupetit.eu

Tradition. Unser Traum ging 1989 in Erfüllung, wir ließen uns im Odenwald in Nordbayern nieder, wo wir die friedliche, unberührte Landschaft und Natur fanden, um ...

<http://dupetit.de/de/geschichte/wie-alles-begann/>

[Wie alles begann: dupetit natural products GmbH](#)

dupetit.de

1989 als alles begann dupetit Natural Products erprobte sich seit 1989 in der Produktion von 100% natürlichen Aromen und ätherischen Ölen. Nach umfangreicher ...

We look forward to answering any questions you may have and to contribute valid information to assist in your assessment process.

On the phone I also mentioned that the Home Office suggested we contact to the FSA with regards to trace amounts of the contaminant THC present in hemp foods.

Would it be possible to either include the person with responsibility for contaminants in our meeting or otherwise could you let us know who is responsible so we can contact them directly please?

We look forward to hearing from you with regards to suitable dates.

Kind regards,

[Section 40]

Email 4

Title: Re: Update on Novel Food Application - **[Section 40]**

Dear **[Section 40]**,

thank you for your reply. Alongside an application for a higher concentration of CBD and different types of extracts, there remains the subject of traditional food. I thought you may like to peruse the expert report from Dr.med. Dr.phil Gerhard Nahler, CIS Clinical Investigation Support GmbH on hemp - a traditional food. A copy of this is being shared with the COM.

Kind regards,

[Section 40]

On Fri, Jul 12, 2019 at 9:14 AM **[Section 40]** wrote:

Hi **[Section 40]**

Thank you for your email. Putting in an application is the way forward and we are encouraging organisations to do this so they can become compliant with the Novel Food Regulations and can continue to trade. You may like to think about putting in an application for a range of concentrations of CBD.

The applications which have been sent to **[Section 27]** so far have not had sufficient data for a safety assessment to be completed so using a consultant such as Intertek is a very good idea. Intertek have a lot of experience in novel food applications, as have a few other companies and will be able to guide you. Toxicological studies are expensive but are required for the assessment. This is the main area where data is lacking as there have been very few studies undertaken to date.

Thank you for keeping me informed and hopefully everything will go well.

Kind Regards

[Section 40]

Food Policy Division, Food Standards Agency

6th Floor, Clive House, 70 Petty France, London, SW1H 9EX

<https://www.food.gov.uk/business-guidance/novel-foods>

Working pattern: **[Section 40]**

From: [Section 40]

Sent: 11 July 2019 18:54

To: [Section 40]

Cc: [Section 40]; [Section 40]

Subject: Update on Novel Food Application - [Section 40]

Dear [Section 40],

I'm getting in touch to update you on [Section 40] members and the novel food process.

We are pleased to inform you that [Section 40] members voted at the AGM to create an [Section 40] Consortium with the aim to submit a NF application. We decided to do this application via a consortium as it needs to be comprehensive and the high cost would otherwise be prohibitive for smaller companies. Working together not only enables us to pool funds but also to share expertise.

We are currently in the process of reviewing different companies experienced in novel food applications who can support us through this process. UK's [Section 40] is on the shortlist.

We understand that the application is to be submitted to EFSA directly and we will keep you informed with updates.

Kind regards

[Section 40]

Attachment:

CIS Clinical Investigation Support



CIS Clinical Investigation Support GmbH
Kaiserstr. 43, A-1070 WIEN, Austria, ☎ +43-1-5234015,
✉ nahler@aon.at

Hemp – a traditional food

Expert Report

On behalf of the “European Industrial Hemp Association (EIHA)”

Date 11 July 2019

Author,
Signature

Dr.med., Dr.phil. Gerhard Nahler

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3	Hemp flowers and leaves are used as food in Europe since more than 500 years	8
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Executive Summary

Hemp has been a source of food in Europe for more than two thousand years. The presence of cannabinoids as well as of other components notably terpenes and polyphenols, can be demonstrated in all major parts of hemp, flowers, leaves, stem, roots and seeds. A number of these phytochemicals are shared with hops, as the closest related plant. Many phytochemicals in hemp, except Δ^9 -tetrahydrocannabinol (THC), are found in other herbs of the plant kingdom. A notable number of phytochemicals in hemp flowers, leaves, stem, roots and other parts of hemp overlap in their qualitative profile, although quantitatively cannabinoids and terpenes are highest in buds (flowers). Cannabinoids have always been present in hemp food and in hemp products, in the past certainly in much higher concentrations than today. Historic documents prove that hemp has continuously played an important role as food. Flowers, leaves and other parts were cooked with fat, oil, water and wine, often in combinations, which are, in chemical terms, simple extraction processes similar to those of our days. Nothing about hemp as food is new or "novel". Despite of the traditional use and despite of a number of identical phytochemicals, in particular cannabidiol (CBD) and THC, which occur in flowers, leaves, roots and seeds, only the latter are currently accepted as "not novel".

After focussing health and legal concerns on THC for many decades and after the reduction of respective concentrations close to zero or at least to insignificant amounts in hemp food, new regulatory concerns target CBD as the second important cannabinoid in cannabis and the primary in hemp, despite that CBD is neither psychotomimetic nor toxic. In dried herbal material of varieties permitted for cultivation in the European Community, CBD concentrations are around 2-6% with 10 to 30-times lower THC concentrations, although cultivars producing more CBD exist. Without the artificial addition of purified CBD or a deliberate concentration, most hemp foods and dietary supplements would demonstrate CBD amounts in the order found in the original plant (around 20-60 mg/g for varieties permitted in the EC). Nothing about such products can be considered as "novel". In comparison to pure CBD which has demonstrated therapeutic effects as active pharmaceutical ingredient in mean daily doses of 400 to 800 mg or higher, concentrations of CBD in hemp food or supplements are minor and human exposure is insignificant.

Effects of a single substance, CBD or THC, can never mirror effects of a phytocomplex of hundreds of interacting substances where cannabinoids represent only a very small percentage, and vice versa. If used as medication, CBD needs much higher dosages than those commonly achieved with hemp food. Pure CBD is safe, and this assures also a high safety margin for hemp products with respect to CBD as by-product, even in case they are taken in excess and not as directed.

An ever increasing amount of publications underline the importance of phytochemicals for the maintenance of human health and the prevention of chronic diseases. Hemp food, rich in terpenes, polyphenols and other antioxidants can contribute to a healthy diet. Therefore, no reasons exist that necessitate a protection of the population against hemp products in particular CBD, and to withhold their trade and consumption.

1 Introduction

To many, cannabis (*C. sativa* L.) is a recreational drug; to some, it is a medicine, to others a source of food, fibres or bio-energy. Cannabis is a plant with a huge number of varieties; approx. 1,000 cultivars are known (<http://ocpdb.pythonanywhere.com/>, website hosted by Open Cannabis Project) that differ mainly in their content of the two principal cannabinoids, the psychotomimetic, intoxicating delta-9-tetrahydrocannabinol (in short THC) which is the primary cannabinoid found in “drug-type” cannabis (“marijuana”, a pejorative slang term for drug-type cannabis), and cannabidiol (CBD) which is the main cannabinoid in hemp (“fibre-type” cannabis). The term “hemp” is therefore used for those cannabis varieties that are low in THC (<0.2% by current European law, after 0.5 and 0.3%), “drug-type cannabis” for those that are rich in THC, and “cannabis” as overall term. This difference between drug-type cannabis and hemp is important for legal and forensic reasons.

The current threshold of 0.2% in the European Community (after Council Regulation 1672/2000/EC) is not uniform among countries. Swiss Federal Law of Drugs allows cannabis with less than 1%, New Zealand allows the growth of industrial hemp if the THC concentration does not exceed 0.35 %, and Canada accepts an upper limit of 0.3% for non-drug type cannabis. Recently, the WHO recommended to change the wording of the 1961 Single Convention on Narcotic Drugs about hemp extracts (to read: “Preparations containing predominantly cannabidiol and not more than 0.2 per cent of delta-9-tetrahydrocannabinol are not under international control”; WHO Expert Committee on Drug Dependence, 2018, 41st Report, Sec.7.5). The “Single Convention on Narcotic Drugs, 1961” clearly differs between *hemp* and *cannabis*, specifically excluding from control plants that are used for industrial or horticultural purposes (hemp). However, the role of hemp specifically for food and preparations thereof was not defined at that time. To note, in Canada, cannabis is legal for medicinal and recreational purposes since 30th of July 2018, in Jamaica since 2015.

In fact, neither CBD nor THC is formed naturally (enzymatically) by the plant. Both substances are the decarboxylated form of cannabidiolic acid (CBDA) and delta-9-tetrahydrocannabinolic acid (THCA-A, THCA-B, in short THCA) respectively, induced in nature by slowly aging (mainly by light), or in post-harvest processing by heating. In general, about 20 to 50-times higher concentrations of acid cannabinoid (THCA) are found in dried resp. fresh but otherwise unheated cannabis plants (Nahler et al., 2019). This is particularly important because THCA is not psychotomimetic/intoxicating in contrast to the parent compound THC; THCA (THC) is unique to cannabis. It is worth mentioning that THC or THC-like cannabimimetic compounds have never been detected in other plants than cannabis. In contrast, a compound with properties similar to CBD has been found in flax (in fibres and all other flax tissues) although this still awaits further confirmation (Styrczewska et al., 2012). Flax is a well-known fibre-type plant, and is - similar to hemp - used to produce oil (linseed oil). To note, heating changes not only the composition of cannabinoids (decarboxylation of cannabinoid acids) but also the profile of polyphenols and other phytochemicals such as terpenes (Lewis et al., 2017). One of the characteristic differences between hemp and drug-type cannabis is the significantly higher mean content of CBD in hemp (Hazekamp et al., 2016) paired with a low content of THC.

Cannabis (hemp) may contain, in addition to about 120 cannabinoids, an estimated number of 600 or more of other phyto-compounds that widely occur in nature such as polyphenols (flavonoids), terpenes, and unsaturated fats (American Herbal Pharmacopoeia 2013); many of

them are well known for their health benefits. No other plant is so intensively studied as drug type cannabis. Whenever it comes to hemp, it must be stressed that the characteristics and properties of the plant and its derivatives cannot be attributed to a single active compound such as THC or CBD as it is often the case in discussions; in hemp, ~ 95% to ~ 98% are other phytocompounds and not CBD. Focussing on a single compound would completely ignore the multiplicity of effects and interactions of hundreds of other concomitant phytosubstances (activity of the “phyto-complex” / “entourage effect”), in addition to the fact that pure cannabinoids are used as medications in about 100 to 1,000 times higher doses.

All parts of the hemp plant contain cannabinoids, in addition to terpenes, polyphenols and other phytocomponents, although in varying amounts. In drug type cannabis, grown in greenhouse as an example, ten times higher concentrations of cannabinoids have been reported in flowers compared to leaves (Richins et al. 2018). However, this may not be the case for out-door grown hemp where the difference is much smaller with cannabinoid concentration in flowers less than twice the concentration in leaves [total THC (sum of THC + THCA) in flowers 0.07%, total CBD (= CBD + CBDA) 1.96% compared to 0.04 and 1.42% resp. in dried leaves (personnel communication, data on file)]. Even seeds and roots, long time considered as free of cannabinoids, contain small amounts of THC (THCA), CBD (CBDA) and others (below 0.5 to 2.0 mcg/g dry weight; Farag, Kayser 2015; Gul et al., 2018; Ross et al., 2000). In addition to the concentrations of cannabinoids which differ between hemp and drug-type cannabis, the profile (chemical fingerprint) of other phytocompounds in particular terpenes is a further characteristic. **Hemp is therefore definitively not “marijuana-light”**. Hemp is genetically different and must not be mixed up with drug-type cannabis as it is often the case.

Cannabis has as “cousin”, namely hops, with a common ancestor about 27 million years ago. Unsurprisingly, cannabis and hops still share a number of the same phytocompounds in particular sesquiterpenes (e.g., β -caryophyllene, alpha-humulene), monoterpenes (e.g., β -myrcene, alpha-pinene, limonene, linalool), and polyphenols (flavonoids) such as quercetin, rutin, kaempferol and stilbenes, but not cannabinoids (Knez et al., 2018). A wide range of these phytocompounds have been studied for their biological activity and beneficial effects on health. Limonene and perillyl alcohol, a precursor of limonene, given as examples, demonstrated anticancer effects in phase I/II clinical studies (da Fonesca et al., 2011; Shojaei et al., 2014); β -caryophyllene and its oxide possess significant anticancer activities, affecting growth and proliferation of various cancer cells; β -myrcene, widely used as flavouring additive in food and beverage and as a scenting agent in fragrances, is a TNF α inhibitor and demonstrates cardioprotective effects (Burcu et al., 2016). Polyphenols and other phytocompounds are increasingly recognised to play an important role in the maintenance of health (Almeida et al., 2016; Lagoa et al., 2017; Li et al., 2016; Shehzad et al., 2016). Hemp food, rich in phytocompounds, can therefore significantly contribute to the maintenance of health. Intriguingly, in both, hemp and hops, the most prominent secondary phytocompounds are β -myrcene and β -caryophyllene. Like cannabis, hops plays a dual role in nutrition and folk medicine since many centuries (Koetter, Biendl 2010; Dietz et al., 2016; Dostalek et al., 2017).

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All parts of the hemp plant contain cannabinoids, in addition to terpenes, polyphenols and other phytocomponents, although in varying amounts. In drug type cannabis, grown in greenhouse as an example, ten times higher concentrations of cannabinoids have been reported in flowers compared to leaves (Richins et al. 2018). However, this may not be the case for out-door grown hemp where the difference is much smaller with cannabinoid concentration in flowers less than twice the concentration in leaves [total THC (sum of THC + THCA) in flowers 0.07%, total CBD (= CBD + CBDA) 1.96% compared to 0.04 and 1.42% resp. in dried leaves (personnel communication, data on file)]. Even seeds and roots, long time considered as free of cannabinoids, contain small amounts of THC (THCA), CBD (CBDA) and others (below 0.5 to 2.0 mcg/g dry weight; Farag, Kayser 2015; Gul et al., 2018; Ross et al., 2000). In addition to the concentrations of cannabinoids which differ between hemp and drug-type cannabis, the profile (chemical fingerprint) of other phytocompounds in particular terpenes is a further characteristic. **Hemp is therefore definitively not “marijuana-light”**. Hemp is genetically different and must not be mixed up with drug-type cannabis as it is often the case.

Cannabis has as “cousin”, namely hops, with a common ancestor about 27 million years ago. Unsurprisingly, cannabis and hops still share a number of the same phytocompounds in particular sesquiterpenes (e.g., β -caryophyllene, alpha-humulene), monoterpenes (e.g., β -myrcene, alpha-pinene, limonene, linalool), and polyphenols (flavonoids) such as quercetin, rutin, kaempferol and stilbenes, but not cannabinoids (Knez et al., 2018). A wide range of these phytocompounds have been studied for their biological activity and beneficial effects on health. Limonene and perillyl alcohol, a precursor of limonene, given as examples, demonstrated anticancer effects in phase I/II clinical studies (da Fonesca et al., 2011; Shojaei et al., 2014); β -caryophyllene and its oxide possess significant anticancer activities, affecting growth and proliferation of various cancer cells; β -myrcene, widely used as flavouring additive in food and beverage and as a scenting agent in fragrances, is a TNF α inhibitor and demonstrates cardioprotective effects (Burcu et al., 2016). Polyphenols and other phytocompounds are increasingly recognised to play an important role in the maintenance of health (Almeida et al., 2016; Lagoa et al., 2017; Li et al., 2016; Shehzad et al., 2016). Hemp food, rich in phytocompounds, can therefore significantly contribute to the maintenance of health. Intriguingly, in both, hemp and hops, the most prominent secondary phytocompounds are β -myrcene and β -caryophyllene. Like cannabis, hops plays a dual role in nutrition and folk medicine since many centuries (Koetter, Biendl 2010; Dietz et al., 2016; Dostalek et al., 2017).

A lot of ancient rituals around hemp demonstrate its unbroken popularity and social role over centuries and across generations. In Baden, Germany, for example, cakes have been baked to stimulate hemp growth (*Hanffeier*) (Benet 1975). In Poland, married women dance "the hemp dance" on Shrove Tuesday. The hemp dance ('for hemp's sake') is also danced at weddings by the young bride. Hemp was very popular at the turn of the last century as is demonstrated even by children's books. End of the 19th century, two booklets have been published with nursery rhymes and pictures for kids ("Der Hanfanbau im Elsass", Blattlaus Vlg. 1896, and "Das Büchlein vom Hanf", Carl Flemming Vlg. 1899).

As has already been mentioned, European hemp is not intoxicating and distinct from drug-type cannabis ("*Cannabis indica*") which needs a warmer climate and longer day time. It should be reminded that all parts of hemp (cannabis) contain THCA (THC) and CBDA (CBD), sometimes in very low concentrations. Therefore cannabinoids have always been present in hemp food since ancient times, and most likely in higher concentrations in the past than today.

3 Hemp flowers and leaves are used as food in Europe since more than 500 years

Early man roaming around in search of edible plants (so called “vegetables”) has certainly discovered the seeds and powerful odour of the ripened tips of the weeds. Through the ages, fibres are used for cordage and clothes, flowers, leaves and seeds were crushed, and extracted with butter, milk, oil, water or alcohol (wine) or combinations thereof. Beside a consumption of raw parts, hemp is used mainly in form of cooked products. Leaves, while not as nutritional as the seeds, are edible and are consumed raw or, most often, infused with water and used as infusion. All these steps are, in chemical terms, simple extraction processes, and are similar to modern techniques using supercritical carbon dioxide (sCO₂) as liquid. Supercritical carbon dioxide extraction is an environmentally friendly, inert solvent widely used since the 1970s for the preparation of flavours and pungencies from spices, hops and other plants, and is “Generally Recognised as Safe” (GRAS) by the FDA. Whereas fats and oils extract a higher amount of cannabinoids and terpenes from cannabis (Romano, Hazekamp 2013), the profile of compounds extracted with sCO₂ seems to be, by and large (reduction of nitrates, heavy metals, myrcene, etc.), comparable to an ethanol-extract as can be assumed from data of hops (Hopsteiner 2016).

Over many generations, an uncountable number of variations of hemp preparations have been developed and became, eventually, part of a local culture. Inscriptions on the vault of the Tower of the Escape, Canton de' Fiori in Bologna, dating around 1390, point to the importance of hemp: “*Panis vita, cannabis protectio, vinum laetitia*” that in Latin means: “Bread is life, cannabis is protection, wine is fun”.

The importance of a healthy nutrition is increasingly recognised in our days, whether we call it simply as healthy diet, functional food, nutritional/dietary supplement, nutraceutical, superfood or else. Hemp products contribute to a healthy nutrition by a large number of micronutrients, in addition to minerals, vitamins, essential amino acids and fatty acids. Many compounds of hemp have been related to disease-preventing effects such as polyphenolics (e.g., quercetin, rutin, kaempferol, naringenin), terpenes and stibonoids as has been mentioned briefly before (Cassia et al., 2013; Carvalho et al., 2019; Russo 2011; Guo et al., 2017; Gupta et al., 2016; Pollastro et al., 2018). Although the profile and concentrations of phytocompounds vary across flowers, leaves, seeds, roots a.s.o., many of the same substances, cannabinoids, terpenes, polyphenols and others have been identified in different parts of hemp. Hemp is therefore a perfect “healthy food”, whether flowers, leaves or seeds are consumed.

The oldest European recipe for a hemp dish is found in the cookbook of Bartholomaeus Platina (1475) where he describes a “health drink of cannabis nectar”. The drink is based on crushed buds (flowers) taken as food in wine or cake (Appendix A). Other recipes that use flowers and leaves can be found in cookbooks such as that of Jean de Bockenheim, cook of the pope Martin V, written around 1430 (Appendix B), in a cookbook of an anonymous author of the 14th century (Frammento di un libro di cucina del Sec. XIV, Appendix C) or in form of the ingredients for a hemp soup for monks of the 16th century (Appendix D). Based on the traditional use, many more recent cookbooks describe a number of hemp dishes; for example, the Alice B. Toklas Cook Book (1954), one of the bestselling cookbooks of all time, which includes a recipe that uses ground buds. Various other hemp dishes can be found in similar cookbooks (Gottlieb Adam 1993; Rippchen Ronald 1995). As long as fresh herbal material is not heated above 100°C, even drug type cannabis would contain only insignificant amounts of psychotomimetic (decarboxylated) THC. Fresh leaves of hemp can be eaten raw

as salad, or cooked, juiced, powdered and blended into smoothies. The leaves are a rich source of fibre, free radical scavenging polyphenols, flavonoids, 9 essential amino acids (including lysine and arginine), essential oils, as well as the minerals magnesium, calcium, and phosphorous (Audu et al., 2014).

In Europe, hemp was widely grown between the 16th and the 18th century. After a boom in the 2nd half of the 19th century with a number of very popular cannabis (hemp) based products such as the Swedish "*Maltos-Cannabis*", a hemp-based drink (Appendix E), the production and use of hemp (cannabis) went down. *Maltos-Cannabis*, was a "food remedy" widely available in Sweden, Denmark, and Norway. It has also been exported to the US, and was described as a Swedish nutrient in form of a yellowish-white powder, possessing a taste at first saline, later sweetish, and then acrid and bitter (Coblentz Virgil: *Newer remedies. A reference book for physicians, pharmacists, and students.* P. Blakiston's Son & Company, 1899). It was promoted as "*an excellent lunch drink, especially for children and young people*"; the product had won a prize at the "Exposition Internationale d'Anvers", Belgium, in November 1894.

After the wars, the use of hemp declined in West Europe by the prohibition in the 20th century, in contrast to East Europe where hemp continued to play a role as traditional food.

When the ban of hemp, lasting since 1982, was partially lifted in Germany in 1996 (Änderung des deutschen Betäubungsmittelgesetzes, i.e. 2. BTMG-Änderungsgesetz vom 04.04.1996) a number of companies cultivated hemp again and started marketing of a wide range of products made of hemp flowers, leaves, extracts or seeds, such as hemp beer, soft drinks and body care products. On the fair „*Biofach-Messe*“ in Frankfurt, Germany, in 1995, nearly 40 exhibitors presented a selection of 20,000 possible products of hemp, including hemp seed oil and hemp pastries; (ZEITonline, 21. April 1995). Some of the products were already backed by respective European Patents, e.g., EP 0844304 A2, priority date 22.11.1996 (Appendix F), concerning an alcoholic hemp drink prepared with hemp flowers, extracts of flowers, pellets, distillations of flowers, and Patent EP 0878 536 A2, about an alcoholic hemp drink prepared with hemp flowers and a hemp leave, priority date 22.4.1997 (Appendix G). Products were developed and reached the market before the "Novel Food Regulation" (Regulation 258/97 of 27.01.1997) became applicable on 15.5.1997. During the hemp fair (the "*Hanferrntefest*", Berlin) in autumn 1996, *Cannabia*, an alcoholic hemp beer/drink, was served in large amounts as a draught beer. At the opening ceremony, the Minister of Health, Horst Seehofer, took over the keg. In fact, hemp has been used as flavouring agent for beer already in the Middle Ages, and before the German "Reinheitsgebot" law has been enacted in 1516 (Steinmetz 1998; Walzl, Hlatky 2017).

Switzerland followed the German example; the 1st hemp beer based on hemp flowers has been produced by the brewery "*Wäd Brau-Haus*" in Wädenswil, also already in 1996 (<http://www.waedenswiler.ch/index.php/hanf.html>; accessed 15.6.2019), and in 1997, Patrick Glauser, a Swiss national, came up with the concept of a hemp flavoured vodka (Elation Hemp Flavored Vodka). Patrick's vodka was produced from the hemp blossom, creating a very unique and stunning tasting vodka. It has commanded a huge following in the European market (<https://www.universalflvs.com/p-6442-elation-hemp-flavored-vodka.aspx>; accessed 15.6.2019)

In 1997, the *Designer Food P&S GmbH*, Düsseldorf, another "hemp entrepreneur", started marketing of new hemp products such as a lemonade called "*Hemp*", a chocolate, a drink

“Green Hemp & Vodka” with 4% alcohol, a fruit jelly and an extract. (<http://news.bio-based.eu/markterfolge-fuer-hanfgetraenke-aus-deutschland/>).

End of 1997, the *nova institute Hürth* has conducted a survey that collected data from a total of 23 companies in Germany, Austria, UK and the Netherlands concerning the use of hemp, and the volume of production of hemp-based food products before the 15.5.1997. Drinks had been produced in an amount of 115,000 litres and other hemp products in an amount of 55 tons using hemp flowers and leaves, obviously containing cannabinoids among other phytochemicals (EIHA Document of 12.3.2019, page 10).

It is fair to say that time between the lift of the “hemp ban” and the entry into force of the “Novel Food Regulation” was only one year which is extremely short for putting innovative products on a completely new market. A “*significant use*” should therefore be judged in relation to the time available to demonstrate such a re-use after a long interruption dictated by law.

In Germany, the character of hemp products was officially assessed soon after 1996. It was determined that they have prevailing attributes as food. Therefore, such products do not fall into the requirements of regulation No 258/97 (EC) regarding novel food products and ingredients (Taschan 1999). The traditional food character is also stressed by a recent legal opinion of Hermes Piper, addressed to the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), dated 11.4.2019.

Early in 1998, *dupetit Natural Products GmbH* had contacted the European Commission in order to receive an official statement whether parts of hemp used in food are “novel” or not. The answer was clear: Food that contains parts of hemp is not considered as “Novel Food” (Appendix H). This includes hemp flowers used for flavouring beer; they are used as ingredients in the same manner as hops and are not additives.

As the number of hemp food products increases, the question arises again whether they are so called “novel foods” or not. This can be clearly answered: The “Novel Food Catalogue” of the European Commission (EC) points out without any ambiguity:

“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” And further: *“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...”* (http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm#).

To note, no restriction is made to hemp seeds in this document.

Soon after the reappearance of food products made from hemp, concerns aroused whether the content of THC and the consumption of these products is safe, without provoking psychotropic effects. Therefore, hemp food has been repeatedly analysed for its THC content as will be summarised in the next section. It must be stressed, that for forensic reasons, in most of these analyses, worst case scenarios have been used that are directed to the total content of THC (i.e., the psychotropic THC + its precursor, the carboxylic acid THCA which is not psychotropic). In natural, unheated extracts, the non-psychotropic THCA may be up to 50 times above the content of THC; this distorts results to a much higher (total) THC content than in reality. Acids and other cannabinoids such as CBD have rarely been included in analyses in the past. CBD as a “new” topic came up later, after 2010, following to ground-breaking news on treatment-resistant epilepsy that responded to CBD-rich preparations. Misleading promotions of CBD-containing products as “cures-all” medication unfortunately fuelled concerns about hemp food.

4 Concentrations of main cannabinoids in flowers, leaves and hemp food

Cannabinoids have been part of the human diet as long as man uses hemp as source of food. As genetic distinct group, hemp produces unique cannabinoid and terpenoid content profiles, whereas phenolic compounds failed to be a specific marker for cultivars (Lynch et al., 2016; Hazekamp et al., 2016). Hemp flowers and leaves can be used fresh, but they are most often processed in dried form or as extracts. The total content of terpenes, phenols and flavonoids is higher in young and fresh hemp than in mature or dried hemp (Drinić et al., 2018; Ross, ElSohly 1996).

Hemp flowers have the highest concentration of cannabinoids and terpenes, and are the source most often used for the preparation of extracts and essential (volatile) oils. Flowers rank among the most studied parts. The THC/CBD ratio in flowers is usually taken as the characteristic chemical marker for a given cultivar, although the production of CBD and THC by the plant is influenced by agroclimatic conditions. CBD concentrations of varieties permitted in the European Community are around 2-6%, with at least 10 to 30-times lower concentrations of THC (de Meijer et al., 1992; Thouminot 2015).

In dried **hemp leaves**, CBD concentrations are between 22.0 and 79.3 mg/kg, with THC between about 4.37 to 15.53 mg/kg (Lachenmeier et al., 2004; Lachenmeier, Walch 2006; Below, Rosenstock 2008). Along with low amounts of cannabinoids, hemp leaves contain stilbenoides (Guo et al., 2018), terpenes (Booth, Bohlmann 2019) and polyphenols (Choudhary et al., 2014) among many other compounds. A number of phytochemicals in hemp flowers and leaves is similar and overlaps with the profile in other parts. The monoterpene β -myrcene as well as the sesquiterpenes β -caryophyllene and α -humulene appear to be present in notable amounts in most hemp strains; β -myrcene is known to possess anti-inflammatory, analgesic, and anxiolytic properties, whereas β -caryophyllene was found to be anti-inflammatory and to exert a gastric cytoprotector activity among others (Pellati et al., 2018). Other common compounds of hemp include the monoterpenes α -pinene, limonene, and linalool. It is worth mentioning that not only cannabinoids but many other phytochemicals in hemp flowers and leaves such as quercetin, β -caryophyllene, myrcene, α -/ β -pinene, linalool, limonene, humulene and phytosterols (e.g., β -sitosterol) are also found in hemp seeds which are used as food since ancient times (Smeriglio et al., 2016; Leizer et al., 2000; Zhou et al., 2017) and which are not considered as "novel food".

Hemp extracts (and derivatives such as "edibles" and drinks) differ in their composition in so far as they contain a large number of phytochemicals that contribute to the maintenance of health in a more selected form than the native plant (Ramirez 2016; Pellati et al., 2018). Concentrations vary with the nature of the hemp cultivar, agroclimatic conditions and post-harvest processes including the extraction as main factors of influence (Nahler et al., 2019). Heat matters: concentrations of native cannabinoid acids are about 20 to 50 times that of the decarboxylated forms in fresh material and have different properties than their parent substances. Heating above 100°C transforms the cannabinoid acids, CBDA and THCA into the decarboxylated products CBD and THC as has been mentioned, but changes the profile of other phyto-chemicals as well (Lewis et al., 2017). The speed of this transformation depends on the temperature and duration of exposure; therefore transformation can be more or less complete for a specific cannabinoid acid and a specific extract. Extracts are not used in pure, concentrated form but are diluted (often with oil) and further processed to the final product. It is evident that this reduces the content of cannabinoids and other phytochemicals.

Tea infusions made from hemp flowers or leaves can contain between 0.03 and 0.40 mg THC/kg (Lachenmeier et al., 2004) or 1.0 and 2.4 mg THC/L (Lachenmeier, Walch 2006), depending on the method of preparation. As the solubility of substances increases with temperature, the concentration of cannabinoids (and other compounds) is higher and probably over-saturated in water of freshly boiled, otherwise unheated drug-type flowers (THC \approx 10mg/L, THCA \approx 43 mg/L; Hazekamp et al., 2007). Because cannabinoids are almost insoluble in water, solubility at room temperature is near the saturation concentration of \sim 2.8 mg THC/L. This contrasts with infusions prepared with hemp flowers and boiling water that contain after 10 to 15 minutes (the time for simmer) CBDA as the main compound in a concentration around 20 to 30 mg CBDA/L and 0.2mg THCA/L; CBD and THC was not detected (personnel communication, data on file). This demonstrates that transformation of THCA and CBDA into THC and CBD is insignificant at 100°C. Nonetheless, tea made from hemp flowers or leaves can contribute to a healthy diet. Hemp tea/infusion contains among other substances polyphenols (flavonoids) which are better water-soluble than cannabinoids and terpenes, and which play an important role in the maintenance of health (Nahler, Likar 2017).

THC concentrations in other food products were similar low. In other watery hemp drinks like hemp beer only insignificant amounts of THC in the range of micrograms per litre are found (0.004 – 0.016 mg THC/kg; Lachenmeier, Walch 2006, and 0.0018 mg THC/L or lower; Below, Rosenstock 2008).

THC and CBD is also a by-product in very low concentrations in hemp chocolate (THC: 0.03 to 0.11 mg/kg, CBD 0.03 to 1.12 mg/kg, Lachenmeier et al., 2004).

In **hemp flour** derived from hemp seeds, the concentrations of THC was 1.527 mg/kg (0.153%), that of CBD 0.762 mg/kg (0.076%); Lalge et al., 2016). Twelve years earlier, Lachenmeier et al. (2004) had reported lower concentrations for THC (0.26 mg/kg) and higher concentrations for CBD (10.06 mg/kg). Hemp protein preparations from seeds also contained THC (0.93 mg/g) and CBD (0.62 mg/g) (Lalge et al., 2016).

In 40 Canadian consumer products of hemp tested recently for CBD, CBDA, THC and THCA concentrations for CBD ranged from below the limit of quantification (LOQ < 0.19 mg/kg) to 8,410 mg/kg; those for THC ranged from below LOQ to 10.01 mg/kg, with one exception measuring 337 mg/kg (the legal limit in Canada is 10mg/kg) (Meng et al., 2018).

An analysis of 26 hemp products from the Swiss market (including 4 drinks, 2 chocolates, 2 bakery products, 4 hemp seed oils, 3 hemp seeds and 11 cosmetics) demonstrated that in 12 of 15 food samples THC concentrations were below the limit of detection, and in three samples in very low concentrations between 1.3 and <5mg/kg (Kantonales Laboratorium Thurgau 2011).

Experiments with seven different hemp foods from the German market (chocolate, cereal/granola bar, nuts, hemp beer, soft drinks, hemp leaf-liqueur and hemp tea) ingested by healthy volunteers demonstrated that this does not induce positive urinary test, even not after drinking 2 litres of a hemp tea with a high amount of 4.72 mcg THC/ml (Below, Rosenstock 2008).

Assuming a very conservative lowest observed effect level (LOEL) of 5 mg THC (EiHA Position Paper 2017), it is obvious that intoxication with THC is unrealistic to occur by

consumption of hemp products. Other estimates for a LOEL were two to four times higher (10-20mg/day; Geiwitz 2001).

A recent critical commentary to the current opinion of the Bundesinstitut für Risikobewertung (BfR) by the nova Institut GmbH concludes that risk assessment for THC by the BfR is substantially different and much more stringent compared to assessments of other substances potentially causing dependence such as nicotine, alcohol, opium or coffee (Skoczinski et al., 2019). Such different standards are not justified: The risk of dependence/risk to become addicted is roughly twice as high for alcohol and more than 3 to 6 times as high for nicotine compared to drug type cannabis (Watson et al., 2000; International Centre for Science in Drug Policy 2015). Furthermore, the assessment of the THC content in hemp-containing foods by the BfR is faulty as analytical methods do not differ between THC and THCA-A; this falsely increases overall THC content in products.

For CBD, no LOEL or defined acceptable non-medical CBD level exists. Therapeutic effects in clinical trials have been observed after about 200 mg/day for adults; in general, effective dosages were however much higher, between 400 to 800 mg CBD orally/day. Equivalent or lower side effects as compared to placebo have been reported after 300-600 mg/day (Bergamschi et al., 2011; Iffland, Grotenhermen 2017). A very recent systematic review concluded that there was a tendency of studies with positive outcomes to have used higher doses of CBD (Millar et al., 2019). There is consensus that CBD has no deleterious effects in humans. Experts of the WHO conclude in their 40th report: "*In humans, CBD exhibits no effects indicative of any abuse or dependence potential*"; and further "*CBD is generally well tolerated with a good safety profile*" (WHO 2018, Cannabidiol (CBD) Critical Review Report). With maximal concentrations in food products between 10 mg CBD/kg in hemp flour and 30 mg CBD/L in tea-infusions, the possible CBD exposure from consumer products is therefore far below a therapeutically effective dose range.

In conclusion, hemp food is not "novel". Hemp food, including flowers and leaves has existed in many forms since hundreds, most likely since thousand of years, and was never restricted to seeds and seed products. THC and CBD have always been present in hemp food, in the past in higher concentrations than in our days. The actual THC- and CBD- content in hemp food and industrial hemp extracts from EU-certified hemp is low; when taken as directed, hemp products are safe. Different, even conflicting requirements according to national laws are confusing consumers and hinder the free trade of hemp products in the EC.

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Appendix A - Bartolomeo Platina 1475

Barolomeo de Sacchi Platina : De Honesta Voluptate Et Valetudine. 1475

On honest indulgence and good health; written ca. 1465; the first cookbook ever printed.

It was largely a translation of recipes by Martino da Como from his *Libro de Arte Coquinaria* (ca. 1465).

The book was frequently reprinted over the next century, and translated into French, German and Italian.

Recipe for "a health drink of cannabis nectar"

To make cannabis yourself known as flax for thread
[the fiber hemp variety]

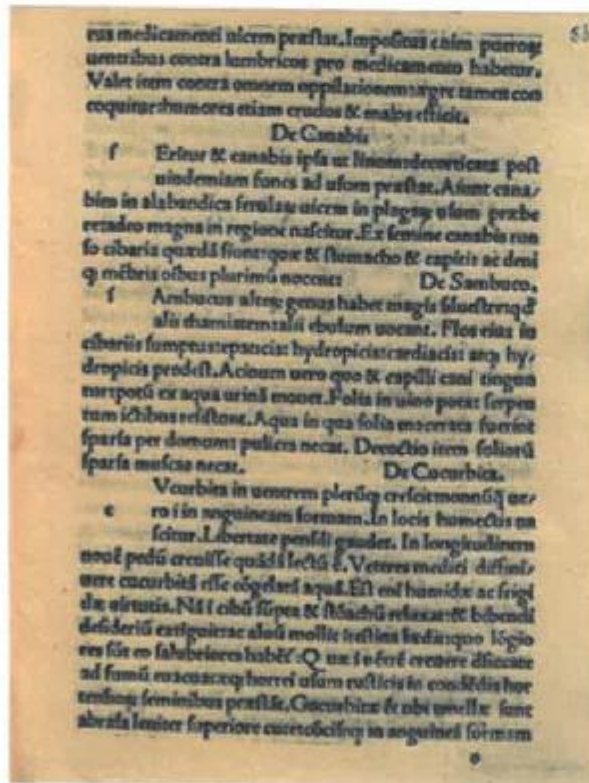
Use a mallet to crush clods [buds] collect after good
harvest

Taken as food in wine or cake

Add cannabis to nard oil In an iron pot

Crush together over some heat [decarboxylation]
until juice

A health drink of cannabis nectar



A further hemp dish:

[...] cook a pound of well-washed hemp until it splits open. When it is cooked, add a pound of almonds. When it has been pounded with bread crumbs in a mortar, moisten it with lean stock, and stir it into a pot through a sieve. Then, when it has been placed on the hearth, stir it frequently with a spoon. When it is almost cooked, put in a half-pound of sugar, a half-ounce of ginger, and a little saffron with rose water. When it is cooked and apportioned on serving dishes, sprinkle with rather sweet spices.

Appendix B - Johannes von Bockenheim) 1430, Registrum Coquine

Jean de Bockenheim (Johannes von Bockenheim) 1430, Registrum Coquine
(Le registre de cuisine, par Laurioux Bruno, 1988)

59 – Sic fac ministrum de canapo. Recipe eum, et munda eum in aqua callida, et mitte cum lente bulire, ita quod coagulatur superius; et tunc remove partem superiorem, et mitte per straminiam, ut aqua exeat; et tunc mitte eum ad ignem cum pane grattato, et cepis rostitis in oleo olive; et tunc tempera illum cum lacte eius, zapharano, et aliis speciebus; et sparge uva passa ad scutellam. Et erit bonum pro infirmis.

60 – Sic fac ministrum de farris. Recipe eas, et munda bene in aqua,

Ministrum de canapo is prepared like follows.

Boil flowers and leaves (of hemp / canapo) in water. Once ready, press them to eliminate water. Ad the mixture with bread crumbs and onion cooked in olive oil. Slowly add the water in which canapo was boiled to the mixture and add saffron and spices. ...

Le *registre de cuisine* a été écrit vers 1430 (entre 1431 et 1435 d'après Bruno Laurioux) par Jean de Bockenheim, un cuisinier allemand du pape Martin V. Comme il n'était pas seulement cuisinier, mais aussi clerc, Jean Herbordi de Bockenheim a poursuivi une carrière ecclésiastique dans les diocèses de Worms et Mayence, après avoir quitté le service du pape à Rome.

Le manuscrit écrit en latin, *Registrum coquine*, comprend 74 recettes, écrites dans le style succinct du manuscrit de Sion, contrairement aux livres de cuisine de Maître Chiquart ou Maestro Martino, davantage rédigés à la même époque.

Appendix C - libro di cucina del Sec. XIV

Frammento di un libro di cucina del Sec. XIV : edito nel di delle nozze Carducci-Gnaccarini
By Guerrini Olindo, ed., Bologna, Nicola Zanichelli 1877.

[Guerrini, Olindo. 1845-1916](#)

gruogo e se fosse troppo agra, temprala con zucchero.

*26 (xxvj) Se vuoi tortelli con fiori
di canapaccia.*

Togli questi fiori di canapaccia senza foglie e cuocili colla pancia del porco. Quando ella è presso che cotta (metti) a bollire li fiori e (quando) la carne è cotta, batti ciascuno per se. Togli finissimo cascio, altrettanto quanto è la carne, e fine spezie e fa tortelli.

27 (xxvij) Se vuoi torta di latte vivo.

Take the hemp flowers without leaves and cook them with bacon. When the bacon is almost cooked add the flowers, finish cooking, chop everything, add grated cheese, as much as the mixture and with this filling, make the tortelli.

Appendix D - Medieval hemp soup for monks, 16th century

Germany – Monk Recipe for Hemp Soup **Regional Cuisines of Medieval Europe: A Book of Essays** edited by Melitta Weiss Adamson, 2013

nineteenth-century editor calls the dishes Lenten fare. However, a closer look at the material reveals that the Tegernsee monks marked feast days by indulging in little pleasures, among them eggs, milk, and dairy products, as well as the occasional luxury such as almonds, figs, rice, and saffron. At the time the meal plans were written, the monastery must have housed approximately forty monks, because the quantities mentioned in the cookbook section are usually for forty people.⁸⁸ Hemp soup for forty monks required six pounds of hemp, three quarts of wine, one white bread, mashed apples, vinegar, and spices.⁸⁹ By medieval standards, these recipes are quite unusual in that they provide the quantities for ingredients but no cooking instructions. Normally, medieval culinary recipes contain information on ingredients and their processing but no quantities, as the following analysis of the oldest German cookbooks will show.

From a 16th century manuscript from the Benedictine monastery of Tegernsee. Listed is the food which the Convent was served throughout the year in the refectory. Apart from ingredients, cooking instructions are missing.

Six pounds = 2.7 kgs hemp. / 40 monks = 67g per person

RDI is 30g hemp seeds for western modern diet

Monks lived subsistence life. This indicates that 67g/pp included green parts

Med Lungsot, Bröst- och Magkatharr, Blåskatharr m. m. enl. Intyg.



Solen vi nu anlagt en fabrik för tillverkning af stor skala och under offentlig kontroll af

Hampfröextrakt, Extrakt-Cannabis och Maltos Cannabis,

komma vi erbjuda dessa artiklar som ganska litet stor framgång utmärkta på svenska bäckstugor (enl. Caneberkers innehållande ca 3 gånger mer än tidigare bäckstugor). Pris per burk 1 kr. för Extrakt-Cannabis och 1.25 för Maltos-Cannabis.

Af vackra paketet flaras nästan tusen kvar till nedsatt pris 75 öre.

Maltos-Cannabis

är en frö af funnen sammansättning af Hampfröets värdefulla beståndsdel med Maltospreparat.

Det Hampfröextrakt pulst, för att återbereda Hampfröet, användes en del af det som i sig sjelft ej äger så stort värde. Här användes detta ämnen att Hampfröet absorbera af Maltossocker etc. som äro af störst värde för sjelfva Hampfröextraktet. Dessa lemn för sig så värdefulla ämnen och förberedande har således uti sina olika tillagningar lyckats, och utgör således detta Maltos-Cannabis ett starkt koncentreradt medel mot sjukdomar i

Lungor, Luftrör, Bröst och Mage

samt mot Kraftlöshet och Afmagring af mänsklighet såväl äldre än själva Hampfröextraktet. Detta preparat, hvarjå patent sålts i flera länder, liksom af alla som försäkra det, komma uti föredrag framför Extrakt-Cannabis.

Cacao Maltos-Cannabis

är en närings, smid och välsmakande frukostdryck, som kan rekommenderas af alla. Smakar precis som vanlig Lima-Cacao.

Maltos sockerens 1887 af Läkarsocieteten X. Mo Dillon och har sedan dess vunnit spridning öfver nästan hela Europa som ett lämpligt medel för bröst- och maglidande samt erhållit 3 guldmedaljer. Den svenske Professorerna Mikael Sten och dessutom i ett längre intyg, uti vilket nämns dess såväl som uti många andra intyg, och af dellig sammansättning konstgjort till följande förfärdande och återställande.

Såväl att tillvara Maltos med Hampfrö och Cacao m. m. är för Sverige värdefullast medel, som vi skola hitta på goda ämnen till förtäring.

»Ej tvifla till högskoleliga, utan i många andra fall, så det är beaktligt, att patienten skall äta i fullt har jag ordinerat Maltos-Cannabis, såsom åt personer med bröstkatarr, skrofuler, liten mag, till blodfattiga, nervsaga och konvalescenter och i af då fall, rodnad under den ännu af långa tid, jag observerat allringmedlets verkan, till ett gott resultat förut, såsom ökade krafter och bättre humör. Preparatets smak är ren, kraftig och enligt min uppfattning behaglig.»

Om detta är en längre sympatisk artikel i Hälsevännens för i Mars och af den kände läkaren i Stockholm

Doktor Henrik Berg.

Tekniska Fabriken Röda Korset, Stockholm.

In Sweden, *Maltos-Cannabis*, a hemp-seed based drink was on the market between late 1890-ies and early 20th century. It was a "food remedy" that was widely available in Sweden, Denmark, and Norway. It has also been exported to the US, and was described as a Swedish nutrient in form of a yellowish-white powder, possessing a taste at first saline, later sweetish, and then acrid and bitter (Virgil *Coblentz* Newer remedies. A reference book for physicians, pharmacists, and students. P. Blakiston's son & Company, 1899).

It was promoted as "*an excellent lunch drink, especially for children and young people*"; the product had won a prize at the "Exposition Internationale d'Anvers", Belgium, 5. 1894 to 5.11.1894.



The article of 11th April 1895 describes Maltos as:

"The healthiest and in most cases the safest medicines are those in which they not only constituents are most nourishing and at the same time as tasty and stimulating. One such preparation is Maltose -- Cannabis newest in medicine had prepared of hemp seed and malt sugar, its name comes of it. The notable drug was rewarded with two medals at the exhibition in Antwerp and is advocated in Europe by of such prominent doctors as Professor Leyden, who was the physician of his Imperial Majesty Zar Alexander and Professor senator (?) at the renowned of mercy hospital in Berlin, besides a large number of second medicinal authorities in different countries. Dr. Frolsen, one of the presenters at the exhibition in Antwerp, certifies that he has "with great success prescribed Maltos-Cannabis to people who suffered from lungstot, magyra and andanaemia." He also finds it to be "a digestible and very nourishing medicine and gives in a short time good results."

+++++

De Lager, Best- och Magasin. Biskopst. S. S. af 1871.



Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis
Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis
Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis
Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis
Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis

Maltos-Cannabis

Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis
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Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis

Cacao Maltos-Cannabis

Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis
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Hampfröextrakt, Extrakt-Cannabis och Maltos-Cannabis

Tekniska Fabrikken Roka Korsnäs, Södertälje



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(54) **Alkohohaltiges wässriges Getränk und Verfahren zu seiner Herstellung**

(57) Die vorliegende Erfindung betrifft ein alkohohaltiges wässriges Getränk, welches Inhaltsstoffe von Hanfpflanzen, insbesondere von Blüten, Blütenteilen, Pellets, Blütenextrakten und/oder Blütendestillaten enthält.

Das Verfahren zur Herstellung eines alkohohaltigen wässrigen Getränks durch übliches Maischen, Läutern, Kochen, Kühlen, Gären und Lagern zeichnet sich dadurch aus, daß zu einem beliebigen Zeitpunkt beim Kochen, Kühlen, Gären oder Lagern Hanfpflanzen, insbesondere Blüten und/oder Blütenteile und/oder aus ihnen hergestellte Produkte zugesetzt werden. Bevorzugt werden Inhaltsstoffe von Hanfpflanzen der Sorten Felina, Fedora und/oder Futura eingesetzt.

Beschreibung

Die vorliegende Erfindung betrifft ein alkoholhaltiges wäßriges Getränk, welches Inhaltsstoffe von Hanfpflanzen enthält, sowie ein Verfahren zu seiner Herstellung.

Aus der Literatur sind eine Reihe von alkoholhaltigen Getränken, die Zusatzstoffe enthalten, bekannt. So beschreibt die DE 15 17 804 einen Zusatzstoff zum Bierbrauen, der aus einem Getreide einschließlich Roggen dadurch hergestellt wird, daß die Körper zunächst in Wasser geweicht und anschließend in einem Kocher bei Temperaturen zwischen 93° und 105°C wärmebehandelt werden. Dabei werden die Stärke gelatinisiert, die Enzyme zerstört und die flüchtigen Aromen verdampft. Nach Trocknung und eventueller Konditionierung kann der Zusatzstoff gelagert und beim Bierbrauen eingesetzt werden.

Aus der DE-A-14 42 279 ist die Herstellung eines Bieres bekannt, bei dem die verwendeten Rohstoffe als Konzentrate vorliegen. Dabei können z. B. auch Kaffee, der Koffein enthält, zugesetzt werden. Die Zugabe von Kaffee erfolgt dabei zu dem Zweck, die Geschmacksrichtung des Bieres zu verändern.

Die EP 0 252 063 beschreibt ein Kohlensäure und Koffein enthaltendes Getränk. Dieses Getränk besteht aus einem auf Basis von Hopfen und Malz hergestellten Bier, dem Koffein in einer Menge von 65 bis 150 mg/l zugesetzt wurde.

Die Getränke des Standes der Technik weisen Geschmacksrichtungen auf, die nur einen Teil der Konsumenten befriedigen.

Der Erfindung liegt nun die Aufgabe zugrunde, ein Getränk zur Verfügung zu stellen, welches ein fruchtiges Aroma und Geschmack aufweist.

Die Aufgabe wird durch ein alkoholhaltiges wäßriges Getränk gelöst, das sich dadurch auszeichnet, daß es Inhaltsstoffe von Hanfpflanzen, insbesondere von Blüten, Blütenteilen, Pellets, Blütenextrakten und/oder Blütendestillaten enthält.

In einer bevorzugten Ausführungsform enthält das erfindungsgemäße Getränk Inhaltsstoffe von Hanfblüten und/oder Hanfblütenteilen und/oder Pellets in Mengen von 0,05 bis 10 Gew.% oder von Hanfblütenextrakten und/oder Hanfblütendestillaten in Mengen von 0,005 bis 5 Gew.-%.

Besonders bevorzugt werden Inhaltsstoffe von Hanfpflanzen der Sorten Felina, Fedora und/oder Futura eingesetzt. Ferner werden Hanfpflanzen mit einem Tetrahydrocannabinol-Gehalt von < 0,3 % bevorzugt eingesetzt.

Eine weitere bevorzugte Ausführungsform des erfindungsgemäßen alkoholhaltigen wäßrigen Getränks zeichnet sich dadurch aus, daß es 3 bis 20 Gew.% Extrakt, der aus Getreidemalz oder Rohfrucht gewonnen wird bzw. durch Zuckerzugabe, 0,03 bis 0,7 Gew.% Hopfen und 0,0002 bis 0,005 Gew.% Hefe enthält.

Ein weiterer Gegenstand der Erfindung ist ein Ver-

fahren zur Herstellung eines alkoholhaltigen wäßrigen Getränkes durch übliches Maischen des Malzes, Läutern, Kochen, Kühlen, Gären und Lagern, das sich dadurch auszeichnet, daß zu einem beliebigen Zeitpunkt beim Kochen, Kühlen, Gären oder Lagern Hanfpflanzen, insbesondere Blüten und/oder Blütenteile und/oder aus ihnen hergestellte Produkte zugesetzt werden.

In einer besonders bevorzugten Ausführungsform des erfindungsgemäßen Verfahrens werden Hanfblüten und/oder Blütenteile und/oder aus ihnen hergestellte Produkte von Hanfpflanzen der Sorten Felina, Fedora und/oder Futura zugesetzt. Ferner werden Hanfpflanzen mit einem Tetrahydrocannabinol-Gehalt von < 0,3 % bevorzugt zugesetzt.

Eine weitere besonders bevorzugte Ausführungsform des erfindungsgemäßen Verfahrens ist dadurch gekennzeichnet, daß Hanfblüten und/oder Hanfblütenteile und/oder Pellets in Mengen von 0,05 bis 10 Gew.% oder Hanfblütenextrakte und/oder Hanfblütendestillate in Mengen von 0,005 bis 5 Gew.% zugesetzt werden.

Die Herstellung der Pellets, Extrakte und Destillate aus den Hanfblüten oder Hanfblütenteilen erfolgt nach dem Fachmann bekannten Methoden. Das erfindungsgemäße alkoholhaltige wäßrige Getränk weist ein fruchtiges Aroma und einen fruchtigen Geschmack, dessen Nuancen von Grapefruit über Mango bis Passionsfrucht reichen, auf.

Vor dem Abfüllen des Getränks in Flaschen, Dozen, Fässer, Container oder anderer Gebinde können dem Getränk Hanfblüten und/oder Hanfblütenteile und/oder aus ihnen hergestellte Produkte im Bereich der vorab angegebenen Konzentrationen zugesetzt werden.

Das Getränk kann vor der Abfüllung nach bekannten Filtrationsmethoden von den vorhandenen Hefezellen und Eiweißstoffen, gegebenenfalls unter Verwendung von üblichen Filterhilfs- und/oder Stabilisierungsmitteln, befreit und/oder anschließend mittels einer dem Fachmann bekannten Hochkurzzeitheizung (Flash-Pasteurisation) haltbar gemacht werden.

Die Erfindung wird an den nachfolgenden Beispielen näher erläutert.

Beispiel 1

Einem auf übliche Weise gebrauten Bier werden pro Hektoliter Bier 125 g Hanfblüten der Hanfpflanzenart Felina beim Kochen zugesetzt und das so hergestellte Getränk abgefüllt.

Beispiel 2

Einem nach Art eines Bieres auf Basis von Getreidemalz, Hopfen und Hefe in an sich bekannter Weise hergestelltes Gärungsprodukt, das einen Alkoholgehalt von 4,9 Vol. % aufweist, werden pro Hektoliter 4000 g Hanfblütenextrakt der Hanfpflanzenart Fedora zuge-

setzt und das so hergestellte Getränk abgefüllt.

Beispiel 3

Ein Gerstenbier mit einem 9 %igen Stammwürzegehalt wird in üblicher Weise gebraut. Nach dem Gärungsvorgang werden dem Getränk im Lagertank pro Hektoliter 7850 g Hanfblütenteile der Hanfpflanzensorte Futura, die einen Tetrahydrocannabinol-Gehalt von 0,00003 % aufweisen, zugesetzt, das Getränk filtriert und in Flaschen abgefüllt. Bei Genuß dieses Getränkes wird die nach einem Biergenuß bei manchen Menschen auftretende Müdigkeit durch die anregende Wirkung des fruchtigen Aromas und Geschmacks der Hanfblütenteile zumindest teilweise kompensiert.

Beispiel 4

Verfahren zur Herstellung des alkoholhaltigen wäßrigen Getränks.

Das Getreide-Malz wird mittels einer Mühle geschrotet und in einem geeigneten Gefäß mit Wasser vermischt. Das Verhältnis von Malz zu Wasser kann im Bereich von 1 : 2 bis 1 : 8 schwanken, je nachdem, welcher Alkoholgehalt im fertigen Getränk erreicht werden soll. Die Gesamtmaische wird in einem brauereiblichen Infusions- oder Dekoktionsverfahren über verschiedene Temperaturstufen bis zu einer Temperatur von max. 80°C erhitzt. Dieser Vorgang dauert je nach der verwendeten Malzqualität und der gewünschten Getränkeigenschaften zwischen 60 und 220 Minuten.

Die festen Bestandteile des Malzes (Spelzen oder Treber genannt) werden von den gelösten und während des Maischens in flüssige Form überführten Extraktbestandteilen getrennt. Dies geschieht entweder in einem mit einem Siebboden ausgestatteten Läuterbottich oder mittels eines Maischefilters. In der Regel wird der in den Trebern zurückgehaltene Extrakt nach der ersten Filtration nachträglich mit maximal 80°C heißem Wasser ausgewaschen. Dieser Vorgang ist jedoch keine Bedingung.

Die durch das Läutern gewonnene Würze wird mit Hopfen gekocht, die Kochtemperatur beträgt je nach Verfahren zwischen 96°C und 150°C, die Kochdauer zwischen 60 Sekunden und 180 Minuten.

Zu einem beliebigen Zeitpunkt während dieses Vorganges bietet sich die Möglichkeit, Hanfblütenteile oder aus ihnen hergestellte Produkte im Bereich der erfindungsgemäß angegebenen Konzentrationen einzeln oder in Kombination zuzusetzen.

Nach Beendigung des Kochvorganges wird die nun Würze genannte Flüssigkeit durch ein geeignetes Gefäß (z. B. Whirlpool) oder ein entsprechendes Gerät (z. B. Zentrifuge) vom Kochtrub befreit.

Danach wird die Kühlung entweder mittels eines Wärmetauschers oder auf einem Kühlschiff bis auf die angestrebte Anstelltemperatur durchgeführt. Die Anstelltemperatur beträgt je nach verwendeter Hefeart

und Hefestamm zwischen 4°C und 26°C.

Zu einem beliebigen Zeitpunkt während dieses Vorganges bietet sich die Möglichkeit, Hanfblütenteile oder aus ihnen hergestellte Produkte im Bereich der erfindungsgemäß angegebenen Konzentrationen einzeln oder in Kombination zuzusetzen.

Die Hauptgärung wird durch eine unter- oder obergärige Bier- oder Brauereihefe und/oder eine Weinhefe vorgenommen. Die Würze wird vor, während, oder nach der Hefegabe belüftet. Der angestrebte Sauerstoffgehalt in der Würze liegt zwischen 8 mg/l und 12 mg/l.

Die Gärung erfolgt in dafür vorgesehenen offenen oder geschlossenen Gefäßen oder Behältern, die mit einer Kühlung (Direkt- oder Raumkühlung) ausgestattet sind, um die Gärtemperatur zu steuern. Die Gärtemperatur schwankt im Bereich von 4°C bis 26°C, je nach Hefeart und Hefestamm. Die Dauer der Hauptgärung beträgt - ebenfalls abhängig von Hefeart und Hefestamm, sowie vom Extraktgehalt der Würze - zwischen 2 und 14 Tagen.

Zu einem beliebigen Zeitpunkt während dieses Vorganges bietet sich die Möglichkeit, Hanfblütenteile oder aus ihnen hergestellte Produkte im Bereich der erfindungsgemäß angegebenen Konzentrationen einzeln oder in Kombination zuzusetzen.

Die Nachgärung oder Lagerung stellt einen Reifungsprozeß dar, bei dem der Restextrakt bei Temperaturen zwischen 2°C - 12°C und einer Dauer zwischen 7 - 120 Tagen langsam bzw. still vergoren wird. In speziellen geschlossenen Lagergefäßen, welche direkt oder raumgekühlt und mit einer Spundapparatur versehen sind, reichert sich das Getränk je nach eingestelltem Gegendruck mit gärungseigener Kohlensäure an.

Zu einem beliebigen Zeitpunkt während dieses Vorganges bietet sich die Möglichkeit, Hanfblütenteile oder aus ihnen hergestellte Produkte im Bereich der angegebenen Konzentrationen einzeln oder in Kombination zuzusetzen.

Das Getränk kann vor der Abfüllung filtriert und gegebenenfalls pasteurisiert werden. Die Abfüllung erfolgt entweder direkt vom Lagertank oder nach einer Filtration und Pasteurisation. Nach der Filtration wird das Getränk in einem Puffertank aufgefangen. Auch hier bietet sich die Möglichkeit, Hanfblütenteile oder aus ihnen hergestellte Produkte im Bereich der erfindungsgemäß angegebenen Konzentrationen einzeln oder in Kombination zuzusetzen. Hiernach wird das Getränk auf Flaschen, Dosen, Fässer, Container oder andere Gebinde abgefüllt.

Beispiel 5

Verfahren zur Herstellung eines alkoholhaltigen wäßrigen Getränks (alle Mengenangaben beziehen sich auf 100 Liter).

Rohstoffe

- a) 7 kg Pilsener Malz, 7 kg Münchner Malz, 2 kg Cara-Hell, 2 kg Weizenmalz
 b) 52 Liter enthärtetes Wasser (Hauptguß)
 c) 110 g "Hallertauer Perle"-Aromahopfen
 d) 300 g "Felina 34"-Nutzhanfblüten

Schroten

die gesamte Malzmenge, auch Schüttung genannt, wird mittels einer Walzenmühle geschrotet.

Maischen

das Malzschrot wird nun mit dem auf 52°C vorgeheizten Wasser (Hauptguß) vermengt. Anschließend wird hochgeheizt auf 62 - 64 °C (1. Temperaturrast, Dauer: 30 min.). Es erfolgt ein erneutes Hochheizen, nun auf 72 - 74 °C (2. Temperaturrast, sog. Verzuckerungsrast, Dauer: 30 min.)

Bei Jodnormalität der Maische (es liegt keine Stärke mehr vor) wird aufgeheizt auf 76 - 78 °C zum Abmaischen (Umpumpen der Maische vom Maisch- in den Läuterbottich).

Läutern

nach dem Abmaischen erfolgt eine Läuterruhe (Absetzen der festen und ungelösten Bestandteile der Maische, die dann auf dem Siebboden des Läuterbottichs eine Filterschicht bilden). Nach dem Abziehen und Zurückpumpen der Trubwürze erfolgt der Vorderwürzeablauf (20 - 24 Liter, Extraktgehalt: 18 - 22 Gew.%, Dauer: 30 - 35 min.). Nun beginnt das Aussüßen des Treberkuchens durch 3 aufeinanderfolgende Nachgüsse (ebenfalls enthärtetes Wasser, 76 °C heiß), die sich wie folgt zusammensetzen:

1. NG: 30 Liter, Dauer: 35 - 45 min., Extraktgehalt: 12 - 18 Gew.%;
2. NG: 25 Liter, Dauer: 25 - 35 min., Extraktgehalt: 6 - 12 Gew.%;
3. NG: 25 Liter, Dauer: 25 - 35 min., Extraktgehalt: 1,5 - 6 Gew.%

Nach dem "Trockenziehen" des Treberkuchens (15 - 20 Liter, Dauer: 25 - 35 min., Extraktgehalt: 0,5 - 1,5 Gew%) ist der Läutervorgang beendet, es kann nun ausgetrebert werden (Entfernen des Treberkuchens aus dem Läuterbottich) und gleichzeitig bringt man durch Hochheizen die gewonnene Würzmenge in der Würzpfanne zum Kochen. Resultierend aus den eingesetzten Mengen erhält man ein "Pfanne voll"-Volumen von 115 - 120 Litern mit einem Extraktgehalt von 10,5 - 11,5 Gew.%.
 4

Kochen

Nach Einsetzen der Kochung erfolgt unmittelbar die Hopfengabe (einstellen der Grundbittere). Bei Halbzeit der 90 minütigen Kochung wird die Hanfgabe vorgenommen.

Ausschlagen

Die Würze wird nun in eine Rotationsbewegung (sog. "Whirlpool-Effekt") versetzt, damit der Trub (koagulierte Eiweiß + Hopfengerbstoffe) sich in der Mitte der Würzpfanne absetzen kann. Dieser Trub wird dann abgeschieden. Das eigentliche Ausschlagen erfolgt durch Abziehen der Würze über eine Kühlvorrichtung. Die gekühlte Würze wird dann direkt in das Gärgefäß eingelassen.

Anstellen

Beim Köhlen erfolgt eine ausreichende Belüftung. Anschließend werden 0,5 Liter dickbreiige Hefe unter gleichmäßigem Rühren zugegeben. Nach 12 - 24 Stunden setzt die Gärung ein.

Gärung

Wird obergärig bei 18 - 22 °C vollzogen und dauert in der Regel 6 - 8 Tage. Bei einem Spindelwert von 3,5 - 4,0 Gew.%, also 1,0 - 1,5 Gew.% über dem Endvergärungsgrad hat das Jungbier seine "Schlauchreife" erreicht und kann in die Lagertanks gefüllt werden.

Lagern


Das "Jungbier" lagert nun in geschlossenen Tanks bei einer Temperatur von 0 - 2 °C für eine Dauer von 3 - 4 Wochen. Nach Ablauf dieser Lagerdauer erfolgt ein Umdrücken auf Ausschankbehälter, von denen aus der Trunk unfiltriert ausgeschenkt wird.

Patentansprüche

1. Alkoholhaltiges wäßriges Getränk, dadurch gekennzeichnet, daß es Inhaltsstoffe von Hanfpflanzen, insbesondere von Blüten, Blütenteilen, Pellets, Blütenextrakten und/oder Blütendestillaten enthält.
2. Alkoholhaltiges wäßriges Getränk nach Anspruch 1, dadurch gekennzeichnet, daß es Inhaltsstoffe von Hanfblüten und/oder Hanfblütenteilen und/oder Pellets in Mengen von 0,05 bis 10 Gew.% oder von Hanfblütenextrakten und/oder Hanfblütendestillaten in Mengen von 0,005 bis 5 Gew.% enthält.
3. Alkoholhaltiges wäßriges Getränk nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß es Inhalts-

stoffe von Hanfpflanzen der Sorten Felina, Fedora und/oder Futura enthält.

4. Alkoholhaltiges wäßriges Getränk nach Anspruch 3, dadurch gekennzeichnet, daß es Inhaltsstoffe von Hanfpflanzen mit einem Tetrahydrocannabinol-Gehalt von < 0,3 % enthält. 5
5. Alkoholhaltiges wäßriges Getränk nach mindestens einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß es zusätzlich Getreidemalz, Hopfen und Hele enthält. 10
6. Verfahren zur Herstellung eines alkoholhaltigen wäßrigen Getränkes durch übliches Maischen des Malzes, Läutern, Kochen, Kühlen, Gären und Lagern, dadurch gekennzeichnet, daß zu einem beliebigen Zeitpunkt beim Kochen, Kühlen, Gären oder Lagern Hanfpflanzen, insbesondere Blüten und/oder Blütenteile und/oder aus ihnen hergestellte Produkte zugesetzt werden. 15
20
7. Verfahren nach Anspruch 6, dadurch gekennzeichnet, daß die Hanfblüten und/oder Blütenteile und/oder aus ihnen hergestellte Produkte von Hanfpflanzen der Sorten Felina, Fedora und/oder Futura zugesetzt werden. 25
8. Verfahren nach Anspruch 7, dadurch gekennzeichnet, daß Hanfpflanzen mit einem Tetrahydrocannabinol-Gehalt von <0,3 % zugesetzt werden. 30
9. Verfahren nach mindestens einem der Ansprüche 6 bis 8, dadurch gekennzeichnet, daß Hanfblüten und/oder Pellets in Mengen von 0,05 bis 10 Gew.% oder Hanfblütenextrakte und/oder Hanfblütendestillate in Mengen von 0,005 bis 5 Gew.% zugesetzt werden. 35
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(19)  **Europäisches Patentamt**
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(11) **EP 0 878 536 A2**

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(54) **Alkoholisches Getränk mit Hanfbestandteilen**

(57) Ein alkoholisches Getränk, dessen Hauptbestandteil aus Branntwein oder Met besteht, enthält 2 bis 30 Vol.% aus Hanfblüten gewonnenem und mit Zucker versetztem Hantsirup und mindestens ein Hanfblatt in ganzer oder grob geschroteter Form.

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Beschreibung

Die Erfindung betrifft ein alkoholisches Getränk, dessen Hauptbestandteil aus Branntwein oder Met

besteht. Es sind in durchsichtige Flaschen abgefüllte, alkoholische Getränke bekannt, in denen aus optischen Gründen besonders auffällige Bestandteile enthalten sind, beispielsweise golden schimmernde Plättchen, die sich insbesondere beim Kippen der Flasche innerhalb der Flüssigkeit bewegen und einen besonderen optischen Effekt verursachen.

Der Erfindung liegt die Aufgabe zugrunde, ein alkoholisches Getränk zu schaffen, das sowohl geschmacklich als auch optisch von bekannten Getränken dieser Art abweicht und dabei einfach und kostengünstig herzustellen ist.

Diese Aufgabe wird erfindungsgemäß durch die Merkmale des Anspruchs 1 gelöst. Vorteilhafte Ausführungsformen der Erfindung sind in den weiteren Ansprüchen beschrieben.

Das erfindungsgemäße alkoholische Getränk enthält 2 bis 30 Vol.% Hanfsirup und mindestens ein Hanfblatt in ganzer oder grob geschroteter Form.

Das erfindungsgemäße alkoholische Getränk weist durch die Zugabe von Hanfsirup eine besondere Geschmacksrichtung auf, die es von bisher bekannten Branntwein- oder Metgetränken unterscheidet. Bei Hanfsirup handelt es sich um eine Flüssigkeit, die aus Hanfblüten gewonnen und mit Zucker versetzt wird.

Mit dem Hanfblatt, das jeder das alkoholische Getränk enthaltenden, transparenten Flasche zugegeben wird, wird eine zusätzliche optische Wirkung erzielt, welche das erfindungsgemäße alkoholische Getränk von anderen Getränken dieser Art deutlich hervorhebt.

Anstelle von Branntwein mit einem Alkoholgehalt von 20 bis 50 Vol.% als Hauptbestandteil des alkoholischen Getränks kann auch Met verwendet werden, der üblicherweise einen Alkoholgehalt von 10 bis 12 Vol.% hat.

Für das erfindungsgemäße alkoholische Getränk wird ein sog. Euro-Hantl verwendet, welcher eine Cannabisart darstellt, die nicht die Wirkung eines Rauschmittels hat.

Vorzugsweise hat das Hanfblatt einen mittleren Durchmesser von 2 bis 150 mm. Die Größe des Hanfblattes wird in Abhängigkeit von der Flaschengröße bestimmt, die üblicherweise 0,02 bis 3 l betragen kann.

Vorzugsweise besteht der Hauptbestandteil des alkoholischen Getränkes aus einem Kartoffelbranntwein (Wodka). Alternativ können jedoch auch andere Branntweine, wie beispielsweise Korn- oder Hanfbranntwein, verwendet werden.

Zweckmäßigerweise wird klarer Branntwein verwendet, um das Hanfblatt deutlich erkennen zu können.

Gemäß einer vorteilhaften Ausführungsform der Erfindung weist das alkoholische Getränk folgende Bestandteile auf:

- Kartoffelbranntwein oder Met
- 2 bis 30 Vol.% Hanfsirup
- 1 bis 5 % Hanfextrakt
- 1 bis 5 % Zitrone
- Hanfblatt in ganzer oder geschroteter Form

Der Hanfextrakt, auch Hanfessenz genannt, wird aus den Hanfblättern gewonnen. Mit dem Hanfextrakt kann dem Getränk eine charakteristische grüne Färbung verliehen werden. Die Zitrone wird zweckmäßigerweise in der Form von Zitronensaft zugegeben, kann jedoch auch als Zitronenpulver oder -sirup beigemengt werden. Die Zitrone dient zur weiteren Geschmacksverbesserung.

Patentansprüche

1. Alkoholisches Getränk, dessen Hauptbestandteil aus Branntwein oder Met besteht, **dadurch gekennzeichnet**, daß das alkoholische Getränk 2 bis 30 Vol.% aus Hanfblüten gewonnenem und mit Zucker versetztem Hanfsirup und mindestens ein Hanfblatt in ganzer oder grob geschroteter Form enthält.

2. Alkoholisches Getränk nach Anspruch 1, **dadurch gekennzeichnet**, daß das Hanfblatt einen mittleren Durchmesser von 2 bis 150 mm hat.

3. Alkoholisches Getränk nach Anspruch 1, **dadurch gekennzeichnet**, daß der Hauptbestandteil des alkoholischen Getränks aus Kartoffelbranntwein besteht.

4. Alkoholisches Getränk nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, daß das alkoholische Getränk folgende Bestandteile aufweist:

- Kartoffelbranntwein oder Met
- 2 bis 30 Vol.% Hanfsirup
- 1 bis 5 % aus Hanfblättern gewonnenem Hanfextrakt
- 1 bis 5 % Zitrone
- Hanfblatt in ganzer oder geschroteter Form

Appendix H – dupetit 1996

On 4. April 1996, *dupetit Natural Products*, Neunkirchen, Germany (Alfredo Dupetit, owner of the company) made a joint venture with *Bier-Company*, Berlin, to produce the beer *Cannabia®*, based on hemp flowers, on a large scale and together. *Cannabia* was served in large amounts as a draught (draft) beer, for example, at hemp fairs and the “*Hanferrntefest 1996*” in Berlin. Dupetit produced also soft drinks such as *Cannacola®* and *Cannalimo®*, along with hemp lollies, hemp biscuits and hemp bars, and other foods such as hemp tofu pate, vegetable hemp oil, hemp flour, hemp noodles and hemp seeds were marketed (<http://www.dupetit.de/de/geschichte/vom-bio-bier-zur-naturkosmetik/>; accessed 15.6.2019).

At that time, Dupetit Natural Products was already working with hemp for its specialty foods, perfume and organic cosmetic line.





EUROPÄISCHE KOMMISSION
GENERALDIREKTION III
INDUSTRIE
Gewerbliche Wirtschaft III: Verbrauchgüterindustrie
Nahrungsmittel - Rechtsvorschriften, wissenschaftliche und technische Aspekte

Brüssel, den 03-03-1998 004243
DG III/EI AK/ak D(98)

Betrifft: Ihre Anfrage bezüglich Pflanzenteile von *Cannabis sativa*

Bezug: Ihre Telefaxnachricht vom 16. Februar 1998

Sehr geehrter Herr Dupetit,

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
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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/E1/GSAbk D(98)

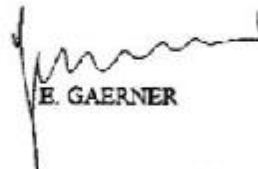
Subject: Your request for information about the opinion of the Standing Committee for Foodstuffs concerning hemp products.

Dear Mr Kreutner,

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

SonnenHaus
ÖKO-Handels GmbH
Mr Andreas Kreutner
Hermine-Berghofer-Straße 48
A-6130 Schwaz

Rue de la Loi 200, B-1049 Bruxelles/Vetstreet 200, B-1049 Brussels - Belgium - Office: RP 11 - 326
Telephone: direct line (+32-2)2955540, exchange 299.11.11. Fax: 2900951.
Telec: COMEU B 21677. Telegraphic address: COMEUR Brussels.

X.400: G=Georg; S=Schreiber; I=GS. Internet: georg.schreiber@dg3.ec.eu

Title: [Section 40] collated evidence that hemp extracts with natural containing levels of CBD is food

Dear [Section 40],

It has been a while since our last communication and I hope you are well. [Section 40] & I had a meeting with [Section 40] some time ago who said that you will be responsible for Novel Food applications.

I would like to send you the latest evidence collated by [Section 40] members that hemp extracts, containing naturally occurring levels of CBD in the plant, have been consumed historically in significant degree in the EU for centuries. The majority of evidence dates prior to the 'war on drugs' and the subsequent prohibition of hemp. However, one evidence, a hemp soft drink made with hemp extract was sold prior to May 1997 in Germany and we have copies of certificates of marketability issued by the UK Home Office and the [Section 27] authorities dated 1997 as well.

I would also like to add that clearly some CBD products, such as isolates have no history of food consumption and that there needs to be framework establishing clear parameters for both industry and regulatory authorities.

You may recall that I mentioned that I have personal experience of developing operational frameworks in an equally challenging industry in the environment sector. I would like to offer the FSA my assistance and provide relevant information to enable you to see 'the wood for the trees' so to speak and make informed decisions. If there is anything you feel that would help in this process, please let me know.

I would be grateful if you could review the evidence provided and maybe we can discuss this in a meeting?

Best regards,

[Section 40]

Attachment



EIHA presentation on Hemp Extracts

Historical evidences

May 2019

Who is EIHA and who we represent



- Originally formed almost 19 years ago; **officially founded in 2005**.
Based in Brussels and Cologne
- The **only pan-European consortium** in the industrial hemp sector
- Membership encompasses **25 EU states** and 12 additional countries including members in North America and APAC; total membership 200, primarily farmers, processors and manufacturers.
- **Policies:** CAP reform, Hemp extracts/NF regulation, THC limits in feed and food, Life Cycle Assessment of hemp materials, CO2 impacts, environment concerns, cosmetics

Evolution of consumers life-style

- Before using so called medicines as we know it, humans balanced their health with **natural foods** (vegetables):
 - plants (leaves and flowers), seeds, fruits, grains and nuts
- After so many decades of highly **processed food**, consumers are increasingly attracted by what is “**natural**”
- **Consumers trends**: physical activity, balanced and healthy diet enhanced with functional food, non-allergic ingredients and food supplements → Healthy life-style model
- To maintain “**homeostasis**” in challenging modern conditions consumers seek out food supplements of botanical origin

EU Institution approach to this shift in consumers' behavior

- 2008 Council of Europe: one of our society's main characteristic is people's growing desire to **improve** one's health condition, **reduce** the risk of disease and try to find the best possible **quality of life**
 - education's improvement/increased general knowledge and awareness
- **Homeostasis**: status of a person whose physiological parameters function within the limits considered normal – optimal balance
- **Food supplements' aim**: support, maintain or optimize the normal physiological condition = balance (homeostasis)
- **Medicines' aim**: bring back physiological functions from critical condition into normality (homeostasis)

What are hemp extracts? (focus on Cannabidiol)

- **Definition** of hemp extracts: from latin “*extrahere*” = draw out, remove) means any method that uses a (solid, liquid or gaseous) extraction agent to remove one or several components from a substance mixture (of solid, liquid or gaseous substances)
- Coffee → Coffee extract / tea → tea extract
- Cannabidiol (CBD) is the **most abundant cannabinoid naturally presents** in the industrial hemp plant and their extracts
 - Non psycotropic, non-intoxicating, not addictive, very well tolerated by humans even in large doses
- Hemp extracts are used in food/supplements for their health maintaining properties

How hemp extracts are made from hemp plant?

1. **Cold pressing:** the most simple extract from hemp fruiting tops is hempseed oil
 2. **Ethanol extraction:** using alcohol to whole fruiting tops (infructescence) and leaves
 3. **CO2 extraction:** using Carbon Dioxide to whole fruiting tops (infructescences) and leaves
 4. **Fat extraction:** can easily be used for home-made preparations
- Moreover...
 - Extract can be left raw or decarboxylated and added to consumer products without further processing
 - Extracts are usually winterized in order to remove plant waxes
 - Extract can be further distilled/rectified in order to remove unwanted elements such as chlorophyll

NF Catalogue last change

- On the 20th of January, 2019 MSs and COM agreed on a **new wording** for the NF catalogue.
- In item Cannabis sativa L:
 - hemp seeds and their derivatives are not assessed as NF
 - leaves and infructescence are left in a grey zone
- Moreover, a new item “Cannabinoids” was introduced into NF catalogue → **hemp extracts are considered NF**
- Conclusion: major confusion regarding interpretations and negative impact on the hemp sector (regarding investments, level playing field)

EiHA already demonstrated in October 2018

- Food Business Operators in EU have been acting in GOOD FAITH based on guidance represented by the information provided in Novel Food Catalogue → investments
- Use of hemp leaves and infructescence have NOT BEEN discriminated in listing for item Cannabis sativa
- Catalogue item Cannabidiol has provide a clear guidance: products with “natural” levels of CBD have been considered “traditional”
- **Only traditional propagating practicies** are used for processing hemp infructescense
- Such practicies include pressing or solvent extraction
- Presence of cannabinoids in human diet is also well documented across middle ages to the modern age. We will demonstrate it on 14 examples.

Traditional cannabinoid-rich products

Evidence #1: ITALY



Inscriptions on the Tower of the Escape, Bologna

Constructed from 1220, the vault of the Canton de 'Fiori carries the following Latin inscription:

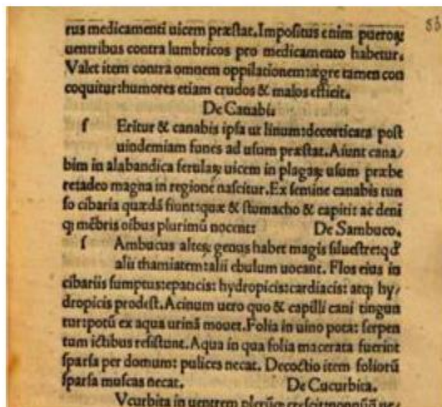
*"Panis Vita / Canabis Protectio / Vinum Laetitia" -
"Bread is Life / **Cannabis is Protection*** / Wine is Joy"*

**Protection = homeostasis*

Traditional cannabinoid-rich products

Evidence #2: ITALY

Use of aerial parts of the hemp plant within European perspective is CLEARLY demonstrated by two citations from [one of the oldest] cookbooks **De Honesta Voluptate Et Valetudine**, published in 1475 AD by Bartolommeo de Sacchi Platina



On Canabis.

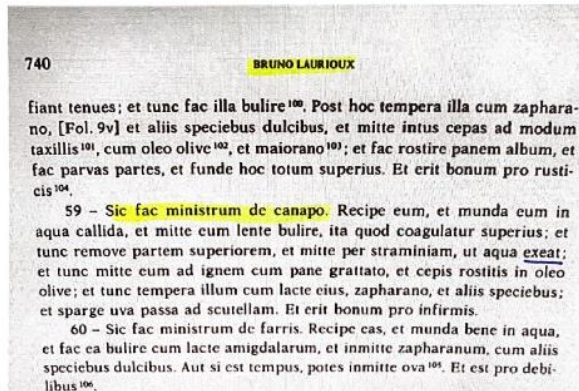
To make cannabis yourself known as flax for thread.

*Use a mallet to **crush clods** collect after good harvest
Taken as food in wine or cake.*

*Add cannabis to nard oil an iron pot. **Crush together over
some heat until juice.***

*A **health drink** of cannabis nectar. Carefully treat food and
divide for the stomach and the head. Finally remember
everything in excess may be harmful or criminal.*

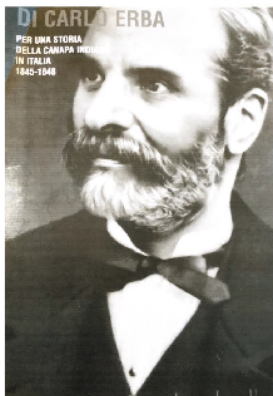
Traditional cannabinoid-rich products Evidence #3: VATICAN



59 - On Ministrum de canapo
Jean de Bockenheim, Registre de cuisine, p.740
n° 59. Reference to Bruno Lauriou, chef of
Pope Martin V

Boil flowers and leaves (canapo) in water. Once ready press them to extract water. Add the mixture with bread crumbs and cooked onion. Slowly add the water in which canapo was boiled to the mixture and add saffron and spices.

Traditional cannabinoid-rich products Evidence #4: ITALY



Carlo Erba focused his studies between 1945 and 1958 on hemp extracts.

Doctor Erba quoted two methods of “cannabina” extracts commonly used at that time:

- British chemist, Smith
- French chemist, Decourtive

Erba after having analyzed these two method he proposed the **ether extraction** as with ether there is no need to heating, no need to use metals and acids elements that could alterate the hemp properties.

Moreover in his book, Doctor Erba mentioned the studies of Doctor Valerzi (from university of Naples) that studied **hemp extracts with fat and honey** (1887).

It is written that in July 1887, Valerzi went to Veneto region in Italy and harvested Sativa hemp. From the harvest Valerzi **extracted** distilled water, essential oil, tinctures alcohol, syrup, liquors, decortications and instilled.

Traditional cannabinoid-rich products Evidence #5: ITALY



FRAMMENTO
DI SE
LIBRO DI CUCINA
DEL SEC. XIV
NEL DI DELLE NOZZE
CARDUCCI-GNACCARINI
BOLOGNA
NICOLA ZANICHELLI
1887

26 (xxvj) *Se vuoi tortelli con fiori di canapaccia.*

Togli questi fiori di canapaccia senza foglie e cuocili colla pancia del porco. Quando ella è presso che cotta (metti) a bollire li fiori e (quando) la carne è cotta, batti ciascuno per se. Togli finissimo cascio, altrettanto quanto è la carne, e fine spezie e fa tortelli.

Tortelli with hemp flowers
Take the hemp flowers without leaves and cook them with bacon. When the bacon is almost cooked add the flowers, finish cooking, chop everything, add grated cheese, as much as the mixture and with this filling, make the tortelli. (recipe dated 1884). Source: [Frammento di un libro di cucina del Sec. XIV : edito nel di delle nozze Carducci-Gnaccharini](#)"

Traditional cannabinoid-rich products Evidence #6: GERMANY

Germany – Monk Recipe for **Hemp Soup** **Regional Cuisines of Medieval Europe: A Book of Essays** edited by Melitta Weiss Adamson

nineteenth-century editor calls the dishes Lenten fare. However, a closer look at the material reveals that the Tegernsee monks marked feast days by indulging in little pleasures, among them eggs, milk, and dairy products, as well as the occasional luxury such as almonds, figs, rice, and saffron. At the time the meal plans were written, the monastery must have housed approximately forty monks, because the quantities mentioned in the cookbook section are usually for forty people.⁸⁸ Hemp soup for forty monks required six pounds of hemp, three quarts of wine, one white bread, mashed apples, vinegar, and spices.⁸⁹ By medieval standards, these recipes are quite unusual in that they provide the quantities for ingredients but no cooking instructions. Normally, medieval culinary recipes contain information on ingredients and their processing but no quantities, as the following analysis of the oldest German cookbooks will show.

Six pounds = 2.7 kgs hemp. / 40 monks = 67g per person
RDI is 30g hemp seeds for western modern diet
Monks lived subsistence life. This indicates that 67g/pp included green parts

Traditional cannabinoid-rich products

Evidence #7.1: SWEDEN

The ad specifically states:
Hampfroeextract: Extrakt-Cannabis och Maltos Cannabis

This ad confirms **that hemp extract was used in the preparation of Maltos Cannabis** nourishing food remedy.



Traditional cannabinoid-rich products

Evidence #7.2: SWEDEN

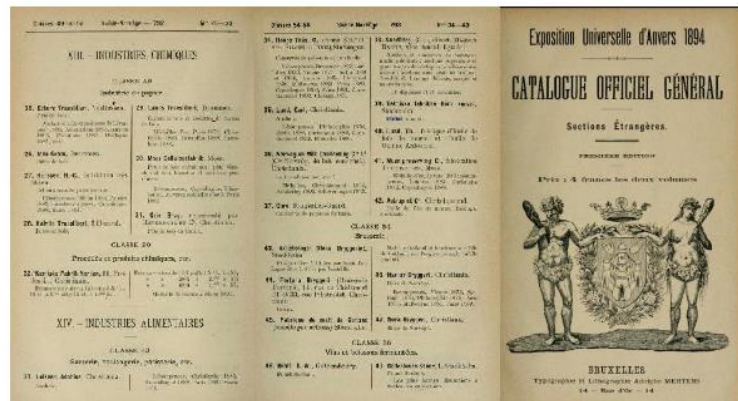
World Exhibition in Antwerp 1894 – official catalogue

Exhibition was held from 5 May to 5 November 1894 attracting 3 million visitors.

In category XIV – **Industries Alimentaires (Food Industries)**, point 39:

Tekniska fabriken Roeda korset, Stockholm

Maltos Cannabis



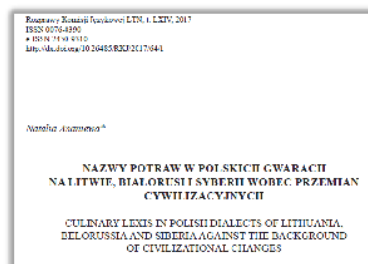
Traditional cannabinoid-rich products Evidence #8 LITHUANIA 1984

šnitka

ENG: The dish called "šnitka" was prepared in the lands of the north-eastern GDL. The dish is made from hemp leaves and is used to improve overall well-being.

Podczas głodu, którego doznał zarówno mieszkańcy polskich wiosek syberyjskich, jak i użytkownicy północno-wschodniej pokrzyzyny kresowej, jedło się różne trawy. Z tych „jadalnych” traw mieszkańcy Włdzy wymieniają osotę, litmanizm w krowy ‘nazywa’, polczyw ‘pokrzywa’, konop’ ‘kozogic’, sz’itka (poc. cni’ma, cni’ma: C šnitka – zimmarae trpa, sšimoz, kopowem i osoty cymocy sopoz... (Burzywa m i dół: N.A.), kanika i cymocy opozu i em [SBH 4, 1984, s. 514]; cni’ma: Litmowy em y ošobij, Zepnoe osomy opozu: Litmna emmwa eza [SIII 5, 1986, s. 489]. Pot. teksty z Włdz: ty’š i trawa jed’š osota/ y’awok’ i cni’ma/ šnitka gotawal’š y’ikawa, osota jed’š dawa’š’ osota’šitka pokrywa gotawal’š a gnos’š’ jed’š; konop’š’ al’š’ konop’š’ jed’š’ traw’š’ cymozka glida.

Informatorzy z Wierseyuy opowiadają: Ty’š’ jed’š i trawy/ mark’ica ‘uaz-chewnik’, Leb’oda jed’š, cyrank’š kopal’š i jed’š cyranka kv’ia’š cylevona: ca bon’š’ jed’š – sarak’š, l’š’ c’š z burakij; ny dow’š konop’š’ sol’š’ zial’š. Jedyna roślina trawiasta, która je się na Syberii doychczas, to derymka (ros. шершневá). Natomiast na Litwie i Białorusi je się kawał’š ‘szaszaw’ (pożyżka z rosyjskiego, ros. shashaw). Pot. šimawl’ (nazywała’ nakawil’ skrawil’ spawal’š i zakry’š’u ban’š’š’ s’oda’š’ šiml’ony) (zapis z okolic Włdz).



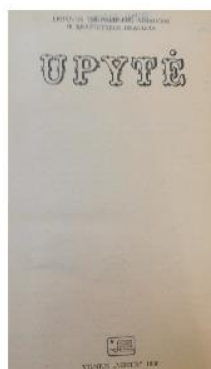
Natalia Ananiewa, "Nazwy potraw w polskich gwarach na litwie, białorusi i syberii wobec przemian cywilizacyjnych", Rozprawy Komisji Językowej ŁTN, t. LXIV, 2017 (tekście šaltiniai- SBH 4, 1984 s. 514; SBH 5, 1986 s. 489):

Traditional cannabinoid-rich products Evidence #9 LITHUANIA 1986

Cannabis Sativa Tea

ENG: "Sick person with pneumonia, was given to drink hemp (Cannabis Sativa L.- cannabis) tea."

Šerpančiam plautų užteginu (šmantinjo) duodaavo pert balsojo bezo, šermukšnio (Sercus cucuparia L. – paprastasis šermukšnis), levu (Podus avium Mill. – paprastoji levy), šibėčių (Viola collina Bess. – šaltinė nakšaitė) žieru, morki šakų, kanapių (Cannabis sativa L. – šėjamo); kanapė), vingiarykšės (Filipendula ulmaria Maxim. – pelkinė vingiarykštė) arbata, taip pat nasturtų



Lietuvos TSR paminklų apsaugos ir kraštotyros draugija, "Upytė", Vilnius "Mintis", 1986

Traditional cannabinoid-rich products Evidence #10: LITHUANIA 1992

Hemp Milk

ENG: "Hemp is also suitable for treatment. Seedless hemp blossom tea have been given to children from measles, fright, cough and all sorts of pain. Adults used to drink this tea to help pneumonia. Hemp milk was also given to children to threat measles. It was known that hemp blossom tea helps with kidney diseases and bladder inflammation. Hemp compress helps with any kind of pain. Steamed seedless hemp blossoms were mixed with rye flour and applied to sore spot of the body. People in Kalnyčių village used such compress to treat ear inflammation. In some villages, such as Paragaudžio village people used to drink boiled milk mixed with **seedless hemp blossoms** to release fright."

Klekas. Pildavo daugiausia valstiečiai, kuriems priklauso su-
vi. Sekles kartais būdavo supiramos d'iesnišs klekiais aliejui
spausi. Kanapės timka ir pydymai. *Plašanių žiedų* arbatos duo-
davo vaikams nuo tygų, išgėčio, kosulio ir visokių skausmų.
Suaugusieji gerdavo šią arbatą nuo plaučių uždegimo. Pūtyca
kaime maplikytą vietą patėdavo kanapių aliejumi. Nuo tygų vai-
kais gydė ir kanapių pienu. Sakydavo, kad kanapių žiedų nuovir-

ras gelbėti nuo inkstų ligų ir pūles uždegimo. Ant skaudulių ir
ras rožės dedavo užplikytą begrūdžią kanapių žiedų kompresą. Pa-
rašė dedavo užplikytą begrūdžią *kanapėkūda*. Sušildus *plāška*
dėvalio kaimė rožę vadinu *arbatą kanapėkūda*. Sušildus *plāška*
dėvalio žiedus sumaišydavo su ruginiais miltais, suvyniodavo į skū-
dūrą ir dedavo ant skaudulio. Kalnyčių kaime toki kompresą da-
davo ant skaudančius ausies, kai būdavo ausies uždegimas.
davo ant skaudančius ausies, kai būdavo ausies uždegimas.
Paragaudžio kaime nuo išgėčio buvo geriamas su *plāšanių žie-*
Paragaudžio kaime nuo išgėčio buvo geriamas su *plāšanių žie-*
dais virtas pienas. Jai kėlė apsinuodijavo nusimėmė, jai
dais virtas pienas. Jai kėlė apsinuodijavo nusimėmė, jai
medavo į kanapių daržą, sakydavo, kad ten ji išlyventis, iš-
čiudi, išspazgirta ir pareina sveika. Kanapių pienu supūdavo
arklių garde kampe arba į edžių galę, apė arčiau nesirgų pa-
žandėms. Kai kur nuo pažandėlių gydė begrūdžią kanapių žiedais.
Populiarusios šilalės kanapių vulgis — *spigūlis* (kana-
pienė), dar juokais vadinamas *kanapių tabaka*. Šis patiekalas
ne visur viendabai gaunamas. Kai kuriuose kvėdaruos apylinkėse
ne visur viendabai gaunamas. Kai kuriuose kvėdaruos apylinkėse

Vladas Statkevičius, "Šilaliskiai. Works and
customs", Vilnius "Mokslas", 1992

Traditional cannabinoid-rich products Evidence #11: POLAND

Podczas głodu, którego doznali zarówno mieszkańcy polskich wiosek sybe-
ryjskich, jak i użytkownicy północno-wschodniej polszczyzny kresowej, jadło
się różne trawy. Z tych „jadalnych” traw mieszkańcy Widz wymieniają *osotę*, li-
tuanizm *v'iksva* 'turzyca', *pokšyva* 'pokrzywa', *konop'i* 'konopie', *šn'itka* (por.
сні́тка, сны́тка: Сні́тка — ланнагая трава, сніпям, каровым і сама сніткы
варылі... (kursywa tu i dalej — N.A.); *калісь і сніткы варылі і елі* [SBH 1,
1984, s. 514]; пні́тка: *Пні́тку елі ў ваіну*; *Цоўней шнітку варылі*: Пні́тка —

Ananiewa N. 2017. Nazwy potraw w polskich gwarach na Litwie, Białorusi i Syberii wobec przemian
cywilizacyjnych. Rozprawy Komisji Językowej LTN, t. LXIV, 8.

During the famine suffered by both the inhabitants of Polish Siberian villages, as
well as users of the north-eastern Polish borderland, ate different grasses. From
these **"edible" grasses**, the inhabitants of the Widzew exchange osyt, and lituanizm
v'iksva 'sedge', *pokšyva* 'nettle', **hemp 'hemp'**, *šn'itka*

Traditional cannabinoid-rich products Evidence #12: POLAND

Kuchnia polska dawna

Urywki z jej dziejów od czasów najdawniejszych do końca wieku XVII.

ze źródeł archiwalnych i opracował
Dr. Med. JÓZEF PESZKE.

Konopie w „Rachunkach” wymieniane bywają częstokroć, jako siemię konopne (*semen canapi*), w dni postne. Wiemy już, że wybijano z nich olej, do kraszenia potraw służący w poście, ale bardzo być może, iż siemienia owego używano już wtedy do przyrządzania polewek, jadanych i dziś jeszcze tu i owdzie u nas, szczególnie na wieczerzę w wigilję Bożego Narodzenia, ale tego nie mówią nam „Rachunki” **). Konopie uprawiano w dobrach królewskich, atoli kupowano też siemię na targu.

Peszke J.1904. *Kuchnia polska dawna. urywki z jej dziejów od czasów najdawniejszych do końca wieku XVII.* Gazeta Domowa nr 9, 133.

Jednak największy podziw musi budzić liczba i różnorodność używanych jarzyn i ogrodnin (warzyw). Wśród nich najpopularniejsze były: buraki czerwone, cebula, chrzan, czosnek, giersz, później już nieużywany, kucmerka (kucmorka) jadana w poście wielkim, groch, kapusta, konopie, kminek, koper, mak, marchew, ogórki, pietruszka, rzepa, rzodkiew, rzeczucha, soczewica. Powyższy zestaw wskazuje, że polska kuchnia średniowieczna była wyjątkowo dobrze zaopatrzona w jarzyny i warzywa, a ich stosowanie było dość powszechne (Peszke 1904, nr 9, s. 133-134). Na uwagę zasługują też owoce, wśród których spotykamy: czereśnie, gruszki, jabłka, orzechy, śliwki, poziomki oraz również często spożywane figi i migdały.

Chmiel A.2015. *Kuchnia I Rzeczypospolitej.* ZNUV, 45(7):11.

Translation:

However, the greatest admiration must be aroused by the number and variety of used **vegetables and garden plants (Vegetables)**. Among them the most popular were: red beets, onions, horseradish, garlic, grysz, later unused, kucmork (kucmorka) eaten in a great post, peas, cabbage, **hemp**, cumin, dill, poppy, carrot, cucumbers, parsley, turnip, radish, cress, lentils. The above set indicates that Polish medieval cuisine was exceptionally well stocked with vegetables and vegetables, and their use was quite common (Peszke 1904, No. 9, pp. 133-134).

Traditional cannabinoid-rich products Evidence #13: POLAND



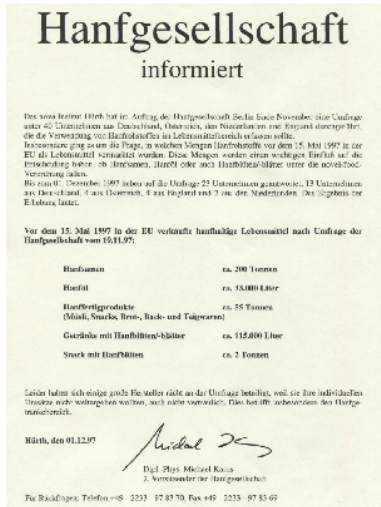
<https://alchetron.com/Siemieniołka>, 6.03.2019

HEMPSEED SOUP, SILESIAN (*siemieniołka, siemianka*): Rinse 1½ c hempseeds in cold water and drain. Scald with boiling water, bring to boil and drain again. In pot combine hempseeds with 5 c warm water, bring to gentle boil, reduce heat and simmer until seeds begin to burst. Drain, reserving liquid. **Transfer hempseeds to sieve and with wooden spoon squeeze out their contents (hempseed milk)**. Scald seeds in sieve with a little boiling water and continue squeezing out their milk. Transfer partially crushed seeds from sieve to another bowl add a little boiling water, mix well, drain and squeeze them some more. When no more juice can be extracted, discard seed husks left in sieve. Combine hempseed milk (squeezeings) with 3 c milk and the reserved stock (in which the hempseeds were cooked). Thicken with 3 T flour dissolved in a little water, add 2 t salt, and 1–2 T sugar. Mix, bring to boil and simmer several min, stirring so it doesn't burn. Remove from heat, add 1 T butter and serve. This is a traditional Christmas Eve soup in Silesia (Śląsk).

Stryber R. 2007. *Polish Holiday Cookery.* Hippocrene Books, INC, Nowy Jork: 44.

Traditional cannabinoid-rich products

Evidence #14: GERMANY



The Nova Institute was commissioned by the Hanfgesellschaft to undertake a survey on the request of EU Commission to obtain data on volume of hemp products sold prior to May 1997.

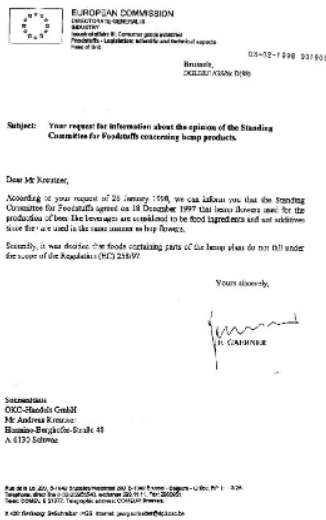
Out of 40 companies contacted, **23 companies from Europe**, including Germany, Austria, the Netherlands and the UK responded:

Hempseeds	ca 200 tonnes
Hempseed oil	ca 33,000 litres
Hemp ready made products (snacks, flour, muesli, bread, bakery & pasta)	ca 55 tonnes
Drinks with hemp flowers/leaves	ca 115,000 litres
Snacks with hemp flowers	ca 2 tonnes

The letter also states "unfortunately several large hemp companies did not participate in the survey because they did not want to share their data, especially from the drinks sector."

Traditional cannabinoid-rich products

Evidence #15: GERMANY



The letter of European Commission, dated 03.02.1998, to Mr Kreutner (Öko-Handels GmbH, Austria) stated "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.**"

Important, paragraph 2:

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

NOTA BENE: Hemp flowers (EU) are not Cannabis in the meaning of the UN SC, otherwise contradiction to definition of food in Reg. (EC) 178/2002, Art. 2 (g).

Traditional cannabinoid-rich products Evidence #16: GERMANY



Betreff: Ihre Anfrage bezüglich Pflanzenstoffe von Cannabis sativa
Betreff: Ihre Telefonanfrage vom 16. Februar 1998

Sehr geehrter Herr Dupetit,

Inwiefern diese von Anfrage kann ich Ihnen mitteilen, daß der ständige Ausschuss sich am 18. Dezember mit der Frage der Verwendung von Hanf in Lebensmittel befaßt hat. Es wurde übereinstimmend festgestellt, daß Teile der Hanfpflanze enthalten, nicht unter die Verordnung (EG) Nr. 258/97 der Europäischen Kommission und des Rates über neuartige Lebensmittel und neuartige Lebensmittelzutaten fallen.

Mit freundlichen Grüßen



E. Guzman
Abteilungsleiter

Letter of the European Commission to Mr Dupetit, dated 03.03.1998, saying the Standing Committee on Food agreed on 18.12.1997 that

foods which contain parts of the hemp plant do not fall under Regulation (EC) No. 258/97 on Novel Food and Novel Food Ingredients. "

Alaino Dupetit
dupetit Natural Products
Esauptze, 41
D - 63950 Rietelbach

Wie in der Nr. 258, Nr. 258/97 des Amtsblatts und 258, Nr. 258/97, vom 18. Februar 1997, ist in der Verordnung (EG) Nr. 258/97 der Europäischen Kommission und des Rates über neuartige Lebensmittel und neuartige Lebensmittelzutaten.

Traditional cannabinoid-rich products Evidence #17: SLOVAKIA

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

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:**

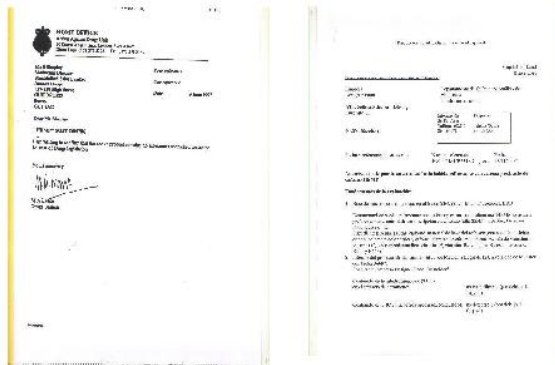
LIST OF PLANTS AND THEIR PARTS SUITABLE FOR PRODUCTION OF TEAS without recommending any restrictions on the amount [of herb] used.

Traditional cannabinoid-rich products Evidence #18: GERMANY

A hemp soft drink containing hemp extracts have been patented and authorised in Germany in 1997.

The FBO placed the hemp soft drink i. a. on the Spain and UK markets.

According to the two free sale certificates released by the national authorities in both countries the drink was allowed to be marketed.



www.eiha.org



Registered logos:



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EIHA position on hemp extracts

- Leaves and flowers of industrial hemp plants are non NF → regulated like food and food supplements (rules and labelling)
- Extracts, with traditional extraction technologies, from hemp plants legally growing in EU are not NF
- Naturally occurred cannabinoids in the whole plant extracts are not NF
- For consumer safety EIHA proposes a maximum daily intake of 160 mg (for an average adult) for food or\and food supplements
- Genetic modified plants and synthetic material are NF

www.eiha.org

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Further reflections

- Hemp flower products such as hempseed and its extract - hempseed oil - are traditional food exempt from authorization as Novel foods due to demonstrated consumption in Member States prior to May 1997.
- Naturally incidental to the long history of consumption of the hempseed is a sticky resin, on the outside of the seed shell → cannabinoids are found inside this resin
- Cannabinoids are found on seeds and other part of the plants (which are not NF) as residues and are therefore consumed without authorisation.
 - In the process of pressing, the hempseed oil can get contaminated with other elements of infructescence of the plant that contain cannbinoids, resulting in cannabinoids presence in hempseed oil
 - In the past, up until the beginning of the 20th century, when the mechanical threshers were introduced, any seeds - be it wheat grain or hemp seed - were obtained in the process of manual threshing with flails. The inevitable presence of such combination from which the oil was pressed results in inflated levels of cannabinoids in the hempseed oil.
- In the pre-industrial era hempseed oil obtained in this way was the primary source of plant oil in human diet, hence cannabinoids have been consumed in larger amounts than today and have a long history of consumption prior to 1997
- The parts making up the whole are inseparable from the whole; if the whole is exempt then so are the parts.

Further reflections

- It must also be considered that hemp and hops are the same plant family of **Cannabaceae**, which includes about 170 species grouped in about 11 genera, including *Cannabis* (hemp, marijuana), *Humulus* (hops) and *Celtis* (hackberries). (<https://en.wikipedia.org/wiki/Cannabaceae>)

One will surely not question that hops, its flowers, leaves and whole tops are used as food, ingredients and extracts.

- As long as the product
 - has no added Cannabidiol isolate or synthetics, and
 - is less than 2.000 ppm THC and recommended intake to fulfill the guidance values re THC, and
 - is from an approved Hemp cultivar or non-Cannabis source...

...then it must be considered a traditional product, not Novel Food needing pre-marketing authorization

Implications if MSs enforce the NF Catalogue

- **End of the internal market** creating a vacuum which will be filled by the 'grey market' (54% of consumers are willing to buy CBDs it even if they are illegal)
- **Loss of jobs** in production, processing and sales
- **Loss of market control** represents significant potential consumer risk as they access products which do not comply with any safety, labeling or compliance standards.
- **Loss of competitiveness** for EU enterprises (vs Canada, the US, China and Switzerland) → no equal level playing field for all actors
- **Discrepancy on the labelling** → impossible for consumers to compare products
- All the **environmental benefits** of cultivating hemp (e.g. CO² absorption) will be **outside of Europe** (not in line with CAP orientations)

Benefits for MS

- CBD helps maintain homeostasis; which in turn supports better health for all = improved productivity and **reduced public health service costs**
- Facilitating the growth of the CBD industry will create **new jobs** at a range of skill levels and deliver **increasing tax revenues** (VAT and income tax)
- Hemp extracts represent an **additional income for farmers**
 - Enabling farmers to utilise the entire hemp plant including the leaves will encourage **much more cultivation of this key crop** with numerous additional benefits including carbon sequestration, enhanced biodiversity, land reclamation and phytoremediation.
- Safe and clear framework which will guarantee an **even playing field** for all actors in the hemp sector (SMEs vs big companies)



Thank you for your
attention!

For further information:
Lorenza Romanese
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Email 6

Title: [Section 40] Position Paper on UN Single Convention 1961

Dear [Section 40],

It was a pleasure meeting you recently and thank you for your time. [Section 40] has just issued a position paper on the UN Single Convention which has been sent to various members at [Section 27] yesterday and we are now asked to share it with our national agencies.

I hope you find it of interest.

With kind regards,
[Section 40]

Attachment

EIHA position on the Single Convention on Narcotic Drugs, 1961

In the light of the latest development of the international industrial hemp market and its raw material *Cannabis sativa* L., the European Industrial Hemp Association (EIHA) would like to reiterate its position on this topic and stress the need for clarification and a transparent debate on the classification of industrial hemp. The current market barriers and challenges for a growing hemp industry are originated from an interpretation of the updated provisions of the Single Convention on Narcotic Drugs, 1961 to which EU regulations on food and cosmetics make reference. Therefore, it seems appropriate to clarify that

- industrial hemp and its downstream products are not narcotic or psychotropic drugs, and therefore
- industrial hemp is clearly exempted from the scope of the Single Convention, 1961.

Industrial hemp is out of the scope of the Single convention

As per definition by EIHA industrial hemp (or "hemp") is a type of the *Cannabis* genus plants, with a low, non-narcotic level of Tetrahydrocannabinol (THC¹) that is grown specifically for the industrial uses of its derived products. It is also referred to formerly as "fibre-type cannabis" plant in UN language.

Considering as a fundamental principle the hierarchy of laws, at international level, all signatory countries have to comply with the Single Convention on Narcotic Drugs, 1961 (the so-called "Single Convention"), as amended by the 1972 Protocol.

According to its definition a preamble is the preliminary part of a document, legislation, a contract or a treaty, and states the reasons for and intention of the law, it expresses the general purposes of a piece of legislation. It can be referred to for the purposes of statutory interpretation by setting out what it is all about or why it has been prepared.

Starting from the preamble, it is clearly stated that the Convention aims at protecting the health and welfare of mankind. Hence, the Parties (countries) recognized that narcotic drugs are indispensable for the relief of pain and suffering of people while at the same time the Parties committed to fight the related health hazards (abuse and dependence). As clearly stated in its preamble, the scope of the Single Convention is to prevent and combat the abuse of narcotic drugs². Industrial hemp is a not narcotic or psychotropic drug and neither part of the plant nor any product derived from it can be abused as a narcotic or psychotropic drug.

As any parts from industrial hemp cannot be used to produce narcotic or psychotropic drugs, it cannot be included in the intention and meaning of the preamble and therefore industrial hemp in general is not restricted by the Convention.

As a logical consequence, industrial hemp is clearly exempted from the scope of the Single Convention.

To avoid any doubt about this exemption of industrial hemp from the intention of the Convention the writers of this international document additionally mention this clear distinction between drug-type

¹ THC (Tetrahydrocannabinol, exactly Δ^9 -THC) was not mentioned yet in the Single Convention 1961 because it was not yet known as the active drug principle of cannabis, and its chemical structure not yet elucidated. THC is listed in the Convention on Psychotropic Substances 1971 as Dronabinol (IDS Code PD 010) in Schedule II.

² See definition of "drug" under Article 1, 1.j) of the Single Convention

Cannabis (in today's language with high THC levels) and industrial hemp (in today's language with low THC level) in multiple articles of the Convention.

Reading the definition of cannabis in Article 1, 1.b) of the Convention, the distinction is clear: seeds and leaves (when not accompanied by the flowering or fruiting tops, the latter being defined as "cannabis" only) are excluded from the scope of the Convention, because they are not considered a narcotic drug. Therefore, industrial hemp (*expressis verbis* seeds and leaves) and any products or ingredients derived from industrial hemp are exempted from the scope of the Single Convention.

Based on this it can be stated that the definition of "Cannabis plant" in Art. 1, 1.c) - considering the underlying intention and statement of purpose already manifested in the preamble - is only referring to Cannabis plant which is used for the "production" (1.t) and "manufacture" (1. n) of (narcotic/psychotropic) drugs.

Article 4 of the Single Convention ("General obligations") refers to the exclusive limitation to medical and scientific purposes of all activities related to "[narcotic] drugs". Industrial hemp and its derived products are not considered narcotic/psychotropic drugs due to their low content of THC. As a consequence, also this article is not including the activities related to industrial hemp, meaning as well that the use of industrial hemp is not restricted to medical or scientific use.

Furthermore, the Convention states in Art. 28, paragraph 2, that: "This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes".

The official Commentary on the Single Convention on Narcotic Drugs concludes on page 312 that "[T]he cannabis plant is grown for its fibre, its seeds, for drugs (cannabis and cannabis resin) and for its leaves.", and "... the leaves are not "drugs"". The commentary follows that [this] "control régime applies only to the cultivation of the cannabis plant for the production of cannabis and cannabis resin". And even more importantly that "cultivation for any other purpose, and not only for the purposes mentioned in paragraph 2 [i.e. "industrial purposes (fibre and seed) or horticultural purposes"], is consequently exempted from the control regime provided for in article 23"".

The exclusion of the cannabis plant for industrial and horticultural uses from the intention and the legislation of the Single Convention itself authorises therefore the cultivation and use of this specified type of Cannabis plant, industrial hemp, and its derivatives for uses that differ from those related to drugs manufacturing. As leaves from industrial hemp cannot be used to produce narcotic/psychotropic drugs they therefore cannot be included in the intention and meaning of Art. 28 (3). The misuse of the leaves is prevented by most of the signatory states through the setting of very low THC limits in their national drug control acts, thus exempting industrial hemp and its plant parts from their controlled substances schedules.

Considering that ingredients that are derived from seeds or leaves of the (industrial) Cannabis plant, for example Cannabis sativa seed oil/extract/powder/etc. are not prohibited by the Convention, as they are wittingly exempt based on Article 1 (b), it should also be considered that ingredients that are derived from other parts of the Cannabis plant and destined to non-medical and non-scientific purposes should not be prohibited either, as they are exempt based on Articles 2 (9) and 28 (2).

In other words: due to the fact that it is acknowledged that the industrial use of non-drug-type Cannabis plant is not prohibited, and this definition of non-drug-type Cannabis plant (industrial hemp) is covered by the drug control laws of each state, all part of the plant and the derived products of industrial hemp are excluded from the scope of control measures conveyed by the Single Convention.

The exclusion of the cannabis plant for industrial and horticultural uses from the intention and the legislation of the Convention itself authorises therefore the cultivation and use of this specified type of Cannabis plant, industrial hemp, and its derivatives for uses that differ from those related to narcotic drugs manufacturing.

Taking into consideration all the above reflections and assumptions, EIHA would like to point out that:

- *Cannabis sativa* L. is considered as an agricultural product in EU.
- Equally, *Cannabis sativa* L. is considered as an "industrial plant".
- The cultivation and processing of *Cannabis sativa* L. is subject to compliance with a certain level of THC. EIHA proposes ≤ 0.3 % post-decarboxylation as a limit of THC in industrial hemp. (Other examples see Annex 2)
- No other substance (i.e. cannabidiol (CBD) or other cannabinoids) is considered for the determination of the lawfulness or unlawfulness of the processing of Cannabis plants in EU.
- The reason for international control of "cannabis" and "cannabis extracts" (from high THC Cannabis) is the fact that both contain "resin", considered as a narcotic drug and containing the psychotropic substance THC in quantities liable to abuse.
- "Hemp plant extracts/tinctures" should be defined as preparations of the non-narcotic cannabis plant, which again is defined as industrial hemp, that contain various constituents of the cannabis plant, but that have a very low content of THC. They are obtained virtually from any part of the plant, e.g.: leaves, flowers, fruits, roots, seeds.
- The European hemp industry does not separate the resin from the plant. Besides the harvest of seed and fibre, the extraction of the biomass, with the naturally present level of cannabinoids, is done. This extraction of industrial hemp biomass and the dilution of hemp extracts need to comply with national narcotic laws."

Claiming otherwise would mean the creation of a new layer of *sui generis* regulations (unrelated to the Single Convention, disregarding the interpretation of the Secretary-General's the Commentary, and undermining the WHO's recent scientific assessment of CBD and its recommendation that it should not fall under the scope of the Single Convention). This would likely enshrine stricter and stronger measures of controls than those of most signatories of the Single Convention, undermining an agricultural sector already subject to an important set of rulings. Worst, this would go in the exactly opposite direction than the global trend, where countries such as Australia, Canada, China, Uruguay and the United States of America are reforming their hemp laws towards simplification, to support a constantly growing industrial hemp market. Further arguments may be found in Technical Annexes of this position paper.

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Technical Annex 1: Industrial hemp and the European Union

At EU level, the TFEU (Treaty on the Functioning of the European Union), in annex I, lists the agricultural products for which the provisions of the Treaty itself are applied, among them under chapter 57.01 the "True hemp (*Cannabis sativa*), raw or processed but not spun; tow and waste of true hemp (including pulled or garneted rags or ropes)".

At community level, the Cannabis plant (*Cannabis sativa* L.) is considered as an agricultural product and as an "industrial plant" both for cultivation and seed production according to Regulation (EU) 1308/2013.

The Regulation (EU) 1307/2013 (see articles 32.6, 35.3 and 52) underlines that "Areas used for the production of hemp shall only be eligible hectares if the varieties used have a tetrahydrocannabinol content not exceeding 0.2 %.", and: "In order to preserve public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 70 laying down rules making the granting of payments conditional upon the use of certified seeds of certain hemp varieties and the procedure for the determination of hemp varieties and the verification of their tetrahydrocannabinol content referred to in Article 32(6)."

Basically, the lawfulness of the cannabis production and trading as "agricultural product" and "industrial plant" depends on the THC (tetrahydrocannabinol) percentage that cannot be higher than (currently) 0.2 %, in accordance to the methods indicated by the above-mentioned law and specified in Commission Delegated Regulation (EU) 639/2014 and Commission Implementing Regulation 809/2014. According to the same regulation, European farmers cultivating industrial hemp and respecting the imposed limits of THC are entitled to receive CAP payments.

Technical Annex 2: Industrial hemp at national levels

Countries have adopted their own drug control laws making in their turn a clear distinction between drug-type cannabis plant and low-THC industrial hemp.

Examples of THC levels for this distinction: EU in general (currently) $\leq 0.2\%$, Austria $\leq 0.3\%$, Czechia $\leq 0.3\%$, Canada $\leq 0.3\%$, USA $\leq 0.3\%$, Australia $\leq 0.3\%$, Switzerland $< 1.0\%$. With these national drug laws all Parties acknowledge the competence of the UN and stay within the framework of its Conventions. They clearly exempt industrial hemp from the jurisdiction of the 1961 treaty.

Several EU member states have completely exempted varieties of *Cannabis sativa* L. complying with provisions of EU Common Agricultural Policy³ from the scope of their drug-related schedules. These exemptions do not only mention the cannabis plant itself, but also its flowering and fruiting tops, extracts, tinctures and even the resin. Examples of such member states are Luxembourg and Slovakia. Other states, such as Austria, applied an arbitrary value of 0.3% of THC as a concentration to delimitate between drug and non-drug derivatives of the plants of genus *Cannabis*.

In 2015, Slovak Republic included hemp leaves into a list of plants and their parts suitable for production of teas.⁴

Recently, in July 2019, Belgium created a room for marketing industrial hemp herbal products for smoking not containing tobacco as long as business operators are registered as excise-tax payers.⁵

Thanks to such and similar legislative clarifications adopted at national level, a flourishing hemp industry has started to grow significantly in the last ten years.

In the USA, the Congress has passed an Agriculture Improvement Act of 2018⁶ (so called "2018 Farm Bill") which defines hemp as "the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not" and exempts it from the federal definition of "Marijuana" provided the delta-9 THC concentration is not higher than 0.3% post-decarboxylation on a dry weight basis.

³ Article 9 of Commission Delegated Regulation (EU) No 639/2014 of 11 March 2014 supplementing Regulation (EU) No 1307/2013 of the European Parliament and of the Council establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and amending Annex X to that Regulation.

⁴ See Annex III, Table 1 of 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

⁵ <https://www.health.belgium.be/fr/liste-positive-des-produits-fumer-base-de-plantes>

⁶ US Public Law 115-334: <https://www.govinfo.gov/link/plaw/115/public/334?link-type=pdf>

Technical Annex 3:

Case study on hemp extracts/tinctures and hemp resin

Taking into consideration all the above reflections and assumptions, EIIHA would like to point out that:

The reason for international control of "cannabis" and "cannabis extracts" derived from high-THC Cannabis is the fact that both contain "resin", considered as a narcotic drug and composed of the psychotropic substance THC in quantities liable to abuse.

"Hemp plant extracts" may be defined as extracts of the cannabis plant that contain various constituents of the cannabis plant, but that have a very low, if any, content of THC. They are obtained virtually from any part of the plant, e.g.: leaves, fruits, flowers, roots, seeds.

The European hemp industry does not separate the resin from the plant. Besides the harvest of seed and fibre, the extraction of the biomass, with the naturally present level of cannabinoids, is done. This extraction of industrial hemp biomass, and the dilution of hemp extracts needs to comply with national drug control laws."

In "hemp plant extracts", the starting material is already low in THC. The extraction of industrial hemp biomass and the dilution of hemp extracts need to comply with national narcotic laws. Thus, due to their low THC content, these products cannot be, in practice, abused or the THC recovered from them. "Hemp plant extracts" so become "products not covered by the 1961 Convention" - they are neither a narcotic drug nor a psychotropic substance. Additionally, these products and the plants used to obtain them are not associated with purposes of pharmaceutical applications of scientific research. "Hemp plant extracts" therefore correspond to all criteria defining the products not covered by the 1961 Convention.

Remaining trace-amounts of THC in "hemp plant extracts" obviously do not disqualify this reasoning, and are permitted as these quantities are "not liable to be abused or have ill effects" and are present "in such ways that THC cannot be recovered by readily available means or in a yield which would constitute a risk to public health."⁷ It was neither the intention of the Single Convention nor the objective of the Regulation (EC) No 178/2002 on food to disqualify products such as "hemp plant extracts" that contain quantities of THC not liable to abuse. The international drug control conventions do not consider this product as dangerous. It would be absurd, if these Regulations would disqualify "hemp plant extracts" by referring to the drug control conventions.

In this connection, it should be noted that there are also other cases when controlled substances are present in food. This is the case of morphine and other controlled opium alkaloids in poppy seeds (due to unavoidable contamination of the seeds with poppy straw dust during the process of their industrial separation). Poppy seeds continue to be allowed for use as food while limits on opium alkaloids content are set, where necessary.

European hemp farmers and industries use hemp seeds, hemp roots, flowers, leaves (after the flowering and mostly even after the seed ripening) for producing different types of hemp extracts. These products were already excluded from the scope of the control regime of the Single Convention as enforceable and enforced regulations complying with the Convention have been in place for two decades. New regulations should be aimed at simplifying and correcting errors, not adding layers of complexity.

⁷ Questions to WHO on 41st ECDD recommendations, 5th CND Intersessional meeting, 23 September, 2019, page 19.

Technical Annex 4: Case study on Cannabidiol

Pure Cannabidiol (whether produced synthetically or by isolation from Cannabis plants) has been given a clear “*carte blanche*” by the 40th WHO ECDD Critical review.

In this context, the outcomes of the 39th and 40th WHO ECDD meetings, merits attention. In July 2018, WHO recommend “that preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions.”

EIHA has welcomed this recommendation not to include products considered to be pure Cannabidiol (CBD) in the Schedules of the International Drug Control Conventions, published in a *Note Verbale* to the United Nations Secretary-General dated July 23rd, 2018. However, EIHA has formally objected⁸ to the reasoning of the Experts according to which “... if prepared as an extract or tincture of cannabis [Cannabidiol] is controlled in Schedule I of the 1961 Single Convention on Narcotic Drugs.”

An important element of the WHO ECDD outcome is a refusal of the differentiation between Cannabis compounds produced synthetically and those obtained by isolation from the Cannabis plants. The same that applies to THC also applies to CBD, and the Experts, while considering the issue on the basis of evidence, dismissed the option of differentiating Cannabis compounds according to their method of isolation. For example, German DAC/NRF monograph C-052 on Cannabidiol⁹ mentions a chromatographic purity between 98.0–102.0 % and defines $\Delta 9$ -THC, $\Delta 8$ -THC and Cannabinol (CBN) as “specified impurities”. Moreover, it states that the CBD may be of natural as well as of synthetic origin. Without prejudice to other legal requirements concerning the manufacture of the extracts of cannabis and subsequent isolation of pure CBD there from, considering “Cannabidiol” of plant origin as an “extract of cannabis” does not hold up to principles of any of the relevant international standards; neither the nomenclature of organic chemistry (IUPAC) system, Chemical Abstracts Service (CAS), nor WTO Harmonized System Codes:

Extracts and tinctures of cannabis	Cannabis sativa, ext. (Hemp Extract)	Cannabidiol	Hempseed / Hemp oil	Hemp Essential oil
CAS: 6465-30-1	CAS: 89958-21-4	CAS: 13956-29-1	CAS: 8016-24-8	CAS: none particular
HS Code: 1302.19	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

The toxicological and pharmacological properties of a substance or extract as well as its potential for abuse mainly depend on its constituents and composition. What matters is the content of a drug component and the substance’s effect, not the origin of the substance or its manufacturing procedure.

Moreover, the impurity profile of an isolated chemical compound (in this case with $\Delta 9$ -THC as an impurity) may not be unique or characteristic in order to distinguish it from a synthetic version. The impurity profile (by-products) of a synthetic product may even be very similar to the “impurity profile” of the natural isolated product, in particular if the synthetic pathway is a biomimetic one.

On these same grounds, purified Cannabidiol (CBD) obtained from *Cannabis sativa* L. is not an Extract of “cannabis” and therefore is not scheduled under the Single Convention (1961).

⁸ http://eiha.org/media/2014/08/18-12-04_EIHA_contribution_41th_ECDD.pdf
⁹ DAC/NRF 2016/2, C-052, Cannabidiol, 12 pages.

Technical Annex 5: The case of Croatia

On April 25, 2019 the Drug Abuse Act have been amended making it easier and easier for farmers to grow industrial hemp. It is now possible to use the whole industrial hemp plant for industrial purposes in the construction, textile, food and cosmetics, paper, automotive and biofuels industries.

The Croatian Ministry of Agriculture decided to create a definition for industrial hemp that clearly exempt it from the list of the controlled substances.

In article 2, paragraph 1 item 5 of the current Drug abuse Act it states that *Industrial hemp is cannabis (Cannabis sativa L.) with a total THC content of 0,2%¹⁰ and less, of which the varieties are on the European Union Common Variety List and not listed in the list of drugs, psychotropic substances and herbal drugs¹¹.*

As per article 13 of the same Act, *the production of industrial hemp referred to in article 2, paragraph 1 item 5 of this Act is authorized.*

EIHA welcomes Croatia's interpretation and suggests its adoption at European level.

The European Industrial Hemp Association (EIHA) is an international organization which gathers and represents the interest of hemp manufacturing and processing companies in Europe.

¹⁰ EIHA advocates to restore the former 0,3% level of THC in the plant entitled for CAP payments (Art 32, point 6 of EU Regulation 1307/2013). The EU hemp sector has a significant competitive disadvantage to producers in Switzerland, North America, Asia and Canada (where limits from 0.3% up to 1% are successfully and legally established).

¹¹ Official Gazette 39/19

Email 7

Title: Our meeting last Thursday

Dear **[Section 40]**,

Thank you for meeting with us at such short notice last week, please find attached our letter following up on what was discussed and addressing some of our wider concerns.

As I have said in my letter, we would respectfully ask you to consider all of the points included, and would welcome a further meeting to address these and any follow-up questions you may have.

Regards,

[Section 40]

Attachment

11 February 2019

[Section 40], Food Policy Division

Food Standards Agency

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Clive House

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London

SW1H 9EX

Dear **[Section 40]**

Our meeting last week re. Novel status of CBD and media coverage undermining consumer trust in the Sector prompted by revision to the Novel Food Catalogue

This letter is a follow-up to our meeting on Thursday afternoon. We have a proud history of working closely with FSA officials and we sincerely thank you and **[Section 40]** for your time and for giving us the opportunity to have some clarification from you, and to express some of our concerns, about recent developments. The brevity of that meeting did not allow for an appropriate exploration of all of points raised by this matter, hence the need for this follow-up letter.

We were pleased to hear you confirm that there would be no proactive or pre-emptive enforcement action, and you ruled out a product withdrawal.

But not least of our concerns is the lack of consultation before **[Section 27]** and the FSA's announcements. You stated that your consultation was limited only to stakeholders that had contacted you to question the status of CBD, which rather begs the question as to why organisations such as the **[Section 40]**, with whom the FSA has consulted closely on many issues in the past, and **[Section 40]**, were not consulted? Instead, we learned of these developments through the media.

And this raises the further question about what the FSA's response at the time to those stakeholders who were consulted was? In other words, did you respond then that you considered the products were novel, in which case why did you permit this industry to flourish unchecked for all this time? Or alternatively, did you say that the products were not novel – in which case how can they now have suddenly become novel?

We have serious reservations about many aspects of the line that the FSA has/is taking on this issue, and I would summarise some of the non-exhaustive points below. These are developed in more detail later in the body of this correspondence:

Irregularities in the precipitous amendment of the Novel Food Catalogue

Lack of sufficient Consultation

How can products that were confirmed by the Commission as not novel earlier suddenly become novel today.

The **[Section 40]** is registered in England as a company limited by guarantee. Company No. **[Section 40]**

Determinations about the status of a food substance are based primarily on information from FBOs since they are the ones with knowledge of first marketing and the applicable manufacturing processes.

Neither we, nor the FSA are aware of any specific issues relating to these products that would give rise to a safety concern.

The FSA Cannot Adopt a Blanket Approach to Enforcement

There does NOT appear to have been a proper consideration of the definition of a Novel Food.

Other potentially applicable regulatory regimes have no bearing on the classification of a substance as a novel food or not

In view of the above, a discussion on enforcement (which must be proportionate and not unnecessarily hinder economic activity) is precipitous

Novel Food Catalogue

The FSA has said in its social media account that it would be consulting with industry, local authorities and the like to consider the way forward in light of clarification at EU level that “some” cannabidiol products may be novel.

Yet, during our meeting it was intimated that all CBD was considered Novel, unless shown to be otherwise. Can you please clarify your definitions of “all” or “some”, as we need to be clear on why you might consider some of these products to be novel, and others not?

We note that the FSAI website cites an examples of both novel and non-novel forms, supporting our belief that this is surely a case-by-case assessment. Moreover, it seems precipitous to:

1. Prioritise CBD in the absence of safety concerns

2. Make pronouncements without a proper review of the full landscape for this product.

Lack of sufficient Consultation

As we have said above, there was no consultation with **[Section 40]** or any of its members on the proposed or potential changes to the novel food catalogue. This is procedurally unfair as a matter of English law and a fundamental breach on the **[Section 27]** part of EU good administration and the right to be heard.

This is particularly so since the change represents a U-turn on **[Section 27]** prior view that extracts from the Cannabis sativa (hemp) plant were not covered by the new novel food regulation. Members and other FBOs have relied on that entry for years along with their own records regarding the legal marketing of their products.

Those products that were not novel yesterday (as confirmed by the Commission) cannot suddenly become novel today.

What was the UK's position on the change in classification?

Since investigating the issue, it seems that the UK along with some other Member States like **[Section 27]** and **[Section 27]** had been pressing for clarifications and changes?

Note, that determinations about the status of a food substance are based primarily on information from FBOs since they are the ones with knowledge of first marketing and the applicable manufacturing processes (confirmed by Recital 19 of the Novel Food Regulation).

Although the novel food catalogue has some practical utility in that companies rely on the entries to support legal classification, the catalogue is not legally binding and is only an informational tool.

Hence, any enforcement taken on the basis of the change in the novel food catalogue would not be a proportionate or fair approach.

That said, we are concerned that the FSA might use its extra-legal status to excuse the uncertainty and undermining of consumer trust that has been fueled by this precipitous and incorrect amendment, and the media it has generated.

Further, we are not aware of any specific issues relating to these products that would give rise to a safety concern, and noted that neither were the FSA. Recital 2 of the founding 1997 Regulation that brought in the EU Novel Foods regime 'in order to protect public health' (Recital 2)

Responding to ad-hoc queries from manufacturers and continuing to consult merely with those individuals and entities does not constitute a consultation and does not come anywhere near compliance with the FSA's own documented approach to consultation (see <https://old.food.gov.uk/about-us/data-and-policies/consultation-approach>).

The FSA will recall that it is under a duty to ensure its decisions and policy approaches are properly informed and indeed the FSA states that "we seek to consult all relevant stakeholders".

Given the significance of the change in the novel food catalogue, a formal consultation should have taken place.

The FSA Cannot Adopt a Blanket Approach to Enforcement

□ The FSA cannot adopt a blanket approach to extracts or ingredients derived from hemp. A "case-by-case" assessment is required "*taking into account all of the characteristics of the food product and of the production process*" (see par. 30, Case C-383/07 M-K Europa GmbH). Hence, an individualised assessment is needed, and therefore there should be no restrictions on CBD products being placed on the market now or in the future.

□ Regarding an individualised assessment, the European Court of Justice has confirmed that "foods or food ingredients must satisfy **two cumulative conditions**" to be considered novel:

o First, it is "necessary that human consumption of those **substances** was not 'significant' within the EU before 15 May 1997" (our emphasis);

o Second, it is necessary that "the substances also fall within one of the categories expressly described" in Article 3(2)(a)(i) to (x) of Regulation 2015/2283.

Definition of a Novel Food: Specific Comments on the Two Limbs above.

First Limb: History of Use

□ On the first limb, demonstrating a **history of use** in foodstuffs prior to May 1997, FSA should bear in mind that many of [Section 40] members would market products that today we classify as food supplements. However, the Food Supplements Directive did not enter into force in the UK until 2003. Prior to that they would have been classed as foods or potentially unregulated substances (e.g., on the basis that they did not fall squarely into prior definitions of food). Hence, it will not be surprising if documented evidence of use in foods simply is not available.

This is also why reliance on the Novel Food Catalogue was important since the catalogue already confirmed in relation to hemp (*Cannabis Sativa*) that "*Regulation 258/97 is not applicable to most foods and food ingredients from [Cannabis sativa]*". The prior entry for cannabidiol also said that "*extracts of Cannabis Sativa in which cannabidiol (CBD) levels are higher than the CBD levels in the source of Cannabis sativa are novel in food. Cannabidiol (CBD) is one of the cannabinoids in Cannabis sativa plant*".

These entries confirmed that extracts, including those containing CBD, were not necessarily novel.

□ It is also relevant to define the food under investigation. For example, food can be defined down to the molecular level as per the definition of a food under Regulation 178/2002 ("a product or substance"). This is confirmed by the Court of Justice in the

novel food context by C-448/14 *Davitas*, which confirmed that the focus was on the “*primary molecular structure*” of the substance/ingredient.

So when looking specifically at CBD, the Commission already confirmed that CBD is present in extracts of hemp that were circulating as foods prior to 1997. Provided there is no change in the molecular structure of the CBD, the food would not be novel irrespective of the manufacturing process used (see point (2) below on novel processing techniques).

□ In any event, we believe that with sufficient investigation, the FSA will find evidence of a hemp food market dating prior to 1997. This is exactly why the FSA should have consulted with UK industry before allowing **[Section 27]** to make changes unilaterally. For example, the reference to use of hemp seeds in foods was discussed in Parliamentary debates and regulatory impact assessments as far back as 2000, showing a well-established UK industry.

o

<https://publications.parliament.uk/pa/cm199900/cmstand/euroa/st000329/00329s01.htm> “*The proposals envisage the compulsory denaturing of hemp seeds, other than seeds for sowing, imported from outside the European Union. **The Committee may have noted from the draft regulatory impact assessment that there is a small United Kingdom industry which uses hemp seed in the manufacture of foodstuffs, non-prescription medicines and cosmetics. Most of the seed used by that industry is sourced from within the European Union, but some is obtained from third countries. That supply would be effectively blocked, as the denaturing process destroys the seed's essential properties, thus making it unusable. We have questioned whether there is a need for this further regulation in the absence of evidence that a loophole exists that needs to be plugged.***”

Second Limb: Product Categories and Emphasis on New Processing Techniques

□ Nothing in the Novel Food Regulation suggests that both the food substance and the production process should have a significant history of use before 15 May 1997. Rather, the provisions under the second limb that refer to a new or non-traditional processing techniques will only render a food novel if it “*gives rise to significant changes in the composition or structure of the food, affecting its nutritional value, metabolism or level of undesirable substances.*” Provided the structure of the “food” at issue is identical to the food in existence prior to 1997, the fact that it results from a novel processing technique is largely irrelevant provided there is no compromise in safety (e.g., by the introduction of undesirable substances).

So by way of example, if a company is marketing CBD, and CBD was in existence in hemp oil prior to 1997, the fact that it might be extracted using a novel process should be irrelevant provided the CBD is chemically the same molecule and the product is safe. Similarly, an improvement in the manufacturing procedure for lecithin leading to a higher lecithin amount in an extract from eggs would not qualify the product as novel (Scientific Committee on Food, Opinion 17 June 1999).

□ The main point under the rules governing novel processing is safety. This is also underlined by Regulation 1925/2006 on the addition of vitamins, minerals and other

substances to food, which specifically envisages “extracts” and “concentrates” from traditional foods being introduced provided they are safe (see Recital 20).

□ The **[Section 27]** website example underlines the point regarding levels of undesirable substances

Other potentially applicable regulatory regimes have no bearing on the classification of a substance as a novel food or not

□ We note that the entries are “*without prejudice to other legal requirements concerning consumption of hemp*”. These other legal requirements relate primarily to medicines rules and rules governing controlled substances. Neither of these are relevant to the FSA’s assessment of whether a substance is novel or not.

The **[Section 40]** has already concluded that hemp extracts are not medicinal unless medicinal claims are made. The regulation on the misuse of drugs also makes clear that pure CBD is not controlled, and where there are trace amounts of THC (which is controlled) these levels fall under an exemption in the vast majority of finished products.

Enforcement must be proportionate and not unnecessarily hinder economic activity

□ Whilst we were pleased to see the word “proportionate” in the FSA social media account, **a discussion on enforcement (which must be proportionate and not unnecessarily hinder economic activity) is precipitous in view of all of points made above.**

□ Section 108 of the Deregulation Act 2015 requires regulatory authorities when considering action to take action only when necessary, where it is proportionate and also to have regard to the potential impact on economic growth.

□ This is particularly important in light of Brexit, since the Novel Food Regulation is primarily a single market measure. Given the uncertainty with Brexit and our relationship with the EU, it seems odd to prioritise this matter given there are no apparent safety issues.

Request for Information

You mentioned that the FSA had been consulting with the industry for more than two years on this issue although as indicated above neither **[Section 40]** nor our members have been consulted and we doubt whether any dialogue meets the FSA's own standards of consultation. However, please send us the following documents so that we can assess the adequacy of the consultation:

□ All internal and external emails, letters, meeting minutes, enforcement notices and any other document (internal or external and whether in electronic form or otherwise) held by the FSA or any one of its advisory bodies that relates to the classification of *Cannabis sativa (hemp)*, and extracts of *Cannabis sativa (hemp)* and cannabidiol (CBD). Note, we do not expect confidential or trade secret information being disclosed so we do not take issue with redactions of such material (e.g., to the extent

the document is from a manufacturer, confidential information about the product formula or manufacturing process could be redacted).

□ All information held by the FSA regarding the history of use of hemp extracts in foods anywhere in the EEA prior to May 1997.

If necessary, please treat this as a request for information under the Freedom of Information Act 2000. We expect a response to this request within 20 working days.

We would therefore respectfully ask you to consider all of the above points, and we would welcome a further meeting to address these and any follow-up questions you may have.

Regards,

[Section 40]

Executive Director

Email 8

Title: Meeting with [Section 40]

Dear **[Section 40]**,

I understand that you are due to meet with **[Section 40]** in a few weeks and wanted to provide some details of the discussions we have been having with them in the UK. Last week I presented at their AGM to explain the work that has been going on understanding which CBD extracts are novel foods. The presentation I gave is attached.

The issues for **[Section 40]** should be seen in the context that there are wider discussions in the UK on whether any CBD extracts can be considered medicinal by function under limb 2 of the definition in the EU Medicines regulation. The current position of our Medicines authority MHRA can be found [here](#). We have encouraged **[Section 40]** who believe that alcohol extracted whole plant extracts have been used for a long time to gather the evidence for a history of consumption. Their key area of interest is likely to be the issue we raised in response to the Novel Food Catalogue entry, around whether a whole plant extract would be novel if you are removing plant material/ fibre and keeping the remaining parts of the composition in particular the ratio of cannabinoids the same as the plant. ie. You are not selecting for one cannabinoid and not overtly selecting for any individual component.

I hope this supports you having a constructive discussion with **[Section 40]**.

Kind regards

[Section 40]

Radiological and Novel Food Policy

Food Standards Agency

Clive House, 70 Petty France, London, SW1H 9EX

www.food.gov.uk

Phone [Section 40]

Attachment



Introduction

- Relevance of food legislation to hemp products
- What a novel food is and how these rules apply to businesses
- Current work on the novel food status of hemp products
- Next steps

DEFINITIONS

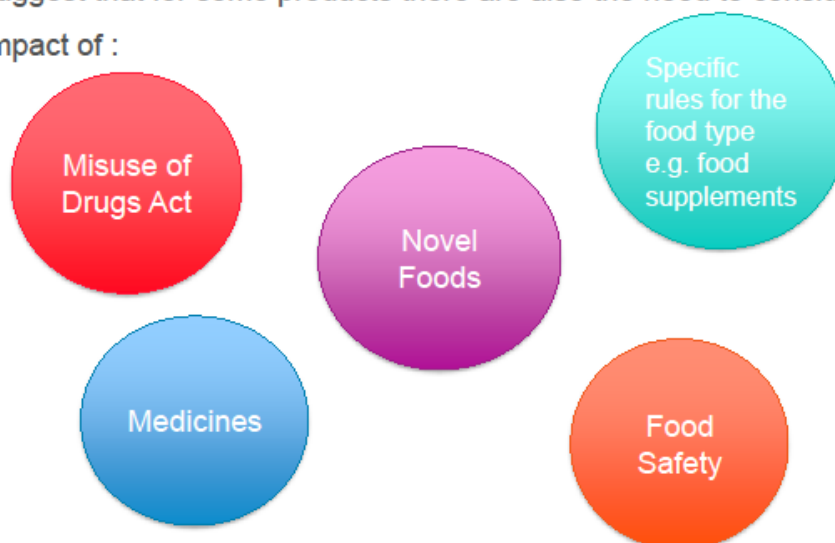
What is food?

In the general food law, 'food' is defined as anything that is consumed or reasonably expected to be consumed that is not:

- A medicine
- A controlled substance
- A tobacco product
- A cosmetic
- Live animals or plants in the field
- Feed
- Contaminants and residues

Hemp products and CBD – Regulatory frameworks

While Food Standards Agency can advise on the food safety aspects we suggest that for some products there are also the need to consider the impact of :



What is a Novel Food (NF)?

- All novel foods are subject to a pre-market safety assessment in accordance with the Novel Food Regulation (EU) 2015/2283.
- Novel foods are defined as foods or food ingredients that do not have a significant history of consumption within the EU prior to the 15 May 1997.

And fit into one of the categories in the regulation.....



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Types of novel food

- Foods and food ingredients with a new or intentionally modified primary molecular structure;
- Foods from micro-organisms, fungi or algae;
- Foods produced from minerals
- Foods from plants or animals except where obtained by traditional propagating or breeding practices and having a history of safe use;

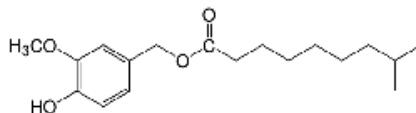


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Types of novel food 2

- Foods produced by cell or tissue culture
- Foods which are engineered nanomaterials.
- Vitamins or minerals
- Foods produced by a new production process or
- Foods exclusively used in foods supplements that are now to be used in other food types.



EC Novel Foods Regulation (2015/2283 EU)

The original regulation and the principles came into force 15 May 1997 – recently updated.

- Provides EU-wide mandatory pre-market approval system
- Applies in all 28 Member States
- Exemptions for food additives, flavourings etc.
- Basic Principles:
novel foods must not present a danger, mislead consumers, be nutritionally disadvantageous
- All novel foods require a pre market risk assessment and authorization at EU level before being placed on the EU market.

.....

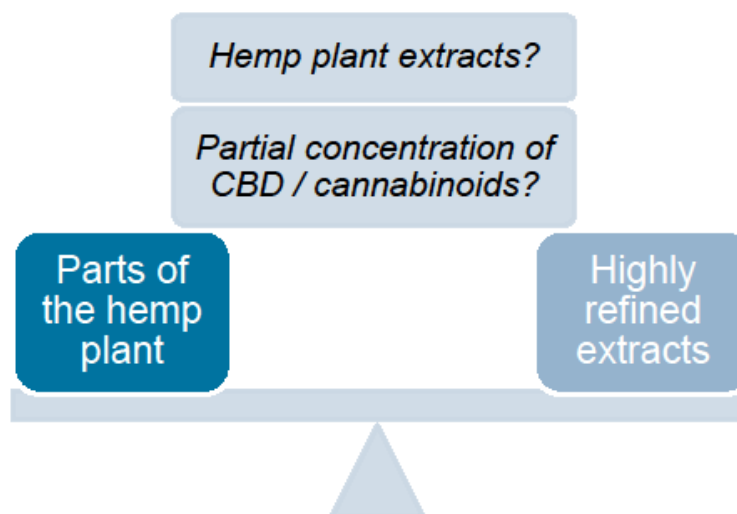
HEMP PRODUCTS AND THE NOVEL FOOD REGULATION

.....

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Understanding the novel food status of hemp products

Emerging issue on the status of different products under the regulation.

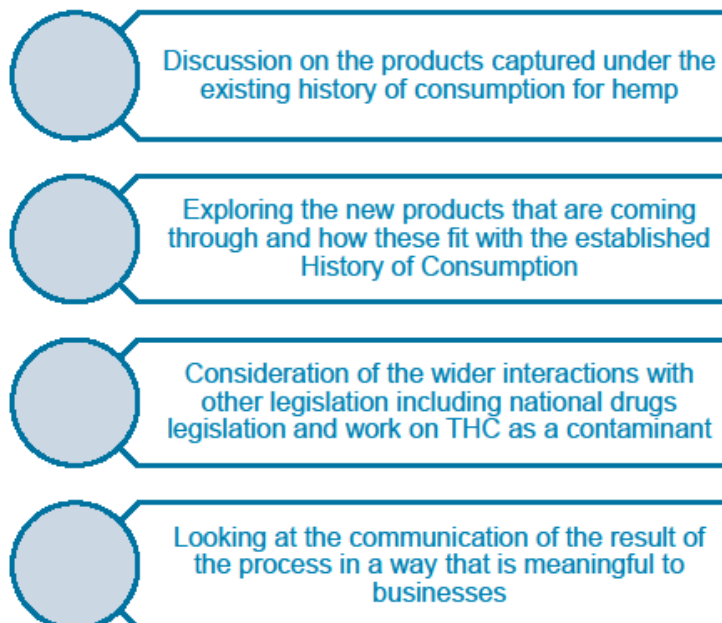


Advice in the novel foods catalogue

In recent months following questions from the industry there has been work at EU level to clarify the text in the novel food catalogue so industry can be clear on the novel food status of:

- Parts of the hemp plant (seeds, stalks, leaves and flowers)
- Seed extracts / hemp seed oils and the pomace remaining after the pressing process.
- Cannabis sativa plant extracts
- Concentrated extracts of particular components from the hemp plant

Work at EU level



Key questions asked

- Which products have developed in the sector and their nature?
 - Discussion with industry.
- Understanding of the sector – stakeholder engagement including Cannabis Trade Association.
- What information is available and does the evidence support the history of consumption of the relevant food?
- For extracts at what point are they a new food that is different to the original so any existing history of consumption in the EU does not apply?
- How does the outcome of the considerations fit with other legislative frameworks?

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Outcome so far

The novel foods catalogue has been updated with the latest understanding based on the information available to Member States.

- This clarifies that the species for use as food is industrial hemp strains of *Cannabis sativa*.
- That many parts of the plant are not considered novel.
- Hemp seed extracts are not novel
- Extracts in which concentrate the level of particular components of the plant such as CBD are concentrated beyond the levels naturally present in the plant are novel .

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Work is ongoing to reshape the entry in the novel food catalogue so that the current understanding of the products with a history of consumption is more clearly communicated.

Options available to Industry for products considered novel.





IMPLEMENTATION

Enforcement measures (England)

- The Novel Foods (England) Regulations 2018 (SI 2018/154)
(Separate, equivalent legislation in other UK countries)
- Aim – to put in place a proportionate and risk based approach to enforcement that provides enforcers with a set of tools to encourage compliance.
- Within the current hierarchy of enforcement, specific tools the Regulations provide for enforcement authorities in England are:
 - Compliance notices;
 - Fixed monetary penalties;
 - Stop Notices and
 - Back stop offences where needed.
- Other sanctions in other parts of the UK.

EU Exit

- The Government has confirmed that the UK will be leaving the EU in March 2019.
- At this point, the European Union (Withdrawal) Act and subordinate legislation will come into effect and;
- The provisions of the EU Novel Foods Regulation will become UK law and the national enforcement provisions will continue to apply.
- We will not know what the future UK system for regulated products will look like until our future relationship with the EU is agreed.

Thank you for your time and attention

**Any Questions
Please forward to Novelfoods@food.gov.uk**

File 1

Title: 190312 Item 6.1 opracowanie_CBD w suplementacji_ENG.pdf

CBD as a dietary supplement - an overview

These days, a good quality hemp oil is exclusively produced from carefully cleaned hemp seeds. It should be cold pressed - this method of production will grant oil a translucent green-to-olive colour as well as the characteristic nutty smell and aftertaste. In the process of pressing the hemp oil can get contaminated with elements of the plant, such as the plant's secretory outgrowths ('hairs' or trichomes). Due to this, any hemp oil can contain small amounts of CBD and terpenoids. Although the content of such elements in the final product is not high, there is enough of them to produce a positive effect on the organism.

Source:

Lecznicze właściwości konopi i możliwości ich zastosowania w medycynie (Medical properties of hemp and its application in medicine)

by: Ilona Kaczmarczyk-Sedlak MD-PhD, prof.; Weronika Wojnar, MS; Maria Zych PhD, prof and Sławomir Dudek MD-PhD.

Department of Pharmacognosy and Phytochemistry, School of Pharmacy with the Division of Laboratory Medicine in Sosnowiec, Medical University of Silesia

Full article (in Polish):

https://katowice.oia.pl/files_news/news_7341/files/Lecznicze_wlasciwosci_konopi_Kaczmarczyk_Sedlak_Ilona_SUM_2017.pdf

It is worth stressing that currently the hemp oil is usually obtained from seeds that not only have been thoroughly cleaned but also had their hulls removed, which enhances the efficiency of the whole pressing process.

In the past, up until the beginning of the 20th century, when the mechanical threshers were introduced, any seeds - be it wheat grain or hemp seed - were obtained in the process of manual threshing with flails. A detailed description of the process can be found in the article "Work and everyday life in rural Poland", available here (in Polish): <http://muzeum.lasochow.pl/zboze.html>

The description reads as follows:

„It was not enough to simply thresh the wheat, one had also to separate the wheat from the chaff - as well as from weeds' seed, shards or lumps of earth. Before grinders, fans and cylinder separators became a standard, the grain was separated - as Moszyoski observes - with use of a shovel or spade with a short shaft, combined with... a natural wind: >>the grain was tossed in the air, and the wind would carry off chaff and talings<<. Needless to say, this method was primitive and inefficient, yet the poorest peasants continued to use it as late as in the interwar period.”

It seems obvious that using methods as primitive as those described above to separate hemp seeds from the rest of the plant could not guarantee that the seeds would be clean and that all unwanted elements (such as leaves or fragments of perch) would be completely removed. The inevitable presence of such elements in the mass of the seeds from which the oil was pressed could result in inflated levels of CBD in the hemp oil.

In addition, since no dehulling machines were available, back in the days the hemp oil was pressed from seeds with hulls, and it is on the surface of the hulls that all the plant residuals (such as leaves or pollen from the perch) remain. Those elements contain a much higher CBD content, so the cannabidiols' levels measured on the surface of the seed hulls are much higher than those in the clear and dehulled seeds.

In the pressing process, the pressed oil would rinse the ground seeds (as well as the hulls and the remains of the perch and leaves), effectively washing out CBD (CBD is fat-soluble, that is why rinsing cannabis buds with olive oil is currently one of the popular methods of obtaining CBD). This process clearly led to the even higher CBD content in the final product.

As stated by the Polish Research Centre for Cultivar Testing (Centralny Ośrodek Badań Odmian Roślin Uprawnych, COBORU) there are currently 8 varieties of *Cannabis Sativa L.* hemp classified as a fibre-grade. These are Beniko, Białorzęskie, Glyana, Henola, Rajan, Tygra, Wielkopolskie i Wojko. All of them are monoicous varieties with the THC content not exceeding 0,2%. All these varieties are an effect of inter-breeding processes. It is possible that in the past cultivated were also other varieties of hemp, with higher THC- and CBD content.

Taking into consideration all the above factors, it is easy to reach the conclusion that the CBD content in hempseed oil produced in the preindustrial era was higher than that observed in modern products.

Scientific sources state that CBD content in the hemp seeds obtained at present does not exceed 25 mg/kg level, while the CBD content in the oil pressed from those seeds usually does not exceed 75 mg/kg.

The results of a study presenting the concentration of various cannabinoids in different parts of the plant as presented in Table 1 (below). Those results can be found in:

Andre C.M. et al.: *Cannabis sativa: the plant of the thousand and one molecules*", *Frontiers in Plant Science* 2016; 7:19.

Especially interesting are also the results of the study conducted by the Croatian team published in the following paper:

Petrović M., Debeljak Ž, Kezić N., Džidara P. : *Relationship between cannabinoids content and composition of fatty acids in hempseed oils*. *Food Chem.* 170 218–225. [10.1016/j.foodchem.2014.08.039](https://doi.org/10.1016/j.foodchem.2014.08.039).

The results of the study have been included in Table 1 above - the maximum CBD content in the hempseed oil was 224 µg/g which translates to 224 mg/kg.

The authors of the paper make a supposition that the increased CBD level detected in 5 out of 11 samples of hemp oil available on the Croatian market which have been put to the test could have been caused either by an invalid production process... or by illegal use of *Cannabis Indica* varieties. However, the latter possible explanation is little probable, as the average CBD levels in oils obtained from *Cannabis Indica* plants (that is, from the 'drug-type' plants), as quoted in Table 1, are significantly lower than those measured in the Croatian samples and comparable with an average CBD content of hemp oils (that is, below 75mg/kg)

Of course, there can be no certainty that the increased CBD levels observed in hemp oils by the Croatian scientists are comparable with those typical for oils produced in the pre-industrial era and using methods typical for that period. However, taking into account the CBD levels observed in different parts of the *Cannabis sativa* plant, mainly in its leaves (1790 – 20000 µg/g in dry mass) as well as the above-described conditions in which the hemp oil used to be pressed up until the wake of 20th century, we can contend with a high degree of probability that the increased CBD content observed by the Croatian team in the hemp oil is similar to the CBD levels typical for the pre-industrial era hemp oils.

The next goal of this overview is to prove that prior to the 20th century the typical CBD intake of a hemp oil consumer was comparable to the amounts recommended nowadays for the purposes of dietary supplementation. If the above claim turns out to be true, it could be safely said that the consumption of CBD in the amounts typical for the present dietary supplement has a long-term tradition.

To support this claim, the probable typical CBD intake for a pre-industrial era hemp oil consumer was estimated below. The following assumptions have been made:

X the CBD content in the hemp oil is 244 mg/kg (as measured by the Croatian researchers)

X the hempseed oil consumption by our predecessors was comparable with the current consumption of other plant-derived fats and oils

The data concerning the average consumption of plant-derived fats and oils have been drawn from the EFSA database - EFSA Comprehensive European Food Consumption Database. This database contains data regarding the levels of consumptions for different groups of food products among the citizens of the EU countries. As the database lacks the data for Polish consumers this overview uses the data for the Czech Republic. This country is a neighbour of Poland, so one can assume that the Czech dietary customs would be similar to the Polish ones and somehow representative for Middle Europe. Such an assumption can be confirmed by comparing the data on the plant-derived fats and oils consumption in Czechia as gathered by EFSA with findings of Polish study conducted by the Polish National Food and Nutrition Institute and published as „Badania indywidualnego spożycia integralną częścią systemu zapewnienia bezpieczeństwa żywności w Polsce”

(Warsaw 2003); the data used for this comparison were the data for rapeseed and rapeseed-soy oils.

The following data on plant-derived fats and oils consumption in the Czech Republic were used in the reasoning (grammes/person/day):

- average consumption: 23,2
- median of consumption: 18,7
- consumption for the 95th percentile ('high consumer'): 56,9

Assuming that the CBD content in the hemp oil is 244 mg/kg and that in the pre-industrial era this oil was a basic source of plant oil in a typical diet (which was especially true for the peasantry), the typical CBD intake in that period would be as follows:

- average consumption: **5,6 mg of CBD/person/day**
- consumption for the 95th percentile: **13,9 mg of CBD/person/day.**

This estimated daily CBD intake should be now compared with the CBD levels currently recommended in dietary supplementation.

Polish Institute of Natural Fibers and Medicinal Plants (an official and scientific institution) has created its own dietary supplement containing CBD and CBDa. The recommended daily dose of this supplement (five drops) contains **5 mg CBD and CBDa.**

In the massive body of literature available on the Internet, different hemp preparation can be found mentioned, differing not only in the CBD levels but also in the purpose (being either dietary supplements or medicine). In general, the recommended CBD doses for an everyday consumption vary from **0,5 – 20 mg CBD/day**. Consumed in such amounts CBD improves the quality of sleep, it also helps for headaches, mood swings, nausea or stress and anxiety. In a bigger doses CBD is recommended for more serious ailments and conditions, therefore it cannot be considered a dietary supplements.

Comparing the estimated probable daily consumption of CBD for the pre-industrial era consumers of hemp oil with the doses recommended currently in dietary supplementation, it is safe to conclude that the CBD consumption in such doses has a long-term tradition and had been a common practice at least to the beginning of the 20th century.

File 2

Title: 180117 Point 6.2 [Section 40] Presentation

What is a cannabis extract?

Types of extracts

Water extraction (tea)

Alcohol Extraction

Other extraction methods

Water Extraction

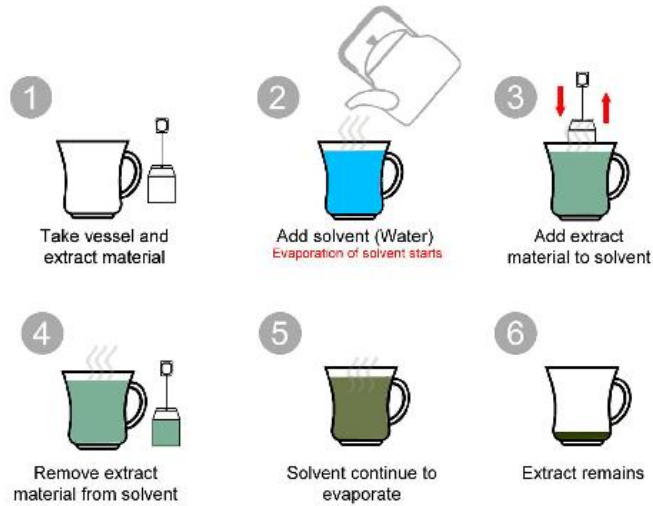
A water extraction is the most well know method of extraction, it is a method used daily by millions of EU citizens for thousands of years

The preparation of a tea, is a water extraction

1. The plant material is saturated in a cup of water
2. The plant constituents are dissolved into the water
3. The plant material is removed from the water
4. The extract will be naturally concentrated due to the evaporation of the water
5. All water will evaporate naturally after a period of time



Water Extraction Method



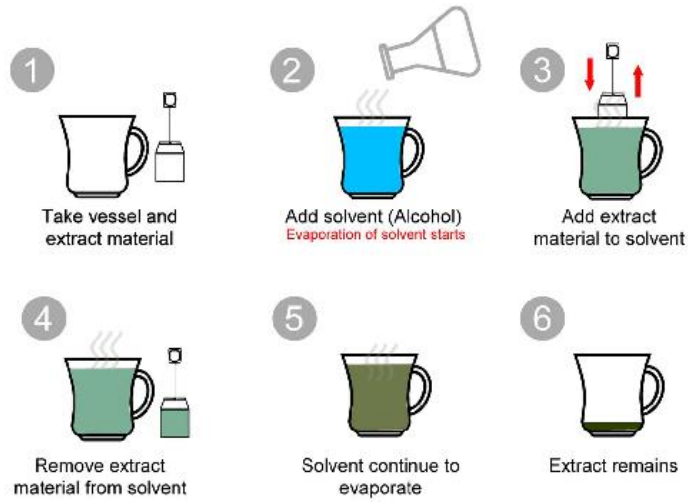
Alcohol Extraction

An alcohol extraction is exactly the same as a water extraction, the method is identical.

The preparation of a tea, is a water extraction

1. The plant material is saturated in alcohol
2. The plant constituents are dissolved into the alcohol
3. The plant material is removed from the alcohol
4. The extract will be naturally concentrated due to the evaporation of the alcohol
5. All alcohol will evaporate naturally after a period of time

Alcohol Extraction Method



Alcohol Extraction Method



Video: Demonstrating an alcohol extraction of cannabis

Water extraction vs Alcohol Extraction

The method of extraction is identical

Water Extraction	Alcohol Extraction
The plant material is saturated in water	The plant material is saturated in alcohol
The plant constituents are dissolved into the water	The plant constituents are dissolved into the alcohol
The plant material is removed from the water	The plant material is removed from the alcohol
The extract will be naturally concentrated due to the evaporation of the water	The extract will be naturally concentrated due to the evaporation of the alcohol
All water will evaporate naturally after a period of time	All alcohol will evaporate naturally after a period of time

Other extraction methods

Other extraction methods like co2 work on exactly the same principles
All these extractions requires a solvent.

- In water extractions, **water** is the solvent
- In Alcohol extractions, **alcohol** is the solvent
- In Co2 extractions **CO2** is the solvent

Nutritional Profile

Nutrition	Hemp Seed Oil	CBD Oil
Total sugars	99.4	99.7
Energy value (kcal)	895	897
Energy value (kJ)	3678	3689
Monounsaturated fatty acids	15.16	15.81
Polyunsaturated fatty acids	69.55	68.63
Saturated fatty acids	9.82	10.16
Trans Fatty Acids	0.37	0.40

File 3

Title: 170929 Note to [Section 27] on CBD extracts final

Discussion paper from the United Kingdom:

Consideration of the novel food status of CBD extracts of hemp

Background

In the UK managing products of hemp and in particular CBD containing extracts has become a complicated and key issue for both producers and enforcement authorities. The novel food catalogue entries make clear that hemp products are not novel but highly refined extracts are novel. However, in practice there is a continuum of products on the market and we think it is important to explore the circumstances in which extracts are no longer consistent with the history of consumption for hemp and would therefore require authorisation under the Novel Food Regulation.

We are reaching a point in the UK where we need to be in a position to provide clear guidance for operators in order to ensure a level playing field. We therefore welcome the opportunity to discuss the issue and have identified some areas we feel are important to discuss in reaching a decision on how these products should be managed in relation to the EU novel foods framework.

We recognise that on this novel food issue, there is interaction with other legal frameworks, including medicines and drugs. However, as these aspects are outside the scope of consideration of this group and arrangements under these frameworks differ from Member State to Member State, they should not be the focus of the debate.

Key Questions

In considering the novel food status of hemp extracts we have identified the following key questions we think need to be given consideration when making decisions on hemp extract products, on which we would welcome discussion with the Commission and working group colleagues:

- What influences the higher level of CBD (the selling point of the product)?
- Is this a selective extraction which increases the intake of CBD by consumers compared to the non novel extracts?
- Does the production process make the product novel?

Consideration of the Key Questions

What influences the higher level of CBD (the selling point for the product)?

We are aware from the information from industry that there can be a number of reasons for the CBD in a product to be higher than traditional hemp oils. For example, there may be naturally higher levels of CBD in the plant starting material where a higher CBD-containing strain produced by traditional plant breeding techniques is used, or where parts of the plant higher in CBD such as leaves, stalk and flowers is used. It is unclear that if these naturally higher CBD levels in the plant would be consistent with the history of consumption for hemp products and, if so, whether this would affect the novel food status of the product.

Is this a selective extraction that alters the intake of CBD by consumers compared to the non novel extracts?

There are cases where foods ordinarily considered to be non novel can be considered to be novel foods when they have been obtained by a selective extraction process e.g. green tea extract. These have largely been highly purified extracts, but the level of purification has varied and could, at least in principle, apply to any extract where selective extraction significantly alters consumers' intake of the material extracted in comparison to the non-novel version of the food.

Extracts, including seed oils, fall within the existing history of consumption for hemp products. In products with higher levels of CBD, careful consideration needs to be given to the techniques and level of purification required to obtain the product and whether this may mean that the product is no longer consistent with the history of consumption and should therefore be considered to be novel.

Some products are simple alcohol extracts of the plant subjected to a rotor evaporation process which leads to an increased concentration of CBD. If this

process is repeated, extracts with greater concentrations can be obtained as other components of the oil such as terpenes and flavanoids are removed. Further advanced processes can be carried out to produce highly purified isolates of between 60% and 99% pure CBD. The key questions are: (a) At what point is the extract considered selective? and (b) At what level of purification is a product no longer considered consistent with the existing history of consumption?

[Section 40] have argued that the distinction between foods, food supplements and medicinal uses should be based on daily dosage. However, for managing these potentially novel foods a purity criterion would be more consistent with categorising a food within the novel food framework.

Equally, if the terpene and flavonoid components are removed in the process and then reintroduced to the product would this result in a change to its novel food status? And would a more concentrated ingredient that is standardised to a lower concentration of CBD through use of Hemp oil for use by consumers be treated differently?

Would the production process in itself be novel?

Processes not used in the food industry prior to 1997 that give rise to significant changes in a food are considered novel. Would the use of processes to remove undesirable substances such as THC etc. for safety reasons or in order to be compliant with national drugs legislation mean that a product should be considered to be novel?

Summary

In conclusion, the UK feels there is a need to consider these issues in order to facilitate the provision of consistent advice on which hemp products should be subject to the provisions of the Novel Foods Regulation. We are aware that in some Member States, highly purified extracts are considered medicinal. Given the case-by-case approach to classifying medicines, we think it is necessary to understand how these products should be managed if they are marketed as foods. This work could perhaps also be used to develop a framework for considering extracts ahead of the new Article 4 process on establishing novel food status under which these issues could be raised more regularly.

File 4

Title: 181016 10. WHO letter to UN ref hemp and CBD



World Health
Organization

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Tel. direct: +41 22 791
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In reply please
refer to: ECDD/0

Your reference:

His Excellency
Mr António Guterres
Secretary-General of the United Nations
New York, NY 10017
USA

23 July 2018

Dear Mr Secretary-General,

The fortieth meeting of the WHO Expert Committee on Drug Dependence (ECDD) convened from 4 to 7 June 2018 at WHO headquarters in Geneva. The fortieth ECDD meeting was dedicated to the review of cannabis and its component substances.

CND Resolution 52/5 noted that the health effects of cannabis had not been recently reviewed and requested the WHO ECDD to provide an updated report. The thirty-eighth ECDD (November, 2016) reviewed updates presented by the Secretariat and recognised an increase in the use of cannabis and its components for medical purposes and the emergence of new cannabis-related pharmaceutical preparations for therapeutic use. The Committee further recognised that cannabis had never been subject to a formal review and therefore recommended that pre-reviews of cannabis and its component substances be evaluated at a specific ECDD meeting dedicated to those substances.

Following those recommendations, the fortieth ECDD undertook a critical review of cannabidiol (CBD). It also carried out pre-reviews of cannabis plant and resin; extracts and tinctures of cannabis; delta-9-tetrahydrocannabinol (THC); and isomers of THC.

With reference to Article 3, paragraphs 1 and 3 of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol, I am pleased to submit the recommendations of the fortieth ECDD as follows:

Cannabidiol (CBD)

The Committee recommended that preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions.

ENCL: (1)

cc: Ms J. Dedejne-Amann, Chief, Secretariat to the Governing Bodies, UNODC

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Organisation mondiale de la Santé • Всемирная организация здравоохранения • Organización Mundial de la Salud

Cannabis plant and resin

The Committee concluded that there is sufficient evidence to proceed to a Critical Review

Extracts and tinctures of cannabis

The Committee concluded that there is sufficient evidence to proceed to a Critical Review

Delta-9-THC

The Committee concluded that there is sufficient evidence to proceed to a Critical Review

Isomers of THC

The Committee concluded that there is sufficient evidence to proceed to a Critical Review

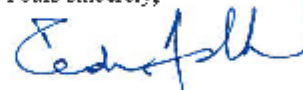
The recommendations and the assessments and findings on which they are based are set out in detail in the WHO Expert Committee on Drug Dependence *Fortieth report*. An extract of the report is attached in Annex 1 of this letter.

I would like to take this opportunity to inform you that the forty-first meeting of the ECDD will take place in November 2018. At that time, the Committee will undertake critical reviews of the above-mentioned cannabis components (cannabis plant and resin; extracts and tinctures of cannabis; Delta-9-THC; Isomers of THC) as well as of a number of New Psychoactive Substances (NPS), including fentanyl-analogues and other psychoactive substances.

I am very pleased with the ongoing collaboration between WHO, the United Nations Office on Drugs and Crime (UNODC) and the International Narcotics Control Board (INCB), in particular, how this collaboration has supported the work of the WHO Expert Committee on Drug Dependence, and more generally, the implementation of the operational recommendations of the United Nations General Assembly Special Session (UNGASS) 2016.

With my very best
personal regards.

Yours sincerely,



Dr Tedros Adhanom Ghebreyesus
Director-General



Annex 1- Extract from the WHO Expert Committee on Drug Dependence: Farlieth report

Cannabidiol (CBD)

Cannabidiol is one of the naturally occurring cannabinoids found in cannabis plants.

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 use include loss of appetite, diarrhoea, and fatigue.

Therapeutic applications of CBD are being researched for a variety of clinical uses. Research in this area is most advanced in the treatment of epilepsy. In clinical trials, one pure CBD product has demonstrated effectiveness for treating some forms of epilepsy such as Lennox-Gastaut Syndrome and Dravet Syndrome that are often resistant to other forms of medication. Since the Committee met, a pure CBD product has received marketing approval by the US Food and Drug Administration (FDA).

Cannabidiol (CBD) is not specifically listed in the schedules of the 1961, 1971 or 1988 United Nations International Drug Control Conventions. However, if prepared as an extract or tincture of cannabis it is controlled in Schedule I of the 1961 Single Convention on Narcotic Drugs.

There is no evidence that CBD as a substance is liable to similar abuse and similar ill-effects as substances in the 1961 or 1971 Conventions such as cannabis or THC, respectively.

The Committee recommended that preparations considered to be pure CBD should not be scheduled.

Cannabis plant and resin

Cannabis is defined as the flowering tops or separated resin of the *Cannabis sativa* plant. Cannabis contains 121 reported phytocannabinoids, with the most prominent of these compounds being Δ^9 -THC (THC) and cannabidiol (CBD). THC is thought to be the principal intoxicant constituent of cannabis.

When consumed acutely, cannabis causes adverse effects such as dizziness and impaired motor control and cognitive function. Cannabis can cause driving impairment. There are particular reported risks for children such as respiratory depression, tachycardia, and coma. The adverse effects of cannabis consumption are similar to those produced by THC alone.

Most of the adverse effects associated with cannabis result from chronic use. Regular cannabis use is associated with increased risk of mental health disorders such as anxiety, depression, and psychotic illness. Chronic regular cannabis use is particularly problematic for young people as a result of the effects on the developing brain.



Cannabis can cause physical dependence in humans as evidenced by the onset of cannabis withdrawal symptoms upon abstinence. Withdrawal syndromes include mood changes, irritability, and sleep impairment. Clinical diagnostic guidelines such as DSM-5 and ICD-10 recognise cannabis use disorder.

The Committee considered information regarding the therapeutic indications of cannabis and ongoing research for its possible medical applications. Several countries permit the use of cannabis for the treatment of medical conditions such as back pain, sleep disorders, depression, post-injury pain, and multiple sclerosis. Research with cannabis for its potential medical applications is ongoing.

Cannabis plant and cannabis resin are placed in Schedule I and Schedule IV of the 1961 Single Convention on Narcotic Drugs. Substances that are included in both Schedules I and IV of the 1961 Convention on Narcotic Drugs are particularly liable to abuse and to produce ill-effects. Other substances included in both Schedules I and IV are fentanyl analogues and other opioids considered especially dangerous.

The evidence presented to the Committee did not indicate that cannabis plant and cannabis resin were liable to produce ill-effects similar to these other substances that are in Schedule IV of the 1961 Convention on Narcotic Drugs. The inclusion of cannabis and cannabis resin in Schedule IV may not appear to be consistent with the criteria for Schedule IV.

The Committee concluded that there is sufficient evidence to proceed to critical review of cannabis plant and cannabis resin at a future ECDD meeting and explore further the appropriateness of their current scheduling within the 1961 Convention.

Extracts and tinctures of cannabis

Extracts and tinctures of cannabis are substances that have been extracted from the *Cannabis sativa* plant. These include preparations such as cannabis oils, teas, and nabiximols (an extract with approximately equal quantities of THC and cannabidiol). These substances can be administered through various routes including through oral consumption and smoke inhalation.

Evidence around the dependence potential of extracts and tinctures of cannabis varies by substance. There are no published studies that have evaluated the dependence potential of nabiximols, but there is limited evidence of a withdrawal syndrome upon abrupt cessation (e.g. sleep disruption, mood changes). The frequent use of butane hash oil has been associated with physical dependence. The psychoactive constituent Δ^9 -THC present in a majority of extracts has been separately examined and has been shown to have dependence potential.

There are few published studies that have evaluated the abuse potential of cannabis extracts in animals or humans. There are, however, studies that have investigated the abuse potential of various components of extracts and tinctures of cannabis. Whilst particular components, such as Δ^9 -THC, have demonstrated abuse potential, other components in these preparations, such as CBD, do not have abuse potential.



The Committee recognised that the term 'extracts and tinctures' as cited in the 1961 Single Convention on Narcotic Drugs encompasses preparations that have psychoactive properties as well as those that do not have such properties. The Committee also recognised that the psychoactive properties of these preparations are due to $\Delta 9$ -THC and possibly isomers of THC, substances which are currently scheduled in the 1971 Convention on Psychotropic Substances. Amongst the substances that are not psychoactive within the preparations that are derived as extracts or tinctures of cannabis, some like cannabidiol have promising therapeutic indications. Cannabis extracts and tinctures are placed in Schedule I of the 1961 Single Convention on Narcotic Drugs.

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.

The Committee therefore concluded that there is sufficient information to progress extracts and tinctures of cannabis to critical review at a future ECDD meeting in order to address the necessity of continuing to include the nomenclature 'extracts and tinctures of cannabis' in the 1961 Convention.

Delta-9-tetrahydrocannabinol (THC)

Delta-9-tetrahydrocannabinol (THC) refers to four stereoisomers of $\Delta 9$ -THC. One of these stereoisomers is known by the International Nonproprietary Name (INN), dronabinol, and has recognised therapeutic uses.

Chronic administration of $\Delta 9$ -THC can induce physical dependence in laboratory animals and in humans. This has been evidenced by the presence of withdrawal effects in animals and human subjects.

The subjective effects of $\Delta 9$ -THC when administered orally resemble those of cannabis. However, there is little evidence that oral $\Delta 9$ -THC is used for non-medical purposes so as to cause a public health problem.

$\Delta 9$ -THC (dronabinol) has approval in a number of countries for therapeutic indications including anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS) and for nausea and vomiting associated with cancer chemotherapy. $\Delta 9$ -THC (dronabinol) is routinely administered orally.

$\Delta 9$ -THC and its stereoisomers are listed in Schedule II of the Convention on Psychotropic Substances of 1971.

In previous ECDD reviews, $\Delta 9$ -THC and especially dronabinol had been considered in a synthetic form as a pharmaceutical preparation.