



Cannabis, Extracts of Cannabis and Cannabidiol: Several Legal Perspectives

13th EIHA
Conference

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June 2, 2016

Ladies and Gentlemen

The fact the scheduling of cannabis happened in 1961 without a lot of scientific knowledge about cannabinoids, does not mean the officials have not been following these rules ever since. They are and this is their job.

Our job, I believe, is to find bullet-proof ways of doing what we want to be doing: to become successful in the emerging cannabis industry in the long run.

There are no significant policy changes to be seen after recent UN General Assembly Special Session on the world drug problem and are not expected in the next three years. In the mean time, we should be working step-by-step showing good examples how to be diligent, honest and profitable. There are ways available already: some are rather evident but some are little harder to accept.

Name of this lecture is: "Cannabis, Extracts of Cannabis and Cannabidiol: several legal Perspectives."

Maybe its main message is: the fact Cannabidiol is not scheduled by UN does not necessarily mean it is not regulated already; especially in the European perspective. I also believe, our industry is mature enough to allow calling things their proper names and it can live with it.

PART I

SINGLE CONVENTION ON NARCOTIC DRUGS, 1961
Yellow List

CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971
Green List

UN CONVENTION AGAINST ILLICIT TRAFFIC
IN NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES, 1988

In the first part we will discuss the ultimate legal framework which sets rules for our governments. Do keep in mind many countries went beyond these rules or are not completely in line with them. I strongly advise you always check with your national authorities and your lawyers before engaging in any kind of cannabis enterprise.

General obligation of countries is to limit the production, manufacture, export, import, and distribution of, trade in, use and possession of drugs, exclusively to medical and scientific purposes.

Schedules				
Category	Schedule I	Schedule II	Sched. III	Schedule IV
Narcotic Drugs Yellow List http://bit.ly/1Tm36Ka	<i>Cannabis</i> and <i>Cannabis Resin</i> , Extracts and Tinctures of <i>Cannabis</i>			<i>Cannabis (plant)</i> and <i>Cannabis Resin</i>
Psychotropic Substances Green List http://bit.ly/1TWaity	THC, it's isomers and stereoisomeric variants (1971) DMHP, Parahexyl – synthetic homologues of THC (1971)	delta-9-THC, <i>Dronabinol</i> (1991) <i>Cannabidiol</i> (Canada, Slovakia)		
<i>Cannabidiol</i> is not a scheduled substance on UN level.				
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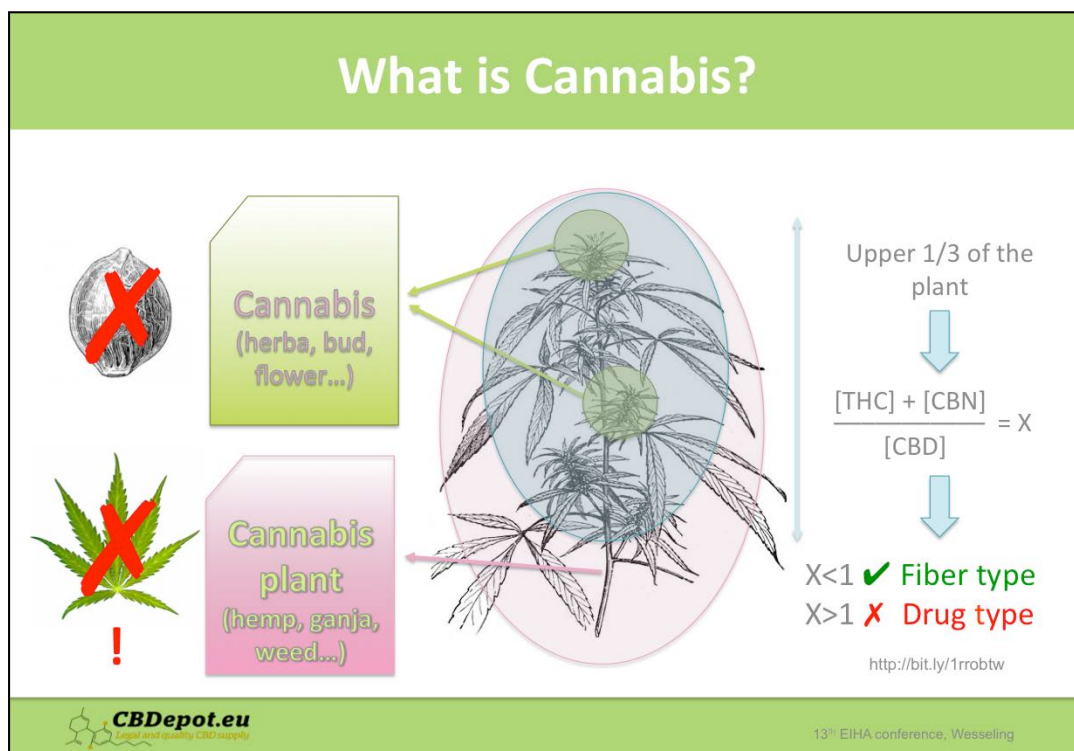
UN conventions recognize two Categories of substances and four Schedules.

Categories are Narcotic drugs, as defined by a so called Yellow List, and Psychotropic substances, as defined by the Green List. These lists are published by the International Narcotics Control Board with last updates in 2015.

Schedules are defined by their abuse potential. Schedule One drugs are deemed most dangerous. Schedule Two can be prescribed on a specialist prescription, Schedule Three contain various medicinal preparations on regular prescription and Schedule Four defines particularly dangerous Schedule One substances with potential medicinal and scientific research applications left to discretion of individual countries.

A specific isomer of THC, the delta-9 also called Dronabinol, was allowed a controlled medicinal use and was moved into Schedule Two in 1991. Several countries have allowed medicinal Cannabis programs.

As we can see, Cannabidiol, as a chemical substance, is not Scheduled by international law, however at least two countries Canada and Slovakia moved it into Schedule II several years ago.



Let us now discuss how the Single Convention defines Cannabis and what makes it different from a Cannabis plant.

“Cannabis plant” means any plant of the genus Cannabis.

“Cannabis” stands for the flowering or fruiting tops of the “cannabis plant” from which the resin has not been extracted.

Seeds and leaves are not defined as “Cannabis” if they are separated from the flowering tops. However, countries should prevent misuse and trafficking the leaves of the cannabis plant.

The term hemp (or industrial hemp) is not defined by UN Conventions. It is only mentioned in a so called “cannabis Manual” of UN Office on Drugs and Crime. For this purpose, upper third part of the “Cannabis plant” is probed for its cannabinoid profile, in order to differentiate between Drug type and Fiber type. Contents of total THC and Cannabinol are divided by total Cannabidiol content with result of the formula lower or higher than 1.

Production



“Production” means the separation of cannabis and cannabis resin from the plants from which they are obtained.

Manufacture

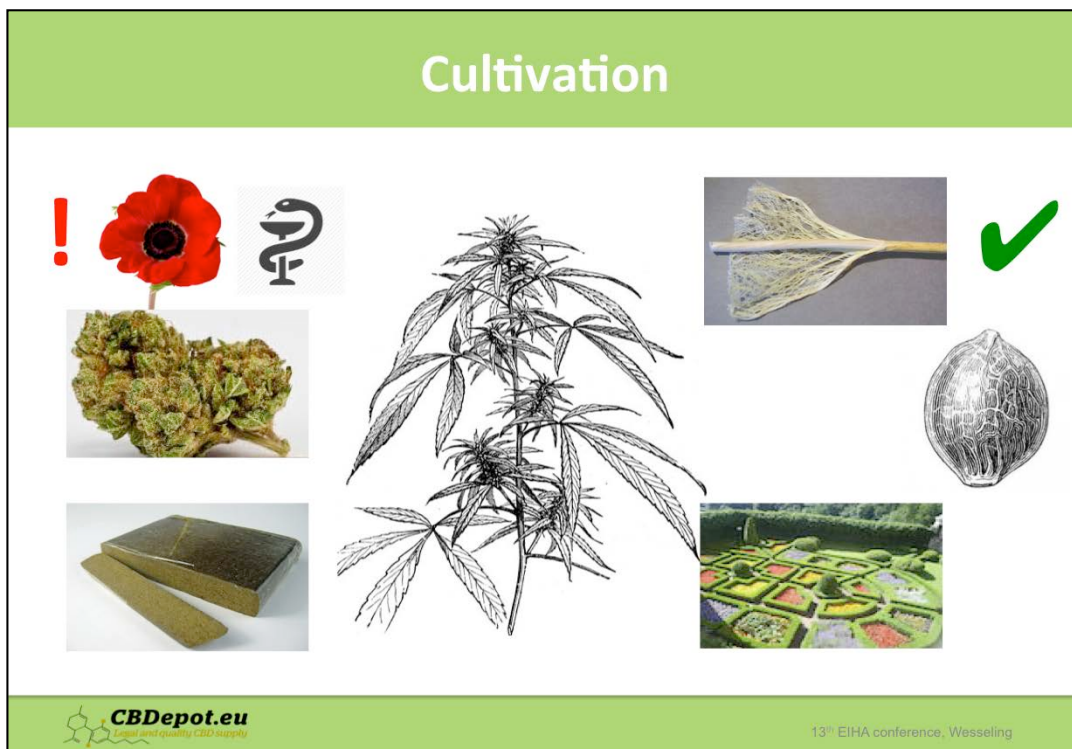


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“Manufacture” means all processes, other than production, by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs.

Since we have seen that extracts and tinctures of cannabis are Schedule I narcotic drugs, manufacture of extracts of Cannabis is also classified as “manufacture” and is subject to mandatory licensing form national governments, which is also the case for our CBD isolation facility in Prague.



As per Article 28, the Single Convention does not apply to the cultivation of the cannabis plant exclusively for industrial purposes, meaning production of fibre and seed or horticultural purposes. Any country that limits production of hemp seed and hemp stalks goes clearly beyond its international engagements.

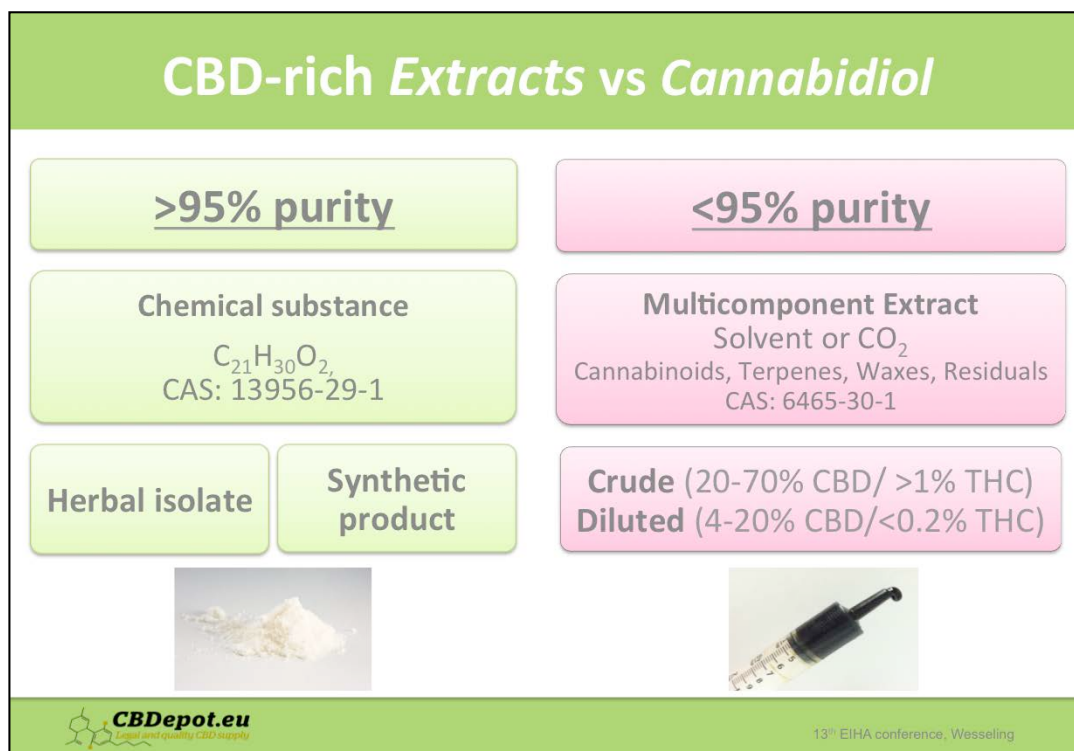
If a country permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it must apply the system of controls respecting the use of the opium poppy for medicinal use. They create Cannabis agencies and follow rules described in Article 23.

Now wait. Do not you smell something fishy here? There is absolutely no engagement by international law that commands governments to ban cultivation of this excellent renewable source of raw materials and ingredients, as well as to bar their citizens, from accessing this amazing natural remedy under prescription. So why, after more than 50 years is our industry emerging only?

PART II

EXTRACTS OF CANNABIS VS CANNABIDIOL

Let us go deeper into CBD agenda.



Please note that 95% purity level is the distinguishing point between plant extracts and isolated chemical substances with their formulae and CAS numbers. From the perspective of legislation and a permitted way of use, it does not really matter, if it is of herbal or synthetic origin. No claims such as organic apply to chemical substances.

We recognize two main grades of the extract: crude and diluted. Extraction of cannabis boosts concentration of all cannabinoids including THC. Since THC levels usually go well over 1 per cent, dilution to less 0.2 per cent is therefore advised in order to avoid criminal prosecution before placing this raw material on a business-to-business market.

What Oil?



Hemp Seed Oil
HS 1515 90

Hemp Essential Oil
HS 3301 90

Cannabis Extract
HS 1302 19

It is a real pity a certain otherwise honorable Canadian gentleman has named his powerful cannabis extract by a term "hemp oil". It makes me want to shed a tear of Phoenix when people call to our Hemp Seed Oil Europe Customer Service number, asking for that magical medicine to cure their cancer and all you can do is to disappoint them. Honestly, this is a customer deception taken to the max.

There is and there will ever be only one real oil related to hemp. The hemp seed oil. All the other „oils“ are technically extracts or tinctures. With an exception of hemp essential oil which is a vapor fragrance distillate of the green parts.

Whole plant extracts are practically non-existent. Who would want to spend resources and machine time on processing low resin material? And I will not comment further on a term "seed and stalk extract".

However, whoever enriches any kind of vegetable oil with the cannabis extract or Cannabidiol, should declare their blended product properly according to Intrastat nomenclature which just follows.

What Oil? Combined nomenclature			
Hemp Seed Oil	Hemp Essential Oil	Cannabis Extract	Cannabidiol
Chapter 15 ANIMAL OR VEGETABLE FATS AND OILS AND THEIR CLEFTAGE PRODUCTS; PREPARED EDIBLE FATS; ANIMAL OR VEGETABLE WAXES	Chapter 33 ESSENTIAL OILS AND RESINOIDS; PERFUMERY, COSMETIC OR TOILET PREPARATIONS	Chapter 13 LAC; GUMS, RESINS AND OTHER VEGETABLE SAPS AND EXTRACTS	Chapter 29 ORGANIC CHEMICALS
Group 1515 Other fixed vegetable fats and oils (including jojoba oil) and their fractions, whether or not refined, but not chemically modified	Group 3301 Essential oils (terpeneless or not), including concretes and absolutes; resinoids; extracted oleoresins; concentrates of essential oils in fats, in fixed oils, in waxes or the like, obtained by enfleurage or maceration; terpenic by-products of the deterpenation of essential oils; aqueous distillates and aqueous solutions of essential oils	Group 1302 Vegetable saps and extracts; pectic substances, pectinates and pectates; agar-agar and other mucilages and thickeners, whether or not modified, derived from vegetable products	Group 2907 Polyphenols; phenol-alcohols
CN 1515 90 59 – Other (food grade) CN 1515 90 60 – For technical or industrial uses...	CN 3301 90 90 – Other – Other	CN 1302 19 70 – Other – Other	CN 2907 29 00 – Phenols, phenol-alcohols
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But it is not only about statistical reporting to European Commission. Consumers should know what they are buying and all products on a consumer market should be properly labeled in line with applicable legislation.

As to Cannabidiol itself, it is an organic chemical compound belonging to a group 2907 of the Harmonized Tariff System called Phenols and phenol-alcohols.

PART III

RECOMMENDED AND „SAFE“ CBD APPLICATIONS IN ENDUSER PRODUCTS

Medicine
Cosmetics
E-liquids
Foods and Food Supplements

Before we move on, let us clarify a major misconception.

What 0.2%?



Common Catalogue =
Upper 1/3 of
the plant
<0.2%
(2000 ppm)
THC
÷ by 10000

LOD = 0.2 ppm = 0.00002%
LOQ = 0.6 ppm = 0.00006%

Food category / THC content	
	5 ppm
	0.15 ppm
	0.005 ppm

<http://bit.ly/1OhhOmp>


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What 0.2 per cent?

0.2 per cent or 2000 parts per million of THC is a limit for registration of new and control of existing cultivars of *Cannabis sativa* in a *Common catalogue* of agricultural species. Period.

The above limit may be used for legality assessment from perspective of a criminal law for any intermediate product on a B2B market. But this limit has nothing to do with safety of products intended for end-consumers, when there is a general zero tolerance on THC in end-consumer products on the European market.

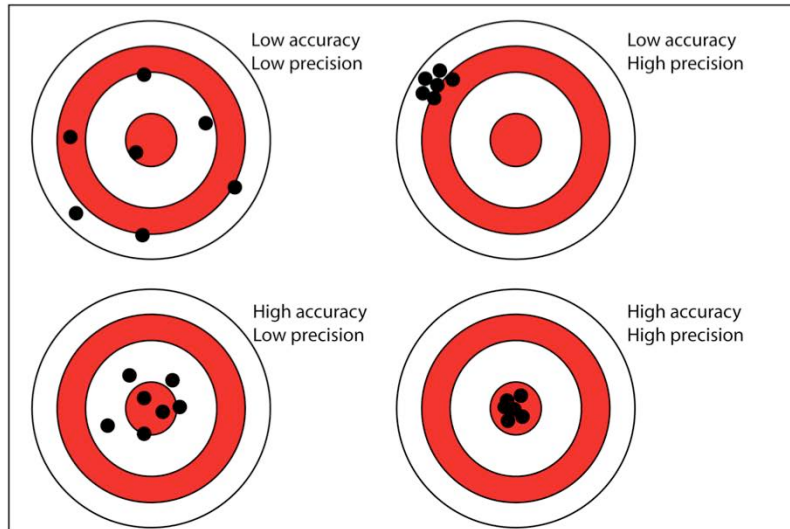
Some national food safety THC guidelines exist, such as in Germany, Belgium or Austria and we are now presenting valid German values for hemp seed oil, other foods and drinks. These values were also unofficially adopted by several other member states, such as Czech Republic.

EIHA is working hard on introduction of Scientifically Sound Guidelines for THC in Food in Europe but this is not the scope of this lecture.

Usually, accredited labs have their levels of detection for THC at 0.2 ppm using either GC/MS or HPLC/MS analytical instruments. Showing the THC result less than Level of Quantification of an accredited lab, is the best due diligence when placing any CBD-enriched product on a consumer market.

So in order to get there, market players should divide their expectations by a factor of ten thousand.

Accuracy and Precision



We are not going to ponder further on to what extent is a measurement of THC on sub-ppm levels accurate and precise. Dr Jace Callaway could throw an hour-long lecture on this topic easily. I am sending best regards to him wherever he is right now.

Medicinal product?		
Orphan Drug Designation (USA)	Investigational New Drug (USA)	Orphan Medicinal Product (EU)
○ Neonatal hypoxic-ischemic encephalopathy (2014) ○ ...and many other	○ Dravet Syndrome (2015)	○ Dravet Syndrome (2014) ○ Perinatal asphyxia (2015) ○ Prevention of graft-versus-host disease (2016)
○ Orphan medicinal products in EU are governed by Regulation EC/141/2000. ○ <i>Cannabidiol</i> is a Nationally Authorised Product (NAP) with a record in EMA's EU Reference Date (EURD) list under Periodic Safety Update Report (PSUR) number PSUSA/00000529/202501 (Germany, Finland...) ○ <i>Cannabidiol</i> <u>is not</u> a medicinal product within the meaning of Council Directive EEC/65/65.		
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Is *Cannabidiol* a medicine or just a helpful chemical substance? The ultimate answer to this open question will be a game changer since there is no place for medicinal products in foods, food supplements, cosmetics or other over-the-counter consumer goods.

Some market players are working hard on evidence-based-medicine business models, many more would prefer playing this game on the open field.

Cannabidiol has been granted the shown investigational or orphan drug statuses. This is indeed a great achievement!

However, up to this moment, *Cannabidiol* has not been classified as a medicinal product by either European Medicines Agency, Food and Drugs Administration or the World Health Organization. Any discussion about use of Cannabis extracts and/or *Cannabidiol* in non-medicinal end-user products in EU must be held with this in mind.

Cosmetics Regulation EC/1223/2009			
INCI Name	CAS No.	Claim	Restriction
CANNABIS AND CANNABIS RESIN; CANNABIS SATIVA, EXTRACT	8063-14-7 89958-21-4		Annex II/306
CANNABIS SATIVA SEED EXTRACT	89958-21-4	EMOLLIENT	None
CANNABIS SATIVA SEED OIL	89958-21-4	EMOLLIENT SKIN CONDITIONING	None
CANNABIS SATIVA SEED OIL PEG-8 ESTERS		EMOLLIENT, EMULSIFYING, SKIN CONDITIONING, SURFACTANT	Annex II/306 R4
CANNABIS SATIVA SEED OIL GLYCERETH-8 ESTERS		EMOLLIENT, EMULSION STABILISING	None
CANNABIS SATIVA SEEDCAKE		ABRASIVE, SKIN CONDITIONING	None
CANNABIS SATIVA SEEDCAKE POWDER	89958-21-4	ABRASIVE	Annex II/306 R4
CANNABIS SATIVA STEM POWDER	89958-21-4	SKIN CONDITIONING	None
CANNABIDIOL	13956-29-1	ANTIOXIDANT, ANTISEBORRHOEIC, SKIN CONDITIONING, SKIN PROTECTING	None
http://bit.ly/1GknHWG			
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This schedule presents a filter for key words *Cannabis* and *Cannabidiol* in CosIng, an unofficial database of cosmetics ingredients in EU.

The Annex II of Regulation 1223/2009 lists restricted raw materials and item 306 stands for Narcotics listed in Tables I and II of the Single Convention on narcotic drugs.

A restriction on use of cannabis, cannabis resin and cannabis extract is understandable since they are classified as Schedule I narcotics.

While restrictions of use of seed oil PEG-8 esters and seedcake powder has no logic at all if use of hemp seed cake itself and seed oil is not restricted.

As we can see, *Cannabidiol* is listed in CosIng with four functional claims: ANTIOXIDANT, ANTISEBORRHOEIC, SKIN CONDITIONING, SKIN PROTECTING

e-liquids

Tobacco Products Directive EU/2014/40

Definitions	Notes
○ <i>Electronic cigarette</i> means a product that can be used for consumption of <u>nicotine-containing</u> vapour ○ <i>Refill container</i> means a receptacle that contains a <u>nicotine-containing</u> liquid	○ E-liquids without nicotine are out of scope of Tobacco Products Directive ○ Can be freely marketed as “<i>chemical mixtures</i>” under REACH regulations (EC/1907/2006 and EU/453/2010) ○ Material Safety Data Sheet (MSDS) is needed to assess toxicity ○ Volatile Emission Test as per ISO 3308 is advised to assure product safety ○ THC critical: < LOQ in final product




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Vaporization is an exciting new way of --- keeping you hooked on nicotine.

Vape pen refills without nicotine are not governed by Tobacco Products Directive. Rather, such formulations should be marketed as “chemical mixtures” under a set of REACH regulations.

As with any other potentially toxic chemical mixtures, especially if they contain fragrances and colorings, manufacturers should hire an authorized person to work out an MSDS. And we also recommend performing a standardized “smoke test” as per ISO 3308.

As long as the final consumer product does not contain THC above level of quantification, use of Cannabidiol or extract is safe.

Foods and Food Supplements

General Food Law Reg. EC/178/2002	Food additives and Food flavourings Reg. EU/1130/2011, EEC/388/88	Food Supplements and Health Claims Reg. EC/46/2002 and EU/432/2012	Novel foods Reg. EC/258/1997
Article 2 “Food” shall not include: <u>(d) medicinal products</u> within the meaning of Council Directives EEC/65/65 and EEC/92/73 (medicines and homeopathic products) <u>(g) narcotic or psychotropic</u> substances within the meaning of the UN Single Convention on Narcotic Drugs, and the UN Convention on Psychotropic Substances.	Union list of food additives including carriers approved for use in food additives, food enzymes, food flavorings, nutrients. Cannabis extracts and Cannabidiol are not approved food additives.	Nutrients and list of permitted health claims: ○ Vitamins ○ Minerals ○ MUFA, PUFA ○ Fibre ○ Protein	Foods and food ingredients which have not been used for human consumption to a significant degree within the Community prior 1996 Concerns mainly Herbal extract and isolated chemical substance.

This schedule presents four areas of food legislation we shall discuss in next few slides: General food law, Food additives and flavoring, Foods Supplements and health claims regulations and Novel foods regulation.

General Food Law Reg. EC/178/2002	
Article 2 "Food" shall not include:	Notes
(d) <i>medicinal product</i> within the meaning of Council Directives EEC/65/65 and EEC/92/73	<i>Cannabidiol</i> and extracts of cannabis are not <i>medicinal products</i> within the meaning of Council Directives EEC/65/65 and EEC/92/73. <i>Orphan medicinal products</i> are governed by Regulation EC/141/2000.
(g) <u>narcotic</u> or <u>psychotropic</u> substances within the meaning of the UN Single Convention on Narcotic Drugs, and the UN Convention on Psychotropic Substances.	<i>Cannabidiol</i> is not scheduled by any UN conventions.
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General food law defines what is and what is not food. Foods are not medicinal products and scheduled substances.

On one of the previous slides we have demonstrated that Cannabidiol is not a medicinal product. It also not listed in any UN schedules. So we would likely assume the use of Cannabidiol on EU food market is OK. But there is a catch to be discussed further.

Food additives and Food flavorings

Reg. EU/1130/2011, EEC/388/88

Annex III: list of "E"s	Note
Union list of food additives including carriers approved for use in food additives, food enzymes, food flavourings, nutrients	○ Extracts and Tinctures of Cannabis and Cannabidiol are not recognized food additives. ○ Company "dupetit Natural Products GmbH" introduced in 1996 Cannabía® first hemp beer (Cannabis beer) of mankind using hemp as a flavor bearing ingredient. ○ There are more products on the market using either "Cannabis sativa" or "hemp essential oil" as a flavoring agent. ○ Use of hemp flavoring agetns derived from cannabis, leaves or seeds, is not restricted as long as these do not add any THC into a final product.



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There are various hemp flavored food products on EU market already using essential oils, hemp or its extracts to add a distinctive organoleptic experience.

Food Supplements and Health Claims

Reg. EC/46/2002 and EU/432/2012

Food supplements are:	Notes
...foodstuffs the purpose of which is to supplement the normal diet	Food supplements are also governed by General Food Law and same restrictions apply, such as "NO THC" rule.
...concentrated sources of nutrients or other substances with a nutritional or physiological effect	Vitamins, Minerals, PUFA (LA, ALA), Fibre, Protein, Herbal extracts
...marketed in dose form	Capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles
The labeling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties	Any CBD-infused edible products <u>must not</u> advocate any of the known medicinal effects of Cannabidiol. There are only 222 nutrient-specific health claims approved in EU: http://bit.ly/25bSBhM
Mandatory notification and/or registration before placing on the market in each member state.	





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Food supplements are foods to supplement normal diet. Very similar safety rules apply as to regular foodstuffs.

Food supplements are concentrated sources of nutrients, such as vitamins and minerals, or other substances with a nutritional or physiological effect, such as herbal extracts. They are marketed in dose forms. The labeling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

Also, any health claims can only be selected from 222 approved nutrient-specific claims.

Food operators must be aware of the mandatory notification or registration before placing food supplements on the market in each individual member state.

A major precedent!

Test report

Client name: Propaganda Production s.r.o.
Client address: 29. augusta 12
 048041 Rožnava
e-Mail: info@hempseedoil.eu
Laboratory: ÖHMI Analytik GmbH
 Berliner Chaussee 66
 39114 Magdeburg
Producer: CANNABIS Pharma s.r.o.
 Masarykova 54
 415 01 Teplice
 Czech Republic
 ☎ 0391/8507-131; Fax - 137
Sampling: by customer
Date of receipt: 29.06.2015/ 10:50 Uhr / 18,5°C
Storage: at room temperature
Testing period: 26.06.2015 – 06.07.2015
Sample description: CBDex® Parkin = A 15.1564-2-2/1

- Product line of CANNABIS Pharma s.r.o. from Czechia has recently got a “food supplement status” approval of State Health Institute.
- Ministry of Agriculture has been duly notified prior product launch.
- This innovative line of vitamin supplements is enriched with “*Cannabis Sativa Flower Extract*”.
- Total THC concentration is less 0.1 ppm (<0.00001%), i.e. below Level of Detection of accredited labs.

Sample-no:			CBDex® Parkin
OHMI-test-report-no:			A 15.1564-2-2/1
Item	unit	method	A 15.1564-2-2/1
THC total (sum THC, THCA, calc. as THC)	mg/kg	SAA A 004/ LC-MS/MS	< 0,10

A major precedent happened in Czech Republic in 2015 when State Health Institute approved use of Cannabis Sativa Flower Extract in food supplements provided the final product does not contain THC above 0.15 ppm.



Many CBD-infused products on the market mimic food supplements by retail format when usually sold in drop-dispensing bottles. However, THC content, product labelling and declarations are very often outside of the food industry rules.

One horrific example is shown here where the company even mistakenly says their product contains more than 0.2 per cent of THC.

Novel foods Regulation EC/258/1997		
Novel foods Catalogue listing for <i>Cannabis sativa</i>: "Without prejudice to other legal requirements concerning the consumption of hemp (<i>Cannabis sativa</i>) and hemp products, Regulation (EC) No 258/97 is not applicable to <u>most</u> foods and food ingredients from this plant."	Czech Republic – State Health Institute Letter to CANNABIS Pharma, s.r.o., ref. 1846/15 EX 150626 dated 12/08/2015 ○ "Based on the submitted documentation, the main ingredient of the preparations is the extract of hemp (<i>Cannabis sativa</i>)." ○ "<i>Cannabis sativa</i> belongs to the category of traditional plant constituents of food supplements." ○ "...it will be necessary to assess [pure cannabidiol] as a potential novel food ingredient in accordance with Regulation EC/258/1997".	Austria – AGES http://www.ages.at/en/service/ask-us-we-answer/hanf/ ○ "A quite new trend are cannabinoid-containing oils/extracts, which are marketed as food supplements." ○ "The Cannabidiol concentrations of such extracts are much higher as compared to conventional food products made from hemp." ○ "These drops and oils are therefore classified as novel foods in accordance with Regulation EC/258/1997./
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If we said there is a catch, we were referring to the novel food legislation governing food sources not used in EU before year 1996. Examples are Stevia or Chia seeds. An approval process on the European Commission level is needed before such foods may be placed on the market.

Novel food catalogue listing for *Cannabis sativa* clearly says the novel food Regulation is not applicable to most foods and food ingredients from this plant. Sounds like a great news. But please note the word most in the previous sentence.

Market regulators may have quite contradictory opinions! While Czech authorities have approved use of cannabis extract, Austrian AGES says "cannabinoid-containing" extracts are novel foods. Clearly there is a job to be done on EIHA level and our position paper is going to be drafted soon.

As to Cannabidiol as a chemical substance, even Czech authorities agree that it is a novel food ingredient.

RASFF - Rapid Alert System for Food and Feed - THC alerts 2014-2016


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[Next 100](#)
[Last](#)

	Classification	Date of case	Reference	Notifying country	Subject	Product Category	Type	Risk decision	
1.	information for follow-up	13/02/2015	2015.0166	Cyprus	unauthorised substance tetrahydrocannabinol (THC) (>0.2 %) in alcoholic drink with plants from the Czech Republic	alcoholic beverages	food	undecided	Details
2.	information for follow-up	05/12/2014	2014.1665	Czech Republic	unauthorised substance tetrahydrocannabinol (THC) (4.97 mg/kg - ppm) in food supplement from Poland, with raw material from China	dietetic foods, food supplements, fortified foods	food	not serious	Details
3.	information for follow-up	05/12/2014	2014.1663	Czech Republic	unauthorised substance tetrahydrocannabinol (THC) (0.101 mg/kg - ppm) in food supplement from Poland, with raw material from China, via Hong Kong	dietetic foods, food supplements, fortified foods	food	not serious	Details
4.	alert	28/08/2014	2014.1205	Czech Republic	unauthorised substance tetrahydrocannabinol (THC) (0.244 mg/kg - ppm) in Tribulus terrestris extract from Romania, with raw material from China	dietetic foods, food supplements, fortified foods	food	serious	Details
5.	alert	13/08/2014	2014.1137	Czech Republic	unauthorised substance tetrahydrocannabinol (THC) (2.53 mg/kg - ppm) in food supplement from Hungary	dietetic foods, food supplements, fortified foods	food	undecided	Details
6.	alert	06/08/2014	2014.1104	Czech Republic	unauthorised substances androstenedione (0.417; 1.34 mg/kg - ppm) and tetrahydrocannabinol (THC) (14.8; 31.4 mg/kg - ppm) in food supplement from Germany	dietetic foods, food supplements, fortified foods	food	serious	Details


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We would like to share with you a screenshot from Rapid Alert System for Food and Feed filtered to show THC incidents in foods on EU market for the last two and a half years. I believe it is no market player's wish for his product to appear on this list.

Do CBD edibles comply with proposed ADI?

10 ml Solution / After full decarboxylation	Diluted Extract 20% CBD equivalent		Diluted Cannabidiol 99% CBD equivalent	
	[%]	[mg]	[%]	[mg]
Net Weight, out of which:	100.00%	9200.00	100.00%	9200.00
Vegetable oil	86.41%	7950.00	97.26%	8944.89
CBD-rich base containing:	13.59%	1250.00	2.74%	255.11
CBD+CBDA equivalent	20.00%	250.00	99.00%	250.00
THC+THCA equivalent	0.15%	1.875	0.02%	0.051
Daily intake CBD	x	20.00	x	20.00
Daily intake THC	x	0.150	x	0.004
ADI BgVV/BfR (2000) = 0.125 mg	!		✓	
ADI EFSA (2015) = 0.083 mg	X		✓	
ADI EIHA (2015) = 0.240 mg	✓		✓	

Before we recap, let's do some complimentary math here.

As Luis Sarmiento has discussed earlier, there exist some calculated Acceptable Daily Intakes provided by, and advocated by several institutions, including EIHA.

This schedule shows potential total THC intakes from a regular 250mg CBD product made of a) 20 per cent CBD extract and b) 99 per cent Cannabidiol if 20 milligrams of CBD equivalent are to be ingested.

The intake of THC from diluted extracts may be higher at certain doses and THC concentrations than advised by national or international authorities. But may well be OK if EIHA's opinion is accepted by EU officials.

Total THC intake from diluted *Cannabidiol* isolates is indeed marginal.

Brief recap				
Ingredient	Cosmetics	e-Liquids	Foods	Food supplements
<i>Cannabidiol</i>	✓	✓	✗ Novel food	✗ Novel food
<i>Cannabis Extract</i>	✗ Annex II/306	✓ THC critical / Toxicity	✗ THC critical / Novel food?	✓ Czech precedent THC critical


13th EIHA conference, Wesseling

This schedule summarizes our understanding of use of Cannabidiol and *cannabis* extracts on Business-To-Consumer market from perspective of EU regulations.

There must be some kind
of way out of here...

I wish my master
could... It's HACCP
ready already!

Hear me saaay:
"Five emgeees
a daaay!"



The image features a dog on the left and a kitten on the right. Between them are two images: a pile of white powder and a glass containing a yellow liquid. The dog has a thought bubble above it, and the kitten has a speech bubble above it. The entire scene is set against a white background with a green header and footer.

CBDepot.eu
Legal and quality CBD supply

13th EIHA conference, Wesseling

Feeling depressed? I believe there is plenty of room for creative marketing in companion pet food segment.

Thank you for your attention.

Thank you for your attention.

