

E.U.: “Hempseed oil is exempt but one of the naturally-occurring chemicals in it is not”

by Richard Rose

- Hemp Flower Products such as Hempseed and the extract Hempseed oil are authorized Novel Foods under Catalogue v1.1, exempt from registration as new 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.
- Naturally incidental to that resin are cannabinoids, inside the resin.
- The predominant cannabinoid in that resin in Hemp is Cannabidiolic Acid (CBDa), second-most is Tetrahydrocannabinolic Acid (THCa). Cannabidiol content could legally be as high as 6% in Hempseed oil.
- The parts making up the whole are inseparable from the whole; if the whole is exempt then so are the parts. Since Hempseed and the extract Hempseed oil are exempt from registration as new Novel Foods, so should be the resin and thus Cannabidiol.
- The recent E.U. *Novel Food Catalogue* update was incorrect, Hemp Flower Products indeed have demonstrated long use, including Cannabidiol.
- If any one of the over 500 chemicals in Hemp Flower Products is extracted or concentrated, such as the oil in the seed or the essential oil in the leaves, it is substantially equivalent to the underlying authorized Novel Food.
- If Cannabidiol is not “added,” a concentration of Cannabidiol from an exempt (<0,2% THC) source which is also an exempt Novel Food is an authorized Novel Food.
- Many other foods are extracts, such as Hempseed oil and essential oil of the flowers, a popular food flavorant and perfume. Carbon Dioxide Supercritical Fluid Extraction is often used to extract botanicals and foods, and by itself use should not render a Cannabidiol extract a new Novel Food needing registration.
- The E.U. update to the *Novel Food Catalogue* regarding Cannabidiol applies to more than just *Cannabis sativa* L. Non-*Cannabis* Cannabinoids should not be regulated like *Cannabis*.

Definition

Cannabis sativa L. is an authorized Novel Food in the E.U. Novel Food Catalogue v1.1. Common names include Kaņepe (sējas) (LV), Hampa (SE), Hemp (EN), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), harilik kanep (ET), konopí seté (CZ), Cáñamo (ES), indiai kender (HU), ινδική κάνναβις (EL), navadna ali industrijska konoplja (SL), and hamppu (FI). Here I will use “Hemp,” and “Hemp Flower Products” which includes primary products in Hemp flowers such as whole seed, shelled seed, seed oil, defatted meal, seed shells, pollen, terpenes,



essential oil, flowers, leaves, and compounds within them such as trichomes, cannabinoids including Cannabidiol, flavonoids, Cannabisin, enzymes, and others.

In the European Union (E.U.), the cultivation of Hemp varieties of *Cannabis* is permitted provided they are registered in the E.U.'s Common Catalogue of Varieties of Agricultural Plant Species, and the tetrahydrocannabinol (THC) content does not exceed 0,2% (w/w, or 2.000 ppm).

Products derived from the *Cannabis sativa* plant or plant parts such as Hempseed, the extract Hempseed oil, Hempseed flour, and defatted Hempseed meal have a history of consumption in the E.U. prior to the Novel Food cut-off date of May 1997, and therefore are considered authorized Novel Foods, exempt from registration as new Novel Foods.

Trace amounts of THC found upon analysis are due to contamination of the seed by adherent resin or other plant residues. From Small (2017): "Birds are well known to occasionally become drunk by feeding on fermented berries, and there may be a parallel situation with respect to hempseeds. While the seeds (achenes) of *Cannabis sativa* do not contain intoxicating constituents, resin from the surrounding bracts can coat the seeds, and thus marijuana varieties could produce seeds with appreciable intoxicant ability. *Cannabis* seeds with adherent resin have been shown to be capable of making birds giddy." There is 20 to 30 times or more Cannabidiol than THC, as CBD is the predominant cannabinoid in Hemp. "Seed oil prepared from seeds coated with resin may have small levels of THC, and the same is true for foods made with the seeds. It has been suggested that trace amounts of cannabinoids (and also terpenes) could have health benefits." See Small (2015).

Hempseed Oil Often Contains THC, Thus Much More Cannabidiol

The study Delta 9-Tetrahydrocannabinol Content of Commercially Available Hemp Products revealed 15 of 28 (54%) of the Hempseed oils tested exceeded Health Canada's 10 ppm maximum THC, with one as high as 117 ppm. A later study found all 8 of the oils tested exceeded Health Canada's 10 ppm maximum. THC and CBD have been in Hempseed oil and foods for millennia. In the U.S., the max THC in Hemp products is 3.000 ppm (0,3%).

Where does the THC come from? Resin in the hemp flowers sticks to the outside of the seed shell (called "adherent"), and it then goes into the oil when the seed is pressed. There could legally be as much as 2 kilograms of THC in a hectare of low-THC (<0,2%) Hemp. At a 30:1 ratio of CBD:THC at a 0,2% maximum THC, as Table 2 shows is possible, the Cannabidiol content in Hempseed oil could be over 60.000 ppm (6%).

In Consumption and quantitation of delta9-tetrahydrocannabinol in commercially available hemp seed oil products is "These Hemp oil products contained THC concentrations of 36.0, 36.4, 117.5, 79.5, 48.6, 45.7, 21.0, and 11.5 mg/g, respectively."

In Urinary cannabinoid detection times after controlled oral administration of delta9-tetrahydrocannabinol to humans is "Results: At the federally mandated immunoassay cutoff (50 microg/L), mean detection rates were <0,2% during ingestion of the two low doses typical of current hemp oil THC concentrations. The two high doses produced mean detection rates of 23-46% with intermittent positive tests up to 118 h. Maximum metabolite concentrations were 5.4-38.2 microg/L for the low doses and 19.0-436 microg/L for the high doses."



In Hemp oil ingestion causes positive urine tests for delta 9-tetrahydrocannabinol carboxylic acid is “Abstract: A Hemp oil product (Hemp Liquid Gold) was purchased from a specialty food store. Fifteen milliliters was consumed by seven adult volunteers. Urine samples were taken from the subjects before ingestion and at 8, 24, and 48 h after the dose was taken. A total of 18 post-ingestion samples were submitted. Fourteen of the samples screened above the 20-ng cutoff, seven were above the 50-ng cutoff, and two screened greater than the 100-ng cutoff.”

Evaluating the impact of hemp food consumption on workplace drug tests states “At a daily THC dose of 0.6 mg, one specimen screened positive. A THC intake of 0.6 mg/day is equivalent to the consumption of approximately 125 mL of hemp oil containing 5 microg/g of THC or 300 g of hulled seeds at 2 microg/g.”

Hemp is Naturally High in Cannabidiol (CBD)

In Variations of .9-THC Content in Single Plants of Hemp Varieties, CBD content in Hemp is much higher than THC content is “As shown in fig. 2, virtually all single-plant samples from modern hemp varieties are found on a line representing a **THC/CBD-ratio of about 1/20 (non-drug type).**” [My emphasis]

Land race Cannabis is 1:1 CBD:THC. And the U.N.’s Office on Drugs and Crime states: “Industrial cannabis [Hemp] is characterized by low THC content and high cannabidiol (CBD) content. In most European countries the current upper legal limit for cultivation is 0.2 per cent THC (Canada: 0.3 per cent). **The ratio of CBD to THC is greater than one.**” [My emphases]

Table 2. Average content of THC and CBD in hemp varieties of different origin. The data are based on the analysis of 1000 samples of hemp varieties, including landrace, industrial and drug varieties. The data are presented in order of increasing THC content, and subdivided in order of increasing CBD content.

Accession	Origin	THC (%)	CBD (%)
8001	Landrace (Hungary)	0.02	1.00
8002	Landrace (Hungary)	0.02	1.00
8003	Landrace (Hungary)	0.02	1.00
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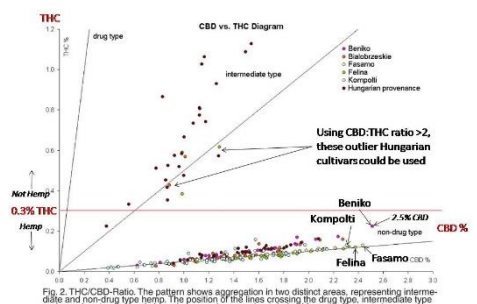


Fig. 2. THC/CBD-Ratio. The pattern shows aggregation in two distinct areas, representing intermediate and non-drug type hemp. The position of the lines crossing the drug type, intermediate type and non-drug type areas is based on experience and not derived from the data set shown.

“Industrial cannabis [Hemp] is characterized by low THC content and high cannabidiol (CBD) content. In most European countries the current upper legal limit for cultivation is 0.2 per cent THC (Canada: 0.3 per cent). **The ratio of CBD to THC is greater than one.**” [My emphases]

In Table 2 [left] from Characterisation of Cannabis accessions with regard to cannabinoid content in relation to other plant characters, we see Hemp is typically much higher in Cannabidiol than THC.

Hemp Extracts

The E.U. Novel Food Catalogue was recently updated to state “extracts of *Cannabis sativa* L. and derived products containing cannabinoids, including Cannabidiol, are considered novel foods as a history of consumption has not been demonstrated.” **However**, since a history of consumption has already been demonstrated for hempseed oil, and it is well-known that hempseed oil is known to contain cannabinoids from the resin adhering to the outside of the seed, and it is well-known that Cannabidiol is the predominant cannabinoid in hemp varieties of *Cannabis sativa* L., it logically follows that a history of Cannabidiol consumption has already been demonstrated. The E.U. has, long before May 1997, allowed the free sale of hempseed oil which was well-known to contain THC and CBD. Its silence, despite numerous studies, indicates assent.

“Adding” Cannabidiol

Further, the E.U. Novel Food Catalogue update adds: “This applies to both extracts themselves and any products to which they are **added as an ingredient** (such as hemp seed oil).” [Emphasis mine.] Therefore, if Cannabidiol is not “added as an ingredient” to a product, it is exempt. One can get Cannabidiol into a product without “adding CBD to a product.” This can be achieved a few ways:

adding Hempseed oil naturally high in cannabinoids to the product, or powdered Hemp flowers (such as one would use for tea). The Hempseed oil industry has been able for years to sell Hempseed oil sometimes quite high in THC simply by never disclosing the THC content, and it was “not added.” No Regulator in any member state objected.

Non-Cannabis Cannabinoids

The update continued: “This also applies to extracts of other plants containing cannabinoids.”

However, cannabinoids and cannabinomimetics are known to occur in several plant species besides *Cannabis*. See CB Receptor Ligands from Plants, detailing the plant species in which cannabinoids are known to occur besides *Cannabis*, including coneflower (*Echinacea*), oxeye (*Heliopsis helianthoides*), electric daisy (*Acmella oleracea*), *Helichrysum umbraculigerum*, liverwort (*Radula marginata*), black pepper (*Piper nigrum*), chocolate (*Theobroma cacao*) plants, as well as *Echinacea purpurea*, *Echinacea angustifolia*, *Acmella oleracea*, *Helichrysum umbraculigerum*, and *Radula marginata*, with alkamides from *Echinacea* species being the best-known.

TLC and HPLC Analysis of Alkamides in Echinacea Drugs identifies at least 25 different alkylamides, some of which shown affinity to the CB2-receptor, like a cannabinoid. Same with Alkylamides from Echinacea Are a New Class of Cannabinomimetics: Cannabinoid Type 2 Receptor-Dependent and -Independent Immunomodulatory Effects.

Alkamide Levels in Echinacea purpurea: A Rapid Analytical Method Revealing Differences among Roots, Rhizomes, Stems, Leaves and Flowers noted that while cannabinoids are found throughout the plant, they are most concentrated in the roots and flowers in some *Echinacea* species. As did Analysis of alkamides in roots and achenes of Echinacea purpurea by liquid chromatography–electrospray mass spectrometry.

See also Kavalactones and the endocannabinoid system: The plant-derived yangonin is a novel CB1 receptor ligand, and Tea catechins' affinity for human cannabinoid receptors, Identifying a common dietary terpene--beta-caryophyllene, a component from the essential oil of cannabis and other medicinal plants--as a selective agonist of peripheral CB2-receptors in living organisms, and Truffles contain endocannabinoid metabolic enzymes and anandamide.

Summary

- Hemp Flower Products such as Hempseed and Hempseed oil are authorized Novel Foods under Catalogue v1.1, exempt from registration as new Novel foods due to demonstrated consumption in member states prior to May 1997. All Hemp Flower Products should be considered exempt.
- Naturally incidental to the long history of consumption of the Hempseed is a sticky resin, on the outside of the seed shell.
- Naturally incidental to that resin are cannabinoids, inside the resin.
- The predominant cannabinoid in that resin in Hemp is Cannabidiolic Acid (CBDA), second-most is Tetrahydrocannabinolic Acid (THCA). Cannabidiol content can legally be as high as 6%, in Hempseed oil.



- The parts making up the whole are inseparable from the whole; if the whole is exempt then so are the parts. Since Hempseed and the extract Hempseed oil are exempt from registration as new Novel Foods, so should be the resin and thus Cannabidiol.
- The recent E.U. *Novel Food Catalogue* update was incorrect, Hemp Flower Products indeed have demonstrated long use, including Cannabidiol.
- If any one of the over 500 chemicals in Hemp Flower Products is extracted or concentrated, such as the oil in the seed or the essential oil in the leaves, it is substantially equivalent to the underlying authorized Novel Food.
- If Cannabidiol is not “added,” a concentration of Cannabidiol from an exempt (<0,2% THC) source which is also an exempt Novel Food such as Hempseed, is an authorized Novel Food.
- Many other foods are extracts, such as Hempseed oil and essential oil of the terpenes. Carbon Dioxide Supercritical Fluid Extraction is often used to extract botanicals and foods, and by itself use should not render a Cannabidiol extract a new Novel Food needing registration. It is merely concentrating somewhat one naturally-occurring compound from the authorized Novel Food, not a new Novel Food.
- The E.U. update to the *Novel Food Catalogue* regarding Cannabidiol applies to more than just *Cannabis sativa* L. Echinacea, flax, oranges, oxeeye, electric daisy, Helichrysum, liverwort, black pepper, cacao, all can be used to produce Cannabidiol and are authorized Novel Foods. Non-*Cannabis* Cannabinoids should not be regulated like *Cannabis*.

As long as the product...

- ✓ has no **added** Cannabidiol isolate or synthetics, *and*
- ✓ is made from hemp which contains less than 2.000 ppm THC, *and*
- ✓ is from an approved Hemp cultivar or non-*Cannabis* source...

...then it should be considered an authorized product, not a new Novel Food needing registration.

Since undisclosed THC has been in Hempseed oil for millennia of use and was allowed without objection by E.U. member states, so should non-intoxicating, safe Cannabidiol be allowed. Otherwise, the policy is “hempseed oil is exempt but only one of the naturally-occurring chemicals in it is not”.

Richard Rose
 The Richard Rose Report
 1 March 2019
 v2.0



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