

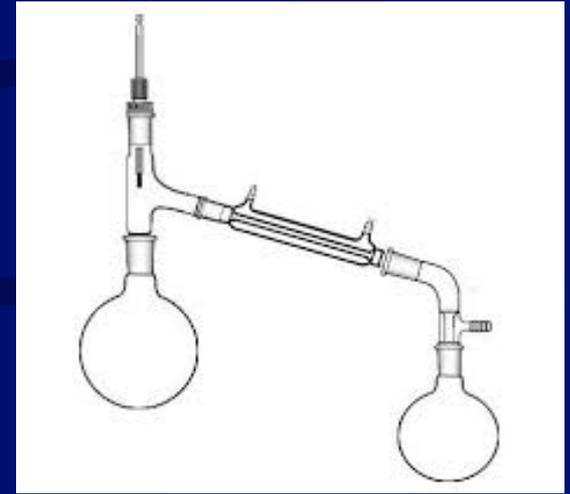
# **European Regulations For Cannabidiol (CBD) In Different Sectors**

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## CBD

**Where does it  
come from ?**



**Hemp (THC <0.2%)**

**Chemical synthesis**



**Pure CBD (>95%)**

**= a chemically defined constituent**

**No difference is made whether it is extracted  
from hemp or chemically synthesized**

**However, THC as impurity can be an issue**

(EMA/CPMP/QWP/2819/00 Rev.2, Guideline dated 31 March 2011)

CBD exists as 2 enantiomers;

**Cannabis produces only the (-)-trans cannabidiol**

CBD derived from *Cannabis sativa* is permanently linked to the question about its origin (hemp vs marijuana, flowers vs leaves) and to the psychotropic D9-tetrahydrocannabinol (THC) as potential impurity

“*Cannabis*” means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.

**Art. 1, Definition; UN Convention on Narcotic Drugs 1961**

as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs 1961

# Current Restrictions

- The regulatory chaos on (phyto-) cannabinoids has been caused by politics; it was - and is – not supported by science!
- The chemical structure of cannabidiol was elucidated in 1963, THC was first isolated in 1964 (by Raphael Mechoulam);

**Neither THC nor CBD were known at that time of the UN Convention, 1961**

# CBD - Basic Aspects

- Cannabidiol (CBD) is found in some but not all Cannabis sativa strains, and in variable amounts.
- Pure CBD (>95%) is not regulated as it is not psychotropic.
- Extracts made from Cannabis sativa flowering or fruiting tops (including hemp) are considered illegal as they concentrate also D9-tetrahydrocannabinol (THC).
- Products are considered legal as long as no THC is present.
- **The use of products derived from cannabis such as extracts suffers therefore from the lack of unanimously accepted maximum levels of (residual) THC**

## **The cannabinoid CBD seems to be more widely distributed than originally thought**

A substance with identical properties in UV spectra and retention time in UPLC analysis, confirmed by mass spectra analysis, has been detected in flax. This will likely influence regulatory attitudes with regard to CBD.

**Styrczewska M, Kulma A, Ratajczak K, Amarowicz R, Szopa J: Cannabinoid-like anti-inflammatory compounds from flax fiber. *Cellular & Molecular Biology Letters* 2012, March 29;17:479-499.**

# Options

**Hemp-Extract  
(multicomponent)**

**CBD  
(pure)**

Mostly from dried flowers  
various **extracts**  
THC-content critical

**From hemp  
or synthesis**

**Cosmetics /  
Body Care**

**Nutrition**  
CBD is NOT  
Active Ingredient

**„Chemical“ Use**  
Antioxidant, Preservative  
Cosmetics, Food Additive

**Medical Use**  
Human therapy  
(magisterial prescr.)  
CBD=Active Ingredient

**In the US, hemp seed oil is not included in the GRAS list**

# CBD in Cosmetic Products

- **Conditions for use:**
  - Production must be according to **GMP**
  - Cosmetic products must be **centrally registered** (Cosmetic Products Notification Portal)
  - Some products are **excluded or restricted** (e.g., containing one of the substances listed in Annex II & III (e.g., boric acid & derivatives))
- The list of cosmetic ingredients (“CosIng”, Art. 33 of Reg 1223/2009) does not constitute a list of substances authorised for use in cosmetic products.
- CBD can be used; it is not mentioned in any of the resp. regulatory documents
- However, extracts made from Cannabis sativa (including hemp) are considered illegal as long as they contain also D9-tetrahydrocannabinol (THC).

**Reg 655/2013, Reg 1223/2009**

# Cannabis sativa Products

(European Cosmetic Ingredient Database, CosIng)

Product	Functions
Cannabis sativa seed extract	Emollient
Cannabis sativa seed oil	Emollient, skin conditioning
Cannabis sativa seed oil Glycereth-8 esters	Emollient, emulsion stabilising
Cannabis sativa stem powder	Skin conditioning

<http://ec.europa.eu/consumers/cosmetics/cosing/>

# Excluded Cannabis sativa Cosmetic Ingredients

Product	Functions
Cannabis sativa extract, cannabis resin (II/306)	Prohibited (annex II)
Cannabis sativa seed cake powder (II/306 R4)	Abrasive
Cannabis sativa seed oil PEG-8 esters (II/306 R4)	Emollient, emulsifying, skin conditioning, surfactant

Cannabis sativa, cannabis resin, cannabis extracts and seedcake powder are considered as narcotic products by the UN Convention.

Generally, cosmetics from hemp must comply with standards for edibles

<http://ec.europa.eu/consumers/cosmetics/cosing/>

# CBD in Food Additives / Dietary Supplements

- **Conditions for use:** (Regulation 1333/2008)
  - **Approval**; only food additives included in the Community List ... may be placed on the market (Art.4)
  - a food additive (FA) must have advantages and **benefits for the consumer** ... does not pose a safety concern ... must have a reasonable technological need that cannot be achieved by other economically and technologically practicable means (Art.6)
  - the level of use shall be set at the **lowest level necessary** to achieve the desired effect (Art.11)
- Substances should not be considered as food additives when they are used for the purpose of imparting **flavour** and/or **taste** or for **nutritional purposes**, such as salt replacers, vitamins and minerals.
- Food derived from hemp such as hemp seed oil can be used as long as the (varying) limits for THC are not exceeded.

# CBD in Food, Supplements and Additives

CBD could have a role in supplements and additives

**Food supplements** are concentrated sources of nutrients or other substances with a nutritional or physiological effect, whose purpose is to supplement the normal diet.

<http://www.efsa.europa.eu/en/topics/topic/supplements.htm>

**Food additives** must be authorised; CBD (and even less Cannabis extract) is not listed in the „*Union List of Food Additives*“; therefore CBD is currently not approved for use.

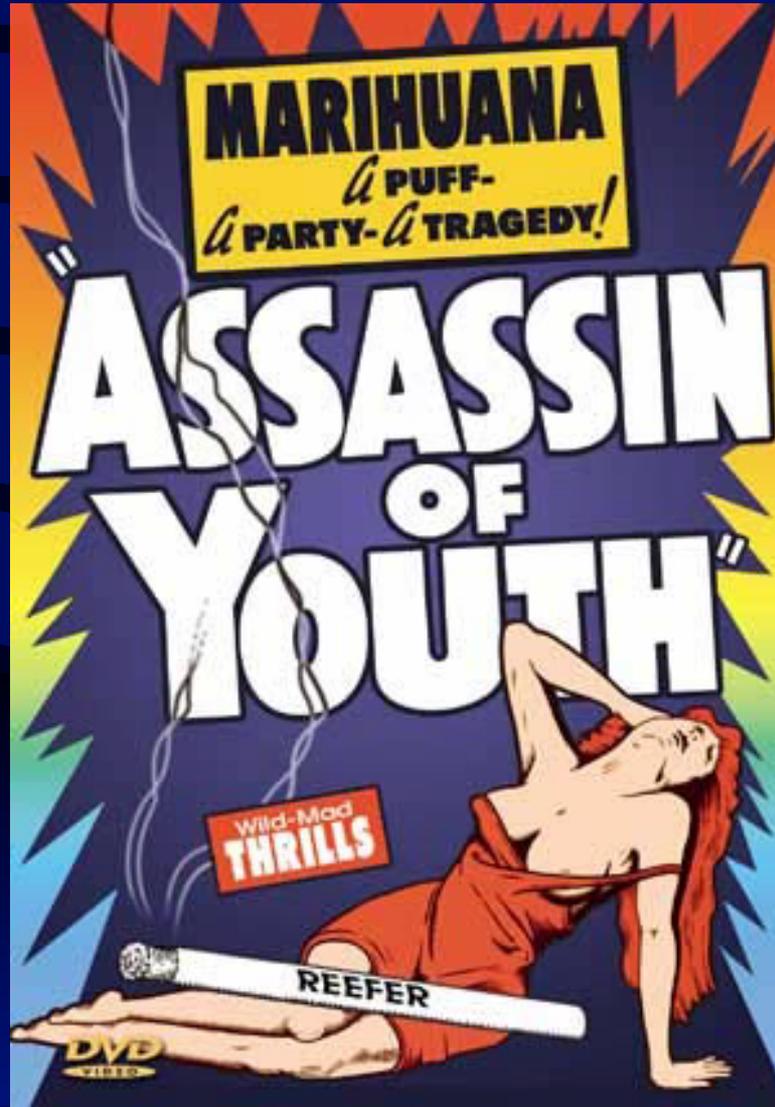
**Reg 1130/2011 on food additives**

# CBD in Medicinal Products

- **CBD is used as (i) (refined) extract, as (ii) purified herbal CBD and as (iii) synthetic CBD**
- **Conditions for use:**
  - Production must be according to **GMP**
  - Use in clinical trials must be **centrally registered** (EudraCT)
  - Magisterial use as prescription product requests that CBD is listed in the resp. (national or European) **pharmacopoeia**.
- On 15 October 2014, orphan designation (EU/3/14/1339) was granted by the European Commission to GW Pharma Ltd, United Kingdom, for CBD for the treatment of Dravet syndrome.
- Currently, EudraCT lists 27 clinical trials (search date 18.2.2015)

<https://www.clinicaltrialsregister.eu/ctr-search/search?query=cannabidiol>

The greatest obstacle for the use of CBD is the general attitude that everything coming from *Cannabis sativa* is a piece of devilry



# Conclusion

- **Cosmetics:**
  - **CBD can be used** as long as there is no THC as by-product;
  - Production must be according to GMP
  - Notification to the *Cosmetic Products Notification Portal*
- **Food Additives:**
  - **CBD cannot be used** as long as it is not included in the „*Union List of Food Additives*“;
  - Demonstration of a *technological need* as well as of *advantages and benefits for the consumer* are required.
- **Medicine:**
  - **CBD is already used** in clinical trials;
  - A „magisterial use“ would request the inclusion of CBD in a pharmacopoeia

**Thank you**