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Cannabidiol as Novel Food in EU

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Trusted science for safe food

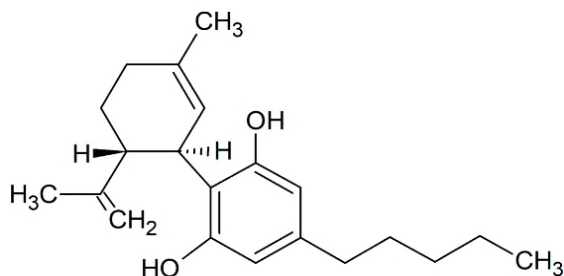


Outline of the presentation

- What is Cannabidiol
- Regulatory status of CBD
- EFSA assessment
- Conclusions

What is cannabidiol

Cannabidiol



- **Cannabidiol** (CBD) is a chemical substance present in *Cannabis sativa* plant.
- Use of CBD is attracting the attention of the food business operators, due to the assumed benefits not associated with the psychotropic effects.

Regulatory status of Cannabidiol

CBD – Regulatory status

- Hemp and CBD products is reported to be one of the fastest growing market
- January 2019 the WHO issued specific recommendations to the UN Commission on Narcotic Drugs (CND) regarding the review of cannabis and cannabis-related substances.
“Preparations containing predominantly cannabidiol and not more than 0.2 percent of THC are not under international control.”
- The Regulatory status as food ingredient and food supplement is different in different countries in the World

- In Europe....



- The only authorised CBD product is **Epidyolex**.
- Epidyolex has been approved by **European Medicines Agency** (EMA)
- The active substance is CBD from the milled botanical raw material (*Cannabis sativa* L.).
- Epidyolex is an adjunctive therapy for seizures associated with Lennox Gastaut syndrome (LGS) or Dravet syndrome (intractable childhood epilepsy) for patients 2 years of age and older.

- EU **Court of Justice** ruled in November 2020:
 - CBD cannot be regarded as a “narcotic drug.”
 - According to the current state of scientific knowledge, unlike THC, the CBD at issue does not seem to have any psychotropic effect
- “Cannabidiol should not be considered as a drug within the meaning of the United Nation Convention Schedule IV of the 1961 Single Convention on Narcotic Drugs. This means that cannabinoid can be **qualified as food.**”
- Cannabidiol is qualified as **Novel Food**

Cannabidiol as Novel Food

Novel Food Catalogue

- Cultivation of *Cannabis sativa* L. is permitted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and THC content does not exceed 0.2 % (w/w)
- Extracts of *Cannabis sativa* L. and derived products containing cannabinoids are considered novel foods
- Synthetically obtained cannabinoids are considered as novel food

CBD under EFSA RISK ASSESSMENT



CBD Dossiers – What is on our plate



At EC level:

- More than **150** dossiers



Under suitability at EFSA:

- **15** CBD (Extracted)



Under RA at EFSA:

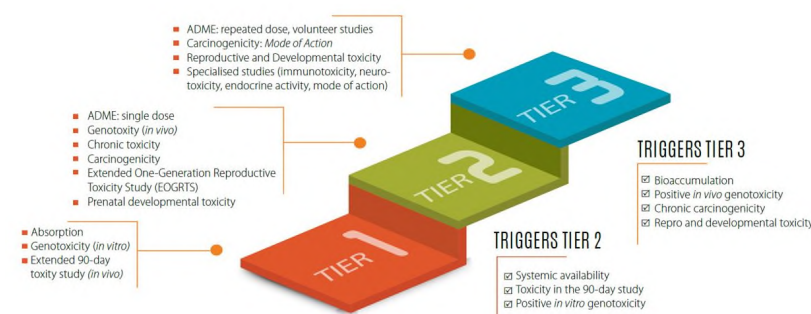
- **5** CBD (Synthetic)



EFSA Risk Assessment

- EFSA assessment will perform an **independent RA**:
 - Assessment is **NOT based on risk-benefit**
 - EFSA target **general population**, not patients
 - **Different production** process
- Evaluation of CBD will follow the approach from **EFSA NDA Guidance for NF**

- **Tiered toxicity testing** approach as the default approach. It integrates the core areas of:
 - Absorption, Distribution, Metabolism and Excretion
 - Genotoxicity,
 - Repeated dose toxicity testing, and
 - Reproductive and developmental toxicity.
- Additional studies may be needed:
 - Immunotoxicity,
 - Hypersensitivity and food intolerance,
 - Neurotoxicity,
 - Endocrine activity, and
 - Mechanisms and modes of action.



Known gaps in CBD assessment

- Liver toxicity
- ADME issues:
 - accumulation of CBD in long term exposure
 - Major metabolites identified in human
 - drug-drug interaction
- Neurotoxicity and Psychiatric/psychologic effect
- Hormonal levels
- Fertility and Reproductive toxicity

Conclusions

- The only authorised CBD product in Europe is Epidyolex
- CBD is considered in Europe as Novel Food and the Risk assessment of individual dossiers is still ongoing.
- During the risk assessment recognised data gaps will be taken into consideration in the assessment

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