Document 23

AGES
Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH



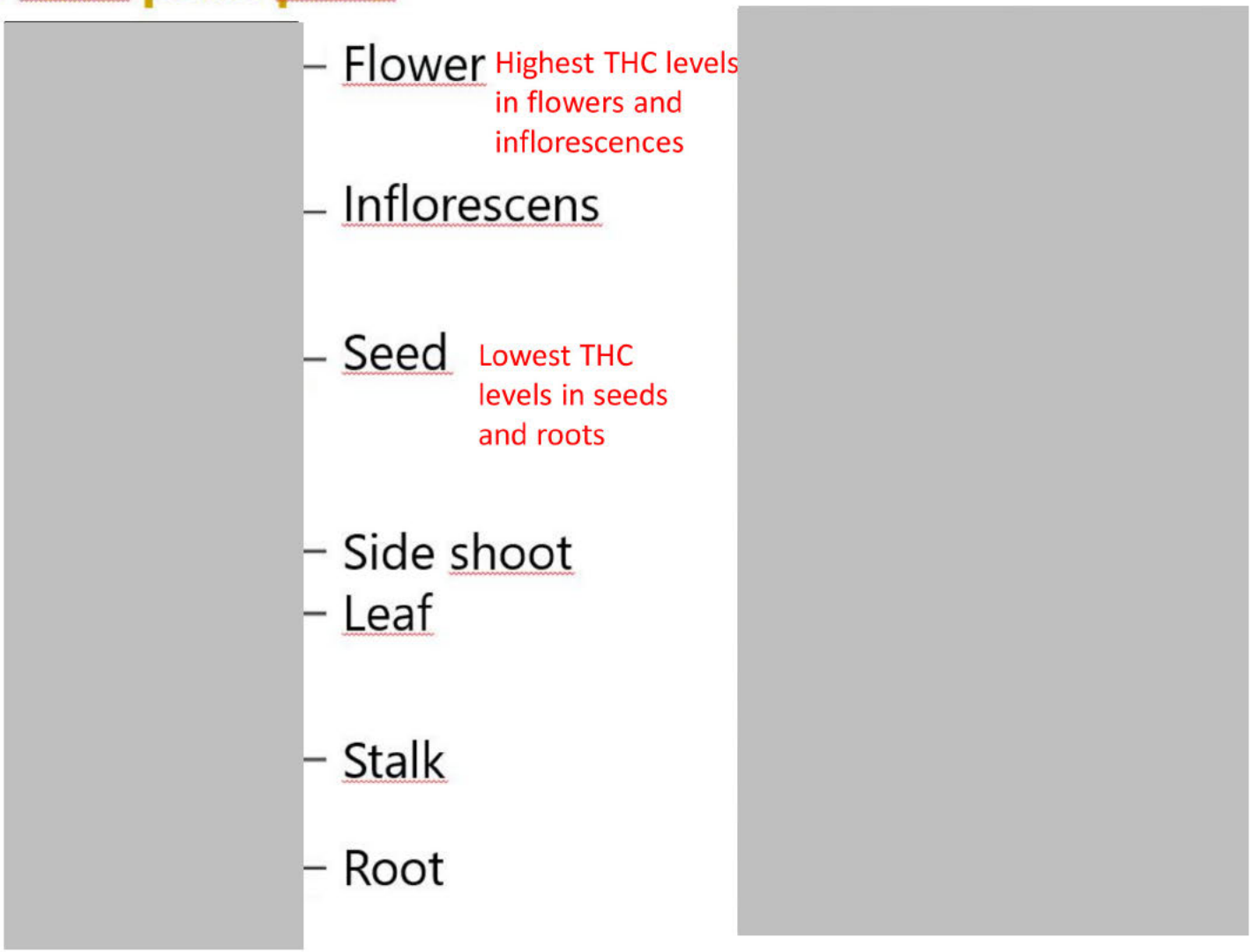
sozial MINISTERIUM
FEDERAL MINISTRY OF LABOUR, SOCIAL AFFAIRS, HEALTH AND CONSUMER PROTECTION

# *Cannabis sativa* L.

## Cannabidiol and other Cannabinoides

# Botanical description

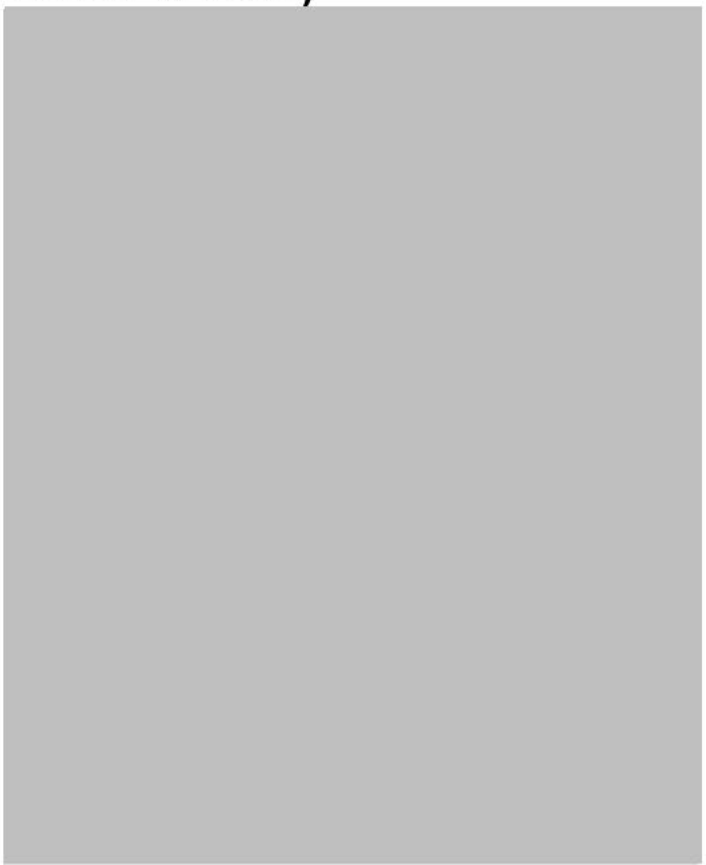
## The used plant parts *Cannabis sativa* L.



# Botanical description 2

Hemp: density of glands (trichomes)
= increasing cannabinoid levels

1. female inflorescences
   (without seeds with leaves growing between them)
2. male inflorescences
3. young shoots, shoot tips
4. Leaves
   a) next to the flowers (small)
   b) on the branches (medium)
   c) on the main stalk (large)
5. Petioles (ranking as in leaves)
6. Stem
7. Seeds and roots (no glands present)



# Comparison of Cannabis traits

Taxonomic classification of the genus Cannabis

- **C. *sativa* Linn. subsp. *sativa* var. *sativa* (Small et Cronq.)***
- C. *sativa* subsp. *sativa* var. *spontanea* (Vavilov)
- C. *sativa* subsp. *indica* var. *indica* (Lam.) (Wehmer)**
- C. *sativa* subsp. *indica* var. *kafiristanica* (Vavilov Small et Cronq.)

## *Cannabis indica***

„drug hemp"

## *Cannabis sativa* L.*

„fiber hemp"

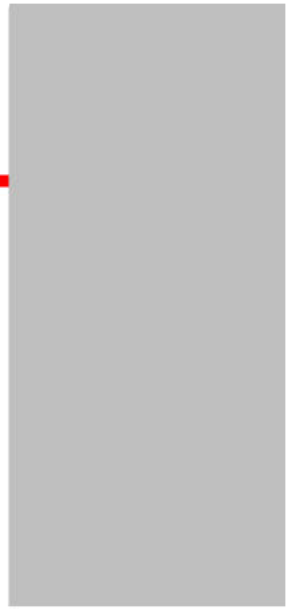
- variety and seeds are regulated in EU
- Cultivation is not subject to Narcotic Substance Regulations, as long as THC-content is < 0,2 %
- For obtaining fibers, seeds, leaves
- Promotion of fiber hemp varieties in the EU according to Art. 30 of Reg. (EC) No 73/2009 when THC-content is < 0,2% in dry matter

# Comparison of Cannabis traits 2

# Comparison of Cannabis traits 3

Chemovars of hemp

?



# Comparison of Cannabis traits 4

- A **chemotype** (sometimes called **chemovar**) is a chemically distinct entity in a plant or microorganism, with differences in the composition of the secondary metabolites. Minor genetic and epigenetic changes with little or no effect on morphology or anatomy may produce large changes in the chemical phenotype.
- Simply put, a chemotype is derived from a plant that has the same appearance and characteristics but has chemical differences.
- **Chemotype differs throughout the world and between what has come to be falsely differentiated as "marijuana" and "hemp"**.
- **Again, it is the same plant and the only major true difference is the THC content of the plant**.
- **All other cannabinoids and terpenes etc. will differ between the chemotype of both categories.**
- There are many marijuana chemovars that have THC as the highest component. Alternatively, it could be seen as the same as some hemp chemovars that have CBD as the highest component.
- Domestic "hemp" is marijuana that was bred to be higher in CBD and lower than 0.3% THC so therefore now is by definition "Hemp".

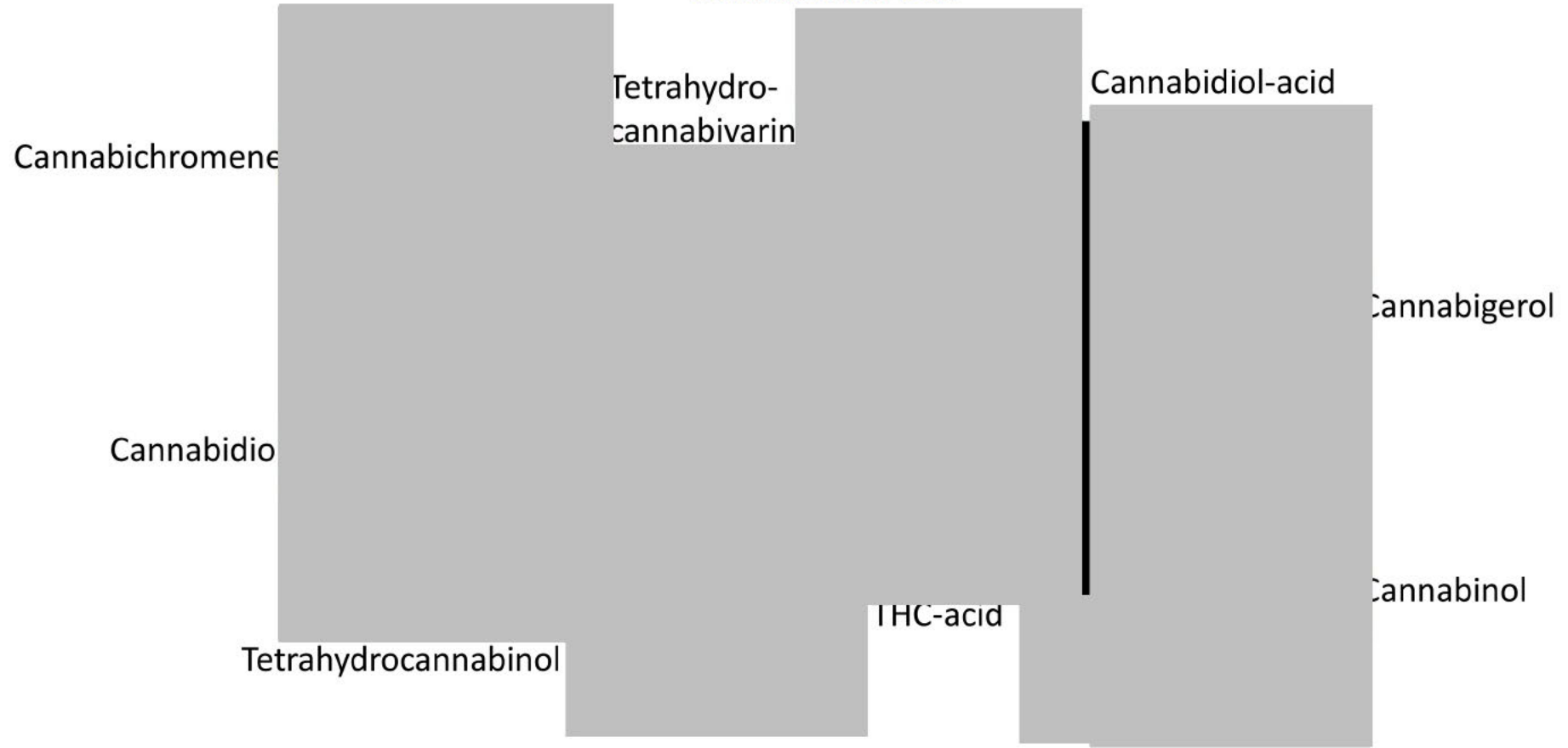
https://www.solcbd.com/pages/hemp-cbd-vs-marijuana-cbd

# RECOMMENDATIONS

## COMMISSION RECOMMENDATION (EU) 2016/2115

### of 1 December 2016

### on the monitoring of the presence of Δ⁹-tetrahydrocannabinol, its precursors and other cannabinoids in food



# Monitoring in Food

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016H2115

(1) Member States should, with the active involvement of food business operators and other interested parties, **perform monitoring** for the presence of Δ9-Tetrahydrocannabinol (Δ9-THC) in food of animal origin and Δ9-Tetrahydrocannabinol (Δ9-THC), its non-psychoactive precursors delta-9-tetrahydrocannabinolic acids (2-COOH-Δ9-THC termed Δ9-THCA-A and 4-COOH-Δ9-THC termed Δ9-THCA-B) and other cannabinoids (such as delta-8-tetrahydrocannabinol (Δ8-THC), cannabinol (CBN), cannabidiol (CBD) and delta-9-tetrahydrocannabivarin (Δ9-THCV) **in hemp-derived foods** and **foods containing hemp** or **hemp-derived ingredients**.

For the monitoring of food of animal origin, evidence should be available that the food of animal origin is produced by animals being fed with feed containing hemp or hemp derived feed materials.

(2) In order to ensure that the samples are representative for the sampled lot, Member States should follow the sampling procedures laid down in Commission Regulation (EC) No 401/2006 ([2]).

(3) The **method of analysis** to be used for monitoring is preferably chromatographic separation coupled with mass spectrometry (**LC-MS or GC-MS**) following an appropriate clean-up step (liquid-liquid (**LLE**) or solid phase extraction (**SPE**)). Preference should be given to **chromatographic techniques** that allow the determination of Δ9-THC separately, its precursors and other cannabinoids in hemp-containing food products.

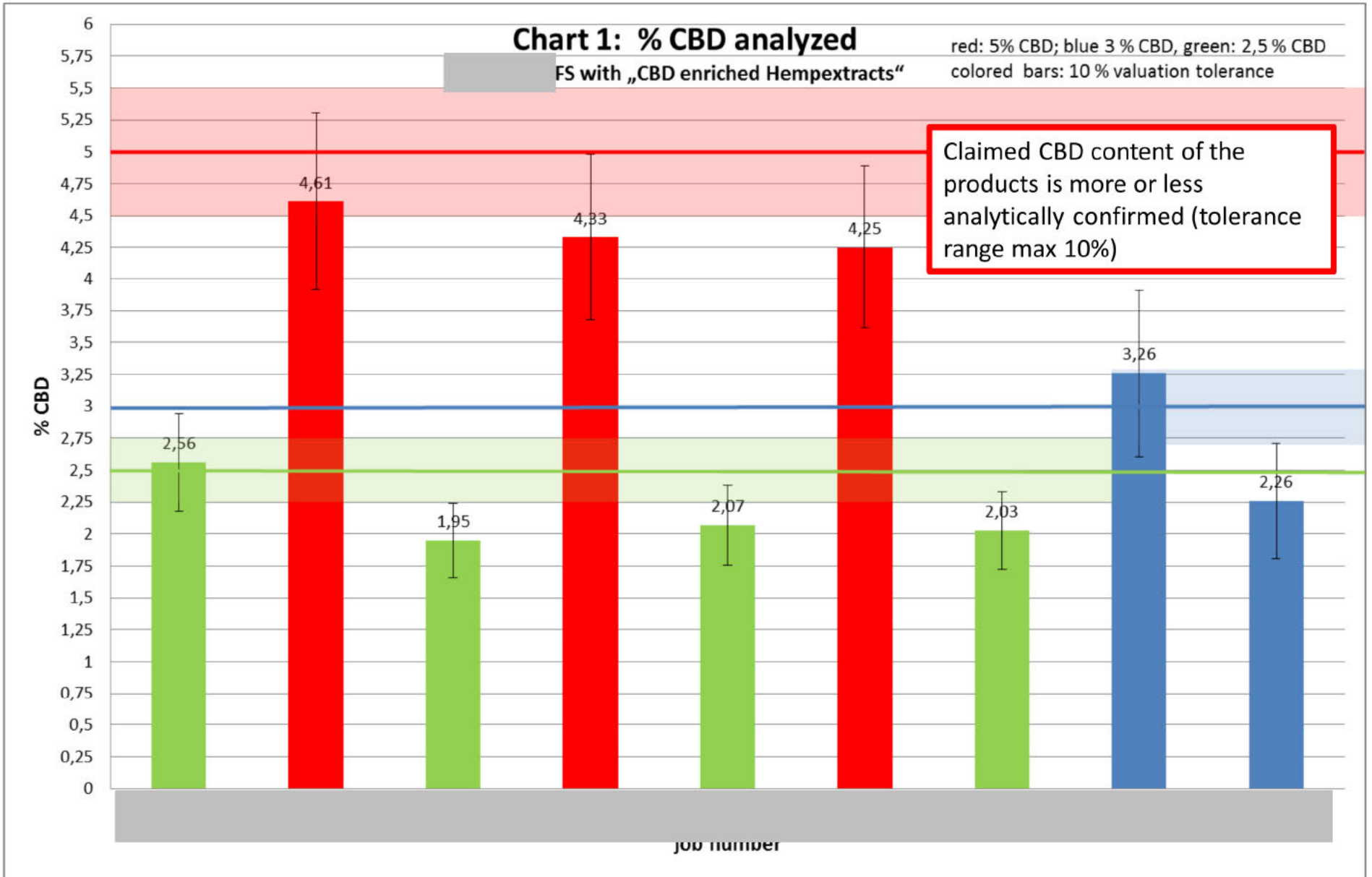
(4) Member States, food business operators and other interested parties should ensure that the analytical results are provided on a regular basis and by the latest by October 2018 to EFSA in the EFSA data submission format in line with the requirements of EFSA's Guidance on Standard Sample Description (SSD) for Food and Feed ([3]) and the additional EFSA's specific reporting requirements.

([2]) Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9.3.2006, p. 12).

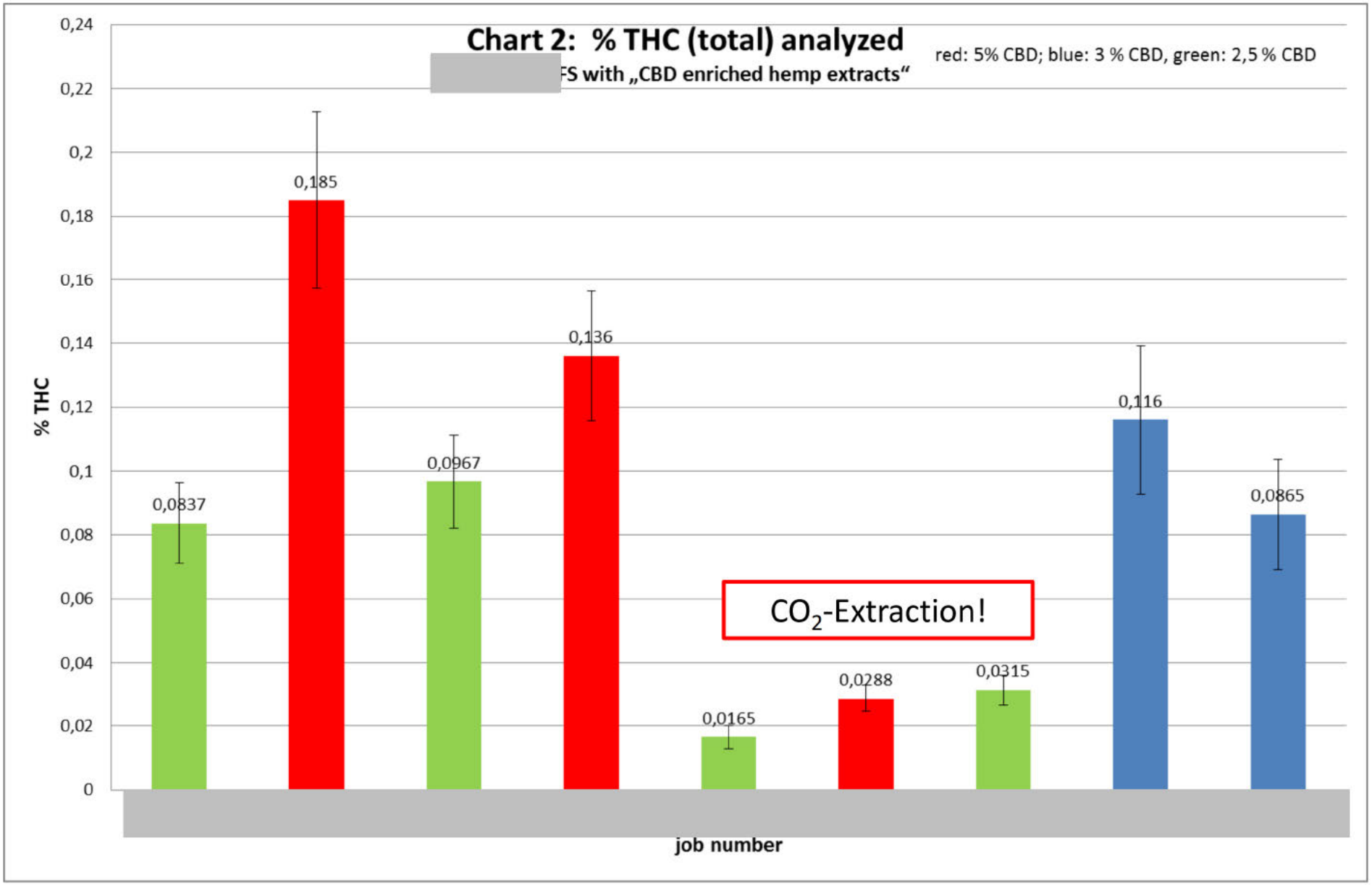
([3]) http://www.efsa.europa.eu/en/data/toolbox

# *Cannabis sativa* L. as „food“

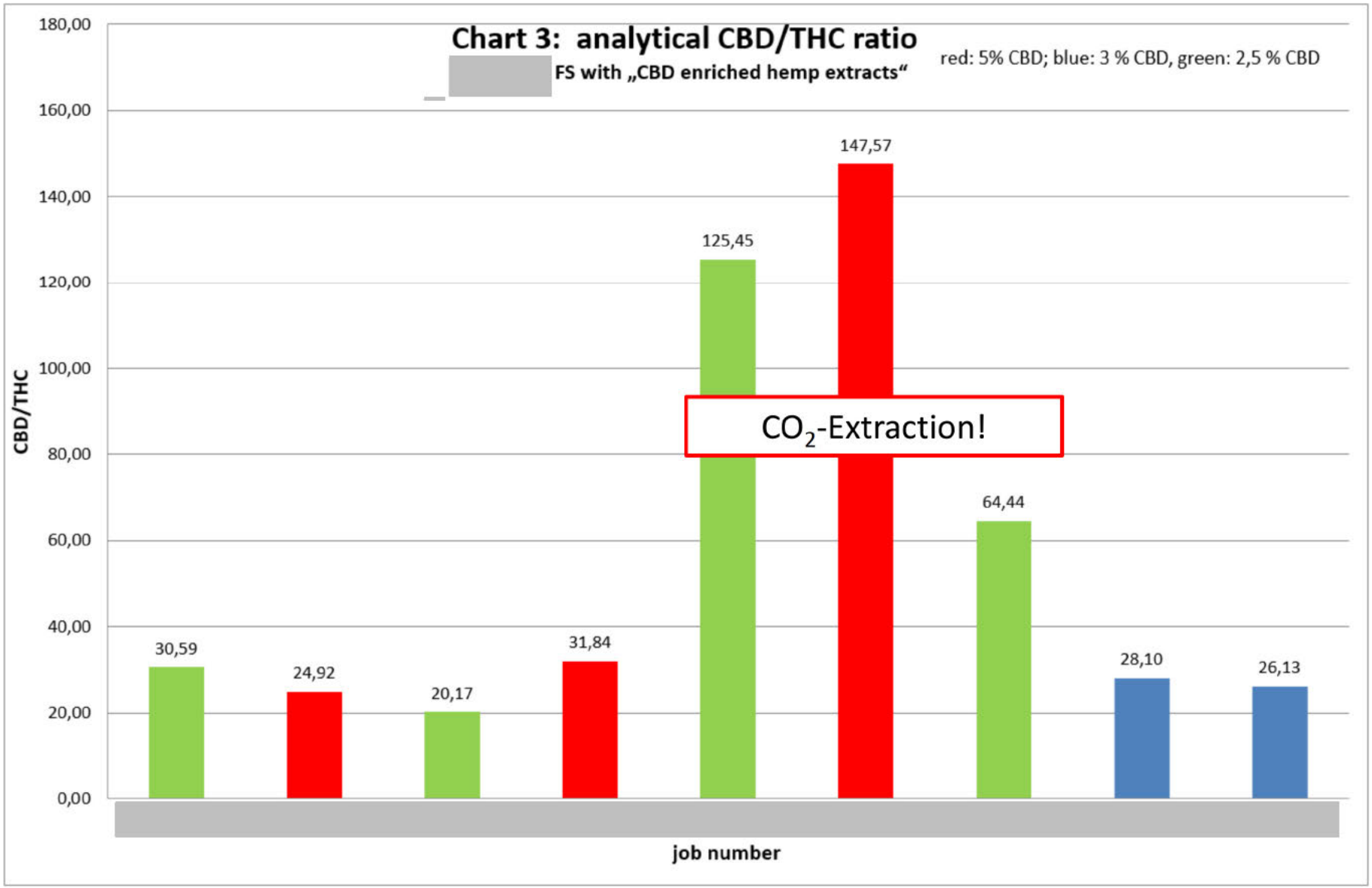
# Analysis of CBD in CBD-rich oils



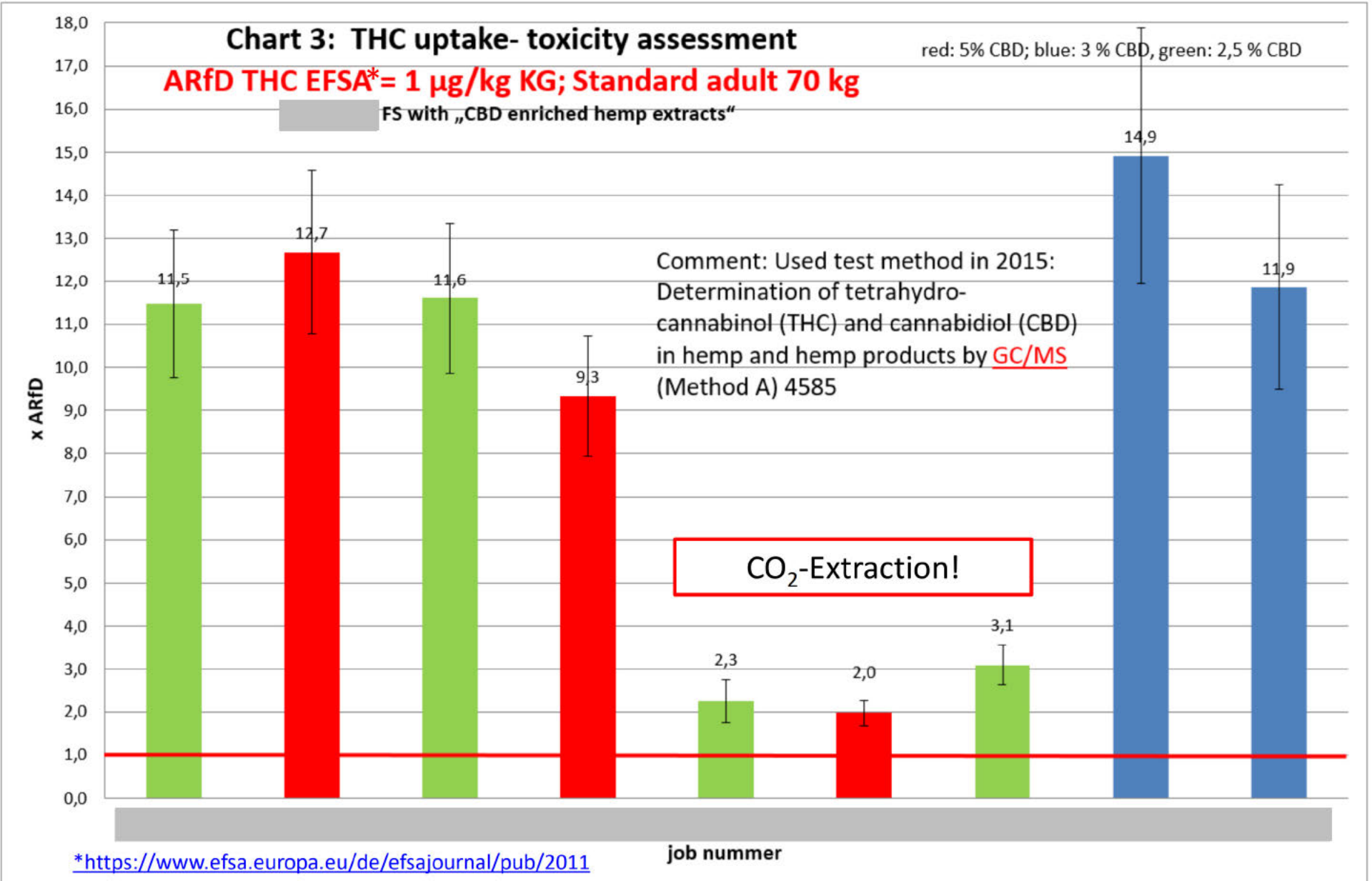
# Analysis of THC in CBD-rich oils



# Ratio CBD/THC in CBD-rich oils



# Toxicity assessment of CBD oils



# Levels of CBD / THC as contaminants in hemp food (overview AT 2013-2018)

**Creative Beer (**

- 0.066 ± 0.0178 mg/kg CBD; < 0.02 mg/kg Δ9-tetrahydro-cannabinol

**Hemp seeds:**

- 5 samples < LOQ for CBD and Δ9-THC;
- 3 samples: CBD/THC: 30/ < 0.5 mg/kg; 93/6 mg/kg; 185/ <10 mg/kg (Mean Value: 40 mg/kg CBD, 0.8 mg/kg THC)

**Hemp oil (⅔ Organic (BIO)):**

- 17 samples: < 0.5-11 mg/kg Δ9- THC (Mean Value: 8 mg/kg THC); 9-265 mg/kg CBD (Mean Value : 53 mg/kg CBD)

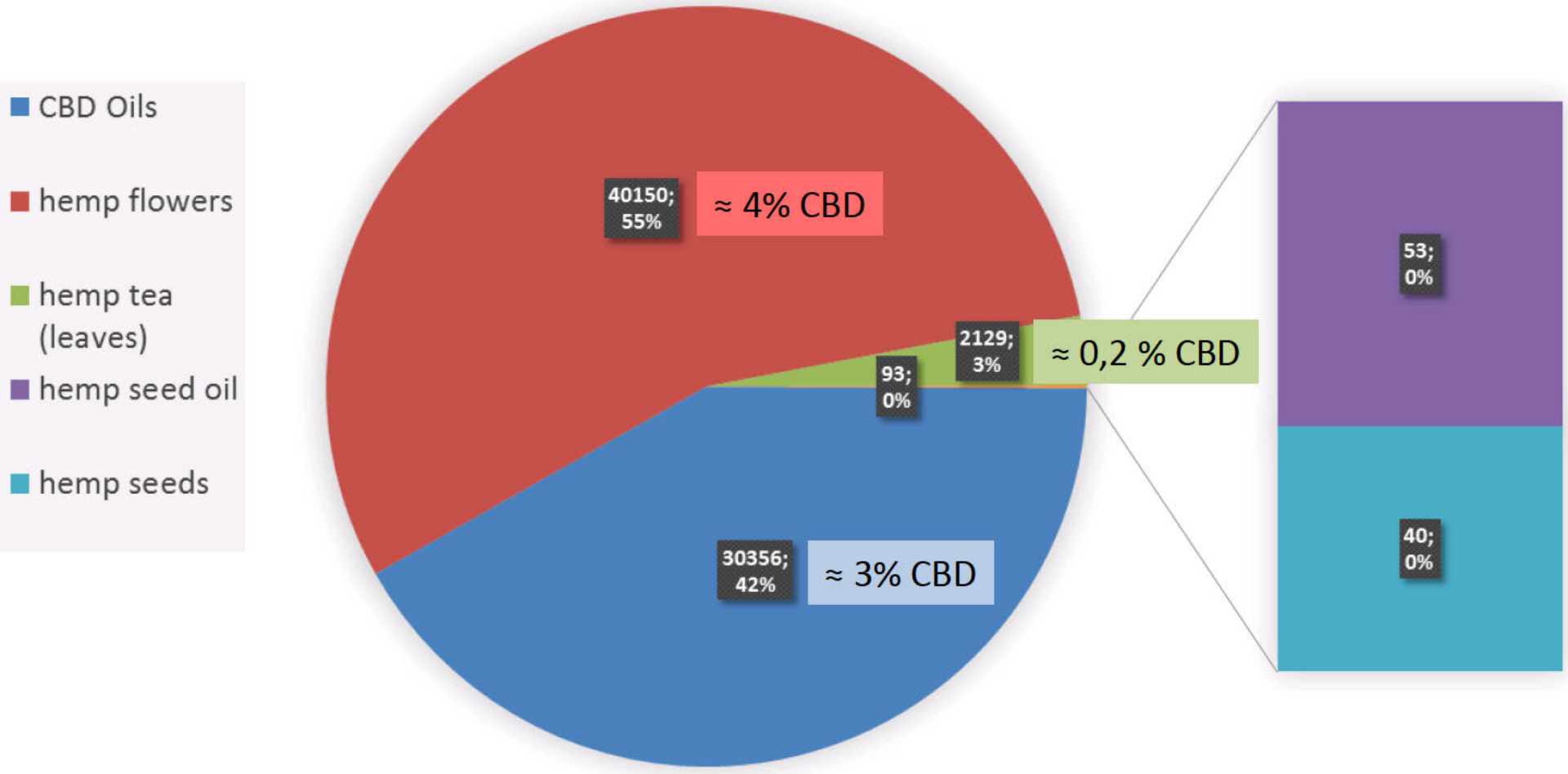
**Hemp leaves (for tea-like infusions):**

- 21 samples: 200-7.300 mg/kg CBD (MV: 2.129 mg/kg CBD); 20-350 mg/kg THC (MV: 130 mg/kg THC)

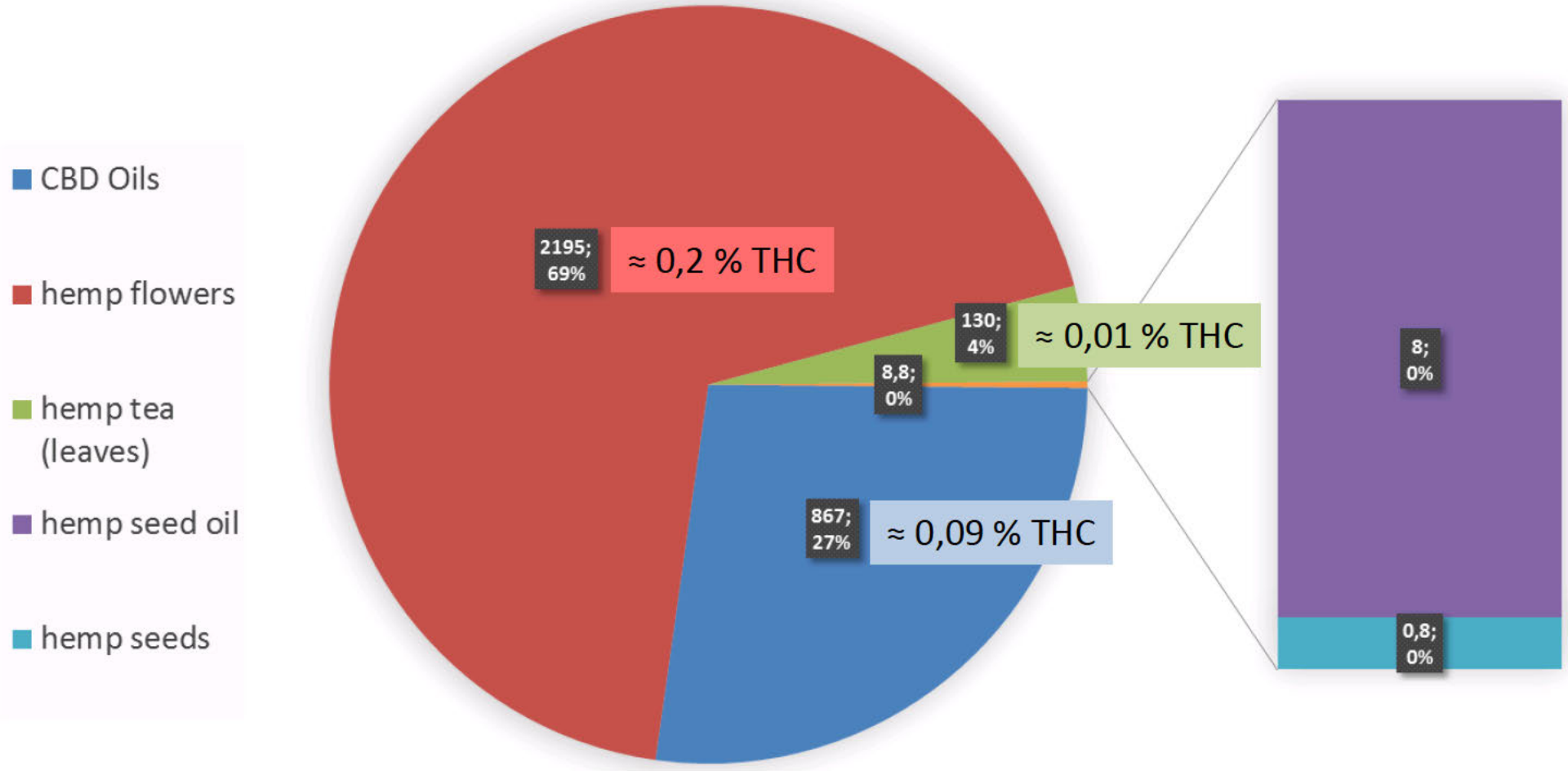
⇨ 2,5 – 98 % CBD = 25.000 – 980.000 mg/kg CBD in products !

⇨ 0,2 % THC = 2.000 mg/kg THC in products!

# Comparison of analyzed austrian hemp foods 2013-2018
## CBD MV [mg/kg]



# Comparison of analyzed austrian hemp foods 2013-2018
# THC MV [mg/kg]



# Definition – Novel Food Catalogue

*Cannabis sativa L*

**Common Names**

Kaņepe (sējas) (LV), Hampa (SE), Hemp (EN), marijuana (PT), hamp (DK), Hanf (DE), hennep (NL), chanvre (FR), cânhamo (PT), konopie siewne (PL), harilik kanep (ET), konopí seté (CZ), Marihuana (ES), indiai kender (HU), ινδική κάνναβις (EL), navadna ali industrijska konoplja (SL), hamppu (FI)

**Common Names**

In the European Union, the cultivation of Cannabis sativa L varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant. Without prejudice to other legal requirements concerning the consumption of hemp (Cannabis sativa) and hemp products, Regulation (EU) 2015/2283 on novel foods is not applicable to most foods and food ingredients from this plant". Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities

**Status**

What does it mean?

Cross-check needed regarding legal aspects of chemovars?

# Definition – Novel Food Catalogue

## Cannabidiol

**Common Names**

Extracts of Canabis sativa L in which cannabidiol (CBD) levels are higher than the CBD levels in the source Canabis sativa L are novel in food. Cannabidiol (CBD) is one of the cannabinoids in Cannabis sativa plant. In the European Union, the cultivation of Cannabis sativa L. varieties is granted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant.

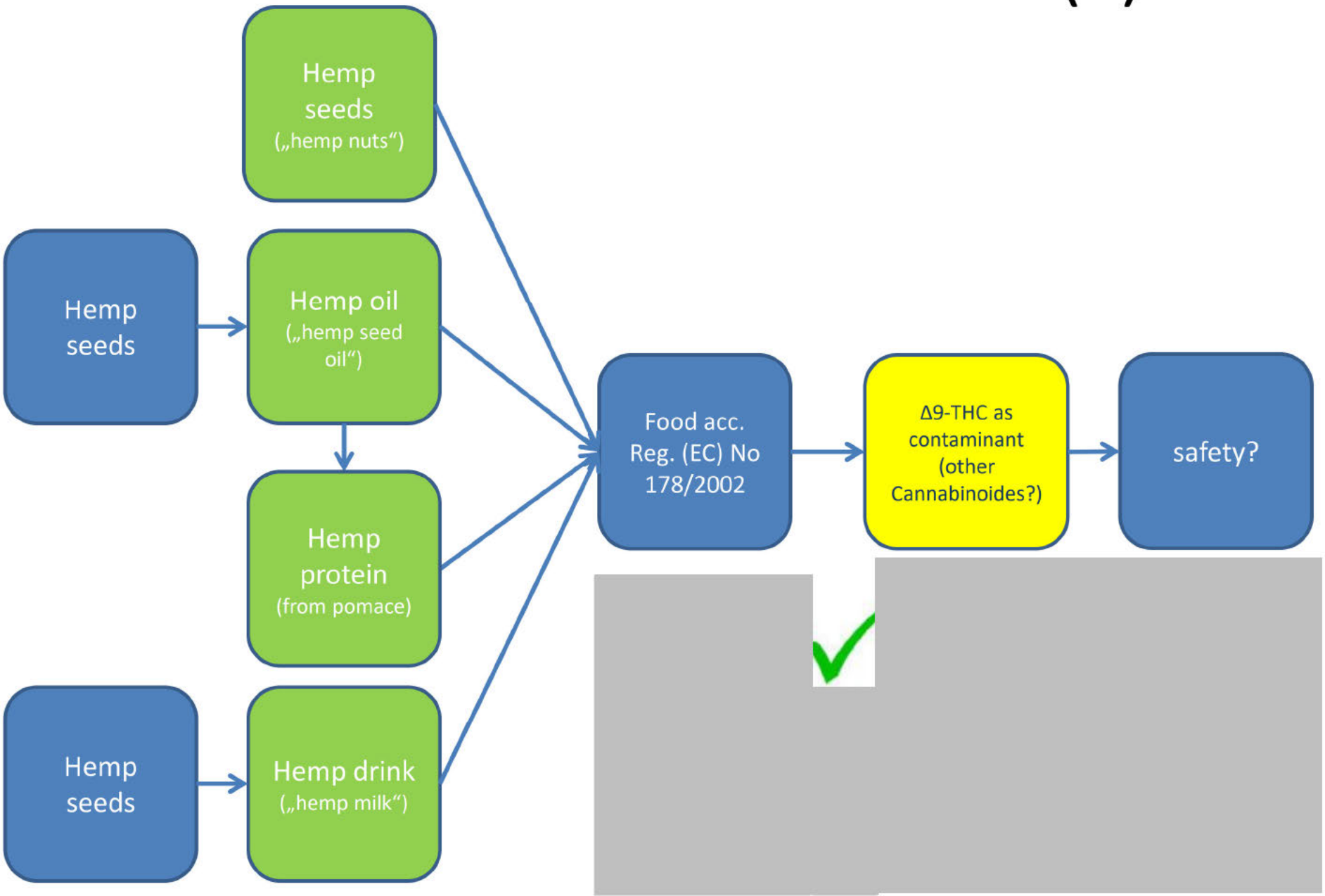
**Status**

What does it mean?

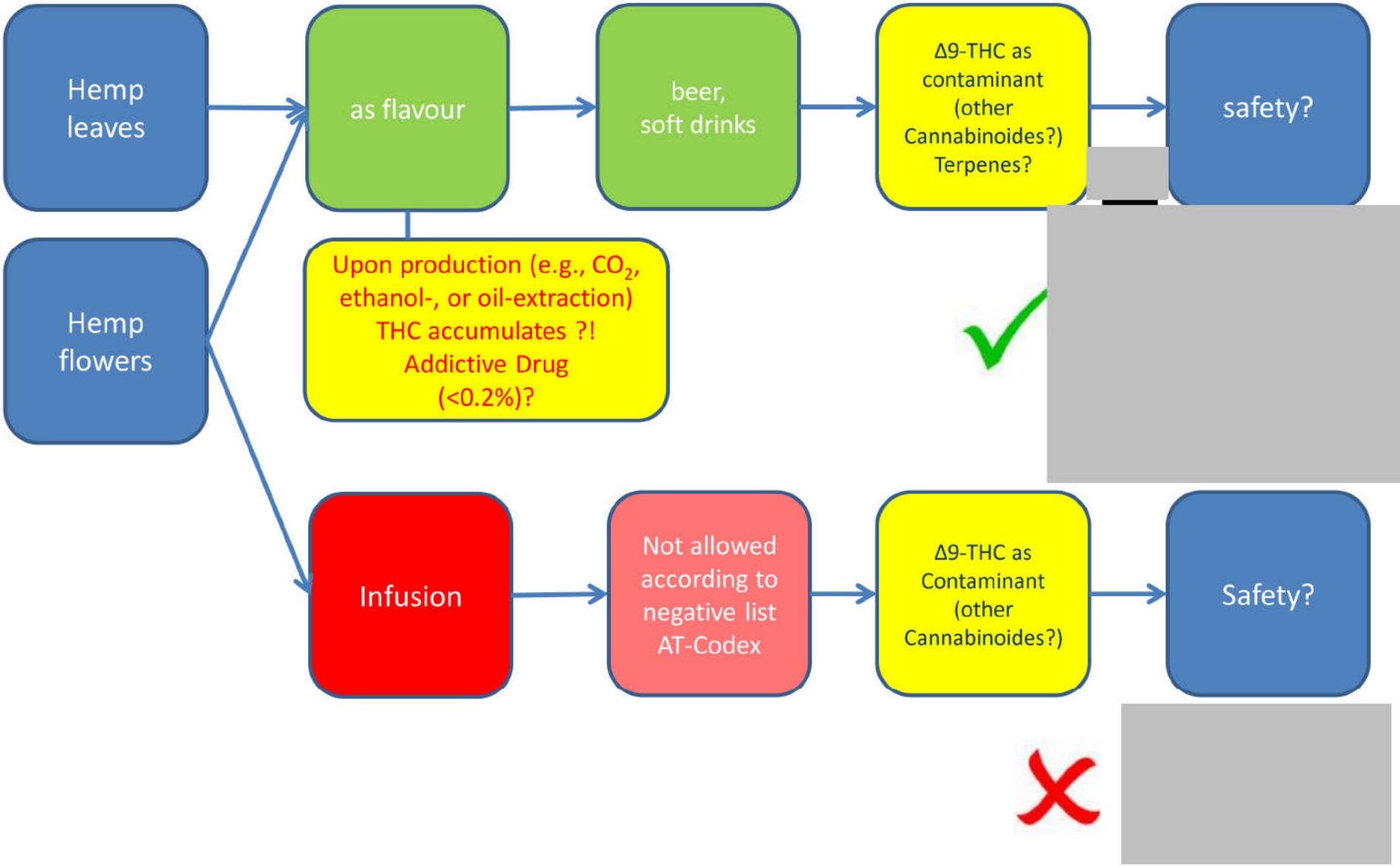
Recommendation:

- Cannabinoids per se instead of only Cannabidiol (CBD)
- Further discussion needed:
  - only extracts?
  - Synthetic vs. Natural?
  - Levels („higher content“?)?
  - Cross-check needed regarding chemovars?

# Food from *Cannabis sativa* L. (1)

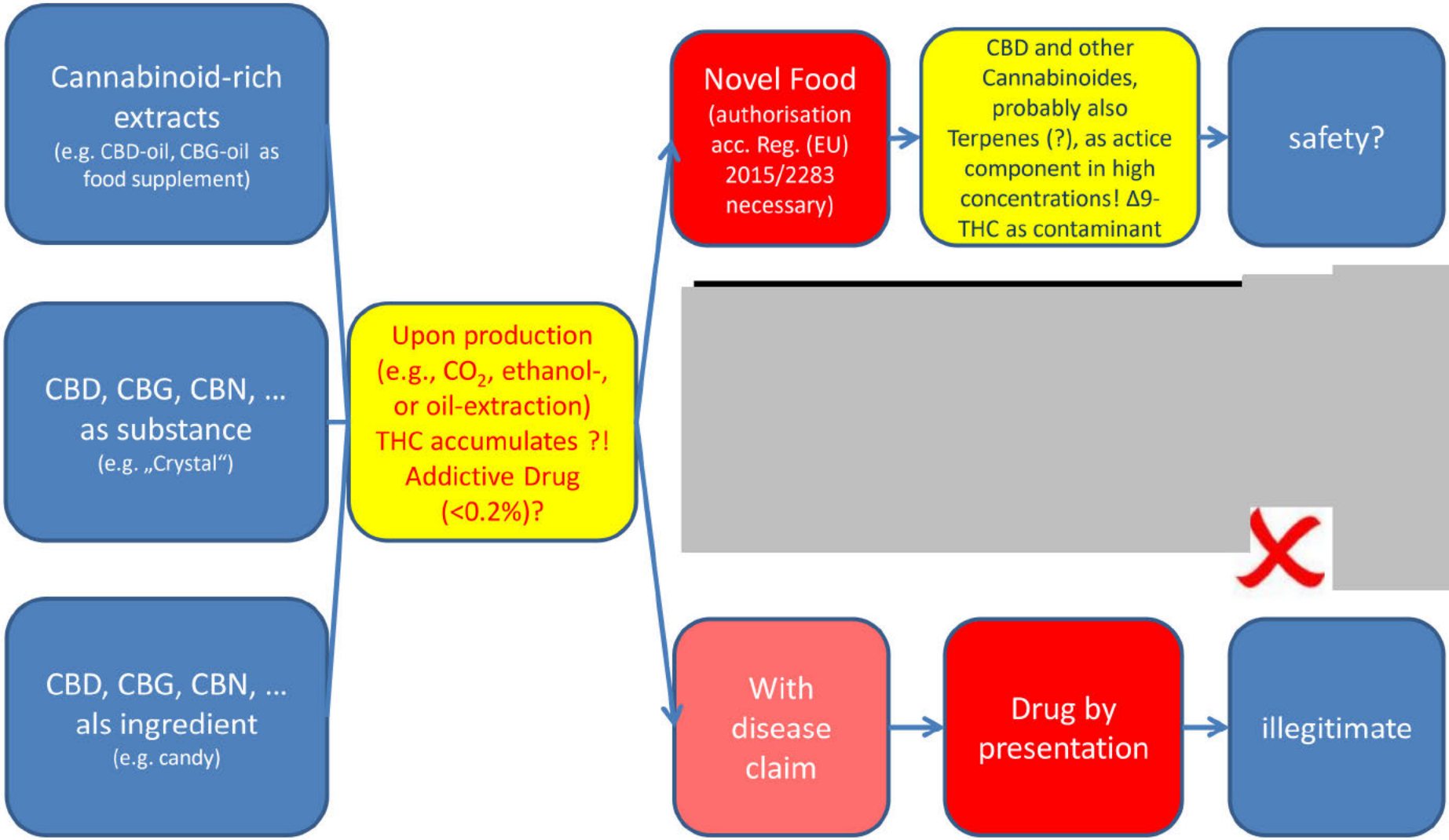


# Food from *Cannabis sativa* L. (2)



# Food from *Cannabis sativa* L. (3)

# Cannabinoid-enriched Products



# Ideas!

# RISK MANAGEMENT TOOL

Article 8 and Annex III of Regulation (EC) No. 1925/2006



**REGULATION (EC) No 1925/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of 20 December 2006**

**on the addition of vitamins and minerals and of certain other substances to foods**



*ANNEX III*

**SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY**

Part A — Prohibited substances

Part B — Restricted substances

Part C — Substances under Community scrutiny

# Article 8 Procedure

EFSA risk assessment→ COM

L 67/4 EN Official Journal of the European Union 12.3.2015

**COMMISSION REGULATION (EU) 2015/403**

**of 11 March 2015**

**amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards *Ephedra* species and Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)**

**(Text with EEA relevance)**

*Article 1*

Annex III to Regulation (EC) No 1925/2006 is amended as follows:

(1) in Part A, the following entry is added:

'Ephedra herb and its preparations originating from *Ephedra* species';

(2) in Part C, the following entry is added:

'Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)'.

Part A — Prohibited substances

Part B — Restricted substances

Part C — Substances under Community scrutiny

Also for Cannabinoids (CBD, CBG…)?

# Exchange with…

- WG „**Agricultural Contaminants**" experts
  - Good Agricultural Practice (e.g. EC recommendation on good practices to prevent and to reduce the presence of opium alkaloids in poppy seeds and poppy seed products)
  - Analytics (Methods? Data? Monitoring? EFSA?)
- other **institutions** (**EFSA, EMA,…**)
- EUMS on **borderline-issues** (food vs. medicine vs. product safety of chemicals and other goods)
  - European pharmacopoeia / national pharmacopoeia (e.g. DE: CBD) – „magistral preparations"
  - Regulation on cosmetic products (near future change of UN Single Convention on Narcotic Drugs!?)

# Cosmetic Regulation

Annex II of Regulation (EC) 1223/2009 on cosmetic products – prohibited substances

| | | | | |
|---|---|---|---|---|
| 306 | Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on Narcotic Drugs signed in New York on 30 March 1961 | | | 15/10/2010 |

Information from EC/DG GROWTH:

- Schedules I and II of the Convention are lists of drugs.

  Art. 1 "definitions" of the convention, “Drug” means any of the substances in Schedules I and II, whether natural or synthetic.

- The list of drugs in Schedule I includes:

  CANNABIS and CANNABIS RESIN and EXTRACTS and TINCTURES OF CANNABIS.

- **Article 1 of the convention** defines these terms as follows:

  (b) “***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.

  (c) “***Cannabis plant***” means any plant of the genus Cannabis,

  (d) “***Cannabis resin***” means the separated resin, whether crude or purified, obtained from the cannabis plant.

⇨ **Provided that Cannabidiol qualifies as an *extract* of cannabis within the meaning of the Convention, it should then be prohibited from use in cosmetics**, irrespective of whether the responsible person has provided a safety assessment of the substance.

AGES
Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH

sozial
MINISTERIUM

FEDERAL MINISTRY OF LABOUR, SOCIAL AFFAIRS, HEALTH AND CONSUMER PROTECTION