

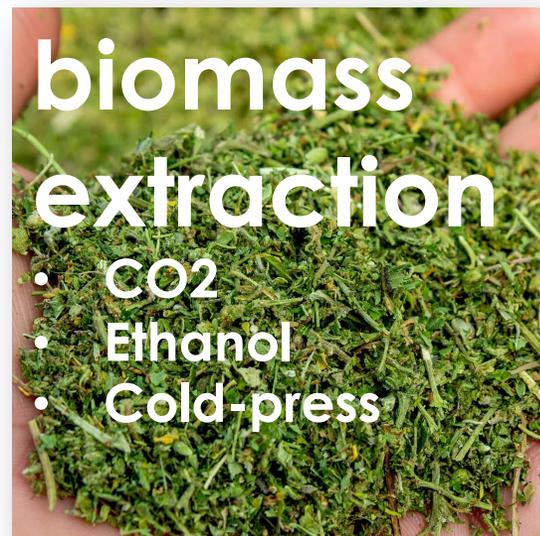
# **the EU cannabinoids market**

## ***Kanavape impact & challenges ahead***

# The product



The **flowers and leaves** of an agricultural crop (***Cannabis sativa L.***) are used for the production of **extracts/CBD**



# The product



## Cannabidiol (CBD)

is the most abundant cannabinoid in a **hemp extract** -

It can be **extracted** or **isolated**



raw/regular  
extract



gold  
extract



CBD  
isolate

# The product



A hemp extract or isolate CBD  
is **diluted** in a carrier

usually hempseed oil or any other vegetable oil

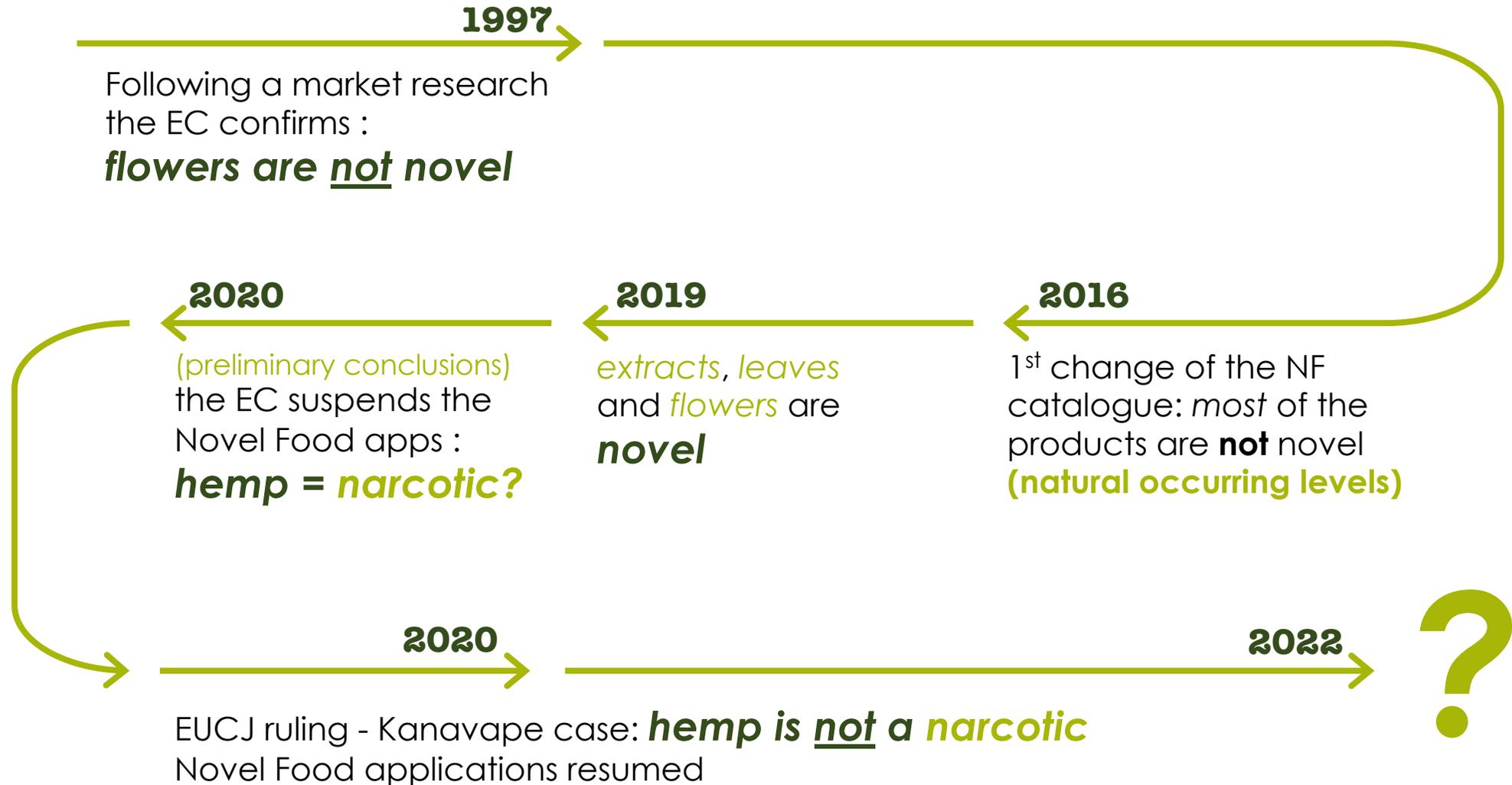


or

+



# Evolution of reg. framework



# Novel or not ? - EIHA position



## Novel Food

(art.10 / EIHA consortium) for *CBD isolate* or *enriched* extracts

*Natural occurring level*

## Traditional food

for *low and natural* concentration

history of safety of consumption + historical evidences

*(Dr. van Breemen recently confirmed)*

*(submitted to MS already in 2019)*

# EIHA Novel Food application



1. CBD **isolate** (novel)

3. **Synthetic** CBD (novel)

The only THC-free product

2. **Full spectrum** extract

(traditional depending on concentration levels)

*Raw/regular or Gold*

acid forms of cannabinoids (not only CBD)

waxes, chlorophyll, terpenes, flavonoids

Sold in the EU as  
*food supplements*  
- Novel Food App  
*ongoing*

CBD molecule is *the same* everywhere!

# EIHA Novel Food application



In the framework of the Novel Food Application the EIHA is performing...

**Tox study on CBD isolate and full spectrum** on rats (with Eurofins) 1,9M€

- Objective: derive the *Tolerable Daily Intake* (TDI), the *No Observed Adverse Effect Level* (NOAEL) and the *Low Observed Adverse Effect Level* (LOAEL) for **CBD**.
- Status: CBD isolate completed / full spectrum ongoing

**THC clinical trial** on humans (with Opis) 1,6M€

- Objective: establish the *Acute Reference Dose* (ARfD) of 7µg/kg BW (today EFSA opinion 2015 says 1 µg/kg BW), derive a proper *NOAEL* and *LOAEL* for THC
- Status: start in June 2022

*! Results will be **shared with authorities** to help them implementing policies !*

# The state of the sector



**Growing differences** among MS promote market distortions and divergence of competitiveness (: inequalities increase)

**Persistent unclearness** refrains investors and food business operators to further support the sector (: investors turn away)

**CBD isolate** imports from USA and China are so much cheaper, the EU as production location has lost this competition. The EU operators aim at the **full spectrum** products to compete at least with int. competition by “made in Europe”. (: EU farmers and processors are losing ground)

# The state of the sector



TODAY

Changing **EU policies**  
Diverging **national initiatives**

TOMORROW

**EU policy framework**  
following the Kanavape ruling

# Kanavape case: scope



**CBD isolate**  
naturally derived (not synthetic)  
used in e-cigarettes.



: a pure molecule (on average 98%) obtained from the aerial parts (leaves and/or flowers) of the *Cannabis sativa L.* plant.

Isolate CBD is produced using CO<sub>2</sub>, ethanol (or any solvent under Dir 2009/32/EC) or cold pressed extraction.

Same CBD used as food supplement, in cosmetics or as feed additive.

# Kanavape case: impact



1. Isolate CBD extracted from the entire hemp plant (including leaves and flowers) is **not a drug**.
2. Isolate CBD benefits from the **free movement** of goods.
3. The **French ban** on isolate CBD derived from hemp is against the principle of free movement of goods (art. 34, 36 TFUE).

Same reasoning *should apply*  
to **hemp extracts** in general and **flowers!**

*upon approval of NF App → change of the NF Union list*

# Take home messages



1. Define hemp flowers and extracts as **NOT narcotic**
2. Establish a **EU single market** for all hemp products
3. Recognize **traditional food status** of hemp extracts with natural occurring level of cannabinoids
4. Establish a **common method of analysis** for cannabinoids to facilitate testing and market surveillance
5. Build **knowledge** for national administrations (customs, market, ...)



**thank**  
**you**