



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**



The product



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

usually hempseed oil or any other vegetable oil

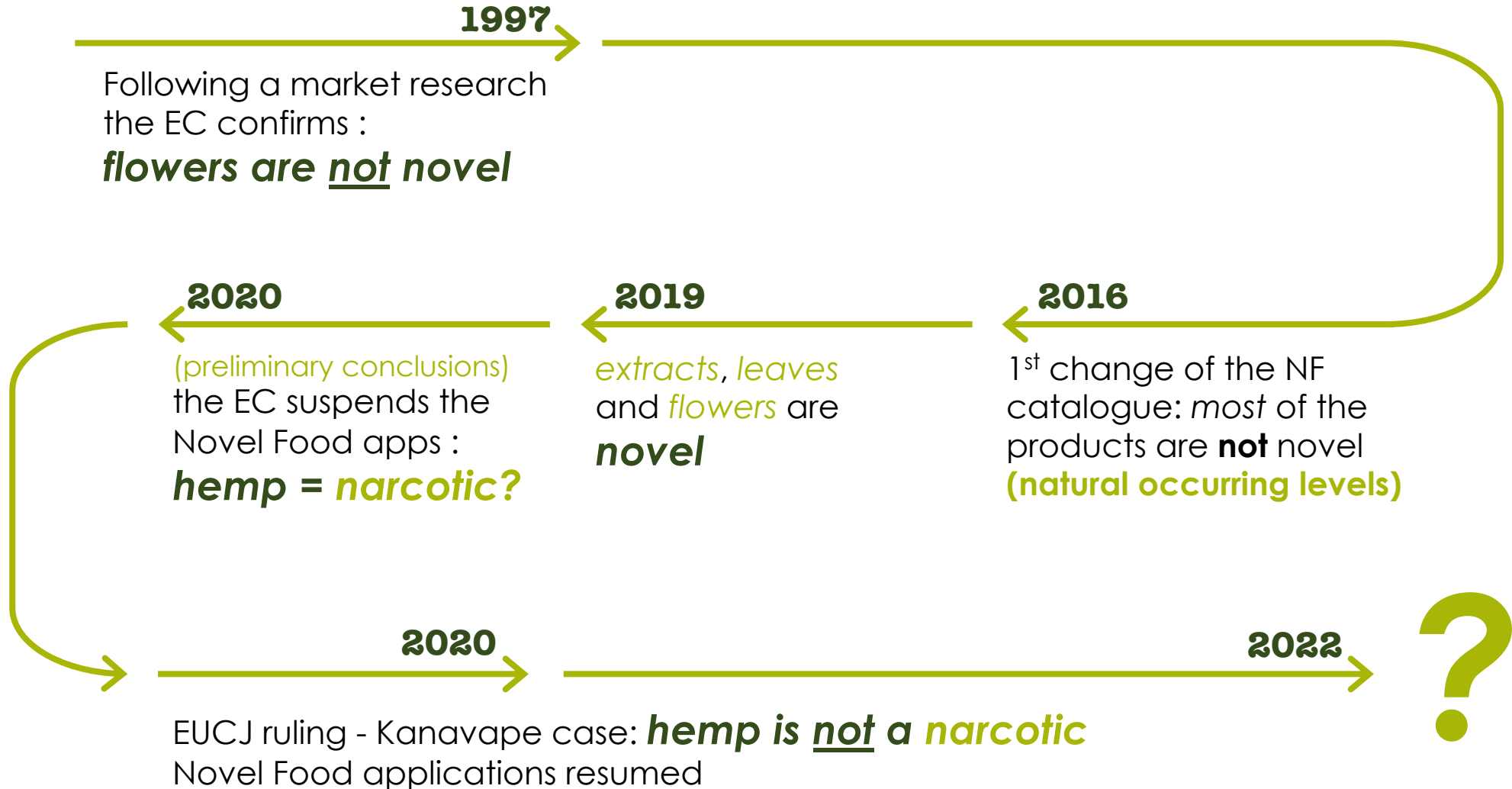


or

+



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)

EHHA 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!

EHHA Novel Food application



In the framework of the Novel Food Application the EHHA 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 CO₂, 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