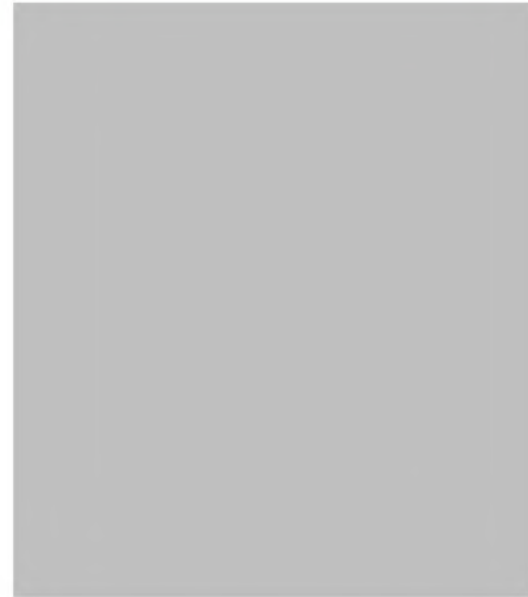


Defining the Novel Status of CBD

Introduction



EU Definition of Novel Food

- (iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
 - traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
 - non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

- Article 2 Part iv of
Regulation (EU) 2015/2283

Predicament

Question:

When is a CBD Food Product Considered a Novel Food?

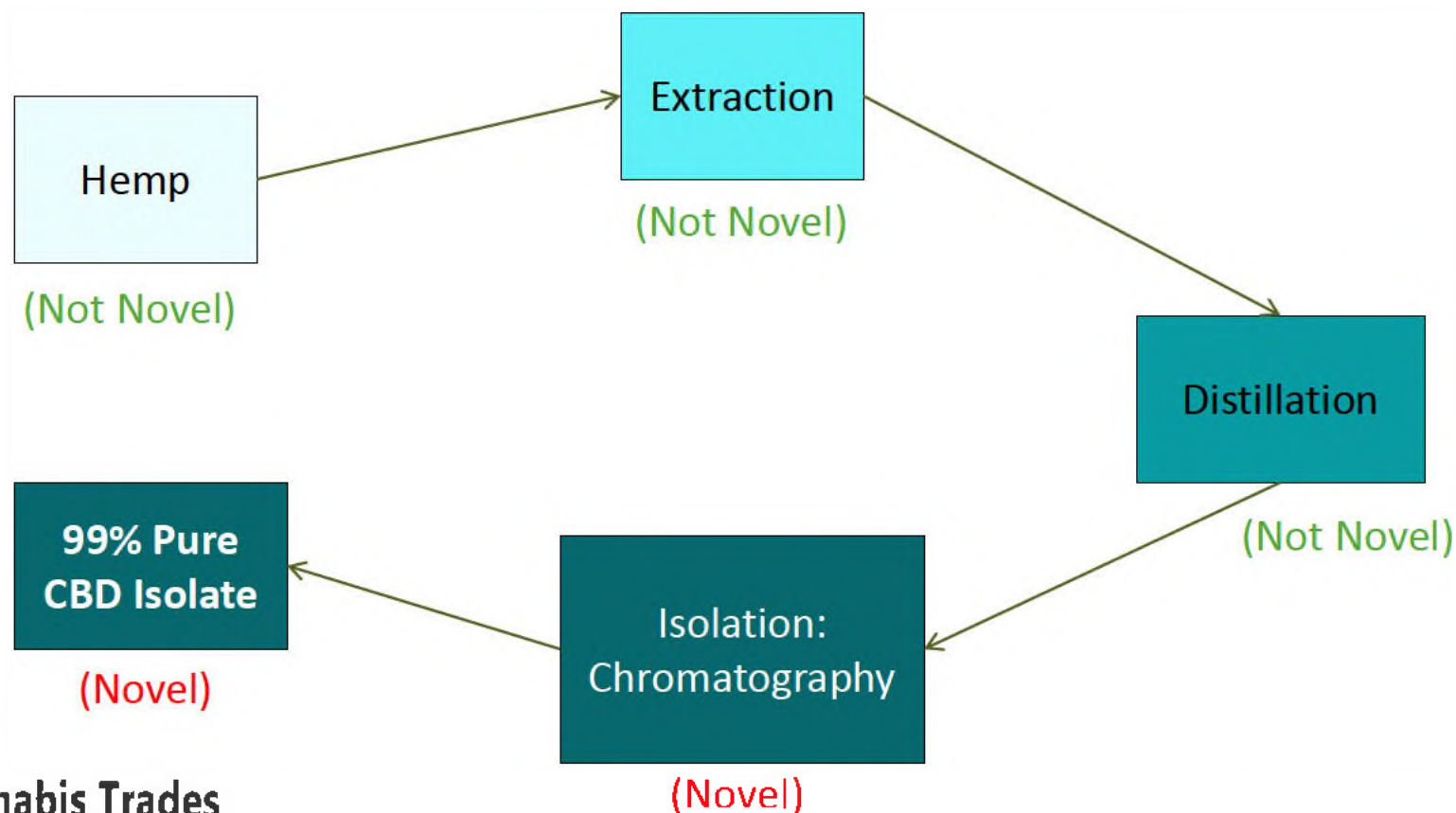
Current Answer:

When it contains Isolated CBD

Problem:

At what point does a Hemp Product (**Not Novel**) become an isolate product (**Novel**) and how can we identify whether or not it has been used?

The Different Stages of Making a Hemp Extract



Solvent Extraction

A process used and applied to Hemp for hundreds of years in the Europe. (Not Novel)

Extraction is like making a cup of tea or espresso, it dissolves the plant constituents into a solution.



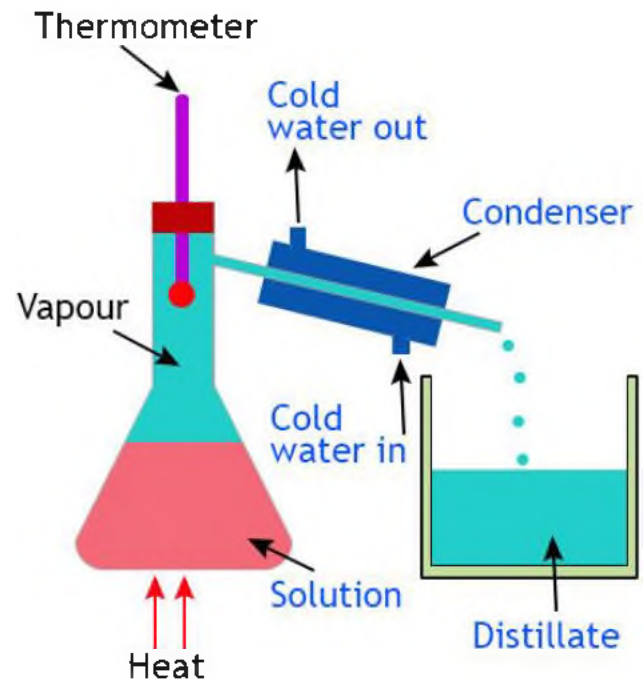
CBD Concentration in Solvent Extraction

49.32% CBD

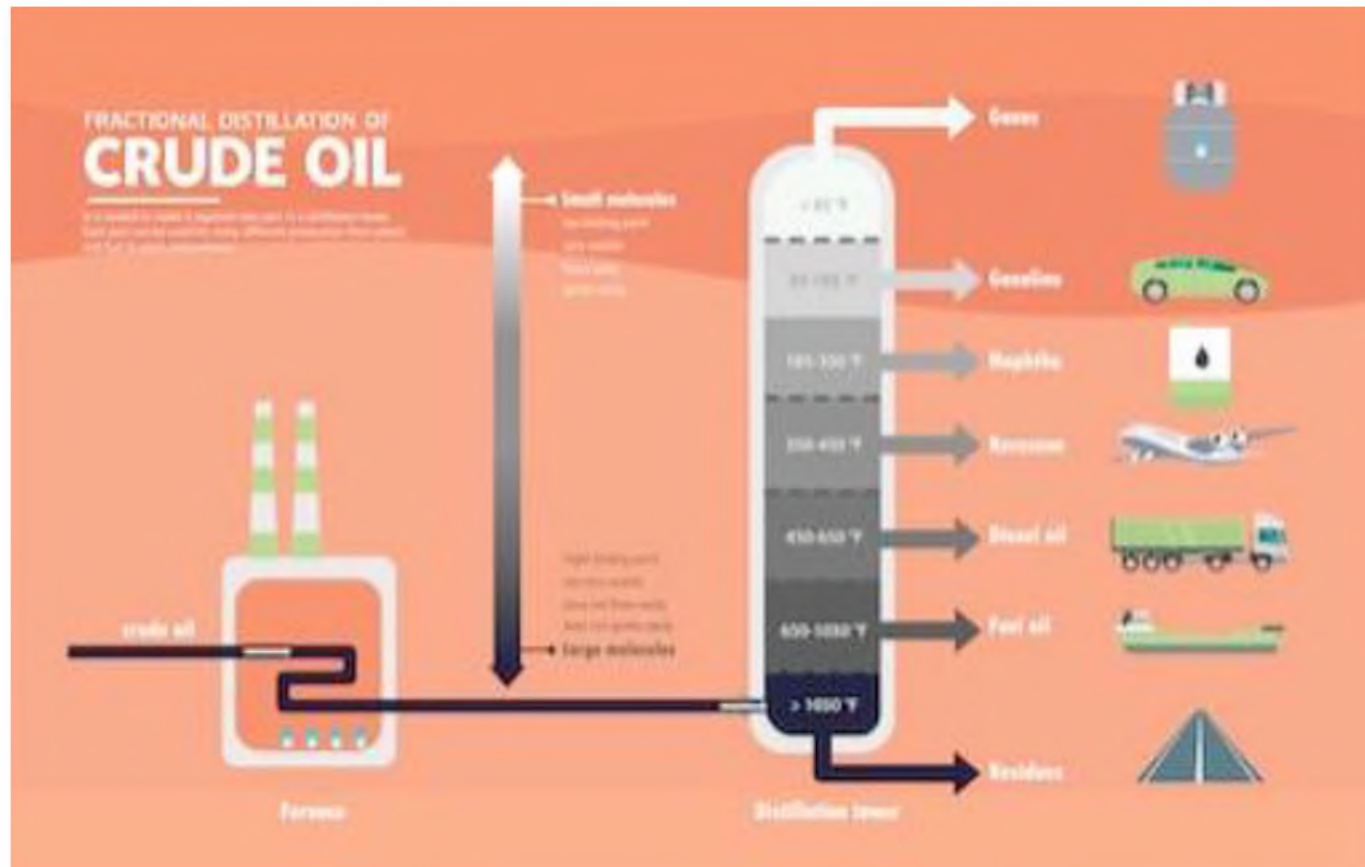
With solvent extraction a consistent concentration of 50% CBD can be achieved

Distillation

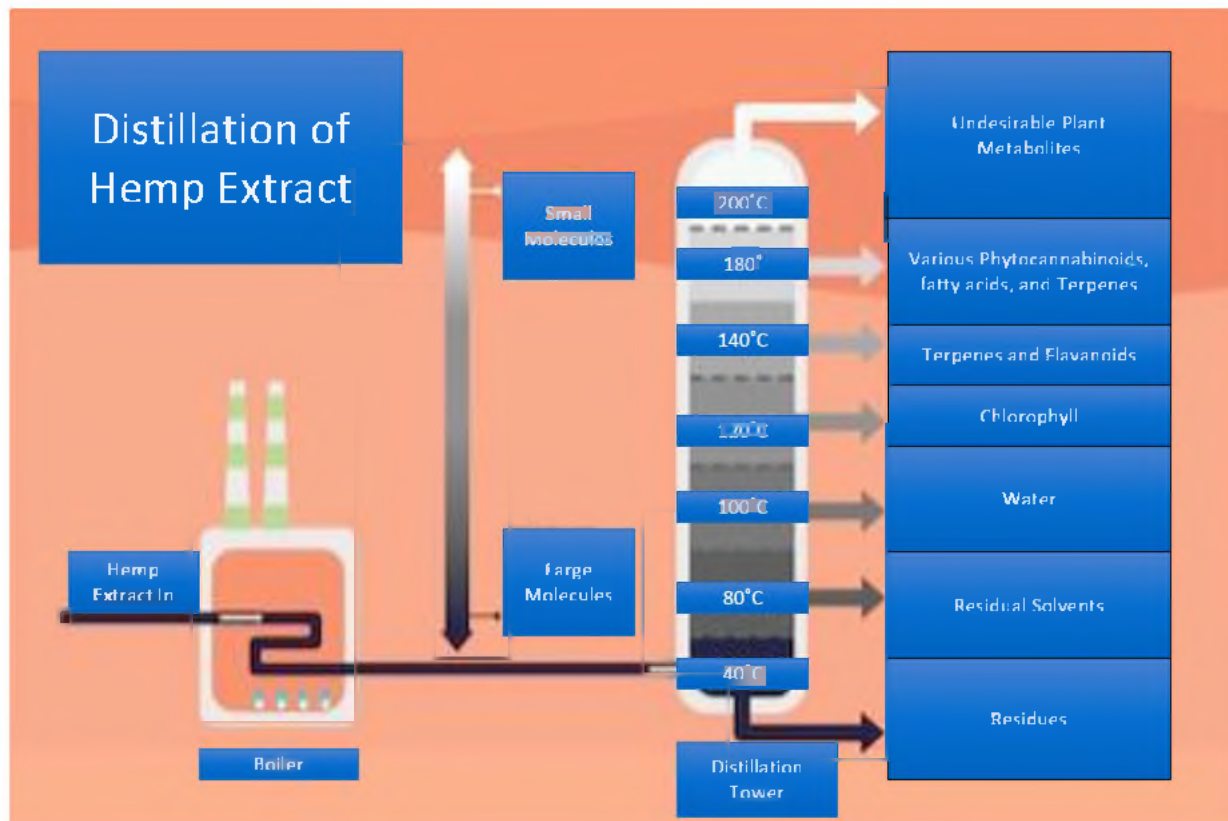
Distillation separates compounds based on their respective vaporization temperatures allowing for the removal of unwanted compounds



Example of Distillation



Distillation of Hemp Oil/Extract



What can we do with distillation?

Distillation can keep a full spectrum of plant compounds:

- Terpenes
- Fatty acids/...

However, can use to remove:

- Chlorophyll (Bitter Taste)
- THC (Controlled Substance)
- Mycotoxins

CBD concentration with Full Plant Distillate?

A process maintaining all plant chemicals except unwanted, dangerous, or toxic compounds (Not Novel), thereby not affecting the...

Nutritional Value

Metabolism

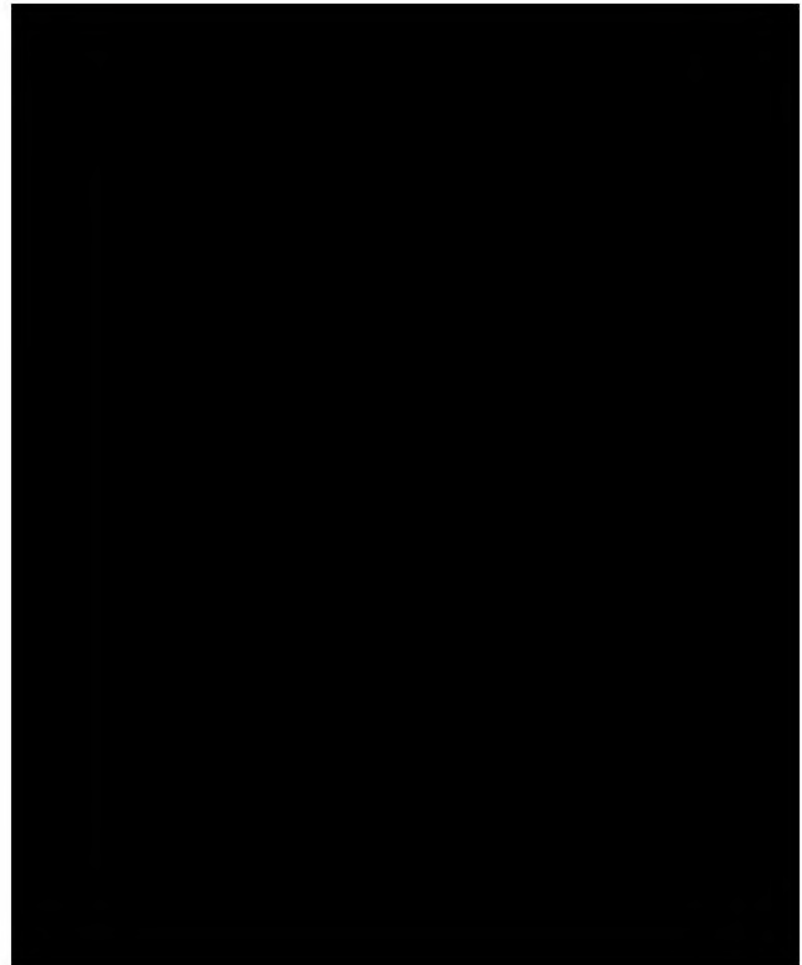
Level of Undesirables

85% **(Not Novel)**

Example of Full Spectrum Distillate

85% CBD

With full spectrum distillate



CBD Concentration of a Selective Plant Distillation?

A process which increases the CBD concentration to the detriment of the other plant chemicals, thereby affecting the:

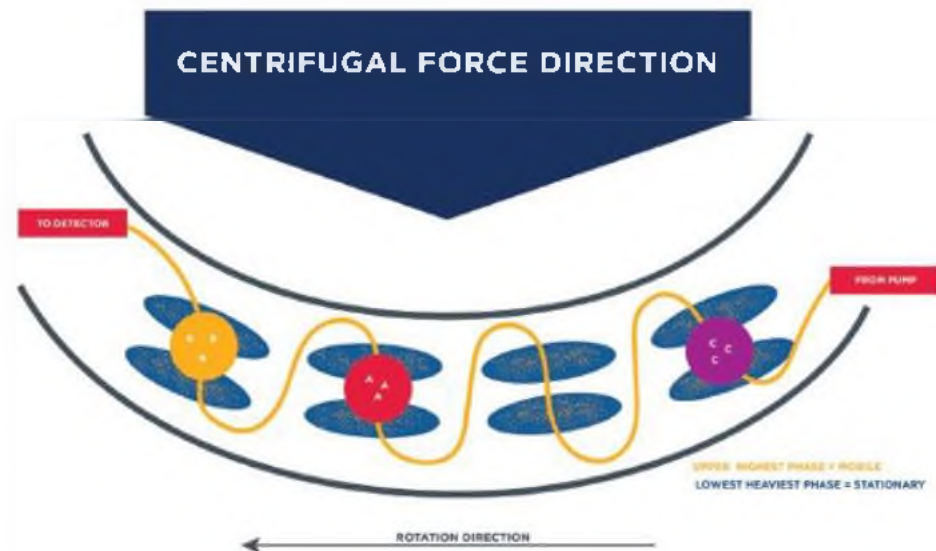
Nutritional Value
Metabolism

95%

(Novel)

Other Methods of Isolation

- Centrifugal Partition Chromatography (CPC)
- Flash Chromatography



Summary



NOT NOVEL

FULL PLANT DISTILLATE

NOVEL (Isolates)

SELECTIVE PLANT DISTILLATE

CPC

FLASH CHROMATOGRAPHY

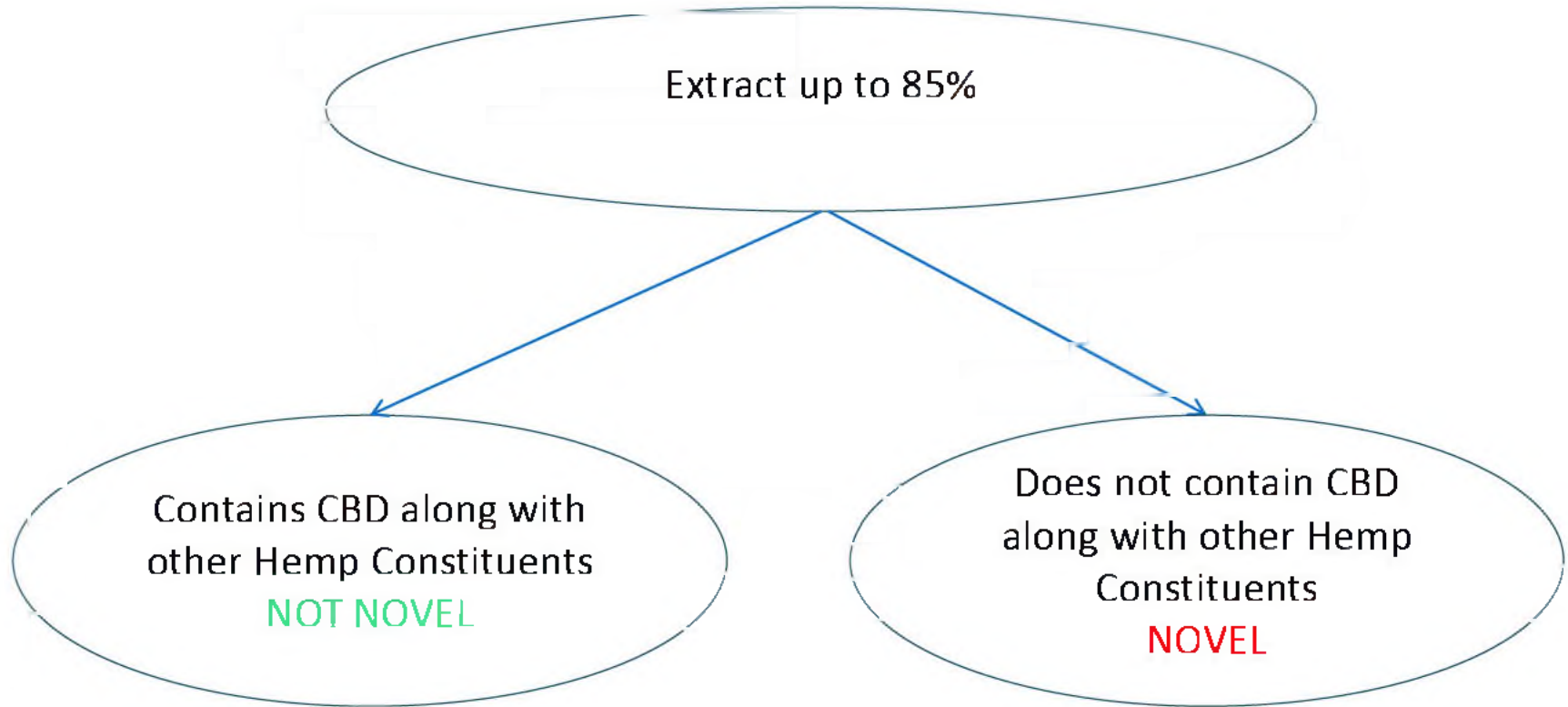
Identification of novel product

To identify compliant from non-compliant products we need a reliable method to identify a full plant distillate from an isolate

Can be done by identifying the other compounds within the hemp plant that would not be there in an isolated product

- mass spectrometer can achieve this by identifying single molecules within a complex solutions
(needle in a haystack)

How we Differentiate the Novel Status



Possible issues with this method

Can't you just add Isolated CBD to hemp constituents?

Yes but it would be uneconomical to produce an extract in this way

Can't you top up a compliant extract with isolate?

We would be able to identify the levels of those compounds to ensure the ratios of those compounds are within the reasonably expected range of those of the raw material.

In Conclusion

It is the opinion of CTA UK that High-CBD Hemp Oil can be used in food products as long as it is below an 85% CBD concentration and contains other plant constituents found in the raw material.

As this would not fall under the definition of a novel food, as it would not be affecting its nutritional value, metabolism, and undesirable substances.

Need for Demonstration

- Demonstrate the reliability of isolate identification using Mass Spectrometry