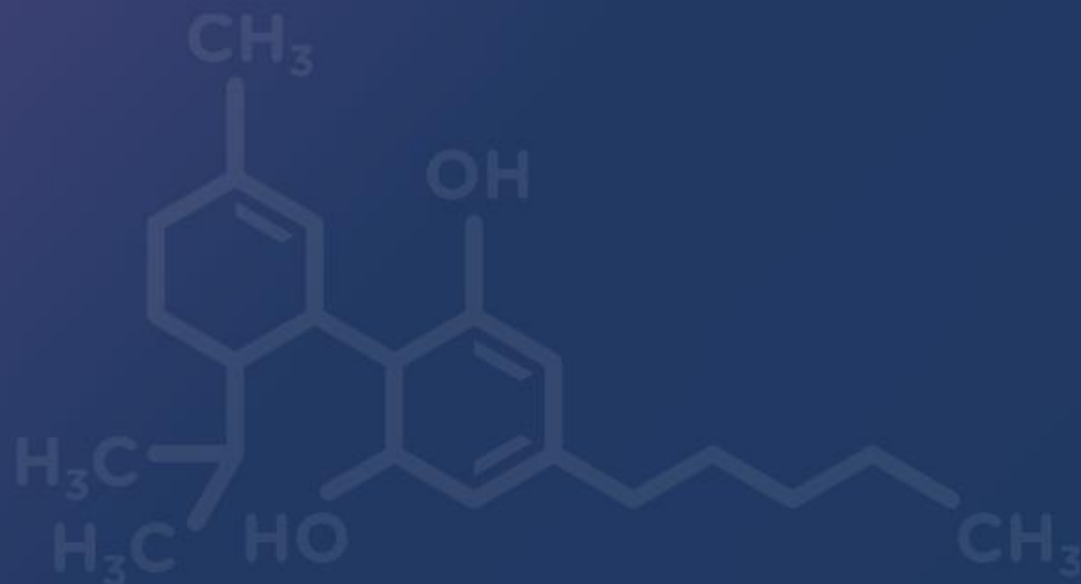


**Chanelle McCoy Health**

#NewScience

# CBD Regulatory Landscape



# THE CBD MARKET IS IN THE PROCESS OF CHANGE

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## WHY?

- CBD has become hugely popular as a food supplement with an estimated 8 million people consuming CBD in the UK alone
- The CBD market is currently in regeneration; we are moving away from a largely unregulated market landscape to that of one requiring strict regulatory adherence by CBD companies due to the EU classification of CBD as a Novel Food in January 2019
- However as the market up until this point had been largely unregulated, many poor quality and potentially unsafe products have remained on the market unknown to the average consumer
- As discussed in our other education material, but worth reiterating in this context; a 2020 study<sup>1</sup> of the UK CBD market published the following in relation to products they had tested off the shelf:
  - 34% of products **had 50% less of the CBD content advertised**
  - 1 product had **no CBD content**
  - 55% of products had **measurable levels of THC**, above limit
  - CBN (which is another cannabinoid that is classed as a controlled substance therefore illegal) was present in products
  - One product had levels of ethanol (i.e. alcohol content)
  - **Lead and arsenic** were also detected
- It was evident regulatory change was needed in order to protect consumers safety

## RECENT REGULATORY CHANGES IN THE CANNABIS MARKET

**Jan 2019:** CBD permitted as a Novel Food

**Nov 2020:** the EU highest court rules that CBD is not a narcotic

**Dec 2020:** UN de-schedules Cannabis, it is no longer a narcotic

# EU NOVEL FOOD

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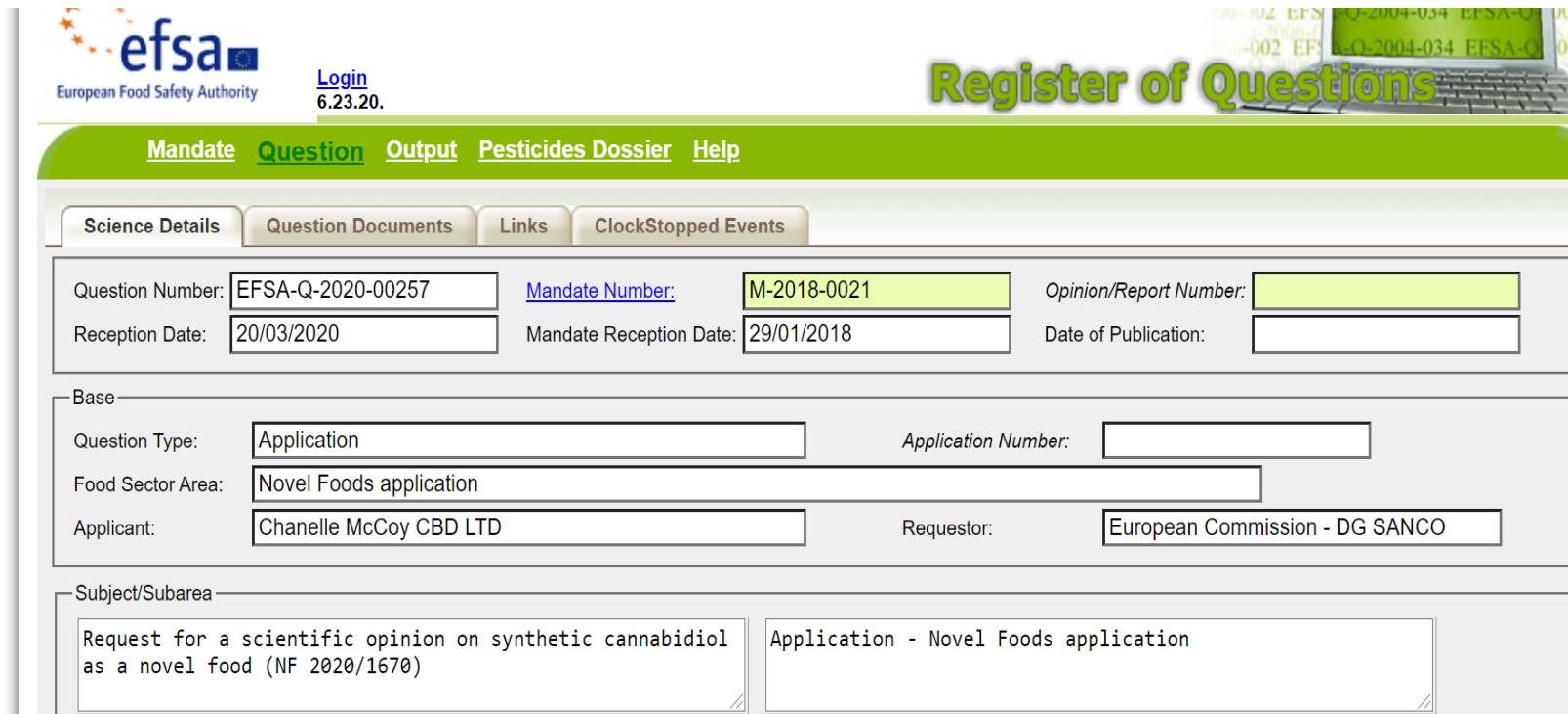
## WHAT IS IT AND WHAT DOES IT MEAN FOR CBD COMPANIES?

- CBD was placed on the EFSA (European Food Safety Authority) catalogue of Novel Foods in January 2019; in doing this EFSA were assuring that CBD food supplements would fall under their regulatory watch
- To achieve a license CBD companies are now required to undergo extensive analytical and clinical safety studies; ensuring products are safe to use and compliant
- Companies now need to submit a comprehensive dossier to the authorities demonstrating product safety, consistency, quality and stability in order to obtain a novel food licence and legally sell their products in the EU
- However where this regulation does apply to the EU as a whole, each member state may adopt a different approach towards the legality of CBD and CBD companies must check with the local authorities prior to placing any CBD product on sale in each member state

# EU NOVEL FOOD CONT.

## WHAT IT MEANS FOR PUREIS®

- Chanelle McCoy Health has completed a full suite of clinical studies equivalent to Phase I toxicology studies that would be required for a new drug application on **Pureis® Ultra Pure CBD** ( please see our clinical trials slide for further information)
- Due to the extensive studies carried out by the team at Chanelle McCoy Health; Pureis® Ultra Pure CBD is the 1<sup>st</sup> company to receive a validated Novel Food Application from EFSA and the UK Food Standards Agency
- Our Application reference is NF 2020/1670 which can be seen on the EFSA website:



The screenshot shows the EFSA Register of Questions interface. The header includes the EFSA logo and a 'Login' link dated 6.23.20. The main title is 'Register of Questions'. Below the header is a navigation bar with 'Mandate', 'Question', 'Output', 'Pesticides Dossier', and 'Help'. The 'Question' tab is active, showing sub-tabs for 'Science Details', 'Question Documents', 'Links', and 'ClockStopped Events'. The main content area displays the following details:

Question Number:	EFSA-Q-2020-00257	Mandate Number:	M-2018-0021	Opinion/Report Number:	
Reception Date:	20/03/2020	Mandate Reception Date:	29/01/2018	Date of Publication:	

Base

Question Type:	Application	Application Number:	
Food Sector Area:	Novel Foods application		
Applicant:	Chanelle McCoy CBD LTD	Requestor:	European Commission - DG SANCO

Subject/Subarea

Request for a scientific opinion on synthetic cannabidiol as a novel food (NF 2020/1670)	Application - Novel Foods application
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# UK's approach

## The UK Food Standards Agency (UK FSA) approach

- The UK FSA have adopted a slightly different approach to the EU Novel Food regulation
- They have set a clear deadline of the 31 March 2021 for all CBD product companies to have submitted a validated Novel Food application
- Brands not in compliance will be removed from sale after this date
- The UK FSA have published a list of products that can remain on the market from this date available on their [website](#)
- We at Pureis® are so please to announce that we appear **1<sup>st</sup> on this prestigious list** and may continue to sell our product on the UK market
- We recommend that consumer only buy CBD products listed as this assures a high quality safe CBD product

CBD Public List for Suppliers and Producers (updated 26/04/21)						
Product Name	Application Number	Manufacturer or supplier	Product ID or Barcode	Product/s linked to validated application	Product size/volume/quantity	Remarks
Pureis® Ultra Pure CBD Advanced Absorption Capsules, 10mg per day, 7 days	RP07	Chanelle McCoy Health	5060772900125	Primary	packs size 7s	Chanelle McCoy CBD LTD trading as Chanelle McCoy Health. Registration number 649492. Chanelle McCoy Health is listed as the supplier of the packaging of all of our products, we are a primary application- we are the brand owners of Pureis®
Pureis® Ultra Pure CBD Advanced Absorption Capsules, 10mg per day, 14 days	RP07	Chanelle McCoy Health	5060772900132	Primary	packs size 14s	Chanelle McCoy CBD LTD trading as Chanelle McCoy Health. Registration number 649492. Chanelle McCoy Health is listed as the supplier of the packaging of all of our products, we are a primary application- we are the brand owners of Pureis®
Pureis® Ultra Pure CBD Advanced Absorption Capsules, 10mg per day, 28 days	RP07	Chanelle McCoy Health	5060772900149	Primary	packs size 28s	Chanelle McCoy CBD LTD trading as Chanelle McCoy Health. Registration number 649492. Chanelle McCoy Health is listed as the supplier of

<https://www.food.gov.uk/business-guidance/cbd-products-linked-to-novel-food-applications>

# SUMMARIZED

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## OVERVIEW OF WHAT WE COVERED

- The implementation of EU and UK Novel Food regulations is a positive step in the right direction for the CBD market, as it aims to provide consumers with the necessary reassurance that they are receiving, high quality, fully certified CBD products
- Prior to implementation the CBD market was largely un-regulated, leading to poor quality and potentially harmful products being placed on the market
- Under this new regulatory landscape; CBD companies are now required to undergo extensive safety clinical studies assuring product quality and safety
- UK FSA have allowed companies with a validated Novel Food application by 31<sup>st</sup> March 2021 to remain on the market
- Pureis<sup>®</sup> Ultra Pure CBD is the 1st company to receive dual validation with EFSA and UK FSA. Pureis<sup>®</sup> is also the 1<sup>st</sup> to appear on the UK FSA's list of CBD companies to remain on the market.

# Thank You

Chanelle McCoy Health

#NewScience

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**pureis**<sup>®</sup>  
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