

### Updates to FSA policy on CBD products

THC safety update and CBD Public List policy change

### Agenda



Introduction to the FSA

Progress to date on CBD

THC safety update

Updates to the CBD Public List policy

Questions



#### The FSA and CBD

#### The Food Standards Agency





We are an independent government department working to protect public health and consumers' wider interests in relation to food. We make recommendations to Ministers.



Our role covers food safety and consumer interests in food, which include price, availability, and aspects of food production standards like environmental concerns and animal welfare.



Our work is underpinned by the latest science and evidence and agreed at our open Board meetings.

#### **Background on CBD**



CBD is a cannabinoid found within hemp and the cannabis plant or produced synthetically

In the UK, CBD food products are classed as a novel food

Novel foods must receive pre-market authorisation to have legal status

The FSA is operating a "Public List" of CBD products moving towards authorisation

The FSA is working towards recommending the first CBD products for authorisation

#### **CBD** consumer guidance



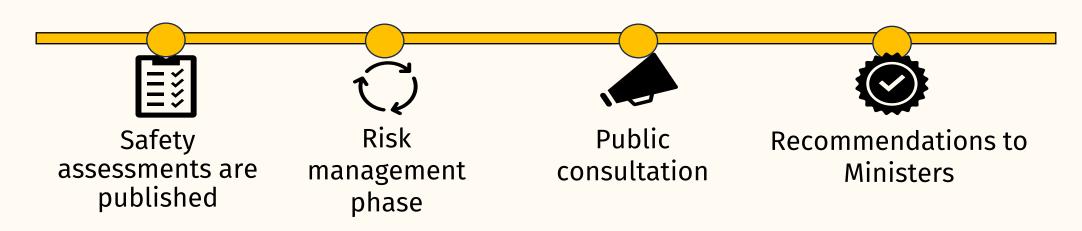


- We continue to recommend that healthy adults should limit their consumption of CBD from food to 10 mg per day - the provisional Acceptable Daily Intake (ADI)
- We continue to advise that under-18s, people taking medication, and those who are breast feeding, pregnant or trying to conceive do not consume CBD

# Progress towards first potential authorisations



- 11 safety assessments have been published to date
- Very close to launching public consultation on the first set of applications for authorisation



### **Important**



- The following information is embargoed
- We will announce these changes in our online business guidance and to the media on 1 July 2025



# **THC Safety Statement**

### Introduction



- What is the THC Safety Statement?
- Tetrahydrocannabinol (THC)
- Reasons for conducting the work
- The aim of the THC Safety Statement
- How the work was conducted
- Safe Upper Limit and impact of the statement

Joint position paper from the Advisory Committee on Novel Foods and Processes (ACNFP) & Committee on Toxicity (COT) on establishing a Safe Upper Limit for delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) and its precursor as contaminants of hemp-derived products including CBD novel foods.

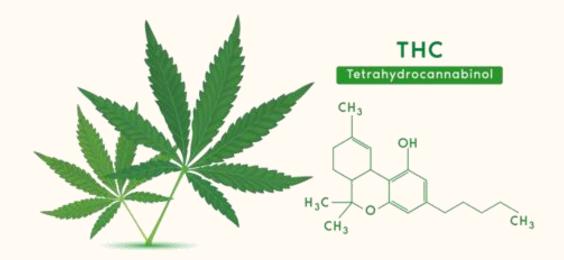
#### **Executive summary**

1. A joint Subgroup of the ACNFP and COT was formed to address a series of over-arching questions in relation to the safety of hemp-derived ingredients and cannabidiol (CBD). The primary aim of the Subgroup is to enable the Food Standards Agency (FSA) to perform risk assessments for CBD and other minor cannabinoids in food. One such minor cannabinoid found within hemp-derived ingredients and CBD novel food products, as an incidental contaminant, is tetrahydrocannabinol (THC), which exists naturally in hemp (Cannabis sativa Linnaeus) as various isomers. Concerns have been raised specifically around delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) in foods due to its physiological and psychoactive effects, observed after consumption at quite low doses. THC is a controlled





- Cannabinoid found in Hemp (Cannabis sativa)
- THC exists in multiple forms
  - Δ-9-Tetrahydrocannabinol (Δ9-THC)
  - Δ-8-Tetrahyrocannabinol (Δ8-THC)
  - Δ-9-Tetrahydrocannabinolic acid (Δ9-THCA)
- Widely known as a recreational substance
- It has psychoactive and physiological effects





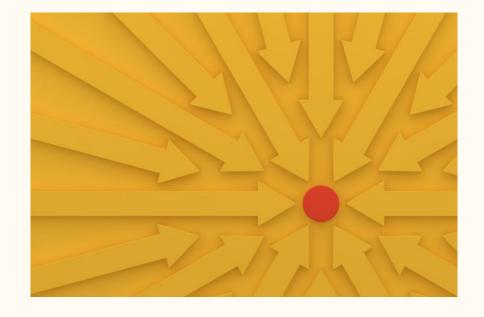


- It is a contaminant found in CBD novel foods
- Known health effects from consumption
- No established Safe Upper Limit
- Opinions/guidance on THC from other authorities available

### Aim of the statement



- To establish a Safe Upper Limit
- Outline the evidence and approach used
- To remain consistent with other authorities on advice
- To be used to inform risk assessments



### Methodology



- Initiated as part of ongoing CBD novel food assessments
- Advisory Committee on Novel Foods and Processes Committee on Toxicity joint subgroup.
- Literature review
  - Scientific opinion on the risk for human health related to the presence of THC in milk and other food of animal origin – European Food Safety Authority (EFSA)
  - Advisory Council on the Misuse of Drugs (ACMD) advice on consumer CBD products
  - Clinical trial data
  - Other relevant publicly available literature

### **Safe Upper Limit**



- Safe Upper Level established:
  - 1 µg/kg body weight/day (0.07 mg/day for a 70 kg adult)
- Based on most sensitive effects:
  - Cognitive effects
  - Tachycardia
- Lowest observed adverse effect (LOAEL) identified:
  - 0.036 mg/kg bw/day

#### **Impact**





All applied in CBD novel food assessments that are published and will continue for the future



Provides evidence to the public



Supports regulatory decisions



Ensures consumer safety



### CBD Public List Update

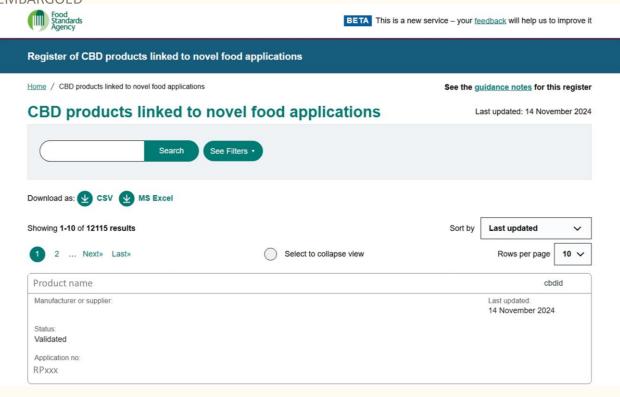
## What is the CBD Public List?

A list of CBD products that are associated with progressing novel foods applications for market authorisation

Created to enable CBD products to stay on the market after novel food status determined. It is a temporary measure

Applies in England and Wales

Any products which are not on the list, or are marked as 'Removed', must be withdrawn from the market



# What is the status of products on the List?



- 8147 Validated: application contains all information required to proceed through the risk assessment process
- 3307 Awaiting evidence: applications that have not been validated but are progressing
- 661 Removed: products may be removed for multiple reasons, including that an application has not made sufficient progress towards validation



# What is our current policy for products on the List?



- The List was intended to freeze the market as it was in 2021 whilst CBD applications make their way through our system
- We have not allowed new products to be added or allowed any major changes to listed products
- We remove products from the List where we are made aware that they exceed the legal Home Office 1 mg THC per container limit

# Why are we updating our policy now?



- The THC safe upper limit has set a new standard. We recognise that businesses may want to reformulate their products to be within recommended CBD and THC limits
- The first potential authorisations will follow high safety standards
- We want to make it easier for businesses to meet our standards and do the right thing
- We want consumers to have access to more products that meet our recommended standards

### Permitted product changes 1



1. Limited reformulation: Products on the list are permitted to reformulate to meet our safety standards on cannabinoid levels



We encourage suppliers to reformulate where necessary so that:

Product doses do not exceed 10 mg CBD per day

Product doses do not exceed 0.07mg (70 μg) THC per day

# How will reformulation work for businesses on the List?



Consider if reformulation to reduce CBD and/or THC levels is possible or appropriate for your products

Consider if the reformulation changes the product details on the list, e.g. the name includes the quantity of CBD

If list details need to be changed, contact the FSA

If not, products
may be
reformulated
without
contacting the
FSA

# What reformulations are allowed?



#### Reformulations are permitted for safety reasons only

- Examples include reduction in the amount of CBD and/or THC ingredient in the end product through dilution or reduction in the amount that makes up a single portion
- Products on the List must still use CBD ingredients that meet their associated novel food application composition, production process and specification
- Any products that do not meet their associated application specification will not be covered by the potential authorisation

# How will List changes be made?



- We will make administrative updates to the List where necessary, e.g. a change of product name to reflect the CBD quantity
- We recognise that companies may need to change suppliers to reformulate, which we would permit and reflect on the List where appropriate
- We will require a statement that the changes were for safety reasons
- We will update the List at least every four months

### Permitted product changes 2



2. Limited relabelling: All businesses are now encouraged to display our consumer advice on their product labels





This includes the following, which we will outline in our guidance:

The amount (or size) of CBD per serving

The 10 mg/day CBD maximum ADI

Warnings for vulnerable groups

#### Are these changes mandatory?



We will not mandate these changes for products on the List

CBD products exceeding the provisional ADI or the THC safe upper limit can remain on the List (products must not exceed the 1 mg THC per container limit)

It is our **expectation** that businesses move to meet our standards as best practice

Local Authorities will be aware of our advice and will still be responsible for enforcement

### Benefits of the policy update





Businesses that want to meet our standards can do the right thing



Increased consumer choice for products that meet our standards



Harmonisation of standards with potentially authorised products



Supports safe consumer habits through labelling



Act of good faith between industry and regulator

#### What is the future outlook?



#### Authorisations:

- If the first potential CBD foods are authorised, products with the CBD ingredient must meet high safety standards as set out in the Terms of Authorisation
- The Terms of Authorisation will include what types of CBD products the CBD ingredient is allowed in
- It is possible that products will need to reformulate or relabel to comply with their potential future Terms of Authorisation
- **Safety assessments**: We plan to continue working through the safety assessments of all CBD applications individually
- **The List**: We intend to maintain the List until all associated applications have been processed

### Summary of policy update



From **1 July 2025**, the FSA will permit and encourage limited changes to existing CBD products on the List for safety whilst novel food applications progress:

- 1) Limited reformulation to meet our safety standards, particularly on CBD and THC levels
- 2) Limited relabelling to display our consumer advice on product labels, including the 10 mg provisional ADI and warnings for vulnerable groups

### Where will you find this information?



FSA CBD Business guidance webpage: <u>Cannabidiol (CBD) guidance for England and Wales | Food Standards Agency</u>

THC Safety Statement: <a href="https://acnfp.food.gov.uk/Statements">https://acnfp.food.gov.uk/Statements</a>

FSA news story: <u>Food Standards Agency updates guidance allowing CBD</u> <u>businesses to reformulate products on the Public List for safety reasons |</u> <u>Food Standards Agency</u>

Contact the CBD Public List email: <a href="mailto:cbdpubliclist@food.gov.uk">cbdpubliclist@food.gov.uk</a>



### Thank you