Consultation on applications for authorisation of 3 Cannabidiol (CBD) food products as novel foods August 2025

Date of publication: 28 August 2025

Document subject and purpose

In this document we publish the Food Standards Agency (FSA) risk management recommendations for 3 CBD food products as novel foods.

Our risk assessors deliver the science behind our advice and publish their safety assessments, links to which are available within each recommendation annex. Risk assessors are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure.

The risk management recommendations consider any safety assessments as well as potential impacts that may result from the authorisation of these applications. They also consider other legitimate factors that ministers may want to consider before making a decision on authorisation of these applications.

The final FSA recommendations that are made to ministers in England, Wales and Northern Ireland will consider stakeholders' views received from this consultation.

Annexes to Risk Management Recommendations

Annex A: RP 7, Synthetic cannabidiol (CBD) (new authorisation of a novel food)

Annex B: RP 350, cannabidiol (CBD) isolate, (new authorisation of a novel food)

Annex C: RP 427, Isolated cannabidiol (CBD) derived from hemp (Cannabis sativa), (new authorisation of a novel food)

Annex A: RP 7, Synthetic cannabidiol (CBD) (new authorisation of a novel food)

Background

In accordance with assimilated Regulation 2015/2283 on novel foods, the application RP 7 for Synthetic cannabidiol (CBD), was received from Chanelle McCoy CBD Ltd.

The subject matter of this application is Synthetic CBD which is a highly pure ingredient produced by chemical synthesis in a multi-step process. The novel food is a synthetic purified white to slightly beige crystalline powder of 100% ± 2% purity.

The applicant sought authorisation for intended use as a food supplement for adults in the form of an oil sold as capsules and drops at the dose of 10 mg/day of CBD.

FSA Risk Management Recommendation RP7 – Synthetic Cannabidiol

Introduction

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain (GB), an application shall be submitted in accordance with assimilated Regulation (EU) 2015/2283[1]. The following articles for submission are to be used:

- Article 4 for novel food consultation process
- Article 10 for novel foods administrative and scientific requirements
- Article 14 for traditional foods from third countries

The following novel food application has been submitted to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) for authorisation in GB, where the authorisation is laid down in law by respective ministers in England, Wales and Scotland.

Safety Assessment Summary

- An application was submitted to the FSA and FSS in January 2021 from Chanelle McCoy CBD Ltd (“the applicant”) for the authorisation of synthetic cannabidiol (CBD) as a novel food. The novel food is a synthetic >98% pure form of CBD which is intended to be used in food supplements for adults. The FSA and FSS concluded that the applicant had provided sufficient information to assure the novel food, synthetic CBD, was safe under the proposed conditions of use. The anticipated intake levels and the proposed use in food supplements were not considered to be nutritionally disadvantageous.

- A provisional acceptable daily intake (ADI) of 10 mg/day for CBD was published by the FSA and was considered in assessing this novel food. The provisional ADI was recommended, subject to the existing advice to consumers that pregnant and

[1] https://www.legislation.gov.uk/eur/2015/2283/contents

breastfeeding women and people taking any prescription medication should avoid the consumption of CBD. Consumers on regular medications should seek advice from a medical professional before using any type of CBD food product. In addition, prospective parents trying for a baby and children are advised against consumption of CBD, as are those who are immunosuppressed, due to remaining data gaps and residual uncertainties concerning the safety of CBD for these groups of consumers. These contraindications would al

- so apply to this novel food.

- The FSA and FSS did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the food is safe and not putting consumers at a nutritional disadvantage. The FSA/FSS safety assessment for RP07 was published on 29/04/2024 and can be found here: **Safety Assessment: Synthetic Cannabidiol (CBD) as a novel food for use in food supplements**

- The safety assessment concluded that a weight of evidence approach was used to arrive at a provisional ADI of 10 mg/day (0.15 mg/kg bw/day). The most sensitive human health effects, that this provisional ADI protects against, are seen consistently in the liver and thyroid in a number of studies using >98% pure CBD. This value also takes account of the lack of human-based long-term evidence as well as evidence regarding potentially vulnerable groups, which is applied here for this synthetic CBD. The maximum safe exposure for healthy adults of 70kg, as identified in the provisional ADI, is 10 mg/day. If the inclusion level of this synthetic CBD leads to an intake per individual serving of each product type of 10 mg/day, only one serving per day should be consumed to ensure the provisional ADI is not exceeded. If consumers choose to consume CBD from multiple sources, consumers should ensure their exposure is kept to a minimum below the provisional ADI.

- THC is a controlled substance present in the Cannabis plant and can be present at low levels in CBD. THC was detected at levels at or below 0.02 % (w/w) of CBD in all six batches tested. The safety assessment confirmed that the levels of THC in the novel food, once adjusted to take account of the proposed uses – 10 mg of CBD being consumed a day, were below the acute reference dose (ARfD) identified by

EFSA of 1 µg/kg bw/day or 70 µg/day for a healthy adult. This level does not present a concern in terms of consumer safety for the novel food under the proposed conditions of use. To ensure THC levels remain consistently low in the production of CBD, THC should be a standard substance included in the specification as relevant to all batches produced.

Any Relevant Provisions of assimilated law

- Assimilated Regulation (EU) No 1169/2011[2] of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers includes provisions for consumer information on food products, such as labelling. More information on the specific provisions has been included in the labelling section below.

- The application applies to Great Britain only. The Food Supplements Regulations (England) 2003[3], Food Supplements Regulations (Wales) 2003[4], Food Supplements Regulations (Scotland) 2003[5] are the relevant regulations in Great Britain. These regulations broadly provide the rules for marketing food supplements in each jurisdiction. Regulation 2 provides a definition of a food supplement. The requirements in these regulations are relevant to the proposed food category of "food supplements" and the marketing of the novel food as a food supplement must be in compliance with these regulations.

TOA

The proposed terms of authorisation (TOA) are set out below

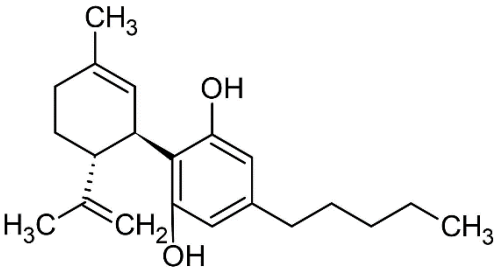
Authorised Novel Food	***Conditions under which the novel food may be used***		***Additional specific labelling requirements***	***Other requirements***	***Data protection***
	Specified food category	***Maximum levels***			

[2] https://www.legislation.gov.uk/eur/2011/1169/contents
[3] https://www.legislation.gov.uk/uksi/2003/1387/contents,
[4] https://www.legislation.gov.uk/wsi/2003/1719/contents
[5] https://www.legislation.gov.uk/ssi/2003/278/contents

Authorised Novel Food	***Conditions under which the novel food may be used***		***Additional specific labelling requirements***	***Other requirements***	***Data protection***
Synthetic cannabidiol (CBD)	Food Supplements as defined in Food Supplements (England) Regulations 2003 and The Food Supplements (Wales) Regulations 2003 for persons 18 years or over excluding pregnant or breastfeeding women or men or women trying to conceive.	In accordance with the acceptable daily intake of 10 mg/day CBD	The designation of the novel food on the labelling of food containing it must be “Synthetic cannabidiol (CBD).” Food supplements containing the novel food must bear the statements “Not suitable for use by persons under the age of 18.” “Not suitable for use during pregnancy or breastfeeding or for males and females trying to conceive.” “If you are taking any medications or are immunosuppressed, please consult a healthcare professional before using this product.” “The maximum acceptable daily intake (ADI) of CBD for an adult is 10 mg per day. If you consume a CBD product that		Authorised on XX Month 20XX. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Chanelle McCoy CBD LTD, Chanelle House, Barrack Street, Loughrea, Co. Galway, H62 YX07, Ireland. During the period of data protection, the novel food is authorised for placing on the market within [relevant jurisdiction] by Chanelle McCoy CBD Ltd., unless a subsequent

Authorised Novel Food	***Conditions under which the novel food may be used***		***Additional specific labelling requirements***	***Other requirements***	***Data protection***
			has an individual serving of 10mg/day, only one product type per day should be consumed to ensure the ADI is not exceeded. Multiple intakes of products containing CBD on the same day should be avoided." The labelling of food, including food supplements, containing the novel food shall bear instructions for use for the final consumer so that the acceptable daily intake of 10mg is not exceeded, including an expected portion size or dose, and the amount of CBD in that individual portion or dose.		applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Chanelle McCoy CBD Ltd. The data protection will expire at the end of [5 years after authorisation].

Specifications

Authorised Novel Food	*Specifications*
Synthetic cannabidiol (CBD)	**General description:** Synthetic cannabidiol is a white to slightly beige powder produced by chemical synthesis. **Definition / Chemical name:** Synthetic cannabidiol (CBD) is a highly pure ingredient produced by chemical synthesis in a stereoselective multi-step process. The primary starting materials, olivetol and menthadienol undergo mixing, filtration, and distillation steps with catalysts present, resulting in the formation of the desired synthetic >98% pure CBD form. 2-[(1R,6R) -3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl] -5-pentylbenzene-1,3-diol **Chemical Formula:** $C_{21}H_{30}O_2$ **Chemical Structure:**  **Molecular Mass:** 314.46 (g/mol) **CAS number:** 13956-29-1 **Purity:** Cannabidiol (CBD) (%): ≥98

Authorised Novel Food	*Specifications*
	Delta-9-tetrahydrocannabinol (Δ9 -THC) (%): ≤0.02 Individual unspecified impurities (%): ≤0.1 Total impurities (%): ≤1.0 **Residual solvents (ppm):** Methanol: ≤300 n-Heptane: ≤500 Dichloromethane: ≤60 Triethylamine: ≤500 Isopropanol: ≤500 Isooctane: ≤500

Proposed uses

- Covered above

Labelling

The novel food is subject to the general labelling requirements laid down in assimilated Regulation (EU) 1169/2011. This regulation sets out the general requirements for food labelling, such as the mandatory particulars for labelling, allergen labelling and use by/best before dates. You can find more information on food labelling here.

Additionally, food supplements must also comply with the Food Supplements Regulations (England) 2003 and the Food Supplements Regulations (Wales) 2003.

These regulations set out additional requirements for products marketed as food supplements, covering aspects such as dose size and labelling.

The labelling provisions set out in Regulations 6 and 7 of the Food Supplements Regulations (England) 2003 and the Food Supplement Regulations (Wales) 2003 set out the requirements for labelling of food supplements and the manner of marking or labelling of the end products for the ultimate consumer.

Regulation 6(2) requires that food supplements are marked or labelled with the following particulars:

a) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;

b) the portion of the product recommended for daily consumption;

c) a warning not to exceed the stated recommended daily dose;

d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

e) a statement to the effect that the product should be stored out of the reach of young children; and

f) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.

Regulation 7(1) requires that these particulars appear:

a) on the packaging;

b) on a label attached to the packaging; or

c) on a label which is clearly visible through the packaging.

Transitional requirements/ provisions

N/A

Further explanation/ Rationale

TOA/ Specifications/proposed uses

Novel food name: Synthetic cannabidiol (CBD)

Naming (in ingredients list):

- The name originally applied for by the applicant was *'Synthetic cannabidiol (CBD).'*

- The FSA considered many options such as *'Cannabidiol'* but noted that this would not have a reference to if the cannabidiol is made from extract, isolate or synthetically. Such differentiation may be important on an ingredients list for consumers information

- The FSA considered that including *'(CBD)'* would help consumers recognise the ingredient by its common name.

Specified food category

The FSA considered if the definition should be 'Food Supplements as defined in Food Supplements (sold as capsules, liquids and drops)' **or** 'Food Supplements as defined in Food Supplements.' The FSA has concluded that a reference to the form in which supplement is prepared is not required to be included in the designation of the food category to which the novel food is to be added.

The Food Supplements Regulations (England) 2003 and the Food Supplement Regulations (Wales) 2003 already require food supplements to be sold in dose form and subsequently define such forms as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities. Food supplements containing the novel food must be sold in dose form in order to meet the definition and therefore the permitted use.

THC as a contaminant

- THC, as a potential contaminant in the novel food, was detected at levels at or below 0.02 % (w/w) CBD in all 6 batches tested. The safety assessment confirmed that the levels of THC in the novel food, once adjusted to take account the proposed uses – 10 mg of CBD being consumed a day, were below the acute reference dose (ARfD) identified by EFSA of 1 µg/kg bw/day or 70 µg/day for a healthy adult. This level does not present a concern in terms of consumer safety for the novel food under the proposed conditions of use.

- To ensure THC levels remain consistently low in the production of CBD for the protection of consumers, THC should be a standard substance included in the specification as relevant to all batches produced. We have therefore proposed a level of 0.02% (w/w). We are proposing to lower the THC level in the specification in line

with the results in the CoA for batch testing, applying the as low as reasonably possible (ALARA) principle for the further protection of consumers. Noting that 0.02% is the limit of detection.

- Under drugs law, CBD products must not contain more than 1mg of THC per container. This limit is set by the Misuse of Drugs Regulations (2001) which outlines the criteria for "exempt products". CBD products which contain THC (even at trace levels) must be able to meet the definition of an exempt product.

Residues of solvents or processing aids

- The safety assessment stated that the ACNFP considered whether the use of solvents as processing aids left any residues that needed to be flagged to risk managers. Comparison was made to residue limits for other consumed products. The evidence presented on composition indicates compliance with the specification for residues of solvents. When considered at the level of consumption the evidence suggests the levels of solvent residues in the novel food are below those which would represent a safety concern.

- Not all solvents are extraction solvents and are therefore not subject to the requirements of Part 3 and Schedule 6 to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013[6] and the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales)[7]. Only extraction solvents are subject to these regulations. Other solvents that are permitted for use have their maximum levels set via the terms of authorisation for the novel food.

- In the original specifications of the novel food, the applicant specified residual solvent levels in accordance with the EMA guideline on residual solvents[8] but their batch results were consistently 10-fold lower than safe maximum levels, therefore, we propose to use the results from batch testing to keep the contaminant levels as low as reasonably possible. Original solvent concentrations in applicant submitted specifications are detailed below and the proposed levels are reported in the Specifications table in the Terms of Authorisation.

[6] https://www.legislation.gov.uk/uksi/2013/2210/contents
[7] https://www.legislation.gov.uk/wsi/2013/2591/contents
[8] Q3C (R8) Step 5 - impurities: guideline for residual solvents (europa.eu)

Residual solvents (ppm)

Methanol: ≤3000

n-Heptane: ≤5000

Dichloromethane: ≤600

Triethylamine: ≤5000

Isopropanol: ≤5000

Isooctane: ≤5000

Heavy metal and microbiological contaminants

- Analytical data, presented as the mean of 3 independent batches of the novel food, demonstrated that heavy metals were present in very low levels and were below established UK regulatory limits where applicable (arsenic, cadmium, mercury, and lead). Analytical data concerning the microbiological content from 3 independent batches of the novel food were reported in the safety assessment. The process in manufacturing this novel food uses extreme high and low temperatures, harsh pH conditions and alcohol solvents. Full microbial risk assessment confirmed that the novel food does not raise a safety concern and consistently meets the proposed microbial specification levels. The safety assessment concluded, following discussion with the applicant, that information on microbiological and heavy metal limits did not need to be included in the specification to appropriately characterise the novel food. No specific recommendations were made to amend the specification. Mycotoxin levels were not provided but are not considered a safety concern for this synthetically produced novel food.

- The FSA recommendation is not to include heavy metal and microbiological safety specifications in the proposed TOA of synthetically produced CBD as they have been consistently low in batch testing and fall below the limits that pose a safety concern.

Heavy metals, minerals, and trace elements / Maximum concentration measured (mg/kg):

- Arsenic Not more than 0.1 mg/kg
- Cadmium Not more than 0.1 mg/kg
- Mercury Not more than 0.1 mg/kg
- Lead Not more than 0.1 mg/kg
- Cobalt Not more than 0.1 mg/kg
- Nickel Not more than 0.2 mg/kg
- Vanadium Not more than 0.1 mg/kg

- Silver Not more than 0.1 mg/kg
- Gold Not more than 0.2 mg/kg
- Iridium Not more than 0.1 mg/kg
- Osmium Not more than 0.7 mg/kg
- Palladium Not more than 0.1 mg/kg
- Platinum Not more than 0.1 mg/kg
- Rhodium Not more than 0.1 mg/kg
- Ruthenium Not more than 0.1 mg/kg
- Selenium Not more than 0.1 mg/kg
- Thallium Not more than 0.1 mg/kg
- Barium Not more than 1 mg/kg
- Chromium (III) Not more than 0.1 mg/kg
- Copper Not more than 0.1 mg/kg
- Lithium Not more than 0.1 mg/kg
- Molybdenum Not more than 0.4 mg/kg
- Antimony Not more than 0.1 mg/kg
- Tin Not more than 0.1 mg/kg

- ***Microbial:***
- Total aerobic microbial plate count Not more than 100 CFU/g
- Total yeast and mould plate count Not more than 100 CFU/g

Other specifications not included in the TOA:

- In the Safety Assessment, Table 6 lists additional specifications of the novel food. The FSA recommendation is to not include these in the specification table as per previous novel food authorisations in the legislation. The FSA recommendation is to only include the specifications relating to the purity of the novel food, residual solvents, contamination with THC as mentioned above, and include the percentage of other impurities if it is specified by the applicant in the dossier and considered by the safety assessment.

List of ingredients and allergen labelling

- There are no allergens in this product. The safety assessment determined that the synthetic CBD is unlikely to trigger allergic reactions in the target population under the proposed conditions of use.

Stability / Use by / Best before

- The stability of the synthetic CBD was assessed in the safety assessment under real-time conditions and under refrigerated conditions in 3 batches for 3 months, in a further 3 batches for 6 months and another 3 batches for 9 months. Results showed that the novel food meets the specification criteria for CBD content, and no changes in appearance, water content and impurity levels are seen over these time periods.

The THC content was also tested and remained consistently below 0.05% w/w across the time period which is below the 0.10% w/w in the specification. The stability of the synthetic CBD was assessed under accelerated conditions in 6 batches over a maximum period of 9 months. Results confirmed that the novel food meets the specification criteria for CBD content and no changes in appearance, water content and impurity levels are seen over these time periods over this time period. The data provided supports the stability of the novel food for a period of at least 9 months.

Amendment to/ Revocations of current authorisations

- N/A

Labelling

- *General labelling requirements*
- Covered above
- *Additional labelling*
- Covered above

Transitional requirements/ provisions

- N/A

Post market monitoring

N/A

Definitions

- **Supplement** – Food Supplements are defined in the Food Supplements (England) Regulations 2003 and The Food Supplements (Wales) Regulations 2003 as:
    - “food supplement” means any food the purpose of which is to supplement the normal diet and which—

a. is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and

b. is sold in dose form[9]

Other Legitimate Factors

Economic

- A full impact assessment has been deemed not necessary.

Consumer interests

- The FSA conducted dedicated research into the behaviours and attitudes of CBD extracts users to better understand how they use CBD and whether they are aware that it is classified as a “novel food”. This research was conducted in 2019 and published in 2020[10].

- This research is supplemented by data from the FSA’s consumer insights tracker (latest data December 2024[11]).

- The latest data from the FSA's consumer insights tracker indicate that 12% of respondents have used or consumed CBD in the past 6 months.

- The FSA’s dedicated research indicates that over a third of CBD users say that they are reliant on it or that they would be bothered if they could no longer buy it.

- Respondents reported that the main reason they use CBD is for pain relief. They also reported that CBD helped relieve anxiety, aided relaxation and sleep, supported mental health and relieved depression.

- Around two thirds of respondents feel CBD has benefitted their overall health and / or helped them with a medical condition. The conditions that people are most likely to say it has helped them with are anxiety / stress relief, arthritis and back pain.

[9] Dose form” is defined as “a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities
[10] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/consumer-research-report-on-cannabidiol-cbd-extracts
[11] https://science.food.gov.uk/article/122705

- The FSA has a clear statutory duty to protect the interests of consumers with respect to food. The results of the FSA's own research demonstrates that access to CBD products is important to a significant number of consumers.

Political

- No other legitimate factors identified.

Legality

- The meaning of "food" is legally defined by Article 2 of assimilated Regulation (EC) No 178/2002. This definition excludes substances that are considered narcotic or psychotropic under the United Nations Single Convention on Narcotic Drugs 1961 and the United Nations Convention on Psychotropic Substances 1971(the Conventions). Despite CBD being an extract or a tincture of the Cannabis plant, it is not considered to fall under the Conventions as it does not have a psychotropic effect.

- The FSA considers CBD products that contain very low amounts of THC to be preparations that contain a narcotic/psychotropic substance rather than being a narcotic/psychotropic substance themselves. The application indicates that only trace residues of THC are present in the novel foods. The FSA and Home Office therefore regard CBD food products as foods and should be regulated under food law.

- CBD can contain trace levels of other cannabinoids, some of which are controlled drugs. This includes THC. The Misuse of Drugs Act (1971) (MDA) and the Misuse of Drugs Regulations (2001) (MDR) act as the implementing legislation for the control of controlled substances in the UK. Controlled substances are listed in Schedule 2 of the MDA. CBD is not contained within Schedule 2 of the MDA and is therefore not a controlled drug. THC, and other controlled cannabinoids, fall within Schedule 2 of the MDA. The MDA operates to render any product or preparation that contains a controlled substance as a controlled drug itself.

- Therefore, CBD containing any level of controlled cannabinoids is a controlled drug itself under the MDA. However, on the basis of the UN Conventions, the FSA has concluded that CBD is both a food under food law and a controlled drug under drugs law.

Wider application of drugs law

- Regulation 2 of the MDR sets out the “exempt product definition” (EPD). It is the Home Office view that the applicable unit of measurement (i.e. the component part of the product or preparation) for the 1mg ‘threshold’ referred to in Limb (c) is that of the container (such as a bottle of oil) and not (for example) the supposed typical dose (of any product).

- Products that meet the EPD will not be subject to the prohibitions on importation, exportation, production, supply, and possession under the MDA. Therefore, CBD products that received a novel foods authorisation would be able to remain on the market legally provided they met this definition. Where they do not meet the EPD, it is illegal to possess, supply, produce or export them.

Licences

- Those producing cannabis-derived products to which the EPD applies will require a domestic licence if their process involves cultivation of the cannabis plant (including hemp), handling the controlled parts of the plant in their separated form, and any production or handling of bulk CBD product to which the exempt product definition does not apply. These licences are granted by the Home Office and CBD businesses should ensure they have the correct licences in place if required.

Enforcement

- Under current legislation, local authority and district council officers are unable to lawfully take possession of CBD products which exceed the 1mg limit in the EPD as they would no longer be exempt from the prohibitions on importation, exportation, production, supply, and possession under the MDA. Non-exempt products can only be possessed with lawful authority (for which local authority and district council officers do not have under the MDR) or under a Home Office licence. Importation, exporting, producing, supplying, and possessing controlled drugs is a criminal offence. They must be removed from sale by being seized by the police, or voluntarily or in compliance with the condition of a notice and surrendered to the police. However, this can only be enforced (by seizure) by the police.

- Local authority enforcement officers will be able to make use of enforcement provisions contained within the Novel Food Regulations 2018 ahead of seizure such

as stop and improvement notices and fines whilst simultaneously requesting that the police make a seizure if required/ if it suspected the EPD is not met.

- To support local authorities in England and Wales, the FSA will develop guidance which will provide clarity on the application of food and drugs law to CBD food products. The guidance will set out what LAs are able do within food law in relation to CBD and when and how they should work with the police on matters that could fall under drugs law.

Impacts

Trade

EU

- This application has been submitted and validated as an application in the European Union: Application Number NF2020/1670, European Food Safety Authority (EFSA) Question Number EFSA-Q-2020-00257.

- In November 2020, the EU Court of Justice (Case C - 663/18)[12] ruled that CBD cannot be regarded as a narcotic drug, since CBD does not seem to have any psychotropic effects. This means that CBD can be qualified as food, specifically a novel food, and according to Regulation (EC) No 178/2002 and Regulation (EU) 2015/2283, foods, including novel foods, must be safe. Therefore, EFSA evaluated the health risks and based the conclusions in their opinions solely on the safety of CBD.

- In 2022, EFSA published a statement[13] on safety of CBD as a novel food and addressed data gaps and uncertainties. Their aim was to Identify the hazards of CBD and how they relate to physical, chemical, and pharmacological properties when used as food supplement and/or food ingredient. As a result, they provided an overview of the uncertainties and data gaps that need to be addressed before the safety assessment of applications for CBD as a novel food can be concluded. They highlighted:

[12] Case C-663/18 - REQUEST for a preliminary ruling under Article 267 TFEU from the Cour d'appel d'Aix-en-Provence (Court of Appeal, Aix-en-Provence, France)
[13] https://www.efsa.europa.eu/en/efsajournal/pub/7322

- a number of limitations of available studies, including high variation of mixtures used for toxicological studies,
- lack of information about the content and the identity of other components of these mixtures,
- the confounding factor of other medicines used concomitantly with CBD in involved patients,
- the difficulty to establish NOAEL as most human studies referred to the efficacy of Epidyolex®[14] at therapeutic doses, at which adverse effects were sometimes observed.

- The opinion also summarised the data gaps in the absorption, distribution, metabolism, and excretion of CBD. They stated that the matrix used, the form of the CBD and the food consumed at the same time could affect bioavailability with additional concerns about accumulation of CBD with time in animal studies but not enough evidence being available about what occurs at lower doses in humans and if that could increase potential harmful effects of CBD. Furthermore, evidence of interactions between CBD and neurological drugs has been presented with uncertainties about the scale of the effect of CBD on metabolism of other foods and drugs and vice versa.
- As a result of these uncertainties and data gaps on the effect of CBD on the liver, gastrointestinal tract, endocrine system, nervous system and on people's psychological well-being, EFSA has paused the safety assessment process in June 2022 whilst they wait for applicants to fill data gaps and have issued a statement advising how the additional information can be provided to help address the uncertainties.
- Since that time further data has become available, and this has informed the position in GB on 98% or above purity and the level at which it can be safely consumed.

[14] https://www.ema.europa.eu/en/medicines/human/EPAR/epidyolex

Northern Ireland

- Under the Windsor Framework, CBD food products approved as novel foods in GB will be able to be placed on the market in Northern Ireland, if eligible for, and moved through Northern Ireland Retail Movement Scheme (NIRMS). Under the terms of NIRMS, only pre-packed retail goods can be moved into Northern Ireland, so it would not be permitted for Northern Ireland based businesses to manufacture their own CBD products, but it would be legal for them to import premanufactured products from GB.

Risk Management Recommendation

- The FSA Risk Management recommendation is that Synthetic cannabidiol (CBD), as described in this application, does not, on the basis of the scientific evidence available, pose a safety risk to human health and the foods intended use does not mislead the consumer.

Annex B: RP 350, cannabidiol (CBD) isolate, (new authorisation of a novel food)

Background

In accordance with assimilated Regulation 2015/2283 on novel foods, the application RP 350 for cannabidiol (CBD) isolate was received from Cannaray Brands Ltd.

The subject matter of this application is CBD isolate which is a white crystalline powder of purity equal to or greater than 98%. The CBD isolate is manufactured from industrial hemp using a multi-step extraction process under controlled conditions.

The applicant sought authorisation for use as a food ingredient in food supplements, beverages, and confectionary.

FSA Risk Management Recommendations on RP350 – Cannabidiol (CBD) isolate

Introduction

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain (GB), an application shall be submitted in accordance with assimilated Regulation (EU) 2015/2283[15]. The following articles for submission are to be used:

- Article 4 for novel food consultation process
- Article 10 for novel foods administrative and scientific requirements
- Article 14 for traditional foods from third countries

The following novel food application has been submitted to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) for authorisation in GB, where the authorisation is laid down in law by respective ministers in England, Wales, and Scotland.

Safety Assessment Summary

- An application was submitted to the FSA and FSS in February 2021 from Cannaray Brands Ltd for the authorisation of CBD isolate as a novel food. The novel food is a >98% pure isolate CBD which is intended to be used as a food ingredient in food supplements, beverages, and confectionary for adults. The FSA and FSS concluded that the applicant had provided sufficient information to assure that the novel food, CBD isolate, was safe under the proposed conditions of use.

[15] https://www.legislation.gov.uk/eur/2015/2283/contents

The anticipated intake levels and the proposed use in food supplements was not considered to be nutritionally disadvantageous.

- A provisional acceptable daily intake (ADI) of 10 mg/day for CBD was published by the FSA and was considered in assessing this novel food. The provisional ADI was recommended, subject to the existing advice to consumers that pregnant and breastfeeding women and people taking any prescription medication should avoid the consumption of CBD. Consumers on regular medications should seek advice from a medical professional before using any type of CBD food product. In addition, prospective parents trying for a baby and children are advised against consumption of CBD, as are those who are immunosuppressed, due to remaining data gaps and residual uncertainties concerning the safety of CBD for these groups of consumers. These contraindications would also apply to this novel food.

- The FSA did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the food is safe and not putting consumers at a nutritional disadvantage. The FSA/FSS safety assessment for RP350 was published on 30/04/24 and can be found here **Safety assessment: Cannabidiol (CBD) isolate as a novel food for use in a range of food categories including food supplements | Food Standards Agency**

- The safety assessment concluded that a weight of evidence approach was used to arrive at a provisional ADI of 10 mg/day (0.15 mg/kg bw/day). The most sensitive human health effects, that this provisional ADI protects against, are seen consistently in the liver and thyroid in a number of studies using >98% pure CBD. This value also takes account of the lack of human-based long-term evidence as well as evidence regarding potentially vulnerable groups, which is applied here for this isolated CBD. The maximum safe exposure for healthy adults of 70kg, as identified in the provisional ADI, is 10 mg per day. If the inclusion level of this CBD isolate leads to an intake per individual serving of each product type of 10 mg/day, only one serving per day should be consumed to ensure the provisional ADI is not exceeded. If consumers choose to consume CBD from multiple sources, consumers should ensure their exposure is kept to a minimum below the provisional ADI.

- THC is a controlled substance present in the Cannabis plant and can be present at low levels in CBD. THC was not detected at levels at or above 0.004% (w/w) (the Limit of Quantification) of CBD in all five batches tested. The safety assessment confirmed that the levels of THC in the novel food, once adjusted to take account of the proposed uses – 10 mg of CBD being consumed a day, were below the acute reference dose (ARfD) identified by EFSA of 1 µg/kg bw/day or 70 µg/day for a healthy adult. This level does not present a concern in terms of consumer safety for the novel food under the proposed conditions of use. To ensure THC levels remain consistently low in the production of CBD, THC should be a standard substance included in the specification as relevant to all batches produced

Any Relevant Provisions of assimilated law

- Assimilated Regulation (EU) No 1169/2011[16] on the provision of food information to consumers includes provisions for consumer information on food products, such as labelling. More information on the specific provisions has been included in the labelling section below.

- The application applies to Great Britain only. The Food Supplements Regulations (England) 2003[17], Food Supplements Regulations (Wales) 2003[18], Food Supplements Regulations (Scotland) 2003[19] are the relevant regulations in Great Britain. These regulations broadly provide domestic rules on the rules for marketing food supplements in each jurisdiction. Regulation 2 provides a definition of a food supplement. The requirements in these regulations are relevant to the proposed food category of “food supplements” and the marketing of the novel food as a food supplement must be in compliance with these regulations.

[16] https://www.legislation.gov.uk/eur/2011/1169/contents
[17] https://www.legislation.gov.uk/uksi/2003/1387/contents,
[18] https://www.legislation.gov.uk/wsi/2003/1719/contents
[19] https://www.legislation.gov.uk/ssi/2003/278/contents

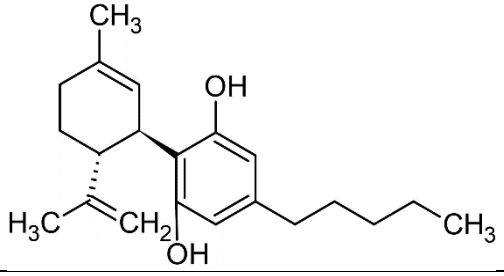
TOA

Authorised Novel Food	***Conditions under which the novel food may be used***		***Additional specific labelling requirements***	***Other requirements***	***Data protection***
	Specified food category	*Maximum levels*			
Cannabidiol (CBD) isolate from *Cannabis sativa*	Cocoa and Chocolate products as defined in the Cocoa and Chocolate Products (England) Regulations 2003, and The Cocoa and Chocolate Products (Wales) Regulations 2003 Other confectionery with added sugar or without added sugar Chewing gum CBD infused water	In accordance with the acceptable daily intake of 10 mg/day CBD	The designation of the novel food on the label of the food, including food supplements, containing it must be "Cannabidiol isolate (CBD) from *Cannabis sativa.*" Food, including food supplements, containing it must bear the statements "Not suitable for use by persons under the age of 18". "Not suitable for use during pregnancy or breastfeeding or for males and females trying to conceive." "If you are taking any medications or are	The amount of Cannabidiol (CBD) isolate from *Cannabis sativa* in the food must be indicated on the label of the food containing it. Food containing the novel food ingredient must be presented in such a manner that can be easily divided into portions that contain either a maximum of 10 mg of CBD or clearly marked portion size with a maximum of 10 mg per portion.	Authorised on XX Month 20XX. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Cannaray Brands Ltd, 76 Charlotte Street, 2nd Floor London, W1T 4QS, UK. During the period of data protection, the novel food is authorised for placing on the market within [relevant jurisdiction]

Authorised Novel Food	*Conditions under which the novel food may be used*		*Additional specific labelling requirements*	*Other requirements*	*Data protection*
	Fruit based drinks or fruit-flavoured drink Non-alcoholic flavoured drinks Food Supplements as defined in Food Supplements (England) Regulations 2003 and The Food Supplements (Wales) Regulations 2003 for persons 18 years or over excluding pregnant or breastfeeding women or men or women trying to conceive.		immunosuppressed, please consult a healthcare professional before using this product." "The maximum acceptable daily intake (ADI) of CBD for an adult is 10 mg per day. If you consume a CBD product that has an individual serving of 10mg/day, only one product type per day should be consumed to ensure the ADI is not exceeded. Multiple intakes of products containing CBD on the same day should be avoided." The labelling of food, including food supplements, containing the novel food shall bear instructions for use for the final consumer so that the acceptable daily intake of 10mg is not exceeded, including an expected portion size or dose, and		by Cannaray Brands Ltd., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Cannaray Brands Ltd. The data protection will expire at the end of [5 years after authorisation]."

Authorised Novel Food	*Conditions under which the novel food may be used*		*Additional specific labelling requirements*	*Other requirements*	*Data protection*
			the amount of CBD in that individual portion or dose.		

Specifications

Authorised Novel Food	*Specifications*
Cannabidiol (CBD) isolate from Cannabis sativa	General description: Cannabidiol isolate is a white crystalline powder free of particulates produced from industrial hemp by a multistep extraction process. Definition / Chemical name: Cannabidiol (CBD) isolate is a highly pure ingredient manufactured from industrial hemp through a multi-step extraction process. It starts with chipped or destemmed botanical material, which is extracted using ethanol and winterised to create a crude extract. This extract is refined into a high-potency distillate, then undergoes crystallisation to produce the pure CBD isolate. 2-[(1*R*,6*R)* -3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl] -5-pentylbenzene-1,3-diol Chemical Formula: $C_{21}H_{30}O_2$ Chemical Structure: 

Authorised Novel Food	*Specifications*
	Molecular Mass: 314.46 (g/mol) CAS number: 13956-29-1 Purity: Cannabidiol (CBD) (%): ≥98 Delta-9-tetrahydrocannabinol (Δ9 -THC) (%): ≤0.004 Delta-9-tetrahydrocannabinolic acid (Δ9 -THC A) (%): ≤0.032 Residual solvents (ppm): Pentane: ≤100 Acetone: ≤10 Isopropyl-Alcohol (2-propanol): ≤10 Ethanol: ≤50 Ethyl Acetate: ≤10 Hexane: ≤60 Benzene: ≤1

Proposed uses

- Covered above

Labelling

The novel food is subject to the general labelling requirements laid down in assimilated Regulation (EU) 1169/2011. This regulation sets out the general requirements for food labelling, such as the mandatory particulars for labelling, allergen labelling and use by/best before dates. You can find more information on food labelling here.

Additionally, food supplements must also comply with the Food Supplements Regulations (England) 2003 and the Food Supplements Regulations (Wales) 2003.

These regulations set out additional requirements for products marketed as food supplements, covering aspects such as dose size and labelling.

The labelling provisions set out in Regulations 6 and 7 of the Food Supplements Regulations (England) 2003 and the Food Supplement Regulations (Wales) 2003 set out the requirements for labelling of food supplements and the manner of marking or labelling of the end products for the ultimate consumer.

If the use of the novel food is within the specified food category of food supplements as defined by these regulations, the requirements in these regulations must be met.

Regulation 6(2) requires that food supplements are marked or labelled with the following particulars:

a) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;

b) the portion of the product recommended for daily consumption;

c) a warning not to exceed the stated recommended daily dose;

d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

e) a statement to the effect that the product should be stored out of the reach of young children; and

f) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.

Regulation 7(1) requires that these particulars appear:

a) on the packaging;

b) on a label attached to the packaging; or

c) on a label which is clearly visible through the packaging.

Transitional requirements/ provisions

N/A

Further explanation/ Rationale

TOA/ Specifications/ proposed uses

Novel food name: Cannabidiol (CBD) isolate from *Cannabis sativa*

Naming (in ingredients list):

- The name originally applied for by the applicant was *'Cannabidiol (CBD) isolate.'*
- The FSA considered many options such as '*Cannabidiol*' but noted that this would not have a reference to if the cannabidiol is made from extract, isolate or synthetically. Such differentiation may be important on an ingredients list for consumers information.

- The FSA considered that including *'(CBD)'* would help consumers recognise the ingredient by its common name.

- "from *Cannabis sativa*" has been included to specify that this product is an extract from the *Cannabis sativa* plant and has not been synthetically produced.

Specified food category

- The FSA considered if the definition should be 'Food Supplements as defined in Food Supplements (sold as capsules, liquids and drops)' **or** 'Food Supplements as defined in Food Supplements.'

- The FSA has concluded that a reference to the form in which supplement is prepared is not required to be included in the designation of the food category to which the novel food is to be added.
- The Food Supplements Regulations (England) 2003 and the Food Supplement Regulations (Wales) 2003 already require food supplements to be sold in dose form and subsequently define such forms as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities. Food supplements containing the novel food must be sold in dose form in order to meet the definition and therefore the permitted use.
- The applicant originally applied for the following proposed uses and categories:
    - Cocoa and Chocolate products as covered by Directive 2000/36/EC
    - Other confectionery with added sugar
    - Other confectionery without added sugar
    - Chewing gum with added sugar
    - Chewing gum without added sugar
    - Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packed waters
    - Fruit juices as defined by Directive 2001/112/EC

- Flavoured drinks with sugar
- Flavoured drinks with sweetener
- Food supplements as defined in Directive 2002/46/EC

- Whilst reviewing the above proposed categories, the FSA considered how and if the requested food categories met the definitions of and complied with wider legislation. Under the UK food compositional standards and labelling provisional common framework[20] the FSA has worked with other government departments in each nation to agree upon the amendments to the categories as required ahead of consultation.

- Regulation 6 of the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 and The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2007[21] ("the NMW Regulations") prohibits any addition to natural mineral water, other than the addition of carbon dioxide to produce sparkling mineral water. Mineral water that has been infused with CBD would not be compliant with this regulation and therefore cannot be marketed as "mineral water" or "natural mineral water".

- Regulation 6(2) of the NMW Regulations provides that natural mineral water can be used in the production of soft drinks. Once CBD is added it becomes a soft drink. "Mineral water" can and should be listed as an ingredient in the ingredients list, but the resulting product cannot be called "mineral water".

- Given that CBD added water does not have a legal name or customary name, a descriptive name would have to be used, for example, CBD water, CBD infused water or 'Cannabidiol' water. The product cannot be labelled as mineral water or natural mineral water as this would have the potential to mislead the consumer. Based on discussions with other government departments under the FCSL common framework, we are proposing to amend this food category to CBD infused water.

[20] https://www.gov.uk/government/publications/food-compositional-standards-and-labelling-provisional-common-framework
[21] https://www.legislation.gov.uk/uksi/2007/2785/contents; https://www.legislation.gov.uk/wsi/2007/3165/contents/made

- If CBD is added to Fruit juice, the product cannot be called “fruit juice, fruit juice from concentrate, concentrated fruit juice, water extracted fruit juice, dehydrated fruit juice, powdered fruit juice or fruit nectar” as this would not be in line with the requirements in Regulations 4 to 10 of The Fruit Juices and Fruit Nectars (England) Regulations 2013 and The Fruit Juices and Fruit Nectars (Wales) Regulations 2013[22] (“the Fruit Juice Regulations”). These names are legally reserved for products that meet the compositional requirements under these regulations.

- Under the Fruit Juice Regulations, only authorised ingredients can be added to fruit juice and CBD is not an authorised addition or ingredient. Once CBD is added to fruit juice, the product is no longer considered as ‘fruit juice’ as it would not meet the compositional standards under the Fruit Juice Regulations. Labelling the product as ‘fruit juice’ would be misleading under Article 7 of assimilated Regulation (EU) 1169/2011.

- The product can be labelled with a descriptive name of the fruit, for example, fruit based or fruit flavoured drinks. As the Fruit Juice Regulations do not prohibit the use of the name of the fruit on labels and “orange-flavoured drink” would be an example of a permissible name.

Proposed amendments to food categories:

- Water, including natural mineral water as defined in NMW Regulations and spring water and all other bottled or packed waters - this category has been amended to "CBD infused water". Where CBD is added to a Mineral or Spring water product, the resulting product would no longer be a Mineral or Spring Water product. This category has therefore been amended to water-based drinks so that CBD can be added to water-based drinks and marketed as such. Where CBD is added to a water product with no flavouring, this food category would apply.

- Fruit juices as defined by The Fruit Juice Regulations do not permit the addition of CBD in fruit juices. It is therefore not appropriate to include Fruit Juices as a food

[22] https://www.legislation.gov.uk/uksi/2013/2775/contents; https://www.legislation.gov.uk/wsi/2013/2750/contents;

category in the proposed Terms of Authorisation. This request has been amended to "fruit based drinks" and “fruit-flavoured drink”.

- Flavoured drinks category has been amended to “Non-alcoholic flavoured drinks.” Concerns were raised around the potential misuse of this category with alcoholic drinks as “flavoured drinks” are not defined in legislation. To mitigate this risk, the FSA has included “non-alcoholic” to narrow the definition.

- Consolidation - Some food categories have been consolidated where the application is for both *“with and without added sugar."*

Labelling

The FSA considered many options for the labelling for food categories and the rationale for additional labelling for food categories.

Other requirements of authorisation

The terms of authorisation include further “other requirements” for this application, as this applicant has applied for use in food supplements and a variety of food categories. The additional requirements are to ensure that the consumer is provided with sufficient information to enable them to make safe choices about consuming CBD food products in line with the ADI. FSA officials are in agreement that these requirements are reasonable and justified in relation to consumer safety and protection.

The proposed labelling and other requirements are consistent with other novel food authorisations and will ensure that businesses must make clear to consumers how much CBD is in a portion.

THC as a contaminant

- THC, as a potential contaminant in the novel food, was not detected at levels at or above 0.004 w/w CBD in all six batches tested. The safety assessment confirmed that the levels of THC in the novel food, once adjusted to take account the proposed uses – 10 mg of CBD being consumed a day, were below the acute reference dose (ARfD) identified by EFSA of 1 µg /kg bw/day or 70 µg/day for a healthy adult. This level does not present a concern in terms of consumer safety for the novel food under the proposed conditions of use.

- To ensure THC levels remain consistently low in the production of CBD for the protection of consumers, THC should be a standard substance included in the specification as relevant to all batches produced. We have therefore proposed a level of [0.004%w/w] in line with the applicants limit of detection. The applicant did not detect THC as specified in the Certificates of Analysis and the specification level can be considered to reflect a safe level of THC and within the detection limits. We are proposing to lower the THC level in the specification in line with the results in the CoA for batch testing, applying the as low as reasonably possible (ALARA) principle for the further protection of consumers. Noting that 0.004% is the limit of detection.

- Under drugs law, CBD products must not contain more than 1mg of THC per container. This limit is set by the Misuse of Drugs Regulations (2001) which outlines the criteria for "exempt products". CBD products which contain THC (even at trace levels) must be able to meet the definition of an exempt product.

Residues of solvents or processing aids

- The evidence presented on composition indicates compliance with the specification for residues of solvents. When considered at the level of consumption the evidence suggests the levels of solvent residues in the novel food are below those which would represent a safety concern. Not all solvents are extraction solvents and are therefore not subject to the requirements of Part 3 and Schedule 6 to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013[23] and the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013[24]. Only extraction solvents are subject to these regulations. Other solvents that are permitted for use have their maximum levels set via the terms of authorisation for the novel food.

- In the original specifications of the novel food, the applicant specified residual solvent levels in accordance with the EMA guideline on residual solvents[25] but their batch results were consistently 10-fold lower than safe maximum levels, therefore, we propose to use the results from batch testing to keep the

[23] https://www.legislation.gov.uk/uksi/2013/2210/contents
[24] https://www.legislation.gov.uk/wsi/2013/2591/contents
[25] Q3C (R8) Step 5 - impurities: guideline for residual solvents (europa.eu)

contaminant levels as low as reasonably possible. The applicant accepted these revisions with the exception of Pentane where they requested a max level of 100ppm. This is due to the difference in LOQ for internal vs external laboratories. The FSA has accepted this and revised the max level of pentane to 100ppm in the specification table. All solvent levels are reflected in the specification table.

- **Original solvent** concentrations in applicant submitted specifications are detailed below and the proposed levels are reported in the Specifications table in the Terms of Authorisation.

Solvent	Specification (ppm)
Ethanol	<1000
Pentane	<1000
Acetone	<1000
Isopropyl-Alcohol-(2-propanol)	<1000
Ethyl Acetate	<1000
Hexane	<60
Benzene	<1

Heavy metal and microbiological contaminants

- Analysis of five representative batches of CBD isolate found that the levels of heavy metals arsenic, cadmium, mercury, and lead were all below the limit of quantification (see below). These are lower than the established UK regulatory limits. Analysis of five representative batches of CBD isolate found that the levels of mycotoxins aflatoxins and ochratoxin A were also below the limit of quantification. The process in manufacturing this novel food involves checks on the hemp coming in, solvents and high temperatures. Full microbial risk assessment confirmed that the novel food does not raise a safety concern and consistently meets the proposed microbial specification levels.

- Analytical data concerning the microbiological content from one batch of the novel food was reported. The safety assessment concluded that since the data presented did not indicate any additional hazards for inclusion in the specification, microbial analysis is not a required parameter for inclusion in the specification of the CBD isolate. The FSA recommendation is not to include heavy metal,

mycotoxin or microbiological safety specifications in the TOA of ≥98% pure CBD as they have been consistently low in batch testing and fall below the limits that pose a safety concern.

Analysis of heavy metals, mycotoxins and microbiology that are not included in the TOA:

Heavy metals (mg/kg)	
Arsenic	<0.01
Cadmium	<0.005
Lead	<0.005
Mercury	<0.005
Mycotoxins (µg/kg)	
Aflatoxins total	≤4.0
Ochratoxin A	≤2.0
Microbial	
Escherichia coli (E. coli)	Absent / 10 g
Salmonella USP	Absent / 10 g
Staphylococcus aureus	Absent / 10 g
Aerobic Plate Count	<100 CFU/g
Yeast Count	<100 CFU/g
Mould Count	<100 CFU/g

Other specifications not included in the TOA:

- In the safety assessment, Table 6 lists additional specifications of the novel food. The FSA and FSS decision is to not include these in the specification table as per previous novel food authorisations in the legislation. Policy decision is to only include the specifications relating to the purity of the novel food, residual solvents, contamination with THC as mentioned above, and include the percentage of other impurities if it is specified by the applicant in the dossier and considered by the safety assessment. In the case of this CBD isolate, other impurities were not stated and do not form part of the specifications table.

List of ingredients and allergen labelling

- There are no allergens in this product. The safety assessment determined that the CBD isolate from Cannabis sativa is unlikely to trigger allergic reactions in the target population under the proposed conditions of use.

Stability / Use by / Best before

- The stability of the CBD isolate was assessed in the safety assessment under real-time conditions and under refrigerated conditions in 3 batches for 3 months, in a further 3 batches for 6 months and another 3 batches for 9 months. Results showed that the novel food meets the specification criteria for CBD content, and no changes in appearance, water content and impurity levels are seen over these time periods.

- The THC content was also tested and remained consistently below 0.004% w/w across the time period which is below the 0.10% w/w in the specification. The stability of the CBD isolate was assessed under accelerated conditions in six batches over a maximum period of 9 months. Results confirmed that the novel food meets the specification criteria for CBD content and no changes in appearance, water content and impurity levels are seen over these time periods over this time period. The data provided supports the stability of the novel food for a period of at least 9 months.

Amendment to/ Revocations of current authorisations

- N/A

Labelling

General labelling requirements

- Covered above

Additional labelling

- Covered above.

Transitional requirements/ provisions

- N/A

Post market monitoring

N/A

Definitions

- Supplement – Food Supplements are defined in the Food Supplements (England) Regulations 2003 and and The Food Supplements (Wales) Regulations 2003 as:

  - "food supplement" means any food the purpose of which is to supplement the normal diet and which—

(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and

(b) is sold in dose form[26].

Other Legitimate Factors

Economic

- A full impact assessment has been deemed not necessary.

Consumer interests

- The FSA conducted dedicated research into the behaviours and attitudes of CBD extracts users to better understand how they use CBD and whether they are aware that it is classified as a "novel food". This research was conducted in 2019 and published in 2020[27].

- This research is supplemented by data from the FSA's consumer insights tracker (latest data December 2024[28]).

- The latest data from the FSA's consumer insights tracker indicate that 12% of respondents have used or consumed CBD in the past six months.

- The FSA's dedicated research indicates that over a third of CBD users say that they are reliant on it or that they would be bothered if they could no longer buy it.

- Respondents reported that the main reason they use CBD is for pain relief. They also reported that CBD helped relieve anxiety, aided relaxation and sleep, supported mental health and relieved depression.

[26] dose form" is defined as "a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities

[27] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/consumer-research-report-on-cannabidiol-cbd-extracts

[28] https://science.food.gov.uk/article/122705

- Around two thirds of respondents feel CBD has benefitted their overall health and / or helped them with a medical condition. The conditions that people are most likely to say it has helped them with are anxiety / stress relief, arthritis and back pain.

- The FSA has a clear statutory duty to protect the interests of consumers with respect to food. The results of the FSA's own research demonstrates that access to CBD products is important to a significant number of consumers.

Political

- No other legitimate factors identified.

Legality

- The meaning of "food" is legally defined by Article 2 of Regulation (EC) No 178/2002. This definition excludes substances that are considered narcotic or psychotropic under the United Nations Single Convention on Narcotic Drugs 1961 and the United Nations Convention on Psychotropic Substances 1971 (the Conventions). Despite CBD being an extract or a tincture of the Cannabis plant, it is not considered to fall under the Conventions as it does not have a psychotropic effect.

- The FSA considers CBD products that contain very low amounts of THC to be preparations that contain a narcotic/psychotropic substance rather than being a narcotic/psychotropic substance themselves. The application indicates that only trace residues of THC are present in the novel foods. The FSA and Home Office therefore regard CBD food products as novel foods and should be regulated under food law.

- CBD can contain trace levels of other cannabinoids, some of which are controlled drugs. This includes THC. The Misuse of Drugs Act (1971) (MDA) and the Misuse of Drugs Regulations (2001) (MDR) act as the implementing legislation for the control of controlled substances in the UK. Controlled substances are listed in Schedule 2 of the MDA. CBD is not contained within Schedule 2 of the MDA and is therefore not a controlled drug. THC, and other controlled cannabinoids, fall within Schedule 2 of the MDA. The MDA operates to render any product or preparation that contains a controlled substance as a controlled drug itself.

- Therefore, CBD containing any level of controlled cannabinoids is a controlled drug itself under the MDA. However, on the basis of the UN Conventions, the FSA has concluded that CBD is both a food under food law and a controlled drug under drugs law.

Wider application of drugs law

- Regulation 2 of the MDR sets out the “exempt product definition” (EPD). It is the Home Office view that the applicable unit of measurement (i.e. the component part of the product or preparation) for the 1mg ‘threshold’ referred to in Limb (c) is that of the container (such as a bottle of oil) and not (for example) the supposed typical dose (of any product).

- Products that meet the EPD will not be subject to the prohibitions on importation, exportation, production, supply, and possession etc under the MDA 1971. Therefore, CBD products that received a novel foods authorisation would be able to remain on the market legally provided they met this definition. Where they do not meet the EPD, it is illegal to possess, supply, produce or export, etc. them.

Licences

- Those producing cannabis-derived products to which the EPD applies will require a domestic licence if their process involves cultivation of the cannabis plant (including hemp), handling the controlled parts of the plant in their separated form, and any production or handling of bulk CBD product to which the exempt product definition does not apply. These licences are granted by the Home Office and CBD businesses should ensure they have the correct licences in place if required.

Enforcement

- Under current legislation, local authority and district council officers are unable to lawfully take possession of CBD products which exceed the 1mg limit in the EPD as they would no longer be exempt from the prohibitions on supply and possession etc under the MDA. Non-exempt products can only be possessed with lawful authority (for local authority and district council officers do not have under the MDR) or under a Home Office licence.

- Importation, exporting, producing, supplying, and possessing etc controlled drugs is a criminal offence. They must be removed from sale by being seized by the police, or voluntarily or in compliance with the condition of a notice and surrendered to the police. However, this can only be enforced (by seizure) by the police.

- Local authority enforcement officers will be able to make use of enforcement provisions contained within the Novel Food Regulations 2018 ahead of seizure such as stop and improvement notices and fines whilst simultaneously requesting that the police make a seizure if required/if it suspected the EPD is not met.

- To support local authorities in England and Wales, the FSA will develop guidance which will provide clarity on the application of food and drugs law to CBD food products. The guidance will set out what LAs are able do within food law in relation to CBD and when and how they should work with the police on matters that could fall under drugs law.

Impacts

Trade

EU

- In November 2020, the EU Court of Justice (Case C - 663/18)[29] ruled that CBD cannot be regarded as a narcotic drug, since CBD does not seem to have any psychotropic effects. This means that CBD can be qualified as food specifically a novel food, and according to Regulation (EC) No 178/2002 and Regulation (EU) 2015/2283, foods, including NFs, must be safe. Therefore, EFSA evaluated the health risks and based the conclusions in their opinions solely on the safety of CBD.

- In 2022, EFSA published a statement[30] on safety of CBD as a novel food and addressed data gaps and uncertainties. Their aim was to Identify the hazards of CBD and how they relate to physical, chemical, and pharmacological properties when used as food supplement and/or food ingredient. As a result, they provided

[29] Case C-663/18 - REQUEST for a preliminary ruling under Article 267 TFEU from the Cour d'appel d'Aix-en-Provence (Court of Appeal, Aix-en-Provence, France)
[30] https://www.efsa.europa.eu/en/efsajournal/pub/7322

an overview of the uncertainties and data gaps that need to be addressed before the safety assessment of applications for CBD as a novel food can be concluded. They highlighted number of limitations of available studies, including high variation of mixtures used for toxicological studies, lack of information about the content and the identity of other components of these mixtures, the confounding factor of other medicines used concomitantly with CBD in involved patients and the difficulty to establish NOAEL as most human studies referred to the efficacy of Epidyolex®[31] at therapeutic doses, at which adverse effects were sometimes observed.

- The opinion also summarised the data gaps in the absorption, distribution, metabolism, and excretion of CBD. They stated that the matrix used, the form of the CBD and the food consumed at the same time could affect bioavailability with additional concerns about accumulation of CBD with time in animal studies but not enough evidence being available about what occurs at lower doses in humans and if that could increase potential harmful effects of CBD. Furthermore, evidence of interactions between CBD and neurological drugs has been presented with uncertainties about the scale of the effect of CBD on metabolism of other foods and drugs and vice versa.

- As a result of these uncertainties and data gaps on the effect of CBD on the liver, gastrointestinal tract, endocrine system, nervous system and on people's psychological well-being, EFSA has paused the safety assessment process in June 2022 whilst it waits for applicants to fill data gaps and has issued a statement advising how the additional information can be provided to help address the uncertainties.

- Since that time, further data has become available that has informed the position in GB on 98% or above purity and the level at which it can be safely consumed.

Northern Ireland

- Under the Windsor Framework, CBD food products approved as novel foods in GB can be moved into Northern Ireland through the Northern Ireland Retail Movement Scheme (NIRMS). NIRMS applies to pre-packed retail agri-food goods

[31] https://www.ema.europa.eu/en/medicines/human/EPAR/epidyolex

intended for final consumer sale. This includes retail goods containing novel foods, such as CBD products if authorised in GB.

Risk Management Recommendation

- The FSA risk management recommendation is that cannabidiol (CBD) isolate, as described in this application, is safe and is not liable to have an adverse effect on the target population, environmental safety, and human health at the intended concentrations of use.

Annex C: RP 427, Isolated cannabidiol (CBD) derived from hemp (Cannabis sativa), (new authorisation of a novel food)

Background

In accordance with assimilated Regulation (EU) 2015/2283 on novel foods, the application RP427 for Isolated cannabidiol (CBD) derived from hemp (Cannabis sativa), was received from EIHA projects.

The subject matter of this application is isolated cannabidiol (CBD) derived from hemp (Cannabis sativa), which is a highly pure ingredient produced by extraction from hemp (Cannabis sativa). This is dissolved and standardised to between 2.5% and 10% CBD concentration in hemp seed oil. The novel food is a purified colourless-to-yellow crystalline powder of 100% ± 2% purity.

The applicant sought authorisation for use as a food supplement in the form of an oil sold as capsules and drops at the dose of 10 mg per day of CBD.

FSA Risk Management Recommendations on RP427 - Isolated cannabidiol (CBD) derived from hemp *(Cannabis sativa)*

Introduction

For new novel foods and extensions of use to authorised novel foods to be placed on the market in Great Britain (GB), an application shall be submitted in accordance with assimilated Regulation (EU) 2015/2283[32]. The following articles for submission are to be used:

- Article 4 for novel food consultation process
- Article 10 for novel foods administrative and scientific requirements
- Article 14 for traditional foods from third countries

The following novel food application has been submitted to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) for authorisation in GB, where the authorisation is laid down in law by respective ministers in England, Wales and Scotland.

Safety Assessment Summary

- An application was submitted to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) February 2021 from EIHA Projects and associated product partners pertaining (“the applicant”) for the authorisation of Isolated cannabidiol (CBD)

[32] https://www.legislation.gov.uk/eur/2015/2283/contents

derived from hemp (Cannabis sativa) as a novel food, which is intended to be used as food supplements for adults. The novel food is an isolated >98% pure form of CBD extracted from Cannabis sativa which is intended to be used as food supplements for adults. The FSA and FSS concluded that the applicant had provided sufficient information to assure the novel food, isolated CBD, was safe under the proposed conditions of use. The anticipated intake levels and the proposed use in food supplements was not considered to be nutritionally disadvantageous.

- A provisional acceptable daily intake (ADI) of 10 mg/day for CBD was published by the FSA and was considered in assessing this novel food. The provisional ADI was recommended, subject to the existing advice to consumers that pregnant and breastfeeding women and people taking any prescription medication should avoid the consumption of CBD. Consumers on regular medications should seek advice from a medical professional before using any type of CBD food product. In addition, prospective parents trying for a baby and children are advised against consumption of CBD, as are those who are immunosuppressed, due to remaining data gaps and residual uncertainties concerning the safety of CBD for these groups of consumers. These contraindications would also apply to this novel food.

- The FSA did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the food is safe and not putting consumers at a nutritional disadvantage. The FSA/FSS safety assessment for RP427 was published on 15/08/24 and can be found here: **Safety Assessment on Isolated Cannabidiol (CBD) as a Novel Food for Use in Food Supplements (RP427) | Published in FSA Research and Evidence**

- The safety assessment concluded that a weight of evidence approach was used to arrive at a provisional ADI of 10 mg/day (0.15 mg/kg bw/day). The most sensitive human health effects, that this provisional ADI protects against, are seen consistently in the liver and thyroid in a number of studies using >98% pure CBD. This value also takes account of the lack of human-based long-term evidence as well as evidence regarding potentially vulnerable groups, which is applied here for this CBD isolate. The maximum safe exposure for healthy adults of 70kg, as identified in the provisional ADI, is 10 mg/day. If the inclusion level of this CBD isolate leads to an intake per individual serving of each product type of 10 mg/day, only one serving per day should

be consumed to ensure the provisional ADI is not exceeded. If consumers choose to consume CBD from multiple sources, consumers should ensure their exposure is kept to a minimum below the provisional ADI.

- THC is a controlled substance present in the cannabis plant and can be present at low levels in CBD. THC was detected at levels at or below 0.00001 % (w/w) of CBD in all five batches tested. The safety assessment confirmed that the levels of THC in the novel food, once adjusted to take account of the proposed uses – 10 mg of CBD being consumed a day, were below the acute reference dose (ARfD) identified by EFSA of 1 µg/kg bw/day or 70 µg/day for a healthy adult. This level does not present a concern in terms of consumer safety for the novel food under the proposed conditions of use. To ensure THC levels remain consistently low in the production of CBD, THC should be a standard substance included in the specification as relevant to all batches produced.

Any Relevant Provisions of assimilated law

- Assimilated Regulation (EU) No 1169/2011[33] of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers includes provisions for consumer information on food products, such as labelling. More information on the specific provisions has been included in the labelling section below.

- The application applies to Great Britain only. The Food Supplements Regulations (England) 2003[34], Food Supplements Regulations (Wales) 2003[35], Food Supplements Regulations (Scotland) 2003[36] are the relevant regulations in Great Britain. These regulations broadly provide the rules for marketing food supplements in each jurisdiction. Regulation 2 provides a definition of a food supplement. The requirements in these regulations are relevant to the proposed food category of “food supplements” and the marketing of the novel food as a food supplement must be in compliance with these regulations.

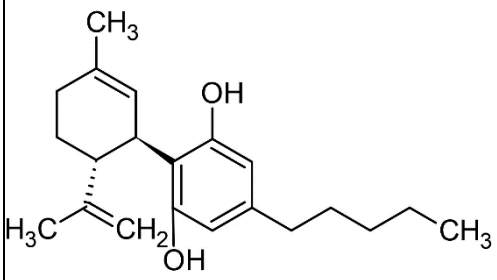
[33] https://www.legislation.gov.uk/eur/2011/1169/contents
[34] https://www.legislation.gov.uk/uksi/2003/1387/contents,
[35] https://www.legislation.gov.uk/wsi/2003/1719/contents
[36] https://www.legislation.gov.uk/ssi/2003/278/contents

TOA

Authorised Novel Food	***Conditions under which the novel food may be used***		***Additional specific labelling requirements***	***Other requirements***	***Data protection***
	Specified food category	***Maximum levels***			
Isolated cannabidiol (CBD) derived from *Cannabis sativa.*	Food Supplements as defined in Food Supplements (England) Regulations 2003 and The Food Supplements (Wales) Regulations 2003 for persons 18 years or over excluding pregnant or breastfeeding women or men or women trying to conceive	In accordance with the acceptable daily intake of 10 mg/day CBD	The designation of the novel food on the label of food supplements containing it must be "Isolated cannabidiol (CBD) derived from *Cannabis sativa*." Food supplements containing the novel food must bear the statements "Not suitable for use by persons under the age of 18". "Not suitable for use during pregnancy or breastfeeding or for males and females trying to conceive." "If you are taking any medications or are immunosuppressed, please consult a healthcare professional before using this product."		Authorised on XX Month 20XX. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: EIHA projects GmbH, Münsterstraße 336, 40470 Düsseldorf, Germany During the period of data protection, the novel food is authorised for placing on the market within [relevant jurisdiction] by EIHA Projects GmbH., unless a

Authorised Novel Food	*Conditions under which the novel food may be used*		*Additional specific labelling requirements*	*Other requirements*	*Data protection*
			"The maximum acceptable daily intake (ADI) of CBD for an adult is 10 mg per day. If you consume a CBD product that has an individual serving of 10mg/day, only one product type per day should be consumed to ensure the ADI is not exceeded. Multiple intakes of products containing CBD on the same day should be avoided." The labelling of food supplements containing the novel food shall bear instructions for use for the final consumer so that the acceptable daily intake of 10mg is not exceeded, including an expected dose, and the amount of CBD in that individual dose.		subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of EIHA Projects GmbH. The data protection will expire at the end of [5 years after authorisation].

Specifications

Authorised Novel Food	*Specifications*
Isolated cannabidiol (CBD) derived from *Cannabis sativa*.	**General description:** Cannabidiol is a colourless-to-yellow crystalline powder. **Definition / Chemical name:** Isolated cannabidiol (CBD) derived from hemp *(Cannabis sativa)* is a highly pure ingredient produced by a multi-step extraction process. The basic steps of the full production process are as follows: Cultivation and harvesting of raw hemp; drying of the raw hemp; production of primary extract through solvent extraction; decarboxylation; winterisation; distillation; isolation of CBD through solvent extraction; crystallisation; filtering, washing, and drying; final formulation and dilution in oil. This extracted CBD is dissolved and standardised in oil to contain between 2.5% and 10% CBD. 2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol **Chemical Formula:** $C_{21}H_{30}O_2$ **Chemical Structure:**  **Molecular Mass:** 314.46 (g/mol) **CAS number:** 13956-29-1 **Purity:** Cannabidiol (CBD) (%): ≥98 Delta-9-tetrahydrocannabinol (Δ9 -THC) (%): ≤0.00001% **Residual solvents (ppm):** Pentane: ≤ 2

Authorised Novel Food	*Specifications*
	Isopropyl- alcohol (2-propanol): ≤ 2 Ethanol: ≤ 5000 Hexane: ≤ 2

Proposed uses

- *Covered above*

Labelling

The novel food is subject to the general labelling requirements laid down in assimilated Regulation (EU) 1169/2011. This regulation sets out the general requirements for food labelling, such as the mandatory particulars for labelling, allergen labelling and use by/best before dates. You can find more information on food labelling here.

Additionally, food supplements must also comply with the Food Supplements Regulations (England) 2003 and the Food Supplements Regulations (Wales) 2003.

These regulations set out additional requirements for products marketed as food supplements, covering aspects such as dose size and labelling.

The labelling provisions set out in Regulations 6 and 7 of the Food Supplements Regulations (England) 2003 and the Food Supplement Regulations (Wales) 2003 set out the requirements for labelling of food supplements and the manner of marking or labelling of the end products for the ultimate consumer.

Regulation 6(2) requires that food supplements are marked or labelled with the following particulars:

a) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;

b) the portion of the product recommended for daily consumption;

c) a warning not to exceed the stated recommended daily dose;

d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

e) a statement to the effect that the product should be stored out of the reach of young children; and

f) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.

Regulation 7(1) requires that these particulars appear:

a) on the packaging;

b) on a label attached to the packaging; or

c) on a label which is clearly visible through the packaging.

Transitional requirements/ provisions

N/A

Further explanation/ Rationale

- **Novel food name**: Isolated cannabidiol (CBD) derived from hemp *(Cannabis sativa)*.

Naming (in ingredients list):

- The name originally applied for by the applicant was *'Natural cannabidiol (CBD) isolate in hemp seed oil.'* The applicant has since requested the inclusion of 'other food grade oils'. The FSA has considered this request, as well as the name originally applied for. The FSA has concluded that "Isolated cannabidiol (CBD) derived from *Cannabis sativa"* sufficiently describes the product and therefore is proposing this as the name of the authorised novel food.

- The FSA considered many options such as *'Cannabidiol'* but noted that this would not have a reference to whether the cannabidiol is made from extract, isolate or synthetically. Such differentiation may be important on an ingredients list for consumers information. The FSA and FSS also rejected the use of the name *'natural.'*

- The FSA considered that including *'(CBD)'* would help consumers recognise the ingredient by its common name.

Specified food category

The FSA and FSS considered if the definition should be 'Food Supplements as defined in Food Supplements (sold as capsules, liquids and drops)' **or** 'Food Supplements as defined in Food Supplements.'

The FSA has concluded that a reference to the form in which supplement is prepared is not required to be included in the designation of the food category to which the novel food is to be added.

The Food Supplements Regulations (England) 2003 and the Food Supplement Regulations (Wales) 2003 already require food supplements to be sold in dose form and subsequently define such forms as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities. Food supplements containing the novel food must be sold in dose form in order to meet the definition and therefore the permitted use.

THC as a contaminant

THC is a controlled substance present in the Cannabis plant and can be present at low levels in CBD. Batch testing of the novel food and the safety assessment shows that THC was either not detected or present at <0.00001% The safety assessment confirmed that the levels of THC in the novel food, once adjusted to take account the proposed uses – 10 mg of CBD being consumed a day, were below the acute reference dose (ARfD) identified by EFSA of 1 µg /kg bw/day or 70 µg/day for a healthy adult. This level does not present a concern in terms of consumer safety for the novel food under the proposed conditions of use.

To ensure THC levels remain consistently low in the production of CBD for the protection of consumers, THC should be a standard substance included in the specification as relevant to all batches produced. Given the detection levels in the batch testing, the FSA and FSS are proposing a specification of [0.00001% w/w]. The FSA and FSS are proposing to lower the THC level in the specification in line with the results in the CoA for batch testing, applying the as low as reasonably achievable principle (ALARA) for the further protection of consumers, noting that is the limit of detection.

Under drugs law, CBD products must not contain more than 1mg of THC per container. This limit is set by the Misuse of Drugs Regulations (2001) which outlines the criteria for “exempt products”. CBD products which contain THC (even at trace levels) must be able to meet the definition of an exempt product.

Residues of solvents or processing aids

- Based on the ACNFP's advice the FSA considered whether the use of solvents as processing aids resulted in residues that require highlighting to risk managers. Four potential extraction methods are identified as being used by partners on the plant biomass to make a crude CBD extract: ethanol extraction, CO_2 extraction, 2-propanol extraction, or 1,1,2-Tetrafluoroethane extraction. In this context, "partners" refers to the different businesses manufacturing CBD under this application. The other solvents are used as part of the crystallization (purification) process and are therefore not subject to the requirements on extraction solvents as set out in Part 3 and Schedule 6 to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 and The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013. Only extraction solvents (i.e. those used to extract components from the plant biomass) are subject to these regulations. Other solvents, that are not regulated as extraction solvents, are controlled by setting maximum residue limits in the specification for the product. It should be noted that 1,1,2 Tetrafluoroethene was originally listed as being used as an extraction solvent, however, this is not an authorised extraction solvent for CBD production and so has not been included in the specification and draft terms of authorisation. The applicant has requested this to be removed as this solvent can only be used in the preparation of flavourings.

- There are variations in the solvents used as part of extraction and purification of the CBD which result in different production processes. However, the specification set for the isolated CBD remains the same for all production processes and includes solvent residues for each of the processes used.

- The potential hazards from the solvents used by partners are considered in the relevant section. Certificates of analysis for raw starting materials used in the production of both CBD isolate and CBD isolate in hemp seed oil were provided, to demonstrate the effectiveness of the controls at this point in the process. The data is provided for one partner as an example of the effectiveness of controls in the partners systems.

- The evidence presented on composition indicates compliance with the specification for residues of solvents including extraction solvents. When considered at the level of

consumption the evidence suggests the levels of solvent residues in the novel food are below those which would represent a safety concern.

- In the original specifications of the novel food, the applicant specified residual solvent levels in accordance with the EMA guideline on residual solvents[37] but their batch results were consistently 10-fold lower than safe maximum levels, therefore, we propose to use the results from batch testing to keep the contaminant levels as low as reasonably possible. Some solvents are included in the specifications by the applicant and in the safety assessment but were not reported or detected in the batch testing, therefore only ethanol, pentane, hexane, and isopropyl alcohol (propan-2-ol) were included in the reviewed specifications. The applicant did not accept the lowering of Ethanol to <2ppm. They requested that this be set at <5000ppm in line with safety assessments. The FSA is content to accept this, and it has been reflected in the specification.

- Original solvent concentrations in applicant submitted specifications are detailed below and the proposed levels are reported in the Specifications table in the Terms of Authorisation.

- The applicant has been notified of the intended change to residual solvent limits in the ToA.

Residual solvents (mg/kg CBD)

Solvent	Specification (ppm)
Hexane (and cyclohexane)	20
Pentane	100
Heptane	100
Methanol	10
Propan-2-ol	10
Methyl Acetate	20
Ethylmethylketone	20
Dichloromethane	2
Ethanol	5

[37] Q3C (R8) Step 5 - impurities: guideline for residual solvents (europa.eu))

Heavy metal and microbiological contaminants

- Analytical data from tests of five independent batches of the novel food, produced through each of the four production methods, demonstrated that heavy metals were present in very low levels and were below established UK regulatory limits where applicable (arsenic, cadmium, mercury, and lead). Total aflatoxins and ochratoxin A were also tested and consistently found to be within their specifications. Analytical data concerning the microbiological content from tests of the novel food were reported in the safety assessment. Full microbial risk assessment confirmed that the novel food does not raise a safety concern and consistently meets the proposed microbial specification levels. The FSA recommendation is not to include heavy metal, mycotoxin and microbiological safety specifications in the TOA of ≥98% pure CBD as they have been consistently low in batch testing and fall below the limits that pose a safety concern.

Analysis of heavy metals, mycotoxins and microbiology that are not included in the TOA:

Mycotoxins	
Aflatoxins total µg/kg	<0.050
Ochratoxin A µg/kg	<1.0
Heavy Metals	
Lead mg/kg	<0.1
Cadmium mg/kg	<0.02
Mercury mg/kg	<0.01
Arsenic mg/kg	<0.025
Microbial	
Total plate count (30°C) cfu/g	$<10^3$
Enterobacteriacae cfu/g	<10
Escherichia coli cfu/g	<10
Yeast and mould cfu/g	$<10^2$

Salmonella (absent/present in 25g)	Absent
Total coliforms cfu/g	<100
Pseudomonas aeruginosa cfu/g	<100
Staphylococcus aureus cfu/g	<100

Other specifications not included in the TOA:

- In the safety assessment, Table 6 lists additional specifications of the novel food. The FSA recommendation is to not include these in the specification table as per previous novel food authorisations in the legislation. The FSA recommendation is to only include the specifications relating to the purity of the novel food, residual solvents, contamination with THC as mentioned above, and include the percentage of other impurities if it is specified by the applicant in the dossier and considered by the safety assessment. In the case of this CBD isolate, other impurities were not stated and do not form part of the specifications table.

List of ingredients and Allergen labelling

- There are no allergens in this product. The safety assessment determined that the Isolated cannabidiol (CBD) derived from hemp (Cannabis sativa) is unlikely to trigger allergic reactions in the target population under the proposed conditions of use.

Stability / Use by/ Best before

- The stability of five batches of the novel food, and five batches of the novel food in hemp oil, was assessed under accelerated conditions at 40°C for 36 weeks. Results showed there were no significant changes in cannabinoid content or microbiological profile over this period. Analysis for THC was included in the stability studies, which showed the level of THC remained consistent within the specification limits during the study. The data provided supports the stability of the novel food for a period of 24 months.

Amendment to/ Revocations of current authorisations

N/A

Labelling

General labelling requirements

- Covered above

Additional labelling

- Covered above

Transitional requirements/ provisions

N/A

Post market monitoring

N/A

Definitions

- **Supplement** – Food Supplements are defined in the Food Supplements (England) Regulations 2003 and and The Food Supplements (Wales) Regulations 2003 as:

  - "'food supplement" means any food the purpose of which is to supplement the normal diet and which—

(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and

(b) is sold in dose form.[38]

Other Legitimate Factors

Economic

- A full impact assessment has been deemed not necessary.

Consumer interests

- The FSA conducted dedicated research into the behaviours and attitudes of CBD extracts users to better understand how they use CBD and whether they are

[38] dose form" is defined as "a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities

aware that it is classified as a “novel food”. This research was conducted in 2019 and published in 2020[39].

- This research is supplemented by data from the FSA’s consumer insights tracker (latest data December 2024[40]).

- The latest data from the FSA's consumer insights tracker indicate that 12% of respondents have used or consumed CBD in the past 6 months.

- The FSA’s dedicated research indicates that over a third of CBD users say that they are reliant on it or that they would be bothered if they could no longer buy it.

- Respondents reported that the main reason they use CBD is for pain relief. They also reported that CBD helped relieve anxiety, aided relaxation and sleep, supported mental health and relieved depression.

- Around two thirds of respondents feel CBD has benefitted their overall health and / or helped them with a medical condition. The conditions that people are most likely to say it has helped them with are anxiety / stress relief, arthritis and back pain.

- The FSA has a clear statutory duty to protect the interests of consumers with respect to food. The results of the FSA’s own research demonstrates that access to CBD products is important to a significant number of consumers.

Political

- No other legitimate factors identified.

Legality

- The meaning of “food” is legally defined by Article 2 of Regulation (EC) No 178/2002. This definition excludes substances that are considered narcotic or psychotropic under the United Nations Single Convention on Narcotic Drugs 1961 and the United Nations Convention on Psychotropic Substances 1971(the Conventions). Despite CBD being an extract or a tincture of the Cannabis plant, it

[39] https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/consumer-research-report-on-cannabidiol-cbd-extracts
[40] https://science.food.gov.uk/article/122705

is not considered to fall under the Conventions as it does not have a psychotropic effect.

- The FSA considers CBD products that contain very low amounts of THC to be preparations that contain a narcotic/psychotropic substance rather than being a narcotic/psychotropic substance themselves. The application indicates that only trace residues of THC are present in the novel foods. The FSA and Home Office therefore regard CBD food products as novel foods and should be regulated under food law.

- CBD can contain trace levels of other cannabinoids, some of which are controlled drugs. This includes THC. The Misuse of Drugs Act (1971) (MDA) and the Misuse of Drugs Regulations (2001) (MDR) act as the implementing legislation for the control of controlled substances in the UK. Controlled substances are listed in Schedule 2 of the MDA. CBD is not contained within Schedule 2 of the MDA and is therefore not a controlled drug. THC, and other controlled cannabinoids, fall within Schedule 2 of the MDA. The MDA operates to render any product or preparation that contains a controlled substance as a controlled drug itself.

- Therefore, CBD containing any level of controlled cannabinoids is a controlled drug itself under the MDA. However, on the basis of the UN Conventions, the FSA has concluded that CBD is both a food under food law and a controlled drug under drugs law.

Wider application of drugs law

- Regulation 2 of the MDR sets out the “exempt product definition” (EPD). The EPD is set out in Regulation 2 of the MDR. It is the Home Office view that the applicable unit of measurement (i.e. the component part of the product or preparation) for the 1mg ‘threshold’ referred to in Limb (c) is that of the container (such as a bottle of oil) and not (for example) the supposed typical dose (of any product).

- Products that meet the EPD will not be subject to the prohibitions on importation, exportation, production, supply, and possession etc under the MDA 1971. Therefore, CBD products that received a novel foods authorisation would be able

to remain on the market legally provided they met this definition. Where they do not meet the EPD, it is illegal to possess, supply, produce or export etc. them.

Licences

- Those producing cannabis-derived products to which the EPD applies will require a domestic licence if their process involves cultivation of the cannabis plant (including hemp), handling the controlled parts of the plant in their separated form, and any production or handling of bulk CBD product to which the exempt product definition does not apply. These licences are granted by the Home Office and CBD businesses should ensure they have the correct licences in place if required.

Enforcement

- Under current legislation, local authority and district council officers are unable to lawfully take possession of CBD products which exceed the 1mg limit in the EPD as they would no longer be exempt from the prohibitions on importation, exportation, production, supply, and possession under the MDA. Non-exempt products can only be possessed with lawful authority (for which local authority and district council officers do not have under the MDR) or under a Home Office licence. Importation, exporting, producing, supplying, and possessing etc. controlled drugs is a criminal offence. They must be removed from sale by being seized by the police, or voluntarily or in compliance with the condition of a notice and surrendered to the police. However, this can only be enforced (by seizure) by the police.

- Local authority enforcement officers will be able to make use of enforcement provisions contained within the Novel Food Regulations 2018 ahead of seizure such as stop and improvement notices and fines whilst simultaneously requesting that the police make a seizure if required/ if it suspected the EPD is not met...

- To support local authorities in England and Wales, the FSA will develop guidance which will provide clarity on the application of food and drugs law to CBD food products. The guidance will set out what LAs are able do within food law in relation to CBD and when and how they should work with the police on matters that could fall under drugs law.

- **Environmental**
  N/A
- **Societal**
  N/A
- **Technical feasibility**
  N/A

Impacts

N/A

Trade

EU

- This application has been submitted and validated as an application in the European Union: Application Number NF2020/1670, European Food Safety Authority (EFSA) Question Number EFSA-Q-2020-00257.

- In November 2020, the EU Court of Justice (Case C - 663/18)[41] ruled that CBD cannot be regarded as a narcotic drug, since CBD does not seem to have any psychotropic effects. This means that CBD can be qualified as food, specifically a novel food, and according to Regulation (EC) No 178/2002 and Regulation (EU) 2015/2283, foods, including novel foods, must be safe. Therefore, EFSA evaluated the health risks and based the conclusions in their opinions solely on the safety of CBD.

- In 2022, EFSA published a statement[42] on safety of CBD as a novel food and addressed data gaps and uncertainties. Their aim was to Identify the hazards of CBD and how they relate to physical, chemical, and pharmacological properties when used as food supplement and/or food ingredient. As a result, they provided an overview of the uncertainties and data gaps that need to be addressed before the safety assessment of applications for CBD as a novel food can be concluded. They highlighted number of limitations of available studies, including high variation of mixtures used for toxicological studies, lack of information about the content and the identity of other components of these mixtures, the confounding factor of other medicines used concomitantly with CBD in involved patients and the

[41] Case C-663/18 - REQUEST for a preliminary ruling under Article 267 TFEU from the Cour d'appel d'Aix-en-Provence (Court of Appeal, Aix-en-Provence, France)
[42] https://www.efsa.europa.eu/en/efsajournal/pub/7322

difficulty to establish NOAEL as most human studies referred to the efficacy of Epidyolex®[43] at therapeutic doses, at which adverse effects were sometimes observed.

- The opinion also summarised the data gaps in the absorption, distribution, metabolism, and excretion of CBD. They stated that the matrix used, the form of the CBD and the food consumed at the same time could affect bioavailability with additional concerns about accumulation of CBD with time in animal studies but not enough evidence being available about what occurs at lower doses in humans and if that could increase potential harmful effects of CBD. Furthermore, evidence of interactions between CBD and neurological drugs has been presented with uncertainties about the scale of the effect of CBD on metabolism of other foods and drugs and vice versa.

- As a result of these uncertainties and data gaps on the effect of CBD on the liver, gastrointestinal tract, endocrine system, nervous system and on people's psychological well-being, EFSA has paused the safety assessment process in June 2022 whilst it waits for applicants to fill data gaps and has issued a statement advising how the additional information can be provided to help address the uncertainties.

- Since that time, further data has become available that has informed the position in GB on 98% or above purity and the level at which it can be safely consumed.

Northern Ireland

Under the Windsor Framework, CBD food products approved as novel foods in GB will be able to be placed on the market in Northern Ireland, if it is eligible for, and moved through Northern Ireland Retail Movement Scheme (NIRMS). Under the terms of NIRMS, only pre-packed retail goods can be moved into Northern Ireland, so it would not be permitted for Northern Ireland based businesses to manufacture their own CBD products, but it would be legal for them to import premanufactured products from GB.

Risk Management Recommendation

- The FSA risk management recommendation is that Isolated cannabidiol (CBD) derived from hemp (Cannabis sativa), as described in this application, does not,

[43] https://www.ema.europa.eu/en/medicines/human/EPAR/epidyolex

on the basis of the scientific evidence available, pose a safety risk to human health and the foods intended use does not mislead the consumer.