Consultation Pack on applications for authorisation of 3 CBD food products as novel foods

This consultation seeks stakeholders' views, comments and feedback in relation to regulated product applications considered in this document. Launch date: 28 August 2025 Respond by: 20 November 2025

Consultation pack on applications for authorisation of 3 CBD food products as novel foods

This consultation seeks stakeholders' views, comments and feedback in relation to 3 regulated product applications. The applications are for authorisation of "synthetic cannabidiol (CBD)", "cannabidiol (CBD) isolate" and "isolated cannabidiol (CBD) derived from hemp (*Cannabis sativa*)" as novel foods. The FSA will consider stakeholder responses before preparing final advice to ministers in England and Wales, with the Minister for Health in Northern Ireland kept informed. The determination on authorisation sits with ministers; the FSA has prepared draft recommendations for each application, which are included in the consultation. The draft recommendations are to authorise the 3 novel foods, subject to meeting the terms of authorisation that are set out in the consultation.

As these are the first applications for authorisation of CBD food products as novel foods to be subject to public consultation, the consultation also sets out a proposed approach to broader policy issues that will be relevant to future applications for CBD products, including enforcement issues and the protection of vulnerable groups.

The overall aim of the Food Standards Agency (FSA) in developing these proposals has been to ensure a high level of consumer health protection, and to consider the wider consumer interest. Whilst the FSA is developing the policy and advice on these issues, ministers in England, Wales, and Scotland (advised by Food Standards Scotland (FSS)) are ultimately responsible for taking the decisions to authorise CBD food products as novel foods. This consultation and corresponding responses from stakeholders are intended to support the development of the FSA's advice to ministers. The content of this consultation pack is not an indication of any UK minister's views. Final advice to ministers in England, Scotland and Wales will be informed by the outcome of this consultation.

Launch date: 28 August 2025
Respond by: 20 November 2025

This consultation will be of most interest to

All England, Wales, and Northern Ireland food businesses, local and port health authorities, and other stakeholders with an interest in food safety.

- Producers and suppliers of CBD, novel foods, importers, distributors and wholesalers and retailers
- Food Industry Trade Associations covering novel foods and CBD
- Consumers and the public
- Campaign groups with an interest in CBD and CBD food products
- Organisations representing consumer interests in the food
- Enforcement authorities across the United Kingdom (UK), including local authorities, Port Health Authorities and district councils

Consultation subject and purpose

This consultation seeks stakeholders' feedback on the regulated product applications considered in this document. These applications have been submitted for a new authorisation (3 novel foods).

A parallel consultation is being published by FSS to inform ministers in Scotland before they make a decision.

A summary of the risk management recommendations, safety assessment and proposed terms of authorisation can be found below.

England, Northern Ireland and Wales

PDF
View Annexes - Consultation on applications for authorisation of 3 Cannabidiol (CBD) food products as novel foods August 2025 as PDF(Open in a new window) (1.37 MB)

How to respond

Responses to this consultation should be submitted via the online survey. If this is not possible, you can email a response to:

Email: RPconsultations@food.gov.uk

Full details on how to respond are given below.

Details of consultation

What are novel foods and how are they authorised?

Novel foods are any food that was not used for human consumption to a significant degree within the UK or the EU before 15 May 1997. This means that the foods do not have a 'history of consumption'. Examples of novel foods include:

- new foods, for example, phytosterols and phytostanols used in cholesterol reducing spreads
- traditional foods eaten elsewhere in the world, for example, chia seeds, baobab
- foods produced from new processes, for example, bread treated with ultraviolet light to increase the level of vitamin D present

Novel foods need to be authorised by ministers in England, Wales and Scotland before they can be placed on the market in GB. The placing of novel foods on the market in GB must be in accordance with the assimilated Regulation (EU) 2015/2283.

What is CBD?

CBD is one of many chemicals called cannabinoids. It is found within hemp and cannabis plants and can be produced synthetically.

CBD extracts can be derived from most parts of hemp or cannabis plants. They can be selectively extracted, which can concentrate CBD. Some processes can alter other chemical components.

CBD products are being sold as foods, often as food supplements, in the UK. They are widely available in shops, cafés and online.

CBD sold as food, or as a food supplement, includes:

- oils
- drops, tinctures and sprays
- gel capsules
- sweets and confectionery
- bread and other bakery products
- drinks

On 15 January 2019 (and prior to the UK's withdrawal from the European Union), the European Commission included CBD in the novel foods catalogue, confirming its status as a novel food. As novel foods CBD food products are subject to the regulatory requirements of the Novel Food Regulation, a pre-market authorisation in accordance with that regulation is required before placing on the market.

CBD food products, as novel foods, must be authorised before they are put on the market. This is to ensure they are safe.

CBD market in Great Britain

An extensive domestic market of CBD products has existed in Great Britain (GB) for over a decade, predating the confirmation by the European Commission on CBD's status as novel in the novel foods catalogue. Following the UK's withdrawal from the European Union, the FSA and FSS inherited responsibilities for risk analysis of regulated products, including novel foods (and CBD). This presented the FSA and FSS with a policy challenge of how to address the continued growth of the unregulated CBD food products market whilst managing novel food applications through the risk analysis process.

The FSA decided to take a proportionate approach to enforcement, advising local authorities in England and Wales to prioritise enforcement against CBD products that are not taking steps to achieve authorisation. Existing products on the market in England and Wales can remain on sale if they are linked to a credible novel food application for authorisation. This decision took into account the World Health Organization Expert Committee on Drug Dependence statement that concluded, in its pure state, CBD does not appear to have abuse potential or cause harm.

The criteria that products must meet to be eligible for this proportionate regulatory approach are that:

- they were on the market at the time of our announcement on CBD (13 February 2020)
- we received an authorisation application for the products before 31 March 2021
- we have validated the application or agreed that it is sufficiently progressing towards validation

CBD Public List: products linked to novel food applications

The FSA published a Public List of the tolerated CBD food products to assist local authorities with enforcement decisions and to help consumers make informed choices about the products they buy. Products on the Public List are not formally authorised for sale, but they are linked to applications which are moving through the novel foods process. Inclusion on the Public List is no guarantee that a product will be authorised. Whilst the Public List does not apply to Scotland or Northern Ireland, a substantial number of CBD products on the list are available in both markets, making the operation of the list relevant to all four nations.

This consultation considers the first 3 novel food applications for CBD food products that have progressed through the safety assessment stage of the joint FSA and FSS risk analysis process, and for which draft risk management recommendations have been produced. There are approximately 3,000 individual CBD products linked to these applications on the Public List of CBD food products. In total, there are approximately 11,500 CBD food products included on the Public List linked to applications that are progressing through the authorisation process.

The Public List of CBD products creates a unique context for the risk management considerations for the novel food applications in this consultation because decisions about authorisation for individual products will have an impact on the Public List. This consultation includes questions in relation to the operation of the Public List and the impact of authorisation decisions on consumers, enforcement agencies and food businesses.

Authorisation process for regulated products

To be placed on the market in Great Britain, applications for the authorisation of regulated products must be submitted to the FSA and FSS. The FSA and FSS then work together to assess the applications and develop advice for ministers aimed at ensuring the continued high standard of food and feed safety and consumer protection in the UK. The decision on authorisation is made by respective ministers in England, Wales and Scotland, with the Minister of Health in Northern Ireland kept informed. In taking their decision, ministers consider the FSA and FSS recommendations, any relevant provisions of assimilated law, and any other legitimate factors, including those raised during the consultation process.

The provisional common framework for Food and Feed Safety and Hygiene is a non-statutory arrangement between the UK government and devolved administrations to establish common approaches to policy areas where powers have returned from the EU within areas of devolved competence. This consultation has been developed under the commitments to collaborative four-nation working set out in this framework.

The FSA and FSS adopted technical guidance and quality assurance processes used by the European Food Safety Authority (EFSA) to be able to undertake GB risk assessments for regulated product applications. Please see the links within each annex to the individual safety assessments.

FSA and FSS risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing exposure levels. The novel food applications have undergone an FSA and FSS safety assessment, including a review of the applicant’s dossier and supplementary information.

The FSA risk management document outlines the FSA’s recommendation to authorise the 3 novel foods. This consultation presents the factors that the FSA has identified as relevant to these applications, including the potential impacts of any decision made by ministers. Stakeholders are invited to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of ministers before a final decision is made.

Do you have any concerns about the safety of the novel foods with respect to the intended consumers? If so, please provide additional evidence if available.

Do you have any comments or concerns on the impacts of authorising or not authorising the novel foods and, if in favour of authorisation, the terms on which the novel foods are authorised (outlined in the FSA risk management recommendations)?

Are there any other factors that should be considered by Ministers that have not already been highlighted?

Factors considered during risk management

For the applications in this consultation, the FSA has considered all known legitimate factors and identified a range of potential impacts relevant to consumers and industry as a result of these factors, which are set out below. This consultation invites views on both general impacts in relation to CBD as a class of products, and on issues specific to each individual application, which are described in the risk management document for each application in the annexes.

Potential for misuse of the novel food and acceptable daily intake (ADI)

In 2023, the Advisory Committee on Novel Foods and Processes (ACNFP) and Committee on Toxicity published a paper which established a provisional acceptable daily intake ("the ADI") for CBD, below which no harm is expected for the general consumer population.

The ADI is established at 0.15 mg/kg bw/day i.e., 10 mg CBD/day for a 70 kg healthy adult.

The safety assessments concluded that a weight of evidence approach was used to arrive at the ADI. The most sensitive human health effects, that the 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.

The safety assessments also included the following, '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 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 to support minimising exposure to below the ADI.'

In carrying out the safety assessment, the ACNFP explored the potential for foreseeable misuse of the novel food. The ADI is established so that, regardless of how often/frequently someone consumes CBD in an indefinite period, 10mg/day is a safe amount considering variable factors for the individual consuming it. Consuming CBD on a daily basis would not be an 'expected' consumption habit. However, the ADI provides a safe consumption level if a person decides to consume CBD products permanently, and on a daily basis. This same consideration is made regardless of the product/format it is consumed within.

The FSA's draft risk management recommendations have included a prescribed maximum level of "In accordance with the acceptable daily intake of 10 mg/day CBD" and separate labelling provisions to ensure the ADI is not exceeded and to support consumers in making safe choices about consumption.

We are seeking views from stakeholders on whether the labelling provisions with respect to the ADI are sufficient in helping consumers making safe choices when consuming multiple CBD food products in a day.

Do you consider the labelling provisions with respect to the ADI to be sufficient to help consumers make safe choices when consuming multiple CBD products in a day?

Following consultations, the FSA and FSS will evaluate stakeholder responses and consider whether any additional provisions are required.

Potential for consumers to be misled by authorising the novel food in the category of food supplements

Article 7(b) of assimilated Regulation (EU) 2015/2283 requires that the appropriate authority (ministers in each jurisdiction of GB) must only authorise a novel food if the food's intended use does not mislead the consumer. Additionally, it is a legal requirement under assimilated (EU) Regulation 1169/2011 ('the Food Information to Consumers Regulation') that food information must not be misleading, particularly by attributing to the food effects or properties which it does not possess.

All 3 applicants have applied for the novel foods to be authorised for use in the food category "food supplements". In the case of 2 of the 3 applications, the applicants are only seeking authorisation in the food supplements category and do not intend to market the novel food in other food categories.

Authorisation within the category of food supplements presents the potential for consumers to be misled. The purpose of this consultation is to seek views on whether authorisation of CBD within the category of food supplements is misleading to consumers or if it supports consumer interests.

This section explores the context in which our recommendations are based and presents the rationale as to why we think that, on balance, a recommendation to authorise within this category is the best option for supporting consumer choice and consumer interest.

To set this out clearly, we have included information on what food supplements are, how they are defined, and what the FSA knows about consumer attitudes and habits with respect to CBD food products.

What is a food supplement?

In England and Wales, food supplements are defined by the Food Supplements (England) Regulations 2003 and the Food Supplements (Wales) Regulations 2003 ("the 2003 Regulations") respectively.

In the 2003 Regulations 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 ;

Food supplements can impact the body in a variety of ways and are primarily intended to address deficiencies by restoring levels of essential nutrients when dietary intake is insufficient. Certain food supplements are designed to support particular physiological processes, such as bone health (calcium and vitamin D), heart health (omega-3 fatty acids). Some food supplements may also be used for performance enhancement (creatine).

The 2003 Regulations apply to food supplements sold as food and presented as such, and establishes restrictions on the marketing of food supplements, including the manner in which products are labelled and packaged. Food businesses found to be in contravention of these

requirements would be subject to enforcement under these regulations.

In England, the legislative and policy responsibility for food supplements sits with the Department for Health and Social Care. This responsibility is devolved to Welsh Government in Wales and FSS in Scotland. The FSA retains policy responsibility for food supplements in Northern Ireland, however the applications for authorisation of the novel foods pertain to GB only.

As the 2003 Regulations define food supplements as any food the purpose of which is to supplement the normal diet and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination and sold in dose form, food supplements containing the novel food must therefore either contain a concentrated source of vitamin or mineral or have a nutritional or physiological effect in order to meet the definition and therefore the permitted use under the food category of food supplements. It is the responsibility of the Food Business Operator to ensure that they comply with the law.

Consumer interests

The safety assessments evaluated the use of CBD in the “food supplements” food category. The assessments found that the novel food is safe under the proposed conditions of use. The FSA’s function when carrying out the safety assessment was not to determine whether CBD had any therapeutic effect as the focus was on safety and adverse effects to human health. This is in line with the FSA’s statutory function as the Food Safety Authority in England and Wales under Article 11 of Regulation 2015/2283. However, this is a valid area for the FSA to consider in its risk management advice and when making recommendations to ministers on authorisations. The safety assessments do state that there is no nutritional effect. The FSA has not considered any evidence during safety assessment pertaining to any physiological effects of CBD and therefore cannot confirm whether there would be physiological effects as a result of consuming CBD under the proposed conditions of use.

The FSA’s own research into consumer habits indicates that CBD users use CBD products for a range of issues. CBD users 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 CBD users felt CBD had 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. 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.

Whilst the FSA’s research into consumer habits provides insight into the perceptions of consumers with respect to CBD at an anecdotal level, it does not provide empirical evidence for any physiological effects of CBD. Furthermore, the FSA’s research does not provide data on how individual consumers are using CBD (for example, the amount of CBD they are taking, in what form and with what regularity). We cannot confirm that the consumers habits align with the recommended consumption levels provided in FSA guidance or as requested by applicants in their applications. Therefore, this research does not fill any remaining data gaps concerning the physiological effects of CBD.

The FSA has not seen any evidence to determine whether a physiological effect can be confirmed at a dose of 10/mg per day. There are studies that indicate there could be physiological effects of CBD, but those studies involved much higher doses than the provisional ADI of 10mg/day CBD.

It is on this basis that the FSA considers that a CBD product at the proposed maximum level of 10mg/day may not meet the legal definition of a food supplement under the 2003 regulations, due to the lack of evidence of physiological effect. Although, CBD products are commonly marketed

as food supplements and consumers have reported therapeutic effects from consuming CBD. The marketing of CBD as food supplements presents the potential for the consumer to be misled.

Proposal

Our research indicates that many consumers believe CBD has a positive impact on them. Since the safety assessments did not identify any safety concerns relating to the use of CBD in the food supplement category, the FSA is proposing to recommend that these novel foods are authorised within the food category of food supplements, in line with the applicants' requests.

The FSA is aware of the potential for consumers to be misled, as recommending the authorisation of CBD in the food supplements category could be interpreted as confirming that CBD meets the legal definition of food supplement. However, on balance and taking into account the reasons consumers are choosing to use CBD products, the FSA considers such a recommendation is reasonable and justified, since consumers generally recognise CBD products as food supplements. Recommending that CBD products are not authorised in the food supplements category at this stage is likely to have negative impacts on the marketing of CBD products, and a negative impact on consumers who feel reliant on CBD food supplements.

Additionally, where CBD food products meet the definition of food supplements and are marketed as such, Food Business Operators are legally required to adhere to labelling and packaging requirements outlined in food supplements legislation. These extra requirements should ensure consumers are provided with adequate information about the CBD products they are consuming, when marketed as food supplements.

We are seeking stakeholder views about whether authorising the novel foods in the category of food supplements supports consumer interests or has the potential to mislead consumers.

Do you have any comments on whether there is the potential for consumers to be misled by authorising the novel foods in the category of food supplements, or whether this supports consumer interests?

Following consultation, the FSA will consider stakeholder responses and engage with officials in devolved governments and other government departments, as well as FSA officials working on food supplements policy in Northern Ireland, where relevant and appropriate. Ministers also retain the power to revisit the authorisation, should new evidence become available that categorically precludes the novel foods meeting the definition of a food supplement.

Status of CBD as a food and a controlled substance

Schedule 2 of The Misuse of Drugs Act 1971 ("the MDA") provides the list of substances classified as controlled drugs. Whilst CBD is not included in this schedule, cannabinol (CBN) and CBN derivates are included in Part II of this schedule and are classified as Class B drugs. This includes tetrahydrocannabinol (THC) as a derivative of CBN. The MDA and the associated Misuse of Drugs Regulations 2001 ("the MDR") are the legislative responsibility of the Home Office and subsequently policy on CBD as a controlled substance sits with the Home Office. The FSA has worked with the Home Office in considering implications of policy on controlled substances with respect to CBD food products as novel foods.

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). Pure CBD is not considered to fall under the Conventions as it does not have a psychotropic effect. This was established by the EU court and is a part of assimilated EU case law in the UK.

Under the Conventions, THC is classed as a psychotropic substance. 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 applications indicate 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.

Due to the difficulties in extracting it in its pure form, CBD may contain trace levels of other cannabinoids, some of which are controlled drugs under the MDA. This includes THC. The MDA renders any product or preparation containing a listed drug as a controlled drug itself. CBD containing even very low trace levels of THC (or any other controlled cannabinoids) is therefore both a controlled drug under the MDA and a food under food law.

Wider application of drugs law

Regulation 2 of the MDR sets out the "exempt product definition". An "exempt product" means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where:

a) the preparation or other product is not designed for administration of the controlled drug to a human being or animal;
b) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; and
c) no one component part of the product or preparation contains more than one milligram of the controlled drug.

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 part (c) of the definition is that of the container (such as a bottle of oil) and not (for example) the supposed typical dose (of any product).

Exempt products will not be subject to the prohibitions on importation, exportation, production, supply, and possession etc 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 are not exempt products, it will generally be unlawful to import, export, possess, supply or produce them except under a Home Office licence.

Licences?

Those involved in any stage of production, processing or distribution of cannabis-derived products must ensure they comply with the Home Office licencing requirements, if applicable, as set out in the Home Office Drug licensing factsheet on cannabis, CBD and other cannabinoids. A licence is always required for the cultivation of the cannabis plant. Additionally, those handling the controlled parts of the plant, or bulk CBD products that do not meet the exempt product definition, also require a licence. These licences are granted by the Home Office (or, in Northern Ireland, the Department of Health) and CBD businesses should ensure they have the correct licences in place if required. Applications should be made in good time, and licensees should note that where they need a licence to lawfully handle controlled drug substances, there is no provision to do so while an application is pending. Further information about applications can be found on the Government website.

The Home Office are responsible for issuing licenses in GB only. For applications in Northern Ireland, applicants should contact the Department of Health.

Enforcement??

Under current legislation, local authority and District Council officers may be unable to lawfully take possession of CBD products which exceed the 1mg limit in the Exempt Product Definition. Non-exempt products can only be possessed with lawful authority (which local authority and District Council officers do not have under the MDR) or under a Home Office licence. The products should be removed from the market by being seized by the police or removed from the market voluntarily or in compliance with the condition of a notice and subsequently seized by, or 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 there is suspected non-compliance with drugs legislation.

To support local authorities in England and Wales, the FSA will develop guidance to provide clarity on the application of food and drugs law to CBD food products. The FSA will also work with FSS to ensure local authorities in Scotland are provided with relevant guidance. The guidance will set out what local authorities 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.

The extent of the applications in this consultation is GB; however, under the Windsor Framework, pre-packed retailed goods, approved as Novel Foods, may be able to be placed on the market in Northern Ireland, if eligible for, and moved to Northern Ireland via the Northern Ireland Retail Movement Scheme. The FSA intends to draft additional guidance to support district councils in Northern Ireland with CBD food products being marketed in Northern Ireland, should GB ministers make decisions to authorise the novel foods.

We are seeking stakeholder views on impacts, if any, resulting from the legal status of THC and resultant complications, if any, relating to enforcement under drugs legislation or the Novel Food Regulations 2018.

Do you have any comments on the impacts, if any, resulting from the legal status of THC and resulting complications, if any, relating to enforcement under drugs legislation or the Novel Food Regulations?

Are there any other impacts on enforcement you wish to make the FSA aware of?

Following consultation, the FSA will consider stakeholder responses and work with FSS to ensure that enforcement authorities in each part of the UK have adequate guidance to undertake enforcement.

Vulnerable groups

The safety assessments confirmed existing advice to consumers which states that CBD should not be consumed during pregnancy or breastfeeding, 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.

In the absence of data, the FSA and FSS are proposing that the novel foods should not be consumed by persons under the age of 18. The applications were clear that their associated CBD food products containing the novel food are not intended to be consumed by under 18s. In our consumer guidance, the FSA already recommends that under 18s do not consume CBD food products. Our draft risk management recommendations reflect this advice and the FSA's view that products should not be targeted to children through any means, packaging, labelling or advertisement in any form.

The FSA will continue to work closely with industry, retailers, the Advertising Standards Authority and local authorities to strengthen and embed our consumer messaging on under 18s.

The FSA will also explore voluntary schemes with industry and retailers to ensure under 18s cannot access these products. There will be proactive engagement with key stakeholders in the CBD industry before the first authorisations come into effect, to communicate the FSA position and messaging that this population group should not be targeted.

The FSA has not identified any safety justification for recommending to ministers that the products are not authorised due to the uncertainties regarding safety for children. We are instead proposing that our advice to ministers includes specific labelling requirements that will make clear to consumers that CBD food products should not be consumed by vulnerable groups as defined below. The applicants have requested in their applications the use of labelling to mitigate against consumption by under 18s.

The FSA will also cooperate with other Government departments and devolved administrations through the provisional Food and Feed Safety and Hygiene Common Framework to communicate messages about vulnerable groups whilst simultaneously engaging with industry to further mitigate risk to consumers. Engaging at both retail level and using established Government frameworks should strengthen the following additional labelling requirements for vulnerable groups included in the draft recommendations:

- 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.

We are seeking stakeholder views on whether our proposals for labelling are sufficient to mitigate against consumption by under 18s.

Do you consider the labelling proposals included in the draft risk management recommendations to be sufficient to mitigate against consumption by under 18s?

Do you have any other comments about our approach to use labelling for the protection of vulnerable groups, or any of the specific labelling proposals for individual applications?

Following consultation, the FSA will consider stakeholder responses and engage with officials in devolved governments and other government departments, including the Advertising Standards Authority, on any further potential measures related to the marketing, labelling or advertising of the novel food, as appropriate.

Products on the Public List linked to applications

The FSA's Public List provides details of CBD food products, including administrative information (e.g., product name, supplier), but not a detailed composition of the products. Retailers use the list when considering which products to stock, and suppliers may use the list to demonstrate

credibility to retailers and investors.

Should ministers agree to the authorisation of the novel foods, any products linked to the applications will legally need to comply with any conditions of use imposed by ministers as part of an authorisation. In some cases, products on the Public List as currently marketed may not be in line with the most up to date guidance published by the FSA or proposed terms of authorisation, such as labelling requirements. In these cases, unless businesses reformulate and relabel to be in compliance with the authorisation, those products could be subject to enforcement as novel foods marketed not in line with the terms of authorisation of the novel food and would need to be removed from sale. Significant removals of existing products could impact consumers who are currently using CBD food products.

The latest data from the FSA's consumer insights tracker (June 2025) indicate that 11% of respondents have used or consumed CBD in the past 6 months. Currently, there are approximately 3,000 CBD food products on the Public List linked to the three applications that are the subject of this consultation.

We are aware that businesses work with complex supply chains and that the lead in times for new products can often be planned many months in advance. Should products not be immediately compliant with any of the agreed terms of authorisation, there could be disruption to supply chains and retailers as businesses take the necessary steps to update their product in line with the authorisation. This could lead to reduced availability for consumers of CBD food products.

The FSA recognises the need to mitigate any impacts on consumers using these products as a result of the proposed authorisations, should the terms of authorisation as proposed affect the marketing of these products.

The FSA has recently updated its policy with respect to the reformulation and relabelling of CBD food products on the Public List and updated its guidance accordingly. We engaged with the CBD industry over this policy change to the Public List ahead of the launch of our new business guidance. The new advice should give stakeholders certainty on the standards that the FSA now expects them to meet.

Prior to this policy change, businesses were not permitted to make any changes to the formulation or presentation of CBD food products on the Public List. Our new advice recognises that businesses want to reformulate their products to be line with the FSA’s latest safety advice and encourages businesses to take the necessary steps to make changes to their products and notify the FSA of any required changes to the corresponding entry on the Public List.

At the same time, the FSA has encouraged businesses to relabel their products to reflect the FSA’s most up to date consumer guidance on safe consumption of CBD products. In taking this approach, we expect most of the impacts to be mitigated, since businesses who take the opportunity to reformulate and relabel now should be in a position to meet the new terms of authorisation as set out in the FSA’s draft risk management recommendations, should ministers agree to authorisation.

We are seeking views from stakeholders on how authorisations may impact existing products on the list that are associated with the 3 applications, as well as other existing products that are not associated with the 3 applications.

Do you have any comments on how authorisations may impact existing products on the Public List of CBD food products?

Should the novel foods be authorised, what impacts, if any, are there on consumers or businesses in relation to the marketing of existing products on the Public List?

Following consultation, the FSA and FSS will evaluate stakeholder responses and consider whether additional proposals are required to manage the impact on existing products and consumers, prior to making recommendations to ministers.

Data protection

Under Article 26 of assimilated Regulation (EC) 2015/2283, the 3 applicants have requested data protection of proprietary data provided in support of the safety of the novel foods in their applications. Under this regulation, the applicants are entitled to data protection, which is reflected in the proposed terms of authorisation for each application.

The proposed terms of authorisation include a period of data protection of 5 years from the date of authorisation for certain proprietary scientific evidence and scientific data provided for each novel food. During this period, the novel food can only be marketed by the applicant unless a subsequent applicant obtains authorisation of the novel food without reference to the proprietary data protected under Article 26, or with the initial applicant's consent.

The data protection being proposed may lead to impacts on other businesses marketing CBD food products. In normal circumstances, a novel food authorisation that grants the authorisation holder data protection would not impact existing businesses or products because there would not be an existing market of products to affect. In the case of CBD food products, however, a market has existed for over 10 years. The Public List currently includes approximately 11,500 CBD food products linked to applications that are proceeding through the authorisation process. The data protection provided within the terms of authorisation could prevent other businesses from using the authorised CBD in their products, irrespective of their inclusion on the list, unless they obtained a separate authorisation without reference to the proprietary data for which data protection has been granted.

We are seeking views from stakeholders on how the data protection provisions in the terms of authorisation for each recommendation may impact existing products, the CBD industry as a whole, or the enforcement of CBD food products on the market.

Do you have any comments about how the data protection provisions in the draft risk management recommendations may impact existing products, the CBD industry as a whole, or the enforcement of CBD food products on the market?

Following consultation, the FSA will evaluate stakeholder responses to better understand the impact of data protection on the existing CBD market.

Cannabinoid content

The safety assessments for the applications in this consultation found that CBD content is consistently above 98% pure with negligible amounts of other cannabinoids detected across batches or not detected at all.

THC, a cannabinoid, is the principal psychoactive constituent of cannabis (Cannabis sativa) and one of at least 113 total cannabinoids identified in the plant. The most abundant isomer of THC found naturally in hemp and cannabis plants is Delta-9 Tetrahydrocannabinol (?9-THC).

For ?9-THC, a maximum level is proposed in the terms of authorisation. The level is specific to each application and is based on testing results submitted by each application. The approach taken by the FSA is to set this level as low as reasonably achievable (ALARA). This is consistent with the approach to controlling other contaminants in food.

Other controlled cannabinoids are expected to only be present in very low trace amounts in the novel foods. The Advisory Council on the Misuse of Drugs (ACMD) recognises that the available data on these other controlled cannabinoids suggest that their potency is lower or similar to ?9-THC. This is set out in the ACMD advice on consumer cannabidiol (CBD) products - GOV.UK. It is not expected that these cannabinoids will be present at levels in the novel foods that would cause adverse effects. Consumers will be protected from these controlled substances by following the FSA's consumer advice on the provisional ADI for CBD.

Northern Ireland

In Northern Ireland, CBD food products are unauthorised novel foods. CBD food products require authorisation under EU law, specifically in line with EU Regulation 2015/2283, before being placed on the market.

The European Commission have not yet authorised any CBD food products as novel foods for the EU market. Therefore, there are currently no authorised CBD food products in the Northern Ireland market.

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

Post market monitoring

Post Market monitoring is not required as part of these applications; however, the FSA plans to work with industry and other government departments to see how the CBD market develops and how products are marketed and consumed.

FSA recommendation

The FSA has prepared draft risk management recommendations for each of the applications in this consultation (full details provided in the respective annexes):

- 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)

England, Northern Ireland and Wales

PDF
View Annexes - Consultation on applications for authorisation of 3 Cannabidiol (CBD) food products as novel foods August 2025 as PDF(Open in a new window) (1.37 MB)

For each of the applications, the FSA is proposing to recommend authorisation under the specified terms of authorisation. Following consultation and consideration of stakeholder responses, the FSA will prepare final recommendations for ministers in England and Wales, who will make decisions on whether or not to authorise the CBD food products as novels foods for the respective markets.

Engagement and consultation process

Details of all valid applications for regulated products are published monthly on the Register of Regulated Product Applications - available on the FSA website.

Stakeholders are invited to consider the questions posed below in relation to any relevant provisions of assimilated law and other legitimate factors.

Following the consultation process, responses will be made available on the FSA website and shared with ministers.

Questions

Questions asked in this consultation:

1. Do you have any concerns about the safety of the novel foods with respect to the intended consumers? If so, please provide additional evidence if available.

2. Do you have any comments or concerns on the impacts of authorising or not authorising the novel foods and, if in favour of authorisation, the terms on which the novel foods are authorised (outlined in the FSA risk management recommendations)?

3. Are there any other factors that should be considered by ministers that have not already been highlighted?

4. Do you have any comments on how authorisations may impact existing products on the Public List of CBD food products?

5. Do you have any comments about how the data protection provisions in the draft risk management recommendations may impact existing products, the CBD industry as a whole, or the enforcement of CBD food products on the market?

6. Do you consider the labelling provisions with respect to the ADI to be sufficient to help consumers make safe choices when consuming multiple CBD products in a day?

7. Do you have any comments on whether there is the potential for consumers to be misled by authorising the novel foods in the category of food supplements, or whether this supports consumer interests?

8. Do you have any comments on the impacts, if any, resulting from the legal status of THC and resulting complications, if any, relating to enforcement under drugs legislation or the Novel Food Regulations?

9. Do you consider the labelling proposals included in the draft risk management recommendations to be sufficient to mitigate against consumption by under 18s?

10. Do you have any other comments about our approach to use labelling for the protection of vulnerable groups, or any of the specific labelling proposals for individual applications?

11. Do you have any comments about the novel foods being authorised in any of the other categories specified in the draft risk management recommendations?

12. Are there any other impacts on enforcement you wish to make the FSA aware of?

13. Should the novel foods be authorised, what impacts, if any, are there on consumers or businesses in relation to the marketing of existing products on the Public List?

14. Do you have any other feedback on the information presented in the consultation, or on anything that has not been covered?

Responses

Responses are required by close 20 November 2025. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Please respond to the consultation via the online survey (Opens in a new window). If this is not possible, you can email a response to: RPconsultations@food.gov.uk

Please indicate which application(s)/product(s) you are responding about by using the following subject line for your response:

Response to [insert RP number(s) if relevant] and the subject of the consultation [CBD - novel foods].

If responding by email, please state in your response whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which nation you are based.

We aim to publish a summary of responses to this consultation within 12 weeks of the consultation closing.

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.

Responses will be shared with ministers in England, Scotland, Wales and Northern Ireland.

Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government Consultation Principles.

Thank you on behalf of the FSA for participating in this public consultation.

Market Authorisation of Regulated Products Team

Definitions

The Regulated Product type in this consultation is Novel Foods.

The following information and definitions may be of use when responding to this consultation.

Regulated Products - Certain food and feed products, called regulated products, must go through a safety assessment as part of the risk analysis process, and require authorisation before they can be sold in the UK. You can find out more about the application process, including the safety assessment and risk management processes, and ministerial involvement here: Background on placing a regulated product on the market.

Novel foods are foods that were not used for human consumption to a significant degree within the UK or EU before 15 May 1997. In order to place new novel foods on the GB market or to change the specifications or conditions of use of authorised novel foods, applicants must submit an application in accordance with assimilated Regulation 2015/2283.
Novel foods authorisation guidance

Assimilated Law - Directly applicable EU legislation no longer applies in GB. EU legislation, retained when the UK exited the EU, was assimilated on 31 December 2023. References to any legislation with 'EU' or 'EC' in the title should now be regarded as assimilated law where applicable to GB. Assimilated law is published on legislation gov.uk. References to 'Retained EU Law' or 'REUL' should now be regarded as references to assimilated law.

The Food and Feed Safety and Hygiene Provisional Common Framework is a non-statutory arrangement between the UK Government and Devolved Administrations to establish common approaches to policy areas where powers have returned from the EU within areas of devolved competence. This consultation has been developed under the commitments to collaborative four-nation working set out in this Framework. As such, this consultation has been developed through a four-nation approach. Final recommendations will be agreed on a four-nation basis before being presented to ministers in England, Scotland and Wales, with the Minister of Health in Northern Ireland kept informed. Northern Ireland continues to fully participate in the risk analysis process processes concerning food and feed safety. This reflects Northern Ireland's integral role within the UK and ensures that any decision made fully considers the potential impacts on the whole of the UK.

Transitional Periods - Transitional arrangements may be applied; for example, where the criteria of a new authorisation differ from the existing food or feed authorisation to allow existing stocks and products on the market to be used up. Transitional arrangements are only referenced where applicable, based on significant change between the existing and new authorisation.

Windsor Framework For goods eligible for Northern Ireland Retail Movement Scheme (NIRMS):

- In October 2023, the Windsor Framework was implemented providing a unique set of arrangements to support the flow of agrifood retail food products from Great Britain to Northern Ireland.
- These goods can meet the same standards applied in the rest of the United Kingdom (UK) in public health, marketing (including labelling) and organic foods when moving through NIRMS.
- Goods authorised in Great Britain can be moved into Northern Ireland through the NIRMS.
- The FSA remains committed to ensuring that consumers across the UK can be confident that food is safe and is what it says it is, even where rules applicable to the same type of food may be slightly different.

Safety Assessment - the FSA/FSS risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health and assessing exposure levels. Links to the safety assessment for each application can be found in the relevant corresponding Annex below.

Risk Management - Our policy advisors are responsible for the risk management outputs. The FSA risk management recommendations document presents the factors that they have identified as relevant to these applications, including the potential impact of any decision made by ministers, and contain proposed terms of authorisation and other relevant provisions. Links to the risk management recommendations document for each application can be found in the relevant corresponding Annex below.

Cannabidiol (CBD) - CBD is one of many chemicals called cannabinoids. It is found within hemp and cannabis plants and can be produced synthetically. CBD extracts can be derived from most parts of hemp or cannabis plants. They can be selectively extracted, which can concentrate CBD. Some processes can alter other chemical components.
Tetrahydrocannabinol (THC) - THC is the principal psychoactive constituent of cannabis (Cannabis sativa) and one of at least 113 total cannabinoids identified in the plant. THC is classed as a controlled substance and is subject to control under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001. It is known for its psychoactive effects, which can cause a sensation of euphoria and relaxation.

Delta-9 Tetrahydrocannabinol (?9-THC) – The most abundant isomer of THC found naturally in hemp and cannabis plants. The presence of ?9 -THC and its precursor acid form, ?9 -THCA, as contaminants is unavoidable in CBD novel foods and in other hemp-derived products.

Advisory Committee on Novel Foods and Processes (ACNFP) - An independent expert committee comprising of scientists and specialist experts from a wide range of scientific disciplines, who actively advise the FSA on matters pertaining to novel foods, traditional novel foods, food and feed products of genetic technologies and novel food processes including food irradiation.

Committee on Toxicity (COT) - An independent scientific committee that provides advice to the Food Standards Agency, the Department of Health and Social Care, and other government departments and agencies on matters concerning the toxicity of chemicals.