Cannabidiol (CBD) guidance

Business guidance on cannabidiol (CBD) as a novel food.

Cannabidiol (CBD) is one of many chemicals called cannabinoids. It is found within hemp and cannabis 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 status as a novel food

The novel food status of CBD was confirmed in January 2019. This means CBD extracts, CBD isolates (highly purified CBD), CBD synthetic products, and any products to which they are added as an ingredient, are classed as novel foods.

CBD food products being classed as novel means that they require authorisation before they can be sold legally in the United Kingdom.

There are currently no CBD extracts or isolates that have been authorised as novel foods.

Hemp-derived non-novel foods

The following food products are not classed as novel because a history of consumption has been demonstrated:

1. Hemp seeds: this includes hemp seed oil, ground hemp seeds and partially defatted hemp seeds.
2. Water infusion of hemp leaves, when not accompanied by the flowering and fruiting tops, consumed as such or as part of herbal infusions.

Hemp-derived novel foods

Hemp-derived products other than those listed above are likely to be considered novel foods, unless a history of consumption can be demonstrated to a significant degree in the EU before 15 May 1997. This is defined under assimilated Regulation (EU) 2015/2283 (Regulation 2015/2283 for Northern Ireland).

Products derived from the selective extraction of CBD from any part of the hemp plant are CBD extracts and are therefore classed as novel foods. Products to which they are added as an ingredient are also classed as novel foods.

Consultation requests for novel food status

Food businesses are required to verify if a food they intend to place on the market is novel. If they are unsure, they must submit a consultation request (also known as an Article 4 request) before they bring a product to the market. This procedure requires evidence to demonstrate the extent of

the history of consumption so that the FSA can determine whether the food is novel.

For food businesses in Northern Ireland, consultation requests for novel food status are assessed by the European Commission.

Applying for authorisation

Food businesses must apply for authorisation of their CBD extracts, isolates and associated products to be placed on the GB market using our regulated product application service.

In most cases the applicant will be the manufacturer, but others such as trade bodies and other suppliers may also apply.

Once a CBD ingredient is authorised, that authorisation applies to that ingredient only. This means using the same detailed production methods, for the exact same uses as described within the authorisation and using the same safety evidence base.

If a novel food has been authorised and included on the list based on proprietary scientific data or information that has been granted data protection, it is authorised for placing on the market only by the applicant for a period of 5 years.

Application guidance

You need to apply for authorisation of your CBD extracts and isolates using the procedure for full novel food applications.

An important part of any CBD novel food application is a consideration of the product's safety. Without such information or a justification for the delay in providing the necessary information, we will not be able to validate an application.

Meeting the validation standard does not mean the product will necessarily be authorised. Each application will be considered on its own merits. Applications will be progressed and potentially authorised only if directly relevant safety information is included.

Toxicological information

Following the additional data provided to support novel food authorisations, further animal study data should only be generated for CBD ingredients with greater than 98% CBD. We are unable to accept literature information alone for the toxicological aspects of the application. In addition, we cannot use information from one novel food application to benefit another applicant without the permission of the data owner. To minimise the use of animals we encourage applicants to access, where relevant, the existing data sets that have been generated.

Data generated to support novel food applications should be on a relevant test material that reflects the composition of the novel food seeking authorisation. It should be also undertaken in line with internationally recognised toxicological methods such as OECD TC 408 protocol.

The statement from the ACNFP and COT outlines several areas where additional data could be generated and how this information could inform the knowledge of the safety of CBD. We encourage applicants looking to generate data to consider these data gaps and where possible use standardised methods. Where new data is being generated, we encourage applicants to work collaboratively to maximise the information generated.

Northern Ireland guidance

In Northern Ireland, CBD food products are unauthorised novel foods. CBD food products require authorisation under EU law, in line with 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.

Businesses seeking to place their products on the NI market should follow EU rules and the European Commission's authorisation process. For guidance on starting this process, visit?the EFSA?website.

Information on novel foods currently authorised for sale in the EU and Northern Ireland can be found in the EU Union List of Novel Foods. The EU Novel Food Status Catalogue can also be used to search for the status of specific products.

Retail agri-food goods moving through the Northern Ireland (NI) Retail Movement Scheme will be able to meet Great Britain public health requirements as set out in legislation, including in relation to novel foods. NIRMS applies to pre-packed retail agri-food goods intended for final consumer sale.?A novel food authorised in England, Wales or Scotland will therefore be able to move into Northern Ireland via NIRMS. A list of these can be found in the register of novel foods.

CBD food products linked to novel food applications

The list of CBD products linked to novel food applications contains CBD food products which meet the following criteria:

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

All CBD products must comply with other legislative requirements and should not be:

- incorrectly labelled
- unsafe
- regarded as controlled substances

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

More information about CBD products linked to novel food applications.

Search the Register of CBD products linked to novel food

List of CBD products linked to novel food applications.

This list applies to England and Wales. You can find more information about CBD products in Northern Ireland in our CBD guidance for Northern Ireland. Novel foods regulations in Scotland are covered by Food Standards Scotland.

Other CBD food products

From the date of our announcement (13 February 2020), no new CBD extracts, isolates or associated final products using this novel ingredient, including new brands and white label products, should be put on the market until they have the necessary authorisation. A validated

application is not sufficient to put new products on the market. We expect any CBD products not on the list to be voluntarily withdrawn. Local authorities are responsible for enforcement and may remove these products from the market if products are not voluntarily withdrawn.

Detailed information on invalidated CBD product applications can be found on our invalidated CBD authorisation applications page. In England and Wales, only products on the CBD products linked to novel food applications list as awaiting evidence or validated are proposed to remain on the market pending a decision on authorisation.

Safety of CBD products

We have issued consumer advice on the consumption of CBD for healthy adults and vulnerable groups.

Sellers of CBD should be aware of this information and be able to inform consumers on the maximum recommended daily limit for healthy adults. As a precaution, we do not recommend CBD for people in vulnerable groups, unless under medical direction. This includes children (those under the age of 18), people taking any medication, those trying to conceive and those who are pregnant or breast feeding.

New evidence on the safe use of CBD as a food

Since implementation of the list, the Joint Advisory Committee on Novel Foods and Processes (ACNFP) & Committee on Toxicity (COT) has published statements with respect to the provisional acceptable daily intake (ADI) for CBD in foods, and the safe upper limit of Delta-9 tetrahydrocannabinol (?9-THC).

Important
Following these safety assessments and publications, to provide the best levels of protection for consumers, we are strongly encouraging all CBD food business operators (FBOs) to make the necessary changes to existing products to reflect the new advice. This can be achieved by reducing the concentration of CBD products, to at or below the ADI of **10mg/day CBD** and safe upper limit of **70 µg/day ?9-THC**, to help consumers to not exceed these daily limits.

Advice to businesses on the list of CBD products linked to novel food applications

From the date of our announcement (13 February 2020), the FSA's existing advice is that no new CBD extracts, isolates or associated final products using this novel ingredient, including new brands and white label products, should be put on the market until they have the necessary authorisation.

It was recommended that products already on the market should be tolerated, allowing them to remain available if linked to a credible live application for authorisation. Such products were placed on a list maintained by the FSA. The FSA has not permitted amendments to the list to reflect changes to products, such as name changes, since this would render them new products and ineligible for inclusion on the list.

The FSA recognises that CBD businesses may want to reformulate their products in response to the new evidence published by the Joint Advisory Committee with respect to the provisional ADI of **10mg/day CBD** for pure form ? 98% CBD and the safe upper limit of **70 µg/day ?9-THC** in foods.

The FSA is now recommending that products are reformulated in line with the evidence of the Joint Advisory Committee. This approach will make it easier for businesses to align with the updated guidance and will give consumers access to more CBD products that meet the FSA's advised limits. Products that do not reformulate at this stage can remain on the list, pending the outcome of the novel food application their products are linked to.

Businesses with products on the list should follow these steps:

1. Consider if reformulation to reduce CBD and/or ?9-THC levels to meet our advice is possible or appropriate for your product(s).
2. If the reformulation does not change the product details on the list, you are not required to contact the FSA.
3. If the product details on the list require amending as a result of the reformulation, contact the FSA with the below information.
4. Update packaging, noting that other food legislation may be relevant when relabelling or repackaging.
5. The FSA will only update the list for the purposes of supporting the safety of consumers. The list will be updated every four months, or when major changes are required.

If necessary, please contact us with the following:

- your application number and CBDID number of the product
- the updates to?the product details on the list that are necessary (i.e. product name changes to reflect the quantity or change in supplier) - please see the example in the table
- confirming that the reformulation is for safety reasons only and outlining your reasoning

Table 1: An example to demonstrate which information to submit to request changes to product details on the list

CBD ID number	RP number	Manufacturer, supplier or product name	Proposed amendment to entry	Confirmation reformulation is for outlined safety reasons
cbdidxxx	RPxxx	CBD oil 20 mg	CBD oil 10 mg	Yes, I confirm reformulating from 20 mg to 10 mg is for the outlined safety reasons and no other changes have been made to the product(s).

Advice to businesses on the list of CBD products linked to novel food applications no longer progressing

Important

Switching applications policy update

Businesses can request changes to the public list to enable products to be switched from one application to another.

Requests will only be considered for products which are already on the public list and products which are linked to applications that are no longer progressing. This might include invalidated or withdrawn applications, or applicants which were subject to a negative authorisation

determination by the Minister because of an inconclusive safety assessment.

What is switching?

Switching a product means that a change has been made to a product listed on the CBD public list, changing the listed product to a progressing application that meets the specification and uses of the product. Applicants can switch their products on the CBD public list to another application that is still progressing. The purpose of switching is to allow products to remain on the CBD public list by matching their specification to an active application.

Requests to switch

Businesses must provide confirmation their products meet the specification and product uses of the alternative application. The registered applicant must also provide proof that an appropriate agreement is in place with the alternative application owner. Further information may be requested by the FSA to ensure the products are suitable for switching.

Each request to switch will be reviewed on a case-by-case basis. Changes to products on the CBD public list will only be considered if products meet the specification and product uses of an active application. For example, if an application only requested authorisation in the food category of food supplements, the FSA would not accept products from other food categories to switch to this application.

In the case of applications which are no longer progressing (for example if it has been invalidated, withdrawn or not authorised), the FSA will consult with the business operator linked to that application to ascertain if they have found a suitable application to cover their product specification and uses. The FSA will also consult with the business operator on timescales before specifying a?reasonable period?to submit the necessary information to support a request to make changes to the list.

If adequate information to support a request to make changes to the public list is not received within the time specified, the products will be marked as removed on the CBD public list and businesses will be expected to remove the products from the market.

Product details will be retained if businesses provide information at a later date that demonstrates their products can be linked to a suitable application. This information will be reviewed before a decision is made on re-adding the products.

How to request a switch

Before requesting a switch, businesses must check with the application holder that their products meet the specification and intended uses. They must also secure the applicant's agreement. Requests to switch must be sent to CBDPublicList@food.gov.uk.

When requesting a switch, businesses must provide:

- signed confirmation from the business that the alternative application covers the specification and uses of the products being switched
- signed confirmation from the alternative application owner, confirming they have checked the products and that they are covered by their application's specification and uses - this must include the application's regulated products (RP) number
- a list of products being switched, with CBDID numbers
- details of any reformulation required
- details of any updates needed to the product entry on the public list

What happens next

The FSA will review your request and let you know if the changes can be approved.

A request to switch does not guarantee approval. The FSA may ask for more information before making a decision.

Next steps

All businesses with products on the list must check that the application their products are linked to covers their product types, uses and specification.

Labelling of products on the list for safety

FBOs on the list are encouraged to label products to display our existing consumer advice whilst their associated novel food application progresses, including a statement of the ADI of 10mg/day CBD. This will help consumers make informed choices.

Any changes to labels may need to be updated to comply with the specification of any future authorisation of applications in the market authorisation service.

FBOs must also ensure that CBD products are labelled as required by general labelling requirements laid down in Regulation (EU) No 1169/2011.

We encourage labelling to include:

- 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 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
- the amount (or size) of CBD per serving
- 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

Novel food taste trials guidance

If you conduct a taste trial in the UK, you should refer to the recently updated novel food taste trial guidance to ensure the trial does not amount to an unlawful placing on the market of an unauthorised novel food.

CBD and Controlled Cannabinoids

CBD food products containing controlled cannabinoids must be 'exempt products' as defined in the Misuse of Drugs Regulations 2001. Non-exempt food products containing controlled cannabinoids are likely to be controlled drugs under the Misuse of Drugs Act 1971 that cannot ordinarily be possessed, supplied, produced, imported or exported except under a Home Office controlled drug licence. CBD products which are not exempt products should be referred to the police for appropriate action.

FBOs are strongly encouraged to review the Home Office drug licensing factsheet, on cannabis, CBD and other cannabinoids. This factsheet provides guidance on the domestic control

measures, including licensing and exemptions applicable to cannabis, CBD and controlled cannabinoids under drugs legislation (namely, the Misuse of Drugs Act 1971 and associated secondary legislation).

If you have any questions about this guidance, please contact CBDPublicList@food.gov.uk.