

# Cannabidiol (CBD) guidance

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

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.

Hemp seeds, hemp seed oil, ground hemp seeds, (partially) defatted hemp seeds and other hemp seed-derived food are not novel. Water infusion of hemp leaves (when not accompanied by the flowering and fruiting tops) are also considered not novel. This is because there is evidence to show a history of consumption before May 1997. This is not the case for CBD extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids as outlined in the [EU Novel Food Catalogue](#).

## CBD status as a novel food

The novel food status of CBD was confirmed in January 2019. That is why CBD food products require authorisation before they can be sold legally in Great Britain (GB).

There are currently no authorised CBD extracts or isolates on the market.

## 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).

## 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.

## 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](mailto:CBDPublicList@food.gov.uk)