

# Cannabidiol (CBD) guidance for England and Wales

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

This guidance applies to England and Wales. Go to [CBD guidance for Northern Ireland](#).

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.

## **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.