

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.

CBD extracts can be derived from most parts of hemp or cannabis plants. They are selectively extracted, concentrating CBD and removing or reducing other chemical components. This process means the final product is different from hemp.

Hemp and related products, such as cold-pressed oils, are not novel because there is evidence to show a history of consumption before May 1997. This is not the case for CBD extracts.

CBD status as a novel food

The novel food status of CBD extracts was confirmed in January 2019, and the European Commission updated their Novel Foods Catalogue to reflect this change. The catalogue itself has not got legal status. The European Commission uses this tool to show the decisions made on novel food status and it is these decisions that have legal status. This makes it clear that CBD extract and isolate products are legally novel foods.

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

Applying for authorisation

Food businesses should [apply for authorisation of their CBD extracts and isolates](#) to be placed on the GB market using our [regulated products application service](#).

This is the only route to compliance for these CBD products, and no separate arrangement has been made with any specific business or industry sector. In most cases the applicant will be the manufacturer, but others such as trade bodies and other suppliers may also apply. The specific novel CBD products you sell must be included within an application and they must be made the same way as detailed in the application.

Once a CBD product is authorised that authorisation applies to that product 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.

The authorisation itself is not specific to the applicant and the final product may be branded in different ways. However, if the applicant requests and is granted confidentiality, then key aspects of production and the research evidence base may not be available to others for five years.

If you buy CBD products from others, you must ensure these products are correctly authorised, and that you only use them in ways described in the authorisation.

The EU law that applies to Northern Ireland after the transition period is specified in Annex II to the [Northern Ireland Protocol](#). This means that if you're seeking an authorisation for a CBD product to be placed on the Northern Ireland market you will have to continue to follow EU rules

and its [authorisation procedures](#).

Novel food application guidance

The content of any application for CBD products should follow the usual [application process for novel foods](#).

An important part of any application will be a consideration of the product's safety. Applicants will need to include details of the toxicological studies they have undertaken, or propose to undertake with clear details of the reasoning for these particular tests. Where all information isn't available at the time of submission, a justification for the delay and when results will be available must also be included. Without such information it is unlikely we will 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, but with so little publicly available information on the safety of CBD we anticipate that directly relevant studies will be needed. Applications will be progressed and potentially authorised only if this directly relevant safety information is included.

Deadline for businesses to have CBD applications validated

Businesses need to submit, and have fully validated, novel food authorisation applications by **31 March 2021**.

After this date, only products which were on the market at the time of our announcement on CBD (13 February 2020) and for which the FSA has a validated application will be allowed to remain on the market.

We have advised local authorities that businesses can continue to sell their existing CBD products during this time, provided they:

- are not incorrectly labelled
- are not unsafe
- do not contain substances that fall under drugs legislation

However, no new CBD extracts or isolates, including new brands, should be sold until they have the necessary authorisation. A validated application is not sufficient to put new products on the market.

The deadline applies in England, Wales and Northern Ireland. Novel foods regulations in Scotland are covered by [Food Standards Scotland](#).

Ongoing EU applications

If you submitted your application to the EC, you will need to submit it to us, using our [regulated products application service](#).

Article 4 consultations

Article 4 of the Novel Food Regulations provides a consultation process for a business to check if their product is novel or not. An Article 4 submission is not a route to compliance for any novel food, including CBD.

Submitting an Article 4 consultation request does not mean unauthorised novel products are permitted on the market. If a business submits an Article 4 request, they are expected to have not placed the products on the market until an answer is formed. This is not what has happened with CBD extract products as there are hundreds of products on the market without authorisation.

Submitting an Article 4 request will not alter any enforcement position and offers no protection against enforcement for unauthorised novel foods placed on the market.

If any business believes they have a significant history of consumption for their CBD extracts from before May 1997, they should follow the consultation process on the [novel food page](#).

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 recommended dose for healthy adults, and the potential risk to those who are pregnant, breast-feeding or taking medication.

Trade bodies

We have discussed CBD with various trade bodies and many other organisations involved in the novel food and CBD industry. We will continue to do so. While it is important that we understand their views, we have not in any way endorsed any specific trade body's approach to the route to compliance for CBD extract products.

There are no specific agreements with individual trade bodies and all businesses marketing novel CBD products are treated the same.