# 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 / 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 Novel Foods Catalogue has been updated to reflect this change.

The Novel Foods Catalogue is a way of recording decisions made on the novel food status of foods and food supplements. 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. 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 this may be the manufacturer, but others such as trade bodies and other suppliers may also apply. What is important is that 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 but the application can be made by someone else, such as your supplier.

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. Whilst the authorisation itself is not specific to the applicant and the final product may be branded in different ways, where 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. Where a business buys CBD products from others, they must ensure these products are correctly authorised, and that they only use them in ways described in the authorisation.

Applications can be made by following the links on our Novel Foods page and there is no fee for this. In addition to submitting them to the European Commission as usual, we strongly recommend businesses also send them to us to allow us to consider them. We can then give businesses guidance and answer any queries we may have, in order to ensure they progress at pace through our UK authorisation process from 1 January 2021. If you have an application

ready to send to us, please contact us at novelfoods@food.gov.uk.

## 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 for which the FSA has a valid 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 and do not contain substances that fall under drugs legislation. However, no new CBD extracts or isolates should be sold until they have the necessary authorisation.

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

## 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.