businesscompanion
trading standards law explained

Novel foods (including CBD and hemp)

In the guide

Although the United Kingdom has left the European Union (EU), certain pieces of legislation (formally known as 'retained EU law') will still apply until such time as they are replaced by new UK legislation; this means that you will still see references to EU regulations in our guidance.

To fully understand this guidance, it is important to note the difference between the United Kingdom and Great Britain:

- UK: England, Scotland, Wales and Northern Ireland
- GB: England, Scotland and Wales

This guidance is for England and Wales

This guidance relates to both the manufacture and sale of prepacked food, food that is prepacked for direct sale, non-prepacked food (food sold loose etc), and food sold from catering establishments (cafés, restaurants, etc).

What are novel foods?

For the purposes of this guide only, and highlighting the difference between 'food' and 'novel food', food is defined as:

- food and food ingredients that come from plants, animals and other sources, that have been produced by traditional growing, raising or propagating methods, and have a history of safe consumption by humans in the EU or the UK before 15 May 1997

By contrast, a novel food is any food or food ingredient that has not been eaten to a significant degree by people within the EU or the UK prior to 15 May 1997, and also fits into one of the following categories:

- food / ingredients produced from animals that do not meet the definition of 'food' above
- food / ingredients produced from plants that do not meet the definition of 'food' above **except** food from plants that **do** have a history of safe consumption in the EU or the UK prior to 15 May 1997, **but** have been produced through **non-traditional** means that **do not** affect the following:
    - the composition / structure of the food
    - the nutritional value
    - how the food is turned into energy by the body (metabolism)
    - the undesirable substances the food contains
- food / ingredients that have been subjected to a production process that is not currently being used on that food / ingredient, and significantly changes its composition or structure, nutritional value, how it is turned into energy by the body (metabolism), or the undesirable substances that it contains*
- food / ingredients with a new or modified molecular structure*
- food / ingredients that are, or come from, micro-organisms, fungi or algae
- food / ingredients that are, or come from, minerals*
- food / ingredients that are, or come from, cell culture or tissue cultures from animals, plants, micro-organisms, fungi or algae
- food / ingredients consisting of, or containing, engineered nanomaterials (100 nm or less)*
- vitamins, minerals and other substances used in food supplements, food intended for infants and young children, food for special medical purposes and foods intended as total diet replacements, that have been subjected to a production process not used in the EU or the UK prior to 15 May 1997*
- food / ingredients that have only been used in food supplements within the EU or the UK prior to 15 May 1997, when they are intended to be used in foods other than food supplements*

[*See 'Traditional foods' below for more information on the asterisked text.]

What is the significance of being a novel food?

Novel foods cannot be used in food unless they have been through an approval process to check that:

- they do not present a danger to consumers
- their use does not mislead consumers
- they are not so different from the foods or food ingredients that they are intended to replace that their consumption would be nutritionally disadvantageous to consumers (in other words, that choosing to eat them over traditional foods would not leave consumers lacking in vital nutrients)

These are checked in a process referred to as a safety assessment.

If a food / ingredient you wish to use is a novel food that has not yet been authorised, you must not use it in, or as, food.

When using an ingredient that you know or suspect meets all or part of the definition above, you should research whether the food / ingredient is a novel food. Things to look out for include unusual ingredients, ingredients from outside the EU or the UK (and not in common usage within the EU or the UK), or an ingredient that is common but being used in a new or different way (for example, Chia seed oil rather than Chia seed).

Identifying a novel food

If you are concerned that a food / ingredient might be a novel food, you can do the following (preferably in this order) to check its novel status:

1. Check the list of authorised novel foods
2. Check the Novel Food Catalogue
3. Conduct online research

1. Check the list of authorised novel foods
The list of authorised novel foods can be found in the Annex to Regulation (EC) 2017/2470 *establishing the Union list of novel foods* (see 'Key legislation' below). To search for the common or scientific name of the food / ingredient on the web page use Ctrl-F (on Windows computers) or Cmd-F (on Macs).

The legislation is updated regularly but the most recent updates can be found at the bottom of the Union list of novel foods page on the European Commission website.

A separate GB list of novel foods has not yet been created. Everything on the EU list that was authorised prior to 1 January 2021 (the date that the UK left the EU) is authorised in GB; however, anything authorised by the EU since that date may not be. If you wish to sell a product that appears in the EU list after 1 January 2021, contact the Food Standards Agency (FSA) Novel Foods Team (novelfoods@food.gov.uk) to check whether it is authorised in GB.

2. Check the Novel Food Catalogue
The Novel Food Catalogue is arranged in alphabetical order and can be searched with keywords.

When searching you must use the scientific name of the food / ingredient - for example, if you want to find pomegranate you have to search for '*Punica granatum*'. You can find the scientific name by searching 'scientific name of X' online ('X' being the name of the food / ingredient you are searching for).

Each entry will have one of four icons below the text:

The food / ingredient is not a novel food but its use may be restricted in some EU Member States.

The food / ingredient can be used in food supplements but cannot be used in other foods without going through the authorisation process.

The food / ingredient is a novel food and cannot be used until a safety assessment has been completed.

The product may be a novel food, but more information is required before a decision can be made. If you want to use a food / ingredient displaying the '?' icon you should contact your local Trading Standards service for further advice.

3. Conduct online research
If you are unable to find the food / ingredient in the authorised list or the catalogue, you can research it online.

The best place to start is to search 'What is X?' online and use the results to try and determine if the product was commonly eaten in the EU or the UK prior to 15 May 1997.

The European Commission's *Human Consumption to a Significant Degree: Information and Guidance Document* (see 'Related links' at the bottom of the linked page) will help you understand how to assess consumption of the food prior to 15 May 1997.

If your research leaves you in any doubt as to whether the food is novel, you should contact your local Trading Standards service for advice.

If your research shows that the substance is a food additive you can check the European Food Additives Database to see if it is listed.

The database specifies what types of food each additive can be used in. If it can be used in categories outside of food supplements, then it is not a novel food. If it can only be used in food supplements, then it may still be novel; check its status in the Novel Food Catalogue.

Novel food authorisation

If you want to use an unauthorised novel food you must apply for authorisation.

The first step will always be to determine whether the food is novel (see 'Identifying a novel food' above).

If your research conclusively shows that the food is not novel there is nothing more you need to do.

If your research is inconclusive, and you have concerns that the food may be novel, you will need to go through a consultation process (referred to as an Article 4 request), which will determine whether the food is novel. You can make an Article 4 request through the regulated products application service.

Your local Trading Standards service will be able to offer some advice on whether you need a consultation but you may ultimately have to discuss it with the Food Standards Agency (FSA) Novel Foods Team (novelfoods@food.gov.uk).

If either your research or the consultation process determines that the food is novel, you must apply for

authorisation and will need to gather and submit enough evidence to prove that the food meets the three criteria in 'What is the significance of being a novel food?' above.

If you don't provide sufficient evidence to conclusively meet the criteria, the food will not be authorised.

The evidence you submit should be specific to your product; therefore, gathering together publicly available information will not be sufficient. Any business seeking approval for a novel food will probably need to conduct independent scientific research (which will be beyond the technical / financial means of some small and medium-sized businesses).

Making an application is free; however, the process of gathering and submitting the evidence is expensive and takes a long time to complete, although there is a simplified process for traditional foods with a history of safe consumption (see below).

For more information on the authorisation process and what information your application should contain, please visit the novel foods section of the Food Standards Agency website.

If you wish to make an application for sale of a novel food on the GB market you must follow the GB regulated product authorisation process (using the regulated products application service).

If you wish to make an application for sale of a novel food on the EU or Northern Ireland (NI) markets you must follow the EU novel food authorisation process.

Traditional foods

Traditional foods are those from countries outside the UK or EU with a history of safe consumption for 25 years or more. A history of safe consumption is more than anecdotal evidence and must be based on both compositional data and evidence of use.

A traditional food must also meet the definition of novel food in 'What are novel foods?' above, except for those items marked with an asterisk (*); foods that are / contain the asterisk-marked items are not considered to be traditional foods.

Additionally, traditional foods must be the products of primary production (rearing, growing, harvesting, milking, farmed animal production, hunting, fishing and the harvesting of wild products).

A novel food application for a traditional food requires less information to be submitted than a normal novel food application and has a streamlined process of approval.

Guidance on preparing an application for a traditional food can be found in this scientific opinion from the European Food Safety Authority (EFSA).

If you wish to make an application for sale of a traditional food, the same processes for GB and NI / EU apply as in the 'Novel food authorisation' section above.

CBD-based foods and food supplements

Cannabidiol (CBD) is a type of cannabinoid isolated from cannabis plants or produced synthetically.

CBD is increasingly being used in foods and food supplements; this section of the guidance explains the legal status of using CBD in this way.

Are they controlled drugs?

Cannabis sativa L is the most common strain of cannabis in the EU; it contains many cannabinoids, one of which is CBD. The most widely known cannabinoid is tetrahydrocannabinol (THC) which causes the 'high' associated with cannabis use.

THC and other cannabinoids are controlled drugs; their possession, use in manufacture, etc is a criminal offence under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.

CBD can be isolated from other cannabinoids present in *Cannabis sativa L*, and in its pure form it is not a controlled drug.

Extraction and purification of CBD is a complicated and expensive process. If the CBD is contaminated with other controlled cannabinoids, at any detectable level, the product is a controlled drug and its possession, use in manufacture etc, is a criminal offence.

A licence can be obtained to grow low-THC hemp (less than 0.2% THC). However, this does not mean that the final product may contain up to 0.2% THC; if THC is present at any detectable level, the product is a controlled drug.

Are they medicinal products?

The definition of a medicinal product has two parts, as follows:

- any substance administered to treat or diagnose an illness or medical condition
- any substance that claims to be able to prevent or treat disease (including pain relief)

Medicinal claims are significantly different to health claims, although the two are often confused. Please refer to 'Nutrition and health claims' for more information.

If the product meets either part of the definition it is treated as a medicinal product. It will need to be authorised by the Medicines and Health Care products Regulatory Agency (MHRA), and will be subject to strict rules on composition and labelling.

The Department of Health and Social Care (DHSC) has accepted clinical evidence that cannabis and CBD can be used to treat certain illnesses and medical conditions, and cannabis-derived medicinal products (CDMP) are now available on prescription.

However, the levels of CBD recorded in the clinical evidence is usually many times more than is typically present in CBD-based food / food supplements. This means that CBD-based food / food supplements are not typically able to provide the medicinal benefits seen in the evidence. Merely containing CBD is not enough for the product to be classed as a medicinal product.

Provided the product makes no claims about treating or preventing illness (including pain relief), the product is not a medicinal product.

Claims can be in any form, including:

- writing - for example, a statement that states or implies a medical benefit
- pictures - for example, a picture of a heart or a red cross
- sounds - for example, the sound of a heart monitor

Claims that are made elsewhere than on the product (website, social media, publications, etc) may result in the product being classed as a medicinal product.

If you have any concerns about whether your product is a medicinal product you can obtain a regulatory opinion from the MHRA by submitting a medicines borderline advice form to borderline_medicine@mhra.gov.uk. Please refer to the MHRA document *A Guide to What is a Medicinal Product* for further information. (Links to the document and the form can be found in 'Getting advice about your product' on the GOV.UK website.)

Are they novel foods?

The CBD industry has been unable to provide sufficient evidence that CBD and other cannabinoids have been consumed to a significant degree within the EU prior to 15 May 1997.

CBD, and cannabinoids in general, are novel foods and cannot be legally included in food or food supplements until a safety assessment has been completed and their use as a novel food has been authorised. The assessment (and any subsequent authorisation) is specific to the product containing the CBD. Any variation from the authorised product (a different flavour, for example) will require a new authorisation specific to that product.

Are they legal?

Due to their classification as novel foods, they cannot be legally sold until they have been authorised.

The FSA allowed CBD products meeting the following criteria to continue to be sold in England, Wales and NI until 31 March 2021:

- the food is safe
- the food is not contaminated with other cannabinoids
- the food is correctly labelled
- the food was placed on the market in England, Wales or NI before 13 February 2020

This relaxation of the rules did not apply to any new products placed on the market after 13 February 2020, nor to products that were placed on the market in the EU but not in England, Wales or NI. Information about Scotland can be found on the Food Standards Scotland website.

For all CBD food / food supplements on sale before 31 March 2021, a validated (see below) novel foods application for authorisation must have been made by that date. If a validated application was not made, the products must be removed from sale, pending possible future authorisation.

The FSA has published a list of CBD products, identifying products for which validated applications have been received and those that have not yet met the full legal requirements for validation but have the potential to become validated within a specified time limit (referred to as 'on-hold' or 'awaiting evidence'). The FSA has advised local authorities that CBD-based products that do not appear on these lists should be removed from sale.

Any CBD food / food supplement that meets the criteria listed at the beginning of this section and for which an application for authorisation was submitted by 31 March 2021 (which has subsequently been validated or is currently on hold / awaiting evidence) can continue to be sold while the authorisation

process is ongoing. Any products that are on the list and are not subsequently authorised must be removed from sale immediately.

If your product was not on the market prior to 13 February 2020 and/or you were not able to make a validated application for authorisation before 31 March 2021, you can still make an application for authorisation but the product must not be placed on the market until authorisation has been granted.

If you wish to place your product on the GB market you must follow the GB regulated product authorisation process (using the regulated products application service).

If you wish to place your product on the EU or NI market you must follow the EU novel food authorisation process.

Applications for authorisation must be validated (confirmed to meet a minimum standard capable of satisfying a safety assessment), which can take up to 30 days. Validated applications will then be subject to a safety assessment that will determine whether the product can be authorised for sale. A validated application does not mean that the application will be authorised.

As stated above, the evidence you submit should be specific to your product and will likely need to be based on independent scientific research, which will be beyond the means of many small and medium-sized businesses. If you submit an argument based on pre-existing, publicly available information, this will not be accepted as sufficient evidence and the application will be dismissed.

If you intend to submit an application you should discuss the content with the FSA Novel Foods Team beforehand so that they can offer advice on whether your application contains sufficient detail and what additional information you might need to include. Liaising with the FSA does not guarantee that your application will be successful.

For more information please refer to the FSA update of 9 May 2022.

For further advice on making a novel food application for CBD-based foods / food supplements please contact the FSA Novel Foods Team via novelfoods@food.gov.uk.

Are they safe?

So far the evidence is inconclusive; however, the Committee on Toxicology (COT) has found evidence of potential adverse health effects and as a result the FSA has issued safety guidance. It is particularly important to note that, for healthy adults, the recommended maximum dose is 10 mg a day (approximately 28 drops of 5% oil). This recommendation is based on a 70 kg adult.

Hemp-based foods / food supplements

Hemp / industrial hemp / low-THC industrial hemp is a product of cannabis plants that contain less than 0.2% THC. Licences to cultivate and process such plants can be obtained from the Home Office.

Cannabis is a controlled drug; however, this classification does not apply to certain parts of the cannabis plant, and therefore these parts (and anything made from them) are not controlled drugs. The parts of the plant to which the classification does not apply are:

- seeds

- plant fibre
- mature stalk

Cannabis has a significant history of consumption in the EU prior to 15 May 1997. This means that the cannabis plant itself (*Cannabis sativa L*) is not a novel food, and as such those parts of the plant not controlled by other legislation (seeds / plant fibre / mature stalk) can be used in food, providing the following conditions are met:

- the material comes from low-THC cannabis plants
- the business has any licences necessary to process the product
- the purpose of consuming the product is something other than ingesting a controlled drug - for example, to add flavour, aroma, etc
- the cannabis cannot be extracted from the product and consumed in sufficient quantities to pose a risk to health
- the entire product contains less than 1 mg of THC
- the product is not contaminated with other cannabinoids

Trading Standards

For more information on the work of Trading Standards services - and the possible consequences of not abiding by the law - please see 'Trading Standards: powers, enforcement and penalties'.

In this update

The FSA has dropped its recommended maximum dose of CBD from 70 mg a day to 10 mg.

Last reviewed / updated: October 2023

Key legislation

Misuse of Drugs Act 1971

Food Safety Act 1990

Misuse of Drugs Regulations 2001

Human Medicines Regulations 2012

Regulation (EU) 2015/2283 *on novel foods*

Novel Foods (Wales) Regulations 2017

Regulation (EU) 2017/2468 *on traditional foods from third countries*

Regulation (EU) 2017/2470 *establishing the Union list of novel foods*

Novel Foods (England) Regulations 2018

Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (England) Regulations 2022

Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022

Food Additives, Food Flavourings and Novel Foods (Authorisations) (England) Regulations 2023

Food Additives, Food Flavourings, and Novel Foods (Authorisations) and Food and Feed (Miscellaneous Amendments) (Wales) Regulations 2023

Please note

This information is intended for guidance; only the courts can give an authoritative interpretation of the law.

The guide's 'Key legislation' links often only shows the original version of the legislation, although some amending legislation is linked to separately where it is directly related to the content of a guide. Information on changes to legislation can be found by following the above links and clicking on the 'More Resources' tab.

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