Novel foods authorisation guidance

Novel foods authorisation requirements and what you need to submit as part of a novel food application.

Novel foods are any food that was not used for human consumption to a significant degree within the United Kingdom (UK) or the European Union (EU) before 15 May 1997. This means that the foods don't have a 'history of consumption' (HoC), examples of novel foods include:

- New foods, for example, phytosterols and phytostanols used in cholesterol reducing spreads.
- Traditional foods eaten elsewhere in the world, for example, chia seeds, baobab.
- Foods produced from new processes, for example, bread treated with ultraviolet light to increase the level of vitamin D present.

Novel foods need to be authorised before they can be placed on the market in Great Britain (GB). The placing of novel foods on the market in GB must be in accordance with the assimilated? Regulation (EU) 2015/2283. There are two authorisation routes:

- Traditional food notification (Article 14)
- Full application (Article 10)

Register of novel foods

The FSA maintains a register that accurately reflects the authorisation status of novel foods as determined by the appropriate authority (ministers) in England, Scotland and Wales. The? Register of novel foods sets out a list of novel foods permitted for use in GB and provides references to their terms of authorisation. Assimilated?Regulation (EU) 2015/2283??is the legal basis for the placing on the market and use of novel foods.

Unless data protection measures are triggered, you can sell an authorised novel food in accordance with the conditions set out in the register. The register shows where data protection is in place.

Further guidance on specific novel foods

- Cannabidiol (CBD) Guidance
- Cell-cultivated products guidance
- Edible insects guidance

Guidance for Food Business Operators (FBOs) on researching novelty status of food

This guidance applies to Great Britain only. For details on the process to determine whether a product is authorised for sale in Northern Ireland (NI) see section titled 'Northern Ireland application guidance'.

Food products without a significant HoC prior to 15th May 1997 in the UK or the EU are classed as novel foods and require authorisation before being placed on the GB market.

It is the responsibility of an FBO to verify whether their product would be covered by novel foods regulation before they place the product on the market. This guidance page provides some useful resources which may help FBOs begin their research into the novel food status of their product. Please thoroughly consult all resources in this guide to help determine the novelty status of your product.

Please note that the FSA can only provide legal verification on novel status via the Article 4 consultation process. The FSA does not respond to informal requests from FBOs to determine the novel status of foods.

The following table lists resources which FBOs may use to research novel food status. When consulting these resources, it is the responsibility of the FBO to know the identity of the ingredients (such as roots / leaves) which are incorporated into their product as well as the intended use of each component. For example, the FBO must know whether the intended use of a given part is as a food, food supplement, or both.

Resources FBOs may use to research novel food status

Name	Description	Additional information
The Register of Novel Foods Authorisations	FSA Register of novel foods that are authorised and permitted for use in Great Britain.	Guidance on using the Register of Novel Foods
Outcomes on novel food consultations	This page details the outcomes of novel food consultations in the UK, also known as Article 4 consultations. This consultation process determines whether or not a food is novel.	A brief justification of the decision is also published here and may include helpful information around history of consumption of the product in the UK and EU.
EU Novel Food Status Catalogue	An EU database containing information about the EU novel food status of different foods. The Catalogue is not exhaustive, but only provided as an indicative source of history of use information on the product. The exclusion of a product from the list does not mean it is necessarily not a novel food.	Any decisions on the novel food status of a food made by the EU prior to the 1st of January 2021 still apply in GB. EU decisions following this date do not apply in GB but may help to determine whether there is a history of consumption within the EU.
EU consultation process on novel food status	Following an Article 4 consultation request in an EU member state, the Commission publishes the Novel Foods Status determination.	Includes a brief justification of each decision which may include helpful information such as history of consumption of the product in the UK and EU.
BELFRIT List	A list developed by?Belgium, France and Italian authorities of substances, preparations and botanicals approved or rejected for use in food supplements in the EU.	An updated version can be found on the website of the Federal Public Service but is only currently available in French and Dutch. This version includes: • A list of plants which are not allowed for use in or as foodstuffs. This means that any part, preparation or fruit of those plants must not be consumed as such and must not be used for preparing foodstuffs. • A list of edible mushrooms; A list of plants which are allowed in food supplements. For some of those plants, maximum amounts are laid down per daily portion, for which a list of recommended analysis methods has been drawn up
EuroFir-Nettox plant list	A list of 334 major European plants which were on the market in the EU before the novel food regulation entered into force.	The plants appearing in the list may be considered by the EU as not novel food.
Medicines and Healthcare products Regulatory Agency (MHRA) list of banned and restricted herbal ingredients	An alphabetical list of herbal ingredients which are subject to various restrictions in the UK.	MHRA state this document is for guidance purposes only. There are also descriptions and links to legislation which may of relevance to your product.

Please note that products may be referenced in these resources in different languages. If you cannot find the product you are looking for, try searching using alternative names.

For FBOs seeking to place their product on the market in NI see section titled 'Northern Ireland application guidance'.

Article 4 request

As an FBO, it is your responsibility to provide the necessary evidence that your product is not novel. If, having consulted these resources, you are still unsure of whether a product is novel, you must submit an Article 4 request for clarification.

The Article 4 consultation request process is designed to assess novelty by establishing:?

- Whether it meets the definition of a food, and it falls within the scope of novel foods legislation against the definitions set out in legislation.
- Whether it has a significant HoC.?

If the process concludes that the product is novel, then FBOs will need to apply for the authorisation of their product under the novel foods regime to legally market the product in GB.

If the process concludes that the product is not novel, then the product would not need authorisation as a novel food.

For guidance on how to submit an Article 4 request, please see regulated products application guidance. Please ensure you have thoroughly examined the resources in this guide before doing so.

Commission Implementing Regulation (EU) 2018/456 provides details of what you will need to include in your Article 4 request.

Once you are prepared, you can submit an Article 4 request. Select ‘start’, then ‘Novel foods’, then ‘Novel food status (Article 4)’.

For queries relating to CBD or cold-pressed hemp, please see the relevant CBD webpages:

- Cannabidiol (CBD)

Other useful links

Follow the links below for specific FSA guidance according to each type of regulated product. These pages also link to the relevant guidance and regulations applicable to each product type:

- Extraction solvents
- Feed additives
- Feed for particular nutritional uses (PARNUTS)
- Feed detoxification processes
- Flavourings
- Food contact materials
- Food additives
- Food enzymes
- Food supplements
- Genetically modified organisms (GMOs) as food and feed
- Novel foods
- Smoke flavourings

Local authorities seeking to determine foods’ novel status

The FSA may still respond to informal requests from local authorities (LAs) to provide advice on the novel status of foods, if doing so is in the interests of consumer safety, the wider public interest, or for any other reason the FSA deems it necessary and appropriate to do so.

If local authorities have questions about a novel food which are not answered through the FSA’s website, FSA Local Authority Information Network (LINK), or existing Q&As, local authorities

should follow the escalation hierarchy to resolve the issue. More guidance on this process is available on FSA LINK. See our information page on how the FSA engages with local authorities including how to sign up for FSA LINK.

Novel food status ('Article 4')

A consultation process (also known as an Article 4 request)?is available if you:

- Are unsure of the status of your product?.
- Have evidence that it has a history of consumption in the UK or EU prior to May 1997.?

Assimilated?Regulation (EU) 2018/456 details the information we will require to make the decision on whether the product is novel.

If the conclusion of the process is that your product is novel, then you will need to apply for authorisation to legally market the product in GB.?

To submit your Article 4 request and supporting evidence, use our?regulated products application portal. In the ‘Product type’ section select ‘Other’.

We will list the?outcomes of Article 4 consultations once a determination has been made.?

New authorisations

To apply for an authorisation of a novel food in GB, use our?regulated products application portal. ?This is where you will be asked to upload all the documents to support your application, which will form your dossier.?There is no fee for the application.

Northern Ireland application guidance

In NI, novel foods must undergo a safety assessment and authorisation before being placed on the 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?Novel food applications: regulations and guidance page on?the European Food Safety Authority (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 NI Retail Movement Scheme (NIRMS) 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 NI via NIRMS. A list of these can be found in the register of novel foods.

Full application (‘Article 10’)

For novel foods other than those under the traditional food notification route, you need to submit the?full set of information outlined.

Part 1

This should contain the administrative data, such as information relating to the applicant.

Part 2

This should contain information specific to the novel food such as:

- Identity of the novel food
- Production process
- Compositional data
- Specifications
- The history of use of the novel food and/or of its source
- Proposed uses and use levels and anticipated intake
- Absorption, distribution, metabolism and excretion
- Nutritional information
- Toxicological information and allergenicity

Applicants should explain how this information supports the case that the novel food is safe. It should also introduce the supporting data provided and include a list of all references.

Part 3

This should include:

- The glossary or abbreviations of terms quoted throughout the dossier
- The certificates (on the accreditation of laboratories, certificates of analyses)
- Full copies / reprints of all pertinent scientific data (published and unpublished)
- Full study reports
- Scientific opinions of national/international regulatory bodies

Detailed guidance for full applications

Detailed guidance and application requirements are set out in assimilated?Regulation (EC) 2017/2469 and guidance previously developed by?EFSA. The?EFSA?guidance?remains relevant as our approach is based on EU processes. You should follow the parts that relate to the development of dossiers only and not the application process:

- EFSA guidance on the preparation and presentation of an application for authorisation of a novel food

Traditional food notification (‘Article 14’)

This is a simplified route to authorise products which have been consumed outside of the UK or EU for at least 25 continuous years before the application is made.

This route has?reduced data requirements, reflecting their wide use in other parts of the world. Applicants are encouraged to provide information on what can be learned about the safety risks from this existing use. There is a four-month period within which the review is conducted by the FSA. If the FSA has no safety objections, the product is authorised and placed on the authorised list.

Authorisation of traditional food (‘Article 16’)

If the FSA does have safety objections following an Article 14 request, the product is not authorised for placing on the GB market. The applicant may then submit an application through the Article 16 route, where additional information is required, including information directly related to the safety objections raised by the FSA during the Article 14 process.

Detailed guidance for traditional food notifications

Assimilated?Regulation (EU) 2017/2468,?and guidance previously developed by?EFSA,?sets out what the is needed in the application. The?EFSA?guidance remains relevant as our approach is based on EU processes. You should follow the parts that relate to the development of dossiers only and not the application process:

- EFSA guidance on the preparation and presentation of an application for authorisation of traditional foods from third countries

Apply for novel foods authorisation

Use our regulated products application portal to apply.

FSA Explains

Novel food tasting trials

Tasting trials of unauthorised novel foods may be permitted if the intention is to conduct research to develop the novel food.? The FSA recommends tasting trials are guided by?advice published by the Advisory Committee on Novel Foods and Processes (ACNFP)?. Companies may communicate the fact they have conducted a taste trial through media activity where such publicity is ancillary to the main purpose of the trial as research and development.

If the intention of a tasting trial is to publicise a product or a company brand, then the tasting may amount to the unlawful placing on the market of an unauthorised novel food.

If you conduct a taste trial in the UK, you should refer to the recently updated novel food taste trial guidance to ensure the trial does not amount to an unlawful placing on the market of an unauthorised novel food.

Getting help

If you have any questions about the authorisation procedure or process, you can contact us at? regulatedproducts@food.gov.uk.