Novel foods authorisation guidance

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

Novel foods are foods which have not been widely consumed by people in the UK or European Union (EU) before May 1997. This means that the foods don’t have a ‘history of consumption’. 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). There are two authorisation routes under the retained EU law on novel food:

- traditional food notification
- full application

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

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 novel food to be placed on the Northern Ireland market you will have to continue to follow EU rules and its authorisation procedures.

Cannabidiol (CBD) products

The novel food status of Cannabidiol (CBD) extracts was confirmed in January 2019. This means that you need to apply for authorisation of your CBD extracts and isolates using the procedure for full applications outlined in this guidance. You can find more information on CBD products, including when you need to submit your application to continue marketing your product in the GB, in our CBD guidance.

New authorisations
To apply for an authorisation of a novel food in GB use our [regulated products application service](#). After completing an application form, you'll be sent a link where you can upload your application documents which will form your dossier. There is no fee for the application.

**Traditional food notification**

This is a simplified route to authorise products that have 25 years’ continuous use by a significant number of people in a country outside the UK or EU.

This route has reduced data requirements reflecting their wide use in other parts of the world. There is a four-month period within which the review is conducted. If there are no objections the product is authorised and placed on the authorised list.

**Detailed guidance for traditional food notifications**

The retained EU law, [Regulation (EU) 2017/2468](#), and guidance previously developed by EFSA set out what 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](#)

**Consultation process (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

Retained EU [Regulation 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 service](#). In the ‘Product type’ section select ‘Other’.

**Full applications**

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

**Part 1**

It should contain the administrative data, such as information relating to the applicant.
Part 2

It 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

It should also include a list of all references.

Part 3

It 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 retained EU law 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

Ongoing applications

If you submitted a novel food application to the EU before 1 January 2021 and the assessment process for this application has not been completed, you will need to submit your application to us, using our regulated products application service. When completing the application form, you will be asked to provide your EFSA question number.

Existing authorisations

If your novel food has been authorised by the European Commission before 1 January 2021 and the necessary legislation is in place, that authorisation will remain valid in Great Britain and you don’t need to apply for a new authorisation.

How long will my application take?

The law includes deadlines for key steps in the process. In most cases, applications will take at least a year. One month is allowed for the validation process, then up to nine months (on a start stop the clock basis if further information is needed) for the risk assessment element, with up to a further seven months for any subsequent risk management considerations and authorisation
decision.

The quality of the dossier, and the information provided, will significantly affect the time needed for assessment and authorisation. We encourage applicants to follow the guidance and provide as much information as possible to ensure we can process your request as efficiently as possible.

Getting help

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

Apply for authorisation

Apply for a novel food authorisation using our regulated product service.