Novel foods authorisation guidance

Novel foods authorisation requirements and what you need to submit as part of a novel food application.
This page is part of the Regulated products application guidance.

Novel foods and their status

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'. 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
- full application

EU Food Law continues to apply in Northern Ireland, under the current terms of the Protocol on Ireland/ Northern Ireland (Annex II). The novel status of a product in Northern Ireland is based on the European Commission determination and before being placed on the Northern Ireland market, novel foods must go through the EU authorisation processes. Only novel foods authorised by the European Commission may be placed on the Northern Ireland market. Under the provisional Common Framework for Food and Feed Safety and Hygiene, Northern Ireland continues to fully participate in the risk analysis processes concerning food and feed safety

Register of novel foods

The register of novel foods sets out a list of novel foods permitted for use in Great Britain. The register does not replace assimilated Regulation (EU) 2015/2283 which 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

- CBD guidance for England and Wales
- CBD guidance for Northern Ireland
- Cell-cultivated products guidance
- Edible insects guidance

New authorisations

To apply for an authorisation of a novel food in GB use our regulated products application service . 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.

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

Assimilated Regulation (EU) 2017/2468, and guidance previously developed by EFSA set 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

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 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

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, 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 a full novel food application made under Article 10, 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. These add up to a total of seventeen months as the overall legislative timeline for authorisation, noting this can be extended if the clock is stopped and re-started.

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.

Apply for authorisation

Regulated products application service

FSA Explains

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

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 service. In the ‘Product type’ section select ‘Other’.

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

Getting help

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