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'. 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

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

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

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.

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 below.

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 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,?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

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 are 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.

The ACNFP guidance is still accurate, but the contact details on the page are now out of date. If you have any questions about this guidance, please contact?novelfoods@food.gov.uk

Getting help

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