How to use the novel foods authorisation process flowchart

Additional detail on the pre-application steps of the market authorisation process to help applicants understand what is required before submitting a novel foods application.

This novel foods authorisation process flowchart (PDF) and explanatory note give extra detail about the pre-application steps for novel food authorisation. This will help applicants understand what they need to do before submitting an application.

The novel foods authorisation guidance has more information.

To be placed on the market in Great Britain (GB), applications for the authorisation of regulated products such as novel foods must be submitted to the regulated products process. The decision on authorisation is made by the respective Minister in Scotland, England and Wales, with the Minister of Health in Northern Ireland kept informed.

The European Union (EU) has a separate process for novel foods authorisation. Authorisation applications for the European Union should be made to the European Commission.

See the novel foods authorisation guidance for more information.

Applicant reviews relevant FSA regulated products application guidance

Certain food and feed products, called regulated products, must go through a risk analysis process, and require market authorisation before they can be sold.

The Food Standards Agency (FSA) has published regulated products application guidance. This explains the types of products which require regulated products authorisation and what you need to include in a regulated product application.

Food Standards Scotland (FSS) has also published guidance for applicants in Scotland. Applicants should read this guidance before considering applying for a regulated product authorisation.

Applicant chooses appropriate regulated products regime(s)

Under assimilated regulation (EU) 2015/2283, a product can only be regulated as a novel food if it meets the definition of a novel food and does not fall within the scope of another regulated product regime.

A novel food cannot also be regulated as:

- a genetically modified (GM) food
- a food produced from precision pred plants
- a food additive
- a food flavouring
- a food enzyme
- an extraction solvent
- a product regulated under another specific sectoral framework (for example, plant protection food and feed products)

Before applying for novel food authorisation, applicants must therefore assess all relevant regulated product regimes and ensure their product does not fall within one of these alternative frameworks. If it does, refer to the relevant application guidance for that regime.

When determining what regulated product regime applies to your product, you should consider how it is produced, and the intended use(s) of your product.

If your product is a novel food, continue with the steps in the novel foods authorisation flowchart (PDF).

Applicant chooses product class

Article 3 of assimilated regulation (EU) 2015/2283 divides the novel foods category into ten classes. Each of these classes requires different data to be submitted for a safety assessment.

You should review the regulation and identify which class or classes apply to your product.

If your product has a history of safe use outside of the UK and EU, you may be able to apply for a traditional food notification under Article 14 of assimilated (EU) Regulation 2015/2283. This is a separate process from a full novel foods application.

Learn more about this process in the novel foods application guidance.

Applicant gathers relevant evidence for application dossier

Before submitting a novel foods authorisation application, you must gather the data necessary for the FSA and FSS to conduct a full safety assessment of your product. The exact evidence required will depend on the class of novel food which applies to your product.

Guidance on what evidence to include can be found in EFSA's technical guidance on novel foods.

Although the UK is no longer a member of the EU, the?EFSA guidance is still relevant as our approach is based on EU processes. Follow the parts that relate to the development of dossiers only and not the application process.

Applicant submits application via regulated products application portal

Submit your application and supporting evidence through the regulated products application portal.

The regulated products application guidance explains how to use the portal.

FSA or FSS checks application

After you submit your application, the FSA or FSS will carry out initial validation checks to make sure it contains everything needed for us to complete a full safety assessment of your product.

We expect all applications, including dossiers, to be complete at submission. We will not accept an incomplete application. We may request further information from applicants if relevant information is missing.

Validated applications will be added to the public register of regulated products applications.

Requesting confidentiality

If your application contains data that could harm your competitive position, you can request that the FSA and FSS treat this information as confidential. See Article 23 of assimilated regulation (EU) 2015/2283 for more information on this process.

Protecting newly developed scientific evidence

You may also request that newly developed scientific evidence or data supporting your application not be used for the benefit of a subsequent application for 5 years from the date of the product authorisation, without your agreement.

See Article 26 of assimilated regulation (EU) 2015/2283 for more information on the process and necessary conditions for the request to be granted.

Safety assessment and other evidence gathered and analysed by FSA, FSS and independent experts

The FSA, FSS, and independent experts will carry out a safety assessment of each validated application based on the evidence provided in your application.

If additional information is needed, the FSA or FSS will issue you a formal request for information (RFI). You must comply with the terms of the RFI within the given timeline.

Safety assessments, along with scientific committee minutes and papers, will be published online on the FSA and FSS websites. Commercially sensitive information may be excluded where you have requested confidentiality.

FSA and FSS independently consider risk management options

Following the safety assessment, the FSA and FSS will independently develop draft recommendations to either authorise or reject the application, or to approve with conditions. This draft recommendation is then subject to a public consultation.

FSA or FSS finalise and submit recommendations for Ministers

Once the consultation on the draft recommendations closes, the FSA and FSS will finalise their recommendations.

The FSA will submit its final recommendation for approval by Ministers in England and Wales. FSS will submit its final recommendation to the relevant Minister in the Scottish Government. The

Minister of Health in Northern Ireland will be kept informed.

Ministers make authorisation decisions for their respective nations

The relevant Ministers in each nation will decide whether to approve or refuse the application. You will be informed of the outcome of the decision directly by email.

If the application is approved, the public list of novel foods authorisations will be updated.