Background on placing a regulated product on the market

Pre-market approval procedure for food and animal feed products and processes requiring authorisation.

Certain food and feed products, called regulated products, require authorisation before they can be sold in the UK.

Authorisation is required for the following regulated product types:

- extraction solvents
- feed additives
- feed for particular nutritional uses (PARNUTS)
- feed detoxification processes
- flavourings
- food contact materials
- food additives
- food enzymes
- genetically modified organisms (GMOs) as food and feed
- irradiated food
- novel foods
- smoke flavourings

For most regulated product types, once products or processes are authorised, they are listed in relevant legislation, which also sets out how they can be used. These lists are referred to as positive lists.

The positive lists for the following substances or processes are not currently set out in legislation:

- food enzymes
- food contact materials - recycled processes
- food contact materials - active and intelligent materials

Until the positive lists are in place, these products may be placed on the market if they meet requirements of:

- the General Food Law
- any general criteria in the food enzyme and food contact material legislation

You can find more information on these requirements, including when you will need to apply for authorisation of these products in Great Britain (GB), in our guidance for regulated products applicants.

If you are not sure whether your product requires authorisation, contact us at regulatedproducts@food.gov.uk

Placing your product on the market in Great Britain

The FSA with Food Standards Scotland (FSS) will carry out a risk analysis process for regulated products and provide advice to ministers, who will decide whether the product can be placed on the market in England, Wales and Scotland. When a decision is made to authorise a product, this will mean a change to the legislation. The legislation will set out how the product can be used and any associated conditions of use.

Authorisation process

Our risk assessment will be carried out in accordance with the requirements of assimilated law and the guidance previously developed by EFSA. For more details on what you'll need to supply with your application for each product type, read our guidance for regulated product applicants.

After you submit your application, we will carry out initial checks to make sure it contains all the necessary information. We will then carry out an assessment to decide if the product or process is safe to be placed on the market in England, Wales and Scotland. This will involve risk assessment by one of our Joint Expert Groups and/or Scientific Advisory Committees and a consideration of other legitimate factors (for example, risks to the environment). These will be combined to form an evidence package.

Based on this evidence, we will consider possible risk management options and make a recommendation to ministers. The ministers will then decide whether the product should be authorised for use in Great Britain. There will be an opportunity to comment on the application by taking part in a consultation during the risk analysis process and before the final recommendation is made. If a decision is taken to support an authorisation, the legislation will be updated to reflect the change.

The timing of the full risk analysis process will depend on how complex the application is and on the type of product. It is likely to be at least a year. For some products the deadlines are set in legislation.

Throughout the process we will keep in touch to clarify any elements of the application or to seek additional information if needed. If more information is needed to complete the evaluation, we will be able 'stop the clock' on an assessment and start it again once we receive the required information.

Applicants must provide up-to-date details to the FSA for correspondence. Failure to do so may result in the application(s) being deemed invalid or rejected.

New authorisations

To apply for a new regulated product authorisation, use our regulated products application service .

Ongoing applications

If you submitted your application to the EU before 1 January 2021 and the assessment process has not been completed, you will need to submit your application to us using our regulated products application service. It will be worth including your EFSA question number in your submission.

This applies both to new authorisations and re-authorisation applications.

We may take into account the published EFSA opinion and the outcome of any risk management discussions at the end of the transition period (31 December 2020), but in some cases we may still need to carry out a full risk assessment and consider risk management options.

Existing authorisations

If your product or process has been authorised by the European Commission (EC) before 1 January 2021 and the necessary legislation applies, that authorisation will remain valid in the UK.

Re-authorisations

Re-authorisations are required every ten years for the following product types:

- genetically modified (GM) food and feed
- feed additives
- smoke flavourings

You can find more details on how when to apply for these in our regulated products guidance.

Getting help

If you have any questions about authorisations of regulated products, contact us at regulatedproducts@food.gov.uk

Placing your product on the Northern Ireland market

The EU law that applies to Northern Ireland is specified in Annex II to the Northern Ireland Protocol. This means that any business seeking a new authorisation for a regulated food and feed product marketed in Northern Ireland will have to continue to follow EU rules.