

# Genetically Modified (GM) Food & Feed Assessments

## What is a Genetically Modified organism?

A GM food or feed is one which contains or is derived from a genetically modified organism (GMO). A GMO is an organism in which the genetic material has been modified in a way that does not occur naturally by mating and/or natural recombination as defined by UK legislation. This includes genetically modified plants, animals and microorganisms. The FSA takes a comparative analysis approach to GM risk assessment where a GM food or feed is compared with an appropriate comparator such as a traditionally cultivated crop or domesticated animals where there is a history of safe use.

## Placing your product on the market in Great Britain

The FSA and Food Standards Scotland (FSS) will use our [risk analysis process](#) to assess the safety of genetically modified organisms as food and feed 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.

In assessing the safety of food/feed containing GM organisms, the FSA and FSS shall, where appropriate, consider the following:

- Whether it has adverse effects on human health, animal health or the environment;
- Whether it misleads the consumer;
- Whether it differs from the food/feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer/animals/humans.

## Northern Ireland

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 an extraction solvent to be placed on the Northern Ireland market you will have to continue to follow EU rules and its [authorisation procedures](#).

## Authorisation process

Our risk assessment will be carried out in accordance with the requirements of retained EU law and the guidance previously developed by the European Food Safety Authority (EFSA). For more details on what you'll need to supply with your application for a GM food or feed application, [read our guidance for regulated product applicants](#).

After you submit your application, the FSA will carry out initial checks to make sure it contains all the necessary information. The ACNFP will then carry out an assessment to decide if the product is safe to be placed on the market in England, Wales and Scotland. We may request advice from other experts or Committees to help us with our assessment.

Based on this evidence, The FSA 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 genetically modified organisms the deadlines are set in legislation.

Throughout the process, the FSA 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, the FSA will be able 'stop the clock' on an assessment and start it again once they receive the required information.

## The Application Process

## **Before you start**

Read the FSA [advice on the authorisation process](#), including what types of products need to be approved, and the [guidance on the application requirements](#).

You will need to apply using the [Regulated Product Application Service](#)

If you have any questions on the process or the requirements, you can contact us at [regulatedproducts@food.gov.uk](mailto:regulatedproducts@food.gov.uk).

Questions for the ACNFP can be sent to the Secretariat at [acnfp@food.gov.uk](mailto:acnfp@food.gov.uk)