

Genetically modified organisms authorisation guidance

Requirements for genetically modified organisms as food and feed authorisations and what you need to submit as part of your application.

This page is part of the Regulated products application guidance

Genetically modified organisms (GMOs) are plants and animals with a genetic make-up that has been modified using techniques of biotechnology. Genetic modification allows scientists to produce plants, animals and micro-organisms with specific qualities.

Genetically modified food and feed contain or consist of GMOs or are produced from GMOs.

Legislative requirements

Before a GMO food or feed product can be placed on the market in Great Britain (GB) it must be authorised under the assimilated [Regulation \(EC\) 1829/2003 on Genetically Modified Food and Feed](#).

The requirement for authorisation applies to products made from, containing or derived from GMOs that are 'not live' (e.g. soybean oil, maize starch) to be marketed for consumption by humans and animals.

Authorisations are valid for a maximum of ten years. After this period a renewal application will be required for continued marketing.

Register of authorised GMOs

[The register provides information on the GMOs authorised](#) for import and use in GM food and feed in Great Britain.

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 a new authorisation for a GMO to be placed on the Northern Ireland market you will have to continue to follow EU rules.

New authorisations

As part of the application process an evaluation of the analytical method supplied by the applicant must be undertaken by the reference laboratory. Assimilated [Regulation \(EC\) 1829/2003](#) establishes the reference laboratory and defines its tasks.

Application process

To apply for an authorisation of a GMO in GB:

1. Use our [regulated products application service](#) to complete the application. This is where you will be asked to upload all the documents to support your application, which will form your dossier.
2. You should take into account the requirements in retained EU law as appropriate following the EFSA guidance.
3. You should also at this stage upload the documentation on the analytical method and any relevant information needed for the reference laboratory to undertake the evaluation of the method. If relevant, make reference to any evaluation which may have already been undertaken by the EU Reference laboratory on the GMO in question.
4. After receiving your application, we will contact you to agree and set out the process for payment of any fees due to be paid for the analytical assessment as laid down in the legislation. We will also provide details on how to send the three samples (and standards) where applicable to the Reference laboratory.

Application requirements

In “Uploads” folder there are 3 subfolders:

1. Administrative dossier files

Applicants should upload letters and other correspondence related to the dossier.

2. Technical Dossier Files

Applicants should upload all technical files, including studies and data related to specific sections of the safety assessment to the corresponding sub-folder as detailed in the following.

- **Part 1** – General information
- **Part 2** – Scientific information

This folder contains the scientific information alongside a Table of Contents (TOC), the main text, studies and sequencing/bioinformatics files. It is divided into the following sub-folders for each section and applicants should provide the required data for each section in the corresponding sub-folder:

- 1.1. Information relating to the recipient.
- 1.2. Molecular Characterisation (including sequencing files and bioinformatic analyses)
- 1.3. Comparative Analysis
- 1.4. Toxicology Assessment
- 1.5. Allergenicity Assessment
- 1.6. Nutritional Assessment
- 2. Exposure assessment Anticipated intake extent of use
- 3. Risk characterisation
- 4. Post-Market monitoring PMM
- 5. Environmental Risk Assessment
- 6. Post-Market Environmental Monitoring Plan PMEM
- 7. Additional information related to the safety

Applicants should upload any additional information useful for the assessment, also those relating to other regulators' assessments, including EFSA requests.

- **Part 3** – Cartagena protocol
- **Part 4** – Labelling proposal
- **Part 5** – Methods of detection, sampling and identification and reference material

- **Part 6** – Additional information to be provided for GM plants and/or food/feed containing or consisting of GM plants
- **Part 7** – Summary of applications
- **Part 8** – Administrative documents

3. Annexes files

This folder should contain:

- References
- Appendices (not studies/not data files)
- Any other files that do not fall within one of the named sections above

Detailed application guidance

Assimilated law sets out further information on the application requirements:

- [Regulation \(EC\) 641/2004 – authorisation of new genetically modified food and feed](#)
- [Regulation \(EU\) 503/2013 – authorisation of genetically modified food and feed](#)

The European Food Safety Authority (EFSA) has previously developed technical guidance on the requirements of application dossiers. This guidance generally 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 for GMO applications](#)

Renewal applications

Renewal applications must be submitted at least one year before their expiry date using our [regulated products application service](#).

Your previously authorised GMO will continue to be allowed on the market in the GB if you submitted renewal application to EU before January 2021 and at least one year before its expiry date. You will still need to submit your dossier to us after January 2021.

Ongoing applications

If you submitted your application for a new authorisation or for the renewal of an existing authorisation to the EU before 1 January 2021 and the assessment process for this application has not been completed, you will need to submit it to us using our [regulated products application service](#). When completing the application form, you will be asked to provide your EFSA question number.

Existing authorisations

If your GMO has been authorised by the European Commission before 1 January 2021 and the necessary legislation is in place, that authorisation will remain valid in GB.

How long will my application take?

The law includes deadlines for key steps in the process. In most cases, applications will take at least a year.

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 all the required information to ensure we can process your request as efficiently as possible.

Getting help

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

Apply for authorisation

You can now use our online service to make a [regulated product application](#).