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.

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 contains or consists of GMOs, or is produced from GMOs.

GMO food and feed authorisations

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, as amended?.

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.

Register of authorised GMOs

The FSA is required to maintain a register that accurately represents the authorisation status of GMO food and feed as determined by the appropriate authority (ministers).

The register provides information on the GMOs authorised? for import and use in GMO food and feed in GB.

New authorisations

To apply for an authorisation of a GMO in GB:

1. Use our?regulated products application portal?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 assimilated EU law?as appropriate. The European Food Safety Authority (EFSA) has previously developed technical guidance on the requirements for application dossiers which is also applicable for dossiers submitted in GB.? However, you should follow the parts that relate to the development of dossiers only and not the application process.
3. 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. 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 the “Uploads” folder within our application portal 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, as amended, 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

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