



**Annual report on scientific  
method validation activities  
performed in support of GMO  
Food and Feed Authorisation  
(Great Britain)**

FSA Contract Reference Number:  
FS430418  
GMO Food and Feed Authorisation  
(Great Britain)

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## **Glossary**

**CRM** - Certified Reference Material

**DNA** - Deoxyribonucleic acid

**ENGL** - European Network of GMO Laboratories

**EURL GMFF** - EU Reference Laboratory for GMOs in food and feed

**FSA** - Food Standards Agency

**FSS** – Food Standards Scotland

**GeMMA** – Genetically Modified Material Assessment Scheme

**GMO** - Genetically Modified Organism

**JRC** – European Commission’s Joint Research Centre

**NRL** - National Reference Laboratory (appointed under [assimilated] (EU) law 2017/625)

**PBO** – Precision Bred Organism

**PCR** - Polymerase Chain Reaction

**PT** – Proficiency Test



## **Role of the GMO Authorisations (Great Britain) position**

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) are the Competent Authority for the purpose of assimilated (EC) law 2017/625 on Official Feed and Food Controls in the UK. To fulfil the FSA/FSS's obligation under Article 8 of assimilated (EC) law 503/2013, LGC was appointed in 2021 to deliver the functions currently performed by the EU Reference Laboratory (EURL) for supporting the authorisation of Genetically Modified Organisms (GMO) for food and feed uses, in Great Britain (England, Wales and Scotland). Applications for authorisations may include analysis of genetic material derived from plant, animal and microorganism sources.

The GMO Authorisations role was contracted for delivering the provision of method validation laboratory services for the authorisation of new GMO applications for Great Britain (GB), renewal GMO applications for GB and the review and re-validation of existing and ongoing applications as and when necessary on behalf of the FSA.

During the period of this annual report, the FSA was in discussions regarding reforms to the current market authorisation procedure, including a proposal to remove the requirement for submission of renewal applications. Further information can be found under Core Function – Objective 01 (page 7).

### **GMO Authorisations (Great Britain) Services**

The basic duty is to deliver the document review and method validation stage of the GMO Food and Feed authorisation process which forms part of the risk assessment for the Competent Authority. The validation process includes the following six steps:

1. Reception of valid application including relevant documentation and data on method and samples
2. Scientific assessment of documentation and data (primarily DNA extraction method and method of detection)
3. Experimental testing of samples and methods
4. Method validation through collaborative ring trials
5. Reporting to the Competent Authority
6. Secure storage of relevant GMO food and feed samples and control materials for the duration of the contract.

LGC was awarded the GMO Authorisations (Great Britain) position by the Competent Authority in August 2021 following open competitive tender. Pursuant to this role, LGC was contracted to conduct the following activities, as specified in the contract:

#### **Core Function**

##### **Objective 01 – Infrastructure development**

This objective underpins the provision of a support structure to build a resilient base for all GMO method validation authorisations:

- New GMO event applications in Great Britain;
- Renewals – GMOs which are authorised for use in the EU/UK, but are due for renewal following expiration of the initial 10-year validity period of their authorisation (assimilated (EC) law 1829/2003, and assimilated (EC) law 641/2004, as amended by assimilated (EC) law 503/2013).



**Objective 02 – Core support activities**

This objective ensures maintenance of competency of core activities (e.g. reporting structure, storage facilities, internet presence, and contract management) in support of the method validation of GMOs as part of the GB authorisation process.

**Objective 03 – Core authorisation activities**

This objective follows a six-point scientific technical plan to ensure a due process is in place for provision of method validation services as part of the GB based GMO authorisation process:

**03/1 – Reception of the application**

**03/2 – Scientific assessment of dossiers and data**

**03/3 – Experimental testing of samples and methods (where applicable)**

**03/4 – Method validation through collaborative ring trials (where applicable)**

**03/5 – Reporting to the Competent Authority**

**03/6 – Control materials housing**



## Core Function

### Production of the GMO Authorisations (Great Britain) annual report

This report details the activities carried out during the 4<sup>th</sup> year of the GMO Authorisations (Great Britain) operation (April 2024-March 2025) in relation to the duties of the role.

#### Objective 01 – Infrastructure development

##### Tasks:

- 01/0 - Agree an operational protocol with the Competent Authority at the project kick-off meeting**
- 01/1 - Establishment of new quality procedures to ISO 9001 of the processes for quality control of method validation of new GMOs applications as part of the UK GMO authorisation process**
- 01/2 - Description of the method validation process published**
- 01/3 - Guidance on the submission process and expected timeframes published**
- 01/4 - Publication of a note to the applicants on the type and nature of control samples provided in the context of applications for authorisation**
- 01/5 - Publication of an explanatory note to applicants regarding practical instructions concerning the method validation task of the authorisation laboratory pursuant to relevant UK legislation (e.g. retained Regulation (EU) No 503/2013 on applications for authorisation)**
- 01/6 - Publication of an explanatory note for the payment of financial contributions under Commission implementing regulation (EU) No 120/2014 of 7<sup>th</sup> February 2014, amending Regulation (EC) No 1981/2006, on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003**
- 01/7 - Publication of document templates for submission of method validation data**
- 01/8 - Initial maintenance activities**

##### Example activities in relation to these Tasks:

- Development of an operational protocol:
  - Discussions on a proposed new structure for GMO authorisations (method validation services)
    - Participation in several meetings with the FSA to discuss a newly proposed structure for GMO authorisations in Great Britain, based on future streamlining of the process and reducing the burden upon applicants.
- Development of applicant guidance notes and internal reporting forms:
  - A set of seven draft applicant guidance notes and seven draft internal reporting forms were submitted for FSA/FSS appraisal. The FSA provided feedback regarding final outstanding queries in July 2024. This feedback was addressed and requested changes were implemented accordingly.
  - A set of finalised applicant guidance notes and internal reporting forms were provided to the FSA in August 2024.



- Applicant guidance notes are intended to be made publicly available and to help inform on the process involved for authorisations.
- Applicant guidance notes consist of the following documents:
  - Application workflow
  - Financial contributions
  - Control sample guidance
  - CRM workflow and acceptance criteria
  - GM method detection form
  - qPCR method form
  - Validation acceptance criteria
- Internal reporting forms are intended to provide traceability and to communicate the results of LGC's assessment of the method validation results/data to the CAs in a harmonised manner.
- Internal reporting forms consist of the following documents:
  - Scientific Dossier Assessment Form
  - DNA extraction method report
  - In-house method verification report
  - Method validation collaborative trial report
  - Validated method protocol
  - GMO renewals reporting form
  - Application summary report
- It was noted that the draft applicant guidance notes and the internal reporting forms were based on the workflow and process as described in the agreed contract. Should a current proposal for streamlining the future authorisation activities be successful, then the applicant guidance notes and internal reporting forms would need to be reviewed and revised in line with any new procedures.
- Reforms to the market authorisations process for regulated products
  - At the March 2024 FSA Board meeting, plans were proposed to streamline the regulations around bringing regulated products to market in the UK, inclusive of removing renewal requirements for GMOs.
  - The FSA launched an open and public consultation on these proposed reforms to the regulated products authorisation process between the 3<sup>rd</sup> April to 5<sup>th</sup> June 2024. Staff from within the GMO Authorisations (Great Britain) position contributed a response to this.
  - Staff from the GMO Authorisations (Great Britain) position attended the FSA Board meeting on the 18<sup>th</sup> September 2024 as virtual observers, where the proposal and results from the public consultation were briefly discussed.
  - At the FSA Board meeting on the 18<sup>th</sup> September, the (interim) FSA Chief Executive's report to the Board stated that new UK Government ministers had confirmed they were content to proceed with two initial market authorisation reform proposals to remove



renewal requirements for authorised regulated products. Subject to UK Government decisions on legislative timetabling, the FSA aimed to introduce legislation for these proposals in early 2025.

- The FSA have launched a new [register](#) which enables applicants to check the status of, and access information relevant to, their application
  - From the 1<sup>st</sup> April 2025, a Great Britain wide statutory instrument (SI) detailing the [reforms to the market authorisations process for regulated products](#) will be in place.
- 
- Engagement with Official Laboratories
    - Discussions held with an OL regarding potential authorisations routes in the UK for products/organisms regarded as PBOs.



## **Objective 02 – Core support activities**

### **Tasks:**

- 02/1 - Production of an annual report**
- 02/2 - Review and maintain a list of validated reagents**
- 02/3 - Maintain a list of reputable suppliers**
- 02/4 - Maintain appropriate storage facilities to house materials**
- 02/5 - Maintenance of support for ISO/IEC 17025:2017 accreditation**
- 02/6 - Report PT round results to the FSA as part of recognised external quality assessment exercises**
- 02/7 - Maintain a national GMO Compendium (“database”) containing lists of control materials and methods**
- 02/8 - Continue international stakeholder engagement**
- 02/9 - Establish a process for setup costs and overhead costs associated with each GB centric authorisation**
- 02/10 - Maintenance of storage and distribution service**
- 02/11 - Continuous improvement activities**
- 02/12 - Contract management**

### **Example activities in relation to these Tasks:**

- Production of the GMO Authorisations (Great Britain) annual report:
  - Successfully submitted the draft GMO Authorisations (Great Britain) annual activity report for the April 2023 to March 2024 period to the CAs for review.
  - The GMO Authorisations (Great Britain) annual report for the operational period April 2023 to March 2024 was published on the [GMO webpages](#).
  - The current document represents the GMO Authorisations (Great Britain) annual report for the operational period April 2024 to March 2025, providing a summary of the related activities.
  - Four GMO Authorisation Quarterly Review Meetings were successfully held with the Competent Authorities.
  - Copies of the Authorisation presentations from the Quarterly Review Meetings were uploaded onto the FSA Microsoft Teams channel.
  - Monthly logs, providing detailed descriptions of all activities engaged in as part of the GMO Authorisations (Great Britain) function were provided to the Competent Authorities.
- Review and maintain a list of validated reagents:
  - In conjunction with the GMO NRL position, draft lists of reagents and suppliers have been prepared, maintained and updated. Personnel associated with the GMO Authorisations (Great Britain) and GMO NRL positions are in constant contact with Official Laboratories, and are able to provide updated advice on the availability of validated reagents and appropriate suppliers.
- Maintain a list of reputable suppliers:



- In conjunction with the GMO NRL position, draft lists of reagents and suppliers have been prepared, maintained and updated.
- Brought to the attention of the FSA the announcement from JRC (Geel) regarding [future production of EU Certified Reference Materials](#) for GMOs.
- Maintain appropriate storage facilities to house materials:
  - Throughout the fourth year of operation, LGC has continued to maintain space within dedicated secure walk-in cold room facilities for the storage of any control materials on behalf of the GMO Authorisation (Great Britain) function.
- Maintenance of support for ISO/IEC 17025:2017 accreditation:
  - Activities related to the use of validated methods of detection for GMOs is governed by LGC's ISO/IEC 17025:2017 flexible scope of accreditation. LGC has participated in over 64 external quality assessment proficiency test rounds since 2000, being a mixture of both EURL Comparative Tests and GeMMA proficiency test rounds. In all proficiency test rounds, LGC has received satisfactory ( $z < [2]$ ) scores.
  - LGC's ISO 17025 flexible scope of accreditation was subject to a successful audit by UKAS during 2024 and the accreditation maintained.
  - A staff member working within the GMO Authorisations (Great Britain) function was invited to act as the scientific/technical auditor of GMO related activities to ISO 17025 (methods), ISO 17034 (production of reference materials) and ISO 17043 (provision of proficiency tests) at a laboratory within the European Union. The auditing body provided written positive feedback to LGC regarding the thoroughness of the technical audit and the quality of the reports.
- Report proficiency test (PT) round results to the FSA as part of recognised external quality assessment exercises:
  - LGC has participated in over 64 PT rounds since 2000, being a mixture of both EURL Comparative Tests and GeMMA (FAPAS) proficiency test rounds. In all proficiency test rounds, LGC has received satisfactory ( $z < [2]$ ) scores from over 95 separate samples analysed.
  - PT round results are regularly communicated to the FSA as part of the NRL function, and this activity will continue as part of future work.
  - The official FAPAS report for the GeMMA U114 round was published in 2024. LGC received a Z-score of +0.2 following successful participation in the proficiency test round. These results were communicated to the FSA.
- Maintain a national GMO Compendium ("database") containing lists of control materials and methods:
  - Draft web pages for the GMO Compendium are currently being reviewed by the FSA.
  - LGC continues to forward on to the FSA information regarding new GMO authorisations which are published within the EU.



- National engagement activities:
  - Provided proposals in response to the FSA (Scientific Sampling and Laboratory Policy Team) online survey to gather requirements for research and development projects for food and feed analysis, for the 2025/2026 financial year.
  - Brought to the attention of the FSA evidence of digital PCR being increasingly used in the EU for GMO analysis.
  - Forwarded an [EFSA statement](#) to the FSA regarding the use of Whole Genome Sequencing for microorganisms, which is of interest for risk assessment, regulated products and GMO related areas.
  - Brought to the attention of the FSA an article from the U.S. Department of Agriculture regarding a [risk assessment of NGT plants](#).
  - Attended the kick-off meeting for the [Bezos Centre for Sustainable Proteins](#) (Imperial College London) in January 2025. There appears to be significant overlap for traceability, metrology, detection strategies, authorisations, regulations and route to markets for the diverse fields of GMOs, PBOs, engineering biology and sustainable proteins (e.g., cultivated meats, microbial fermentation, plant proteins, etc.,).
  
- Continue international stakeholder engagement:
  - As a recognised independent scientific expert in GMO analyses, a staff member from within the GMO Authorisations (Great Britain) function is a member of the following working groups:
    - ENGL Working Group on New Mutagenesis Techniques (New Genomic Techniques). This Working Group reconvened to discuss how to address development of guidance for the analytical detection of NGT animals and NGT microorganisms, and separate mandates were provided for each group.
    - ENGL Working Group NGT – microorganisms: the mandate/aim of this group is to provide a report on the bespoke challenges and feasibility to detect microorganisms obtained by New Genomic Techniques in food and feed.
    - ENGL Working Group NGT – animals: The mandate/aim of this group is to provide a report on the bespoke challenges and feasibility to detect animals obtained by New Genomic Techniques in food and feed.
  - A staff member from the GMO Authorisations (Great Britain) position participated as a recognised independent expert in GMO analysis at the [35<sup>th</sup> ENGL plenary meeting](#) at the EC-JRC (Italy) in November 2024.
  - A staff member from the GMO Authorisations (Great Britain) position was invited as a recognised independent expert in GMO analysis to provide a presentation at the 20<sup>th</sup> anniversary celebration of the EURL, held at the EC-JRC (Italy) in November 2024.
  - A staff member from the GMO Authorisations (Great Britain) position was invited as a recognised independent expert in GMO analysis to present and run an interactive element on DNA extraction at the EC -RC (Italy) site, as part of a workshop on GMO analytical approaches in December 2024.
  - Forwarded on to the FSA a [guidance](#) article issued by the Food and Drinks Administration (FDA) in the US regarding risk based principles for the assessment of food derived from plants produced using genome editing.



- Attended an EFSA webinar which assessed the adequacy of current guidance for the evaluation of NGT animals and provided a [link](#) to the FSA.
- EU HORIZON project DETECTIVE (DETECTION OF NGT PRODUCTS TO PROMOTE INNOVATION IN THE EUROPEAN UNION):
  - The HORIZON Europe project “New detection methods on products derived from new genomic techniques to enable safe innovation in the food system ([DETECTIVE](#))”, in response to the HORIZON-CL6-2023-FARM2FORK call, was successfully commissioned and started on January 1<sup>st</sup> 2024.
  - The project is aimed at investigating detection of NGT products and organisms in the food/feed supply chain.
  - A member of staff from the GMO Authorisations (Great Britain) position has been appointed as a member of the Scientific Advisory Board associated with this project.
  - Ongoing attendance at meetings including consortium and Work Package meetings, as well as provision of presentations and reviewing project progress and outputs.
- Establish a process for setup costs and overhead costs associated with each Great Britain centric authorisation:
  - A copy of the guidance document outlining Financial Contributions from Applicants has been provided to the FSA.
- Maintenance of storage and distribution service:
  - Throughout the fourth year of operation, LGC has developed and continued to maintain capability for storage and distribution facilities on behalf of the GMO Authorisation (Great Britain) function.
- Continuous improvement activities:
  - Throughout the fourth year of operation of the GMO Authorisations position, regular contact between the FSA and LGC has been augmented through the LGC Key Account Manager, who has also facilitated support for continuous improvement activities (e.g., monthly report structure).
  - Participated in regular UK GM Technical Meetings between LGC, SASA and Fera to discuss technical aspects associated with UK GMO analyses.
  - The [NRL and Authorisation webpages](#) were updated in line with a refresh of the LGC Group website, designed to enhance user experience, showcase impactful work, and make it easy for visitors to access information and connect with business areas faster. The content of the webpages remained unchanged.
  - Operations at the LGC site in Teddington will be migrated by a phased approach to a new premises built in Guildford starting in late Spring 2025, to make use of a more modern, purpose-built and energy efficient premises and facilities.
- Contract management:



- Throughout the fourth year of operation of the GMO Authorisations (Great Britain) position, the Project Management team have provided consistent and continued support for all Contract management related activities.
  - Four quarterly review meetings with the Competent Authorities were attended, to present and discuss progress and activities associated with the GMO Authorisation (Great Britain) function.
  - A number of meetings were held with the FSA to discuss requirements for current and future assessment of GMO renewals within Great Britain.
  - Further discussions were held with the FSA regarding the proposed new operational workflow associated with GMO authorisations in Great Britain.
  - All invoices associated with the GMO Authorisations (Great Britain) function were issued on time in accordance with the contract.
  - Discussed with the FSA that robust procedures were in place to mitigate any potential disruption of GMO authorisations (Great Britain) services during the limited transition period of the NML (LGC) moving from the Teddington to Guildford sites in late Spring 2025.
- FSA Food and Feed Laboratory Workshop 2024:
    - This meeting was held on the 16<sup>th</sup> April 2024 via MS Teams. Following the successful NRL Symposium of 2022, the FSA hosted an online event to showcase the work that UK NRLs had achieved over the last year. This year, Official Laboratories were invited so that the work the NRLs and FSA do behind the scenes could be highlighted. The conference was aimed at fostering collaborative relationships between NRLs and OLs, to further promote OLs and FSA/FSS engagement with NRLs, and to provide updates to laboratories on FSA/FSS strategies.
    - The meeting consisted of two breakout groups discussing engagement and collaboration between NRLs and OLs, and skill gaps in laboratories. Staff from the GMO NRL and Authorisations (GB) were present and provided a presentation as part of the Laboratory Workshop in relation to work from the NRLs and Authorisation areas and answered questions as part of a live Q&A panel session during the workshop.
- ISO/IEC 17025:2017 accreditation support
    - LGC's ISO 17025 flexible scope of accreditation for GMO analysis was subject to a successful audit from UKAS in July 2024. Positive feedback on the quality of the science underpinning the ISO 17025 flexible scope of accreditation for GMO analysis was provided, particularly citing the strong links that LGC maintains with European partners in this area, and the leadership of the science as demonstrated through the publications/guidance list.
    - All methods involved in the GMO analytical workflow were subject to a full internal ISO 17025 audit inclusive of method witnessing in November 2024.
    - A staff member from the UK NRL was appointed by [BELAC](#) (the Belgian Accreditation Body) to act as a technical auditor for GMO related activities to ISO 17025, ISO 17034 and ISO 17043 during an assessment of a European laboratory.



## **Objective 03 – Core authorisation activities**

### **Task:**

#### **03/1 - Reception of the application**

#### **03/2 - Scientific assessment of dossiers and data**

##### **03/2.1 - Scientific assessment of documentation**

##### **03/2.2 - Scientific assessment of data**

##### **03/2.3 - Report and recommendation**

#### **03/3 - Experimental testing of samples and methods**

##### **03/3.1 - Sample and reagent prep**

##### **03/3.2 - DNA extraction method verification (yield, integrity and purity)**

##### **03/3.3 - Experimental design for assessment of key metrics and performance characteristics**

##### **03/3.4 - PCR quality metrics (Dilution series, dynamic range, r-squared, PCR eff. and $\Delta C_t$ )**

##### **03/3.5 - Trueness and RSD<sub>r</sub>**

##### **03/3.6 - LOD/LOQ**

##### **03/3.7 - Detection method comparison to dossier**

##### **03/3.8 - In-silico specificity tests**

##### **03/3.9 - Final report on in-house verification**

#### **03/4 - Method validation through collaborative ring trials**

##### **03/4.1 - Optimise/adjust experimental design for collaborative trial**

##### **03/4.2 - Recruitment of participating laboratories**

##### **03/4.3 - Data collation and analysis**

##### **03/4.4 - Arrange payment of participating laboratories**

#### **03/5 - Reporting to the Competent Authority**

##### **03/5.1 - Summary reports in standard format (validation trial, validated method, DNA extraction method)**

##### **03/5.2 - Publication of method validation results**

#### **03/6 - Control materials housing**

##### **03/6.1 - Reception and storage**

### **Example activities in relation to these Tasks:**

Please note: No official (Great Britain) applications requiring processing for laboratory based method validation services as part of the authorisation procedure were provided to LGC in the fourth reporting year of operation of the GMO Authorisations (Great Britain) function. This included no applications for new GM events (single or stacked) or GMO renewals (due for renewal following their 10-year authorisation/approval date). Nevertheless, for completeness, the following sections have been included in this annual report of activities:

- Recruitment of participating laboratories:
  - Alongside the current expertise and capability offered by specific UK Official Laboratories and two previous ENGL laboratories based in the UK, staff from within the GMO Authorisations (Great Britain) function continue to work closely with several other UK Official Laboratories in support of the FSA initiative on GMO analytical capability building.
- Summary reports in standard format (validation trial, validated method, DNA extraction method):



- A set of finalised applicant guidance notes and internal reporting forms were provided to the FSA in August 2024.
- Applicant guidance notes are intended to be made publicly available and to help inform on the process involved for authorisations.
- Applicant guidance notes consist of the following documents:
  - Application workflow
  - Financial contributions
  - Control sample guidance
  - CRM workflow and acceptance criteria
  - GM method detection form
  - qPCR method form
  - Validation acceptance criteria
- Internal reporting forms are intended to provide traceability and to communicate the results of LGC's assessment of the method validation results/data to the CAs in a harmonised manner.
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  - Application summary report