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)

Period covered: 1st April 2025 – 31st March 2026

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Glossary

CA – Competent Authority

CRISPR - Clustered Regularly Interspaced Short Palindromic Repeats

CRM - Certified Reference Material

DNA - Deoxyribonucleic acid

EC-JRC – European Commission's Joint Research Centre

EFSA – European Food Safety Authority

ENGL - European Network of GMO Laboratories

EU – European Union

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

FAPAS – Food Analysis Performance Assessment Scheme

FSA - Food Standards Agency

FSS – Food Standards Scotland

GeMMA – Genetically Modified Material Assessment Scheme

GMO - Genetically Modified Organism

NGT – New Genomic Techniques

NML – UK National Measurement Laboratory (hosted at LGC)

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

OL – UK Official Laboratory

PBO – Precision Bred Organism

PCR - Polymerase Chain Reaction

qPCR – Quantitative PCR

PT – Proficiency Test

SASA – Science & Advice for Scottish Agriculture

SPS - Sanitary and Phytosanitary

UK – United Kingdom

UKAS – United Kingdom Accreditation Service

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 have been involved in discussions regarding reforms to the current market authorisation procedure, as well as the Sanitary and Phytosanitary negotiations between the UK and the EU. Further information can be found under Core Function – Objective 01 (page 9).

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 (CA)
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 5th year of the GMO Authorisations (Great Britain) operation (April 2025-March 2026) 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 7th 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 were held on a proposed new structure for GMO food and feed authorisations, but these were put on hold pending the outcome of the proposal for reforms to the market authorisations process for regulated products, and the Sanitary and Phytosanitary negotiations with the EU.

- Development of applicant guidance notes and internal reporting forms:
    - A set of seven applicant guidance notes and seven internal reporting forms were provided to the FSA.
    - 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 these applicant guidance notes and internal reporting forms were based on the workflow and process as described in the original contract. Should any proposal for further streamlining the future authorisation activities be successful, then the applicant guidance notes and internal reporting forms should be reviewed and revised in line with any new procedures.

- Reforms to the market authorisations process for regulated products:
  - From the 1st April 2025, a Great Britain wide statutory instrument detailing the reforms to the market authorisations process for regulated products was in place.
  - On the 18th June 2025, the FSA Board meeting discussed the FSA's Market Authorisation Modernisation proposal. The proposal strived to further streamline the authorisation process by giving the FSA/FSS more powers over decisions on market authorisations, including the use of reports from other regulators and control laboratories (e.g., EFSA and EURL) to inform on authorisations in Great Britain.
  - The progress of these proposals may be dependent upon progress associated with the current common understanding on the shared UK/EU Sanitary and Phytosanitary agreement, published on the 19th May 2025. This seeks to follow a model of dynamic agreement with EU law in Sanitary and Phytosanitary policy areas.

- Input into discussions on the Sanitary and Phytosanitary negotiations
  - As part of input into the discussions on the Sanitary and Phytosanitary negotiations between the UK and EU, the GMO Authorisations (Great Britain) function engaged in the following activities:
    - At the request of the FSA Trade Strategy Team, provided input into experiences of EU interactions both pre- and post- EU exit.
    - Attended a Defra led UK-EU SPS agreement: Stakeholder Information Forum.

- 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 2024 to March 2025 period to the CAs for review.
  - The GMO Authorisations (Great Britain) annual report for the operational period April 2024 to March 2025 was published on the GMO webpages.
  - The current document represents the GMO Authorisations (Great Britain) annual report for the operational period April 2025 to March 2026, 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 for Official Laboratories.

- Maintain appropriate storage facilities to house materials:
  - Throughout the fifth 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 65 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.
  - In June 2025, laboratory equipment and processes were successfully decommissioned, re-located and re-validated from the NML (LGC) laboratory Teddington site to the Guildford site. All laboratory instrumentation was calibrated and successfully checked by qualified engineers. All LGC staff completed a formal laboratory induction inclusive of health and safety at the Guildford site. UKAS audited the method verification work at the Guildford site, and in July 2025, UKAS awarded ISO 17025 accreditation for GMO related work at Guildford.

- Report proficiency test (PT) round results to the FSA as part of recognised external quality assessment exercises:
  - LGC has analysed over 100 test samples for a range of GM events as part of PT schemes 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.
  - 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 U123 round was published in 2025. LGC received a Z-score of +0.1 following successful participation in the proficiency test round, submitting an estimated value of 1.12 (m/m) % GM, compared to an assigned value of 1.10 (m/m) % GM. 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 were delivered to the FSA for review.

- National engagement activities:
  - Provided proposals in response to the FSA (Laboratories and Sampling Team) online survey to gather requirements for research and development projects for food and feed analysis, for the 2026/2027 financial year.

- Brought to the attention of the FSA the increased uptake of digital PCR for GMO analysis, particularly in the EU.
- Staff from the GMO Authorisations (Great Britain) function at LGC organised a seminar on the 10th July on an introduction to crop breeding techniques, inclusive of genome editing and precision breeding. A presentation was provided on the basic principles underlying crop breeding, inclusive of using CRISPR technologies, which was followed by a global snapshot of where genome editing was currently being applied in the food sector as well as providing some case studies on the potential advantages of Precision Bred Organisms (PBOs) and the potential role of GMOs and PBOs in fighting climate change. The event was attended by staff from across Defra, the FSA and FSS.
- Discussions with key staff at the Bezos Centre for Sustainable Proteins regarding potential synergies on routes to market and authorisation for related GMO and Engineering Biology products.

- Continued international stakeholder engagement:
  - As a recognised independent scientific expert in GMO analyses, a staff member from within the GMO Authorisations (Great Britain) function was 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.
  - Virtual attendance at the EU-SAGE Annual General Meeting in April 2025. EU-SAGE is a network which shares information about genome editing and promotes the development of European and EU member state policies that enable the use of genome editing for sustainable agriculture and food production
  - Attended online webinar from GeneBEcon regarding the application of genome editing to improve virus resistance and starch content in potato.
  - A staff member from the GMO Authorisations (Great Britain) position participated as a recognised independent expert in GMO analysis at the 36th ENGL plenary meeting at the EC-JRC (Spain) in November 2025. The staff member provided a presentation to EU colleagues on the current progress associated with the UK legislation on PBOs.
  - A staff member from the GMO Authorisations (Great Britain) position was invited to provide a presentation at the National Institute of Biology annual GMO workshop (Slovenia). The workshop included the Slovenian Competent Authorities. The presentation provided was on the current regulatory updates associated with the Genetic Technology (Precision Breeding) Regulations 2025 in England.
  - Participated in the Bezos Centre for Sustainable Proteins 2026 conference, which was attended by over 650 stakeholders and included discussions on GMOs and PBOs.

- GMO authorisations in the EU
    - Provided updates on GMO authorisations in the EU in the 25/26 period to the FSA, including:
        - GM maize event MON 95275
        - GM maize event MON 94804
        - GM maize event DP910521
        - GM soya stacked event MON 87705 × MON 87708 × MON 89788
        - GM maize event DP51291
        - GM oilseed rape event MON 88302
        - Renewal of authorisation for GM maize event MON 87427
        - GM maize event DAS1131
        - Renewal of authorisation for GM maize event MON 87708
        - GM sugar beet event KWS20-1
        - Renewal of authorisation for GM maize event NK603
        - GM soya event DBN-09004-6
        - Renewal of GM cotton stacked event GHB614 x LLcotton25
    - These authorisations relate to EU Commission Implementing Decision (EU) 2025/1898 for placing on the market for use in food & animal feed. Unless otherwise noted, these approvals are valid for ten years and the applications apply to imports for food, feed and processing but not for cultivation.
    - The EU Commission revoked authorisation of specific oilseed rape stacked events Ms8×Rf3×GT73, Ms8×GT73 and Rf3×GT73.

- 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 commenced on January 1st 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 was nominated to be a member of the Scientific Advisory Board associated with this project.
    - Ongoing attendance at meetings including Consortium and monthly Work Package meetings, as well as provision of presentations, review of project progress and outputs, and promoting the DETECTIVE Community of Practice.
    - Participation in the EU Horizon DETECTIVE consortium meeting 2025.
    - Participated in the 4th Responsible Research & Innovation workshop, hosted at the EC-JRC (Spain) in November 2025. The workshop focussed on agreement for co-prioritisation of empowerment and capability needs of EU laboratories for the detection of NGT products in the food supply chain.

- 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 fifth 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 fifth year of operation of the GMO Authorisations (Great Britain) 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.
  - Operations at the LGC site in Teddington were successfully migrated in a phased approach to a new premises built in Guildford in late Spring 2025. Robust procedures were in place to mitigate any potential disruption of GMO Authorisations (Great Britain) services during this limited transition period of the NML (LGC) moving from the Teddington site to Guildford site.

- Contract management:
  - Throughout the fifth 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 organised, to present and discuss progress and activities associated with the GMO Authorisations (Great Britain) function.
  - The annual activity report for the GMO Authorisations (Great Britain) for the 24/25 financial year was published.
  - 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.
  - Following the successful move of the National Measurement Laboratory (LGC) to Guildford, a Change Control Note was issued by the FSA to acknowledge the change of registered address.
  - A project contract wrap-up meeting was held with the FSA, prior to the end of the 5 year service delivery in March 2026.

- ISO/IEC 17025:2017 accreditation support
  - All methods involved in the GMO analytical workflow at LGC were subject to successful internal and external ISO 17025 audits during the reporting period.

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 ΔCt)
03/3.5 - Trueness and RSD_r
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 fifth 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 continued 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 have been provided to the FSA.
- 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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