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 2023 – 31st March 2024

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Glossary

CRM - Certified Reference Material

Defra - Department for Environment, Food & Rural Affairs

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 Testing

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 were appointed 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 is responsible 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.

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 conducts 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 3rd year of the GMO Authorisations (Great Britain) operation (April 2023-March 2024) 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 on a proposed new structure for GMO authorisations (method validation services)
        - Attended a number of 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.
        - LGC presented a suggested flow diagram to the FSA, to outline potential operational aspects associated with this.

- Development of applicant guidance notes and internal reporting forms:
    - Draft applicant guidance notes were developed, intended as guidance to applicants as part of the GMO authorisation procedure in Great Britain in the context of the method validation services workflow and requirements.
    - Draft applicant guidance notes consisted 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
    - Draft internal reporting forms were developed, intended for use as a mechanism to communicate the results of LGC's assessment of the method validation results/data to the CAs in a harmonised and traceable manner.
    - Draft internal reporting forms consisted 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
    - The FSA and FSS reviewed the draft applicant guidance notes and internal reporting forms, raising 46 queries associated with the applicant guidance notes and 12 comments on the internal reporting forms.
    - A planning meeting was held at LGC with the GMO Authorisations Lead, Project Manager and Key Accounts manager to address all of the points. The draft applicant guidance notes and internal reporting forms were updated following the CAs feedback, and an itemised response to each of the comments were provided back to the CAs.
    - 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 the authorisation process be further changed/updated, then the guidance notes and reporting forms would have to be reviewed and revised accordingly.

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:
  - The GMO Authorisations (Great Britain) annual report for the operational period April 2021 to March 2022 was published on the GMO NRL webpages.
  - The GMO Authorisations (Great Britain) annual report for the operational period April 2022 to March 2023 was published on the GMO NRL webpages.
  - The current document represents the GMO Authorisations (Great Britain) annual report for the operational period April 2023 to March 2024, providing a summary of the method validation service 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 secure Microsoft Teams channel.
  - Monthly logs, providing detailed descriptions of all activities engaged in as part of the GMO Authorisations function, were provided on a monthly basis 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. Laboratories 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.

- Maintain appropriate storage facilities to house materials:
    - Throughout the third 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 63 external quality assessment proficiency test (PT) 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 full audit by UKAS during 2024 and the accreditation maintained.
    - A staff member working within the GMO Authorisations (method validation services) function were 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 refence 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 63 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 U105 round was published in 2023. LGC received a Z-score of -0.7 following successful participation in the proficiency test round.

- 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.

- Continue international stakeholder engagement:
    - 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 successful and commissioned at the start of 2023. A member of staff from the GMO authorisations

(method validation services) position has been invited to join the Scientific Advisory Board associated with this successful project.

- Provided a meeting report regarding the "International Conference on GMO Analysis and New Genomic Techniques" in Berlin to the FSA. Following approval from the FSA, distributed a summary of the meeting to all UK Official Laboratories.
- The European Commission (JRC) published updated guidance on "Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis". Staff working within the GMO Authorisations (Great Britain) function contributed to the development of this guidance as an independent expert.
- At the request of the FSA, provided a link to an LGC presentation on detection of genome edited products which was given at the Government Chemist 2023 conference at the Royal Society of Chemistry.
- The NRL discussed with the FSS some interpretative elements associated with Annex I (criteria of equivalence of NGT plants to conventional plants) associated with the EC proposal for a new regulation on plants produced by certain new genomic techniques.
- Attended the 34th European Network of GMO Laboratories (ENGL) meeting on the 27th and 28th September 2023, at the EC-JRC Seville (Spain). A staff member from within the GMO Authorisations (Great Britain) position participated as an invited speaker and independent expert, providing a presentation on the status and key outputs associated with the ENGL Working Group on DNA extraction.
- Provided the FSA, FSS and Defra with the meeting report associated with the 34th ENGL plenary meeting, which is available in the public domain.
- The COST Action PlantEd finished its natural life cycle at the end of October 2023 but was incorporated into the Association of Applied Biology (AAB) as a new specialist group as AAB-PlantEd. The GMO Authorisations (Great Britain) remains a part of the AAB-PlantED network.
- 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.
- Kept FSA informed regarding the European Commission publication on a "Proposal for a new Regulation on plants produced by certain new genomic techniques
- Kept the FSA informed of EU responses to the to the new EC proposal for a regulation on plants obtained by certain new genomic techniques (NGTs) and their food and feed, inclusive of responses from EU-SAGE (and independent network which promotes the development of European and EU member state policies that enable the use of genome editing for sustainable agriculture and food production).

- Establish a process for setup costs and overhead costs associated with each Great Britain centric authorisation:
    - A copy of the draft guidance document outlining Financial Contributions from Applicants was uploaded to the FSA secure Microsoft Teams site.

- Maintenance of storage and distribution service:
    - Throughout the third 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 third 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).
    - Provided a response to the FSA public consultation on proposals for a new framework in England for the regulation of Precision Bred Organisms (PBOs) used for food and animal feed, which opened on the 8th November 2023. On the 7th March 2024 the FSA published their response to the public consultation on the proposed plan for Precision Bred Organisms (PBOs) in England.
    - Attended regular UK GM Technical Meetings between LGC, SASA and Fera to discuss technical aspects associated with UK GMO analyses.
    - Prepared a pre-recorded presentation in preparation for the FSA/FSS Laboratory Workshop 2024, planed for the 16th April 2024. The presentation highlighted the role for method validation services that the GMO Authorisations (Great Britain) function provides.

- Contract management:
    - Throughout the third year of operation of the GMO Authorisations 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.
    - All project work associated with the GMO Authorisation (Great Britain) function have been successfully migrated onto SharePoint in MS Office 365. This is in line with migration of all government projects/contracts and data security compliance.
    - 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.
    - FSA confirmed that the 3-year break point in the contract was not triggered, and the contract will run to its scheduled end date of 31st March 2026.

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 GB based applications requiring processing for method validation services as part of the authorisation procedure were received by LGC in the third reporting year of operation of the GMO Authorisations (Great Britain) function. This included no applications for new GM events (single or stacked), 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.

- Bespoke advice provided to the FSA regarding GMO authorisations:
    - A staff member from within the GMO Authorisations (Great Britain) function, officially recognised as an independent scientific expert in GMO analysis, are members of the ENGL Working group on Genetically Modified Microorganisms, thus remaining abreast of analytical considerations associated with authorisations of these GMOs.
    - Provided a response to the FSA public consultation on proposals for a new framework in England for the regulation of PBOs used for food and animal feed, which opened on the 8th November 2023. On the 7th March 2024 the FSA published their response to the public consultation on the proposed plan for Precision Bred Organisms (PBOs) in England.

- 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, the GMO NRL function is working 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):
    - Draft applicant guidance notes were developed, intended as guidance to applicants as part of the GMO authorisation procedure in Great Britain in the context of the method validation services workflow and requirements.
    - Draft applicant guidance notes consisted 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
    - Draft internal reporting forms were developed, intended for use as a mechanism to communicate the results of LGC's assessment of the method validation results/data to the CAs in a harmonised and traceable manner.
    - Draft internal reporting forms consisted of the following documents:
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        - Method validation collaborative trial report
        - Validated method protocol
        - GMO renewals reporting form
        - Application summary report.