# Annual report on Activities Performed by the UK NRL for GMOs in Food and Feed

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Provision of UK National Reference Laboratory Services for Genetically Modified Organisms in food and feed

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# Contents

# Glossary

**CA** – Competent Authority

**CRM** - Certified Reference Material

**Defra** - Department for Environment, Food & Rural Affairs

**DG SANTE** - European Commission's Directorate-General for Health and Food Safety

**DNA** - Deoxyribonucleic acid

**dPCR** – Digital PCR

**ENGL** - European Network of GMO Laboratories

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

**Fera** – The Food and Environment Research Agency

**FSA** - Food Standards Agency

**FSS** – Food Standards Scotland

**GeMMA** - Genetically Modified Material Analysis Scheme

**GMM** - Genetically Modified Microorganism

**GMO** - Genetically Modified Organism

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

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

**OL** – UK Official Laboratory

**PBO** – Precision Bred Organism

**PCR** - Polymerase Chain Reaction

**SASA** - Science & Advice for Scottish Agriculture

**WG** – Working Group

# Role of the National Reference Laboratory

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) are respectively designated as the Competent Authority (CA) for Official Feed and Food Controls within their area of responsibility. The UK has a legal obligation to appoint National Reference Laboratories (NRLs) pursuant to assimilated Regulation (EU) 2017/625. This regulation relates to official controls designed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. NRLs provide advice and support to food and feed enforcement laboratories and CAs to ensure a harmonised approach to food and feed enforcement. NRLs are responsible for setting standards for routine procedures and reliable testing methods in the regulated areas of food and feed. This delivers consumer protection and effective, risk-based and proportionate regulation and enforcement.

NRLs play an important role following EU transition (1st January 2021) as they incorporate some of the activities previously performed by their lab counterparts in the EU (the European Reference Laboratories). This includes sharing and developing new and emerging disease intelligence, methodologies, reference materials and training. Following EU transition, NRLs continue to play a pivotal role in the UK enforcement process.

## NRL GMO Services

As the duly appointed laboratory, LGC carries out the provision of services for the UK NRL for GMOs. The NRL for GMOs provides support to the UK official laboratories for GMO control and identifies and participates as an independent expert at international GMO meetings and networks to further harness expertise and knowledge in the area.
The NRL liaises with and provides advice to the CA appointed laboratory responsible for the scientific assessment and validation of detection methods for GMOs in food and feed as part of the UK GMO authorisation of regulated products procedure.

The basic duties of NRLs include:

(a) Co-operate internationally in their area of competence, including collaborating and participating inter-laboratory comparative tests organised by international laboratories (where appropriate);
(b) Co-ordinate, for their area of competence, the activities of Official Laboratories (OLs) responsible for the analysis of official controls samples to ensure the verification of compliance with feed and food law;
(c) Where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;
(d) Ensure the dissemination of any information required by the CA;
(e) Provide scientific and technical assistance to the CA, especially for the implementation of Multi Annual National Control Plans;
(f) Participate in relevant national and international networks, workshops and training courses and, where necessary, conduct training courses for the staff of OLs;
(g) Upon request by the appropriate authority, actively assist in relevant foodborne incident and outbreak situations, should be equipped with, or have access to, the necessary equipment to perform their tasks in emergency situations and in cases of non-compliance of consignments, by carrying out confirmatory analysis;
(h) Carry out research, evaluation and development of new and existing methods for the analysis of UK regulated and officially monitored foods and feed and emerging new risks to UK food safety;
(i) Provide advice and expertise on standardisation of methods at CEN and ISO;
(j) Obtain and maintain accreditation for official reference and other relevant regulatory methods for food and feed within the NRL area of competence;

(k) Be responsible for carrying out other specific duties as required by the CA, where appropriate and by prior agreement;

LGC has maintained the position for the UK NRL for GMOs in food and feed since the inception of the position in 2009, following open competitive tenders in 2009, 2013, 2017 and 2021. LGC's appointment by the FSA is pursuant to UK legislation (assimilated Regulation 2017/625). As the NRL for GMOs, LGC conducts the following activities, as specified in the contract with the FSA:

**Core Function**
**Objective 01 – Secretariat services**
**Objective 02 – Advice and representation within the UK and internationally**
**Objective 03 – Production of standard operating procedures, codes of practice, guidance documents and databases**
**Objective 04 – Compliance assessment via audits, ring trials and provision of reference materials**
**Objective 05 – Co-ordination within the UK of international initiatives**
**Objective 06 – Liaison and support work on GMO food/feed authorisation**
**Objective 07 – Communication of results and data use**

# Core Function

## Production of the NRL annual report

This report details the activities carried out during the 15th year of the NRL operation (April 2023-March 2024) in relation to the duties of the NRL.

### Objective 01 – Secretariat services

**Tasks:**

**a) Disseminating relevant information/advice to the OLs, CA, when required, and other relevant laboratories in a timely and effective manner;**
**b) Co-ordinating the activities of OLs and other relevant laboratories in food and feed below;**
**c) Creating and maintaining an efficient two-way channel of communication with OLs and relevant laboratories and international organisations, including information on analytical methods and relevant legislation;**
**d) Providing regular updates to the CA on NRL activities, and up-to-date information on UK OLs and other relevant laboratories to the CA as requested;**
**e) Creation and maintenance of a dedicated website for communication of the work of the NRL including provision of advice and support to OLs, information on methods of analyses, Standard Operating Procedures (SOPs), latest developments and other background information.**

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

- Provided a meeting report regarding the "International Conference on GMO Analysis and New Genomic Techniques" in Berlin. Following approval from the FSA, distributed a summary of the "International Conference on GMO Analysis and New Genomic Techniques" to all UK Official Laboratories.
- 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.
- Kept the FSA informed of the following topics:
    - Provided the FSA, FSS and Defra with the agenda points associated with the 34th ENGL plenary meeting, which is available in the public domain.
    - A copy and link to the EC-JRC publication on guidance for the selection and use of DNA extraction methods was sent to the FSA, FSS and UK Official Laboratories for awareness.
    - The European Commission published its proposal on New Genomic Techniques in July 2023, and the European Parliament adopting its position in relation to this proposal on the 7th February 2024. The press release on the Parliament was also published.
- Updating and maintenance of the NRL website. Feedback was received from the FSA on the draft text for the website. This was reviewed internally and the draft was updated in line with the FSA's comments.

## Objective 02 - Advice and representation within the UK and internationally

**Tasks:**

- **Provide details of analytical methods including reference methods to OLs and co-ordinate application of these methods through proficiency testing (see 4c);**
- **Provide impartial expert advice as requested to the CA, OLs and other relevant laboratories on analytical methodology in the context of official controls and risk assessment;**
- **Represent the UK at relevant international meetings, networks and working groups, consulting the CA on objectives and requirements before each meeting and providing the CA with an internal report of the meeting within 10 working days of each meeting;**
- **Participate in activities organised by international organisations and contributing to the scientific input at international meetings and in manner which supports UK policy based on best available scientific knowledge;**
- **Provide advice to the CA, OLs and other relevant laboratories on best scientific practice in testing for official controls purposes and undertaking activities in consultation with the CA that facilitate and promote their application in the UK within the policy aims of the CA;**
- **Keep abreast of and advise the CA, OLs and other relevant laboratories of research and development for the sampling, testing and detection of GMOs;**
- **Identify and inform the CA, OLs and other relevant laboratories of emerging analytical issues or developments at a national or international level and recommending action to address them;**
- **Provide technical assistance to the CA in cases of contested results of analyses;**
- **Where appropriate, partake and/or keep abreast of standardisation activities (e.g. CEN, ISO, etc.) relevant to the work area.**

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

- **Provision of advice and input into discussions with UK Competent Authorities:**
    - Provided a flash presentation for CCQM (Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology) as part of the World Metrology Day 2023 event, whose theme that year was “Measurements supporting the global food system”. The talk focussed on the status and challenges for detecting GMOs and genome edited products. A link to the presentation was circulated to the FSA.
    - Provided a response to the FSA public consultation on proposals for a new framework in England for the regulation of precision bred organisms 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.
    - In December 2023 UKAS officially issued TPS 57, which provides guidance and policy on the selection and use of reference materials (Edition 5). A copy of TPS 57 was forwarded to the Official Laboratories and the FSA.
    - Provided input into discussions with FSS regarding a sampling exercise for GMOs in Scotland. Provided views on potential GMO targets and commodities to sample, as well as citing recent RASFF reports.
    - The NRL discussed with FSS some interpretative elements associated with Annex 1 (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.

- The Government Chemist function hosted and helped organise a BBC Radio 4 interview with the Head of the National Food Crime Unit (NFCU) from the FSA. The topic of the interview, held on LGC premises, was on food fraud prevention and how the NFCU continue to ensure food is what it says it is on the label and is safe to eat. The role of the NRL was also discussed.
- Provided a presentation at the Government Chemist conference 2023 at the Royal Society of Chemistry (London), outlining some of the current challenges and status of using molecular biology approaches for detection and traceability of genome edited products and organisms in the food supply chain.
- Prepared a pre-recorded short presentation in preparation for the planned FSA/FSS Laboratory Workshop 2024 (scheduled for 16th April 2024), highlighting the GMO NRL support activities that the NRL offers and delivers for GMO controls.
- Held discussions with the FSA regarding viable approaches for DNA extraction from pollen samples in honey.

- **Attendance and input at the European Network of GMO Laboratories (ENGL) Working Groups (WGs) as a recognised independent scientific expert:**
  - ENGL Working Group on DNA extraction:
    - Attended a number of online meetings throughout the year in support of providing a guidance document on DNA extraction as a final deliverable associated with this Working Group.
    - The technical document on guidance on the selection and use of DNA extraction methods, was successfully published.
  - ENGL Working Group on Good practice/quality of DNA sequencing data:
    - Attended an online meeting for the above Working Group, helping address a series of queries on the draft final report.
  - 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.
    - Attended a kick-off meeting and subsequent meeting to discuss tasks associated with the mandate of the group.
  - 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.
    - Attended a kick-off meeting and subsequent meeting to discuss tasks associated with the mandate of the group.

- **Attendance at the following other international meetings, seminars and working groups discussing best measurement practice guidance on GMO analysis:**
  - Held discussions with a European reference laboratory which had received queries regarding measurement uncertainty estimation in the framework of the published

JRC technical report "Guidance document on Measurement Uncertainty for GMO Testing Laboratories – 3rd edition".

- HORIZON Europe bid (HORIZON-CL6-2023-FARM2FORK: New detection methods on products derived from new genomic techniques to enable safe innovation in the food system):
  - The project proposal, entitled DETECTIVE (DETECTION OF NGT PRODUCTS TO PROMOTE INNOVATION IN THE EUROPEAN UNION), was successful. Staff from the UK NRL have been asked and have agreed to be part of the official Scientific Stakeholder Advisory Board associated with the project.
- Presentation delivered for World Metrology Day on behalf of BIPM/CCQM:
  - Delivered a 10-minute recorded webinar entitled "Towards detection of GMOs and gene edited products - Status and challenges", as part of the CCQM/BIPM response to World Metrology Day 2023, focusing on the theme of measurements supporting the global food system.
- Access to the EC-JRC pre-spotted plates:
  - Discussions held with the EC-JRC to permit access to the EC-JRC GMO screening plates for control purposes. These plates afford a ready-to-use and cost-effective screening approach for identification of GMOs, consisting of lyophilized primers/probes in a 96-well plate format.
- Discussions with EU NRL colleagues on the new EC proposal on NGT plants:
  - Contacted by an EU National Reference Laboratory to discuss some interpretative elements associated with the new EC proposal on NGT plants.
- ISO 17025, ISO 17034 and ISO 17043 audits related to GMO work:
  - Staff from the NRL were contacted by BELAC (the Belgian Accreditation Body) to act as the technical assessor as part of an audit of a European laboratory for ISO 17025 flexible scope of accreditation for GMO analysis, ISO 17034 for production of reference materials and ISO 17043 for provision of proficiency test schemes.
- Explore collaborative opportunities with EU laboratories:
  - Held an online meeting with a national state laboratory in the EU to explore collaborative opportunities with a focus on using Next Generation Sequencing (NGS) for GMO analysis.
- Attendance at 34th ENGL plenary session
  - 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 the NRL participated as an invited speaker and independent expert, and gave a presentation on the current status and key outputs associated with the ENGL Working Group on DNA extraction. The meeting report to the 34th ENGL plenary meeting is available in the public domain.
- European Network of Food Allergen Detection Laboratories (ENFADL) meeting:
  - Participated in the ENFADL meeting held at the European Commission's Joint Research Centre (EC-JRC) site in Geel (Belgium), on the 5th and 6th of December, as an independent expert. Provided a presentation on how DNA approaches can be used to augment pre-existing strategies for the effective determination of allergenic species in food samples.
- Presentation on NGTs/PBOs at the International Conference on GMO analysis and NGTs
  - In March 2023, staff from the NRL provided a presentation at the International Conference on GMO analysis and New Genomic Techniques, 14th to 16th March

2023, Langenbeck-Virchow-Haus, Berlin, (Germany), organised by German Federal Offices and the European Commission. The presentation focussed on strategies for the detection of GMOs and NGT products, and the presentation is available in the public domain entitled "Analytical strategies for detection of GMOs and NGT products – Status and challenges".

- Exchange and sharing of information with a European Reference Laboratory regarding best scientific measurement practice associated with testing for GMOs in rice and rice products originating from China.
- Held discussions and provided advice to a European Reference Laboratory regarding characterisation of a material destined to be used as part of a proficiency test round.
- Contacted by a European Reference Laboratory to ask for advice regarding currently available Sanger DNA sequencing instruments and replacements for the laboratory.
- Held discussions with a European Reference Laboratory regarding best scientific measurement practice associated with quantifying GM material in feed samples.

- **Publications:**
  - The FSA commissioned the NRL to deliver a desk-based review of the current state-of-the-art associated with methods for the potential detection of PBOs in the food and feed supply chains. The published report can be found here.
  - The EC-JRC published their technical report on "Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing – Part 2", which a staff member from the NRL is also an author on.
  - 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 NRL function contributed to the development of this guidance as an independent expert.
  - The European Commission has published their Joint Research Centre technical report entitled "Guidance on the selection and use of DNA extraction methods". Staff from within the NRL function contributed to the development of this guidance document as an independent expert, being cited as a named author.

- **Keep abreast of research and development for the sampling, testing and detection of GMOs and advise the CA, OLs and other relevant laboratories:**
  - Made the FSA aware that the Norwegian Committee on Gene Technology had published recommendations on new legislation for genome editing techniques.
  - Informed the FSA of a news article regarding potential EC preliminary views and proposals on the identification of criteria for the deregulation of some NGT plants in the EU.
  - UK GM Technical Meetings:
    - Attended regular catch-up meetings between LGC, SASA and Fera to discuss technical aspects associated with UK GMO analyses.
  - 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)

- 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) and provided as a new specialist group as AAB-PlantEd. The NRL remains a part of the AAB-PlantED network.
- The NRL contributed to discussions held at the Joint in person workshop of Defra's Authenticity Steering Group & Authenticity Methods Working Group. The NRL provided input into the above workshop in terms of views on analytical and technological solutions for identification of GMOs and PBOs in the future.
- Held discussions with FSS regarding some of the presentations held at the International Conference on GMO analysis and New Genomic Techniques (Berlin), and the use of NGS for the identification of genome edited crop lines, as well as ISO 17025 accreditation of such methods.
- At the 2024 Meeting of Food Authenticity Centres of Expertise, the NRL provided input into the above meeting, drawing upon experiences and expertise from the GMO analytical field when interpreting results from a simulated food fraud incident.

- **Keep abreast of standardisation activities (e.g. CEN, ISO, etc.) relevant to the work area.**
  - Continued maintenance of competency for ISO 17025 flexible scope of accreditation for GMO analyses held by the NRL, with additional laboratory-based personnel cross-trained in technical/practical elements.

- **Miscellaneous:**
  - A staff member from within the NRL renewed their membership on the FSA Register of Specialists, with expertise in food authenticity testing, allergen detection and GMO analysis.
  - Discussed with Science & Advice for Scottish Agriculture (SASA) the application and utility of digital PCR for GMO testing and general food authenticity analysis.

## Objective 03 - Production of standard operating procedures, codes of practice, guidance documents and databases

**Task:**

**a) Contribute to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OLs and other relevant laboratories, as requested by the CA.**

**b) Where required, develop a database to store relevant information in relation to GMO official control testing, e.g. GMO methods, SOPs, codes and guidance**

**Activities in relation to these Tasks:**

- **Example activities in relation to development of guidance documents:**
    - The Food Standards Agency (FSA) commissioned the NRL to deliver a desk-based review of the current state-of-the-art associated with methods for the potential detection of PBOs in the food and feed supply chains. The published report can be found here.
    - The EC-JRC published their technical report on "Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing – Part 2", which a staff member from the NRL is also an author on.
    - 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 NRL function contributed to the development of this guidance as an independent expert.
    - The European Commission has published their Joint Research Centre technical report entitled "Guidance on the selection and use of DNA extraction methods". Staff from within the NRL function contributed to the development of this guidance document as independent expert, being cited as a named author.

- Input into discussions and writing of draft guidance documents for the following European Network of GMO Laboratories (ENGL) Working Groups, as an invited independent international scientific expert:
    - DNA extraction (DNAex) – aimed at providing advice and guidance associated with all aspects of practical DNA extractions from simple/complex matrices for GMO analysis. Due to be published late 2024.
    - Genetically Modified Microorganisms (GMM) – aimed at describing a practical workflow for the detection and identification of GMM. The WG is awaiting a steer from DG SANTE regarding interpretation of some of the legal aspects associated with the current EU regulations.
    - DNA sequencing (DNA seq) – aimed at providing advice on sequencing strategies for the traceability of GMOs (inclusive of Next Generation Sequencing), with a focus on methods and related quality aspects. Due to be published late 2024.
    - Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing – Part 2 (MPR(2)) – aimed at providing guidance and acceptance criteria for methods for the detection of GM animals and products from New Genomic Techniques, and performance requirements for application of dPCR for GMO analysis.
    - ENGL Working Group on "Detection of food and feed plant products obtained by new mutagenesis techniques" - aimed at providing an update on approaches for

the detection of products of new mutagenesis techniques, in lieu of the original ENGL 2019 report and in line with current knowledge and evolution of technologies.

- 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. Anticipated to be published in 2025.
- 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. Anticipated to be published in 2025.

## Objective 04 - Compliance assessment via audits, ring trials and provision of reference materials

**Tasks:**

a) **Ensure consistency and quality of testing approaches applied by UK OLs and other relevant laboratories, including advising on corrective action following adverse reports on OLs from UKAS;**
b) **Source and provide suitable reference materials and testing kits to OLs;**
c) **Plan and coordinate GMO proficiency testing for UK OLs and other relevant laboratories as appropriate (taking into account the number of relevant laboratories), analysing and evaluating the outcome, informing the CA and OLs of the results and advising on appropriate follow-up action;**
d) **Co-ordinate the participation of UK OLs and other relevant laboratories in international method validation studies and other initiatives, informing the CA and OLs of the results and advising on further action;**
e) **Where relevant, participate in proficiency tests and method validation studies organised by international organisations, informing the CA of the results and implementing any corrective measures required;**
f) **Co-ordinate training exercises for OLs and other relevant laboratories to promote best laboratory practice in respect of GMO analysis;**
g) **Provide OLs with advanced notification of proficiency testing rounds to enable OLs to implement such activities in a timely manner.**

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

- **Proficiency test rounds**
    - The official FAPAS report for the GeMMA U105 proficiency test round was published with the NRL receiving a Z-score of -0.7. These results were communicated to the FSA.

- **GMO analytical Capability Building Exercise**
    - As part of building a resilient and sustainable OL system, the FSA have provided Capability Building Grants to develop analytical capability in specific targeted areas. The NRL is currently actively working with the FSA and several OLs in terms of technical, scientific and practical laboratory support.
    - A brief summary of example NRL activities in support of this include:

- Official Laboratory #1
    - Provision of advice on maintenance and calibration of laboratory-based instrumentation.
    - Provision of advice on positive controls and reference materials associated with the method for testing for GMOs in rice and rice products originating from China.
    - Informal observational training day
        - At the request of the OL the NRL developed a bespoke one-day training course focusing on GMO analytical capability building in DNA extraction, DNA quantification and real-time PCR associated with testing for GMOs in rice and rice products originating from China. The day consisted of presentations on the background to GMO analysis and the current legislation, followed by interactive sessions in the laboratory where DNA extraction and quantification were demonstrated. The afternoon session consisted of follow up work in the

laboratory inclusive of a tour of the relevant instrumentation, followed by presentations on best practice advice on how to interpret results and an interactive question and answer session.

  - The training day was attended by four representatives from the OL, who remarked on the usefulness and content of the training day, and how they will apply the scientific best measurement practice in their day-to-day activities in the laboratory for GMO analysis.
  - Copies of the presentation pack, along with appropriate instrument and kit protocols which were demonstrated on the day, were provided to the OL.

- Official Laboratory #2
  - Held an online meeting and provided advice to the OL in relation to general food analysis, inclusive of use of digital PCR, weight of evidence approaches and ISO 17025 flexible scope of accreditation for GMO analysis.

- Official Laboratory #3
  - Provision of advice on frequency and content of proficiency test rounds.
  - Provision of advice on ordering CRMs, and use of EURL searchable databases and bioinformatics tools.
  - Provision of advice and assistance on experimental based competency for testing for GMOs.
  - Inspection of data/results from experimental based analyses and provision of advice for corrective actions and how to further optimise methods.
  - Provision of advice on pipette calibration and construction of calibration curves based on serial dilution series.
  - Inspection and annotation of example data sets to help towards demonstration of competency in method verification.
  - Advice on use of calibration curves, amount of template DNA, use of internal positive controls and best scientific measurement practice guidance on deploying GM detection methods.
  - Advice on use of automated DNA extraction instruments.
  - Provision of advice as part of investigatory analysis of data sets following inclusion in a proficiency test round.
  - Provision of advice on DNA extraction from oils.
  - Provision of advice regarding maintenance of qPCR instrumentation, control charts, DNA extraction from difficult matrices, and training for testing for GMOs in rice/rice products originating from China.
  - Organisation of an impromptu meeting with staff to provide advice and assistance on estimating measurement uncertainty associated with qPCR approaches for GMO analysis, as part of application for ISO 17025 accreditation. The NRL provided advice and support in terms of core texts to refer to in the field, requirements from ISO 17025, sources of uncertainty, combining uncertainty and expressions of uncertainty. The NRL also provided advice based on their experiences of optimising qPCR set-ups, number of replicates, reducing bias and

typical levels of uncertainty to expect in an experimental design which is considered fit for purpose.

- Following a request from the OL who was concerned with the underestimation of a positive control and the variability associated with the test sample, the NRL provided guidance on how to construct the calibration curve, suitable dilutions to use for the positive control so that it remained within the linear working range of the calibration curve, and increasing the replication factor of runs and extractions to get a more representative estimate of the sample mean.
- Provision of advice on ISO accreditation, EC-JRC pre-spotted screening plates, and the use of qualitative and quantitative real-time PCR approaches.
- Forwarded on to the OL a copy of the published EC-JRC scientific and policy report on guidance for flexible scope of accreditation for GMO analyses.

- Official Laboratory #4
  - Provision of advice on fixed and flexible scope of accreditation, screening and event specific GM tests, and model GM events to use to demonstrate ISO 17025 accreditation.
  - Provision of advice on published GMO screening approaches, published databases for reviewing screening results, links through to validated GMO detection methods, common GM events, use of DNA spectrophotometers and suitable primer concentrations for real-time PCR.
  - Provision of advice on practical implementation of validated GMO detection methods and best measurement practice guidance for construction of calibration curves for quantitation of GMOs.
  - Provision of support and advice in terms of testing for GMOs in rice/rice products originating from China.
  - Provision of advice on copy number estimates for calibration curves, annealing temperatures, appropriate proficiency test rounds, PCR reaction volumes, combining transgene/endogenous assays on one plate, and appropriate positive and negative controls.
  - Provision of a link through to a webinar on testing for GMOs in rice/rice products originating from China.
  - Advice on generation of melt curves, qualification of detectable GM responses from samples, PCR amplification plots, dual criteria for qualification of a detectable response, occurrence of false positives and primer-dimers, and experiences related to the assay and the use of SYBRGreen.
  - Provision of general advice when using molecular biology (DNA) based methods for food authenticity testing, inclusive of DNA quantity and quality checks.
  - Provided support for inclusion in a GMO proficiency test round, inclusive of construction of calibration curves, dilution series, number of points, number of replicates, CRMs, minimum performance criteria, dispersion of Ct/Cq values and measurement uncertainty estimation.
  - Following reception of example datasets provided by the OL, the NRL provided advice on how to improve the confidence associated with the results.
  - Provided advice in the framework of the FSA grant capability schemes regarding approximate cost estimates associated with laboratory based analytical equipment.

- Official Laboratory #5
    - Worked alongside the OL on their roadmap for successful application and acquisition of ISO 17025 flexible scope of accreditation for GMO analyses.
    - Provided advice on responding to an observation made by UKAS during a recent audit.
    - Provision of advice on recent UK and EC developments in relation to legislation and proposals on genome edited plants.
    - Following successful acquisition of ISO 17025 flexible scope of accreditation for GMO analysis, the Official Laboratory confirmed successful participation in a subsequent GeMMA U109 proficiency test round.
    - Provision of advice on method verification of new qPCR instrumentation, frequency of PT round participation, and outlined the main impact of the recently published UKAS TPS 57 guide on selection and use of reference materials.

- In total, the NRL provided over 129 responses in relation to requests for advice on GMO analyses, and held 18 meetings with Official Laboratories in support of these activities.
- Demonstrable output and impact of the NRL working alongside UK Official Laboratories for GMO analytical capability building have been evidenced through one laboratory acquiring ISO 17025 flexible scope of accreditation for GMO analysis, and a second laboratory submitting an official application for this with supporting documentation.
- Two of the Official Laboratories have successfully developed and validated the method for testing for GMOs in rice and rice products originating from China, such that these methods can now be offered as a testing service to interested parties.
- The NRL has received written positive feedback from the Official Laboratories on the consistent help, advice, training and support it provides with respect to the analytical capability building exercise.

## Objective 05 - Co-ordination within the UK of international initiatives

**Task:**

**a) Where appropriate, co-ordinate the recommendations of international organisations related to the standardisation of testing methods.**

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

- The NRL continues to maintain a dedicated physical and electronic register for control materials received prior to EU exit on the 1st January 2021, held in a secure cold room.
- The full list of the registered ENGL plasmid control materials is provided in Annex 2.

## Objective 06 - Liaison and support work on GMO food/feed authorisation

**Tasks:**

**a) Liaise with the FSA appointed laboratory on GMO food/feed authorisation process and applications.**

**b) Where necessary, provide support/advice to the FSA appointed laboratory for GMO authorisation on the validation of methods of analyses, reference materials.**

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

- The GMO NRL and GMO Authorisations (method validation services) positions are both operated by LGC.
- Staff from both areas are kept fully abreast of developments within each position, augmenting both functions in terms of delivery priorities whilst also providing cost saving opportunities due to synergistic activities.

## Objective 07- Communication of results and data use

**Tasks:**

**a) The Contractor shall ensure that the CA receives regular updates of any developments related to the core functions of the NRL;**
**b) The Contractor shall notify the CA immediately by email of any deviations or significant unexpected situations which may affect the cost, specifications and timing of the annual work programme;**
**c) The Contractor shall notify the CA immediately by email of any unusual occurrences resulting from any of the core functions of the NRL;**
**d) The Contractor shall provide annual reports of work summarising all activities completed as part of their annual work programme, to the CA by 31st March each year. Annual reports will be approved by the CA prior to publication by NRLs on NRL dedicated websites. If requested by the CA, the Contractor may also need to provide interim reports during the annual work programme;**
**e) Any results or reports arising from the work of the NRL will not be communicated to any external parties without the written permission of the CA;**
**f) The use of the data for presentations and/or papers will not be permitted unless written permission has been sought and given by the CA;**
**g) The Contractor will maintain records. Retention periods will be agreed and defined in the contract and if necessary the contractor will assist with transfer of archived reference material; in other work related to the core functions of the NRL, the specified deadlines agreed between the CA and the Contractor should be met;**
**h) If necessary, at the end of the Contract all information and data gained from, and required for, NRL function over the course of the Contract will be handed over to the CA. This will include assisting with transfer of archived reference materials;**
**i) Provide an internal report of meetings with other organisations within 10 working days of the meeting.**
**j) The Contractor will engage in quarterly dialogues with the CA to review contract management requirements and update on progress against work programme. Informal monthly check-ins with the CA may also be organised to ensure any potential or evolving issues are flagged and work is kept on track;**
**k) The Contractor will organise regular network meetings, as appropriate and on at least an annual basis to update their official controls networks and CA on method updates, enforcement, training and other relevant information issues and to discuss PT programmes and results;**
**l) The Contractor will review NRL finances regularly and communicate spending, including a break-down of costs, with the CA on a monthly basis.**

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

- The GMO NRL 2022/2023 annual report and the GMO NRL Annual Workplan 2022-2023 were successfully published on the NRL webpages.
- Monthly logs, providing detailed descriptions of all activities engaged in as part of the GMO NRL function, are provided on a monthly basis to the FSA.
- All invoices have been issued in a timely fashion based on the agreed invoicing profile.
- Four GMO NRL Quarterly Review Meetings were successfully held with the FSA and FSS, with copies of all presentations and action logs shared with the FSA and FSS.
- The UK NRL is in constant contact with the FSA by email, phone and Microsoft Teams in relation to queries, updates, developments and deliverables.

- Contract Change Notice (CCN3) FS616029 for additional training activities to build official laboratory capability was signed in June 2023 and activities completed in March 2024.
- LGC's accounts team have been notified of the FSA's new email address for sending invoices to, and records were updated accordingly.
- The UK NRL is available for provision of advice on GMO analysis to all UK OLs by email, phone, MS Teams and face-to-face meetings where appropriate.
- The FSA provided documents to sign for formal designation as a NRL by the FSA/FSS under Article 100 of assimilated (EU) regulation 2017/625 for GMOs.

# Annex 1: Additional links to NRL annual reports, work programmes and advisory notes

Copies of previous reports, work programmes and advisory notes can be found on the NRL webpages.

# Annex 2: List of ENGL Control materials housed by the NRL

| GM | Species | ENGL plasmid no. |
|---|---|---|
| Event 558 (GMM) | *Bacillus subtilis* | pENGL-00-EM-01/18-01 |
| 281-24-236 | Cotton | pENGL-00-14/05-01 |
| 3006-210-23 | Cotton | pENGL-00-14/05-01-B |
| COT102 | Cotton | pENGL-00-05/16-01 |
| DAS 81910-7 | Cotton | pENGL-00-06/16-01 |
| GHB119 | Cotton | pENGL-00-04/11-01 |
| GHB614 | Cotton | pENGL-00-14/07-01 |
| GHB811 | Cotton | pENGL-00-04/18-01 |
| LL25 | Cotton | pENGL-00-13/04-01 |
| MON1445 | Cotton | pENGL-00-15/04-01 |
| MON15985 | Cotton | pENGL-00-24/04-01 |
| MON531 | Cotton | pENGL-00-16/04-01 |
| MON88701 | Cotton | pENGL-00-01/13-01 |
| MON88913 | Cotton | pENGL-00-05/07-01 |
| T304-40 | Cotton | pENGL-00-05/11-01 |
| GM Strain AG3139 | *E. coli* | pENGL-00-04/08-01 |
| GM Strain 19E | *E. coli* K-12 | pENGL-00-06/08-01 |
| 3272 | Maize | pENGL-00-03/06-01 |
| 5307 | Maize | pENGL-00-07/11-01 |
| 59122 | Maize | pENGL-00-03/05-01 |
| Bt11 | Maize | pENGL-00-10/07-01 |
| Bt11 | Maize | pENGL-00-12/05-01 |
| BT176 | Maize | pENGL-00-18/04-01 |
| DAS-40278 | Maize | pENGL-00-10/10-01 |
| DP-4114 | Maize | pENGL-00-02/14-01 |
| GA21 | Maize | pENGL-00-15/05-01 |
| GA21 | Maize | pENGL-00-29/04-01 |
| LY038 | Maize | pENGL-00-01/06-01 |
| MIR162 | Maize | pENGL-00-08/08-01 |
| MIR604 | Maize | pENGL-00-04/05-01 |
| MON810 | Maize | pENGL-00-25/04-01 |
| MON863 | Maize | pENGL-00-01/04-01 |
| MON87403 | Maize | pENGL-00-02/15-01 |
| MON87411 | Maize | pENGL-00-01/15-01 |
| MON87419-8 | Maize | pENGL-00-02/17-01 |
| MON87427 | Maize | pENGL-00-03/12-01 MON87427 |
| MON88017 | Maize | pENGL-00-16/05-01 |
| MON89034 | Maize | pENGL-00-06/06-01 |
| MZHG0JG | Maize | pENGL-00-04/16-01 |
| MZIR098 | Maize | pENGL-00-04/17-01 |

| GM | Species | ENGL plasmid no. |
|---|---|---|
| NK603 | Maize | pENGL-00-27/04-01 |
| T25 | Maize | pENGL-00-08/04-01 |
| T25 | Maize | pENGL-00-08/04-01 |
| TC1507 | Maize | pENGL-00-02/04-01 |
| VCO | Maize | pENGL-00-07/12-01 |
| DP73496 | Oilseed rape | pENGL-00-02/12-01 |
| MON88302 | Oilseed rape | pENGL-00-09/11-01 |
| Ms1 | Oilseed rape | pENGL-00-11/04-01 |
| Ms11 | Oilseed rape | pENGL-00-03/16-01 |
| Ms8 | Oilseed rape | pENGL-00-06/04-01 |
| Oxy-235 genomic DNA | Oilseed rape | Oxy-235 oilseed rape |
| Rf1 | Oilseed rape | pENGL-00-09/04-01 |
| Rf2 | Oilseed rape | pENGL-00-10/04-01 |
| Rf3 | Oilseed rape | pENGL-00-07/04-01 |
| RT73 | Oilseed rape | pENGL-00-26/04-01 |
| T45 | Oilseed rape | pENGL-00-14/04-01 |
| Topas 19/2 | Oilseed rape | pENGL-00-12/04-01 |
| EH92-527-1 | Potato | pENGL-00-09/05-01 |
| Bt63 | Rice | pENGL-00-EM02/06/01 |
| 40-3-2 | Soybean | pENGL-00-08/05-01 |
| A2704-12 | Soybean | pENGL-00-13/05-01 |
| A5547-127 | Soybean | pENGL-00-01/08-01 |
| CV127 | Soybean | pENGL-00-01/09-01 |
| DAS44406-6 | Soybean | pENGL-00-01/12-01 DAS44406-6 |
| DAS-68416-4 | Soybean | pENGL-00-11/10-01 |
| DAS81419-2 | Soybean | pENGL-00-03/13-01 DAS81419-2 |
| DP-305423-1 | Soybean | pENGL-00-07/07-01 |
| DP-356043-5 | Soybean | pENGL-00-04/07-01 |
| FG72 | Soybean | pENGL-00-04/10-01 |
| GMB151 | Soybean | pENGL-00-01/18-01 |
| MON87460 | Soybean | pENGL-00-04/09-01 |
| MON87701 | Soybean | pENGL-00-05/09-01 |
| MON87705 | Soybean | pENGL-00-01/10-01 |
| MON87708 | Soybean | pENGL-00-02/11-01 |
| MON87751 | Soybean | pENGL-00-03/14-01 |
| MON87769 | Soybean | pENGL-00-07/09-01 |
| MON89788 | Soybean | pENGL-00-05/06-01 |
| SYHT0H2 | Soybean | pENGL-00-04/12-01 |
| H7-1 | Sugar beet | pENGL-00-28/04-01 |
| MON71200 | Wheat | pENGL-00-EM-02/18-01 |