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

FSA Contract Reference Number: FS616029
Provision of UK National Reference Laboratory Services for Genetically Modified Organisms in feed and food

Period covered: 1st April 2013 - 31st March 2014


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# Glossary

**CRM** – Certified Reference Material

**DNA** – Deoxyribonucleic acid

**EFSA** – European Food Safety Authority

**ENGL** – European Network of GMO Laboratories

**EU-RL** – EU Reference Laboratory for GMOs in feed and food

**FSA** – Food Standards Agency

**GMO** – Genetically Modified Organism

**IRMM** - Institute for Reference Materials and Measurements

**NRL** – National Reference Laboratory (nominated under Regulation (EC) 882/2004)

**nrl** – national reference laboratory (under Regulation (EC) 1829/2003)

**OCL** – Official Control Laboratory

**PA** – Public Analyst

**PASS** - Public Analyst Scientific Services

**PCR** – Polymerase Chain Reaction

# Role of the National Reference Laboratory

Commission Regulation (EC) 882/2004 was introduced to remove variation in the way European Community legislation is implemented in different Member States. This regulation relates to official controls designed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The aim is to create an integrated and more comprehensive, risk-based, 'farm to fork' approach to official controls. The objective is to improve the consistency and effectiveness of controls across the EU and, as a consequence, raise standards of food safety and consumer protection.

The Regulation sets out the general approach that must be taken and the principles that must be adopted by the authorities in EU Member States with responsibility for monitoring and enforcing feed and food law. These include the competent authorities organising and undertaking official controls. The various central Government agencies and local authorities that are responsible for organising and undertaking official controls constitute the competent authorities and include (for food and feed) the Food Standards Agency, the Health and Safety Executive and the Department of Environment, Food and Rural Affairs (Defra).

Regulation (EC) No 882/2004 also specifies requirements for certain specialised laboratories to provide the science that underpins regulation:

- Official Control Laboratories (OCLs): Central competent authorities designate official laboratories for the purposes of chemical analysis or microbiological examination of feed or food samples taken by enforcement practitioners (in the UK they are Public Analysts (PAs) and Agricultural Analysts (AAs)).
- Reference Laboratories (RLs): In order to provide technical and scientific support for the official control framework, the European Commission has created a network of National Reference Laboratories (NRLs) co-coordinated by European Union Reference Laboratories (EU-RLs) formerly known as Community Reference Laboratories (CRLs).
    - EU-RLs are appointed by the European Commission. They provide the Commission with scientific and technical assistance. They are responsible for providing NRLs with details of analytical or diagnostic methods, including reference methods, and co-coordinating their application (in particular by organising comparative testing). They conduct training courses for NRL staff and keep them up to date in their field of expertise. They also coordinate practical arrangements needed to apply new analytical/diagnostic methods.
    - NRLs: Each Member State must designate an NRL to correspond to each EU-RL. NRLs must collaborate with the EU-RLs in their particular area of expertise and disseminate nationally information provided by the EU-RLs. They are responsible for co-coordinating the activities of OCLs and should, where appropriate, organise comparative tests between them. In addition, they provide scientific and technical assistance to the central competent authorities.

The functions of NRLs are specified in Article 33 of Regulation 882/2004 and require NRLs to:

a) Collaborate with the European Union Reference Laboratory (EU-RL) in its area of competence.
b) Coordinate, with regard to methods of sampling and analysis, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11 of 882/2004.
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 to the competent authority and official national laboratories of information that the EU-RL supplies.
e) Provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53.
f) Be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3) [that deals with voting rules and working groups] , without prejudice to existing additional national duties.

NRL duties include advising the competent authority (FSA, Defra, Chemicals Regulation Directorate and Veterinary Medicines Directorate), and OCLs on sound measurement science and appropriate sampling methods.

LGC was re-appointed the UK National Reference Laboratory for genetically modified organisms (GMOs) in feed and food in March 2013, following its initial appointment in 2009. LGC's appointment by the Food Standards Agency on behalf of the European Commission is under Regulation (EC) 882/2004, which aims to remove variation in the monitoring and enforcement of feed and food law across the European Union. As the National Reference Laboratory for GMOs LGC is contracted to conduct the following activities, as specified in the contract with the FSA:

**Core Function**

**Objective 01 – Secretariat Service (Core Function A)**

Example Task:

- Disseminating information/advice supplied by the EURL and its working groups to the FSA, OCLs and other relevant laboratories.

**Objective 02 – Advice and Representation within the UK/EU (Core Function B)**

Example Tasks:

- Providing impartial expert advice as requested to the FSA, OCLs and other relevant laboratories on analytical methodology in the context of Official Controls.
- Representing the UK at relevant EURL meetings, and its working-groups.

**Objective 03 – Production of Standard Operating Procedures, Codes of Practice and Guidance Documents (Core Function C)**

Example Task:

- Contributing to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OCLs and other relevant laboratories, as requested by the FSA.

**Objective 04 – Compliance Assessment via audits and ring trials (Core Function D)**

Example Task:

- Participating in proficiency tests and method validation studies organised by the EURL, informing the FSA of the results and implementing any corrective measures required

**Objective 05 – Co-ordination within the UK of EU-RL initiatives (Core Function E)**

Example Task:

- Archiving of Standard materials (Control Materials) provided by the EU-RL

**Objective 06 – Communication of results and data use (Core Function F)**

Example Task:

- The Contractor shall ensure that the FSA receives regular updates of any developments related to the core functions of the NRL.

**Additional Tasks**

**Objective 07 – Additional services and Tasks (as detailed in Annex I of the invitation to tender)**

Example Tasks:

- If required, assist the EU-RL in testing and validating the methods of detection for GMOs, when necessary.
- Participate and contribute to the scientific input at meetings, e.g. the European Network of GMO Laboratories (ENGL) meetings, and working groups in a manner which supports UK policy on GMOs based on best available scientific knowledge.

# Core Function

## Production of the NRL annual report

This report details the activities carried out during the 5th year of the NRL operation (April 2013-March 2014) in relation to the duties of the NRL.

### OBJECTIVE 01 - SECRETARIAT SERVICES - (CORE FUNCTION A)

**Example Tasks:**

- **Disseminating information/advice supplied by the EURL and its working groups to the FSA, OCLs and other relevant laboratories in a timely and effective manner.**
- **Creating and maintaining an efficient two-way channel of communication with OCLs and relevant laboratories and the EURL, including disseminating information on analytical methods and EU Regulations to OCLs and feedback of comments from OCLs to the EURL.**
- **Providing regular updates to the FSA on NRL activities, and up-to-date information on UK OCLs and other relevant laboratories to the FSA as requested.**

Example activities in relation to these Tasks:

- At the request of the FSA the NRL provided views on the current status of documents associated with some of the ENGL Working Groups; IRMM (Institute for Reference Materials and Measurements, Geel, Belgium) implementation of information on zygosity/ploidy and conversion factors from mass/mass to copy number/copy number on the certificates associated with their Certified Reference Materials (CRMs); the occurrence of GM papaya in the UK; the use of EU-RL pre-spotted plates; and stacked events present in the EU-RL Comparative Test 07 (ILC_EURL_GMFF_01_13)
- The NRL notified the FSA upon the publication of Commission Implementing Regulation (EU) 120/2014. This describes amendments, modifications and updates for definitions for stacked events, costs and procedures for the authorisation process, and a revised list of national reference laboratories (nrls) to assist the CRL (EU-RL) with respect to validating the methods for detection of GMOs (1829/2003).
- Provided advice to the FSA in relation to best measurement practice on the interim measures of a SYBR®Green screening approach which had been advocated by the EU-RL for detection of GM glyphosate-resistant wheat (MON71800).
- Advised the FSA in relation to a query on additional topics to discuss at the 26th ENGL Steering Committee meeting, including consideration of updates on GM papaya, the GM wheat issue and IRMM zygosity and ploidy levels.
- Responded to a request for advice from the FSA on an initiative led by the German Federal Laboratories regarding the provision of a harmonised method for the extraction of DNA from honey.

- Advised the FSA in relation to a query on UK Official Control Laboratories (OCLs) signing a Confidentially Disclosure Agreement regarding ENGL information.
- Created and maintained an updated list of contacts at Public Analyst (PA) laboratories.
- Circulated an E-mail from the FSA to OCLs with respect to advice and analysis for the US GM wheat MON71800.
- Circulated an E-mail from the FSA to OCLs regarding the updated legislation on testing for Chinese GM rice (2013/287/EU) highlighting the change in sub-sampling for processed foods and the extension to scope whereby any foods containing rice as an ingredient from China may be sampled

**OBJECTIVE 02 - ADVICE AND REPRESENTATION WITHIN THE UK/EU - (CORE FUNCTION B)**

**Example Tasks:**

- **Providing impartial expert advice as requested to the FSA, OCLs and other relevant laboratories on analytical methodology in the context of Official Controls.**
- **Representing the UK at relevant EURL meetings, and its working-groups, consulting the FSA on objectives and requirements before each meeting and providing the FSA with an internal report of the meeting within two weeks of each meeting.**
- **Participating in activities organised by the EURL and contributing to the scientific input at EURL meetings and in manner which supports UK policy based on best available scientific knowledge.**
- **Advising the FSA, OCLs and other relevant laboratories on best scientific practice in testing for Official Controls and undertaking activities in consultation with the FSA that facilitate and promote their application in the UK within the policy aims of the FSA.**
- **Keeping abreast of and advising the FSA, OCLs and other relevant laboratories of developments for the sampling, testing and detection of analytes.**

Example activities in relation to these Tasks:
Advice provided to the FSA:

- Advised the FSA regarding technical advantages of TaqMan approaches vs. SYBR®Green in the event that the relevant EU legislation for testing for Chinese GM rice (2011/884/EU) changed to advocate use of TaqMan as well as SYBR®Green assays.
- Provided detailed comments, suggestions, critique and advice to the FSA on the revised draft guidance notes for the EURL Guidance on testing for Chinese GM rice in the context of 2013/287/EU.
- Provided the FSA with feedback on the draft guidance for testing for GM Chinese Rice to support the new Commission Implementing Decision of 2013/287/EU.
- Discussed with the FSA topics it would be useful to raise at the 19th ENGL Steering Committee meeting. These included EU-RL provision of control material for testing for Chinese GM rice, and EU-RL provision of guidance for conversion factors from mass/mass

to copy number/copy number taking into account zygosity and ploidy levels of reference materials.

- The NRL raised the topics of control materials for Chinese GM rice testing and Guidance for conversion factors of mass/mass to copy number/copy number taking into account ploidy/zygosity levels at the 19th ENGL plenary meeting, following agreement with the FSA.
- Advised the FSA in relation to the proposed changes in the scope of the legislation for testing for Chinese GM rice varieties. The NRL's view was that if the scope of the proposed TaqMan approaches could be seen to be as applicable and broad as the SYBR®Green approach for detection of the different Chinese GM rice varieties, then TaqMan would be the method of choice due to its robustness, specificity and ease of use and interpretation.
- Provided a rapid turnaround time (within 5 hrs) for comments to the FSA in relation to the proposed revision to the EU-RL Guidance for testing for Chinese GM rice, and also on other EU member states view's on this revision.

Advice provided to Official Control Laboratories:

- Discussed with Edinburgh Scientific Services on technical real-time PCR issues including use and availability of standards; DNA extraction kits; and interpretation of real-time PCR data.
- Advised Worcester Scientific Services in relation to sourcing authenticated Basmati rice standards for a GM test.
- Recommended to Public Analyst Scientific Services (PASS, Hull) the use of a validated event specific protocol for the detection and quantitation of GM soybean event FG72 following PASS's participation in an FSA Imported Feed survey looking for unauthorised GMOs according to EU Reg. 619/2011.
- Discussed with Worcester Scientific Services screening approaches for unauthorised GMOs. The NRL confirmed that the EU-RL are still working on this as a priority but are yet to advocate the use of any one approach. Advised Worcester that the FSA are asking for interested parties to participate in a ring trial of GMOval (an EU project aimed at validating GMO screening methods). In the interim period, screening for common control elements (P-35S, T-NOS, etc.,) is one of the most viable options for detection of GMOs.
- Discussed with Edinburgh Scientific Services aspects related to ISO 17025 accreditation including approaches to help minimise contamination, cleaning requirements and use of negative controls.

Miscellaneous advice and representation:

- Initiated dialogue with expert laboratories and other nrls/NRLs (including Belgium, Germany and Scotland) regarding agreement and a request for the EU-RL to provide additional guidance on conversion of mass/mass to copy number/copy number on reference materials.
- With direction from the FSA, attended a meeting in Brussels alongside the FSA as the UK nominated scientific expert on detection and quantitation of horsemeat. This was on the basis that there is no NRL for meat authenticity testing, and the experience and expertise most in synergy with molecular biology approaches for meat quantitation lies with EU NRLs linked with GMO testing. Provided input and supported UK policy at an EU meeting discussing the approach for the second round of beef product testing in the EU.
- Demonstrated the applicability of the EU-RL 96-well pre-spotted screening plates on control and real test materials.

**OBJECTIVE 03 - PRODUCTION OF STANDARD OPERATING PROCEDURES, CODES OF PRACTICE AND GUIDANCE DOCUMENTS - (CORE FUNCTION C)**

**Example Tasks:**

- **Contributing to the development of standardised operating procedures, relevant codes of practice and guidance documents for use by OCLs and other relevant laboratories, as requested by the FSA.**

Example activities in relation to these Tasks:

- Reviewed the draft report on detection of stacked events produced by the ENGL Working Group, and provided suggested changes to the text for better use of English and technical clarifications. It is the NRL's view that DNA sequencing may be one of the most promising solutions for detection of stacked events because of its cost and availability. Supplementary information from reputable suppliers could be used to infer the likely presence of single or stacked events in a sample, which is beyond the current capability of chemical/molecular approaches to resolve with full confidence.
- The NRL is a named partner on the review of ENGL Guidance Document on the estimation of measurement uncertainty in GMO analysis.

**OBJECTIVE 04: COMPLIANCE ASSESSMENT VIA AUDITS AND RING TRIALS - (CORE FUNCTION D)**

**Example Tasks:**

- **Ensuring consistency and quality of testing approaches applied by UK OCLs and other relevant laboratories, including advising on corrective action following adverse reports on OCLs from UKAS**
- **Participating in proficiency tests and method validation studies organised by the EURL, informing the FSA of the results and implementing any corrective measures required**
- **Co-ordinating training exercises to promote best laboratory practice in respect of analysis.**

Example activities in relation to these Tasks:

- The NRL arranged for a batch of the EU-RL 96-well screening plates to be delivered to Tayside Scientific Services.
- The NRL sent an official expression of interest to the EU-RL for participation in the validation exercise for the revised EU-RL pre-spotted plates.
- The NRL sent an official expression of interest to the EU-RL for participation in the validation exercise for screening approaches under the GMOval project.
- In conjunction with Defra and Government Chemist support, the NRL ran a training course for Public Analysts on the use of molecular biology approaches for species determination in feed and food samples in October 2013.

- The NRL attended a two day training course at IRMM (Institute for Reference Materials and Measurements, Geel, Belgium) entitled "GMO quantification: proper calibration and estimation of measurement uncertainty".
- The NRL participated in the 6th EU-RL Comparative Test (ILC_EURL_GMFF_CT_02_12) organised by the EU-RL under Regulation (EC) No. 882/2004. According to the EURL-GMFF it is mandatory that all NRLs (nominated under Commission Regulation (EC) No. 882/2004 of the European Parliament of the Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules), participate in these Comparative Tests. A letter received from the EURL dated stated that under Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29th April 2004, the EU Reference Laboratory for GM Food and Feed (EURL-GMFF) shall organise comparative testing and ensure an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols.
- This Comparative Test involved screening and quantitation of three GM soya bean and two GM maize varieties. Z-score results for this Comparative Test were reported back to the FSA and showed that the NRL was performing satisfactorily (Z-scores of 0.18; 0; 0.25; 0.51).
- The NRL also participated in the 7th EU-RL Comparative Test (ILC-EURL-GMFF-CT-01/13) which involved screening and quantitation for 14 GM maize events. Results from this Comparative Test have yet to be officially published by the EU-RL.

**OBJECTIVE 05 - CO-ORDINATION WITHIN THE UK OF EURL INITIATIVES - (CORE FUNCTION E)**

**Example Tasks:**

- **Archiving of Standard materials (Control Materials) provided by the EU-RL**

Example activities in relation to these Tasks:

- Development, updating and maintenance of physical and electronic register for control materials housed at the NRL.
- Received and registered new set of EU-RL plasmid control materials:
    - Cotton T304-40
    - Maize DAS-40278
    - Maize Bt176
    - Oilseed rape Rf1
    - Oilseed rape Rf2
    - Oilseed rape Ms1
    - Oilseed rape Topas 19/2
    - Soya MON87708
    - Cotton 3006-210-23
    - Oilseed rape DP73496
    - Oilseed rape MON88302
- The full list of materials archived at the NRL as of 31/03/14 is shown in Annex I

**OBJECTIVE 06 - COMMUNICATION OF RESULTS AND DATA USE - (CORE FUNCTION F)**

**Example Tasks:**

- **The Contractor shall ensure that the FSA receives regular updates of any developments related to the core functions of the NRL.**

Example activities in relation to these Tasks:

- The NRL presented an official review of its activities at two NRL liaison meetings with the FSA during the period covered by this report.

## ADDITIONAL TASKS

**OBJECTIVE 07:- ADDITIONAL SERVICES AND TASKS (as detailed in Annex I of the invitation to tender)**

**Example Tasks:**

- **If required, assist the EU-RL in testing and validating the methods of detection for GMOs, when necessary.**
- **Participate and contribute to the scientific input at meetings, e.g. the European Network of GMO Laboratories (ENGL) meetings, and working groups in a manner which supports UK policy on GMOs based on best available scientific knowledge.**

- The EURL periodically invites ENGL members (EC Regulation No. 1829/2003) to participate in the validation of new methods for GMO (event specific) detection, as part of the EU authorisation procedure for new GMO varieties. These international method validation trials are aimed at providing evidence for the "fitness for purpose" of a method for the detection of new GM varieties. The event specific protocols that are followed describe prescriptive conditions in terms of PCR settings, primers/probes, and DNA extraction/amount. The methods are validated in terms of objective evaluation of performance characteristics such as reproducibility, trueness, LOD/LOQ (biological sensitivity), linear working range (calibration), and specificity (event specific: junction sequence between genomic DNA and insert). The NRL participated in the EU-RL validation exercise to assess the fitness for purpose of a method for the detection and quantitation of maize event VCO_01981_5.
- The NRL attended the 19$^{th}$ ENGL plenary session (Italy), and gave a talk on the development and validation of a CaMV control plasmid in the context of the legislation for testing for Chinese GM rice (2011/884/EU).
- The NRL provided a summary report of the 19$^{th}$ ENGL plenary meeting to the FSA and the UK Official Control Laboratories (OCLs).
- The NRL attended the 20$^{th}$ ENGL plenary session and the 9th NRL meeting (Italy).
- The NRL provided a summary report of the 20$^{th}$ ENGL plenary meeting and the 9$^{th}$ NRL meeting to the FSA and the UK Official Control Laboratories (OCLs).

# Annex 1: List of ENGL Control materials housed by the NRL

(Correct as of 31/03/14)

| GM event | Species | ENGL plasmid no. |
|---|---|---|
| Ms8 | Canola | pENGL-00-06/04-01 |
| Rf3 | Canola | pENGL-00-07/04-01 |
| T45 | Canola | pENGL-00-14/04-01 |
| RT73 | Canola | pENGL-00-26/04-01 |
| LL25 | Cotton | pENGL-00-13/04-01 |
| 281-24-236 | Cotton | pENGL-00-14/05-01 |
| MON863 | Maize | pENGL-00-01/04-01 |
| TC1507 | Maize | pENGL-00-02/04-01 |
| 59122 | Maize | pENGL-00-03/05-01 |
| MIR604 | Maize | pENGL-00-04/05-01 |
| T25 | Maize | pENGL-00-08/04-01 |
| Bt11 | Maize | pENGL-00-12/05-01 |
| NK603 | Maize | pENGL-00-27/04-01 |
| GA21 | Maize | pENGL-00-29/04-01 |
| EH92-527-1 | Potato | pENGL-00-09/05-01 |
| H7-1 | Sugar beet | pENGL-00-28/04-01 |
| 40-3-2 | Soybean | pENGL-00-08/05-01 |
| MON1445 | Cotton | pENGL-00-15/04-01 |
| MON15985 | Cotton | pENGL-00-24/04-01 |
| MON531 | Cotton | pENGL-00-16/04-01 |
| 3272 | Maize | pENGL-00-03/06-01 |
| Bt11 | Maize | pENGL-00-10/07-01 |
| LY038 | Maize | pENGL-00-01/06-01 |
| MON88017 | Maize | pENGL-00-16/05-01 |
| MON89034 | Maize | pENGL-00-06/06-01 |
| A2704-12 | Soybean | pENGL-00-13/05-01 |
| MON89788 | Soybean | pENGL-00-05/06-01 |
| GHB614 | Cotton | pENGL-00-14/07-01 |
| MON88913 | Cotton | pENGL-00-05/07-01 |
| GA21 | Maize | pENGL-00-15/05-01 |
| MON810 | Maize | pENGL-00-25/04-01 |
| A5547-127 | Soybean | pENGL-00-01/08-01 |
| DP-305423-1 | Soybean | pENGL-00-07/07-01 |

| | | |
|---|---|---|
| DP-356043-5 | Soybean | pENGL-00-04/07-01 |
| T25 | Maize | pENGL-00-08/04-01 |
| GHB119 | Cotton | pENGL-00-04/11-01 |
| MIR162 | Maize | pENGL-00-08/08-01 |
| CV127 | Soybean | pENGL-00-01/09-01 |
| MON87705 | Soybean | pENGL-00-01/10-01 |
| MON87460 | Soybean | pENGL-00-04/09-01 |
| FG72 | Soybean | pENGL-00-04/10-01 |
| MON87701 | Soybean | pENGL-00-05/09-01 |
| MON87769 | Soybean | pENGL-00-07/09-01 |
| T304-40 | Cotton | pENGL-00-05/11-01 |
| DAS-40278 | Maize | pENGL-00-10/10-01 |
| BT176 | Maize | pENGL-00-18/04-01 |
| Rf1 | Oilseed rape | pENGL-00-09/04-01 |
| Rf2 | Oilseed rape | pENGL-00-10/04-01 |
| Ms1 | Oilseed rape | pENGL-00-11/04-01 |
| Topas 19/2 | Oilseed rape | pENGL-00-12/04-01 |
| MON87708 | Soybean | pENGL-00-02/11-01 |
| 3006-210-23 | Cotton | pENGL-00-14/05-01-B |
| DP73496 | Oilseed rape | pENGL-00-02/12-01 |
| MON88302 | Oilseed rape | pENGL-00-09/11-01 |