



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

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Provision of UK National  
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for Genetically Modified  
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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

**FVO** - European Commission Food and Veterinary Office

**GeMMA** - genetically modified materials analysis

**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

**PSP** - Pre-Spotted Plate

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



## 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-ordinated 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 conducts 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 7<sup>th</sup> year of the NRL operation (April 2015-March 2016) 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:

- A summary of the 23<sup>rd</sup> ENGL plenary meeting (held on the 15<sup>th</sup>/16<sup>th</sup> April 2015) was written and provided to the FSA.
- A full meeting report of the 23<sup>rd</sup> ENGL plenary meeting was written and provided to the FSA.
- A teleconference was had with the FSA regarding the outcome of 23<sup>rd</sup> ENGL plenary meeting.
- Following approval from the FSA, the summary of the 23<sup>rd</sup> ENGL plenary meeting was circulated to all OCLs.
- Reaffirmed with the FSA the EU Agriculture Committee's decision to reject a draft EU proposal to allow individual EU member states more control on the sale and use of EU approved GMO's in their own territories (<http://www.europarl.org.uk/en/media/news/uknews2015/oct15/gmoproposal.html>).
- Informed the FSA of the initial discussions regarding possible change of location of all ENGL/EURL activities from the JRC (Ispra, Italy) to Belgium.
- A summary of the 11<sup>th</sup> NRL / 24<sup>th</sup> ENGL plenary meeting (held on the 22<sup>nd</sup>/23<sup>rd</sup> September 2015) was written and provided to the FSA.
- A full meeting report of the 11<sup>th</sup> NRL / 24<sup>th</sup> ENGL plenary meeting was written and provided to the FSA.
- Following approval from the FSA, the summary of the 24<sup>th</sup> ENGL plenary meeting was circulated to all OCLs.
- In relation to the presence of unauthorised GM oilseed rape event OXY-235 in conventional oilseed rape, a copy of this information was circulated to all OCLs. This was originally drafted on behalf of the EURL for GMOs in feed and food by the ENGL secretariat.
- Forwarded to the FSA a communication from the EURL on the publication of a summary report of the Standing Committee on plants, animals, food and feed (PAFF) on "Genetically Modified Food and Feed and Environmental Risk" held on 19<sup>th</sup> October 2015.



- A summary of the 30<sup>th</sup> ENGL Steering Committee meeting (held on the 3<sup>rd</sup>/4<sup>th</sup> February 2016) was written and provided to the FSA.
- A full meeting report of the 30<sup>th</sup> ENGL Steering Committee meeting was written and provided to the FSA.





• **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 Official Control Laboratories:**

- Circulated the JRC Scientific and Policy report on “European technical guidance document for the flexible scope accreditation of laboratories quantifying GMOs” to OCLs to raise awareness of available guidance in this area.  
(<http://www.european-accreditation.org/publication/jrc-scientific-and-policy-reports-guidance-iso-iec-17025-2013>)
- Provided advice to an OCL with respect to GMO screening using the P35S promoter and how to monitor for false positives using Cauliflower mosaic (CaMV) analogues.
- Provided advice to an OCL with respect to use of real-time PCR for GMO analysis, choice of available kits and recommendations on what methods to use.
- Provided advice to an OCL in relation to upskilling of molecular biology approaches with a focus on use of real-time PCR, appropriate laboratory apparatus and set-up to optimise work-flow. The OCL was looking to maintain and develop further capability in this area.
- Provided advice to an OCL in relation to the meeting report from the 24<sup>th</sup> ENGL plenary session. This included discussions on the need for further training and knowledge dissemination in the areas of testing for botanical impurities and implementation of EC Regulation No. 619/2011 on the “Low Level Presence” of unauthorised GMOs in feed.
- Prior to 11<sup>th</sup> NRL workshop meeting, the NRL sent an E-mail to all OCLs asking for any requirements on further training activities. One OCL replied asking if any training/guidance was available for some of the emerging point of test next generation sequencing devices. The NRL discussed this matter with the EURL at the 11<sup>th</sup> NRL workshop meeting. The EURL took note of the training request, along with requests for guidance on all new technologies including NGS, ddPCR, bio-informatics, point-of-test devices and multiplexing. The EURL response was that they would keep a watching brief of the matter, although they felt that the issues of point of test next generation



sequencing devices was so new that no current guidance was available at the time. The EURL will monitor the situation with the aim of reviewing the current state of affairs in the near future.

**Miscellaneous advice and representation:**

- Represented the UK NRL for GMOs at the 23<sup>rd</sup> ENGL plenary session (15<sup>th</sup>/16<sup>th</sup> April 2015) and 11<sup>th</sup> NRL/ 24<sup>th</sup> ENGL (22<sup>nd</sup>/23<sup>rd</sup> September 2015) plenary session in Italy.
- Participated in and attended the first digital PCR (dPCR) ENGL Working Group (30<sup>th</sup> June – 1<sup>st</sup> July 2015) meeting at the EURL in Italy.
- Attended a three day workshop in Slovenia (Ljubljana) on the 8<sup>th</sup>-10<sup>th</sup> December 2015 organised by the EURL and NIB (Slovenia) on digital PCR and next generation sequencing. Participated in the workshop and attended as an invited speaker to talk about laboratory expertise in digital PCR.
- Following a consultative period, Malcolm Burns (UK NRL) was nominated by the FSA to become the UK representative on the ENGL Steering Committee.
- Attended the ENGL Steering Committee (SC) 30<sup>th</sup> meeting in Italy on the 3<sup>rd</sup>/4<sup>th</sup> February 2016 as the UK representative.



## **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:**

- Official member of ENGL digital PCR Working Group and attended first meeting held on 30<sup>th</sup> June – 1<sup>st</sup> July 2015 at the EURL in Italy.
- A guidance document on digital PCR (dPCR) is currently being drafted, to which the UK NRL has contributed sections and chapters for.
  - The aim of the dPCR Working Group is to provide a guidance document that identifies future needs of using dPCR for GMO analysis and potential approaches to address these.
  - The guidance document will include a discussion on the potential of the dPCR technologies currently on the market including a comparison with real-time PCR and descriptions of different fields where dPCR has been applied. Additionally, technical issues will be described in line with ENGL acceptance criteria for method verification and future accreditation.
  - The guidance document will address the following issues, identifying future needs and proposing approaches to address them:
    - Transferability of existing real-time PCR methods into a digital PCR format;
    - Accreditation (including in-house validation);
    - Applicability to difficult matrices ;
    - Applicability to analytical areas other than GM food/feed;
    - Definition and assessment of relevant method performance criteria;
    - Data interpretation and reporting;
    - Multiplexing;
    - Summary of technical needs and requirements for implementing and applying digital PCR.
  - The guidance document will summarise relevant existing experience with dPCR and also act as an aid in helping laboratories to decide if dPCR will meet their specific needs.



## **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:**

- LGC maintains ISO 17025 flexible scope of accreditation for GMO analysis, in line with the requirement to be an NRL for GMOs in feed and food.
- In April 2015 LGC was subject to a regularly scheduled ISO 17025 audit for GMO analysis by UKAS. The audits recommendation was that LGC continue to retain its status for ISO 17025 flexible scope of accreditation for GMO analysis.
- Results were submitted to the EURL for the following NRL Comparative Tests:
  - NRL Comparative Test #11 (CT\_01\_15) – soya event DAS-68416 and soya event DP-356043
  - NRL Comparative Test #12 (CT\_02\_15) – soya event DAS-81419 and oilseed rape event MON88302
- LGC received the following Z-scores for previous NRL Comparative Tests:
  - NRL Comparative Test #11 (CT\_01\_15) – Z-scores of -0.53 and -0.29
- The following Z-scores were communicated to the FSA by the NRL from the EURL Comparative Tests:
  - NRL CT#10 (ILC\_EURL\_GMFF\_CT\_02\_14) – UK NRL received a Z-score of -0.50 (
  - NRL CT#11 (ILC\_EURL\_GMFF\_CT\_01\_15) – UK NRL received Z-scores of -0.53 and -0.29
- For NRL CT#10 (ILC\_EURL\_GMFF\_CT\_02\_14), a number of NRLs experienced difficulty in providing results consistent with expectations for the assigned value for RoundUp Ready soya (40-3-2). The results had to undergo extensive re-evaluation by the EURL due to the non-normality of the reported results. Around 25% of participants received an un-satisfactory Z-score associated with this analyte, and were subsequently asked to reanalyse and resubmit their results. The UK NRL received a satisfactory Z-score of -0.5 for this analyte within the Comparative Test, and was therefore not asked to repeat the analysis or re-evaluate the sample.



**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:**

- LGC continues to maintain a dedicated physical and electronic register for control materials held in a secure cold room.
- Received, registered and archived the following new ENGL control plasmids:
  - MON 87427 maize
  - OXY-235 oilseed rape
  - DAS 4406 soybean
  - DAS 81419 soybean
- A full list of the registered ENGL plasmid control materials is provided in Annex 1.



## **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 UK NRL is in constant contact with the FSA by E-mail and phone in relation to queries, updates, developments and deliverables.
- The UK NRL is available for provision of advice on GMO analysis to all OCLs by E-mail and phone.
- Summaries on all ENGL plenary meetings that the UK NRL attends are supplied to all OCLs and the NRL is fully contactable in order to provide further details on each meeting as is necessary.
- Full meeting reports for the ENGL plenary, ENGL Steering Committee and NRL annual meetings are provided to the FSA.
- The UK NRL participated in a scheduled liaison meeting with the FSA in October 2015 to discuss progress according to the NRL contract deliverables.



## **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.**

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

- The NRL attended the following meetings and working groups throughout the financial year:
  - The 23<sup>rd</sup> ENGL plenary meeting (15<sup>th</sup>/16<sup>th</sup> April 2015) – JRC, Italy.
  - ENGL digital PCR Working Group meeting (30<sup>th</sup> June – 1<sup>st</sup> July 2015) – JRC, Italy.
  - The 11<sup>th</sup> NRL / 24<sup>th</sup> ENGL plenary meeting (22<sup>nd</sup>/23<sup>rd</sup> September 2015) – JRC, Italy
  - The ENGL workshop on dPCR and next generation sequencing (8<sup>th</sup>-10<sup>th</sup> December 2015) – Ljubljana, Slovenia.
  - The 30<sup>th</sup> ENGL Steering Committee meeting (3<sup>rd</sup>/4<sup>th</sup> February 2016) – JRC, Italy



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

(Correct as of 31/03/16)

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
MON1445	Cotton	pENGL-00-15/04-01
MON15985	Cotton	pENGL-00-24/04-01
MON531	Cotton	pENGL-00-16/04-01
GHB614	Cotton	pENGL-00-14/07-01
MON88913	Cotton	pENGL-00-05/07-01
GHB119	Cotton	pENGL-00-04/11-01
T304-40	Cotton	pENGL-00-05/11-01
3006-210-23	Cotton	pENGL-00-14/05-01-B
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
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
GA21	Maize	pENGL-00-15/05-01
MON810	Maize	pENGL-00-25/04-01
T25	Maize	pENGL-00-08/04-01
MIR162	Maize	pENGL-00-08/08-01
DAS-40278	Maize	pENGL-00-10/10-01
BT176	Maize	pENGL-00-18/04-01





<b>5307</b>	Maize	pENGL-00-07/11-01
<b>MON87427</b>	Maize	pENGL-00-03/12-01 MON87427
<b>Rf1</b>	Oilseed rape	pENGL-00-09/04-01
<b>Rf2</b>	Oilseed rape	pENGL-00-10/04-01
<b>Ms1</b>	Oilseed rape	pENGL-00-11/04-01
<b>Topas 19/2</b>	Oilseed rape	pENGL-00-12/04-01
<b>DP73496</b>	Oilseed rape	pENGL-00-02/12-01
<b>MON88302</b>	Oilseed rape	pENGL-00-09/11-01
<b>Oxy-235 genomic DNA</b>	Oilseed rape	Oxy-235 oilseed rape
<b>EH92-527-1</b>	Potato	pENGL-00-09/05-01
<b>Bt63</b>	Rice	pENGL-00-EM02/06/01
<b>40-3-2</b>	Soybean	pENGL-00-08/05-01
<b>A2704-12</b>	Soybean	pENGL-00-13/05-01
<b>MON89788</b>	Soybean	pENGL-00-05/06-01
<b>A5547-127</b>	Soybean	pENGL-00-01/08-01
<b>DP-305423-1</b>	Soybean	pENGL-00-07/07-01
<b>DP-356043-5</b>	Soybean	pENGL-00-04/07-01
<b>CV127</b>	Soybean	pENGL-00-01/09-01
<b>MON87705</b>	Soybean	pENGL-00-01/10-01
<b>MON87460</b>	Soybean	pENGL-00-04/09-01
<b>FG72</b>	Soybean	pENGL-00-04/10-01
<b>MON87701</b>	Soybean	pENGL-00-05/09-01
<b>MON87769</b>	Soybean	pENGL-00-07/09-01
<b>MON87708</b>	Soybean	pENGL-00-02/11-01
<b>DAS-68416-4</b>	Soybean	pENGL-00-11/10-01
<b>DAS44406-6</b>	Soybean	pENGL-00-01/12-01 DAS44406-6
<b>DAS81419-2</b>	Soybean	pENGL-00-03/13-01 DAS81419-2
<b>H7-1</b>	Sugar beet	pENGL-00-28/04-01