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 2016 - 30th March 2017

Contact: Malcolm Burns
Tel: 0208 943 7000

Prepared by: Timothy Wilkes

Approved by: Peter Bedson

Date: 10/07/17

Report No.: LGC/R/2016-2017/560

Release: Version 1

Contents

Glossary 3

Role of the National Reference Laboratory 4

Core Function 7

Production of the NRL annual report 7

OBJECTIVE 01 - SECRETARIAT SERVICES - (CORE FUNCTION A) 7

OBJECTIVE 02 - ADVICE AND REPRESENTATION WITHIN THE UK/EU - (CORE FUNCTION B) 9

OBJECTIVE 03 - PRODUCTION OF STANDARD OPERATING PROCEDURES, CODES OF PRACTICE AND GUIDANCE DOCUMENTS - (CORE FUNCTION C) 11

OBJECTIVE 04: COMPLIANCE ASSESSMENT VIA AUDITS AND RING TRIALS - (CORE FUNCTION D) 12

OBJECTIVE 05 - CO-ORDINATION WITHIN THE UK OF EURL INITIATIVES - (CORE FUNCTION E) 13

OBJECTIVE 06 - COMMUNICATION OF RESULTS AND DATA USE - (CORE FUNCTION F) 14

ADDITIONAL TASKS 15

OBJECTIVE 07:- ADDITIONAL SERVICES AND TASKS (as detailed in Annex I of the invitation to tender) 15

Annex 1: Additional links to NRL annual reports and Newsletters 16

Annex 2: List of ENGL Control materials housed by the NRL 17

Annex 3: EURL Annual work program for 2016 – 2017 activities carried out for the implementation of tasks allocated to the EURL under regulation (EC) 882/2004 19

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

JRC – Joint Research Centre (Italy, Ispra)

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

SC – Steering Committee

WG – Working Group

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.

For information, the relevant EU-RL's annual work programme is included in Annex 3 of this document.

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 2017, 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 8th year of the NRL operation (April 2016-March 2017) 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 25th ENGL plenary meeting (held on the 13th/14th April 2016) was written and provided to the FSA and UK Public Analysts.
- A full meeting report of the 25th ENGL plenary meeting was written and provided to the FSA.
- Circulated the draft ENGL 31st Steering Committee meeting agenda to the FSA and UK ENGL members for comment.
- Provided a written summarised report of the 31st ENGL Steering Committee meeting (21st/22nd June 2016) to the FSA.
- Provided a full written report of the 31st ENGL Steering Committee meeting to the FSA.
- For the EURL Comparative Test (ILC_EURL_GMFF_CT_01/16), received Z-scores of 0.1, 0.1 and 0.2 for GM events 40278 maize, 1507 maize and MIR 162 maize respectively. The Z-scores were communicated to the FSA.
- Informed the FSA about the findings in the USA of the unauthorised release of GM wheat Mon 7170, and provided a copy of an email from the EURL in relation to this.
- Following authorisation from the FSA, circulated the copy of an email from the EURL to all OCLs in relation to findings in the USA on the release of unauthorised GM wheat Mon 7170.
- Provided a copy of the draft agenda for the 12th NRL workshop/26th ENGL Plenary session (21st/22nd September 2016) to the FSA for comment.
- Circulated a request to OCLs for any training requirements to suggest at the forth coming 12th NRL workshop in Ispra.
- Provided a summarised meeting report on the 26th ENGL plenary and 12th NRL workshop meeting to the FSA and OCLs.
- Provided the full meeting report of the 26th ENGL plenary and 12th NRL workshop meeting to the FSA.
- Forwarded a copy of the EURL draft minutes to the 12th workshop of NRLs 882/2004 and 26th ENGL plenary to the FSA.

- Forwarded the official EURL minutes to the 12th workshop of NRLs 882/2004 and the 26th ENGL plenary session to the FSA.
- Forwarded the 32nd ENGL Steering Committee draft agenda to all UK ENGL labs for comment.
- Forwarded to the FSA an email from the ENGL Secretariat asking for comments on the final draft report of the ENGL Working Group on Unit of Measurement.
- Attended the 32nd ENGL Steering Committee meeting at the JRC in Italy on the 15th/16th February 2017.
- Wrote and distributed the 32nd ENGL Steering Committee summary report to the FSA and all UK OCLs.

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:

A NRL newsletter (Summer 2016) was produced and circulated to all UK OCLs. Copies of all previous NRL newsletters and NRL annual reports are freely available from the NRL webpages at http://www.lgcgroup.com/services/regulatory-support/national-reference-laboratories/ and are referred to in Annex 1.

Advice provided to Official Control Laboratories:

- Provided advice to an OCL on which GM events are likely to be detected using P35S and TNOS, which was dependent upon the exact primer/probe sequences used for P35S and TNOS in the qPCR assay.
- Provided advice to an OCL on the availability of the EURL pre-spotted plates and the EURL initiative to run another dPCR workshop at the JRC in the future.
- Circulated an email to all of the UK OCLs on behalf of the FSA requesting views, comments and input into the updating of the current FSA guidance document on sampling in food and feed for genetically modified (GM) material.
- Circulated an email to all UK OCLs informing them of the publication of a paper in JAPA reviewing DNA-based screening approaches for GMO detection.
- Provided advice to an OCL on real-time PCR analysis.
- Contacted all UK OCLs to canvas opinion on UK training requirements to discuss with the EURL at the 27th ENGL plenary meeting in April 2017.
- Provided advice to an OCL with respect to real-time PCR primer and probe design, taxon specific assays, and general aspects of real-time PCR analysis.

Miscellaneous advice and representation:

- Prepared and sent a copy of the GMO NRL annual report 2015 to 2016 to the FSA.

- Informed the FSA that DAS 40278 maize in the previous EURL Comparative Test (ILC_EURL_GMFF_CT_01_16) fell under EU Regulation 619/2011 for which LGC had received a Z score of 0.1, helping confirm UK compliance with implementing 619/2011.
- Provided advice to a UK ENGL member on the unit of measurement (m/m or cp/cp) for expressing the GM content of a sample.
- Responded to an enquiry from a UK ENGL member who requested that the issue of methods and a possible working group for the detection of GM fish (ornamental and farmed) be raised with the EURL.
- Provided advice to the FSA on GM Salmon. This followed the announcement that AquAdvantage GM Salmon (produced by AquaBounty) had recently been approved for use in Canada following its approval for use in the USA in 2015. The NRL provided advice to the FSA regarding availability of methods for the detection of the GM Salmon.
- Contacted and spoke with the Federal Office of Consumer Protection (Berlin, Germany) and the EURL requesting information on the availability of methods for the detection of GM Salmon. Relayed the response to the FSA.
- Provided a UK ENGL member and the FSA with an update on the official method for the detection of AquAdvantage GM Salmon from the USA authorities.
- Published a paper in the Journal of the Association of Public Analysts regarding a current review of DNA based screening approaches for GMO detection.
- Provided an update on GMO NRL activities to the Training Officer of the APA Training Committee for inclusion as an agenda point at the APA Training Committee meeting in November 2016.
- Provided advice to the FSA on testing for stacked events and for the conversion of measurement units between cp/cp to m/m for expressing the GM content of samples.
- Provided written comments to the FSA on queries regarding GM measurement units, evaluation of stacked events, and compliance at the 0.1% GM level for the swede-rape stacked events MS1 x RF1 and MS1 x Rf2 (Bayer).
- Responded to an enquiry from the FSA regarding the use of digital PCR for the conversion of m/m to cp/cp with respect to food related studies. Highlighted to the FSA that further detail on the issue was described in the FSA/LGC Horse Comparative Trial final report (FSA project report FS126001).
- Responded to an enquiry from a UK ENGL lab regarding accreditation for GMO analysis using dPCR, and raised the issue at the 32nd ENGL Steering Committee meeting at the JRC (Italy). The ENGL Steering Committee agreed with the UK NRL that this was an important topic and recommended the inclusion of two agenda points at the 27th ENGL plenary meeting (to be held in April 2017) to discuss the matter further and share experiences on this. Fed this information back to the UK ENGL lab who had raised the query.
- Provided advice to a UK ENGL lab regarding two potential workshops (DNA extraction and dPCR) that the EURL would run during 2017 as the result of discussions held at the 32nd ENGL Steering Committee meeting.
- Following consultation with the FSA, circulated an email to all UK OCLs in order to canvas opinion on UK training requirements to discuss with the EURL at the 27th ENGL plenary meeting (to be held in April 2017).

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:

- The UK NRL is a full member of the ENGL WG on digital PCR. The aim of this group is to provide an ENGL Guidance Document detailing advice on best measurement practice for the application of dPCR for GMO analysis in analytical laboratories.
- Following meetings, teleconferences and email discussions, the UK NRL has provided advice on appropriate references for the ENGL dPCR Working Group Guidance Document, and contributed to the compilation of the final draft guidance document. It is anticipated that the draft guidance document will be made available for review by the ENGL SC in Q2 2017.
- Provided input, comments and suggestions to the EURL on parameters to include in a table to capture best practice and experiences on an ENGL shared document on DNA extraction.
- The NRL is a member of a newly formed ENGL Working Group on ENGL Procedures. The ENGL Consortium Agreement provides rules and procedures for all main aspects of the ENGL, including membership, work program and confidentiality. However, it does not cover procedures for the routine activity of the network, e.g. approval workflow of documents, management of observers, participation to meetings of non-ENGL members etc. The new procedures, one approved by the entire ENGL, will become applicable. It is not foreseen that they will become integral part of the Consortium Agreement, which will remain unmodified.
- Attended the first meeting of the ENGL WG on ENGL Procedures in April 2016. Contributed to report writing for the minutes for the first Working Group on ENGL Procedures.

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:

- Participated in and submitted results for the 13th NRL CT (ILC_EURL_GMFF_CT_01_16)
- Received Z-scores of 0.1, 0.1 and 0.2 for NRL CT#13 (ILC_EURL_CT_01/16) for GM events 40278 maize, 1507 maize and 162 maize. These results were communicated to the FSA.

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:
    - Maize MON 87411
    - Cotton MON 88701
    - Soya SYTH0H2
    - Soya 87751
    - Maize VCO-01981-5
- A full list of the registered ENGL plasmid control materials is provided in Annex 2.

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 email 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 email 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.

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:
  - Attended the 25th ENGL plenary meeting at the JRC (Ispra, Italy) (13th/14th April 2016).
  - Attended the first meeting of the ENGL WG on ENGL Procedures in April 2016.
  - Attended the 31st ENGL Steering Committee meeting at the JRC (Ispra, Italy) (21st/22nd June 2016).
  - Attended the 12th NRL workshop and the 26th ENGL Plenary meeting at the JRC (Ispra, Italy) (21st/22nd September 2016).
  - Represented the UK at the 32nd ENGL Steering Committee meeting at the JRC (Ispra, Italy) (15th/16th February 2017).

Annex 1: Additional links to NRL annual reports and Newsletters

Copies of previous GMO NRL annual reports are freely available to download from the UK GMO-NRL website at: http://www.lgcgroup.com/services/regulatory-support/national-reference-laboratories/.

The reports currently available are:

- GMO NRL Annual Report April 2013 – March 2014
- GMO NRL Annual Report April 2014 – March 2015
- GMO NRL Annual Report April 2015 – March 2016

An NRL Newsletter is also available at the same website. Editions of the Newsletter currently available are:

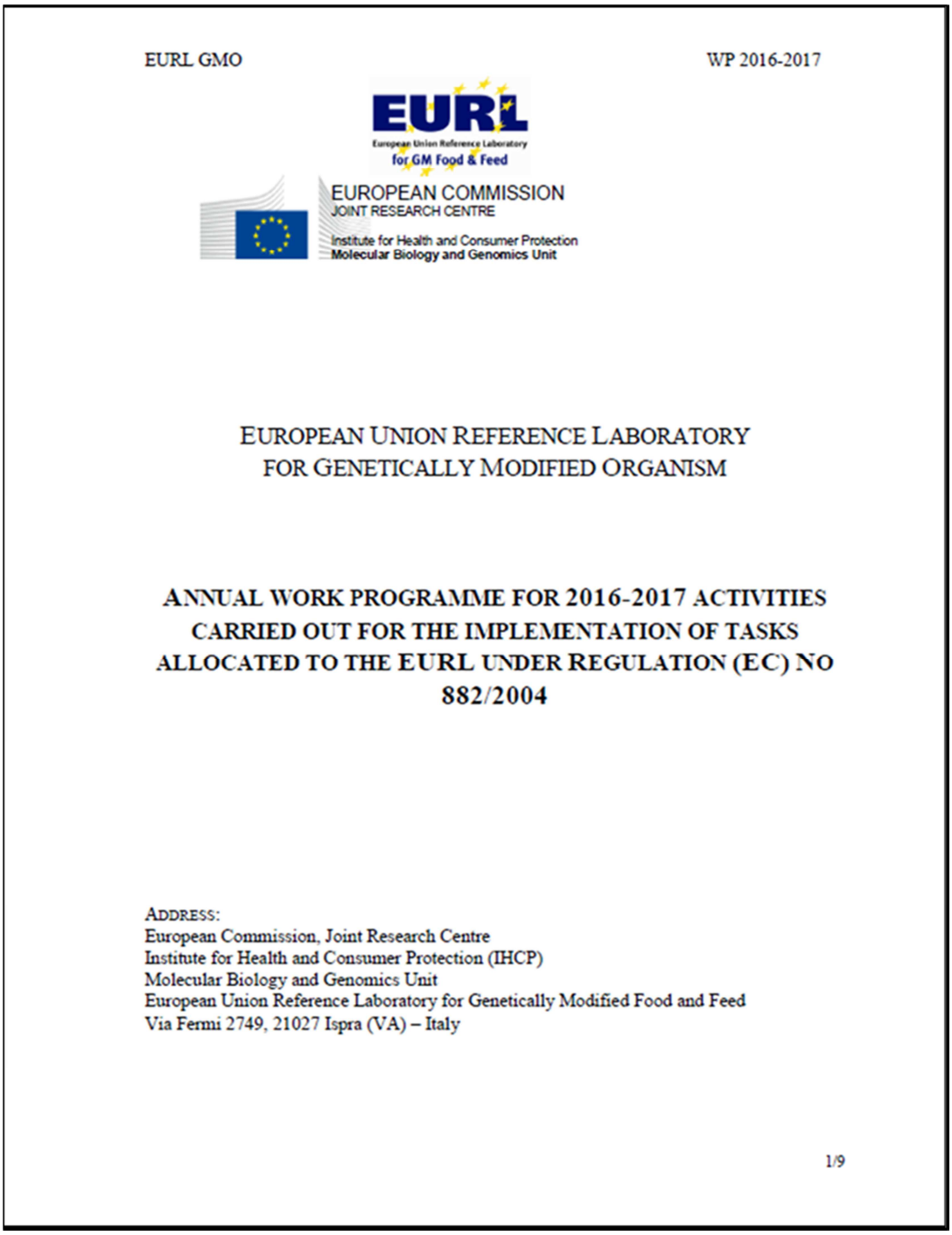
- NRL Newsletter September 2013
- NRL Newsletter Summer 2014
- NRL Newsletter Spring 2015
- NRL Newsletter Summer 2016

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

GM	Species	ENGL plasmid no.
281-24-236	Cotton	pENGL-00-14/05-01
3006-210-23	Cotton	pENGL-00-14/05-01-B
GHB119	Cotton	pENGL-00-04/11-01
GHB614	Cotton	pENGL-00-14/07-01
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
3272	Maize	pENGL-00-03/06-01
5307	Maize	pENGL-00-07/11-01
59122	Maize	pENGL-00-03/05-01
Bt11	Maize	pENGL-00-12/05-01
Bt11	Maize	pENGL-00-10/07-01
BT176	Maize	pENGL-00-18/04-01
DAS-40278	Maize	pENGL-00-10/10-01
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
MON87411	Maize	pENGL-00-01/15-01
MON87427	Maize	pENGL-00-03/12-01 MON87427
MON88017	Maize	pENGL-00-16/05-01
MON89034	Maize	pENGL-00-06/06-01
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

GM	Species	ENGL plasmid no.
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
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

Annex 3: Annual work program for 2016 – 2017 activities carried out for the implementation of tasks allocated to the EURL under regulation (EC) 882/2004



EURL GMO WP 2016-2017

EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit

EUROPEAN UNION REFERENCE LABORATORY
FOR GENETICALLY MODIFIED ORGANISM

ANNUAL WORK PROGRAMME FOR 2016-2017 ACTIVITIES CARRIED OUT FOR THE IMPLEMENTATION OF TASKS ALLOCATED TO THE EURL UNDER REGULATION (EC) NO 882/2004

ADDRESS:
European Commission, Joint Research Centre
Institute for Health and Consumer Protection (IHCP)
Molecular Biology and Genomics Unit
European Union Reference Laboratory for Genetically Modified Food and Feed
Via Fermi 2749, 21027 Ispra (VA) – Italy

1/9

CONTENT

1. BACKGROUND INFORMATION 3
2. THE COMMISSION WORK PROGRAMME 2016-2017 FOR EURLS 3
1 OPERATIONAL COMMISSION OBJECTIVE 1: to ensure the development and use of high quality analytical methods across the EURL network 5
EURL ACTIVITY 1.1: To ensure the development and use of high quality analytical methods 5
Expected ex-ante: 5
EURL ACTIVITY 1.2: Delivery of training, information, updates to NRLs and third countries 6
2 OPERATIONAL COMMISSION OBJECTIVE 2: to maintain appropriate level of inter-laboratory proficiency testing ensuring efficiency of control analysis methods 8
EURL ACTIVITY 2.1: Comparative testing 8
3 OPERATIONAL COMMISSION OBJECTIVE 3: to ensure the availability of scientific and technical assistance provided by the EURLs 9
EURL ACTIVITY 3.1: Handling of *ad hoc* requests from DG SANCO and others 9
4 OPERATIONAL COMMISSION OBJECTIVE 4: to ensure a sound and efficient management of EURL funding cycle 9
EURL ACTIVITY 4.1 Financial and technical reporting and planning 9

1 OPERATIONAL COMMISSION OBJECTIVE 1: to ensure the development and use of high quality analytical methods across the EURL network

EURL ACTIVITY 1.1: To ensure the development and use of high quality analytical methods

Expected ex-ante:
NRLs nominated under Regulation 882/2004 and related official control laboratories are aware and have access to at least the same number of up-to-date validated methods for detection (screening), identification, and (for authorised GMO-events and events falling under the scope of Regulation (EU) No 619/2011) quantification of GMOs in food and feed.

High quality analytical methods
The EURL runs a permanently updated GMOmethods database of analytical reference methods for the detection, identification, and quantification of GMOs. This database is freely accessible via the EURL-website and contains only methods validated in accordance to international standards (ISO, IUPAC), e.g. those validated by the EURL. These methods are event specific, construct specific, or element specific. The detailed method protocols accessible via this database enable experienced laboratories to implement the reference methods and to use it for regulatory controls. Throughout 2016 and 2017 new reference methods will be added to the database. The JRC has developed and made available on its website web based tools that help control laboratories plan their testing strategy and to interpret their testing (screening) results. As only permanent staff is involved in the GMOmethods database management, no additional funds are requested.

Commission priority: Detection of unauthorised GMOs
One of the Commission priorities for the period 2016-2017 is the detection of unauthorised GMOs. A widely used tool for this is the application of a portfolio of validated screening methods that target genetic elements known to be used for the construction of GM-events. In 2016 and 2017 the EURL will carry out or support the validation of up-to 2 screening methods per year, under the condition that the proposed validation project meets international agreed validation standards and a successfully validated method can be included in the GMOmethods database. The methods that will be validated are identified by the ENGL (AG-MSV or SC) as needed to fill a gap in the available portfolio, and hence as essential for the NRLs and their control laboratories to detect unauthorised GMOs. These validations can be carried out by the EURL or other capable organisations (e.g. NRLs), it remains to be seen to which degree the EURL could offer financial or in kind support to these organisations. In any case this financial support would be limited to the budget requested by the EURL for carrying out these validations.

A budget is requested for the validation of up to 2 screening methods per year, to be used for consumables and reagents needed for such an exercise.

Development of high throughput analytical methods for GMO detection and dissemination of NRLs
In 2016 the EURL will introduce a multi target detection system, known as pre spotted plate (PSP), into regulatory GMO control in the EU. Different PSP have been developed by the

JRC over the previous years and successful pilot and demonstration projects have been supported by the EURL budget in 2014 and 2015. The EURL will continue updating these plates in line with new authorisations and new screening methods; it will also set-up a subcontract for the production in semi-industrial scale of the plates (including quality control), and their provision to control laboratories.

During 2016 the JRC will also invite interested companies to apply for a license for producing and marketing the plates in line with strict quality requirements established by the JRC. The licence holder shall be operational in Jan 2017. Depending on the interests of the NRLs and the arrangement with the subcontractor, the specific PSP layout will be restricted to screening or also include plates for event-specific analysis (one plate per crop, or plates covering all main GM crops). The EURL will ensure that adequate quality controls are in place that allow EURL-approved PSPs to be used by the laboratories under their accreditation schemes. For this the JRC is currently executing a proof of concept project which results should become available in 2016/17.

A budget is requested for additional staffing (CA FGIV), consumables, and reagents needed for the updating and testing activities that will be carried out and finished by the EURL in 2016, and for a batch of plates that shall be disseminated to control laboratories for an initial trial. Once their trial-batch is terminated, laboratories may purchase more PSP from a supplier, to be licensed by the JRC during 2016. In 2017, the budget will be used to keep the plates up-to-date.

An important effect of making these tools available will be a further harmonisation of GMO controls in the EU by ensuring that most control laboratories employ the same portfolio of (screening) tests, run under standardised conditions. The potential harmonisation effect of this justifies the support by the Commission.

Deliverable EURL ACTIVITY 1.1:
- Updated GMOmethod database, including at least 2 new methods.
- 1 to 2 validated screening methods.
- Screening (and possibly event-specific) PSP available for regulatory GMO control.

EURL ACTIVITY 1.2: Delivery of training, information, updates to NRLs and third countries

Expected ex-ante:
- An attendance rate of 80% of NRLs nominated by Regulation (EC) No 882/2004 in the annual workshop for these NRLs, with at least 85% of positive responses to the satisfaction surveys of the workshop; negative feedback from satisfaction surveys is clearly and promptly addressed.
- One training event, other than the annual workshop, is offered to all NRL(882), with around 20 participants from NRLs and 3 from non-EU countries, with 85% positive satisfaction survey replies.

Annual NRL workshop

In 2016 and 2017 annual workshops will be organised for the NRL nominated under Regulation (EC) No 882/2004, focussing on issues of general interest identified by the Commission, the EURL, and the NRL. If an NRL offers to host the WS the WS can be held there as long as this would not entail higher costs than doing it in Ispra. This would foster the exchange of practical experience between the NRLs and hence support the communication between them.

Guidance documents on the implementation of analytical methods

The EURL, in collaboration with the ENGL, will develop new guidance documents on the practical arrangements for the implementation of GMO testing methods, if appropriate. Current technical working groups of the ENGL are developing documents on the unit of measurement and reporting, on the use of digital PCR for GMO testing, and on the interpretation and reporting of data. Such guidance documents will be made available to NRLs through meetings, through ENGLnet, and via publication on the EURL-website.

NRL training

Depending on interests and needs identified by the NRLs, one training event will be organised by the EURL, either at the seat of the EURL or in one of the NRLs, subject to availability of appropriate training infrastructures and no increase in cost. Alternatively, and after consultation of DG SANTE, the EURL could finance the participation of experts from the NRLs in specialised courses, organised by other organisations, such as a NRL with specialised knowhow. Currently NRLs have expressed interest in training in using NGS and bioinformatics for GMO detection, and also in digital droplet PCR /digital PCR in general for regulatory GMO testing (including questions linked to accreditation). On-site methods and the application of LAMP for GMO detection are possible other topics for training events in 2016 and 2017.

In line with the mandate of the EURL to train experts from developing countries, up to 3 experts from public GMO control laboratories from developing countries will be invited to each training event.

The training events will be communicated to all ENGL, and additional participants, from non-NRLs, may join at their own cost.

Depending of the interest by the NRLs up-to three additional experts could be invited to the annual NRL workshop and/or the training activity to update participants on relevant topics. At the end of the WS and the training event, the EURL will circulate a satisfaction survey questionnaire.

Budget is requested for covering the cost (travel, lodging, and per-diem or lunch + dinner + local transport) of one participant per NRL(882) (32) for the annual workshops and 20 participants from NRL(882) for the training activities, respectively, plus 3 participants from GMO control laboratories in developing or neighbourhood countries for the training event. In addition, the cost for 3 external experts need to be covered that can be invited to the workshop and/or the training event.

Deliverable EURL ACTIVITY 1.2:
- Financial and technical reports, including information on participation and on satisfaction surveys and any eventual follow-up of the annual workshop and the training event.

2 OPERATIONAL COMMISSION OBJECTIVE 2: to maintain appropriate level of inter-laboratory proficiency testing ensuring efficiency of control analysis methods

EURL ACTIVITY 2.1: Comparative testing

Expected ex-ante:
Two CT rounds per year, with >90% participation of NRLs nominated under Regulation (EC) No 882/2004, other members of the ENGL, and official control laboratories from third countries.
All NRLs (882) completed comparative testing successfully.

In 2016 and 2017 the EURL will organise 2 comparative testing rounds per year and assure the appropriate follow-up. This organisation requires (a) planning, (b) practical preparation and execution, (c) data gathering and analysis, (d) reporting, and (e) follow-up activities. The latter includes, if needed, on-line, on-site or in-house support to under-performing NRLs in order to allow them reaching the required performance level at the next CT round.

The organisation of CT rounds is supported by an Advisory Board for CT (ABCT), which prepares the planning for the CT rounds, reviews the CT reports, and discusses general and strategic aspects of comparative testing. The meetings (two meetings if 1.5 day each year) require preparation, secretarial support, and follow-up.

The EURL is seeking to outsource the technical preparation and distribution to CT participants of the test items used in CT rounds from 2016 onwards. In line with the requirements for CT providers under ISO 17043, the subcontractor will work under the full responsibility of the EURL, and the EURL will continue remaining responsible for the planning, organisation, data analysis and reporting of the CT activitiy. The test items prepared by the subcontractor will be quality controlled by the EURL before their use in a CT round.

A budget is requested to cover the laboratory activities (partly outsourced = subcontract), secretarial needs, shipment costs and non-permanent staff cost resulting from the organisation and execution of the CT activity, including the ABCT, and their follow-up activities.

Deliverables EURL ACTIVITY 2.1
- Two reports of the meetings of the ABCT each year.
- Two CT reports per year within 2 months after the deadline for submission of results.
- Reporting on any CT-follow-up measures taken.

3 OPERATIONAL COMMISSION OBJECTIVE 3: to ensure the availability of scientific and technical assistance provided by the EURLs

EURL ACTIVITY 3.1: Handling of *ad hoc* requests from DG SANCO and others

Expected ex-ante:
- Adequate and timely reactions to all assistance requests.

All resources of the EURL and if needed other parts of the unit, institute or JRC, are available for responding to emergencies. Given that this is fully in line with the overall mission of the JRC, no extra resources are requested for staff that will be only involved in case of need but a part of the staff covered by the AWP is allocated to laboratory work required in the context of ad hoc support. In 2016 and 2017 it is expected that significant amounts of NGS experiments will be required that would need expensive reagents. Hence a budget for consumables is requested in both years under "other consumables".

On a global level, the EURL will continue providing support to the Cartagena Protocol on Biosafety, in 2016 particularly by preparing for the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 8) in Mexico and by hosting the meeting of the informal advisory committee of the BCH in Ispra.

The EURL verifies its efficiency regarding the adequacy of its response from DG SANTE and others by means of an annual customer survey, carried out by its quality manager, a copy of which can be made available to DG SANTE upon request.

Deliverable EURL ACTIVITY 3.1:
- Timely and adequate reaction to all assistance requests, including those requiring significant volumes of laboratory experiments (PCR, NGS), as confirmed by the requesting organisation and the annual customer survey.

4 OPERATIONAL COMMISSION OBJECTIVE 4: to ensure a sound and efficient management of EURL funding cycle

EURL ACTIVITY 4.1 Financial and technical reporting and planning

Expected ex-ante:
- AWPs are provided in time
- Adequate financial and technical reports are delivered in time.

Deliverable EURL ACTIVITY 1.1:
- AWP 2018-19
- Financial and technical reports.