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 2015 ACTIVITIES CARRIED OUT FOR THE IMPLEMENTATION OF REGULATION (EC) NO 882/2004

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CONTENT

1. BACKGROUND INFORMATION

The European Commission's Joint Research Centre (JRC) is the European Union Reference Laboratory for Genetically Modified Food and Feed (EU-RL GMFF) [1,2,3,4] (hereafter named EURL) and has delegated this function to its Molecular Biology and Genomics Unit (MBG Unit), one of five scientific units of its Institute for Health and Consumer Protection. The unit has currently 45 staff members of which around 30 are executing tasks primarily linked to the EURL.

As the Commission's in-house science service, the Joint Research Centre's mission is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle. Working in close cooperation with policy Directorates-General, the JRC addresses key societal challenges while stimulating innovation through developing new methods, tools and standards, and sharing its know-how with the Member States, the scientific community and international partners.

In accordance with its mission statement, different units of the JRC provide scientific and technical support to the policy development and implementation of the EU's regulatory framework for Genetically Modified Organisms (GMOs). The MBG Unit hosts the EURL and contributes to the implementation of this framework through the execution of the two mandates allocated to the EURL in Regulations (EC) No 1829/2003 and (EC) No 1981/2006, amended by Regulation (EU) No 120/2014, and Regulation (EC) No 882/2004.

The EURL is supported by the European Network of GMO Laboratories (ENGL) that includes National Reference Laboratories, most official GMO control laboratories of the EU, Switzerland, Norway and some from accession countries (e.g. Turkey, Serbia and Ukraine), as well as observers, e.g. from China.

In line with its mission, the JRC covers significant activities of the EURL from its own budget, but certain specific activities of the EURL need additional financial support from the Commission, similar to other EURLs for food and feed referred to in Regulation (EC) No 652/2014 [5].

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed; OJ L 269, 18.10.2003, p. 1-23.

[2] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 165, 30.4.2004, p. 1-141, as corrected by OJ L 191, 28.5.2004, p. 1-52.

[3] Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms. OJ L 368, 23.12.2006, p. 99-109.

[4] Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms. OJ L 39, 8.2.2014, p. 46-52.

[5] Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European

This work programme 2015 gives a complete overview of the activities of the EURL, while the requested budget only concerns activities relating to tasks specified in the Commission Implementing Decision of 24 July 2014 establishing the work programme of the Commission for the year 2015 on financial contribution to the European Union reference laboratories (Off J C 244, 26.07.2014, p. 7-13).

2. CHALLENGES AND PRIORITIES FOR 2015

As in previous years the EURL main challenge is to meet the various responsibilities and deadlines flowing from its two mandates:

- Methods, provided by applicants, must be validated within the legal timeframe of Regulation (EC) No 1829/2003, which is very short in case of LLP (Regulation (EC) No 619/2011), and made available to the official GMO-control laboratories in the EU via the network of NRL 882;

- In case of emergencies (e.g. import of unauthorised GMOs, RASFF alerts) the EURL must provide scientific advice – frequently at very short notice, concerning the reliability of the detection and identification of these illegal imports; and

- The NRL 882 must be supported in their task to ensure a homogeneous quality of GMO-control throughout the EU.

As the total number and complexity of GM crops that are cultivated somewhere in the world is increasing, emergencies are increasingly frequent and control laboratories have to be able to run a large number of test methods, going beyond those GMOs authorised in the EU.

This creates practical and economic problems and hence in 2015 an additional major challenge for the EURL is to prepare the introduction of a higher throughput test system (pre-spotted plates - PSP) for GMO controls (screening, identification, and quantification) throughout the EU.

This challenge will be met by means of a demonstration project that has the dual purpose of confirming and demonstrating at a larger scale the good performance that the PSP showed in a small pilot project carried out in 2013/2014 in order to convince NRLs and other control laboratories that the technique is beneficial for their routine control activities, both with regard to harmonisation and quality of testing and the resulting cost.

Ultimately the demonstration project shall provide a solid basis for developing a feasible approach to realise a systematic application of the PSP throughout the EU, in particular for screening. One aspect will be to validate their suitability, by providing participants in the demonstration projects with standard positive control samples. This would make it possible for control laboratories to receive accreditation for all the methods on the plates, in many

Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC. OJ L 189, 27.06.2014, p. 1-32.

cases significantly widening their scope. However, such a systematic use of the PSP will require designing a feasible mechanism to order, produce, quality control, update, and deliver PSPs (for screening and, possibly, identification) to the official control laboratories that would make the use of PSPs economically attractive. An important side effect would be a further harmonisation of GMO controls in the EU by ensuring that all control laboratories employ the same portfolio of tests, run under very standardised conditions. The potential positive effect of this for the internal market is obvious.

3. WORK PROGRAMME 2015 OF THE EURL GMFF

Commission Implementing Regulation (EU) No 652/2014 establishes the actions to be financed and the budget breakdown for year 2015 awarded to the European reference laboratories (EU-RLs) as the Union financial contribution to the implementation of functions and duties in the field of food and feed safety and animal health, animal welfare and plant health as laid down in Article 32 of Regulation (EC) No 882/2004.

The Commission work programme is built to fulfil the *General objective* to contribute to a high level of health for humans, animals and plants, ensuring a high level of protection for consumers and the environment, while favouring competitiveness and creation of jobs.

Specific Commission objectives included are a) to contribute to a high level of safety of food/feed and food/feed production and a higher animal health status; b) to contribute to a timely detection and eradication of pests; and c) to improve effectiveness, efficiency and reliability of official controls.

These overall Commission objectives have been translated into four Operational objectives, which will be addressed in the Annual Work Programme of the EURL by a number of activities.

The activities that the EURL foresees for the year 2015 are detailed below.

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

EURL ACTIVITY 1.1: Dissemination of high quality methods for the detection, identification and quantification of GMO in food and feed to official control laboratories

Expected ex-ante:
NRLs nominated under Regulation 882/2004 and related official control laboratories are aware and have access to validated methods for detection (screening), identification, and (for authorised GMO-events) quantification of GMOs in food and feed. The main instrument for this is the GMOmethods database maintained by the EURL that provides reference methods, i.e. methods that underwent international validation.

The EURL has on its website a permanently updated GMOmethods database of internationally validated (reference) analytical methods for the detection, identification, and quantification of GMOs. The detailed method protocols accessible via this database enable experienced laboratories to implement the reference methods. New reference methods will be identified by literature search and against pre-defined quality criteria, including being validated in accordance with internationally agreed method validation standards (ISO, IUPAC). All methods validated by the EURL, under its mandate from Reg. 1829/2003 or otherwise, will be automatically included in the GMOmethods database and GMOmatrix application. Dissemination of these methods will occur through access and retrieval by interested parties but also promoted through proactive networking activities (e.g. ENGL), workshops and trainings.

In 2014 the EURL has developed and made available on its website a GMOmatrix tool that helps control laboratories to plan their testing strategy and to interpret their testing results. This tool is frequently assessed and the access statistics will be recorded. The JRC supports the maintenance and update of the GMOmatrix tool with own resources.

The following specific EURL activities are planned in 2015.

1.1.1: Survey on use of GMOmethods database

A survey will be carried out showing to which degree NRLs regularly use reference methods (screening/event specific; qualitative/quantitative; PSP/conventional) that are included in the EURL GMOmethods database and to which degree control laboratories make routinely use of the GMOmatrix application developed by the EURL and made available on its website in 2014.

1.1.2: Monitoring of the web-access to EURL-website in general and the GMOmethods database and the GMOmatrix application in particular

For the first 8 month of 2014 the total number of pages visited in the EURL website that provides access to the GMOmethod database, information on the validation progress of the EURL, and access to the GMOmatrix application, was around 270,000. This indicates that the EURL website is an effective means to make analytical and data interpretation methods

available to NRLs and other control laboratories, including from third countries, as soon as they become available, i.e. are introduced as reference method into the GMOmethods database.

Deliverable EURL ACTIVITY 1.1:

- An implemented methods inventory, based on the results of the survey and ENGL feedback.
- Report on the web-access to the EURL website in general and the GMOmethod database and GMOmatrix application in particular.

EURL ACTIVITY 1.2: Demonstration project pre-spotted plates for official controls

Expected ex-ante:
The demonstration project will confirm that a systematic use of pre-spotted plates for official controls is both economically efficient and enhances the quality and the harmonisation of official GMO controls in the EU.

Following the successful pilot phase of the pre-spotted plate project, a demonstration project will be carried out to further explore the suitability of the plates for official control purposes. To this end about 850 plates will be offered to laboratories that are willing to use them routinely and in parallel to their conventional control approach, and that agreed to report back to the EURL.

A budget of 63.750 € is requested for covering the plates and the shipping costs, as support to this demonstration project, which will also consume significant resources (staff time and own budget) of the JRC.

In close collaboration with DG SANCO a business model will be developed in 2015 that would allow, subject to a successful demonstration project, making the screening plates permanently available to control laboratories in the MS.

State of play:
In the context of a pilot project, pre-spotted plates for screening for un-authorised, authorised, or pending GM events have been made available free-of-charge to 20 NRLs in 2014 and it was shown that the use of screening plates would improve the capacity of laboratories to identify GMO contamination in food or feed as follows:

- With one single PCR experiment all screening methods included in the GMOmethods databank will be run, thus covering all authorised and most known unauthorised GMO events. This would not be guaranteed with the current knowledge-based approach used by most laboratories where the laboratory only runs a subset of the available screening methods by excluding those targeting events that are deemed unlikely to be present;
- Due to the standardised experimental conditions required for the plates, the screening experiments will become even more comparable between different control laboratories;

- The plates will increase the screening capacity of those control laboratories that have not implemented all screening methods that are on the plate.

A demonstration project will be carried out in 2015, 850 screening plates to official MS-control laboratories that are interested to use them as initial element of their standard GMO-testing strategy.

Deliverable EURL ACTIVITY 1.2:
- Report on the outcome of the pre-spotted-plates demonstration project, including a proposal for a follow-up (business case).

EURL ACTIVITY 1.3: Method validation

Expected ex-ante:
New event-specific and screening methods are validated by the EURL and included in the GMOmethods database.

Based on historical data the EURL expects in 2015 to receive 4 dossiers from applicants including at least 1 new event specific method for the detection, identification and quantification of a GM event for which no validated method is available. These methods will be validated in line with the EURL's 5-step validation process (see EURL website) and, once validated, published on its website[6] and included in the EURL's GMOmethods database, in accordance with the timelines foreseen by Regulation (EC) No 1829/2003 and, where applicable, Regulation (EU) No 619/2011.

Screening methods are typically not event-specific but target known elements of GMO events. They are often developed by research organisations, universities, or GMO control laboratories and allow first the detection of GMO-presence, which then need to be followed-up by an identification step, ideally with suitable event specific but at least construct specific methods.

NRL or other laboratories may validate new or improved (screening) methods but it is expected that in 2015 also the EURL will organise one or two international validations of methods that would close a gap in the portfolio of testing (screening) methods available to official control laboratories.

Deliverable EURL ACTIVITY 1.3:
- Validation (progress) reports and method description published on the EURL website and introduced into the GMOmethod database and the GMOmatrix application for up to 4 event specific and up to 2 element specific (screening) methods.

[6] http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm

EURL ACTIVITY 1.4: Practical arrangements for promoting the application of new analytical methods

Expected ex-ante:
NRLs are kept informed on scientific progress in relevant fields related to but not only directly concerned with GMO detection methods and new approaches.

Screening of literature is performed to identify new, validated GMO detection methods and these (expected number: 4) are made available to NRLs by introducing them in the publicly available GMOmethods database (see above) as reference methods.

Via links to the EUginius database, a German/Dutch project, and the Biosafety Clearing House (BCH), interested parties can find additional information on GMOs and, in the future, possibly also information on GMO detection methods that do not meet the stringent criteria for being included into the GMOmethod database of the EURL.

Scientific literature and relevant congresses are also monitored in order to identify new approaches to GMO detection, identification and quantification, and own research is performed on this, e.g. relating to bio-informatics and sequencing based approaches.

Via the ENGLnet (an EXTRANET managed by the EURL) and the ENGL related meetings, relevant findings will be made available to the entire ENGL, including all NRL, without delay. In 2015 the ENGLnet will be amended with additional communication platforms and tools, enhancing its use as a platform for the members to inform each other of relevant scientific developments, findings, and practical experience.

This activity is fully covered by JRC institutional funds and no additional budgetary support is requested.

Deliverable EURL ACTIVITY 1.4:
- Presentations and other contributions of EURL staff to ENGL meetings.
- Internal (ENGLnet) or other publications relating to scientific advances.
- Web based communication tools in the ENGLnet.
- Regular updates of the EURL and ENGLnet sites.
- Consolidated links to the EUginius and BCH databases.

EURL ACTIVITY 1.5: Trainings, meetings and workshops for the harmonization of diagnostic techniques and of methods of analysis

Expected ex-ante:
- An attendance rate of 80% of NRLs nominated in line with 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 workshop/training event, other than the annual workshop, for NRL(882) with 85% positive satisfaction survey replies.

All NRLs nominated under Regulation (EC) No 882/2004 will be invited to participate to the obligatory annual 2-day workshop, which will partly be held jointly with one of the two ENGL plenary meetings, and in at least one training activity (see below).

Depending of the interest by the NRLs up-to three additional experts could be invited to the NRL workshop and/or the training activity to update participants on relevant topics.

In 2015, one additional workshop or training course will be organised, or participation supported in training activities organised by other bodies, for NRLs nominated under Regulation (EC) No 882/2004, depending on interests and needs identified by the NRLs in 2014. In line with the mandate of the EURL to train experts from developing countries, up to 5 experts from public GMO control laboratories from developing countries can be invited to participate in the organised or offered workshop(s) or training course(s). Capacity permitting, other participants may join at their own cost. Invitations will be accordingly sent to the entire ENGL (including all NRL(882)) and official GMO-control laboratories in developing and accession countries but preference is given to NRL(882).

At the end of the workshop and the training activity, the EURL will circulate a satisfaction survey questionnaire. Negative replies will be followed-up with a view to improve as much as possible, e.g. by bi-lateral feedback with un-satisfied participants.

Budget is requested for covering the cost (travel, lodging, and per-diem or lunch + dinner + local transport) of one participant per NRL (882) for the annual workshop (32) and for the training activity (28), respectively, plus 5 participants from GMO control laboratories in developing or neighbourhood countries for the training event (see below). In addition, 3 external experts can be invited to the workshop.

Deliverable EURL ACTIVITY 1.5:

- Financial and technical reports, including information on participation and on satisfaction surveys and any eventual follow-up of the annual NRL workshop and the training.

EURL ACTIVITY 1.6: Collaboration activities between EURL and third countries

Expected ex-ante:
EURL cooperation with IRRI concerning Golden Rice is continued, as well as networking activities organised by the MBG Unit of the JRC under the Better Training for Safer Food (BTSF) programme.

The EURL has been requested by IRRI to help with the development and validation of a detection method for the finally chosen version of the Golden Rice GMO. This work was finalised in 2014 (publication forthcoming) but follow-up activities are foreseen in 2015, subject to availability of JRC funds and staff resources.

Deliverable EURL ACTIVITY 1.6:
- Report on the execution of the Administrative Arrangement under the BTSF program.
- If possible, publication or report on the Golden Rice project.

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

EURL ACTIVITY 2.1: Organisation of comparative testing by EURL GMFF

Expected ex-ante:
Up to 2 CT rounds with 80% participation of NRLs in line with Regulation (EC) No 882/2004, a significant (>40%) share of NRLs nominated under Regulation (EU) No 120/2014, and a good participation (around 20%) of other ENGL members and of some official GMO-control laboratories from third countries.

In 2015 the EURL will organise 1 to 2 comparative testing rounds, depending of available JRC resources, and assure the appropriate follow-up. This organisation requires (a) planning, (b) practical preparation and execution (participant management, test item preparation and quality control, storage, packaging and shipping of test items), (c) data gathering and analysis, (d) reporting and (e) follow-up. The latter includes, if needed, on-line or on-site support to under-performing NRLs in order to allow them reaching the required performance level at the next CT round.

As part of its training activities the EURL will invite up to 5 selected GMO-control laboratories from cooperating regional networks in Asia, Africa, the MENA region, and Latin America to participate in the training event.

The JRC requests funding for one CT, as outlined in the attached budget proposal.
Given the fact that one CT round is financed from institutional funds of the JRC, the execution of this round is subject to availability of these funds.

Work to be carried out by the EURL in 2015:

(a) Planning of up to 2 CT rounds.
Independent of the number of CT rounds realised in 2015, the EURL will organise (in Ispra) up to 3 meetings of 1.5 days each of the Advisory Board for CT (ABCT) to prepare forthcoming CT rounds, to review the CT reports and to discuss general and strategic aspects of comparative testing.
A budget is requested to cover the travel, lodging and per-diem for 6 members of the ABCT.

These meetings will be chaired by the EURL and attended by the operational manager (OM-EURL) of the EURL and the entire CT team (team leader, data manager, statistician, laboratory technician). The meetings require preparation, secretarial support, and follow-up.

(b) Practical preparation of CT rounds.

(b1) Participant management

150 to 200 laboratories will be invited for each CT round and up-to 100 are expected to register per round:

- all NRLs listed in Regulation (EC) No 882/2004 (obligatory participation),
- most NRLs listed in Regulation (EU) No 120/2014 (recommended participation),
- most remaining ENGL-members, and
- several public control laboratories from third countries, e.g. identified within the regional GMO networks with which the EURL and the ENGL cooperates.

This activity also includes the day-to-day management of the correspondence with the participants and other interested stakeholders (DG SANCO, NRL, all other participants) and requires primarily secretarial support, as well as supervision by the HoU, the CT team leader and the OM of the EURL.

(b2) Test item preparation and quality control

The comparative testing round(s) of 2015 will have one standardised baseline test item, similar to the ones in the 2014 CTs, and a second, more complex, "real life" sample. Participants will be requested to analyse the following two types of blinded samples:

- Grinded powder containing one GM event, requiring DNA extraction, followed by GM event identification and quantification;
- A processed food and/or feed sample containing two or more GM events and requiring a significantly more difficult DNA extraction, followed by GM event identification and quantification.

While it is expected that the vast majority of participating laboratories will master the baseline challenge, and hence show a sufficient minimum performance, the results for the more complex second test item is expected to be more variable and thus helpful to disclose areas of possible improvement.

The main requirement for CT test items is their homogeneity, i.e. all participating laboratories must receive exactly the same, blinded test items. This requires significant laboratory activities to ensure the necessary quality control, including a full characterisation of the test items in terms of crop species (e.g. maize, soybean, cotton) and GM events contained in the samples. The resulting estimated cost, in particular for staff-time, consumables for DNA-extraction, DNA quality control, (q)PCR experiments as part of the sample characterisation, and (small) equipment (balances, mills, centrifuges, I needed) are included in the requested budget.

(b3) Storage, packaging, and shipment of test items

The storage, packaging, and shipment of the prepared test items to the participating laboratories will also require short term contributions from the entire CT team and beyond. The shipment costs are budgeted on the basis of past experience.

(c) Data gathering and analysis
In 2015 the EURL aims at developing an improved workflow management and data analysis version of its web-based participant registration and data gathering IT tool. This tool shall make registration easier and allow registered CT participants to directly enter data, via pre-defined web-forms into a relational database. The EURL will develop IT-tools supporting the data analysis according to statistical approaches agreed with the ABCT, the preparation of CT reports, and the entire communication flow with the CT participants. The related IT-activities are covered by JRC internal resources but the budgeted data manager and statistician will be involved as user-stakeholder.

(d) Reporting
In 2015 the EURL will work towards a further standardisation and speeding-up of the CT-reporting with the aim to produce a final report on a CT round within 2 months after the deadline for submission of results. This is in line with ISO 17043, which requires that participants with unsatisfactory z-scores are informed as soon as possible in order to allow them to take corrective measures.

In 2015 the EURL will finalise a meta-analysis of all CT rounds organised so far in order to draw generalised conclusion from these, wherever possible. Since 2014, a baseline test item is introduced; this, together with a rather constant complexity of the second test item, will provide an improved basis of future progress measurement. The meta-analysis requires curation, harmonisation, and analysis of historic data, which has to be done largely manually by the CT-statistician. At the end it is expected to show some general trends and provide insight for setting-up future CT rounds, and to trigger discussions within the ENGL, possibly leading to additional guidance, e.g. for best practice relating to DNA extraction. The work will be carried out by the statistician for whom support is requested, under the supervision of the HoU, the CT-team leader and the OM-EURL.

Deliverables EURL ACTIVITY 2.1
- Up to 3 reports of the meetings of the ABCT.
- Test items are prepared, quality controlled, stored (also for future use), and shipped.
- 1-2 CT reports within 2 months after the deadline for submission of results.
- 1 meta-analysis report on laboratory performance in CT rounds over several years.

EURL ACTIVITY 2.2: Addressing underperforming related issues

Expected ex-ante:
- All underperforming NRL(882) receive appropriate follow-up and 95% of them perform satisfactorily in the next CT round, at least for the baseline samples.
- More than 60% of other underperforming CT-participants receive follow-up and 80% of these perform satisfactorily in the next CT-round to which they participate, at least for the baseline samples.

The EURL-organised comparative testing rounds give a measure for the performance of the participating laboratories when carrying out GMO analysis. Underperforming laboratories will be offered on-line support to identify the reason for their insufficient performance. To

this end they will be invited to submit their raw data to the EURL and, if the laboratory wants to re-test, the EURL will ship additional test items to the laboratory.

If the laboratory cannot solve its problems in this way, the EURL will, upon request, send experts to the laboratory in question to help identifying and solving the problem, or, alternatively, invite up to 2 staff members of the concerned laboratories to Ispra for hands-on training.

A budget is requested for sending up-to 2 EURL experts for up-to 5 days to up-to-three underperforming NRL(882) or for their staff (up to 6) being trained in Ispra. The latter training will be open, if possible and requested, to additional underperforming CT-participants, at their own cost or covered with JRC institutional funds (subject to availability).

Confirmation of the success of the follow-up measures will come with the next CT round. Repeated under-performance will trigger intensified efforts of the EURL to solve the underlying problems, in particular for NRL(882). An annual report will inform SANCO of the follow-up measures taken and the results.

In addition to bi-lateral advice and training to underperforming laboratories, the EURL will analyse and describe in the CT reports general causes of underperformance and how these could possibly be avoided.

This will be taken up by the EURL, in cooperation with the ENGL, with regard to the guidance it is providing via its website. In 2014, for example, updated ENGL documents were published concerning method-performance-requirements[7] or giving guidance for data interpretation and reporting. The ENGL continuously works on these guidance documents and regular updates are made available, whenever required.

Deliverables EURL ACTIVITY 2.2:

- Report on the follow-up provided to NRL (882) and other underperforming CT-participants.
- Updated ENGL/EURL guidance.

[7] ENGL Guidance Document (2008). Definition of Minimum Performance Requirements for Analytical Methods of GMO Testing.
http://gmo- crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf

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

EURL ACTIVITY 3.1: Participate in queries for policy making and enforcement

Expected ex-ante:
In line with its accreditation under ISO 17025 and 17043, the EURL has at any time sufficient qualified staff available to adequately react to emergencies, such as commenting on a rapid alert, verifying test results in case of dispute, providing *ad hoc* support in particular to DG SANCO on scientific issues, including for the preparation of legislative acts.
Requests from SANCO's, as well as from other DGs or MS-authorities, will be fully met.

All resources of the EURL and if needed other parts of the unit, institute or JRC, are available for responding to *ad hoc* tasks such as emergencies. Given that this is fully in line with the overall mission of the JRC, no extra resources are requested for this.

The EURL verifies its efficiency regarding the adequacy of its response from DG SANCO 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 SANCO upon request.

Deliverable EURL ACTIVITY 3.1:
- Timely and adequate *ad hoc* advice as delivered.
- Annual customer survey.

EURL ACTIVITY 3.2: Collaboration between EURL and EFSA and international organisations

Expected ex-ante:
- The EURL will fulfil its obligation for the authorisation process and timely provide EFSA with its report on the validation of the event specific methods submitted by industry for the detection, identification and quantification of GMOs in food and feed. With regard to stacks, the EURL will only carry out a bioinformatics analysis and in-house verification of the single event methods when applied to stack-DNA.
- The EURL will continue to actively participate in CEN and ISO activities relating to standardised GMO detection methods.
- The EURL will continue to cooperate with the BCH.

While the EURL participates actively in relevant CEN and ISO groups, it is not consulted by FAO, OECD or WHO but will follow, in close cooperation with DG SANCO, relevant discussions in those fora to the extent possible and necessary.

Currently the EURL acts also as National Focal Point of the EU for the BCH. This includes regular uploading of information into the BCH.

Deliverable EURL ACTIVITY 3.3.2:
- Validation reports submitted to EFSA.
- Report on contributions to CEN/ISO activities.

EURL ACTIVITY 3.3: Provision of scientific and technical assistance in meetings with the Commission

Expected ex-ante:
Upon request by DG SANCO or other policy DGs, the EURL will continue to participate and contribute to meetings in which a policy DG requests scientific/technical support concerning the detection, identification and quantification of GMOs.

Deliverable EURL ACTIVITY 3.3:
- Meeting reports.

EURL ACTIVITY 3.4: Development of guidance documents regarding analytical methods

Expected ex-ante:
Existing guidance, being available on the EURL website, is reviewed, updated, and complemented, as required.

The ENGL Steering Committee (ENGL SC) as well as the ENGL plenary discuss at their meetings and identify needs for reviewing or updating existing guidance, or for new guidance. The reviewing, updating or development of new guidance is carried out by means of dedicated ENGL working groups and the final guidance /document is then adopted by the entire ENGL. The EURL chairs the ENGL SC and the ENGL plenary and supports its work by acting as scientific and organisational secretariat.

As for all ENGL activities, no additional budget is requested.

Deliverable EURL ACTIVITY 3.4:
- Meeting reports.
- Updated or new ENGL guidance documents.

EURL ACTIVITY 3.5: Networking activities managed by the EURL

Expected ex-ante:
- ENGL remains fully operational, managed by the ENGL secretariat provided by the EURL.
- The dedicated website "ENGLnet", which is only accessible to ENGL-members, is maintained and constantly updated.
- New features like workspaces for working groups and discussion fora are made available and increasingly used by ENGL members.

European Network of GMO Laboratories (ENGL)

The mandate of the ENGL is defined in Regulation 1829/2003 as supporting the EURL, while the EURL is responsible for the organisational management of the ENGL (secretariat and chair) and sponsors its activities (2 annual plenary meetings, 2 annual meetings of the ENGL steering committee (SC), 3 to 6 ENGL working group meetings – all financed from JRC institutional budget).

The EURL also maintains a web-based platform (ENGLnet) exclusively dedicated to ENGL members (including all NRLs in line with Reg. (EU) 882/2004 and most NRLs listed by Reg. 120/2014). This secured Extranet connection allows the exchange of information between ENGL members and dedicated collaborative workspaces that support specific activities, including those related to Regulation (EU) No 882/2004, e.g. for the CT activity or working groups that produce guidance. Via its ENGL network the EURL is in direct and permanent contact with the GMO-NRLs and most, if not all official GMO control laboratories of the Member States. It therefore receives feedback on methods-uptake, practicability issues (good practice), and innovative solutions found by ENGL members or elsewhere reported, either by *ad hoc* communication to the ENGL secretariat or during the two annual plenary meetings of the ENGL. This information is disseminated throughout the ENGL during the two plenary meetings and/or a dedicated or the EURL-website. Discussion fora, introduced in 2014, further enhance the interaction within the network and support the uptake of up-to-date technologies and methods.

In 2015, the ENGL (secretariat: EURL) will produce an inventory of the methods implemented in the ENGL member laboratories.

The ENGL management (secretariat, meetings), the management of the EURL and ENGL websites, and the maintenance and regular update of the GMOmethods database and GMOmatrix application are covered by own JRC resources.

Deliverables EURL ACTIVITY 3.5:

- ENGLnet websites and use-report for ENGLnet.
- Reports of 2 ENGL SC, 2 ENGL plenary, and 3 to 6 working group meetings.
- At least one ENGL -"product" published on the EURL website (e.g. new or updated guidance document).

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

EURL ACTIVITY 4.1: Collection, verification and validation of EURL work programmes

Expected ex-ante:
- EURL WP 2016 is provided to DG SANCO E.1 on time.

The EURL will prepare the 2016 EURL work programme in line with the work programme of the Commission. The EURL will start writing this work programme during the third quarter of 2015, and have it finalised before September 2015, provided that the Commission work programme is available on time.

Deliverable EURL ACTIVITY 4.1:
- EURL WP 2016 is provided to DG SANCO E.1 before 01.09.2015.

EURL ACTIVITY 4.2: Control and verification of financial expenditure

Expected ex-ante:
- Funds are spent as planned. Deviations are discussed and agreed with DG SANCO E.1 in advance.

Staff costs will be calculated on the reference basis of 220 working days/ year.
Regarding capital equipment invoices, delivery notes and proofs of payment will be attached to the financial report.

Deliverable EURL ACTIVITY 4.2:
- Financial report of the EURL documenting the spending as foreseen in Annexes 1(a) and 1(b) of the WP 2015 and in accordance with the rules of the Regulation 135/2013.

EURL ACTIVITY 4.3: Communication with EURLs for the execution of their work programmes

Expected ex-ante:
- Communication between DG SANCO and EURL is smooth and in line with good administrative procedures.

The EURL will adequately respond to inquiries from DG SANCO E.1 and communicate any issue identified during the execution of the EURL work programme. Throughout 2015, the EURL will respect the rules defined by the Commission as "good administrative practice". Any deviation is well documented and justified and corrective actions are taken.

Deliverable EURL ACTIVITY 4.3:
- Relevant communication documentation in the EURL archiving system and ARES.
- Report on deviation from the requirements of good administrative practice including the justification and corrective action taken.

EURL ACTIVITY 4.4: Evaluation of the EURL annual technical and financial report

Expected ex-ante:
- Satisfactory annual technical and financial reports are received on time.

The EURL will diligently prepare the annual technical and financial report and ensure that it is in line with the requirements and requested templates and is delivered on time.

Deliverable EURL ACTIVITY 4.4:
- Annual technical and financial report is provided within the stipulated timeframe.

EURL ACTIVITY 4.5: Support to the EURLs for the preparation of their annual work programmes

Expected ex-ante:
- The EURL pro-actively seeks support from DG SANCO E.1 regarding the 2016 WP.

In order to prepare the 2016 EURL work programme in line with the work programme of the Commission, the EURL will pro-actively request discussion with the responsible services of SANCO and provide feedback on the support received.

Deliverable EURL ACTIVITY 4.5:
- Feedback report concerning SANCO support received for the preparation of WP 2016.

EURL ACTIVITY 4.6: Evaluation of the EURL reported performance indicator *ex-ante* and *ex-post*

Expected ex-ante:
- The EURL annual report addresses the performance indicators defined by DG SANCO E.1.

In order to allow the evaluation of the activities performed by the EURL as part of the work programme agreed for 2015, the EURL annual report will address the corresponding performance indicators defined herein as "Expected ex ante" and "Deliverable(s) EURL Activity".

Deliverable EURL ACTIVITY 4.6:
- Annual report, structured along the performance indicators.