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 2014 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 GMO (EU-RL GMO) [1,2,3] (hereafter (EURL) and has delegated this function to its Molecular Biology and Genomics Unit (MBG Unit), one of the five scientific units of its Institute for Health and Consumer Protection. The unit has currently 42 staff members of which 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 in 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 unit for Molecular Biology and Genomics hosts the EURL and contributes to the implementation of this framework through validation of methods for the detection and quantification of GMOs in food and feed together with the provision of control samples to NRLs (Regulations (EC) No 1829/2003 and (EC) No 1981/2006), and by coordinating the network of GMO-NRLs throughout the EU, ensuring its consistent performance (Regulation (EC) No 882/2004).

The EURL is supported by the European Network of GMO Laboratories (ENGL) that includes most NRLs for GMO throughout the EU, laboratories from Switzerland, Norway and from some accession countries.

In line with its mission, the JRC covers significant activities of the EU-RL from its own budget but certain specific projects of the EURL need additional financial support from the Commission, similar to other EU-RLs for food and feed listed in Regulation (EC) No 882/2004. The work programme 2014 gives a complete overview of the activities of the EU-RL, while the requested budget only concerns activities relating to tasks specified in Reg. 882/2004. It follows the structure defined by the "Performance indicators for the EU-RLs in the field of Food and Feed" as defined by DG SANCO.

[1] Regulation (EC) No 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.

2. WORK PROGRAMME 2014 OF THE EU-RL GMO

DG SANCO has defined the following general objectives or performance indicators for the EU-RLs in the area of food and feed:

1. **Performance indicator PT**: to provide NRLs with details of analytical methods, including reference methods and coordinating their application by the NRLs, in particular by organising comparative testing (CT) and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols ;

2. **Performance indicator ANA:** to coordinate, within their area of competence, practical arrangements needed to apply new analytical methods and to inform NRLs of advances in this field;

3. **Performance indicator NRL:** to conduct initial and further training courses for the benefit of staff from NRLs and of experts from developing countries;

4. **Performance indicator COM:**

    - COM.1: To have trained personnel available for emergency situations occurring within the Union (if appropriate);

    - COM.2: To provide scientific and technical assistance to the Commission (and to EFSA, ECDC, EMA), especially in cases where the MS challenge the results of analyses.

Supplementary indicators:

5. **Performance indicator CEN:** to carry out a mutual and reciprocal exchange of information with competent laboratories in third countries or with the global/regional laboratory responsible for analysing food and feed designated by the FAO, WHO (when applicable); to contribute to FAO, WHO, OECD risk assessment and/or reviews of manuals or codes and to CEN/ISO standardisation of analytical methods;

6. **Performance indicator R&D:** take account of scientific development activities at national and EU level and perform applied research and development activities whenever appropriate.

2.1. *Performance indicator PT*

To provide NRLs with details of analytical methods, including reference methods and coordinating their application by the NRLs, in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols

2.1.1. Specific objective 1.1: Provision of analytical methods

The EURL has on its website a permanently updated GMO methods database of 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. If necessary the EU-RL may support method implementation by NRLs.

The update of the methods database is provided by JRC staff, financed from the institutional JRC budget as it relates to the dissemination of scientific knowledge and results.

2.1.2. Specific objective 1.2: Comparative testing and follow-up

FF.PT.1: Number of comparative tests following internationally standardised criteria

Expected ex-ante:
2 CT rounds including the mandatory participation of NRLs nominated under Regulation (EC) No 882/2004, the recommended participation of NRLs nominated under Regulation (EC) No 1981/2006, and the voluntary participation of other ENGL members and of public control laboratories from third countries.

In 2014 the EU-RL GMFF will organise 2 comparative testing rounds 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, support to under-performing NRLs in order to allow them reaching the required performance level at the next CT round.

The JRC requests funding for this activity, as outlined in the attached budget proposal.

Work carried out by the EU-RL in 2014:

(a) Planning of 2 CT rounds.
In 2014 the EU-RL will organise and finance up to 3 meetings of 1.5 days each of the CT Advisory Board (CTAB) (in Ispra) 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 the members of the CTAB.**

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

(b) Practical preparation of CT rounds.
(b1) Participant management
150 to 200 laboratories are invited for each CT round and about 100 expected to register:

- all NRLs listed in Regulation (EC) No 882/2004 (obligatory participation),
- most NRLs listed in Regulation (EC) No 1981/2006 (recommended participation),
- all remaining ENGL-members, and
- public control laboratories from third countries identified within the regional GMO networks with which the EU-RL 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 CT team leader and the OM of the EURL.

(b2) Test item preparation and quality control
In 2014 the 2 CT rounds will require participants to analyse two types of blinded samples:

- Grinded powder containing two GM events, 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.

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, and (q)PCR, and (small) equipment (balances, mills, centrifuges) is included in the attached 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 2014 the EURL will finalise and roll out its web-based participant registration and data gathering IT tool that enables registered CT participants to directly enter their data, following pre-defined templates. The data are then stored in a relational database that allows their analysis according to statistical approaches agreed with the CTAB. The preparation of the web-based tool is covered by JRC internal resources but the data gathering and analysis falls into the responsibility of the budgeted data manager and statistician.

(d) Reporting
In 2014 the EURL will work towards a further standardisation 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. In line with ISO 17043 that requires that participants are informed as soon as possible about their unsatisfactory z-scores in order to allow them to take corrective measures no preliminary report will anymore be prepared. DG SANCO, as customer DG, receives a copy of the report together with an outline of the follow-up measures planned.

Reporting requires significant input from the CT-team leader, the data manager, the statistician and a secretary. Also other scientific staff of the EURL, its operational manager and the responsible Head of Unit will invest time into it.

(e) Handling of "under-performance" (see also FF.PT.3)
Under-performance will always occur and is depending on the complexity of the test item and of the tasks the laboratories are requested to carry out. As the CTAB realised that basic skills are generally sufficiently developed, there is a tendency of increasing complexity from CT round to CT round and hence the under-performance rate might remain rather stable or even increase without indicating major problems. In any case recognising under-performance is essentially and firstly an opportunity to improve and in this sense the EURL will cooperate with any under-performing NRL with a view to improve its performance.

Accordingly, in case of under-performance of an NRL882, the EU-RL will offer the concerned laboratory its assistance and ask for its raw data. This will in many cases allow identifying possible causes of the outlying result which the laboratory could verify and correct through repeating the analyses. The EURL will provide, if requested, additional test items for that purpose. If further follow-up is required, the EURL may send its experts to the NRL or invite NRL staff for hands-on training to Ispra. The required budget is included in the budgetary request and includes travel and per diem for up to 2 EURL experts per visited laboratory. Alternatively the budget could be used for travel, lodging and per diem for up to 4 NRL staff members being trained (up-to 5 days) in Ispra.

Confirmation of the performance improvement will come from the results of the subsequent CT round, which always will include a "simple" test item, which should over time serve as baseline for the minimum performance to be expected from NRLs.

An annual report on follow-up activities will be prepared and provided to SANCO, to the extent possible with indication of the performance of the under-performing laboratories in a subsequent CT round.

Deliverable FF.PT.1:

- Up to 3 reports of the meetings of the CT advisory board
- About 300 test items prepared, quality controlled, stored (for future use) and shipped
- 2 CT reports within 2 months after the deadline for submission of results
- 1 annual report on follow-up activities and results

FF.PT.2: Grading addressing the complexity of each CT

Expected ex-ante:
The comparative testing rounds of 2014 will for the first time have one standardised baseline test item and a second, more complex, "real life" sample. 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.

1. ILC-EURL-GMFF-CT-01/14

One test item of soybean powder, participants shall:

1. Extract DNA
2. Perform soybean events identification
3. Quantify the events found.

One test item of a homogenized feed, participants shall:

4. Extract DNA
5. Perform species identification and report on the species found
6. Perform maize events identification
7. Quantify the events found.

2. ILC-EURL-GMFF-CT-02/14

One test item of maize powder, participants shall:

1. Extract DNA
2. Perform maize events identification
3. Quantify the events found

One test item of a homogenized food/feed product, participants shall:

4. Extract DNA
5. Perform species identification and report on the species found
6. Screen for the presence of GM events
7. Quantify the events found.

Deliverable FF.PT.2:

- 2 CT reports, including discussion of the complexity of the tasks.

FF.PT.3: Average rates of NRL success in relation to PT's grade of complexity and methods and activities to ensure follow-up of poor results

Expected ex-ante:

- Success rate > 85 % for results expressed in mass/mass % and an easy matrix (i.e. ground seeds);
- Success rate > 70 % for results expressed in mass/mass % and a complex matrix (i.e. homogenised food or feed product);

Follow-up of underperformance:

- On line support and analysis of raw data of underperforming laboratories
- Provision of additional samples for re-testing
- On-site visits to 1-3 laboratories (only NRLs)
- Hands-on training in Ispra (funded for NRLs, own cost for other laboratories)

Within 2 months after the deadline for submission of results, laboratories are informed about their performance by means of the CT report and a message with their lab-code.
Those showing inappropriate z-scores (underperforming) will be offered support to identify the reason for this and invited to submit their raw data to the EURL in order to identify possible causes for the outlying result. If the laboratory wants to re-test, the EURL will ship additional test items to the laboratory (see also above FF.PT.1, d)
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. Alternatively the laboratory can ask for sending up to 2 staff members to Ispra for hand-on training. **The budget is requested for sending up-to 2 EURL-experts for up-to 5 days to up-to-two underperforming NRL(882) or for their staff (up to 4) being trained in Ispra.**

Verification of the success of the follow-up measures will come with the next CT round. Repeated under-performance will require intensified efforts to solve the underlying problems. An annual report will inform SANCO of the measures taken and the results.

In addition to bi-lateral advice and training to underperforming laboratories, the EURL will analyse and describe general causes of underperformance and how this could possibly be avoided. To this end the EURL, in cooperation with the ENGL, provides guidance via its website, for example updated ENGL method performance requirements[4] or guidance for data interpretation and reporting.

Deliverable FF.PT.3:

- 2 CT reports, including performance statistics
- 1 Annual report on follow-up measures taken and results

[4] 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

FF.PT.4: Progress made by NRLs on similar comparative tests

Expected ex-ante:
In 2014 the EURL will carry out a meta-analysis of all CT rounds organised so far in order to draw generalised conclusion from these, wherever possible.
A baseline test item will be introduced; this, together with a rather constant complexity of the second test item, will provide an improved basis of progress measurement.

The meta-analysis will require harmonisation and analysis of historic data. It is expected to show some general trends and provide insight for setting up future CT rounds but also to trigger discussions within the ENGL, possibly leading to additional guidance, e.g. for best practice. The work will be carried out by the statistician for whom support is requested, under the supervision of the CT-team leader and the OM-EURL.

Deliverable FF.PT.4:

- A meta-analysis of all CT rounds performed so far.

FF.PT.5: Availability for use by NRLs of analytical methods

Expected ex-ante:

- 52 existing and 8 newly validated event-specific real-time PCR quantification methods are published on the website of the EU-RL and it is expected that 4 additional methods will be validated in 2014 and published.
- 1-3 new or improved methods, validated by other organisation, will be included into the EURL's database of GMO reference methods and published on its website.
- Decision on the usefulness of pre-spotted plates and the feasibility of introducing them into routine GMO-control.
- Validation of 2 screening methods not proposed by industry, that complement the existing portfolio of screening methods and enhance the capacity to detect un-authorised GM contamination.

Based on historical data the EURL expects in 2014 to receive 4 dossiers from applicants including methods for the detection, identification and quantification of GM events for which no validated methods are available.

Once validated by the EU-RL in accordance with Regulation (EC) No 1981/2006, the methods will be published on its website and included in the EU-RL's reference methods database. The validation reports are published on the EU-RL GMFF website[5] in accordance with the timelines foreseen by Regulation (EC) No 1829/2003 and, where applicable, Regulation (EC No 619/2011.

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

If a NRL or others validate a new or improved (screening) method and invite the EURL to verify this validation, the EURL will do so and, if found adequate, include these methods into its database of GMO detection reference methods and publish it on the EU-RL website. It is expected that this will concern between 1 and 3 methods in 2014.

Pre-spotted plates for screening for un-authorised, authorised, or pending GM-events have been made available free-of-charge to some 20 NRLs in the context of a pilot project aiming at assessing their performance under control laboratory conditions in 2013. Results of this assessment will be analysed in 2014. Based on this a proposal will be made to DG SANCO concerning their potential contribution to the overall performance of GMO control in the EU in terms of quality (more complete screening) and quantity (higher throughput in control laboratories) and cost. The aim is to provide a solid basis for a decision on their practical usefulness and the feasibility of introducing them into routine GMO control in the EU. For the time being it is assumed that a demonstration project should start in 2014, requiring the purchase of up to 850 plates in order to demonstrate their practical use. Participating laboratories will be requested to cover 50% of the estimated production cost per plate (currently expected to be around 150 €). **A budget of 63.750 € is requested for covering 50% of the plate-cost as support to this envisaged demonstration project**, which will also consume significant resources (staff time and own budget) of the JRC.

A working group of the ENGL is identifying methods that should be validated in order to close gaps in the screening toolbox of the control laboratories in the EU. It is expected that in 2013 the ENGL will prioritise a number of these methods and a budgetary contribution is requested for validating 2 of them in 2014 (see below).

Deliverable FF.PT.5:

- Additional validated methods on the EU-RL GMFF website and updated GMO method database
- Report on the practical experience with pre spotted plates and input to a decision on their potential introduction into routine GMO control in the EU
- Report on the start of the validation of 2 screening methods (to be finished in 2015).

FF.PT.6: Reported use by NRLs in relation to EURL's specific promotional activities of analytical methods

Expected ex-ante:
70 % of NRLs regularly use methods that are included in the EURL database of GMO methods.

For the first 8 month of 2013 the total number of visits to the EU-RL website, that provides access to the GMOmethod database and information on the validation progress of the EU-RL, was around 6000 visits. This indicates that the EU-RL website is an effective means to make analytical methods available to NRLs as soon as they become available, i.e. are validated.
Via its ENGL network the EU-RL is in direct and permanent contact with the EU-NRL and receives feedback on methods-uptake, practicability issues (good practice), and innovative solutions found by ENGL members or elsewhere reported.

The ENGL management (secretariat, meetings) and the management of the EU-RL website are covered by own JRC-resources.

Deliverable FF.PT.5:

- Report on the use by NRLs of EU-RL published methods included in reports from ENGL and NRL meetings
- Report on the web-access to EU-RL GMO-methods database etc.
- Minutes from ENGL meetings

FF.PT.QI: Presence of additional specific quality assurance schemes

Expected ex-ante:
ISO 17043:2010 and ISO 17025:2005 accreditations maintained and confirmed by the respective accreditation bodies; ISO 9001 certification also valid, via the institute level certification.

All activities of the EU-RL are carried out in accordance with the ISO 9001 requirements as certified by the ISO 9001 certification of the entire IHCP-institute of the JRC.

For its laboratory activities, the EURL is also accredited under ISO 17025, the accreditation being granted by the Italian National Accreditation Body Accredia with a flexible scope for DNA Extraction and PCR Methods for the detection, identification and quantification of GMOs in food and feed materials.

In addition, the EURL obtained in 2011, and is annually renewing, the ISO 17043 accreditation regarding general requirements for proficiency testing organisations from the German accreditation body Deutsche Akkreditierungsstelle GmbH (DAkkS). Since 2013 this accreditation is also delivered by Accredia. Both ISO 17025 and ISO 17043 are essential for guaranteeing the quality of the EURL operations to our customers.

Deliverable FF.QI:

- Reports on the annual audits from the accreditation bodies.
- Accreditation renewals

2.2. *Performance indicator ANA*

To coordinate, within their area of competence, practical arrangements needed to apply new analytical methods and to inform NRLs of advances in this field.

FF.ANA.1: Number of newly available analytical methods disseminated to NRLs

Expected ex-ante:
The GMOmethods database contains 4 to 8 new methods, validated by the EU-RL (up to 4) or elsewhere (up to 4) and the validation of two screening method has started.

Based on previous experience, it is expected that in 2014 the EU-RL will validate 4 new event-specific methods for the detection, identification and quantification of GMOs and make them immediately available to the NRLs via the EU-RL website. (Note: the validation of stacked GMOs does not normally yield new methods because most stacks consist of GM events for which event-specific methods have been validated before.)

The validation activity of the EU-RL is covered by own JRC resources and contributions by the applicants.

The validation of screening methods, which are not developed by the industry, is partly covered by in-house resources of the JRC but **requires some additional budgetary support for reagents and the shipping of reagents and samples to laboratories participating on a voluntary basis in the related validation ring trial.**

Deliverable FF.ANA.1:

- 6 or more newly validated methods published on the EU-RL Website
- 2 screening methods entered into validation / progress reports

FF.ANA.2: Number of non-commercial analytical methods to be validated

Expected ex-ante:
Based on past experience no non-commercial analytical methods for the detection, identification and quantification of GMOs are expected to be submitted for validation under the Regulation (EC) NO 1829/2003 mandate of the EU-RL.
The 2 screening methods (see FF.ANA.2 and FF.PT.5) that will enter validation in 2014 are not developed by industry and will not, as such, generate income for anybody. They might, however, be used, once validated and published, by commercial test laboratories.

Methods for the detection, identification and quantification of GMO are submitted for validation in the context of authorisation dossiers. So far only industry submitted such dossiers. The cost of these validations is (partly) covered by contributions from applicants and partly by JRC resources.

In 2014 there will be 2 screening methods entering validation that are not commercial in so far as they are not provided by industry in the context of a GMO application. ENGL member laboratories (preferably NRLs but in any case accredited) will participate free of charge in these validations. **A budget is requested for reagents and the shipping of reagents and samples to laboratories participating on a voluntary basis in the validation ring trials.**

Deliverable FF.ANA.2:

- 2 screening methods entered into validation / progress reports (see FF.ANA.1)

FF.ANA.QI: Presence of additional specific quality assurance schemes

Expected ex-ante:
No additional specific quality assurance system are needed in 2014

The current quality management system of the EU-RL is sufficient and will be maintained. No additional resources are needed.

In addition to the performance and quality indicators so far listed (FF.ANA.1;2 and FF.ANA.QI), the EU-RL coordinates, within its area of competence, additional practical arrangements needed to apply new analytical methods and to inform NRLs of advances in the field. Hence additional indicators are as follows:

FF.ANA.ai.1: Tools for the interpretation of analytical results

Expected ex-ante:
GMO-matrix available to all NRL

In collaboration with the ENGL, the EURL will make available on its website a GMO matrix and regularly update it. Such a matrix should facilitate the screening for GM events and/or constructs, in particular in combination with pre-spotted plates (see above), through better and more homogenous interpretation of experimental data. It will contribute to the further harmonization of GMO detection activities in throughout the EU.
The JRC supports the development and dissemination of the GMO matrix with own resources.

Work on the EURL's relational GMO sequence and method database will continue with the aim to ultimately provide a tool that allows laboratories identifying suitable testing strategies on-line and provide them with detailed information on the appropriate testing methods that could be used. This project is supported by in-house resources of the JRC.

Deliverable FF.ANA.ai.1:

- EURL/ENGL matrix available on the EURL web site
- Internal progress report on the relational GMO sequence and database

FF.ANA.ai.2: Networking

Expected ex-ante:
ENGL remains fully operational and the dedicated website "ENGLnet" that is only accessible to ENGL-members, is maintained and constantly updated

The mandate of the ENGL is defined in Regulation 1829/2003 as supporting the EU-RL, while the EU-RL 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, 3to 6 ENGL working group meetings).

The EU-RL also maintains a web-based platform (ENGLnet) exclusively dedicated to ENGL members (including almost all NRL listed in Reg. (EU) 882/2004 and all NRLs listed by Reg. 1981/2006). The secured intranet connection allows the exchange of information between ENGL members and dedicated collaborative workspaces support specific activities, including those related to Regulation (EU) No 882/2004, e.g. for the CT activity or working groups.

ENGLnet as well as ENGL as such are used for disseminating information about progress in the field, the origin of which could be any member of ENGL, including the EU-RL.

These activities are fully covered by JRC resources.

Deliverables FF.ANA.ai.2:

- Use-report for ENGLnet
- Reports of 2 ENGL SC, 2 ENGL plenary, and 3 to 6 working group meetings at ENGLnet
- 1-3 ENGL products on the EU-RL website (position papers, guidance documents)
- ENGLnet news section updating on new developments in the field
- Activity related ENGL-workspaces maintained and used

FF.ANA.ai.3: Web based guidance and support documentation

Expected ex-ante:
Public EU-RL website constantly updated, including possibilities for downloading guidance documents, access to on-line GMOmethods database, request for help, and provision of feedback.

On the public web site of the EU-RL there are sections for regular updates on methods, including the EU-RL database on GMO reference methods that allows identifying suitable methods and the related detailed method description that can be downloaded for implementation. The downloadable method descriptions enable experienced laboratories, such as NRLs, to implement the described methods. However, in case of problems the EU-RL offers advice and other help, so far on an *ad hoc* basis and not via a formal helpdesk but already via a link on its website.

The website is regularly updated and all EU-RL GMFF validation reports are publicly available there. It is addressing a wider public, the NRL-specific topics being covered on the ENGL-website, given that all NRL are by definition member of the ENGL.

The JRC manages the EU-RL GMFF website with internal resources.

Deliverable FF.ANA. ai.3:

- Updated EU-RL internet web site, including the GMOmethods database of reference methods

2.3. *Performance indicator NRL*

To conduct initial and further training courses for the benefit of staff from NRLs and of experts from developing countries

FF.NRL.1: Number of participating NRLs in the annual workshops (attendance rate) and
FF.NRL.2: Number of positive satisfaction surveys above 85 % received for the annual workshops and
FF.NRL.3: Measures to address relevant negative feedback from satisfaction surveys.

Expected ex-ante:
An attendance rate of 80% of NRLs nominated under 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 addressed

All NRLs nominated under Regulation (EC) No 882/2004 will be invited to participate to the annual 2-day workshop and in at least one training activity (see below).

Budget is requested for covering the cost of one participant per NRL (882) for the annual workshop and for the training activity, respectively, plus 5 participants from GMO control laboratories in developing countries for the training event (see below).

Depending on interest and upon request 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.

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 to cover the costs of the participants (travel lodging, per-diem or lunch + dinner + local transport),** assuming full participation (33 NRL) in the annual WS.

Deliverable FF.NRL.1.1 + FF. NRL.2 + FF.NRL.3:

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

FF.NRL.4: Number of NRLs visited for training

Expected ex-ante:
2 NRLs that underperformed in a CT round or that requested it for any other reason will be visited by two experts from the EURL for assisting them in identifying and addressing underlying causes for performance issues.

When a NRL underperforms in comparative testing rounds they are offered assistance by the EURL in addressing the underlying causes, see FF.PT.1 and FF.PT.3 for details. This assistance can, upon request by the laboratory, include an on-site visit by experts.

For 2014 up to 2 EURL expert visits to NRLs are budgeted for, each with up to 2 EURL experts and duration of up to one week. **Mission cost is budgeted for accordingly**. Depending on the preference of the underperforming NRLs, alternatively the budget can be used to cover training of NRL staff in the premises of the EURL.

Deliverable FF.NRL.4:

- Up to 2 Reports on underperformance visits to NRLs, including information on the improvements reached, delivered to DG SANCO within 1 month after the visit.

FF.NRL.5: Number of workshops/trainings to be organised other than the annual workshops and
FF.NRL.6: Attendance rate and umber of positive satisfaction surveys above 85 % received for such workshops

Expected ex-ante:
One WS/training event other than the annual WS in which 70% of NRL(882) participate with 85% positive satisfaction survey replies.

In 2014, one 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 2013. The expected participation of 70% means 23 out of 33 NRL participating. 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 or training course. Capacity permitting, other participants may join at their own cost. Invitations will be accordingly sent to the entire ENGL (including all NRL) and official GMO-control laboratories in developing and accession countries but preference is given to NRL(882).

The requested budget covers the cost for 1 participant per NRL(882), assuming 25 out of 33 participating, up to 3 specialist expert participants, and up-to 5 experts from 5 different GMO control laboratories from at least 3 developing countries. As lodging, lunch and dinner as well as local transport will be offered, only one per-diem will be offered to the participants, covering their travel time.

Deliverable FF.NRL.5 + FF.NRL.6:

- Financial and technical reports on 1 training event, including information on participation rate, satisfaction survey and follow-up of negative responses.

2.4 Performance indicator COM

To have trained personnel available for emergency situations occurring within the Union (if appropriate) and to provide scientific and technical assistance to the Commission (and to EFSA, ECDC, EMA), especially in cases where the MS challenge the results of analyses

FF.COM.1: Number of relevant qualified staff in terms of preparedness with relevant completed training; and
FF.COM.2: Adequacy of response to requests in terms of content and timely delivery

Expected ex-ante:
The EURL has at any time sufficient qualified staff available to adequately react to emergencies, such as commenting on a rapid alert, verifying results in case of dispute, providing *ad hoc* support in particular to DG SANCO, including for the preparation of legislative acts. It is expected that SANCO's needs as well as the needs of other DGs or MS-authorities that request *ad hoc* support can be fully met.

All resources of the EU-RL and if needed other parts of the unit, institute or JRC, are available for responding to this task, which is fully in line with the overall mission of the JRC.

The Unit verifies its efficiency regarding this indicator by means of an annual customer survey carried out by the quality manager of the unit, a copy of which can be made available to DG SANCO upon request.

Deliverable FF.COM.1 + FF.COM.2:

- *Ad hoc* advice as delivered to requesting customer DG and to NRLs
- Annual customer survey

Supplementary indicators:

2.5 *Performance indicator CEN*

To carry out a mutual and reciprocal exchange of information with competent laboratories in third countries or with the global/regional laboratory responsible for a

analysing food and feed designated by the FAO, WHO (when applicable), to contribute to FAO, WHO, OECD, risk assessment and/or reviews of manuals or codes, to CEN/ISO standardisation of analytical methods.

FF.CEN.1: Provision of consultant advice to FAO/OECD/WHO; and FF.CEN.2: Participation to leadership for the ISO/CEN standardisation of analytical methods

Expected ex-ante: Non for FF.CEN.1 because the EU-RL is not consulting FAO, OECD or WHO. Regarding FF.CEN.2, the EURL will continue to actively participate in CEN and ISO activities relating to standardised detection methods. In addition the EURL will continue its international networking and a second international workshop on GMO detection will be organised in 2014.

The JRC initiated in 2012 an international forum on scientific support for GMO analysis that shall serve as network of networks, allowing for the mutual and reciprocal exchange of information. An international workshop of this network of networks took place in April 2013 and a second one should be organised in 2014. Participation of NRLs will be made possible if savings in other budget items would allow.

In addition the EURL and/or the JRC co-operates with competent individual public control laboratories in third countries on a bilateral *ad hoc* basis and as BCH NFP.

Within the mission of the JRC, the MBG-unit, including the EU-RL, will respond to requests for advice from its customer DGs, including requests to review scientific/technical or other documents. However, the advice of the JRC and hence the EU-RL will remain limited to its area of competence, i.e. the scientific/technical aspects of detection, identification and quantification of GMOs. The EURL has no mandate for risk assessment.

Given the direct relevance of this objective to the mission of the JRC, the JRC will contribute to the activities needed for responding to this performance indicator with own resources or from support received from the BTSF-programme of DG AGRI/DEVCO/SANCO or other sources.

Deliverables FF.CEN.1. + FF.CEN.2:

- Activities organised in the context of the BTSF programme.
- *Ad hoc* cooperation with laboratories in 3rd countries
- Contribution to CEN/ISO activities
- Act as BCH NFP-EC

2.6 *Performance indicator R&D*

To take account of scientific development activities at national and EU level and perform applied research and development activities whenever appropriate

FF.R&D.1: Number of high quality communication to NRLs on follow-up of research other than analytical method-related

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

The EU-RL actively monitors the scientific developments in fields related to DNA-based detection, identification and quantification of GMOs. Via the ENGLnet and the ENGL related meetings, relevant findings will be made available to the entire ENGL, including all NRL, without delay. At the same time, the ENGL also serves as a platform for the members to inform each other of relevant scientific developments and findings, either during the plenary or SC or WG -meetings, or via the ENGLnet.

Deliverable FF.R&D.1.:

- Presentations and other contributions of EU-RL staff to ENGL meetings
- Internal (ENGLnet) or other publications relating to scientific advances