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JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit

EUROPEAN UNION REFERENCE LABORATORY FOR GENETICALLY MODIFIED FOOD AND FEED

EURL
European Union Reference Laboratory
for GM Food & Feed

ANNUAL WORK PROGRAMME FOR 2013 ACTIVITIES CARRIED OUT FOR THE IMPLEMENTATION OF REGULATION (EC) NO 882/2004

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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

CONTENT

Drafted by:
D. Charels
Scientific Officer

Scientific and technical approval:
M. Mazzara
Competence Group Leader

Compliance with EU-RL GMFF Quality System:
S. Cordeil
Quality Manager

J. Kreysa
Head of Unit Molecular Biology and Genomics

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] 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 34 staff members of which 21 are executing tasks primarily linked to the EU-RL GMFF.

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. Key policy areas include: environment and climate change; energy and transport; agriculture and food security; health and consumer protection; information society and digital agenda; safety and security, including nuclear activities; all supported through a cross-cutting and multi-disciplinary approach.

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 EU-RL GMFF contributes through validation of methods for the detection and quantification of GMOs in food and feed (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 EU-RL GMFF is supported by the European Network of GMO Laboratories (ENGL) that includes all 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 GMFF from its own budget but certain specific projects of the EU-RL GMFF need additional financial support from the Commission, similar to other EU-RLs for food and feed listed in Regulation (EC) No 882/2004.

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[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance). OJ L 268, 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 2013 OF THE EU-RL GMFF

The main activity of the EU-RL GMFF is defined by Regulation (EC) No 1829/2003 and the corresponding implementing Regulations. It relates to the validation of methods for the detection, identification and quantification of GMOs in food and feed. This activity is covered by JRC funds and financial contributions provided by applicants.

Regulation (EC) No 882/2004 lists all EU-RLs for food and feed control, including the EU-RL GMFF, and establishes a list of general objectives to be addressed by each of these EU-RLs. A recently provided list of "Performance indicators for the EU-RL GMFF in the field of Food and Feed", serves as a basis for a budget request for the WP 2013 for the EU-RL GMFF, and is structured accordingly.

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, 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: Provision of analytical methods

The EU-RL GMFF has on its website a permanently updated compendium of validated (reference) methods for the detection, identification, and quantification of GMOs. The compendium enables experienced laboratories, like the NRLs to implement and use these methods. If necessary the EU-RL GMFF supports method implementation in NRLs.

The update of the compendium and any required training or help is provided by JRC staff, financed from the regular JRC budget.

2.1.2. Specific objective: Comparative testing and follow-up

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

Expected ex-ante:
2 CT rounds including: • Mandatory participation of NRLs nominated under Reg. (EC) No 882/2004; • Recommended participation of NRLs nominated under Reg. (EC) No 1981/2006; • Voluntary participation of other ENGL-members and of laboratories from third countries.

In 2013 the EU-RL GMFF will organise 2 comparative testing rounds and assure the appropriate follow-up.

The organisation of a CT round has several phases, ranging from planning, over practical preparation, to data gathering and analysis. It is followed by reporting and, if needed, measures aimed to help underperforming NRLs to improve and to identify those that cannot reach the required level of performance.

Since this activity has little or no RTD-component, the JRC requests funding for it, as outlined in the attached budget proposal.

Work carried out by the EU-RL GMFF:

(a) Planning of CT rounds
In 2013 the EU-RL GMFF will organise and finance 2 meetings of the CT Advisory Board (in Ispra) to prepare and agree on the follow-up (including reporting) of the two CT rounds and to discuss general and strategic aspects of comparative testing.

(b) Practical preparation of CT rounds
The practical preparation of CT rounds includes the invitation of about 150 to 200 potential participants:

- All NRLs listed in Regulation (EC) No 882/2004 (mandatory participation),
- NRLs listed in Regulation (EC) No 1981/2006 (voluntary participation but highly recommended and requested as a condition for participation in validation ring trials),
- All remaining ENGL-members, and
- Selected laboratories from third countries identified by regional GMO networks with which the EU-RL GMFF cooperates (the latter two participate on a fully voluntary basis).

The EU-RL GMFF needs a full-time-equivalent (FTE) for secretarial support for the preparation and general administration of the CT rounds.

(c) Test item preparation and shipment
The preparation of test items is done in-house by the EU-RL GMFF in accordance with the plans agreed with the CT Advisory Board for Comparative Testing (AB-CT). Based on the experience gained so far, the preparation requires about 1 FTE of a scientific officer per year, which also covers intensive quality control of the test items produced. In addition, the EU-RL GMFF cooperates with the Reference Materials Unit of IRMM to make use of potentially suitable samples and materials that they could provide as a by-product of their Certified Reference Material production. Estimated staff costs, consumables, and equipment costs are included in the attached budget.

The EU-RL GMFF also organises the shipment of the prepared test items to the participating laboratories, together with clear advice on how to process these samples. The shipment costs are budgeted on the basis of past experience.

(d) Data gathering and analysis
The EU-RL GMFF prepares a web-based data gathering tool that enables CT participants to directly enter their data, using a pre-defined template. The data are then exported to EXCEL and analysed, according to statistical approaches agreed with the AB-CT. The preparation of the web-based data gathering and the analysis are tasks of the data manager, for whom ½ FTE is budgeted. In addition, meta-analysis of all CT rounds is foreseen for which ½ FTE of a scientific officer is needed.

(e) Reporting
Participants are informed about the outcome of a CT round, within two months after the deadline for submission of results, through a preliminary report. This is in line with ISO 17043 that foresees that participants are informed as soon as possible about underperforming z-scores to allow them to take corrective measures. DG-SANCO, as customer DG, receives a copy of this draft report, for information purpose.

Reporting requires about ½ FTE per year of a scientific officer.

(f) Management of "underperformance"

Underperformance will always occur and is depending on the complexity of the test item and the tasks the laboratories are requested to carry out. Since the AB-CT realised that basic skills are generally sufficiently developed, there is a tendency of increasing complexity from CT round to CT round and hence the initial underperformance rate might remain rather stable or even increase without indicating major problems. In any case underperformance is essentially and firstly an opportunity to improve and in this sense the EU-RL GMFF will cooperate with any underperforming laboratory to improve its performance.

Accordingly, in case of underperformance of a laboratory, the EU-RL GMFF will in first instance ask the laboratory to submit its raw data. The EU-RL GMFF will analyse these and communicate possible causes for the outlying result to the laboratory, together with a fresh set of test items. The laboratory then repeats the analyses, taking due account of the advice from the EU-RL GMFF. It is expected that in 80 to 90% of the cases the repeated experiments will yield satisfactory results. These will be reported in the final CT report.

In case that a given laboratory underperforms in 2 consecutive CT rounds, the EU-RL GMFF will offer additional support for identifying and solving the problem. This may include sending expert staff members to the laboratory and/or the provision of some training to staff from that laboratory in the EU-RL GMFF laboratories in Ispra. Within two months after the visit to a given participant a report will be sent to DG SANCO.

In view of the complexity of the test items and tasks agreed with the AB-CT at its meeting of 23 and 24 August 2012, it is expected that the EU-RL GMFF needs at least ½ FTE of a scientific officer (excluding on-site visits to NRLs and/or training activities) for the management of underperformance in 2013.

The JRC requests support for the preparation and execution of the CT rounds, including sample preparation and shipment, data gathering and analysis, and report preparation.

Deliverable FF.PT.1:

- 2 financial and technical reports of Advisory Board for comparative testing meetings.
- Test items for 2 CT rounds prepared and shipped to participants.
- 2 preliminary CT reports to be sent within 2 months after the deadline for submission of results.
- 2 final CT reports, including information on initially underperforming laboratories that finally were able to produce acceptable results.
- 2 to 4 reports on underperforming laboratories that were underperforming in 2 subsequent CT rounds or could not generate acceptable results when repeating the analyses.

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

Expected ex-ante:
- The complexity will be increased in the comparative testing rounds of 2013 because two processed materials (baked biscuits and rice noodles/biscuits) will be included. Hence the expected success rate is lower than for the ground seed materials and genomic DNA solutions used so far.

1. ILC-EURL-GMFF-CT-01/13

Two test materials of processed food (*e.g.* flour made from baked biscuits) containing wheat and maize will be used as test items. Participants shall

- perform species identification: maize, soybean, oilseed rape and prepare a table with presence/absence;
- screen for a list of maize events provided by the EU-RL GMFF and quantify those GM events that were detected.

The GM content will be known and IRMM will provide GM events from which test items can be prepared by the EU-RL GMFF.

2. ILC-EURL-GMFF-CT-02/13

Official control laboratories will be asked to provide real samples of rice products (noodles, biscuits) to the EU-RL GMFF for the preparation of test items. Alternatively, the EU-RL GMFF would purchase a commercial product as starting material. The material will be ground and spiked with GM-soybean flour (event 356043).
Participants will be informed that a rice sample is provided and shall

- perform species identification: maize, soybean, oilseed rape, rice and prepare a table with presence/absence for each species;
- identify and quantify the added soybean GM event.

IRMM will provide the spiking material (soybean event 356043) and the EU-RL GMFF will prepare the test items.

As in 2011, when the EU-RL GMFF started producing the test items for the comparative testing rounds in-house, a series of tests will be performed on each test item to determine its homogeneity and stability. The absolute quantification of the GM content will be performed using digital PCR. Next generation sequencing might also be employed, in 2013 but mainly on an experimental basis.

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:
- Initial success rate = 65% for a processed material (i.e. baked biscuits, rice noodles); 80% success rate for repeated experiments.
- On-site visits of 1-2 experts from the EU-RL GMFF to 2-4 NRLs.

It must be noted that the expected success rate is a function of the resources foreseen. A higher success rate would require a higher level of advice and support from the EU-RL. The activities to ensure follow-up of poor results are already described in FF.PT.1 management of underperformance.

Deliverable FF.PT.3:
- Reports on follow-up of underperformance as included in the CT reports (see also FF.PT.1).
- Special laboratory-specific reports in case of repeated underperformance (see also FF.PT.1).

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

Expected ex-ante:
- Given the increasing complexity of CT rounds (use of processed materials for test items in 2013), a simple comparison of initial success rates does not make much sense. However, it is expected that 80 to 90 % of initially underperforming laboratories can reach appropriate results when repeating the tests.
- It should also be possible to assess aspects that where addressed in previous rounds and compare progress in this way. However, this would require to re-work old data and to increase the granularity of future reporting. It is not clear to which extent this could be realised in 2013.

In addition to bilateral advice to and training for underperforming laboratories, the EU-RL GMFF tries to influence the performance of participating laboratories by describing the causes of observed underperformance and how these were corrected in the CT reports. If general problems are discovered, training will be offered for all interested laboratories. In addition the EU-RL GMFF provides guidance via its website, for example the ENGL performance criteria[4] that NRLs should always respect. In 2013 the EU-RL GMFF will also continue working with the ENGL on more guidance, including the definition of criteria for identifying positive PCR-signals. Guidance documents will be made available via the EU-RL GMFF website. As mentioned before the meta-analysis of all CT rounds performed until the end of 2012 will require ½ FTE of a scientific officer.

Deliverable FF.PT.4:
- A meta-analysis of all CT rounds performed until the end of 2012 with a view to establish progress made by the participating laboratories in their performance and to establish useful parameters.

[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.5: Availability for use by NRLs of analytical methods

Expected ex-ante:

- In addition to the existing methods, 8 newly validated event-specific real-time PCR quantification methods will be published on the EU-RL GMFF website.
- Pre-spotted plates for screening for authorised or pending GM-events will be made available free-of-charge to the NRLs.
- 1-3 new or improved methods, validated by other organisations, will be included in the EU-RL GMFF's database of GMO-detection methods and published on its website.

Based on historical data the EU-RL GMFF expects to receive in 2013 eight dossiers from applicants including methods for the detection, identification and quantification of single GM events. Once validated by the EU-RL GMFF in accordance with Regulation (EC) No 1981/2006, the methods will be published on its website and included in the EU-RL GMFF's method 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 (EU) No 619/2011[6].

In addition the EU-RL GMFF will make the pre-spotted plates for screening for authorised or pending GM-events available free-of-charge to the NRLs. The pre-spotted plates will be updated as soon as a method is ready to be included in the EU-RL GMFF database on GMO detection methods. In 2013 a transferability study on the pilot production of pre-spotted plates is foreseen. This study would involve the participation of 20 NRLs each receiving 3 pre-spotted plates.

If any NRL or other laboratory validates a new or improved method and invites the EU-RL GMFF to verify this validation, the EU-RL GMFF will do so and, if found adequate, include these methods into its database of GMO-detection methods and publish it on the EU-RL GMFF website. It is expected that this will be between 1 and 3 methods in 2013.

This activity is managed with JRC resources.

Deliverable FF.PT.5:

- Additional validated methods on the EU-RL GMFF website and updated GMO-method database.
- Pre-spotted plates available to NRLs.

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

[6] Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired Text with EEA relevance. OJ L 166, 25.6.2011, p. 9–15.

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

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

During the first 4 months of 2012 the mean daily use of the GMO-Methods database was around 35, i.e. 13.000 per year. The entire compendium is downloaded about 700 times p.a. but single pages (i.e. methods) are downloaded 4156 times p.a. This indicates that the EU-RL GMFF website is indeed an effective means to make analytical methods available to NRLs as soon as they are validated.
Via its ENGL network the EU-RL GMFF is in direct and permanent contact with the NRLs and receives feedback on the uptake of methods.
The ENGL management (secretariat, meetings, meeting minutes) and the analysis of the use of the EU-RL GMFF website are covered by own JRC-resources.

Deliverable FF.PT.6:
- Report on the use by NRLs of EU-RL GMFF published methods included in reports from ENGL and NRL meetings.
- Report on the web-access to EU-RL GMO-methods database etc.

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

Expected ex-ante:
- ISO 17043:2010, ISO 9001:2000 and ISO 17025:2005 certifications and accreditations maintained and confirmed by the respective accreditation bodies.

The activities of the EU-RL GMFF, hosted by the MBG Unit of the IHCP institute of the JRC, 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 technical activities the EU-RL GMFF is 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 and identification of GMOs in food and feed materials.

In addition, the EU-RL GMFF obtained the ISO 17043 accreditation regarding general requirements for proficiency testing from the German accreditation body Deutsche Akkreditierungsstelle GmbH (DAkkS) in November 2011. In 2013 this accreditation will potentially also be delivered by Accredia, however, that is not yet decided.

The cost of accreditation and the Quality Manager of the Unit are covered by JRC resources.

Deliverable FF.QI:
- Reports on the audits from the accreditation bodies carried out in 2013.

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:
- 8 or more newly validated methods published on the EU-RL GMFF Website (see also FF.PT.5).

Based on previous experience it is expected that in 2013 the EU-RL GMFF will validate 8 new event specific methods for the detection, identification and quantification of GMOs and make them immediately available to the NRLs via the EU-RL GMFF website.

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

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.

Methods for the detection, identification and quantification of GMO are submitted for validation in the context of application dossiers to obtain their authorisation for a certain GM event. So far only industry submitted such dossiers.

No resources are needed.

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

Expected ex-ante:
- No additional specific quality assurance system is needed in 2013.

The current quality management system of the EU-RL GMFF 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 GMFF 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 (ai) are:

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

Expected ex-ante:
• GMO-matrix available to all NRLs.

In 2013 the EU-RL GMFF will make available to NRLs, via ENGLnet (see below) a GMO matrix that, in its first version (V1) will be an EU matrix, i.e. it will exclusively include all EU approved/pending GM events and EU-RL GMFF validated methods. Discussions with ENGL have started in 2012.

Only at a later stage this EU matrix could be further developed into a global matrix, including also GM events and constructs which are not authorised in the EU. Such a matrix should facilitate the screening for GM events and/or constructs, in particular in combination with pre-spotted plates, through better interpretation of experimental data.

The JRC supports the development and dissemination of the GMO-matrix with own resources.

Deliverable FF.ANA.ai.1:
• GMO matrix V1 available to all NRLs.

FF.ANA.ai.2: Networking

Expected ex-ante:
• ENGL remains fully operational. • ENGLnet constantly updated.

The ENGL is meant to support the EU-RL GMFF in its tasks and does so through 2 annual plenary meetings as well as through a number of working groups that prepare ENGL positions with regard to any question relevant for the detection, identification and quantification of GMOs and the validation of suitable methods. An ENGL-Steering Committee (SC) prepares the work plan of the ENGL and the agenda for the plenary meetings where ENGL-positions are adopted.

The EU-RL GMFF also maintains a web-based platform (ENGLnet) dedicated to ENGL members (including all NRLs listed in Regulation (EC) No 882/2004 and/or Regulation (EC) No 1981/2006) to which all NRLs have access. A secured intranet allows the exchange of information. Collaborative workspaces are provided for common tasks or activities, including CTs, where also draft documents are made available to the relevant parties. A specific workspace for activities related to Regulation (EC) No 882/2004 is constantly

updated. Other workspaces of relevance in this context are those for the AB-CT, and CT-specific workspaces.
ENGLnet as well as ENGL as such are both used for disseminating information about progress in the field, provided by any member of ENGL, including the EU-RL GMFF, which is running an EU-RL GMFF support group that monitors the scientific development in the field and implements suitable new expertise and technologies in the EU-RL GMFF.

The JRC manages ENGL with internal resources, i.e. it provides the chair and the secretariat of the network and covers the costs of the Steering Committee (SC), plenary and the Working Group (WG) meetings. The regularly updated ENGL website serves as a record of the ENGL-activities. All final ENGL documents (including meeting minutes and adopted positions) are posted on this website. The EU-RL GMFF website contains all documents for the general public, including final ENGL statements and/or position papers.

Deliverables FF.ANA.ai.2:
- Report on the use of the ENGLnet website.
- Minutes of 2 ENGL SC, 2 ENGL-plenary, and 3 to 6 working group meetings.
- 1-3 ENGL products (e.g. position papers, guidance documents, etc.).
- News sections providing information about new developments in the field.
- ENGL-workspaces, used by the participants and well maintained.

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

Expected ex-ante:
- EU-RL GMFF website constantly updated, including possibilities for download of guidance documents and provision of feedback.

The public website of the EU-RL GMFF contains sections for regular updates on methods, including the EU-RL GMFF database on GMO methods that allows identifying suitable methods and the related detailed method description. These downloadable method descriptions enable experienced laboratories, such as NRLs, to implement the described methods. However, in case of problems the EU-RL GMFF offers advice and other assistance, so far on an *ad hoc* basis and not (yet) via a formal helpdesk.

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 NRLs 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 GMFF internet web site, including the compendium 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 65% of NRLs in the annual NRL-workshop
- At least 70% of positive responses to the satisfaction surveys of the NRL-workshop
- Negative feedback from satisfaction surveys clearly addressed.

NRLs and participants from third countries will be invited to participate in an annual workshop for the NRLs nominated under Regulations (EC) No 882/2004 and (EC) No 1981/2006, respectively. The workshop will be organised by the Joint Research Centre in Ispra (Italy) back-to back with the ENGL plenary meetings but with dedicated time frames and agendas.

Up to 3 experts will be invited to each NRL workshop to update participants on relevant topics, identified in a timely manner by the EU-RL GMFF in cooperation with the NRLs in question. The target attendance rate should be obtained through the request to NRLs to add points of their interest to the agenda and the back-to-back organisation with the ENGL plenary meeting.

At the end of each meeting, the EU-RL GMFF will circulate a satisfaction survey questionnaire. Negative replies will be followed-up with a view to improve as much as possible.

Deliverable FF.NRL.1.1 + FF. NRL.2 + FF.NRL.3:
- 1 Financial and technical report, including information on participation rates and on satisfaction surveys and any eventual follow-up, of the annual workshop.

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

Expected ex-ante:
- 2 to 4 NRLs visited by one or two experts from the EU-RL GMFF or identified by the EU-RL GMFF.

When a NRL underperforms in 2 consecutive CT rounds or does not achieve acceptable results when repeating the analyses, after attempting to improve its performance, on-site assistance could be foreseen. The NRL will be visited by one or two experts, one focusing on the process and quality management system and the other on the practical laboratory work. Experts could either be EU-RL GMFF staff members or external people identified by the EU-RL GMFF. The task of these experts will be to identify, together with the NRL, the causes for the persisting underperformance and identify solutions. This might include on-site training in the NRL but it could also result in inviting staff from the NRL to the EU-RL GMFF or another suitable training laboratory to undergo intensive training in the relevant technical skills (see FF.NRL.5).

It is expected that during 2013 2 to 4 such visits to NRLs will be required, each with 2 experts and up to one week. The preparation and follow-up of this activity will require a budget for travel and per-diem as well as ¼ FTE of a scientific officer.

The JRC requests support for these follow-up activities.

Deliverable FF.NRL.4:

- 2 to 4 reports on underperformance visits to NRLs, including information on the improvements reached and recommendations for retaining or delisting the NRL in question. The reports will be delivered to DG SANCO within 2 months after the end of the mission.

FF.NRL.5: Number of workshops/trainings to be organised other than the annual workshops, and

FF.NRL.6: Attendance rate and number of positive satisfaction surveys above 85 % received for such workshops.

Expected ex-ante:

- Up to 2 workshops/training courses with attendance rate of 30% (of NRLs nominated under Regulation (EC) No. 882/2004) and 70% of positive satisfaction surveys.

Any workshop or training course may well support the dissemination of new methods and new knowledge to the NRLs (see above) but most will deal with identified problems and address established methods, focussing on the improvement of technologies, practical skills and knowledge, including quality management training courses.

The EU-RL GMFF will organise in 2013 two dedicated (training) workshops for the NRLs, on issues that are of practical concern under Regulations (EC) No 882/2004 or (EC) No 1981/2006, respectively. Since the topics will be identified following a dialogue with the NRLs, their content cannot be predicted with certainty.

In 2013 it is foreseen to offer 1 intensive training course for a limited number of NRLs in need and 1 training courses/workshops for NRLs and third country participants.

The aim of the first training is to provide individualised hands-on training (up to 5 days) to those NRLs which are either new in the field of GMO detection or have shown recurrent problems with reaching satisfactory performance.

The second type of training course aims to disseminate new methods and knowledge for up to 28 participants, of which up to 8 may come from non-EU countries. The training course will last 2 to 3 days and will take place either in Ispra or in any NRL willing to host such an event and able to provide the necessary facilities free of charge.

The participation should be free of charge, which implies that eventual trainer fees and the travel and per-diem of participants should be covered. Once a relevant topic is identified, the EU-RL GMFF will send an invitation to the entire ENGL and related third country laboratories. In case of an excess number of candidate participants, the selection will be based on the adequacy of the pre-existing expertise and a certain geographical and gender balance, giving 1st priority to NRLs nominated under Regulation (EC) No 882/2004, 2nd priority to NRLs nominated under Regulation (EC) No 1981/2006 and 3rd priority to all other candidates. It is expected that 30 % of NRLs appointed under Regulation (EC) No 882/2004 will participate in each workshop.

One possible topic for such a training course could be the use of pre-spotted plates for GMO detection, to be held in the second half of 2013, after the beginning of the production of the plates. A topic for the training course in the first half of 2013 will be discussed with the ENGL SC in September and at the plenary meeting in December, as well as at the annual workshop of the NRLs that will be organised back to back with the ENGL plenary meeting in December. Possible topics include quality issues, specific skills to improve the performance in comparative tests, the estimation of measurement uncertainty, DNA extraction and quality control.

To prepare these trainings the JRC needs ½ FTE of a scientific officer and ¼ FTE of an administrative assistant.

The JRC is requesting support for these trainings, staff costs, participants' travel expenses, provision of accommodation and per diem to participants, mission costs for JRC staff (in case a NRL offers to host a workshop/training course), travel costs for participants and travel, hotel, per diem and eventual fee for trainers.

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

- Financial and technical reports on the training events including information on participation rate, satisfaction surveys 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:
- Sufficient qualified staff.
- 80 % adequacy of response to requests.

The EU-RL GMFF responds to this performance indicator by means of the EU-RL GMFF support group within the MBG Unit. This group is primarily in charge of responding to overall Performance Indicator R&D (see below) but the entire group is working under the same quality management system as the EU-RL GMFF as such and all staff members are trained to complement the EU-RL GMFF resources in case of emergencies or high workload and short deadlines.

The scientific expertise to provide the appropriate scientific and/or technical assistance, however, is spread over the entire MBG Unit and relevant expertise may also come from other parts of the JRC, if needed. This enables the JRC to master the necessary expertise and resources to deal with most *ad-hoc* requests for advice, providing adequate responses on time as well as in terms of content.

No additional resources are requested.

Deliverable FF.COM.1 + FF.COM.2:
- *Ad hoc* advice as delivered to requesting customer DGs and to NRLs

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:
- International forum on scientific support for GMO analysis.
- Cooperation with laboratories in third countries on *ad hoc* basis.
- Participation in CEN/ISO meetings, for example relating to sampling or method validation.

The JRC initiates in 2012 an international forum on scientific support for GMO analysis that shall serve as a network of networks, allowing for the mutual and reciprocal exchange of information. In addition the EU-RL GMFF and/or the JRC co-operates with particularly competent individual laboratories in third countries on a bilateral but *ad hoc* basis.

Within the mission of the JRC, the MBG Unit, including the EU-RL GMFF, will always respond to requests for advice coming from its customer DGs, including requests to review scientific/technical or other documents from international organisations. However, the advice of the JRC and hence the EU-RL GMFF will remain limited to its area of competence, i.e. the scientific and/or technical aspects of detection, identification and quantification of GMOs. The EU-RL GMFF doesn't have the mandate for risk assessment.

Given the direct relevance of this objective to the mission of the JRC, the JRC will cover any activity needed for responding to this performance indicator with own resources.

Deliverables FF.CEN.1 +FF.CEN.2:
- Mission reports from visits to sister organisations in third countries or to international organisations, reports from visits of experts to the EU-RL GMFF.
- Reports on a*d hoc* advice concerning international cooperation as provided to customer DGs.

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:
- At least 5 high quality (peer reviewed) communications to NRLs (via ENGLnet) on follow-up of research other than analytical method related.

The EU-RL GMFF support group within the MBG-unit of the JRC has the task to monitor the scientific developments in the field of GMOs and identify those that are potentially most relevant for the detection, identification and quantification of GMOs. The group will

regularly report on its findings and co-operate with the NRLs via the ENGLnet with regard to new relevant scientific developments, technologies and approaches. It will present opinions to the extent possible after an initial verification and stimulate discussions within the ENGL. In 2013, for example, a next generation sequencer will be introduced and made available to the EU-RL GMFF and the group will report on this experience as well as describe the potential use of this technology in method validation and/or routine analysis.

The group will also report on its applied research, for example on the development and optimisation of screening methods. In 2013 pre-spotted plates are intended to be made available to the NRLs. The EU-RL GMFF support group will regularly report on progress and co-operate with the NRLs for identifying their preferences.

In 2013 the group will also continue to be involved in the PRICE project addressing *inter alia* the distribution of GM pollen, the identification of GM DNA from pollen and prepare peer reviewed papers on this.

The JRC will support the development and optimisation of the concept with own resources. However, once the routinely production of plates for NRLs is realised, additional support is requested to cover at least the material and some staff cost. Current estimates are indicating a production cost of about 50 to 70 Euro per plate, including staff and material costs. The pilot production of pre-spotted plates foresees a total of 1000 plates in 2013 of which 400 plates for in-house characterisation studies and 600 plates to be distributed to 20 NRLs participating in a transferability study.

Deliverable FF.R&D.1:

- Report/publication on the implementation of Next Generation Sequencing in the EU-RL GMFF support group and a first case study of its application in the context of method validation/optimisation.
- Report/publication on the optimisation of the pre-spotted plates.
- Report/publication on the delivery of pre-spotted plates to NRLs and on their use in screening for approved or pending GMOs.

ANNEX I(A)

ESTIMATED BUDGET PER ACTIVITY

2013	Staff costs	Subcontr.	Capital Equipment	Consumables	Comparative tests	Missions	Meetings	Workshops	Training activities	TOTAL
Plenary meetings and meetings of the Advisory Board							12,720	53,890		66,610
Production of test materials and shipments	156,688.55		13,434	125,600	3,750					299,472
Organisation of CT rounds	84,370.76									84,371
Technical support to NRLs						5,340			17,190	22,530
TOTAL	**241,059.30**	**0.00**	**13,433.61**	**125,600.00**	**3,750.00**	**5,340.00**	**12,720.00**	**53,890.00**	**17,190.00**	**472,983**

ANNEX I(B)

EU-RL GMFF eligible expenditures

ESTIMATED BUDGET FOR LABORATORY EXPENDITURE IN RESPECT OF UNION ACTIVITIES, INCLUDING THE ORGANISATION OF WORKSHOPS FROM 1 JANUARY TO 31 DECEMBER 2013

Goods and services are VAT and EXCISE duty exempted (Directive 77/388 EEC- Article 15 (10) and Directive 92/12/EEC - Article 23 (1)
All costs are expressed in Euros (€)

Name and Address of the EU Reference Laboratory:
European Union Reference Laboratory for Genetically Modified Food and Feed
European Commission - Joint Research Centre
Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit - TP 201
Via E. Fermi 2749
I-21027 Ispra (VA)
Italy

Bank account to which the grant should be transferred:
The sums shall be transferred according to the Commission's accounting rules on internal invoicing to the Legal Entity File (LEF) number 6999999009 mentioning the Recovery Order (RO) number. The JRC will produce a debit note for each payment (including the first provisional transfer).

1. STAFF

Category	Status	Gross monthly salary	Time spent on project (number of days)	Total eligible costs
Head of Unit – AD	F		6	0
Scientific officer – AD	F		110	0
Scientific officer – AD	F		11	0
Quality manager – AST	F		22	0
IT developer – AST	F		11	0
Scientific Officer - GH / CA	GH30 or CA FGIV	**6,474.40**	**495**	**174,808.80**
Scientific / Technical Support Officer - CA	CA FG III	**3,750.00**	**110**	**22,500.00**
Secretary – CA	CA FG II	**2,916.70**	**275**	**43,750.50**
			Total 1	**241,059.30**

2. SUBCONTRACTING

N/A

3. CAPITAL EQUIPMENT 2012

Comparative testing scheme

Description	depreciation cost
Statistica concurrent Network	1,641.66
Glassware and small instr.	1,998.80
Glassware and small instr.	171.88
Turbula mixer	7,052.45
Knife mill	806.82
Stainless steel table	612.00
Total 2	**12,283.61**

4. CAPITAL EQUIPMENT 2013

Comparative testing scheme

Equipment	Estimated cost
Comparative testing - sample preparation	1,150
Total 3	**1,150**

5. CONSUMABLES

Comparative testing schemes - Sample preparation, homogeneity and stability tests

Reagents	Estimated cost
Real-time PCR consumables	27,500
Digital PCR consumables	29,800
Certified Reference Materials	3,200
Reagents	1,350
Pilot production of pre-spotted plates*	60,000
Other consumables	3,750
Total 4	**125,600**

**Estimated production cost for 1 plate = 60 and a total of 1000 plates produced*

6. SHIPMENTS

Description*	Estimated cost
Shipment of samples ILC-EURL-GMFF-CT-01/13*	650
Shipment of samples ILC-EURL-GMFF-CT-02/13**	3,100
Total 5	**3,750**

**Cost for printing of labels for samples = 650*
***Purchase of boxes and printing of labels*

7. MISSIONS

Technical support NRL*	TOTAL
Expert's travel expenses (3 experts, two missions each)	3,000
Expert's accomodation (2 nights per mission, 135,- per night)	1,200
Expert's daily allowances (2 days per mission a 95,-)	1,140
Total 6	**5,340**

Average European flight ticket: 500 €

**: costs are calculated for 3 visits to NRLs, 2 days per visit, 2 EU-RL GMFF staff members, according to Council Regulation (EC, EURATOM) No 1066/2006 of 27 June 2006 adjusting from 1 July 2006 the scale for missions by officials and other servants of the European Communities in the Member States (for Italy)*

8. MEETINGS

Advisory Board 1*	Cost	
Participants' travel expenses	4,000	*Average European flight ticket: 500 €*
Participants' accomodation a 100,- per night	1,600	
Participants' daily allowances	760	
Total expenditure for meeting 1	6,360	
Advisory Board 2*	**Cost**	
Participants' travel expenses	4,000	*Average European flight ticket: 500 €*
Participants' accomodation a 100,- per night	1,600	
Participants' daily allowances	760	
Total expenditure for meeting 2	6,360	
Total 7	**12,720**	

**: costs are calculated for 8 invited experts, 2 days per workshop, according to Council Regulation (EC, EURATOM) No 1066/2006 of 27 June 2006 adjusting from 1 July 2006 the scale for missions by officials and other servants of the European Communities in the Member States (for Italy)*

9. TRAINING ACTIVITIES

Training at EU-RL GMFF premises	Cost	
Training 1*		
Participants' travel expenses	1,000	*Average European flight ticket: 500 €*
Participants' accomodation a 100,- per night	1,000	
Participants' daily allowances a 95,-	950	
Total expenditure for training 1	2,950	
Training 2**		
Participants' travel expenses	8,000	*Average European flight ticket: 500 €*
Participants' accomodation a 100,- per night	3,200	
Participants' daily allowances a 95,-	3,040	
Total expenditure for training 2	14,240	
Total 8	**17,190**	

**: costs are calculated for 2 NRLs appointed under Reg. (EC) No 882/2004, 1 participant of each NRL, 5 days of training given at the EU-RL GMFF premises, according to Council Regulation (EC, EURATOM) No 1066/2006 of 27 June 2006 adjusting from 1 July 2006 the scale for missions by officials and other servants of the European Communities in the Member States (for Italy)*

***: costs are calculated for 16 NRLs appointed under Reg. (EC) No 882/2004, at least 1 participant of each NRL, 2 days of training given at the EU-RL GMFF premises, according to Council Regulation (EC, EURATOM) No 1066/2006 of 27 June 2006 adjusting from 1 July 2006 the scale for missions by officials and other servants of the European Communities in the Member States (for Italy)*

10. OVERHEADS

N/A

11. WORKSHOPS

Annual workshop of the NRLs (max 32)*	Cost		
Participants' travel expenses	37,500	*Average European flight ticket: 500 €*	*Average flight ticket from third country: 2500 €*
Participants' accomodation a 100,- per night	8,600		
Participants' daily allowances a 95,-	7,790		
Total expenditure for workshops	**53,890**		

**: costs are calculated for 32 NRLs appointed under Reg. (EC) No 882/2004, up to 8 representatives of third countries provided they are willing to fly in economy class and only if some NRL do not come, 3 invited speakers, 2 days per workshop, according to Council Regulation (EC, EURATOM) No 1066/2006 of 27 June 2006 adjusting from 1 July 2006 the scale for missions by officials and other servants of the European Communities in the Member States (for Italy)*

12. FINAL ESTIMATED BUDGET FOR 2013

Description	Cost
Total expenditure regarding activities of the EU-RL GMFF*	419,093
Total expenditure regarding workshops	53,890
Final estimated budget for the EU-RL GMFF	**472,983**

**: Total 1 + Total 2 + Total 3 + Total 4 + Total 5 + Total 6 + Total 7 + Total 8*

ANNEX I(C)

1. BREAKDOWN OF STAFF ACCORDING TO PIs

Performance indicator	Requested FTE	Category	Status	Gross monthly salary	Time spent on project (number of days)	Total eligible costs
FF.PT.1	**1**	**Secretary – FGII**	CA (16/08/2012 - 15/08/2015)	**2,916.70**	**220**	**35,000.40**
FF.PT.1	0.025	Head of Unit – AD	F		6	0
FF.PT.1	0.05	Scientific officer – AD	F		11	0
FF.PT.1	0.1	Quality manager – AST	F		22	0
FF.PT.1	0.05	IT developer – AST	F		11	0
FF.PT.1: test item preparation	**1**	**Scientific Officer - GH**	GH30* (01/01/2013 - 31/12/2015)	**6,474.40**	**220**	**77,692.80**
FF.PT.1: data gathering	**0.5**	**Scientific / Technical Support Officer - FGIII**	CA* (16/10/2012 - 15/10/2015)	**3,750.00**	**110**	**22,500.00**
FF.PT.1: reporting	0.25	Scientific officer – AD	F		55	**0**
FF.PT.1: reporting	**0.25**	**Scientific Officer - GH**	GH30* (01/01/2013 - 31/12/2015)	**6,474.40**	**55**	**19,423.20**
FF.PT.1: mgt of underperformance	0.125	Scientific officer – AD	F		27.5	0
FF.PT.1: mgt of underperformance	**0.375**	**Scientific Officer - GH**	GH30* (01/01/2013 - 31/12/2015)	**6,474.40**	**82.5**	**29,134.80**
FF.NRL.4	0.125	Scientific officer – AD	F		27.5	0
FF.NRL.4	**0.125**	**Scientific Officer - GH**	GH30* (01/01/2013 - 31/12/2015)	**6,474.40**	**27.5**	**9,711.60**
FF.NRL.6	**0.5**	**Scientific Officer - GH**	GH30* (01/01/2013 - 31/12/2015)	**6,474.40**	**110**	**38,846.40**
FF.NRL.6	**0.25**	**Secretary – FGII**	CA* (01/01/2013 - 31/12/2015)	**2,916.70**	**55**	**8,750.10**
					Total	**241,059.30**

ANNEX II

List of NRLs nominated under Regulation (EC) No 882/2004 according to the information received from official bodies regarding the NRL status

MS	Organisation
AT	Environment Agency Austria
AT	Austrian Agency for Health and Food Safety
BE	Authentication and traceability
BE	Institute for Agricultural and Fisheries Research
BE	Scientific Institute of Public Health
BG	National Center of Public Health Protection - Bulgarian National Laboratory for Genetically Modified Food
CY	State General Laboratory
CZ	Crop Research Institute - Reference Laboratory for GMO Detection and DNA fingerprinting
DE	Federal Office of Consumer Protection and Food Safety- Berlin
DK	Danish Vetarinary and Food Administration, Laboratory for Diagnostics in Plants, Seed, and Feed
DK	DTU-Food, National Food Institute
ES	National Centre for Food, Spanish Food Safety Agency and Nutrition
ES	Laboratory Agroalimentary of the Spanish Ministry of Agriculture, Food and Environment
FI	Finnish Customs Laboratory
FR	Plant Health Laboratory
FR	Service Commun des Laboratoires du MINIFE
FR	BioGEVES - Groupement d'Intérêt Public – Groupe d'Etude et de contrôle des Variétés et des Semences
GR	Genetic Identification Laboratory of the Hellenic Agricultural Organization (DEMETER)
GR	(GCSL), Food Division- Athens
HU	National Food Chain Safety Office, Food and Feed Safety Directorate, GMO Laboratory
HU	Laboratory
IE	Food and Environment Research Agency
IT	Analysis
LT	National Food and Veterinary Risk Assessment Institute Molecular Biology and GMO Department
LU	National Health Laboratory, Food Control Department
LV	Institute of Food Safety, Animal Health and Environment
MT	Public Health Laboratory
NL	RIKILT Institute of Food Safety
PL	National Research Institute of Animal Production, National Feed Laboratory in Lublin
PL	State Sanitary and Epidemiological Station, Regional Laboratory of Genetically Modified Food
PL	National Veterinary Research Institute in Pulawy, Department of Hygiene of Animal Feedingstuff
PT	National Institute of Biological Resources, I.P./INIA - Food technology Unit
RO	Institute for Diagnosis and Animal Health, Molecular Biology and GMOs Unit
SE	National Food Agency
SI	National Institute of Biology
SK	Central Control and Testing Institute of Agriculture
SK	State Veterinary and Food Institute Dolny Kubin
UK	LGC Limited