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

EUROPEAN UNION REFERENCE LABORATORY FOR GENETICALLY MODIFIED ORGANISM

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

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CONTENT

1. BACKGROUND INFORMATION

The European Commission's Joint Research Centre (JRC) is the European Union Reference Laboratory for Genetically Modified Food and Feed (Reg. (EC) 1829/2003 and the EURL GMO (Reg. (EC) 882/2004) [1,2,3,4] (hereafter named EURL). The Molecular Biology and Genomics Unit (MBG Unit) of Institute for Health and Consumer Protection currently carries out the two mandates of the EURL. The unit has currently 39 staff members of which around 7 FTE are allocated to the mandate of the EURL flowing from Reg. 1829/2003 and 4 FTE to the mandate flowing from Reg. 882/2004.

This work programme gives an overview of the activities of the EURL GMO (Reg. 882/2004) in 2016 and 2017 and requests a budget for some of the activities in line with the Commission Implementing Decision of 24 July 2015 on the adoption of the work program of the Commission for the years 2015 and 2016 and on the financing of the Union contribution to the European Union reference laboratories (Off J C(2015) 4993, 24.7.2015, p. 1-4).

Hereafter "EURL (GMO) mandate" refers only to the mandate carried out under Regulation 882/2004.

2. THE COMMISSION WORK PROGRAMME 2016-2017 FOR EURLS

The Commission Implementing Decision of 24.7.2015 establishes the actions to be financed and the budget breakdown for the activities to be implemented by the European Union reference laboratories (EURLs) in the years 2016 and 2017 in the field of food and feed safety and animal health, animal welfare and plant health as laid down in Article 32 of Regulation (EC) No 882/2004.

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

Specific Commission objectives are

a) to contribute to a high level of safety of food/feed and food/feed production and a better animal health status;

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed; OJ L 269, 18.10.2003, p. 1-23.
[2] Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 165, 30.4.2004, p. 1-141, as corrected by OJ L 191, 28.5.2004, p. 1-52.
[3] Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms. OJ L 368, 23.12.2006, p. 99-109.
[4] Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms. OJ L 39, 8.2.2014, p. 46-52.

b) to contribute to a timely detection and eradication of pests; and

c) to improve effectiveness, efficiency and reliability of official controls.

These specific Commission objectives have been translated into four Operational objectives, see table 1

Operational objectives		Indicator	Expected result
1	To ensure the development and use of high quality analytical methods across the EU-RL framework	Number of available state-of-the-art analytical methods	Maintain or increase number
2	To maintain an appropriate level of inter-laboratory comparative testing ensuring efficiency of control analysis methods	Level of participation and successful completion of comparative testing	All NRLs completed comparative testing successfully
3	To ensure the availability of scientific and technical assistance provided by the EU-RLs	Satisfaction degree of support provided by the EU-RLs	Timely and adequate answer to all the assistance requests
4	To ensure a sound and efficient management of the EU-RL funding cycle	Timelines and level of completion of necessary steps of EU-RL programmes' funding cycle	Timely and completed funding cycle

Table 1: Operational objectives

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

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

Expected ex-ante:

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

High quality analytical methods

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

Commission priority: Detection of unauthorised GMOs

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

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

Development of high throughput analytical methods for GMO detection and dissemination of NRLs

In 2016 the EURL will introduce a multi target detection system, known as pre spotted plate (PSP), into regulatory GMO control in the EU. Different PSP have been developed by the

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

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

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

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

Deliverable EURL ACTIVITY 1.1:

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

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

Expected ex-ante:

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

Annual NRL workshop

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

Guidance documents on the implementation of analytical methods

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

NRL training

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

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

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

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

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

Deliverable EURL ACTIVITY 1.2:

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

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

EURL ACTIVITY 2.1: Comparative testing

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

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

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

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

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

Deliverables EURL ACTIVITY 2.1

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

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

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

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

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

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

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

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

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

EURL ACTIVITY 4.1 Financial and technical reporting and planning

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

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