European Commission

Summary Report

16th WORKSHOP OF GMO NRLs

Webex meeting

29 September 2020

The European Commission's science and knowledge service

Joint Research Centre

Joint Research Centre

16th Workshop of the GMO NRLs

29 September 2020

Draft Summary Report on the Webex meeting

1. Welcome, approval of the agenda

The Chair welcomed the participants (Annex1) and provided technical instructions for the new on line format of the meeting. The Agenda was approved without modifications.

2. Approval of the report on the 15th Workshop

The report of the last meeting was adopted without amendments.

3. Report on EURL GMFF activities

Due to the COVID-19 pandemic, the EURL GMFF laboratory was closed for a few months.

The EURL GMFF has implemented a procedure for assessing the quality of the GMO CRMs including their certificates. As a result, the homogeneity of the CRMs and the information on the certificates have improved. The 3rd edition of the guidance document on Measurement Uncertainty (MU) for GMO Testing Laboratories and a table on DNA extraction problems and solutions were published on the EURL GMFF webpage and the ENGLnet. The ENGL working group (WG) on method performance requirements (MPR) is expanding the document for applications proposing digital PCR methods, for the detection of GM animals and genome-edited products. The new ENGL WG on genetically modified microorganisms (GMM) did not start its activities due to the COVID-19 pandemic and would welcome additional experts. Following the publication of the ENGL report on the detection of genome-edited products in 2019, a new JRC study on the state-of-the–art and future developments in new genomic techniques is being prepared for the Commission. The EURL GMFF also provided ad-hoc support for the evaluation of a detection method for an alpha-amylase overproducing strain, a seed testing convergence document and a SNP detection method for Cibus canola.

A virtual training for NRLs, including presentations and exercises, on the estimation of measurement uncertainty is planned for the 12th of November. Important progress was also made on the pre-spotted plates project and proficiency tests (PT).

The EURL GMFF performed one PT round (GMFF-20/01) involving two test items, each containing a single GM maize event. The test items were processed and characterised at JRC-Geel amid the COVID-19 pandemic. Sixty-one NRLs and official control laboratories (OCLs) participated to this round. The laboratory performance was evaluated by *z* scores (MON88017 in bird feed balls) or *z'* scores (GA21 in maize flour), as well as zeta scores and regarding the reported measurement uncertainties. A total of 74 % and 95 % of the reported results for MON88017 and GA21, respectively, were considered satisfactory. Four unsatisfactory scores had to be attributed. The compliance statements provided for both test materials were good overall. Regarding the event GA21, many laboratories used the CRM ERM-BF414 instead of the official CRM from AOCS and therefore underestimated the GA21 content. It was reminded that the choice of the calibrant is affecting the result of the analysis and would invalidate its legal value. It was suggested retrieving information on official CRMs from the DG SANTE GMO Register at https://ec.europa.eu/food/plant/gmo/eu_register_en. The next PT round will probably be launched in early January 2021 and will consist of meat pâté and rapeseed flour.

Follow-up discussion

The participants did not comment on the presentations.

4. Update from DG SANTE

DG SANTE explained that their past activities covered mainly seed testing, verification of CRM quality, CJEU ruling & Council request on new genomic techniques and GM presence in feed additives.

Seed testing:

The Member States requested in a meeting of the Regulatory Committee 2001/18/EC a further convergence on seed testing for the detection of adventitious GMO presence. A technical WG, established for the purpose, submitted a questionnaire in 2018 and convened in four meetings during 2019. A seed-testing document has been endorsed during a meeting of the Regulatory Committee of Directive 2001/18/EC on the 4th of June 2020. The document is now available on the website of DG SANTE at https://ec.europa.eu/food/sites/food/files/plant/docs/reg-com_2001-18-ec_20200604_result_seed-testing-convergence.pdf and will be annexed to the minutes of the meeting once they are approved.

CRMs:

A systematic check of CRMs has been implemented by the EURL GMFF. According to the new procedure, EFSA publishes its opinion on the authorisation of a GM event only after the EURL GMFF has confirmed the availability and satisfactory status of the CRMs provided by the applicant. Applicants are responsible for providing CRMs of all single lines of a stack event. For applications having already a published EFSA opinion, the EURL GMFF requests the CRM from the applicant and verifies its appropriateness. DG SANTE noted that the quality of CRMs has been improving but that the workload for the EURL GMFF is higher than expected. During the EURL/EuropaBio meeting it was requested to inform the EURL GMFF on the release of new CRM batches. DG SANTE acknowledged that the verification work had been slowed down by the COVID-19 pandemic.

CJEU ruling & ongoing study:

According to the CJEU ruling, GMOs produced from new breeding techniques (NBT) are not exempted from provisions of the EU legislation on GMOs. The Council requested the Commission to perform a study for clarifying issues regarding new genomic techniques. The study is ongoing. The Commission launched also a targeted consultation of MS Competent Authorities (CA) and affected stockholders (STHs) at EU level. DG SANTE is analysing the replies received and noted that the views of the participants are polarised, especially on benefits, safety and ethical aspects of the technology.

GM presence in additives/enzymes:

Since 2014 different notifications have been received by the Rapid Alert System for Food and Feed (RASFF) on cases of GM contamination in feed and food additives/enzymes (i.e. choline chloride, vitamin B_2 and enzymes). The findings have been discussed in several meetings of the Standing Committee on Plants, Animals, Food and Feed (SC PAFF Committee).

DG SANTE reminded that any product containing unauthorised GMOs (except those falling under Reg .611/2011) is non-compliant with EU legislation and asked MS to enforce this rule appropriately.

It was reported that the method developed by the Belgian authorities for the detection of an α-amylase fragment was considered reliable following a EURL GMFF evaluation.

DG SANTE reminded MSs to provide experts for the ENGL WG on GMM detection and encouraged

supporting the work of the EURL GMFF.

Follow-up discussion

A representative from Italy expressed appreciation for the huge work performed on CRMs and underlined that it increases the quality of this important element of the analysis.

DG SANTE recommended using the correct official CRM as indicated in the legal decision.

The Chair added that the table with conversion factors published on the EURL GMFF website includes only CRMs legally endorsed.

5. Pre-spotted plates (JRC)

A representative of the JRC explained that the pre-spotted plates (PSPs) developed by the JRC are plastic plates preloaded with dry primers and probes for performing multi-target GMO analysis. They allow performing up to 96 assays in a single experiment, with limited steps and human intervention. He informed that a multi-target plasmid, also developed by the JRC, could be used as a control sample in the analysis and that the PSPs have been updated with newly authorised GMOs. The plates are compatible with a number of PCR instruments. For the laboratories interested in receiving the plates the JRC has prepared a material transfer agreement (MTA) and arrangements for distribution. The speaker remarked that this is a new agreement and that the authorised users are National Reference Laboratories (NRLs) and laboratories performing official control on GM food and feed. The use and distribution of the plates will have a nominal cost per package to recuperate the administrative and production expenses. It was suggested that nominal costs to cover production, testing, administration and delivery would be in the region of 100 to 130 euro per plate. For logistic reasons, the PSPs will be distributed in packages of five items per type.

Both PSPs and control plasmids will be provided without warranty, however, quality controls will be performed before distribution. The JRC will survey the laboratories for tailoring the manufacturing of the plates to the laboratory needs and will organise a distribution campaign once a year. If a laboratory needs PSPs for a specific PCR instrument, the JRC can verify if a different plastic support could be made available by the manufacturer.

The JRC will initially distribute PSPs for screening and for detection and identification of GM events in maize and soya. The methods are those included in the GMOMETHODS database and cover GM events listed in the DG SANTE GMO Register. Reagents for the detection of events not mentioned in that Register will be removed from the plates.

In the following weeks the EURL GMFF will informally collect from interested parties the number of PSPs to be ordered and the contacts. Interested laboratories will need to sign a MTA. Each laboratory will place its final order on a link that will be made available on the JRC CRM website. The JRC unit already providing CRMs will finally start the distribution campaign. The speaker thanked all colleagues and JRC units involved in the finalisation of the complex process.

Follow-up discussion

The speaker clarified that the plates are stable for one year from the date of manufacturing and at room temperature, but suggested to store them at -20 °C.

A representative from the Netherlands requested information on how to use the PSPs under accreditation. It was remarked that the laboratories had already received a validation report, which was covering the LOD and the performance of the primers and probes included on the plates. The performance of the PSPs could be verified using control samples. The Chair recommended verifying the requirements with their own accreditation body and sharing their request over the network to overcome a lack of EU harmonisation in the accreditation approaches.

A representative from Poland suggested to recommend the methods employed on the PSPs (rather than other validated methods for the same targets) to improve the harmonisation of the screening approaches. The speaker suggested using the JRC GMO-Matrix section dedicated to the pre-spotted plates to review the methods used on the plates. The Chair finally underlined that the JRC does not want to promote one method over the others.

6. Questions & Answers

The participants did not have further questions.

7. Tour de table: issues/opinions/training needs from NRLs

The Chair requested to present two-three slides by each NRL to report on the professional experience during the COVID-19 pandemic as well as the issues/training needs of the laboratory.

In the following presentations, some laboratories reported that they had to stop their activities during the months of March-April 2020; the majority partially reduced them while only a few, from less affected MS, continued their normal function. Most laboratories noticed a reduction of analytical samples obtained during the peak of the COVID-19 pandemic. After an initial period, most laboratories implemented new safety and social distancing measures and teleworking for the other employees. In many cases, the MS laboratories started testing samples for coronavirus presence or initiated new related projects (i.e. testing bacteria filtration efficiency of medical facemasks or detecting a coronavirus presence in wastewaters). The majority resumed their full GMO analytical capacity in June or during the summer. Some participants were able to extend their accreditation online or to participate to PT testing. Many experienced shortages of reagents and PCR plates.

The participants expressed interest in following trainings on NGS and bioinformatics, detection of GMM in feed and food additives/enzymes, accreditation of digital PCR methods, screening of GMOs, use of GMO web tools, detection of genome-edited plants, estimation of measurement uncertainty and on DNA extraction problems. The Chair remarked that the detection of genome-edited products or GMMs in food and feed is currently not at a development level where training could be offered.

Some participants reported on the detection of non-labelled GM soya products in feed, others of non-compliant food and feed enzymes.

A representative from Germany requested if methods for GM events under authorisation renewal were verified for fulfilling the latest method performance requirements. The Chair reported that a procedure for verifying those methods is in the process of being set up together with EFSA and DG SANTE. He acknowledged the difficulty in retrospectively evaluating methods for which the events had been granted re-authorisation. DG SANTE informed that a procedure similar to the one established for CRMs could be envisaged, but that discussions on a regulatory procedure are still ongoing.

8. Outlook 2021 (EURL GMFF)

The Chair commented that quite an impressive number of activities has been collected from the participants and that many participants proposed solutions and performed COVID-19 testing to address the pandemic emergency. He invited a JRC colleague to present a brief outlook on the EURL GMFF activities planned for 2021.

The speaker commented that a new administrative arrangement (AA) with DG SANTE for the period 2021-2022 has been prepared and is awaiting approval. He expected that most of the present EURL GMFF activities would be continued in the following years.

He informed that a collaborative trial on the detection of maize MON810 by a digital PCR method, put on hold by the COVID-19 pandemic, would resume in 2021. Two proficiency tests are planned

to be organised in 2021, the first likely to be announced in early January (on a frozen meat product) and the second in spring. He mentioned that PSPs would soon be available for ordering. Other expected activities concern input into the discussion on the detection of products from genome editing, the verification of CRMs and the update of the related table on conversion factors. The expansion of the MPR guidance and other ENGL documents are also awaiting completion.

The organisation of on-site events will depend on the further developments regarding the coronavirus crisis.

9. AOB and conclusions

The Chair asked to provide suggestions and input by e-mail to the Secretariat. He thanked the participants for their contributions and closed the meeting.