



Report of the

17th WORKSHOP OF GMO NRLs

18 November 2021



**The European Commission's
science and knowledge service**

Joint Research Centre

17th Workshop of the GMO NRLs

18 November 2021



1 Welcome, approval of the agenda

The Chair welcomed the participants and informed to be chairing the meeting as acting Unit Head. He announced that as of 1 December 2021 Mrs Vincent Ursula will be the new Head of the Food and Feed Compliance Unit. The Chair provided some technical instructions on the on-line format of the meeting. The Agenda was approved without modifications (Annex 1).

2 Approval of the 16th Workshop report

The report of the last meeting was adopted without modifications.

3 Report on EURL GMFF activities

The JRC presented the activities of the EURL GMFF in 2021 and the results of the proficiency tests (PTs).

- The speaker announced the revamping of the EURL GMFF website and briefly illustrated its new features.
- He listed the GMOs for which in 2021 the methods were validated and the new plasmid control samples produced and provided to the NRLs. The EURL GMFF considered three methods submitted by the applicants to be not compliant to the minimum requirements and as a result, their validation has been delayed. The EURL GMFF evaluated two methods provided by Sciensano for detection of unauthorised genetically modified microorganisms (GMM) containing the protease 1 gene and published the related protocols on its website.
- A report with screening proposals for identifying all GMOs authorised in the EU has been published on the EURL GMFF website. The proposals are based on *in silico* analysis and are additionally offered on the GMO-Matrix interface.
- The appropriateness check procedure for Certified Reference Materials (CRMs) has triggered a marked improvement in their quality. The workflow has been upgraded to better define the roles of EFSA, DG SANTE and the EURL GMFF. A dedicated functional e-mail box (EURL-GMFF-CRM@ec.europa.eu) has been activated where applicants are required to communicate to the EURL GMFF the CRM code and name of the producer, while a clock has been implemented for stopping the authorisation procedure when the CRMs are not sent to the EURL GMFF for the appropriateness tests.
- A new article was published in "Food Control" on the challenges of expressing GM content in mass fractions from digital PCR data. The EURL GMFF has updated the list of conversion factors (CF) for 17 CRMs batches and updated the Application Note v1.0. Since different batches of the same genomic DNA CRM did not present significantly different results, and the analyses are costly and time consuming, the EURL GMFF will verify from now on only one DNA CRM batch per GMO.
- The EURL GMFF has published a report on "NGTs: State of the art review" as part of a larger Commission study on New Genomic Techniques (NGTs) and experimentally evaluated, in collaboration with the German NRL, the method for detection of Cibus canola. The latter results will be presented at the ENGL meeting. In-house research is being pursued for detecting small sequence variations in GM organisms generated by NGTs. The ENGL WG MPR2 has almost finalised the updating of the Minimum Performance Requirement (MPR)

document including recommendations for methods targeting short DNA alterations.

- The results of the two PT rounds organised in 2021 were presented and discussed. In the first PT (GMFF-21/01), the EURL GMFF faced some difficulties in the preparation of the T1 sample constituted of rapeseed meal containing oilseed rape event MON88302. Since the material was found to be not homogenous, the performance of the laboratories to identify the GM event was evaluated, but no z scores were calculated. The T2 sample consisted of mixed seeds powder spiked with soybean event MON87701. Almost all laboratories (95%) obtained z values lower or equal to two. The compliance statement, however, was correctly expressed only by 69 % of the participants. The speaker explained that samples with reported values - minus the reported expanded measurement uncertainty - that are equal or higher than 0.9 % should be classified as non-compliant and that compliance has to be assessed either under Regulation (EC) No 1829/2003 or, for feed, under Regulation (EU) No 619/2011, but not under both.
- In the second PT (GMFF-21/02), a feasibility study was performed on the meat pate sample (T1) since it was the first time that an animal based material was used in a PT study. The EURL GMFF mixed the pate with soybean containing 1.5 % (m/m) of GM event MON89788. By optimising both the extraction method and the PCR method, using either ddPCR or hot-start polymerase, results were obtained that confirmed the nominal value of 1.5 %. The conclusion is that the validated method is not fit for purpose on this material and that the method needs to be modified to eliminate the effect of PCR inhibitors. Overall, almost all results reported would be considered acceptable when scored with z scores; however, it was announced to attribute percentage difference scores instead of performance scores. The T2 sample consisted of T25 maize spiked into non-GM maize powder. Most of the analyses resulted to be close to the assigned values but surprisingly, some of the participants (15) reported much higher values. The speaker asked whether the laboratories could explain such unexpected results.
- The JRC summarised the results of a survey on possible training topics previously performed for understanding the NRLs interests. Twenty-eight out of thirty-sevens NRLs (75 %) from eighteen Member States (MS) responded to the survey. They indicated high interest for subjects such as next generation sequencing (NGS), bioinformatics, detection of GMM and screening approaches. These suggestions will be evaluated and possible training subjects and dates will be communicated.

Questions

A laboratory from Austria commented that for the pate sample the laboratories could not know the content of the sample and therefore establish the best method for the DNA extraction. He enquired whether a correlation could be observed between the results and the taxon reference method used in the analysis. A laboratory from Belgium suggested that a non-optimal calibration curve could explain a high dispersion of the values.

The JRC acknowledged that the EURL GMFF itself had difficulties in evaluating the inhibition tests because of the low quantity of GM DNA present in the sample but remarked that the participants performed well nonetheless. He commented that laboratories should not report values deriving from non-optimal calibration curves and that, for T2, the results should be based on the official CRM which is a homozygous material. The EURL GMFF will evaluate if the results correlate with the reference gene used in the analysis. Several participants indicated their interest in knowing their z score also for the pate sample.

4 Update from SANTE

SANTE summarised the main points of the presentation, which included the NGTs study, the presence of GMM in feed additives (FA) / enzymes and the Transparency Regulation.

NGTs study

NGTs have been defined as techniques that are capable of altering the genetic material of an organism and that have been developed since 2001, when the current GMO legislation was adopted. The study covered the use of NGTs in plants, animals, and microorganisms in a broad variety of potential applications, including the agri-food, medicinal and industrial sectors. It describes the rapid technological developments of the last two decades, the interest in NGT research, their potential benefits and concerns, possible risks and environmental impact. The study has been finalised and published in April 2021. It concluded that the EU legislation on GMOs provides implementation challenges and legal uncertainties and is not fit for purpose for some NGT products. The current risk assessment procedures cannot be easily adapted to scientific progress and different regulatory oversights cannot be justifiably applied to products having similar risk levels.

As possible follow-up actions, SANTE mentioned adaption to ensure a resilient, future-proof and uniformly applied legislation. The Commission initiated a policy action on plants derived from targeted mutagenesis and cis-genesis. For other organisms and other NGTs, the Commission will continue to build up knowledge, while use of NGTs in medicinal products will be addressed in the Commission's Pharmaceutical Strategy. The Commission performed an impact assessment on these actions including public consultations where it received over 70000 contributions.

SANTE announced that a high-level on-line event on modern biotechnologies in agriculture will be organised on 29 November 2021 with external speakers from different sectors. SANTE informed that the registration to the event was open until 24 November and invited the participants to register.

GMM presence in FA /enzymes

SANTE reported that traces of DNA of unauthorised GMOs has been observed in food and feed ingredients resulting from fermentation. These findings have been addressed with MSs during SC PAFF on 20 September 2021, revealing diverging views between MSs. The discussion is ongoing.

Transparency Regulation

Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain is applicable from 27 March 2021. The Regulation aims at increased transparency, reliability and independence of studies, better governance and more effective risk communication. It provides for automatic free public access to all studies submitted by the industry during risk assessment processes. The applicants have to justify the confidentiality of the information and notify the studies planning to perform.

Questions

Many participants expressed concern on the recent findings in the EU market of live GMM in FA and enzymes and on the detection of antibiotic resistance genes or other GMM enzyme sequences in food and feed samples. A participant from Belgium informed having found live GMM, in a pilot monitoring study, in 15 % of the samples and detected fragments of DNA larger than 600bp in one third of the samples. They also discovered that labelling does not often correspond to the real content, even in products for food intake. It was remarked that, because of confidentiality, it is not possible to verify if the detected genes are derived from a GMO described in an EFSA dossier and stressed the importance of taking measures at all levels. The speaker finally informed that the results of the pilot study will be publically available.

SANTE acknowledged the seriousness of the problem, the lack of transparency in the sector, and the difficulties related to the implementation of a zero tolerance approach.

5 Results of the survey on GMO enforcement analyses in the EU (JRC)

The JRC presented the results of a survey performed in June-July 2021 with GMO Official Control Laboratories (OCLs) for understanding their relationship with Competent Authorities, collect information on the number and type of official controls and on the GMO presence detected in control samples. Sixty laboratories from 22 MSs, representing 75 % of all NRLs, participated to the survey. The outcome of the survey indicated that samples may be received by many different

authorities, the number of food samples analysed are twice the number of feed samples and these numbers vary widely between MS. Roughly half of the laboratories have not detected any GM event in the samples analysed in the past two years. A few GM events, mostly old GMOs, are mostly detected in the food and feed samples taken on the EU market.

6 Questions & Answers

Reporting on the PSP distribution campaign.

The EURL GMFF reported that twenty NRLs and OCLs requested the JRC Pre-Spotted-Plates (PSPs) and announced that a second campaign will be prepared in 2022.

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

Almost all NRLs resumed in 2021 their normal activities. Many participated to the PTs offered by the EURL GMFF; some organised PTs, workshops and trainings for their network of national OCLs and expanded their activities to allergens, GMM, microorganisms, Covid-19 detection or food authenticity testing. Many laboratories have already, or are planning to acquire, a ddPCR instrument or implementing ddPCR methods for GMO detection and expressed therefore interest on training for this technology. A significant number of NRL communicated interested in NGS applications for GMO analyses and few have already purchased an instrument for that purpose. The NRL from Belgium offered to provide its expertise for a training on NGS and bioinformatics analyses. Laboratories from Belgium, Austria and Germany organised workshops and/or participated in research projects for detection of NGT products. Many NRLs have used the JRC PSPs and expressed satisfaction for their performance, time and cost of the analyses. More than half of the laboratories did not detect GMOs in their samples or detected them at a very low level (below the LOQ), especially in animal feed and soybean meals samples. Some NRLs expanded their accreditation status. A laboratory from France informed that non-authorized ornamental fish were found on the EU market.

8 Outlook 2022 (EURL GMFF)

The JRC informed that the next PT would be announced on the EURL GMFF website at the beginning of 2022. The test items will be distributed in May 2022.

The speaker thanked the participants for their feedback on their training needs. The EURL GMFF will evaluate the proposals and communicate topics and dates of the training in few weeks. The speaker noted that quite few laboratories had purchased a ddPCR instrument. He informed that a ddPCR method has been already submitted to a collaborative study and that the MPR2 document, including recommendations for ddPCR methods, will be finalised soon. He also informed that a new application regarding GM yeast has been submitted for EU authorisation. He enquired whether a half-day format for the meeting is too short for in-depth discussions and informed that the next NRLs workshop is planned for the end of September/early October 2022. A participant from the Netherlands suggested a full day meeting to exchange more information.

9 AOB and conclusions

The Chair thanked the participants for sharing their progress in the field and DG SANTE for its policy update. The EURL GMFF will evaluate whether allocating an entire day for the following meeting to allow more time for discussions.

Annex 1 – Agenda

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AP	Time	Topic	Documents/comments
1	9:00	▪ Welcome, approval of the agenda	Agenda
2		▪ Approval of the 16th Workshop report	Report
3		▪ Report on EURL GMFF activities	Presentation
4		▪ Update from SANTE	Presentation
5		▪ Results of the survey on GMO enforcement analyses in the EU (JRC)	Presentation
6		▪ Questions & Answers	
	10:30	<i>Break</i>	
7	11:00	▪ Tour de table: issues/opinions/training needs from NRLs	
8		▪ Outlook 2022 (EURL GMFF)	
9		▪ AOB and conclusions	
	12:30	<i>End of meeting</i>	