

# Report

# 45<sup>th</sup> ENGL Steering Committee meeting

Report 20 June 2023

> Joint Research Centre

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### Report

1. Welcome, apologies, quorum

The Chair welcomed the participants.

2. Approval of the agenda

The Agenda (Annex 1) was approved without modifications.

3. Review of Dynamic Action List (DAL SC44)

The Secretary informed that the report from the previous steering committee (SC) meeting required some clarifications with a member state (MS) and would be available soon. The Secretary reviewed the points of the action list and the activities of the working groups (WGs) of the European Network of GMO Laboratories (ENGL).

The representative from Germany requested if the topic regarding the production of Certified Reference Material (CRM) by the JRC would be addressed during the meeting. The Chair clarified that the issue is not in the agenda and it could be dealt with under the agenda point Any Other Business.

#### 4. Update from SANTE

NGT

SANTE informed that the new genomic techniques (NGT) proposal would be finalised by early July 2023.

#### GMM fermentation aspects

SANTE organised two working group meetings with MSs on fermentation products with genetically modified microorganisms (GMM) where it discussed the interpretation for GMM DNA presence and the related risk assessment (RA) aspects. After the second meeting, SANTE received 14 contributions on RA from MSs, which are currently being discussed with the European Food Safety Authority (EFSA). SANTE will further consult Commission colleagues responsible for other products obtained through GMM fermentation (food additives, feed additives, novel foods). The next WG meetings will focus on RA and enforcement. Finally, it could be useful to clarify to applicants under which legislation they need to apply for their products.

The representative from Germany requested a legal clarification on products containing GMM DNA.

SANTE explained that products containing non-authorised GMOs are not compliant while products containing recombinant DNA originating from a GMM that is used as processing aid would be compliant. It further clarified that the legal interpretation concerns use of GMM as processing aids while fermentation products in which the GMM are not removed are considered as food or feed falling under Regulation (EC) No 1829/2003. The resulting fermentation products in any case always require an application for authorisation, be it as GM food/feed, as food and/or feed

additives, or as novel food. SANTE considers it might be useful in a later stage to clarify the different routes and enforcement on its website.

Many participants commented SANTE presentation. Some remarked that the legal interpretation was covering only processing aids and no other fermentation products such as food additives. The representative from Belgium expressed some safety concerns. She remarked that enforcement laboratories could not verify if the products present in the EU market are those described in the authorisation since the information included in the dossier is confidential. In addition, they cannot measure concentrations of DNA in the final product in terms of ug/uL as indicated by EFSA for RA. She further underlined that some of these products arrive directly in the digestive system of consumers. SANTE agreed on the safety concerns and reminded that the concerns of the MSs on RA would be addressed in the next meeting of the WG. Finally, all involved units of the Commission will discuss internally to ensure that the GMM fermentation products reaching the consumer are safe and properly enforced.

#### 5. Progress ENGL working groups

#### 5.1 AG SMV (Advisory Group on Selection of Methods for Validation)

The group discussed analytical gaps in GMO detection and new submitted methods, particularly an endogenous reference system for potato that is currently being tested on different varieties by the JRC. The gap analysis performed on GMOs under development identified a limited increase in events not containing screening markers. The group reviewed a list of reference methods for detecting GMOs grouped by crop species and related performances, which was previously compiled by the EURL GMFF, and decided to make it available as a JRC technical report. The group requested volunteers from the ENGL for drafting the document. The group also decided to provide to ENGL the list of methods previously collected for detecting reference genes in GM animals. The selected methods are in line, to a certain extent, with the ENGL method performance requirements (MPR).

The representative from Netherlands requested whether the group would perform a survey on favoured reference methods for GM animals. He also requested clarification on methods for detecting poultry. A JRC representative reminded that the CRM conversion factors for transforming DNA copy number in mass fractions are determined using only one reference gene method per species and suggested using the same method for obtaining comparable results. The representative from Italy noted that many working groups (WG) were addressing this topic and suggested sharing the workload to avoid duplication of efforts.

#### 5.2 WG-seq (good practice/quality of DNA sequencing data)

The chair of the WG reported that the final version of the document on next generation sequencing (NGS) strategies for GMO identification has been sent to the ENGL members and that the feedback received has been reviewed and discussed in a meeting organised in May 2023. The JRC is working on the last edits. The group is planning to send the document to the SC in July 2023 and publish it between September and November 2023. The report provides important information on performance criteria for the experimental design of the sequencing and bioinformatics analysis and includes study cases to illustrate the parameters described. Curated databases and harmonisation are essential for this type of analysis. The speaker thanked the previous chair of the group and all members for reviewing the report and suggested presenting it at the ENGL plenary. She further proposed publishing the work as an additional peer review article. A JRC representative supported the suggestion and ensured to follow it up by e-mail.

#### 5.3 WG-DNAex (DNA extraction)

The chair reported that the document has been distributed within the working group and that the comments have been combined, discussed and reviewed. The document will be sent to the ENGL Secretary and then to the ENGL members.

The Secretary acknowledged the successful completion of the deliverable and suggested presenting the document at the next ENGL meeting.

5.4 WG-GMM (Detection of genetically modified microorganisms in food and feed)

The Secretary requested whether the work on methods for detecting GMMs in food and feed should be continued or suspended. Some participants proposed revising the document by excluding references to the EU legislation and focusing on the technical details of DNA detection. Others remarked that, as for the ENGL report on NGTs, the WG could provide an official technical opinion supporting a decision at political level. The chair of the WG underlined that the criteria for the analyses depend on the monitoring required for the products and that a clarification is needed from the Commission for their definition. SANTE suggested waiting for a legal interpretation before resuming the work on the document. A JRC representative suggested requesting a new mandate for the WG. The SC decided to wait the outcome of discussions between MS, expected in autumn 2023.

#### 5.5 WG-NMT (New Mutagenesis Techniques)

The chair summarised the content of the report "Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis", which was finalised by the WG and recently published on the EURL GMFF web site. The report is based on recent publications and aims at harmonising the terminology with other official documents. It covers different types of products resulting from targeted mutagenesis and cisgenesis and the challenges of developing corresponding detection methods. The report concludes that some of the published methods seem to meet the ENGL MPR but that it is not always possible to establish if a sequence variation is the result of a natural mutation or a mutation generated by conventional mutagenesis or targeted mutagenesis techniques. These new products pose also new challenges for establishing screening approaches, which need to include event-specific methods for each endogenous mutation present in the NGT variant. Next-generation sequencing (NGS) strategies could be applied for detecting NGT products from microorganisms, but less easily from plants. The speaker thanked all WG members for their input and acknowledged the JRC for its outstanding contribution. The WG modified its mandate to include microorganisms and animals and is evaluating if the report could be extended to cover them. The WG needs to complete two other deliverables: the first is a survey on research activities by ENGL members on organisms generated by NGTs; the second is the integration of information from databases on NGT products. The members concluded that such a database would be welcomed by enforcement laboratories.

#### 6. Preparation ENGL Annual Meeting 2023/NRL training/NRL workshop

#### Preparation ENGL Annual Meeting 2023

The Secretary summarised the topics suggested at the previous SC meeting for the upcoming ENGL plenary. The list covered the following subjects:

- Update on GM animals and on GM insects used as food and feed;
- Detection of GMOs for bioterrorism;
- Quantification of GM botanical impurities in food and feed;
- Research activities on plants produced by NGTs;
- Presentations of the new documents drafted by the ENGL WGs on NGTs, DNA extraction and DNA sequencing;
- Project proposal selected under Horizon 2021-2024;
- Update from DG SANTE on the NGTs legal initiative.

The Secretary requested additional ideas or comments. The participants proposed discussing at the meeting the Commission proposal on NGTs and suggested conducting a survey for uncovering the problems faced by the laboratories. A JRC representative asked for an update on the Cibus canola method while a representative from Germany offered presenting work from its network on

detection methods for other NGT products. The participants suggested clarifying the legislation for quantification of GMOs in botanical impurities and the labelling of organic food products. SANTE offered to provide a legal overview on botanical impurities. The Secretary requested suggestions on suitable speakers for GM insects and enquired whether in the fall would be known which projects have been awarded the EU's funding programme Horizon 2021-2024 for research and innovation.

#### NRL training/NRL workshop

The JRC informed that at the last workshop the NRLs expressed interest in repeating the training on NGS and bioinformatics analysis. He underlined that the training workshop received a very positive feedback. The representative from Belgium will verify the logistics, the availability of laboratory staff and interest of other ENGL members for organising the training. NRLs would be contacted to gauge interest in participation.

#### 7. New activities

The Secretary presented the new proposal for the mandate of the WG on GM animals. It requires drafting a report on challenges in GM animal's detection, including screening strategies, endogenous targets, databases and matrix DNA extraction, excluding animals derived from NGT and ornamental fish. The first meeting should be held in September 2023 while the report should be completed by the end of 2024. The Secretary reminded that the SC can accept external experts in the WG.

The representative from the Netherlands expressed interest in defining species for certain ingredients (poultry) reported on the labels and in using the same endogenous reference gene for all analyses of the same species. He further suggested providing in the MPR document a list of preferred reference genes per species to harmonize the analytical approaches in MSs. He finally volunteered to join the group. The representative from Italy suggested reflecting on the concept of taxon that would be more suitable for the implementation of the GMO legal framework.

The WG AGSMV made available a list of articles on detection of animal species. The representative from Denmark suggested aligning the methods to the ISO standards already available on animal species identification. The participants approved the mandate.

The Secretary reminded that applicants might use any method for detecting a certain species as long as it complies with the ENGL MPR. He will submit a formal call by e-mail to invite experts joining the group.

#### 8. AOB

The representative from Slovenia requested some clarification on the interpretation of results for events as oilseed rape LBFLFK, carrying two inserts possibly segregating in the F1 progeny, each with a validated event-specific method.

Some members argued that if both methods are used, a successful amplification with only one method is sufficient for declaring the sample as positive. Other participants were uncertain whether segregating single lines resulting positive for only one of the two-event-specific methods could be considered compliant. The representative from Portugal remarked that the oilseed rape LBFLFK event is homozygous for both transgenic insertions and that all progeny lines should be positives to both methods.

The representative from Germany raised some concerns over the possible suspension of CRMs production by the JRC and its impact on laboratories work and harmonisation. He expressed the appreciation of the German network for the quality of the JRC CRMs.

The Secretary reminded that the EURL GMFF is responsible for the appropriateness check of CRMs, not for their production. The Chair thanked for the positive remarks and clarified that the JRC is facing a reduction of resources. She added that discussions are ongoing for finding a solution.

The Chair finally thanked all participants for their contribution and closed the meeting.

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	Time	Topic	Documents In CIRCABC
1	9:00	<ul> <li>Welcome, apologies, quorum</li> </ul>	
2		<ul> <li>Approval of the agenda</li> </ul>	Draft agenda
3		<ul> <li>Review of Dynamic Action List (DAL SC44)</li> </ul>	DAL SC44
4		Update from SANTE	
	10:00	Break	
5	10:30	Progress ENGL working groups	
5.1		<ul> <li>AG SMV (Advisory Group on Selection of Methods for Validation)</li> </ul>	Progress reports
5.3		<ul> <li>WG-seq (good practice/quality of DNA sequencing data)</li> </ul>	
		<ul> <li>WG-DNAex (DNA extraction)</li> </ul>	
5.4		<ul> <li>WG-GMM (Detection of genetically modified microorganisms in food and feed)</li> </ul>	
5.5		<ul> <li>WG-NMT (New Mutagenesis Techniques)</li> </ul>	
	12:00	Break	
6	14:00	<ul> <li>Preparation ENGL Annual Meeting 2023/NRL training/NRL workshop</li> </ul>	
7	15:00	New activities	
8		- AOB	
	16:00	End of meeting	

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