Report

44th ENGL Steering Committee meeting

Online meeting

9 March 2023

Joint
Research
Centre

REPORT

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1. Welcome, apologies, quorum

The Chair welcomed the thirty-three participants noting that the quorum for conducting the meeting was reached.

2. Approval of the Agenda

The Agenda (Annex 1) was approved without modifications.

3. Review of Dynamic Action List (DAL SC43)

The Secretary reported that all points of the Dynamic Action list have been addressed and completed. He informed that the Advisory Group on Selection of Methods for Validation (WG-AGSMV) will organise a meeting in the following two weeks.

4. Update from SANTE

The update regarded the new genomic techniques (NGT) policy initiative and the implementation of legislation on genetically modified microorganisms (GMM) fermentation products in the MSs.

NGT policy initiative

SANTE informed that the public consultation on NGT products received from the MSs more than 2000 replies, which are being analysed with the support of an external contractor. The impact assessment is progressing and is following the better regulation principles. The JRC analysed some case studies while the European Food Safety Authority (EFSA) is addressing the risk assessment component. The legislative proposal is on track and expected by June 2023.

GMM fermentation products

Since the enforcement of GMM fermentation products is not harmonised between MSs, the Commission must intervene to guarantee a level playing field in the European Union (EU) market. SANTE launched working group meetings and prepared a room document exploring an option for a harmonised approach. The first two meetings of the working group focused on legal aspects and risk assessment. SANTE intends to widen the discussion to include food additives, novel foods, and feed aspects in the discussion at a later stage, and plans to invite EFSA to the third meeting to explain in more detail how risk assessment of GMM fermentation products is performed. The intent is to reach a consensus on the issue and proceed.

Questions

A representative from Italy expressed concern on the enforcement of a proposal applying the concept of technical unavoidable and adventitious contamination without a set threshold. In that case, it would be very difficult to imagine a uniform application of the decision at the EU level. Furthermore, the representative considered that the safety limit of 10 ng/g set by EFSA is related to the risk evaluation not to the detection. Furthermore, a method is not available to laboratories for performing official controls. A participant from Belgium expressed the same opinion and proposed a threshold as for the so-called LLP: **Low Level Presence Regulation** (Regulation (EU) No 619/2011) on GM feed. She remarked that the products described in the EFSA documentation are not the ones found on the market and underlined that the antibiotic resistant genes are in the top list components to be avoided in food. She finally recommended a harmonised approach for risk assessment.

SANTE explained that the discussions with MSs are ongoing but that it is premature to state that these would lead to a specific limit value for recombinant DNA in GMM products. In a context of regulated

products, commercialized products need to reflect the corresponding pre-market authorisation.

Regarding GMM, the representative of Germany raised the question about the Commission (legal) view and to what extend such a position can be legally binding for enforcement laboratories. The representative of DG SANTE first explained that at present there is no harmonised approach within MS and that the Commission therefore has to act. He pointed to a Commission/MS WG (50-60 members) on the issue. At its 1st WG meeting the Commission put its (preliminary) view up to discussion which is that a GMM must not be contained in such products but that the mere DNA can be looked at as accidental and technically unavoidable and that such DNA poses no risk. The representative from Italy in the ENGL SC raised concerns about that position as accidental and technically unavoidable [Reg (EC) No 1829/2003] does not refer to non-approved GMO and GMO without a performed risk assessment and that the enforcement and testing of GMM is a difficult task. The representative from DG SANTE pointed out that there were numerous reactions from MS in the WG, among which there were also partly substantial concerns about the position of the Commission. He also explained that there will most likely be no new law on the issue but there will be additional meetings of the Commission/MS WG to find a common approach which then could be put into an annex of a Standing Committee protocol.

5. Progress ENGL working groups

5.1 WG-MPR (Minimum Performance Requirements)

The JRC informed that the final report of the working group (WG) has been approved by the European Network of GMO Laboratories (ENGL) and undergoing an internal revision. The document was expected to be published in few weeks (now it is available at JRC125975_01.pdf).

5.2 Mutagenesis techniques

The speaker presented the work of the group aiming at updating the ENGL report published in 2019 on detection of food and feed plant products generated by new mutagenesis techniques. The group focused on plant products obtained by targeted mutagenesis and cis-genesis. The speaker thanked the members for the fruitful discussions and for drafting the document in a very short time, only few months later than the expected deadline. The group indicated that the challenges are not resulting from the technology but from the genetic mutations or products. The analytical complexity and the different dimensions have also been evaluated against the new method performance requirements (MPR) part 2 document providing recommendations for the detection and quantification of organisms with short genomic alterations generated by NGTs. The WG document is now awaiting comments from the SC members.

The conclusions are similar to those elaborated in the previous report. Methods developed for detecting single nucleotide variations (SNVs) or short mutations may fail to meet the current MPR. It may be impossible to evaluate analytically whether a particular mutation has been produced by targeted or conventional mutagenesis. Screening assays cannot be applied to plants containing endogenous mutations, meaning that each food/feed product will need to be analysed by all event-specific detection methods validated for a certain species. Moreover, multi-edited plants will require validation of multiple detection methods, one for each genetic modification. It is feared that unknown, non-authorised plant products obtained by targeted mutagenesis may enter the food supply chains unnoticed. Traceability through analytical testing currently required by EU laws is not considered feasible for all products obtained by targeted mutagenesis or cisgenesis.

The speaker provided the timeline for the three deliverables included in the WG mandate:

Deliverable 1: a final version submitted to the ENGL Steering Committee (SC) and approved by the WG members is almost completed. A more elaborated report may be provided if necessary, by July 2023.

Deliverable 2: Information on laboratories research activities regarding detection of organisms developed by NGTs may be collected in a survey by September 2023.

Deliverable 3: integration of information including modified sequences and detection methods from existing databases on plant products obtained by targeted mutagenesis and cis-genesis (2024).

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

The chair mentioned that some members have left their respective jobs and consequently also the group and encouraged the participants in joining their activities. She informed that a gap analysis on GMO coverage was performed in 2022 by looking at the pipelines under worldwide development. A meeting is planned for the end of the month to discuss the results of the analysis and consider the validation of a dPCR (digital Polymerase Chain Reaction) method.

The Secretary asked the format on which the information on endogenous reference genes drafted by the JRC should be made available. Some participants wondered if the information deserved publication in a journal or should be shared on the ENGL internal network.

The JRC explained that the purpose of the work was to provide a list of reference genes for GMO analysis combined with the different experimental conditions. The information is mainly addressed to enforcement laboratories. A representative from Germany enquired on the provision of a list of recommended genes and remarked that experimental data and objective criteria could guide the ranking. A member from the Netherlands supported the publication of a guidance on reference genes to decrease the use of PCR protocols including different reagents and volumes for each species and to provide similar information for GM animals.

The speaker acknowledged the need for harmonising the use of reference methods for official control but explained that the group could not provide a ranking system for methods that have been generally considered fit for the purpose. After all, the laboratories could make their own conclusions based on the information provided. She reminded that a list of reference genes for animal species has been made available some years before at one of the ENGL meetings.

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

The speaker informed that the members agreed on the final draft of the document. The group is awaiting comments from the experts before deciding how to proceed. In response to major remarks, it could organise another meeting while for minor observations could reply directly to the reviewers. The speaker thanked all the members and acknowledged the difficulty in defining quality criteria for GMO sequencing analyses. The document covers several aspects and study cases, from library preparation to Sanger and massive parallel sequencing.

The Secretary suggested organising a meeting for addressing the last comments and then submitting the document for approval to the ENGL.

5.5 WG-DNAex (DNA extraction)

The chair of the WG informed that the document on DNA extraction was only missing the drafting of the executive summary, the acknowledgements and conclusion sections for submission to the ENGL and publication. He hoped that the document would meet the needs of the laboratories.

The Secretary acknowledged the huge work performed by the group and looked forward to the completion of the report.

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

The Secretary informed that the group is awaiting a legal position from SANTE to complete the drafting. He further reported that the documents of two WGs and the first deliverable of the WG-NGT will be published in 2023 which is a very good outcome.

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

The Secretary announced that the NRL workshop will be arranged for 26 September 2023 (full day) while the ENGL annual meeting will be organised on 27th (full day) and 28th (half-day) of September 2023. Both meetings will be offered in a hybrid format and at a location still to be decided.

He proposed inviting to the ENGL meeting one or two regional network representatives to know how other parts of the world are addressing the NGT issue. The selected region could cover Asian or South American networks depending on the timing of their last participation. The Secretary requested ideas on topics to be covered, work or publications to be presented or shared with ENGL members.

A representative from Poland suggested providing an update on GM animals and in particular on GM insects used as food or feed. The Secretary informed that the related companies already contacted were not interested in sharing information.

A representative from Belgium offered to present the work of her laboratory on GMM and bioterrorism

or on botanical impurities. In addition she could report on the research performed on plants produced by NGTs, on next generation sequencing (NGS) targeted approaches and dPCR assays. She further suggested communicating the work of the WG-seq which could be already published at the time of the ENGL meeting.

The Secretary proposed to present the documents prepared by the other WGs including the report drafted by the WG-NGT section 2. He requested submitting by e-mail to the SC members input or ideas on research work performed by non-ENGL laboratories. Once the topic had been identified, possible speakers could be invited to the meeting.

A representative from the Netherlands suggested covering quantification of GM botanical impurities in food and feed (i.e. how to quantify adventitious presence of GM soybean in mixed maize feed). A representative from Italy remarked that botanical impurities are tolerated in the EU market but may represent a problem when exporting a product in a third country not contemplating them. The Secretary suggested collecting the analytical difficulties of the laboratories in an EU survey and presenting them at the ENGL meeting to stimulate a discussion for a legal interpretation at Commission level. He will need support from the members to formulate the correct questions. A representative from Denmark informed that botanical impurities measurements are currently performed by microscopy analysis but that a NGS project in her laboratory is aiming at estimating their content by molecular biology assays. She further remarked that the topic is not supported and covered by any European Union Reference Laboratory (EURL) activity. SANTE ensured reporting the issue internally to find a possible solution. Any draft proposal will undergo a consultation with the EU Parliament, and it will be therefore difficult to predict the outcome.

A JRC representative enquired whether in September the proposals under the Horizon Europe Work Programme 2023-2024 for detection of NGT products will have been selected. The group that has been awarded a grant under the call could present the project at the meeting. Members involved in the call could inform the Secretary so that a possible presentation of the project could be considered.

A JRC representative informed that, as agreed at the last meeting, an EU survey will be launched to identify the training needs of the NRLs and the relevant topics to be discussed at the workshop. He will provide at the NRL workshop also an update on the T25 method and discuss testing needs and analytical gaps.

A representative from Poland suggested presenting a summary of research activities on detection of NGT products which is one of the deliverables of the WG-NGT. An update from SANTE on the issue would be also welcomed.

The Secretary requested submitting by e-mail possible additional ideas. These and the Agenda will be evaluated at the following SC meeting in June.

7. New activities

The Secretary reminded that at the end of 2018 the ENGL agreed to provide a report on challenges of detection of GM plants, GMM and GM animals (GMA) produced by NGTs. These reports are needed to support the policy initiatives. The first has been already published (and has now been revised), the one on GMM, which should be drafted by the WG-GMM, is not proceeding because it is awaiting legal definitions. The WG-GMM is covering in its mandate GMM produced by NGTs and conventional GMM. A similar mandate has been drafted for the WG-GMA. The ENGL should decide how to structure the work to produce these two additional reports on NGTs detection requested by SANTE.

SANTE confirmed that it was agreed to have a report on NGT plants first and then to address GMM and GMA produced by NGTs. The field is growing very fast and needs an informed decision.

A representative from Italy suggested a modular approach where a joint task force on NGT detection could benefit from the expertise of the WG-GMM and WG-GMA. The Chair proposed addressing immediately the package relating to NGT aspects, which is more urgent, and to decouple it from the activities of the WG-GMA and WG-GMM. The members that worked on the plant report could take the leadership on the NGT part of the GMM and GMA mandates.

The Secretary proposed amending the mandate of the WG-NGT to include these new tasks as a priority and requesting experts for addressing these two additional tasks. The WG-GMM will address the general aspects but still wait for a clear legal interpretation from the discussions with the MSs, while a new WG on GMA will be activated dealing with specificities not relating to NGTs. The mandate of the two WGs should be modified accordingly. The Secretary suggested referring to the plant report and addressing only the specificity and peculiarity of detection for GMM and GMA produced by NGTs.

SANTE clarified that the report should not concentrate on enforcement but rather on analytical challenges as in the plant document.

8. AOB

The representative of Slovenia requested how to report results from the LBFLFK oilseed rape event which may be positive for one locus and negative for the other.

The Secretary clarified that the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) has validated two methods for the two transgenic loci of the event, which are not genetically linked and therefore may segregate. A JRC representative advised using both methods in parallel.

A representative from Denmark informed reporting the results of this transgenic line as a stacked event if the analysis is positive for both loci and as offspring if positive for only one. A member from Italy remarked that divergent analytical results for the two methods should not be a problem since both loci are traceable with the two validated methods. In the Netherlands laboratories retrieving a positive result for only one loci of the event discuss the results with the competent authority.

The Secretary remarked that the GM percentages obtained with the two methods should be reported by the laboratory separately; the Competent Authority may decide whether summing-up the percentages considering the information that the two single lines may or may not exist separately. A JRC representative added that the respective certified reference material (CRM) contains both loci. The representative from Poland requested clarification on the quantification procedure. The Secretary reminded that the Commission provided a document on how to report results for quantification of stacked events (quantification per species or per ingredient) which was later posted in the chat by a JRC representative.

A member from the Netherlands informed that the German network has drafted a document on analysis of botanical impurities.

The Secretary announced that the next SC meeting will take place on 20 June 2023 as online meeting.

The Secretary and the Chair thanked the participants for the fruitful discussions and input.

Agenda

	Time	Topic	Documents in CIRCABC
1	9:00	▪ Welcome, apologies, quorum	
2		▪ Approval of the agenda	Draft agenda
3		▪ Review of Dynamic Action List (DAL SC43)	DAL SC43
4		▪ Update from SANTE	
	10:00	*Break*	
5	10:30	Progress ENGL working groups	
5.1		▪ WG-MPR (Minimum Performance Requirements)	Progress reports
5.2		▪ WG-NMT (New Mutagenesis Techniques)	
5.3		▪ AG SMV (Advisory Group on Selection of Methods for Validation)	
5.4		▪ WG-seq (good practice/quality of DNA sequencing data)	
5.5		▪ WG-DNAex (DNA extraction)	
5.6		▪ WG-GMM (Detection of genetically modified microorganisms in food and feed)	
	12:00	*Break*	
6	14:00	▪ Preparation ENGL Annual Meeting 2023/NRL training/NRL workshop	
7	15:00	• New activities	
8		▪ AOB	
	16:00	End of meeting	

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