European Commission

Summary report

41st ENGL Steering Committee Meeting

16 June 2021

The European Commission's science and knowledge service

Joint Research Centre

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1 Welcome, apologies, quorum

The Chair welcomed the participants and noted that the number of participants has reached the quorum established for the meeting.

2 Approval of the agenda

The Agenda (Annex 1) was approved without modifications.

3 Review of Dynamic Action List (DAL SC40)

The Secretary reviewed the open points of the list. He informed that the Advisory Group on Selection of Methods for Validation (WG AGSMV) is planning a meeting in June 2021. DG SANTE has reviewed the document submitted by the WG Update of Methods. The document on Minimum Performance Requirements is in its finalisation stage. The Secretary will work on preparing a document on terminology. The Chair informed that a CEN WG has been preparing an extensive guidance on terminology, which could be used as a reference for the ENGL document.

4 Update from SANTE

Study on the status of new genomic techniques under Union law

After the EU Court of Justice Judgement in case C-528/16, the Council requested the Commission to perform a study on the use of New Genomic Techniques (NGT) in plants, animals, and microorganisms covering the agri-food, medicinal and industrial sectors. The Council's request aimed at providing clarity on NGTs and to support further policy actions if needed. Given the limited time, the Commission decided to perform the study in-house with target consultations of stakeholders (Member States and organisations representing actors active in the food/feed chain). The Commission further included contributions from EFSA, ENGL, the group of scientific advisors, and requested the JRC to review the technology landscape as well as current and future market applications.

The speaker presented the main outcomes of the study. The term NGTs has been newly defined as technologies developed since 2001 that are capable of altering the genetic material of an organism. They are a diverse and rapidly evolving group of techniques, which can introduce limited to multiple or more extensive modifications. Respondents to the Commission's consultation expressed quite opposite views on the risks and benefits of NGT products. EFSA and Member States were not able to draw general conclusions on the safety of the whole range of NGTs, because they constitute a very diverse group of techniques. For instance, for targeted mutagenesis and cis-genesis in plants, EFSA concluded that they do not introduce new risks in comparison to conventional breeding techniques. Member States are interested in addressing the challenges of these new technologies but also in explaining their value to the public. The respondents expressed very opposing views on the need to label NGT products as GMOs and on the effectiveness of such a measure.

The speaker presented the final conclusions of the study, remarking first that NGT products are creating implementation challenges and legal uncertainties, secondly that the current legislation is not fit for

purpose for some NGT technologies and needs to be adapted to scientific and technical progress. Thirdly, it is not justified to apply a different regulatory oversight to similar products and finally that the current risk assessment procedure is considered very rigid and difficult to adapt to scientific progress. Possible follow-up actions could confirm the need to adapt the EU legislation on GMOs, enable the contribution of NGT products to sustainability, in line with the objectives of the EU Green Deal, while addressing the concerns and consider an appropriate mechanism to evaluate benefits of NGT products. NGT applications should not undermine other sectors of sustainable food production, e.g. as regards organic agriculture. Finally, the need to inform the public has been recognised.

The Council requested the Commission to submit a proposal or other measures as a follow-up to the study. The Commission will perform by the end of the year an inception impact assessment, followed by a public consultation to examine potential policy options starting from plants derived from targeted mutagenesis and cis-genesis. For other organisms and other NGTs, the Commission will build up the required scientific knowledge. Considerations on the use of NGTs in medicinal products will be addressed in the Pharmaceutical Strategy.

A representative from Belgium enquired on new submissions of NGT products to EFSA and especially on NGT microorganisms (MO). DG SANTE reported that a plant stack application containing an element produced by NGTs is being examined, but is not yet under risk assessment. Other participants commented the opinion of EFSA on cis-genesis and requested whether the intra- and cis-genesis techniques have a clear definition. DG SANTE informed to have for the moment a working definition, which should be finalised by the end of the year also with the contribution of the ENGL, the EURL GMFF and EFSA. A representative from Poland underlined the challenges in developing methods for epigenetic products that meet the current legislative requirements. He and other participants remarked the opportunity of developing an appropriate and proportional legislation on GMOs.

The Chair underlined the importance of having a clear definition for the techniques and clarity on the scope of the legislation. He encouraged the members in participating to the discussion on NGTs for including further scientific perspectives into the debate.

5 Progress ENGL working groups

5.1 WG MPR (Minimum Performance Requirements)

The speaker reminded that the mandate of the WG aimed at reviewing and defining method performance requirements (MPR) for digital PCR (dPCR) methods, the detection of NGT-derived products in food/feed and of GM animals. The group is consisting of 17 members and held 22 meetings.

The speaker reviewed the main outcomes regarding MPR for dPCR and recommendations for the detection of NGTs products and GM animals.

To ensure practicability, dPCR methods will be accepted only if transferable to other dPCR platforms and/or to real-time PCR systems, while for specificity tests a clear separation between positive and negative partitions will be required. The guidance covers other parameters requiring an adaptation to the dPCR technology, as for instance the estimation of PCR inhibition, linearity, dynamic range and robustness. The group concluded that the part of the current MPR document regarding multi-laboratory validation studies could be applied without modifications to dPCR testing. The new guidance includes a section on verification of methods for stack GM events and annexes covering statistical assumptions and calculations, conversion of units of measurement, optimisation parameters and a listing of key experimental information for the analysis.

For the detection of NGT products, the document is providing only recommendations, in

particular for GM events presenting small variations in their sequence. The guidance suggests to design the detection method with an amplicon size of maximum 150 oligonucleotides and to detect products segregating multiple site alterations as for GM stacks. It underlines that a detection of genetic variations does not necessarily lead to the identification of the NGT product. Some remarks on robustness and specificity are still under discussion.

For the detection of GM animals and the verification of specificity, the guidance recommends referring to the main application of the product since different tissues may have a distinct DNA content.

The document will be submitted first to the EURL GMFF, then to ENGL members and finally to a stakeholders consultation. It should be approved by October 2021.

The Chair expressed appreciation for the work performed which covered many difficult aspects. The speaker commented that the document provides recommendations for the detection of NGT products and GM animals because the knowledge and experience in these fields are rapidly evolving.

A representative from Belgium underlined the importance of establishing a guidance on these analytical approaches while the Chair remarked its relevance for laboratory accreditation and therefore for the interlaboratory validation of dPCR methods.

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

A speaker reported on behalf of the WG chair. He informed that the method developers were still optimising the pentaplex method previously submitted for validation, while the JRC was performing additional tests on the detection method for the potato reference gene. The JRC compiled, as requested, a list of optimal reference genes for designing taxon-specific methods that will presented to the ENGL. The gap analysis in 2020 did not find hindrances in the coverage of new GMOs by existing methods. The members decided waiting for the release of the new MPR guidance for evaluating the dPCR method previously submitted. At the next meeting, the group will discuss whether considering methods detecting genetically modified microorganisms (GMM).

A representative from The Netherlands requested whether the recommended endogenous genes would be obligatory for official control analyses; the Chair clarified that the EURL GMFF can encourage using a certain reference gene method but cannot force its use. He reminded that in a court case the outcome of the analysis has to be confirmed nonetheless with the published official method.

A representative from Belgium requested whether the construct-specific method for GMM detection that has been recently verified by the JRC could be published on the EURL GMM website. She remarked that the protocol and the data are not confidential and could be shared with ENGL members. She further enquired whether the WG AGSMV could consider the method for validation given that it is specific for a non-authorised GMO.

The Chair suggested publishing the method on the EURL GMFF webpage and including the discussion point on validation in the agenda of the following WG meeting.

5.3 WG mpPCR (multiplex PCR methods)

The speaker informed that the WG members were evaluating the comments provided by the ENGL. The draft document will be then reviewed by the ENGL SC before its publication. He highlighted that the WG hosted also non-ENGL experts.

The Chair thanked all WG members for providing a series of such critical documents on GMO analysis.

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

Since the speaker could not connect, the Secretary resolved to distribute the progress report by e-mail.

5.5 WG DNAex (DNA extraction)

The speaker remarked that some work still needs to be performed on the organisation of the chapters. A small group will discuss the first draft at the next meeting in June 2021 and then decide how to proceed. He hoped to distribute a first draft in September to the other members of the WG.

The Chair thanked the members of the WG and acknowledged the challenge of producing a coherent document.

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

The chair of the WG presented a progress report. She reminded that the mandate is covering the challenges of detecting authorised and non-authorised GMM. New members were invited to join the WG since the group was lacking expertise on transformation of microorganisms by fungi and on validation of specific methods. The WG had first individual meetings with the new experts and then a general meeting with all members. They discussed the content of each part of the document and decided to work in subgroups for each chapter. She decided with the group leaders to review the draft of each chapter in August. The final draft version of the document will be discussed in a general meeting in September/October.

The Chair expressed his satisfaction for the very good progress of the work despite all challenges.

6 Preparation ENGL Annual Meeting 2021/NRL training/NRL workshop

The Secretary summarised the ideas proposed at the last SC meeting for the organisation of the ENGL annual meeting. He reminded that, as for the previous year, the meeting will be organised online and will be mainly focused on scientific presentations. He asked to identify possible speakers for the different topics. Speakers from JRC.D.4 and EFSA have been proposed for the subjects new genomic techniques (NGT) and alerts on NGT products, respectively.
A representative from Germany proposed presenting their evaluation report on the Cibus canola method, which is in preparation for a peer-review publication. He informed that a presentation could also be provided on activities of German laboratories with regard to developing new methods and verifying the performance of recently published methods on the detection of some new NGT products (Calyxt soybeans, waxy maize etc.).
The Chair suggested having a specific section of the meeting dedicated to NGTs and the Secretary proposed inviting DG SANTE for presenting the study on NGT.
A representative from Belgium offered to present a strategy for detecting NGT products generated by CRISPR/Cas approaches by dPCR methods. She remarked that two experts of the WG GMM could be invited to the ENGL meeting for explaining transformation techniques.
The Chair further suggested presenting the finalised documents of the WGs.

7 New activities

The Chair reminded that Commission services have asked to provide a report on the detection of GM animals and that the drafting of the report is still pending. He recognised that the ENGL members might not have all the necessary expertise for the task. A JRC colleague requested whether any member of the GM animal section of the WG MPR was interested in leading the group. The Chair suggested drafting a proposal for the mandate of the WG and requested suggesting possible experts. A JRC colleague proposed involving ENGL members working in species identification.

The participants did not propose other new activities for the ENGL network.

8 Results of survey on the use of SYBRGreen real-time PCR method for detection of Cry1Ab/Ac in GM rice originating from China

The Secretary presented the outcome of a survey on the SYBR Green method detecting the construct CRY1Ab/Ac in GM rice from China. The survey presented four questions and was launched on 25th May with a deadline of 8th June 2021.

Thirty members participated to the survey; seventeen declared to use, or have used in the past, the method. The vast majority use the method with no modifications, six laboratories reported to have some issue with suspect of non-specific results when using the method. Five different PCR reagent mixes are used.

In the comments section, one laboratory underlined the existing uncertainty on the recommended PCR reagents. The EU legislation and the relevant guidance documents (original and revised) refer to the method of Barbau-Piednoir *et al*. (2012) for the Cry1Ab/Ac detection, which lists the Diagenode SYBR Green PCR master mix (and 25 µl reaction volume), while the original guidance document recommends using the PowerSYBR ® Green PCR Master Mix (and 20 µl reaction volume). The revised 2014 guidance does not directly mention which SYBR Green master mix to use. In the comments section of the survey, some respondents further highlighted that often non-specific amplifications are observed with master mixes other than PowerSYBRGreen (Applied Biosystems), while others pointed out the difficulties in purchasing the Diagenode mix.

A representative from Belgium claimed that the two methods (the official SYBRGreen and a validated TaqMan method) are not equivalent, because they have a different coverage of the targets. A representative from Germany confirmed that the TaqMan method does not detect the synthetic Cry1Ab/Ac target sequence engineered by Monsanto but remarked that this should not affect the relevance of the analytical approach for detecting GM rice in imported Chinese products.

A representative from Austria suggested using the JRC GMO-Matrix to assess the difference in analytical results between the two methods.

The representatives from Denmark and Portugal underlined that their official control laboratories do not perform analysis for the Cry1Ab/Ac target since China has not exported rice products to the two countries. Conversely, a representative from Germany confirmed RASFF notifications for unauthorised GM events in rice products from China. A representative from the JRC informed about the upcoming launch of a survey on the type of samples tested in official control activities, on the GM events identified in the samples analysed and on the detection of non-authorised GM events in rice from China.

DG SANTE informed that the Commission was discussing with the MS whether to maintain the emergency measures for rice products originating from China.

9 AOB

A representative from The Netherlands enquired whether other laboratories had problems in obtaining consumables as e.g. pipette tips. The Chair informed that the JRC has similar experiences.

The Chair thanked all participants for the good cooperation and achievements. He wished all the best to the participants and closed the meeting.

Annex 1: meeting agenda

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	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 SC40)	DAL SC40
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		▪ AG SMV (Advisory Group on Selection of Methods for Validation)	
5.3		▪ WG-mpPRC (multiplex PCR methods)	
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 2021/NRL training/NRL workshop	
7		▪ New activities	
8	15:00	▪ Results of survey on the use of SYBRGreen real-time PCR method for detection of Cry1Ab/Ac in GM rice originating from China.	
9		▪ AOB	
	16:00	End of meeting	

Meeting documents available at: https://classified.circabc.europa.eu/ui/group/7ec72904-538a-4ffd-b143-743b5874b10f/library/44cddc50-ed7e-4274-9bd2-9cfccc814693?p=1&n=10&sort=modified_DESC

JRC Mission

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