



Summary

40th ENGL Steering Committee Meeting

Webex meeting

10 March 2021



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

Joint Research Centre



Joint
Research
Centre

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1 Welcome, apologies, quorum

The Chair welcomed the participants and provided technical instructions for the online format of the meeting. He noted that according to the presence list, there were 26 members registered and concluded that the number 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 SC39)

The Secretary reviewed the open points of the list and remarked that all working groups (WGs) have been actively progressing in their tasks. He suggested discussing under the AOB point the proposals of addressing terminology issues and performing a survey on equipment management. DG SANTE previously requested information on the modifications introduced into GM Tilapia, an event newly authorised in Argentina, but the request can now be removed because the product is not exported to the EU. The Chair remarked that the JRC Unit D.4 had performed market studies, covering also GM Tilapia, for the drafting of the study on new genomic techniques (NGTs) requested by the Council. He announced that the study will be published at the end of April 2021 and that the ENGL will be informed on its publication.

4 Update from SANTE

CJEU C-528-16 & Council request (EU) 2019/1904

DG SANTE reminded that according to the Court of Justice of the EU (CJEU) the organisms obtained by new mutagenesis techniques are GMOs and are subject to the obligations of the GMO legislation. As a follow up the Council requested to perform a study on the status of these novel techniques. The study will contain a state-of-play on the implementation and enforcement based on contributions from targeted consultations of the Member States (MS) and stakeholders and from the EURL GMFF and ENGL work on detection of these products. The JRC will also provide studies on the status and use of NGTs for agri-food, industrial and pharmaceutical applications and related future scientific and technological developments as well as on the market situation. The document will be published in April 2021 and will also be available to the ENGL. EFSA is independently offering on its website an overview on risk assessment of NGT plants.

Transparency Regulation

DG SANTE presented the new Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain, which is applicable from 27 March 2021. The Regulation aims at introducing more transparency, reliability and independence of studies as well as better governance and more effective risk communication. DG SANTE covered the new legal requirements foreseen in the legislation and invited to participate in the debate on NGTs.

Members of the ENGL acknowledged the importance and complexity of this debate. A representative from Germany further commented that the debate is more theoretical than experimental and

stressed the need for obtaining experimental data on detection of NGT products. He noted that in the Transparency Regulation there is a demand for the independence of studies and wondered whether a budget could be provided for supporting studies on NGTs detection. DG SANTE clarified that the Transparency Regulation is focused on safety and the sustainability of risk assessment. The Chair reminded that proposals for new research programs could be submitted to Horizon Europe and that it could be extremely helpful if proposals are coming directly from the MS.

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), the detection of food/feed derived from NGTs and GM animals. He informed that the group has 17 members that convened in ten meetings. The work was based on the ENGL MPR document, the ENGL technical report on recommendations for the application of dPCR and the international standard ISO 20395. The speaker presented the preliminary conclusions of the WG activities focusing on the criteria that needed adaptation for each of the three analytical sections of the mandate.

MPR for dPCR: to ensure practicability the members suggested accepting dPCR methods only if transferable to other dPCR systems or to quantitative PCR (qPCR) format. Most of the parameters of the PCR module were considered applicable to dPCR except those regarding amplification efficiency and R^2 , while the parameter linearity needed to be defined. The group is still discussing how to consider a result as positive in case of considerable 'rain'. In the new document, Annex 1 will cover recommendations for dPCR, Annex 2 the determination of the zygosity ratio in the positive control sample and Annex 3 the data to be reported for dPCR experiments.

MPR for NGT products. The group concluded that new parameters are not necessary for evaluating the detection of NGT products but acknowledged that a new terminology is required. To ensure proper applicability, limitations should be considered for amplicons longer than 150 bp and for the submission of different methods detecting multiple site alterations. The group expressed concerns on the practicability of tests using new PCR chemistries (e.g. LNA, RNase H). More efforts are necessary for proving that a method is event-specific, especially for NGT events carrying alterations similar to known mutations or with short sequence modifications. Additional experimental efforts are also needed for confirming the robustness of the method and excluding false positives or negative results.

MPR for GM animals: The group cautioned that different DNA content per tissue may affect the conversion between copies and mass fractions and remarked that the applicability of a method should be assessed on the tissues marketed. A guidance on the samples to be tested will be provided to verify the specificity of a method. The dynamic range should be assessed on samples in mass percentage considering the tissue/portion of the main food/feed.

The speaker provided a schedule for the finalisation of the document and its possible publication in September 2021. He informed that a group meeting is planned in March 2021 and requested whether the mandate of the group should be extended to next-generation sequencing (NGS) techniques.

The Chair acknowledged the impressive work performed and encouraged the group in publishing the document without enlarging the scope. A representative from Germany explained that the proposal of including NGS approaches intended to concern only massive parallel PCR sequencing, already covered by an ISO standard, and sequencing of amplicons both having many advantages for species identifications. The speaker underlined that the group had limited experience on NGS and proposed waiting for the results of the WG on sequencing. The proposal was accepted. The speaker further indicated that the structure of the document would be discussed at the following WG meeting.

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

The chair of the WG informed that a web meeting has been organised in September 2020. She reported that the multiplex and the potato reference gene methods were being experimentally tested by the method developer and the JRC, respectively. A colleague from the JRC presented a very extensive review on the reference genes used in the validation studies, their performance and observed issues. The presentation will be made available to ENGL members. The speaker informed that a new gap analysis will be performed and that methods for detecting genetically modified microorganisms (GMM) have not yet been submitted to the group. The dPCR method previously proposed for validation was kept on hold until the ring-trial of a dPCR method will be completed by the JRC and the MPR document on dPCR will be finalised.

A representative from Belgium offered to provide information on all methods for GMM detection developed by their laboratory. She requested whether such methods could be considered as an analytical gap. The Chair suggested to discuss the issue under point 8 of the Agenda.

5.3 WG-mpPCR (multiplex PCR methods)

A new draft of the report prepared in September by the WG drafting team was reviewed for language corrections, secondly by the editorial team and lastly by the chair and the ENGL secretariat in December 2020. A second round of language review was performed before final submission to the ENGL president. After resolving the final comments, the draft will be submitted to the ENGL members for final approval. The Chair expressed satisfaction for the fast progress of the work.

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

According to the mandate, the WG had to assess the minimum performance parameters (MPPs) and their associated acceptance values (AAVs) for sequencing-based analyses and the guidelines of the JRC. The WG included 23 members and had many meetings in the last months. Members examined quality aspects of Sanger and massive parallel DNA sequencing for general and GMO analysis purposes. The WG is currently discussing the last chapter on conclusions, future outlook and recommendations. Two meetings are planned in March 2021. The final draft should be submitted in April for approval by the ENGL.

5.5 WG-DNAex (DNA extraction)

The WG chair informed that the WG held a web meeting in December 2020 and that another one is planned for May 2021. Some chapters needed to be merged and considered for review by the middle of April. After the summer holidays the WG will decide the timeline for the finalisation of the document. Given the pandemic situation, the members decided to postpone the workshop on DNA extraction, foreseen in the mandate, to the publication of the document.

The Chair agreed on the proposal and commented that hybrid events will offer new opportunities to participants unable to attend physically. A representative from Denmark supported the idea of electronic participation to have more lively discussions and technical staff involved.

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

The speaker reminded that the WG has the task of addressing the challenges of GMM detection. The analytical questions concern the screening, detection and identification of GMMs and the scientific tools required for the correct implementation of the EU legislation on feed additives, such as enzymes. The WG consists of a multidisciplinary team covering experts on GM detection and on microorganisms such as bacteria and fungi. During the kick-off meeting, held in November 2020, the WG discussed the mandate, tasks, priorities and the content of the document. After the drafting of a first document, the members had a 2nd meeting in March 2021 to review the comments. The WG requested to further clarify the Commission position and interpretation on zero tolerance for unauthorised GMOs with respect to fragments of recombinant DNA.

The Chair acknowledged the challenge of addressing those issues and recommended to discuss them at the end of the meeting.

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

The Secretary proposed to arrange the annual NRLs workshop and the ENGL plenary as in 2020, e.g. a one-day meeting covering a limited number of scientific presentations (possibly five) and additional technical discussions. He suggested to offer also lunch-break informal discussions as in the previous year and proposed to include detection of NGT products in the list of scientific presentations. He invited to provide suggestions for scientific topics and proposals for speakers.

A representative from Italy proposed approaches like “virtual rooms” to improve interactions among participants. The Chair supported the request. The following topics were suggested by participants for the ENGL plenary:

- Detection of GMM
- Development of CRISPR/Cas systems for detection of viruses, bacteria, GMOs or for health care diagnostics
- New NBT products on the market (presentation by JRC.D.4?)
- Risk assessment of NBT products (presentation by EFSA?)
- Genetic transformation techniques for bacteria and fungi
- Vaccines and method validation in the area of medical diagnostics devices (review on clinical selectivity and specificity criteria)
- New GM rice authorisations in China (presentation by Commission services?)
- Approaches for GMO identification after screening (identify the most probable GM event present in the samples or all of them?)
- Metagenomics approaches for sequencing GMOs (presentation by the Belgian NRL)

Many participants highlighted the lack of harmonization between competent authorities (CA) of different MS when interpreting results of biological or botanical impurities containing GMOs. Biological/botanical impurities are used sometimes as an escape for accepting GMO contamination in impurities intentionally introduced into the product at a level inferior to 5% or in ingredients not intentionally listed. The Chair regarded the issue as a topic for internal discussion rather than for a scientific presentation. A representative from Italy remarked the importance of identifying all events possibly present in food/feed samples to have a picture on the GMOs possibly circulating on the market. A JRC representative regarded such information as very useful for the design of the proficiency tests (PTs). The Secretary suggested including the topic in the Agenda of the NRLs workshop.

The Chair thanked the participants for their input and announced that the training workshop will be organised virtually as in the previous year.

7 New activities

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

8 Follow-up on RASFF notification for unauthorized GMM in food enzymes

DG SANTE explained that for food/feed enzymes and feed additives the analytical target of the detection method is the GM DNA, not the processing aid itself.

A representative from Belgium requested to provide this definition in an official communication. It was also asked to provide a clarification on the definition of “market”, since living bacteria were identified in products that companies were claiming not to be yet on the market. The Chair remarked that the request for clarification would be stronger, if addressed directly by the MS. DG SANTE informed that a request for a legal clarification had indeed been received from the MS, but that it has been later withdrawn. DG SANTE assured to convey the need for a clear position to Commission

services. SANTE further explained that a product could be considered to be on the EU market when it has been cleared by the EU customs, not only when it reached the EU consumers.

The representative from Germany commented that despite the legal definition of processing aids, Rapid Alerts for Food and Feed (RASFF) notifications have highlighted the presence of recombinant DNA, antibiotic resistance and alpha-amylase genes in processing aid products. The official control laboratories could not act and proceed, because the respective detection methods had not been validated. It was also asked whether the term GMM was referring to the DNA or the bacteria, the target amplicon of the detection method or the full DNA sequence.

The Chair clarified that it is acceptable to use, according to Regulation (EU) 2017/625 for official controls, a method recommended by the EURL GMFF when a standard method is not available. He also recommended discussing with the competent authorities (CA) whether the LOD or the LOQ should be used for defining the decision limit and therefore the presence or absence of the target in the sample.

The Chair suggested submitting a request to the Commission for a clarification on the definition of the analytical target. The EURL GMFF could evaluate methods for detecting GMMs, if human resources are available and if requested with priority by Commission services. The representatives from Belgium and Germany requested to make the information regarding GMM detection methods verified by the EURL GMFF publicly available and more visible.

9 Exchange of views on implementation of Cibus canola method in Member States

The Chair thanked all participants for their prompt contribution to the evaluation of the Cibus canola method that was included as an Annex in the previous ENGL meeting report. The ENGL evaluation triggered several responses including articles in the media and the invitation of the JRC to a webinar organized by some MEPs. The Chair requested whether the method has been implemented or validated in the MS.

The method was used for official control in Austria, while the German NRL is verifying, according to a request of their Ministry, its performance characteristics (specificity etc.). The representative from Germany highlighted the difficulty in obtaining material from the method developer. The Austrian representative informed that they are using a plasmid as a control sample for the analysis. The EURL GMFF is investigating key characteristics of the method but it is still awaiting CRMs from AOAC for specificity checks.

The Chair commented that the method could be used in a screening approach. While detection of a certain single-nucleotide polymorphism (SNP) could not be sufficient for claiming the presence of Cibus canola, a negative SNP result could be helpful to exclude the occurrence of the GM event in a sample. He clarified that the method could only be used for screening, if its performance would be confirmed by the validation study.

Other participants welcomed the strong support received on the ENGL statement.

10 ENGL Interest Group on CIRCABC

The Secretary informed that for IT security reasons information collected on the ENGLnet platform was migrated to the CIRCABC restricted system. He clarified that a two-step access procedure has been newly implemented consisting of a combination of the EU login password and a SMS associated to a personal mobile phone number. He informed that up to the meeting day 115 ENGL members have been registered in the system. He requested to contact the ENGL Secretariat for resolving access problems or for providing suggestions on how to organize information in the new system.

11 AOB

The Chair proposed organizing the 41st meeting of the ENGL Steering Committee on 16th of June 2021 and requested informing the Secretariat on possible conflicts in the organisation of the event. He thanked all participants for their input, time and energy and closed the meeting.

Annex 1: agenda

40th ENGL Steering Committee 10 March 2021



	Time	Topic	Documents in ENGLnet
1	9:00	<ul style="list-style-type: none"> Welcome, apologies, quorum 	Draft agenda DAL SC39
2		<ul style="list-style-type: none"> Approval of the agenda 	
3		<ul style="list-style-type: none"> Review of Dynamic Action List (DAL SC39) 	
4		<ul style="list-style-type: none"> Update from SANTE 	
	10:00	<i>Break</i>	
5	10:30	Progress ENGL working groups	Progress reports
5.1		<ul style="list-style-type: none"> WG- MPR (Minimum Performance Requirements) 	
5.2		<ul style="list-style-type: none"> AG SMV (Advisory Group on Selection of Methods for Validation) 	
5.3		<ul style="list-style-type: none"> WG-mpPCR (multiplex PCR methods) 	
5.4		<ul style="list-style-type: none"> WG-seq (good practice/quality of DNA sequencing data) 	
5.5		<ul style="list-style-type: none"> WG-DNAex (DNA extraction) 	
5.6		<ul style="list-style-type: none"> WG-GMM (Detection of genetically modified microorganisms in food and feed) 	
	12:00	<i>Break</i>	
6	14:00	<ul style="list-style-type: none"> Preparation ENGL Annual Meeting 2021/NRL training/NRL workshop 	
7		<ul style="list-style-type: none"> New activities 	
	15:00	<i>Break</i>	
8	15:30	<ul style="list-style-type: none"> Follow-up on RASFF unauthorized GMM in food enzymes 	
9		<ul style="list-style-type: none"> Exchange of views on implementation of Cibus canola method in Member States 	
10		<ul style="list-style-type: none"> ENGL Interest Group on CIRCABC 	
11		<ul style="list-style-type: none"> AOB 	
	16:30	End of meeting	

Meeting documents available at: <https://classified.circabc.europa.eu/ui/group/7ec72904-538a-4ffd-b143-743b5874b10f>



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