

JRC CONFERENCE AND WORKSHOP REPORT

43rd ENGL Steering Committee Meeting

Meeting Report

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Report

43rd ENGL Steering Committee Meeting

Online meeting

9 June 2022



The European Commission's
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43rd ENGL Steering Committee

9 June 2022



1 Welcome, apologies, quorum

The Chair welcomed the participants.

2 Approval of the agenda

The Secretary informed that twenty-four members confirmed their participation to the online. One member notified its absence. The Agenda (Annex 1) was approved without modifications.

3 Review of Dynamic Action List (DAL SC42)

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 the following months. The Secretary informed that the coordinator of the WG on sequencing (WG-seq) is no longer available and that the draft document has been submitted for review to its members. The Secretary requested to evaluate the mandate proposals of two new WGs later during the meeting. He finally announced the activation of a new WG for reviewing the [report](#) on detection of food and feed plant products obtained by new mutagenesis techniques published by the ENGL in 2019.

4 Update from SANTE

The DG SANTE representative (SANTE) presented the recent policy action on New Genomic Techniques (NGTs) and on developments related to the GM presence in feed/food additives (FA)/enzymes.

SANTE reminded that the public consultation on NGT launched by the Commission on 29 April 2022 on its [website](#) remains accessible until 22 July 2022. He informed that a link on the same page allows to subscribe to notifications on the progress of the new policy initiative. He remarked that the launch of a possible legal proposal is scheduled for the second quarter of 2023.

SANTE further reported that a Joint WG meeting of Regulatory Committee on Regulation (EC) No 1829/2003, Directive 2001/18/EC and Directive 2009/41/EC was held on 25 May 2022 for discussing the main policy elements of the NGT initiative.

SANTE mentioned that GM presence in FA will most likely be discussed in September with MS and possibly with the ENGL members. The Chair asked SANTE to share the note, if applicable.

5 Progress ENGL working groups

5.1 WG-MPR (Minimum Performance Requirements)

The WG finalised part two of the guidance document on minimum performance requirements (MPR) covering digital PCR (dPCR), recommendations for GM animals and products generated by NGTs. The document has also been submitted to stakeholders since it would be relevant for the implementation of EU GMO Regulations. The JRC presented the most significant remarks provided by stakeholders as a result of the consultation; the main aspects on dPCR concern the transferability of the method to other digital or real-time platforms and the dynamic range of the methods. The remarks on the recommendations for products generated by NGTs regarded the evaluation of specificity in presence of identical natural variants, the definition of a wild type reference genome and the determination of the LOD.

The Secretary enquired whether the JRC only, the WG-drafting team or all members of the WG should address the comments, or the SC members.

Certain participants promoted the involvement of the WG members and underlined that some comments were affecting activities addressed by other WGs. Others suggested submitting the unresolved questions to the SC to facilitate a faster solution. Italy suggested to wait for a clarification of the legal frame given that recommendations are not legally binding and could not justify any decision from the Commission in the authorisation procedure. A representative from Germany underlined the need for providing timely guidelines while members of the JRC acknowledged the necessity of clarifying in the document the distinction between requirements and recommendations.

SANTE explained that the legal process for a new GMO policy could take several years and that recommendations would give at least some guidance for applicants wishing to file an authorisation request. SANTE further reminded that as for EU GMO legislation, the authorisation of a NGT product is requiring the submission of a functioning detection method.

It was finally decided that the JRC would address the comments preparing a proposal for their resolution, while forwarding the most relevant one to the WG sub-groups for consideration; a meeting of the sub-groups will be organised in September 2022.

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

The chair of the WG reported that a pentaplex PCR method is undergoing further assessments in the Belgian NRL, the specificity of the detection method for potato is being tested by the JRC on material provided by the developer, the list of most suitable reference genes has been drafted by the JRC and should be made available to the ENGL, while a gap analysis on GMO coverage performed in 2022 will be distributed and discussed with the WG members. The Chair further informed that methods for GMM detection developed by the Belgian NRL were evaluated by the JRC and published on the EURL GMFF website. A dPCR method previously submitted could be finally considered for validation since the MPR document on digital PCR has been completed and a digital PCR method has been already validated by the JRC.

A JRC member requested if the WG was advocating harmonisation on the choice of reference genes and targets. The chair explained that the list of suitable reference genes has been drafted using data from validation studies and that it would allow selecting different methods according to their performance.

A JRC member and the representative from Belgium suggested publishing the data on the EURL GMFF website or as a peer-reviewed article. Results from digital and real-time PCR methods could be harmonised if it would be clarified which assays have been used for the calculation of the conversion factors (CF). The representative from Belgium requested to provide a link on the EURL GMFF website to the JRC Excel sheet converting those values.

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

The Secretary informed that the activities had been on hold for a while since the chair left the group for a new job. The EURL GMFF has recently produced a new draft document integrating the comments received from the members. The document could be finalised in the following WG meeting, then submitted to the ENGL for comments and finally approved by the SC. The representative from Belgium offered her support for a combined leadership with the JRC.

5.4 WG-DNAex (DNA extraction)

The Chair of the WG informed that a new consolidated version of the document would be finalised by the end of July and provided to the WG members for comments. The JRC requested to present the work at the 2022 ENGL plenary.

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

The chair reported that the document had been reviewed by all members and then by each chapter leader. The finalisation of the introduction and conclusions sections is awaiting a clarification on certain legal aspects by SANTE.

SANTE apologized for the delay and explained to be waiting for a reply from the legal services. Given the many files under scrutiny could not predict the timing of their response.

The Secretary suggested to address all other aspects of the document for its prompt finalisation after the legal service reply.

6 Preparation ENGL Annual Meeting 2022/NRL training/NRL workshop

The Chair proposed defining the date for the 2022 ENGL plenary. The Secretary enquired whether participants would favour a physical or an online meeting and if the full-day NRL workshop should be organised back-to-back with the plenary.

The participants suggested organising a hybrid meeting to allow physical contacts and discussions while offering on-line connection to a wider audience. The Secretary suggested to cover, as in the previous meeting, the topics of NGT, GMM and dPCR. He further proposed a presentation on multiplex PCR.

A representative from Germany recommended an update on GM animals, in particular on their development and approval pipeline. He also offered covering CEN or ISO activities and presenting a study on detection of soybean GM events by multiplex dPCR. A representative from Belgium suggested presenting a high throughput target sequencing analysis on rice and a metagenomics sequencing approach for verifying authenticity of products (i.e. papaya or GMM). Different participants and SANTE offered to propose speakers for the topic.

A representative from Netherland advised addressing which GMO detection strategies should be applied in enforcement laboratories (e.g. to quantify all GMOs identified or only the most abundant one). The Secretary offered to include the subject in the NRL workshop.

The Secretary reminded to submit further suggestions on possible topics shortly after the SC meeting to allow a proper planning of the event.

7 New activities (incl. WG on NMT, WG on GM animals)

7.1 8 WG on Update on detection of products of new mutagenesis techniques report

The Secretary presented the mandate of the WG on the review of the ENGL document on detection of NGT products. Its main task is to review the scientific literature and update the document, also taking into account the recent MPR part 2 guidance on GMOs generated by NGTs. The WG should also consider the implications of regulations on NGT products in other regions of the world. Another deliverable covers the development or integration in a single database of NGT applications worldwide.

A representative from Germany suggested including in the first deliverable the point of availability of reference materials and the setting-up of detection strategies in their absence. A representative from Netherland requested more clarity on the terminology used for NGT products.

SANTE remarked that the ENGL report should cover only products generated from targeted mutagenesis and cis-genesis techniques since the policy initiative is limited to those techniques.

The Chair asked if the November 2022 timeline for delivering the report could be considered realistic. The Secretary underlined that the document could be finalised as expected only if the first meeting would be organised by July 2022. The participants did not raise any objection to the proposed deadline.

In the following days the Secretary would submit the mandate, collect proposals for experts and organise the first meeting of the WG.

7.2 WG on GM animals

The Secretary presented a draft mandate for establishing a new WG on GM animals. He acknowledged that although applications for authorisation of GM animals have not been submitted in EU the ENGL should be prepared for addressing the issue. The tasks of the WG relate to the detection, identification and quantification of GM animals. The Chair clarified that the WG will be activated once other activities are finalised.

A JRC member suggested including the availability of reference materials in the mandate. Some participants commented that the tasks of the WG are unclear and too general and do not have a timeline. The WG could also provide recommendations on NGTs applied to GM animals.

The Secretary agreed on elaborating more specific tasks and expressed appreciation for providing alternative proposals.

9 AOB

The Chair announced that different institutions are organising a GMO analysis conference in Berlin or Ispra for 14-18 March 2023. According to the German representative, the intention of the workshop is to provide an international perspective and a synopsis on the topic. He further announced that in the European farm to fork Framework Programme HORIZON 2022 a new call on NGT products has been launched. He requested to be contacted if interested, to constitute a Consortium.

The JRC informed that a training event on bioinformatics analysis will be organised at the Belgium NRL laboratory in Brussels. A more general part on NGS sequencing would be provided online a week earlier. The representative from Belgium further clarified that the training will be offered on 30 November and 1 December 2022. It will be a practical session at the informatics level and it will require no experience in programming, but a sufficient confidence in bioinformatics analysis. It will be open for a maximum of twenty people. The online theoretical session will be offered in the previous week with no limits on the number of participants.

The Chair thanked the participants for the constructive discussions and closed the meeting.

Annex 1 – Agenda

43rd ENGL Steering Committee 9 June 2022



	Time	Topic	Documents in CIRCABC
1	9:00	▪ Welcome, apologies, quorum	Draft agenda DAL SC42
2		▪ Approval of the agenda	
3		▪ Review of Dynamic Action List (DAL SC42)	
4		▪ Update from SANTE	
	10:00	Break	
5	10:30	Progress ENGL working groups	Progress reports
5.1		▪ WG-MPR (Minimum Performance Requirements)	
5.2		▪ AG SMV (Advisory Group on Selection of Methods for Validation)	
5.3		▪ WG-seq (good practice/quality of DNA sequencing data)	
5.4		▪ WG-DNAex (DNA extraction)	
5.5		▪ WG-GMM (Detection of genetically modified microorganisms in food and feed)	
	12:00	Break	
6	14:00	▪ Preparation ENGL Annual Meeting 2022/NRL training/NRL workshop	
7	15:00	▪ New activities (Incl WG on NMT, WG on GM animals)	
8		▪ Update on detection of products of new mutagenesis techniques	
9		▪ AOB	
	16:00	End of meeting	

Meeting documents available at: https://classified.circabc.europa.eu/u/group/7ec72904-538a-4ffc-b143-743b5874b10f/library/63350eeb-0d05-45da-a575-408d751dcb5d?p=1&n=10&sort=modified_DESC

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