



38th ENGL Steering Committee Meeting

Ispra

18-19 February 2020

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38th ENGL Steering Committee

Ispra (IT), 18-19 February 2020

DRAFT Report



1) Welcome, apologies, quorum

The Chair welcomed the participants and asked to introduce themselves in a tour de table.

2) Approval of the agenda

The agenda (Annex 1) was approved without changes to the draft.

3) Approval of the report of the SC37 meeting

The report of the last SC meeting was approved.

For the future the Chair proposed approving the reports of the ENGL and SC meetings directly by e-mail instead of waiting for the approval at the following meeting. He informed that sharing the draft minutes of the meetings before finalisation of the official minutes could be considered as not being in line with Article 9 of the Consortium Agreement, but the verbal sharing of the issues discussed at the meetings could be considered appropriate. He acknowledged that the finalisation of minutes has to be sped up and therefore the written procedure above is proposed. The Secretary informed that according to the new proposal, the internal draft version of the minutes would be submitted to ENGL members for comments. After taking these on board, the ENGL Secretariat will send by e-mail the final version of the document for a formal approval to the SC meeting participants. Once endorsed, the report will be published on the ENGL web site. The Chair underlined that this new procedure will make the official reports of the meetings publicly available at an earlier stage.

All participants approved the proposal.

4) Review of Dynamic Action List (DAL SC37)

The Secretary reviewed the open points of the action list (Annex 1).

5) Update from SANTE

New CRM procedure for checking CRMs

DG SANTE informed that under the agreed procedure, EFSA publishes its opinion on the authorisation of a GMO only after the EURL GMFF has positively verified the appropriateness of the related CRM and of the detection method. If an EFSA opinion has been already delivered, the EURL GMFF requests the applicant to submit the CRM and is testing its appropriateness. The EURL GMFF also verifies the appropriateness of new CRM batches or of CRMs with updated certificates. DG SANTE noted that the quality of the CRMs had been improving and that the workload for the EURL GMFF is higher than expected. In an upcoming meeting, the EURL GMFF and EuropaBio will monitor the progress of the procedure.

Seed testing

DG SANTE informed that a questionnaire on seed testing had been submitted in December 2018. A WG established for preparing a guidance document on seed testing convened in different meetings during 2019. The text of the document is scheduled for endorsement at an upcoming meeting of the Regulatory Committee 2001/18.

CJEU ruling on mutagenesis

The Council requested the Commission to submit a study on the status of novel genomic techniques and, if appropriate in view of the outcomes of the study, to submit a proposal. The Council acknowledged that the ruling provided legal certainty but recognised the practical difficulties in implementing the EU GMO legislation on these new products. The study will cover plants, animals, microorganisms and derived

products obtained by new genomic techniques (NGTs). It will provide a description and analysis of the status and use of new genomic techniques in particular on four areas:

1. current and future scientific and technological developments;
2. state-of-play on implementation and enforcement of the GMO legislation;
3. safety of new technologies;
4. ethical and societal implications.

Given the limited timeframe, the Commission will draft the study report internally. A survey covering six topics will also collect contributions from Member States (MS) and stakeholders (STH). They shall submit their replies to the survey by 30th April 2020 and 15th April 2020, respectively. The study report must be finalised by 30th April 2021.

The representative from Germany urged the publication of the guideline on seed testing. DG SANTE remarked that the document is now in its final stage. The Chair encouraged the participants to provide input for the survey on NGTs to their Competent Authorities (CA). He also underlined that in order to deliver within the established deadline, the study report draft has to be finalised by the end of 2020. DG SANTE informed that the ENGL members can find more information on this process on dedicated web pages (https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en).

6) Progress ENGL working groups

6.1) WG- MPR (Minimum Performance Requirements)

A JRC representative informed that the mandate approved in the previous SC meeting covered the review and definition of Methods Performance Requirements (MPR) for three areas:

- 1) digital PCR
- 2) detection of food/feed from new mutagenesis techniques
- 3) detection of GM animals

The WG included 15 members divided in 3 subgroups. The WG had insofar one kick-off meeting (videoconference on 28th of November), a preparatory meeting (videoconference on 30th of January 2020) and a meeting for the definition of the agenda (videoconference in February 2020). The subgroup on digital PCR launched a questionnaire to investigate whether the acceptance and performance requirements adopted for real-time PCR or proposed in the ENGL document on dPCR could be applicable. The results of the survey indicated that 38% of the laboratories owned a digital PCR apparatus and that a few are holding an accreditation for performing GMO analysis with dPCR. According to the replies, some performance parameters could be directly applicable (i.e. regarding DNA extraction) while for some other parameters (i.e. regarding purity) modified acceptance criteria have to be defined. The WG will provide a first draft by 15th of May, revise the documents in May-June and provide a final WG draft version for the next ENGL plenary. The speaker invited participants to join the group.

The representative from Germany supported a stepwise approach for the activities of the WG and suggested giving priority to the dPCR part. Participants highlighted that different instrumentation may require specific experimental approaches and that a guideline for accreditation bodies would be helpful to allow a harmonised accreditation approach in all MS. They also remarked that laboratories should not be constrained to use a single digital PCR instrument. The Chair announced that the EURL GMFF performed a comparative study on different dPCR instruments and is drafting a manuscript on the results. He suggested defining performance criteria rather than experimental conditions to avoid promoting a specific instrument for dPCR.

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

The WG chair informed that additional tests have been designed for optimising a pentaplex method and that the detection method for the potato reference gene has been finalised. The EURL GMFF should test the method on the material submitted by the developer and then decide how to proceed. A member from the Czech Republic prepared an overview of available methods for the detection of GM animal

species. The list, presented at the previous ENGL plenary, was published on the ENGLnet web site. The WG will perform a gap analysis at the next meeting. The WG is awaiting the definition of the performance criteria for dPCR before selecting those methods for validation. The optimisation of the JRC GMO-Matrix web interface with the authorisation status of the different GM events was under evaluation by the EURL GMFF. As substantial IT resources and an online connection to other Commission services would be required, the Chair suggested publishing the authorisation status of the GM events on the application web interface at a given day and updating the information every six months. A single table could provide an overview of the authorisation and method validation status of the GM events and their respective methods.

6.3) WG-mpPCR (multiplex PCR methods)

The WG chair informed that three web meetings were organised in October 2019 for improving the document. The main discussion point regarded the validation of the so-called asymmetric LOD/LOQ. The fifth draft of the document should be finalised by the end of February 2020. A physical meeting could be necessary in April/May 2020. The WG expects to present the final draft of the document at the next SC meeting. The WG chair asked if dPCR methods needed to be included in the document. The Chair remarked that digital PCR aspects could increase the complexity of the subject and suggested addressing the topic in another document.

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

The speaker informed that the first draft of the document was submitted to all members in September 2019. A teleconference with the chapter coordinators had been organised in November 2019 and a second version has been reviewed in January 2020. A plenary WG meeting had been organised in Brussels in January 2020. The group performed a good overview of available documents on quality aspects of DNA sequencing. The members divided the tasks for drafting the third version of the document. A plenary meeting will be required for discussing certain items in details. A full version of the document should be provided for the following SC meeting. The Chair commented that the topic is very broad and dynamic and suggested focusing on the main issues to deliver the document in a reasonable time. Other concerns could be covered in a second document. A representative from Belgium commented that more NGS experts in the group could help in sharing the work and in critically reviewing the document. The Chair requested to identify new NGS experts that could possibly contribute to the WG activities.

6.5) WG-DNAex (DNA extraction)

The speaker remarked that the WG officially established in 2018 consists of 18 members. The mandate of the WG was divided into three topics:

- 1) Creating a web space
- 2) Providing a comprehensive guidance document on selection of DNA extraction methods
- 3) Supporting the organisation of a second training workshop on DNA extraction

The work was organised in six tasks. The first task regarded the development of a database for sharing issues/solutions on DNA extraction. The speaker informed that the database has been uploaded on the ENGLnet. The group also produced an ad-hoc working document and a draft guideline, respectively, for curating and using the database. The group was evaluating the possibility of producing a written FAQ document. The members drafted a literature review chapter (task two), a draft chapter on quality criteria for validation/verification of DNA extraction methods (task four) and a chapter on sample preparation and on estimation of DNA yield and quality (task five). The group also plans to develop a decision support system (task six). The different chapters will be finished independently in spring 2020 and then combined for the final draft version of the document. The speaker requested suggestions for organising a second workshop on DNA extraction in the autumn of 2020. It was recalled that at a previous meeting the NRLs had defined extraction from complex matrices as a training need.

6.6) WG-UpMeth (Update of methods)

The Secretary announced the finalisation of the document regarding update of methods and thanked the members of the group for their contributions. Given its legal implications, DG SANTE reviewed the document. The group is planning to collect comments from stakeholders and industry in a future meeting. The Secretary suggested keeping the WG alive to review and verify on a regular basis methods for which a renewal of the GMO authorisation is foreseen. He remarked that the SC has to appoint a new WG chair and has to define the future modus operandi of the group.

6.7) WG-Proc (ENGL Procedures)

The Secretary remarked that the procedure for establishing ad-hoc WG has yet to be drafted.

7) New WG on GMM

The Secretary explained that in the submitted proposal the mandate of the WG on GMM in food and feed products including feed additives (FA) is covering techniques for confirming the absence of GMM and recombinant DNA in those products. He further remarked that the EFSA guidance previously published was focused on risk assessment aspects and not necessarily fit for the detection purpose. The group should address the challenges of detecting GMM, including those obtained by new genomic techniques (NGT), in authorised or non-authorised food and feed. The regulatory framework is provided by Directive 2001/18/EC, Regulation (EC) 1829/2003 and Regulation (EC) 429/2008 on FA (under revision). The WG should have a first video conference in March 2020 for defining a table of content and members' contributions. It should present a draft report at the 31st ENGL plenary and provide a final WG draft document at the SC meeting in February 2021. The Secretary asked to approve the final version of the mandate. The representative from Germany expressed a few objections to the text and some concerns over the feasibility of the task in the defined timeframe. He suggested dividing the activities in multiple deliverables. Different participants highlighted the difficulty in testing the specificity of the methods without sequence information, in distinguishing natural recombination events from transgenic products or defining a limit of detection (LOD). The Secretary proposed to incorporate into the text the participants' suggestions and to approve the newly revised mandate on the following day. He informed that ENGL members could express their interest for participating to the activities of the WG via email to JRC-EURL-GMFF@ec.europa.eu or the ENGL Secretariat.

8) Update on CRM appropriateness checks

A JRC representative illustrated the workflow for verifying the CRM appropriateness in cases (A) of new or pending applications submitted to EFSA or (B) published EFSA opinions or release of new or updated CRM batches. The EURL GMFF test the appropriateness of CRM in both cases A and B. In the cases (A), the EURL GMFF will communicate the results to EFSA and DG SANTE. In the cases (B), the EURL GMFF will request the CRM from the applicant, test its appropriateness and communicate the results to DG SANTE. CRMs that have passed the appropriateness test will be published regularly on the EURL GMFF webpage. If the CRM is not fit for the purpose and the applicant does not resolve the issue the authorisation may be suspended. The speaker commented that the applicants have been very cooperative and willing to fulfil the requirements. The EURL GMFF analysed the CRMs for 60 GM events (cases A and B). The speaker informed that several certificates of CRMs from AOAC no longer contain a certified quantitative value for the GM content. The Chair commented that the very frequent renewal of CRMs by AOAC is undermining the ability of the EURL GMFF to perform all controls. The speaker underlined that the requirements for CRM appropriateness are outlined in ISO/IEC 17025:2017 [6.5.2] and more specifically in Regulation (EU) N. 503/2013. A representative from Slovenia expressed appreciation for the good service provided by the JRC to the official control laboratories.

9) Feedback on the tour the table at the 15th NRL workshop

The Secretary summarised the training needs expressed at the NRLs workshop in 2019. He further requested suggestions for the topics of the workshop that the EURL GMFF would organise in November 2020. Participants suggested offering training on NGS, bioinformatics, DNA extraction from difficult matrices, multiplexing and digital PCR.

10) Preparation of the ENGL Annual Meeting 29 September- 1 October 2020

The Secretary informed that for the ENGL plenary and the NRLs workshop the JRC would propose the same format as of the previous year (half a day for the NRL workshop, one day on ENGL topics and finally an Open Science day). He proposed starting the meeting on the 29th of September at noon and finishing in the evening of 1st of October. The Secretary suggested preparing a summary report for the tour the table at the NRLs workshop. He further requested suggestions for topics to be included in the agenda. The participants proposed inviting specialists on SNPs genotyping, variety identification, GM insects and synthetic biology for food production. Others suggested gene drives and accreditation for digital PCR. A representative from Belgium offered to present the results of a research project on detection of GMM and on the Belgium surveillance on fermentation products. A representative from Slovenia proposed presenting the results of a COST action, a project especially dedicated to genome editing in plants. The Chair suggested discussing progress in the activities of the WG MPR and on harmonisation of the accreditation approaches. He requested if members were interested in inviting representatives from regional networks. The Secretary requested contributing to the list of contacts of the different regions published on the ENGLnet. Members suggested inviting representatives from South America, in particular Brazil and Mexico and from the MENA (Middle East and North Africa) network.

11) International standardisation

The representative from Germany summarised the activities of two standardisation Committees: CEN TC275 WG11 and ISO TC34 SC16. He reported that the scope of the CEN Committee has been limited in 2019 to GMOs analysis and that therefore it was no longer covering nucleic acid based methods for species analysis. He informed that the ISO Committee agreed to revise the standard ISO 21569:2005. As a result, the Annexes to the PCR methods document, which are currently included as EU reference methods in the GMOMETHODS database, might be removed or restored as standalone ISO documents. He finally remarked that the project ISO/CD 22753, covering the statistical evaluation of GMO content in seeds and grains, could be used for harmonising the analysis in the seed area. The speaker invited ENGL members in joining international standardisation committees. The Chair remarked that the ENGL should participate actively in ISO activities.

A JRC representative summarised the activities of the ISO TC276 “Biotechnology” and illustrated the items published by the different working groups. He informed that the standard ISO 20395:2019 covering requirements for evaluating the performance of quantification methods for nucleic acid target sequences - qPCR and dPCR, could be relevant for many ENGL guidance documents. Another document, namely ISO/CD 20397-2 on general requirements for massive parallel sequencing and on methods for evaluating the quality of sequencing data, is at an advanced stage of drafting. The Chair informed that ISO TC276 is considering as a new work item the drafting of an ISO document on terminology for gene editing. He encouraged participating to the activities of that Committee. The representative from Germany reminded that the terms and definitions provided in ISO standards are freely available from an online platform (Online Browsing Platform (OBP) at <https://www.iso.org/obp>).

12) New activities

The Secretary reminded that ENGL members requested reviewing the definitions provided in the ENGL guidance documents and harmonising the terminology. He compiled all definitions and terms from ENGL guidance documents in one unique document of 55 pages. The Chair requested if it was reasonable to work on the consistency of the terminology between ENGL documents and ISO

standards. The participants supported the initiative. The Chair proposed to structure the data in a classifiable format and with internal sorting tools, and to report at the following SC meeting.

13) Report on the dPCR workshop in Geel

A JRC representative reported on a workshop organised in autumn 2019 by the EURL GMFF under NRLs request. The workshop covered the transferability of qPCR methods to the digital PCR format and the use of conversion factors determined by the EURL GMFF. The participants shared their experience on accreditation and on troubleshooting. Most of the 25 participants have already or are in the process of acquiring dPCR instrumentation. The EURL GMFF received very good feedback. A JRC representative informed that a type of calculator has been designed and is put on the EURL GMFF web site for transforming copy number ratio results in mass fractions.

14) Detecting products of gene editing (Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C- 528/16)

The representative from Germany requested whether activities are expected at the ENGL level for supporting this study of the Commission. The Chair clarified that the ENGL Report on detection issues published in March 2019 is considered already as major input. He suggested including the topic of harvesting information on related research activities in the MS into the agenda of the ENGL plenary and promised enquiring DG RTD on research projects possibly covering the subject. A representative from Slovenia remarked that research projects are necessary to address the detection of GE products at experimental level. The Chair recommended waiting for the drafting of the proposal resulting from the study and encouraged supporting European research portfolios.

15) Electronic forum in ENGLnet: general discussion

The Secretary reminded that the ENGL decided using the ENGLnet as a forum to facilitate discussions on different topics and appointing a moderator to stimulate contributions. He requested whether a forum should be activated on a specific topic. Some participants suggested submitting additional information on DNA extraction; others commented that a moderator needs specific training. After the discussion, the Chair concluded that there was no concrete interest in reopening the tool at present.

16) AOB

A JRC representative proposed to approve the mandate of the WG GMM after including the corrections suggested on the preceding day. A few more modifications were noted and amended. All participants finally approved the document. The Chair recommended inviting additional experts outside of the ENGL network for contributing to this WG activities.

The Secretary informed that the list of contact points for regional networks has been published on the ENGLnet. He requested submitting other personal contacts to the Secretariat for completing the list.

17) DAL SC38

The Secretary informed that the next SC meeting will be organised on the 23th-24th of June 2020 and presented the updated DAL (Annex 2). He reminded that a new chair for the WG update of methods needs to be appointed and invited proposals for speakers and topics at the upcoming ENGL plenary.

18) Final meeting conclusions

The Chair thanked the participants for their active contribution and encouraged consulting the ENGLnet. He wished a safe return home and closed the meeting.

Annex 1: agenda

38th ENGL Steering Committee
JRC Ispra, 18-19 February 2020

Room 3, Building 36



Day 1 – 18 February 2020

	Time	Topic	Documents in ENGLnet
1	9:00	<ul style="list-style-type: none"> Welcome, apologies, quorum 	Draft agenda Report SC37 DAL SC37
2		<ul style="list-style-type: none"> Approval of the agenda 	
3		<ul style="list-style-type: none"> Approval of the report of the SC37 meeting 	
4		<ul style="list-style-type: none"> Review of Dynamic Action List (DAL SC37) 	
5		<ul style="list-style-type: none"> Update from SANTE 	
	10:30	<i>Coffee Break</i>	
6	11:00	Progress ENGL working groups	Progress reports
6.1		<ul style="list-style-type: none"> WG- MPR (Minimum Performance Requirements) 	
6.2		<ul style="list-style-type: none"> AG SMV (Advisory Group on Selection of Methods for Validation) 	
6.3		<ul style="list-style-type: none"> WG-mpPRC (multiplex PCR methods) 	
6.4		<ul style="list-style-type: none"> WG-seq (good practice/quality of DNA sequencing data) 	
6.5		<ul style="list-style-type: none"> WG-DNAex (DNA extraction) 	
6.6		<ul style="list-style-type: none"> WG-UpMeth (Update of methods) 	
6.7	<ul style="list-style-type: none"> WG-Proc (ENGL Procedures) 		
	12:30	<i>Lunch</i>	
7	14:00	<ul style="list-style-type: none"> New WG on GMM 	Draft mandate
8		<ul style="list-style-type: none"> Update on CRM appropriateness checks 	
9		<ul style="list-style-type: none"> Feedback on the tour the table at the 15th NRL workshop 	
	15:30	<i>Coffee Break</i>	
9	16:00	<ul style="list-style-type: none"> Preparation ENGL Annual Meeting 29 September-1 October 2020 	
	17:00	<i>End of day 1</i>	
	19:30	<i>Dinner at Pizzeria la Scuderia, Villa Borghi</i>	

Day 2 – 19 February 2020

	Time	Topic	Documents in ENGLnet
10	09:00	<ul style="list-style-type: none">▪ International standardisation	
11		<ul style="list-style-type: none">▪ New activities	
12		<ul style="list-style-type: none">▪ Report on the dPCR workshop in Geel	
13		<ul style="list-style-type: none">▪ Detecting products of gene editing (Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16)	
14		<ul style="list-style-type: none">▪ Electronic forum in ENGLnet: general discussion	
	10:30	<i>Coffee Break</i>	
15	11:00	<ul style="list-style-type: none">▪ AOB	
16		<ul style="list-style-type: none">▪ DAL SC38	
17		<ul style="list-style-type: none">▪ Final meeting conclusions	
	12:30	<i>End of the meeting and lunch</i>	

Meeting documents available at:

<https://englnet.jrc.ec.europa.eu/steering/38th%20Steering%20Committee%20meeting/default.aspx?InstanceID=1>

Annex 2: action list

38th ENGL STEERING COMMITTEE ACTION LIST 19/2/2020				
ACTIONS	Resp.	Timelines	Status	Comments
ENGL GENERAL				
Report of 38th ENGL SC	SEC	15/03/2020	Open	approve by email
Organise SC June meeting 23-24 June	SEC	31/3/2020	Open	send draft agenda to SC for contributions
WORKING GROUPS				
Advisory Group on "selection of methods for validation" (SMV)				
Next meeting on 27/6/2019	SEC	30/4/2020	Open	consider gap analysis 2020 for NMT; organise next meeting
WG-UpMethod				
send doc to Europabio	WG	29/2/2020	Open	
Define next steps (chair, review of methods, ecc)	SEC	15/4/2020	Open	
WG-DNA extraction				
	SEC		Open	
	SEC		Open	
WG-multiplex PCR				
Meeting in april/may	SEC	15/3/2020	Open	to be decided
WG-seq				
WG - MPR				
	SEC		Open	meeting in february
WG-Proc				
Draft procedure for ad-hoc working groups	WG	31/3/2020	Open	
VARIOUS				
Terminology: structure the doc - internal consistency	SEC	30/4/2020	Open	for SC June
Survey on equipment management	SEC	29/2/2020	Open	Ask table again to Sciansano
Survey on capacity building	SEC	29/2/2020	Open	ask F.7 for progress
ENGL WG on GMM in food and feed	SEC	29/2/2020	Open	send mandate to ENGL, ask for WG members; organise kick-off meeting
Contact SC members for speakers at the 2020 Annual meeting	SEC	29/2/2020	Open	
	SEC		Open	

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