



37th ENGL Steering Committee Meeting

Meeting report

JRC Ispra

18-19 June 2019

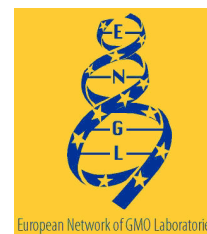


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37th ENGL Steering Committee, JRC Ispra, 18-19 June 2019



Report

1 Welcome, apologies, quorum

The Chair welcomed the participants and asked to introduce themselves in a tour de table. A total of 19 Member States (MS) were present.

2 Approval of the agenda

The draft agenda was approved.

3 Approval of the report of the SC36 meeting

The Secretary informed that all the comments received were incorporated in the final version of the report. The representative from Germany enquired on the update from DG SANTE regarding CRMs produced by AOAC and on the progress of point 13 of the report. The Chair commented that point 11 and 5, respectively, in the agenda will address the first and second issue. All participants approved the report.

4 Review of Dynamic Action List (DAL SC36)

The Secretary reviewed the open points of the list and asked participants to volunteer for preparing a list of ENGL terms and definitions. Since there were no replies the Chair proposed to drop the action from the list. The representative from UK commented that the activity was aiming at harmonising the vocabulary among different ENGL documents. The Secretary offered copying and pasting into one draft the definitions from all ENGL documents to spot inconsistencies. The proposal from the Secretariat was approved. The Chair suggested discussing the outcome at the following SC meeting.

The Secretary listed as an action to be still performed a survey on instrument use and their management by laboratories and asked for volunteers. The Chair commented that JRC could not devote human resources to this task. The representative from Belgium proposed as alternative to circulate a table where laboratories could directly include the relevant data and underlined that the table would need to be first validated by the participants. The Chair questioned the aim of harmonising the management of instruments, given the different needs of the laboratories and diverse requests of their accreditation bodies. Nevertheless, it was agreed that sharing information on the type of instruments used for official control could be useful.

The Secretary remarked that another action, namely the report on a survey on capacity building, is still pending. The representative from Italy commented that the document would be very useful for highlighting the training needs. The Chair proposed to approach the JRC colleagues in charge of conducting the survey and to share the relevant information, if made available, before the next ENGL meeting.

5 Update from SANTE

ECJ ruling on targeted mutagenesis

On 25 April 2019, DG SANTE organised a joint meeting with MS experts responsible for the implementation of Directive 2001/18, Regulation 1829/2003, and Directive 2009/41. During this meeting, the EURL GMFF presented the ENGL report on detection of food and feed plant products obtained by new mutagenesis techniques. Participants acknowledged the conclusions of the report including that not all new GE products can be identified using current techniques.

ENGL report on the detection of microorganisms modified by targeted mutagenesis

No reactions were received from MS on the call for experts on GMM.

CRMs

DG SANTE invited EuropaBio to provide updated information on CRMs. After a meeting, DG SANTE and the EURL GMMF established a procedure including the systematic checking of the appropriateness of the

available CRMs. DG SANTE assured with EFSA that this procedure would not lead to additional delays in the authorisation procedure.

Seed testing

A working group on convergence of seed testing for GM presence had meetings in January and May 2019. Topics related to analysis (e.g. sample preparation, subsampling, proficiency tests (PT) for GM seeds, expression of results...) will be discussed with the EURL GMFF at a meeting planned in September 2019. If further clarifications on analytical aspects are needed, those aspects will be addressed at the following ENGL plenary meeting.

Expression of results for stacked GM events

DG SANTE has replied to the summing up question on stacked GM events received from the ENGL. The answer is included in the folder distributed at the SC meeting. DG SANTE orally informed the MSs of the content of the reply during the meeting of the Standing Committee held on 11 June 2019. The Chair expressed appreciation for the collaborative efforts of DG SANTE and pointed to the last sentence in the paragraph, which is a crucial statement for laboratories. DG SANTE underlined that laboratories provide the analytical result but that only Competent Authorities are accountable for the decision of compliance, as this includes an assessment of whether the detected presence is adventitious and technically unavoidable. The representative from Italy remarked that the interpretation of the results is critical and that if the approach is different in different countries, problems for exports and trade may arise in the future.

Items raised by ENGL members

DG SANTE explained that it decided not to participate to the meeting of the FAO platform for GM food (a joint activity between FAO and CODEX for sharing information on how the safety assessment on GM food is organised in different countries) because risk management and not risk assessment is its core mission.

6 Progress of ENGL working groups

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

The Secretary, on behalf of the WG chair, presented the open points of the group working agenda, i.e. optimisation of a pentaplex method and additional information needed on a potato reference gene method. The group will organise a web meeting on the 27th of June 2019.

6.2 WG-UpMeth (Update of methods)

The Chair of the WG explained that the members have established a workflow for evaluating a method submitted in the application for renewal of authorisation. A different procedure is proposed for the update of a method during the validity period of authorisation. In the guidance a table is provided listing the possible issues and related actions. An Annex is also provided defining how to test robustness for quantitative PCR methods. The members will provide final editorial comments to the chair of the WG. Once these will be integrated into the document, it will be sent to the SC for final comments and approval.

The representative from Germany asked whether a mechanism was foreseen for informing laboratories on the modifications implemented on a particular method. The Chair agreed that a clear line of communication needs to be established. He added that the particular interpretation of "methods" versus "procedures" had to be clarified, since in the text a "method" included all experimental conditions affecting the performance parameters detailed in the MPR document and it was diverging from the ISO definition, where certain experimental parameters can be modified within the same "method".

The representative from UK expressed appreciation for the outcome and encouraged the publication of the document. The representative from Austria requested clarification on the procedure for assessing the fitness of a method submitted for renewal.

The Chair remarked that from the legal point of view compliance to the current MPR document could be considered as the only option for assuring implementation of the EU legislation on GMOs.

6.3 WG-Proc (ENGL Procedures)

The chair of the WG informed that the document on ENGL procedures was circulated and that the comments of the SC members were already included. The document was initially kept inside the SC because it was considered of administrative nature and not scientific. If there are no objections the document could be distributed to the entire ENGL. The Secretary added that an additional procedure on the establishment of ad hoc WGs still needed to be drafted and that it will be added after SC discussion and agreement as 5th rule to the already agreed parts of the document.

The representative from the UK reminded that administrative duties do not necessarily need comments

from ENGL members. All participants endorsed the four ENGL procedures proposed. The Chair added that once the 5th rule has been drafted it could be sent around for comments in an electronic format.

6.4 WG-mpPCR (multiplex PCR methods)

The WG chair provided an update on the work performed. He informed that the WG was drafting a chapter concerning validation of the multiplex methods. There will be a web meeting at the beginning of July and others which still need to be planned.

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

The WG chair presented the organisation in chapters of the planned document. It will include a review of existing literature and a chapter dedicated to different platforms, strategies and related quality aspects. The WG will consider three different scenarios and distinguish between specific strategies: whole genome sequencing, single products, or complex products. Finally a section on future perspectives is envisioned. The first draft should be ready by the end of September 2019. The Chair remarked that treatment of raw data should not be underestimated and that data analysis procedures are often considered as black boxes. Data quality management and internal quality assurance for sequencing approaches are being considered also in ISO TCs. A participant remarked that the ENGL needs to address the issue of reference genomes and that sequencing data generated in one experiment should be comparable with others.

The representative from Belgium commented that the objective of the WG did not involve giving guidance on best practice.

6.6 WG-DNAex (DNA extraction)

The WG chair informed that the group is quite advanced in the establishment of a database containing information on the use of DNA extraction methods. The WG will have a web meeting in June and organise a physical meeting in September. The representative from the UK expressed satisfaction on the quantity of data collected and hoped for a dynamic update of the information.

The Chair remarked that the extraction step is quite crucial but difficult to be harmonised between different laboratories.

6.7 Establishment of a Working group on Minimum Performance Requirements

The Secretary presented the mandate of this new WG. The Chair remarked that the performance criteria would be amended only if necessary and that in chapter four other techniques could be considered, e.g. microarrays. He explained that the scope of the document is to provide performance requirements for all possible techniques to avoid rejecting methods for lack of acceptance criteria. Some participants expressed reservations in including sequencing approaches in the document given their qualitative characteristics and issues of applicability in detecting targets present at low concentration and/or in complex matrixes. The Secretary recalled that in the DECATHLON project some criteria for sequencing approaches had already been established and suggested expanding only to techniques that could be used for quantitative purposes, such as digital PCR. The Chair suggested redrafting the mandate and discussing the proposal again. The representative from The Netherlands remarked that requirements on sequencing approaches should be included to avoid producing a document already outdated before its completion. A participant suggested not opening the document to technologies for which the implementation could not be successfully guaranteed. The mandate was modified and approved.

7 Preparation ENGL Annual Meeting 30 September- 2 October 2019

The Secretary informed that the ENGL annual meeting will be organised from the 30th of September to the 2nd of October.

The Chair asked feedback on topics to be introduced in the agenda. He asked also to submit in advance the progress reports of the WGs. In the afternoon there will be a discussion on specific topics (i.e. food and feed derived from GM animal, synthetic biology) for which experts will be invited. He informed that the EURL GMFF could present the new approach for calculating performance scoring. The representative from Belgium proposed as topics strategies to identify GMM in food, generation of NGS sequences under accreditation and validation of NGS methods.

The science day will take place on the 3rd day. For this part of the meeting the Chair proposed for the international networking section an overview of GMO activities in Central Asia and in India, and for the other sections presentations on using high throughput sequencing for GMO detection and CRISPR/Cas as analytical detection tool. The representative from Germany proposed genome edited organisms listed in the Euginius database as a subject of general interest and a presentation of a tool for calculating the probability of detection (POD) in single laboratory validation. The representative from Switzerland

suggested genomic selection in cows (hybridisation chips) to illustrate techniques for screening genome traits.

The representative from Belgium proposed as topic off-targets effects with CRISPS/Cas to better identify GE products and the use of NGS for GMO detection. The Chair remarked that sufficient time should be allocated for discussions and suggested for the ENGL section to skip synthetic biology and include validation of NGS methods. The Chair asked sending the tentative titles and speakers' names for the talks.

8 Detection of food and feed plant products obtained by new mutagenesis techniques: feedback on the ENGL report and discussion

The Chair reported that a joint meeting of three MS WGs had discussed the ENGL report on new mutagenesis techniques (see point 5 above). At the meeting the MS representatives were informed that a new ENGL WG will be established to evaluate the applicability of the MPR document to these products. Concerns were expressed also on the legal interpretation of Directive 2009/41/EC for the detection of genetically modified microorganisms (GMM). The chair asked if the SC should establish a new WG on GMM or, in alternative, an ad-hoc WG. The task of this WG would be proposing a consolidated draft within the year. Participants favoured following the established procedures for the definition of the WG. The Chair suggested sending a draft proposal to ENGL members and organising a first physical meeting in the following year.

9 New activities (incl. WG on GMM detection)

The mandate of the WG on GMM detection was modified and circulated for further comments.

10 Use of JRC web tools (GMO matrix, GMO amplicons) and GMOMETHODS database

Two proposals for a survey on the use of the GMOMETHODS and JRC-Matrix web applications were prepared by the EURL GMFF. They were designed to receive feedback from the potential users. The EURL GMFF would appreciate feedback on the design of the surveys. The EURL GMFF will submit the survey on GMOMETHODS and GMO-Matrix web applications at the beginning of July.

The Chair asked if participants were employing the applications. About half of them declared to use them.

The representative from Belgium remarked that the JRC GMO Matrix is used as a golden standard, e.g. in the audit of the accreditation body, to confirm the laboratory results.

The representative from the UK considered the tools very useful and suggested, as requested in previous ENGL meetings, allowing in the web interface of the GMO-Matrix application the submission of own laboratory sequences, including stacks in the list of events and offering screening for unauthorised events.

11 Update on issues with Certified Reference Materials

The Chair informed that the problems concerning the quality of certain CRMs were discussed in a meeting between Europabio, the EURL GMFF and the Commission. He recognised that thanks to the feedback of ENGL members the Commission services had strong arguments for requesting an appropriate assessment of the CRMs in the authorisation procedure. A new workflow has been agreed to verify if the CRMs are fulfilling the requirements established by Regulation (EU) No 503/2013. The EURL GMFF will start verifying the suitability of the CRMs as routine assessment. In addition, the EURL GMFF will publish the conversion factors for the existing authorised events and establish the conversion factors for all the CRMs that are new in the application process. Participants asked if the conversion factors for CRMs could be included in the GMOMETHODS database.

A representative from Denmark asked if the CRM material could be provided as DNA. The Chair commented that the EU Regulation does not specify the nature, minimal volume or mass of the CRMs. If the applicant provides DNA this should be in sufficient quantity for performing the assay. It was remarked that sometimes the quantity is much lower than what is specified on the label and that the material is very expensive.

The Chair remarked that the laboratories as purchaser can make a complaint; if there is no answer, they should inform the EURL GMFF so that the problem could be communicated to EuropaBio.

The representative from Germany requested whether it would be possible to receive CRM material in a GM content range useful for the analysis around legal thresholds.

The Chair explained that the applicants cannot be legally obliged to provide such material and that the appropriate preparation of a dilution series is a laboratory responsibility.

12 Update on international standardisation (ISO TC34 SC16; ISO TC 276; CEN TC 275 WG11)

The Chair commented that the EURL GMFF has been more active in an increasing number of international committees. He informed that CEN is activating a new technical committee on food speciation and that the

scope of WG11 will be therefore modified. The last meeting was organised on the 6th of June 2019. CEN may start in the future projects on DNA sequencing and digital PCR.

At the global level the EURL GMFF is following the ISO committee TC34 for food, subcommittee SC 16 on markers for biomolecular analysis. This subcommittee has published a new standard for identification of species in animal food products. WG 8 is dedicated to animal species DNA-based analysis, mainly PCR. A systematic review will be performed in October on the ISO standards for qualitative and quantitative methods and on DNA nucleic extraction methods. WG 10 is dedicated to isothermal methods and it will be useful to have a contribution from ENGL members using those methods. ISO standards are under discussion for bioinformatics and pipeline validation of DNA sequencing approaches and on meta-data and sequence repository. The EURL GMFF is also contributing to ISO TC 276 (Biotechnology) where two items are of interest to ENGL: a draft on ISO general requirements for massive DNA sequence sub-library preparation, and a standard on quality of sequencing data. These drafts will be first voted this year and could be finalised by the end of 2020.

13 AOB

The EURL GMFF informed that a training workshop for NRLs will be organised on 12th-13th of November 2019 in Geel on applications of dPCR. It will be focused on GMO detection, method transferability, accreditation and use of conversion factors. The EURL GMFF will present the results of the work on conversion factors. On the 1st day the workshop will be centred on dPCR transferability and accreditation and on sharing experience on using dPCR for GMO detection. The 2nd day will be dedicated to conversion factors and practical experiences.

14 DAL SC37

The Secretary presented the updated DAL (Annex 2).

15 Meeting conclusions

The Chair noted that a lot of progress was made on a number of issues. The Secretary requested suggestions on speakers for the discussion topics on GM animals and validation of NGS sequencing approaches at the ENGL plenary. An internal moderator is also needed. For the discussion on GM animals the representative from The Netherlands suggested inviting speakers from China. The representative from Germany remarked that the topic of GM animal was better suited for a presentation than for a discussion and that it will be interesting to discover which methods are used for detecting new breeding technique products. The Chair confirmed that a discussion would not increase the general level of knowledge. New types of analysis and CRISPR/Cas tools developed for detection of NBT products should be covered.

The Chair thanked the members for their active participation and announced that the next SC meeting will be organised in February 2020. The Secretary will send a date proposal for the meeting.

Annex 1: agenda

37th ENGL Steering Committee
JRC Ispra, 18-19 June 2019

Room 3, Building 36



Day 1 – 18 June 2019

	Time	Topic	Documents in ENGLnet
1	9:00	<ul style="list-style-type: none">▪ Welcome, apologies, quorum	
2		<ul style="list-style-type: none">▪ Approval of the agenda	Draft agenda
3		<ul style="list-style-type: none">▪ Approval of the report of the SC36 meeting	Report SC36
4		<ul style="list-style-type: none">▪ Review of Dynamic Action List (DAL SC36)	DAL SC36
5		<ul style="list-style-type: none">▪ Update from SANTE	
	10:30	<i>Coffee Break</i>	
6	11:00	Progress ENGL working groups	
6.1		<ul style="list-style-type: none">▪ AG SMV (Advisory Group on Selection of Methods for Validation)	Progress reports
6.2		<ul style="list-style-type: none">▪ WG-UpMeth (Update of methods)	
6.3		<ul style="list-style-type: none">▪ WG-Proc (ENGL Procedures)	
6.4		<ul style="list-style-type: none">▪ WG-mpPCR (multiplex PCR methods)	
6.5		<ul style="list-style-type: none">▪ WG-seq (good practice/quality of DNA sequencing data)	
6.6		<ul style="list-style-type: none">▪ WG-DNAex (DNA extraction)	
6.7		<ul style="list-style-type: none">▪ Establishment of WG- MPR	
	12:30	<i>Lunch</i>	
7	14:00	<ul style="list-style-type: none">▪ Preparation ENGL Annual Meeting 30 September-2 October 2019	Draft agenda
	15:30	<i>Coffee Break</i>	
8	16:00	<ul style="list-style-type: none">▪ Detection of food and feed plant products obtained by new mutagenesis techniques: feedback on the ENGL report and discussion	
	17:00	<i>End of day 1</i>	
	19:30	<i>Dinner at Ristorante Bologna, Varese</i>	

Day 2 – 19 June 2019

	Time	Topic	Documents in ENGLnet
9	09:00	<ul style="list-style-type: none">▪ New activities (incl. WG on GMM detection)	
10		<ul style="list-style-type: none">▪ Use of JRC web tools (GMO matrix, GMO amplicons) and GMOMETHODS database	
11		<ul style="list-style-type: none">▪ Update on issues with Certified Reference Materials	
12		<ul style="list-style-type: none">▪ Update on international standardisation (ISO TC34 SC16; ISO TC 276; CEN TC 275 WG11)	
	10:30	<i>Coffee Break</i>	
13	11:00	<ul style="list-style-type: none">▪ AOB	
14		<ul style="list-style-type: none">▪ DAL SC37	
15		<ul style="list-style-type: none">▪ Final meeting conclusions	
	12:30	<i>End of the meeting and lunch</i>	

Meeting documents available at:

<https://enqlnet.jrc.ec.europa.eu/steering/37th%20ENGL%20Steering%20Committee/default.aspx?InstancelD=1>

Annex 2: action list

37th ENGL STEERING COMMITTEE ACTION LIST 19/6/2019				
ACTIONS	Resp.	Timelines	Status	Comments
ENGL GENERAL				
Report of 37th ENGL SC	SEC	15/07/2019	Open	
Annual meeting October (30 sept-2 october)	SEC		Open	confirm speakers/send draft agenda to ENGL for contributions
WORKING GROUPS				
Advisory Group on "selection of methods for validation" (SMV)				
Next meeting on 27/6/2019	SEC	27/6/2019	Open	
WG-UpMethod				
Prepare template for data collection from ENGL labs	WG		Open	see with WG if necessary
Send final draft with comments to WG and then to SC for approval	SEC	15/7/2019	Open	
WG-DNA extraction				
Organise web meeting	SEC	30/6/2019	Open	June with TF leaders
Organise physical meeting (full WG)	SEC	15/7/2019	Open	
WG-multiplex PCR				
organise sub-group meeting (web)	SEC	30/6/2019	Open	July
WG-seq				
Organise physical meeting (full WG)	SEC	31/12/2019	Open	end of 2019?
WG-Proc				
Draft procedure for ad-hoc working groups	WG	30/9/2019	Open	
VARIOUS				
Prepare list of terms and definitions used by the ENGL	SEC	30/9/2019	Open	SEC will prepare a draft (copy/paste from ENGL docs)
Survey on equipment management	SEC	15/7/2019	Open	Sciensano will provide a table
Survey on capacity building	SEC	30/6/2019	Open	ask F.7 for progress
MPR WG: establish WG and prepare 1st meeting	SEC	30/6/2019	Open	send mandate to ENGL and ask for WG members (whole network): kick-off may be web
ENGL WG on GMM in food and feed	SEC	15/7/2019	Open	send request to all ENGL with the mandate (after mandate is agreed by SC)
Launch 2 surveys on gmmethods and gmmatrix	SEC	07/07/2019	Open	
Update the list of observers with contacts of regional networks	SEC	31/7/2019	Open	with JRC F7

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