



36th ENGL Steering Committee Meeting

JRC Ispra

19-20 February 2019

Report



The European Commission's
science and knowledge service

Joint Research Centre

36th ENGL Steering Committee

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Report



European Network of GMO Laboratories

1 Welcome, apologies, quorum

The Chair welcomed the participants and asked to introduce themselves in a tour de table. The Secretary announced that a nuclear emergency exercise was planned on the following day at the JRC site and requested to remain inside the building until 12:30 h.

2 Approval of the agenda

The draft agenda (Annex I) was approved.

3 Approval of the report of the SC35 meeting

The report previously circulated for comments was endorsed without modifications.

4 Review of Dynamic Action List (DAL SC35)

The Secretary reviewed the open points on the list. The representative from The Netherlands noticed that in the DAL a follow-up point was missing on the Cry method which in some laboratories is thought to provide false positive results on rice samples (corresponding to endogenous rice sequences). The representative from Belgium remarked not having received any reply from the ENGL members on the questions concerning this issue and requested a technical analysis before making any conclusion. The Chair asked to be informed on the results of the discussion between the two institutions.

5 Update from SANTE

Certified Reference Materials (CRM)

DG SANTE received the note prepared by the EURL GMFF on issues with CRMs produced by AOCS. DG SANTE and the EURL GMFF will shortly have a meeting with applicants to address the problems raised and to agree on solutions.

ECJ ruling on targeted mutagenesis

DG SANTE had a discussion with Member States (MS) in the Standing Committee meetings on Regulation (EC) No 1829/2003 and Directive 2001/18/EC. They collected questions from MS, and positions and proposals for solutions. Aspects related to detection were shared with the EURL GMFF. No amendment to the GM legislation is foreseen for the current College of Commissioners.

ENGL report on the detection of genome edited products

DG SANTE actively participated to the elaboration of this document, both in the physical meeting of the drafting group organised by the JRC and in the electronic discussions of the drafting group.

Seeds

Member States favour more convergence on seed testing practices and confirmed their request of having DG SANTE as an acting facilitator on the practical implementation of Recommendation 2004/787/EC. DG SANTE established a WG on the subject. MSs actively participated in the first meeting. Different topics were raised on sample size, traceability of seeds, proficiency tests with GM seeds, homogenisation, statistics, resampling of batches for counter analysis, results and measuring unit, costs, practical enforcement of "zero tolerance", and mutual databases of seed batches to make testing more efficient. Additional meetings are planned during the year with the aim of reaching a consensus by the end of 2019.

A participant requested if seeds should be regarded as a first step in the food and feed marketing chain. DG SANTE informed that according to the legal interpretation sowing GM seeds falls under deliberate release of GMOs, which is covered by the new Official Controls Regulation¹. The Chair commented that an

¹ Regulation (EU) 2017/625

official clarification is still needed on this point.

Withdrawal of UK from the EU

Some MSs use UK-based labs as NRL. DG SANTE informed that these MSs should be prepared to appoint non-UK based labs as NRL.

Items raised by ENGL members:

As regards to the feed additive vitamin B₂, some participants asked whether guidelines are available for the detection of genetically modified microorganisms (GMM) in final commercial products. The Chair remarked that in the previous ENGL plenary meeting the JRC colleague managing the EURL on feed additives (EURL-FA) had already provided a presentation on the topic.

DG SANTE informed that Commission services and MS authorities are revising the feed additives Regulation² to set requirements for the detection of the production strain in the feed product. They released a proposal for consultation, which is under discussion with stakeholders, including EuropaBio. At the previous ENGL meeting it was already mentioned that not only traces of DNA but also of living organisms were detected in some products. DG SANTE remarked that before starting a discussion on this topic at the ENGL level the analytical target would need to be defined.

The representative from Germany reminded that the situation is confusing for official control laboratories. The EFSA guidance document on the characterisation of microorganisms used for feed production does not provide clear guidance on their detection in the final product.

The Chair acknowledged that a major difference exists in designing analytical strategies for detecting living organisms or traces of GM DNA in the final product and reminded that the EFSA guidance is focused on risk assessment, while the EURL GMFF is involved in the analytical detection.

6 Progress ENGL working groups

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

The Chair of the WG reported that information on the detection method for the potato reference gene will be fully evaluated at the next meeting. The pentaplex method submitted for validation is undergoing further experimental optimisation by the method developer. The members are also awaiting the publication of the new guidance on digital PCR to evaluate the ddPCR method previously submitted to the group.

The Secretary asked, if the potato GM event initially submitted for authorisation was currently under the Regulation (EU) 619/2014 or simply not approved; in the latter case validation of the 'potato reference method' would be considered as a low priority. DG SANTE clarified that the request for authorisation of the GM potato was withdrawn so that the Regulation setting the 0.1 m/m% as performance limit would not be applied. The representative from Belgium clarified that the request for authorisation of the GM potato was regarding industrial purposes, not food consumption but noted that it would be useful to have a validated method for the detection of potato.

Information on the optimisation of the GMOMatrix database of the JRC was requested. Some participants proposed considering methods for detection of universal reference genes in plants. The representative from Belgium remarked the difficulty of this endeavor given that the copy number of plant reference genes may change between species. A member suggested the gene actin as a general target since for qualitative purposes the number of copies is not an important criterion. The representative from Germany confirmed their interest in the project and informed that a method for the detection of plant DNA in honey had been published in the journal Food Chemistry.

The Secretary asked, if the WG should take on-board a gap analysis on GMM or GM animals and if its mandate should be enlarged despite its small capacity. Some participants expressed their interest in methods detecting GMM or GM animals and suggested enlarging the group with additional experts.

The representative from Latvia remarked the needs for methods detecting GM animals and in particular GM salmon and ornamental fish. The Secretary informed that a method for the detection of the GM salmon was published. The representative from Austria added that a method published by Norwegian colleagues is used in the laboratory for the detection of glowfish.

² Regulation (EC) No 429/2008

6.2 WG-UpMeth (Update of methods)

The Secretary announced that the group has prepared the draft final report and that this has been submitted for comments to ENGL members.

6.3 WG-Proc (ENGL Procedures)

The Secretary informed that the comments received by the SC members have been incorporated in the WG document. He asked, if these administrative rules should be approved only by the SC or need to be commented also by all ENGL members. He also informed that the WG was requested to draft an additional procedure covering the establishment and functioning of ad-hoc WGs.

6.4 WG-mpPRC (multiplex PCR methods)

The chair of the WG informed that a first draft of the document has been prepared in September 2018. In the following meetings the introduction was shortened and the subgroups on verification and validations were merged. The chair of the WG recognized the delay in delivering the final document. A web meeting has been organised for the end of February 2019 and a physical meeting will take place on 11th April 2019.

The Secretary announced that a call for a bio-informatician has been launched within the ENGL.

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

The WG leader reported that progress in the WG activities was rather limited. During the kick-off meeting a first document structure was defined and tasks assigned. The WG leader informed that the document may still be finalised within 2019.

The Chair suggested setting a more realistic timetable for the finalisation of the document. He informed that quite recently an ISO document on sequencing was drafted by ISO TC 276 and recommended ENGL members to provide substantial contribution to this ISO activity. He proposed organizing a WG physical meeting in conjunction with the ENGL plenary in October.

The representative from Belgium informed that some efforts have been made for defining minimum performance criteria on sequencing data and bioinformatics pipelines in fields other than GMOs. It was suggested to adapt the scope of the document to the GMO analysis needs. Different participants remarked that the area is very dynamic and broad ranging from single Sanger sequencing to entire genome sequencing.

The Chair suggested performing a gap analysis to identify technical approaches reliable enough to be used for regulatory purposes. Several members approved the proposal but underlined the difficulty of the task.

The Chair highlighted that identical sets of data could produce different final sequences because of the uncertainty not only in the raw data but also on their interpretation. The Chair suggested considering selected approaches to avoid the risk of working on a never-ending document and to focus not only on the new sequencing technologies but also on the classical Sanger techniques.

6.6 WG-DNAex (DNA extraction)

The WG leader presented an update of the progress of the group. The speaker reviewed the outline of the document. The members identified eight points and prioritised five tasks. The web space (task 1) was revised with a database including all extraction issues, a literature review (task 2) is under preparation, for task 4 (method verification and validation) the group will make an inventory of the capacity needed, while for task 5, quality assessment, the members are drafting a document. The group is considering the possibility of developing a decision support system, to start reviewing relevant papers and to harmonise the nomenclature. The group is planning a telephone meeting for future discussions. The representative from UK underlined that the database is based on the information collected at the training workshop organised by the JRC and LGC and that the terminology has been harmonised in line with the other ENGL guidance documents.

Participants requested whether the UK representative could continue contributing to the WG. The Chair confirmed the possibility of involving experts in their personal capacity and not as representative of an institution.

The Secretary enquired whether in the different MS a decision support system is existing for selecting extraction methods according to the sample matrix and asked to share that information.

7 ENGL/EURL report on "detection of genome-edited food and feed of plant origin"

The Chair proposed to discuss the latest draft prepared by the drafting group. The representative from Germany commented that the text of the document has been discussed among interested ENGL members the day before the SC meeting and that the SC members were expected only to vote on the approval/disapproval of the document; He also commented that, as the track changes for the modifications introduced in the new version were not available, one could not evaluate in a short time if the text was actually respecting the decisions taken during the discussion the day before.

The Chair acknowledged the remarks and asked whether the SC could proceed with the agreement on the document or if it prefers to discuss the text in detail.

Some participants expressed their preference for quickly reviewing the major changes and offering more time for the approval of the document. They considered it as useful to share with their colleagues the substantial novelties and the outcome of the work performed the day before. The representative from Germany asked to compare the working version discussed by the drafting team before the SC meeting with the new version to make the process transparent. The Chair proposed as alternative to present the major changes introduced in the text now. WB presented the new text, pinpointing to the major changes introduced. He clarified that the drafting group did not reach an agreement on how exactly to phrase some parts in the document. The Chair suggested reviewing the sections where the drafting team received suggestions for modification without having a written text proposal and then to use a written procedure (by email) for endorsing (or not) the document after the meeting. All participants agreed on the proposal and suggested modifications in the text of the new version displayed on the screen.

The Chair finally proposed to send the new draft version with the modifications suggested at the SC meeting to all SC members for comments within 5 working days. Comments will be taken on board only if there will be a phrasing proposal. The EURL GMFF will consolidate the version with the new comments and resubmit it to the SC members for formal vote. The Chair asked for other proposals. No other comments from SC members were received.

New Commission online system AGM

The JRC presented the new Commission online system (AGM) for invitation and reimbursement of experts attending meetings organised by the European Commission. In the invitation letter the participant will find two links (the first is to confirm the participation, the second for reimbursement requests which will be submitted on line by uploading travel details, expenses and supporting documents). The secretariat will review the information submitted and approve the reimbursement. This new system will speed up the reimbursement procedure. Links to the AGM portal and to an introduction video and a manual were provided.

8 Discussion on need to review the document "Definition of minimum performance requirements for analytical methods of GMO testing"

The Chair enquired whether a revision of the Methods Performance Requirements (MPR) document was deemed necessary, considering the recent ruling of the European Court of Justice on genome-edited organisms and the evolving of new detection technologies. According to the responses of the participants it was considered as essential to establish a WG and to define a mandate for reviewing the document. SC members suggested considering also digital PCR (dPCR) in the scope of the document revision. The representative from Italy proposed exploring also other detection principles available on the market. The representative from Slovenia suggested involving the ENGL WGs on sequencing and on digital PCR.

The Chair appreciated the suggestions but remarked that the validation standards provided in the documents need to be at regulatory, not at research level. He explained that it would be up to the WG members to define the new MPR document structure but highlighted that he would favour a MPR document part II covering the new topics to avoid modifying the current requirements for qPCR. Given the legal obligation of providing guidance to applicants on methods for GMO detection he remarked that also performance criteria for dPCR methods have to be explicitly established.

The Chair proposed that an invitation to join the WG and a proposal for the mandate could be submitted to the SC members by the ENGL Secretariat. A call for joining the WG would be submitted to all ENGL members. The proposal was approved.

9 Request of SANTE to prepare a report on detection of genome edited microorganisms

The Chair explained that DG SANTE requested a report also on the detection of microorganisms obtained by genome editing and asked for feedback from the participants.

Representatives of different countries agreed in considering the topic as an entirely new scientific area. They also concluded that it would be difficult to find enough experts within the ENGL. The preparation of the document would require a considerable amount of work and would not realistically be performed in the assigned timeline until June. Participants questioned whether they could address problems regarding genome-edited microorganisms when official control laboratories do not receive sufficient information even on conventional GMMs. Moreover, genome-edited microorganisms could be considered either as a product or a processing aid. In the latter case they would in their understanding not fall under the scope of the current GMO legislation and would be relevant only for incidental release in the final product. Some participants assumed that GMM as production strains for feed additives need their own authorisation under Regulation (EC) No 1831/2003.

The Chair remarked that for feed additives the safety assessment is performed on the final product introduced on the market and not on the production strain. The information on the strain is included in the dossier and the authorisation is not producer related as for GMOs. He commented that depending on the outcome of point 12 in the agenda a WG could be created on GMM in general and not only specifically on genome-edited microorganisms and that experts outside the ENGL could be considered.

The Chair proposed to distribute for comments from SC members a proposal for a reply of the ENGL SC to DG SANTE. SC members will then have at least a full week for providing feedback. All members agreed.

10 Request of SANTE to prepare a report on detection of genome-edited food and feed of animal origin

The Chair requested feedback also on the other report requested by DG SANTE on the detection of genome-edited animal food and feed products.

SC members considered it worthwhile addressing the subject but acknowledged their lack of expertise in the field. They envisioned also the difficulty of collecting information in the requested timeframe. It was further commented that genome editing for animals is already used but that GM animals were not yet detected on the EU market.

The Chair requested whether participants were aware of other organisations having expertise in the field. The Secretary suggested considering some experts from outside the ENGL to be invited for the ENGL plenary.

The Chair proposed to distribute to SC members a draft reply to DG SANTE on genome-edited animals in combination with the draft on microorganism detection. All members agreed.

11 ENGL Annual Meeting 2019

The Chair explained that the point on the ENGL plenary was included in the agenda to allow a timely submission of the invitations to the speakers. He provided information on the new format of the meeting where half a day would be dedicated to the NRLs' workshop, a full day to the ENGL-only meeting (or two half days if the NRL workshop would start in the morning) and finally a day for the open science session. The plenary will last a total of 2.5 days. He proposed as an option to start either in the morning of 1st October or in the afternoon of 30th September 2019. The Chair requested input from the participants on the specific topics to be covered in the closed session and in the open science day.

The representative from Italy proposed organising a brainstorming section with third-country experts on food and feed deriving from GM animals. The representative from The Netherlands proposed synthetic biology as a topic.

The Chair requested formulating more specific suggestions and proposed NGS detection of GMOs.

Other participants approved the proposal and expressed interest in presentations of existing projects using NGS for GMO detection. The representative from Belgium suggested presenting strategies to identify species in food enzymes and to validate NGS approaches for GMO detection.

The Chair informed that as an option other networks outside Europe could be invited and proposed, as an example, the representative from Azerbaijan who was unable to join the last plenary. He invited the participants to provide concrete names of institutions and contact details of candidate experts. He requested to be informed if any Working Group wishes to organise their physical meeting back to back to the plenary since arrangements need to be made in advance.

Some participants suggested starting the ENGL meeting on the 2nd of October so that the WG meetings could be organised either before or after the plenary. The representative from Germany reminded that the 3rd of October is a national holiday in Germany and asked not to overlap that day with an ENGL plenary.

The representative from Denmark asked to vary the date in which the ENGL meetings are organised as the current week may be inconvenient to different people.

The Chair explained that ENGL plenaries could not be organised before the month of October to allow evaluating the results of Proficiency Tests and not later than for the end of the same month to allow finalising the budget issues before the end of the year. However, the JRC will consider finding another week for the meeting in 2020.

12 New activities (e.g. WG on GMM detection, task force on definitions)

The representative from Belgium informed that in the frame of official control the NRL on GMOs from Belgium is using two methods to verify the presence of *Bacillus subtilis* in feed additive samples of vitamin B₂. One method (Paracchini et al., 2017), recommended by the EURL GMFF, is targeting a genomic region while the other (Barbau-Piednoir et al., 2015) is targeting a plasmid sequence. In September 2018 the NRL found a sample positive for both methods. In October 2018 the Belgian authorities notified to the Rapid Alert System for Food and Feed (RASFF) the detection of traces of recombinant DNA in a vitamin B₂ feed additive. MS authorities were invited by the Commission to withdraw affected products from the market. The NRL performed further analysis on several samples derived from this product. It did not find any viable organism but a full 1 kb antimicrobial resistance (AMR) gene in one sample. Upon request of the European Commission, EFSA expressed a new opinion indicating that the results were compatible with, but did not demonstrate the presence of, a full AMR gene in the feed additive.

The Belgian representative called for a constructive discussion at the ENGL level on the general problematics regarding GMM detection. For instance, the method used for official control identifies the GM modification but not the bacterial strain. Therefore, there is no link between the analytical target and the AMR gene. Consequently, it is very difficult for the competent authorities to take a decision on the safety of the product. There was the opinion that the EFSA guidance on the characterisation of microorganisms used as feed additives or as production organisms should indicate a minimum threshold for the related detection methods. Currently the text leaves room for different interpretations and does not provide harmonisation in the expression of minimal contamination units.

The Chair informed that the EURL GMFF had provided many comments to the public consultation for the EFSA guidance but never received a response. The technical Annex of Regulation (EC) 429/2008 will specify performance criteria for microorganism detection, and the proposal will take on board the needs of enforcement laboratories.

The Chair asked if the SANTE request to address the detection of genome-edited microorganisms should be addressed by an ENGL WG; given that the participants did not express any opinion if the WG was considered necessary. The representative from Denmark explained that in their view the ENGL does not have sufficient expertise in this field.

The Chair proposed including additional external experts in the WG and asked to define the possible scope of the working group. The decision on establishing this working group or not was postponed to the next Steering Committee meeting.

The Chair reminded that at the previous ENGL meetings a proposal on the harmonisation of terminology used in various ENGL documents was made. It was asked whether a task force on definitions should be established. Because of a lack of input it was decided to drop this point from the ENGL action list.

13 AOB

The Chair provided an update on the progress of the revision of the document on measurement uncertainty. He informed that the guidance was streamlined to better support the estimation of the uncertainty in the laboratories and that it should be published in 2019.

He announced that the conversion factors (CF) for Certified Reference Materials were to a large extent established. The EURL GMFF is aiming at producing the list of conversion factors, including all authorized CRMs, before summer 2019. He expects from control laboratories to alert the EURL GMFF when discrepancies are observed between the CRMs for which the CF information is provided and the CRMs available to the laboratories from RM producers/distributors.

The Chair informed that the results of the survey on CRM issues conducted within the ENGL was

submitted to DG SANTE. The authorisation holders have now to communicate with the CRM producer to correct the issues identified. NRLs and SC members will be kept informed on future developments.

The Chair reported that the draft note regarding the expression of results for samples containing more than one authorised GM event per species from the last meeting is still in finalization and will then be sent to DG SANTE. The EURL GMFF will include related instructions in the Proficiency Tests (PT) on how to do in the PT the reporting of results when stacked events may be present.

The representative from Germany informed that a German WG on GMO has already published guidance on the topic of detection of GMM.

The Secretary informed that the next SC meeting will be organised on the 18th-19th of June 2019.

14 Dynamic Action List (DAL) SC36

The Secretary presented the updated DAL (Annex 2).

The Chair expressed his appreciation for the work performed by one of the most active members of the ENGL that according to the Consortium Agreement would not be able to participate as ENGL member after the withdrawal of the UK from the EU. He requested the potential availability of the colleague as personal expert, which could relate to ENGL working groups and plenary meetings.

The Chair thanked the participants and closed the meeting.

Annex 1: agenda

36th ENGL Steering Committee JRC Ispra, 19-20 February 2019

Room 3, Building 36



Day 1 – 19 February 2019

	12:30	Lunch	
	Time	Topic	Documents in ENGLnet
1	14:00	<ul style="list-style-type: none">▪ Welcome, apologies, quorum▪ Approval of the agenda▪ Approval of the report of the SC35 meeting▪ Review of Dynamic Action List (DAL SC35)▪ Update from SANTE	Draft agenda Report SC35 DAL SC35
	15:30	Coffee Break	
6	16:00	Progress ENGL working groups <ul style="list-style-type: none">▪ AG SMV (Advisory Group on Selection of Methods for Validation)▪ WG-UpMeth (Update of methods)▪ WG-Proc (ENGL Procedures)▪ WG-mpPRC (multiplex PCR methods)▪ WG-seq (good practice/quality of DNA sequencing data)▪ WG-DNAex (DNA extraction)	Progress reports
	17:30	End of day 1	
	19:30	Dinner at Villa Borghi	

Day 2 – 20 February 2019

	Time	Topic	Documents in ENGLnet
7	09:00	<ul style="list-style-type: none"> ▪ ENGL/EURL report on "detection of genome-edited food and feed of plant origin" 	Draft report
	10:30	<i>Coffee Break</i>	
8	11:00	<ul style="list-style-type: none"> ▪ Discussion on need to review the document "Definition of minimum performance requirements for analytical methods of GMO testing" 	
9		<ul style="list-style-type: none"> ▪ Request of SANTE to prepare a report on detection of products of genome edited microorganisms 	
10		<ul style="list-style-type: none"> ▪ Request of SANTE to prepare a report on detection of genome-edited food and feed of animal origin 	
	12:30	<i>Lunch break</i>	
11	13:30	<ul style="list-style-type: none"> ▪ ENGL Annual Meeting 2019 	
12		<ul style="list-style-type: none"> ▪ New activities (e.g. WG on GMM detection, task force on definitions) 	
13		<ul style="list-style-type: none"> ▪ AOB 	
14		<ul style="list-style-type: none"> ▪ DAL SC36 	
	16:00	<i>End of meeting</i>	

Meeting documents available at:

<https://enqlnet.jrc.ec.europa.eu/steering/36th%20ENGL%20Steering%20Committee/default.aspx?InstanceID=1>

Annex 2: dynamic action list (DAL)

36th ENGL STEERING COMMITTEE ACTION LIST 20/2/2019				
ACTIONS	Resp.	Timelines	Status	Comments
ENGL GENERAL				
Report of 36th ENGL SC	SEC	15/03/2019	Open	
Dates 37th ENGL SC 18/19 June	SEC	28/2/2019	Open	
Annual meeting October (30 sept-2 october)	SEC	15/4/2019	Open	ask SC for proposals on topics/speakers
WORKING GROUPS				
Advisory Group on "selection of methods for validation" (SMY)				
Organise next meeting	SEC	28/2/2019	Open	
WG-UpMethod				
Prepare template for data collection from ENGL labs	WG	28/2/2019	Open	see with WG if necessary
Review comments	WG	31/3/2019	Open	
WG-DNA extraction				
Organise 2nd meeting	SEC	31/3/2019	Open	
WG-multiplex PCR				
Organise 2nd meeting	SEC	28/2/2019	Open	April
WG-dPCR				
Publish final doc	SEC	28/2/2019	Open	
WG-seq				
Organise meeting with tasks coordinators	SEC	28/2/2019	Open	Ask EK for dates, web meeting
Meeting of whole WG in october	SEC	31/5/2019	Open	depending on the progress
WG-Proc				
draft procedure for ad-hoc working groups	WG	15/3/2019	Open	
Send final draft to ENGL for comments	SEC	31/3/2019	Open	
VARIOUS				
Prepare list of terms and definitions used by the ENGL	SEC		Open	for later consideration
Survey on equipment management	SEC	30/4/2019	Open	in preparation to the Annual Meeting
Survey on capacity bulding	SEC	30/04/2019	Open	with JRC F7
Send doc NMT to SC for commnts	SEC	20/2/2019	Open	deadline for comments 27/2 5 pm; final draft to SC on 4/3 for formal voting, end of voting 11th march 5 pm
Prepare request from ENGL to SANTE on summing up GM levels	SEC	28/2/2019	Open	
Point on GMM WG on the agenda of the SC June meeting	SEC			
cry1 rice method specificity	SEC	01/04/2019	Open	wait for join note from EK and NR
Send mandate of WG-MPR to SC	SEC	28/2/2019	Open	for comments and ok by the SC
Prepare draft reply to SANTE on genome edited GMM and animals	SEC	28/2/2019	Open	send it to SC for ok
Update the list of observers with contacts of regional networks	SEC	15/03/2019	Open	with JRC F7

