



32nd ENGL STEERING COMMITTEE MEETING

15-16 February 2017, Ispra (Italy)

MEETING REPORT

1. Welcome, apologies, quorum

The Chairman welcomed the participants and announced that the representatives from Slovenia, Lithuania, Estonia, Greece, Ireland and Norway were not able to attend the meeting. He introduced himself and asked for a tour de table presentation of the participants. He explained that according to the consortium agreement the SC should meet twice a year but should use the meetings more effectively for discussing and sharing information; the Secretariat should systematically collect ideas and reports on the working groups activities before the meeting and publish them on ENGLNet so that participants would be prepared for the discussions. The Chairman acknowledged that a lot of the work in the ENGL is done on a voluntary basis, yet the deliverables should be completed in a reasonable time frame.

Participants agreed and suggested to include these actions in the SC procedures.

The Chairman announced that two additional points regarding JRC training proposals were included in the agenda

2. Approval of the Agenda

The agenda (Annex 1) was approved with those amendments.

3. Approval Report of the 31st ENGL SC meeting

The report previously circulated for comments was approved without modifications.

4. Review of Dynamic Action List (DAL SC31)

The Secretary reviewed the open points of the list and informed that the method of detection of 35SpCambia has been published in the GMOMETHODS database. The Chairman announced that for the following meeting the action list will be distributed for comments in advance.

Participants commented that as an outcome of the CRISPR/Cas technology discussion forum a collection of articles has been made available on the ENGLNet. Participants proposed a follow up on this discussion but the Chairman discouraged starting actions on analytical approaches without a clear legal framework.

5. Update from SANTE

DG SANTE explained that a Scientific Advice Mechanism (SAM) has been set up to support the Commission with high quality, timely and independent scientific advice for its policy-making activities and is currently being consulted for receiving advice on new techniques in agricultural biotechnology. The scientific reports and opinions are prepared by a High Level Group of Scientific Advisors comprising seven independent scientists collaborating with a consortium of European and national academies of the Member States (MS). The Commission submitted a request to SAM in September 2016 covering four points:

- 1) Key characteristics of the various new techniques in agricultural biotechnology
- 2) Comparison with established techniques
- 3) Scientific needs and gaps
- 4) Expected trends and forthcoming developments

The requests included synthetic biology and genes drive. Description and comparison with the established techniques were addressed first and will be the subject of an explanatory note expected by the end of March 2017¹.

In relation to new techniques, the French Council of State (Conseil d'Etat) has requested a preliminary ruling of the Court of Justice of the European Union regarding the exclusion of organisms produced by mutagenesis from the GMO-legislation and whether this exclusion applies to all mutagenesis techniques or only to the ones developed in the past. Pursuant to the Treaties, only the Court of Justice of the European Union (CJEU) can provide legally binding interpretations of acts of the institutions of the Union.

A debate on the use of modern biotechnology in agriculture is being organised by the Commission; a high-level conference will be organised on 28 September 2017 in Brussels. The objective is to gather input and foster constructive debate between a wide range of stakeholders on how to promote innovation and assure safety in the EU.

DG SANTE provided an update on the developments on synthetic biology under the Convention on Biological Diversity (CBD), in particular on the Decision on synthetic biology adopted at the 13th meeting of the Conference of the Parties (COP 13, Mexico, 4-17 December 2016). The operational definition of synthetic biology developed by the Scientific Committees SCENIHR, SCHER and SCCS was taken up and slightly modified in the CBD Decision. However, no agreement for a full endorsement of that definition was reached. Living organisms developed through current and future applications of synthetic biology were considered similar to LMOs (Living Modified Organisms) and can be assessed with existing methodologies for risk assessment. However, there was not agreement on whether or not some organisms, currently in the early stages of research and development, would fall under the definition of LMOs within the Cartagena Protocol. It was also decided to extend the mandate of the Ad Hoc Technical Expert Group on Synthetic Biology for continuing the work with the assistance of an open-ended online Forum and the invitation of experts. The results of these discussions will be a recommendation to COP 14 in Egypt in November 2018.

DG SANTE informed that the Commission recently published a report on the implementation of Directive 2009/41/EC on the contained used of genetically modified microorganisms (GMM); it is based on the reports submitted by the Member States on the implementation of the directive.

Finally DG SANTE informed about the very recent proposal by the Commission to amend the Comitology Regulation in order to increase transparency and accountability in the procedures for implementation of EU legislation (information available at http://europa.eu/rapid/press-release_IP-17-264_en.htm).

6. Progress ENGL working groups

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

The Secretary suggested organising a meeting for reviewing the two methods submitted, a multiplex digital PCR for soybean and a method for detecting potato DNA. The new chair of the group is Nina Papazova.

6.2 WG-UpMeth (Update of methods)

The group is still discussing some definitions and the workflow. Guidelines are needed especially for accreditation. The Chairman proposed a physical meeting for solving the open issues and suggested preparing a report before the next ENGL plenary.

6.3 WG-Mvrf2 (method verification)

A final draft has been agreed but that some comments still need to be addressed to improve the report. The Secretary proposed organising a last meeting for finalising the document.

6.4 WG-dPCR (Digital PCR)

The Chair announced that a subgroup is working on the final corrections. The Chairman suggested providing an updated report before the next ENGL plenary.

6.5 WG-UoM (Unit of Measurement)

¹ At the time of issuing this report, the SAM explanatory note has been published and is available at https://ec.europa.eu/research/sam/pdf/topics/explanatory_note_new_techniques_agricultural_biotechnology.pdf

The speaker announced that the document on "Unit of Measurement" has been submitted for review to all ENGL members and that it will be published shortly. It is believed that it could have an impact in other fields of the scientific community.

6.6 WG-Proc (ENGL Procedures)

The chair reported having drafted some proposals for operational procedures not covered by the Consortium Agreement. The proposals were sent to the other members of the group.

7. New activities

7.1 Future Working groups

The Chairman reminded that the number of WG should correspond to the ENGL capacity to perform the activities. Participants suggested including in the report on "Unit of Measurement" guidance on how to implement conversion factors to avoid the creation of a new WG and the preparation of two documents on the same subject. It was proposed setting up a new a WG on good practice for sequencing approaches. Other participants suggested working on species identification; the Chairman commented that for the ENGL plenary of September 2017 the JRC Unit dealing, among other issues, with species identification could be invited for a presentation. SANTE suggested activities on new approaches for detecting non authorized GMOs.

The Secretary suggested starting by defining, by the end of May, a mandate for the WG on DNA sequencing.

7.2 ENGL guidance on multiplexing (see DAL 26th ENGL plenary)

The Chairman enquired on the need for creating a WG on PCR methods multiplexing. Mr. Grohmann supported the proposal and explained that it should cover especially an approach so that elements of a multiplex assay could be changed in a flexible way.

Participants remarked that multiplex methods for screening purposes are covered by the new "verification" document but that performance criteria for quantitative multiplex methods are not yet included in the Methods Performance Requirement (MPR) document.

7.3 Preparation of training workshops on DNA extraction and on digital PCR

The Chairman enquired over the topics to be covered in the workshop on DNA extraction. It was suggested including matrix-based decision systems DNA quantification after extraction.

The Secretary requested to define the target customers for the training on digital PCR. He remarked that an attendance of maximum 20 participants was foreseen and that hand-on training was not feasible. It was concluded that a reasonable training solution could cover practical approaches and sharing of experiences.

8. ENGL Topics

8.1 Preparation of the 27th ENGL plenary (6-7 April 2017)

8.1.1 Accreditation for GMO analysis using dPCR

The Chairman announced that the JRC will organise as of 2018 one ENGL plenary per year. The meeting will take place in September/October in conjunction with the workshop of the NRLs. This arrangement will allow the presentation of the CT results and leave enough time for the organization of the EURL GMFF activities. He informed however that for the year 2017 the JRC will organize two ENGL plenaries in April and September as planned. The Chair solicited a reflection on the purpose of the ENGL meetings.

Members agreed in considering the ENGL plenaries as an opportunity for discussing and sharing information but also for listening to high quality lectures from experts. The interactive break-out groups were considered very valuable for involving members in the discussion especially for the laboratories not participating to the Steering Committee meetings.

The Chairman suggested having plenary lectures that could serve as a topic for discussion in the break-out groups and proposed improving the preparatory phase of the plenaries. Supporting documents should be distributed not later than 15 days before the meeting so that participants could be prepared for the discussions.

It was proposed to enlarge the participation to GMO networks of other regions to increase exposure to international subjects. In that respect Japan is very active in GMO testing and it was suggested inviting a representative for a presentation.

It was also proposed extending the duration of the plenary by e.g. organizing one day for lectures, another for break-out group discussions, and a final one for presenting and sharing information with other GMO networks. Members supported both proposals. The Secretary remarked that regional network representatives could be invited as observers (Asia, Mena, South America and Japan). The Chairman commented that the number of participants to the ENGL meeting is not restricted but that the financial coverage will remain restrained.

For the scientific technical sessions of the plenary the following topics were collected from the participants:

- Allergens detection (JRC)
- Experience with 17025 accreditation on GMO analysis also for the break-up group discussions
- Guidelines on digital PCR
- New breeding techniques (what to measure)
- Presentation of the results of the Decathlon projects on unauthorized GMOs and species identification, methods performance parameters
- Presentation on new technological developments in Japan

The Chairman solicited submission to the Secretariat of other topics for the break-out group discussions.

8.2 ENGL role in research projects (see DAL 26th ENGL plenary)

In the past the ENGL proposed topics resulting in large EU research projects. It was suggested setting an information platform and exploiting the resources within the ENGL for preparing new research proposals at EU level.

The Chairman enquired whether some participants could be interested in functioning as a moderator for this information platform and asked indicating to the Secretariat needs for research topics.

8.3 AOCS CRMs

Recently the EURL GMFF was informed of findings about two existing AOCS Certified Reference Materials (CRMs) not in line with the declared purity.

The findings of a survey on CRMs conducted by the German NRL among the laboratories of the German national network were presented. A substantial number (30%) of laboratories was not satisfied with the quality of the AOCS CRMs while others were complaining about the insufficient grinding of the material. It was noted that the label on the vials recommended using for the DNA extraction 1 g of CRM material which is a high sample intake. In some cases the concentration or amount of CRM DNA is insufficient for the validation and verification studies. Laboratories further criticized the lack of information on the particle size and their homogenization. One laboratory discovered by digital PCR that for two events the percentage values were different from what was declared on the labels.

The Chairman commented that AOCS is holding an ISO Guide 34 accreditation and that the detected inconsistencies were violating the accreditation standard. The EURL GMFF will send a corresponding letter after having received the information described above.

9. Table on DNA extraction methods

Participants commented that the draft table could be useful for the upcoming JRC workshop of DNA extraction. The EURL GMFF agreed to transform the table into an EU survey giving a six weeks deadline for the response.

10. Cry1Ab detection method (RASFF 2016.0082 spicy sauce shrimps and Thai rice)

The Secretary informed that a Cry1Ab element has been detected in material coming from Thailand. The Chairman commented that the French member will be contacted for clarification. Commission services will be also enquired on the minimum information necessary for an entry into the RAFFS system. The EURL GMFF will report back to the ENGL to give some guidance.

11. AOB

The EURL GMFF informed that the next CT will be launched on the 24th of February 2017.

12. DAL SC32 and End of Meeting

The Secretary reviewed the new DAL (Annex 2) and announced that the next ENGL plenaries will be organised on the 6th-7th of April and 20th-21st of September. The next Steering Committee meeting is planned for the 20th (morning) -21st (afternoon) of June 2017. The Chairman thanked the participants for the interesting and productive discussions and closed the meeting.

Annex 1 - Agenda





32nd ENGL STEERING COMMITTEE MEETING

15-16 February 2017, Ispra (Italy) Building 101

Draft Agenda

Day 1 – 15 February 2017 Room 1302

	12:00	Buffet lunch	
	Time	Topic	Documents in ENGLnet
1 2 3 4 5	13:00	 Welcome, apologies, quorun Approval of the agenda Approval of the report of the SC31 meeting Review of Dynamic Action List (DAL SC31) Update from SANTE 	Agenda Report SC31 DAL SC31
6 6.1 6.2 6.3 6.4 6.5 6.6	14:30	Progress ENGL working groups AG SMV (Advisory Group on Selection of Methods for Validation) WG-UpMeth (Update of methods) WG-Mvrf2 (method verification) WG-dPCR (Digital PCR) WG-UoM (Unit of Measurement) WG-Proc (ENGL Procedures)	
	15:45	Coffee Break	
7 7.1 7.2	16:15	New activities Future Working groups ENGL guidance on multiplexing (see DAL 26th ENGL plenary)	
	17:30	End of day 1	
	19:30	Dinner at Ristorante Villa Borghi, Varano Borghi	

Day 2 – 16 February 2017 Room 1003

8 8.1 8.1.1 8.2 8.3	09:00	Preparation of the 27th ENGL plenary (6-7 April 2017) Accreditation for GMO analysis using dPCR ENGL role in research projects (see DAL 26th ENGL plenary) AOCS CRMs	Draft Agenda
	10:45	Coffee Break	
9 10 11	11:15	Table on DNA extraction methods Cryl Ab detection method (RASFF 2016.0082 spicy sauce shrimps and thai rice) AOB	
12	12:15	DAL SC32 and End of Meeting (12:30)	DAL SC32
	12:30	Sandwich lunch	

Meeting documents available at:

Annex 2 - Action List

32nd ENGL STEERING COMMITTEE ACTION LIST 16/2/2017				
ACTIONS	Resp. ▼	Timelines v	Status	Comments
ENGL GENERAL				
Report of 32nd ENGL SC	SEC	15/3/2017	Open	
Organise 27th ENGL Plenary in Ispra	SEC	15/3/2017	Open	6-7 April. Send draft agenda for input
WORKING GROUPS				
Advisory Group on "selection of methods for validation" (SMV)	050	00/0/0047		the second state of the second state of
Organise next meeting	SEC	28/2/2017		two new methods to be evaluated
WG-UpMethod				
Prepare template for data collection from ENGL labs	EURL + WG	30/4/2017	Open	JRC is working on it
Organise next meeting	SEC	28/2/2017	Open	ASAP
WG-UoM				
Publish the final report	SEC	31/3/2017	Open	
WG-dPCR				
Present the final report at the next plenary meeting	SEC	04/10/2017	Open	
WG-MVrf2				
Organise web meeting	SEC	28/2/2017	Open	ASAP
WG-Proc				
Procedure on functioning of discussion forum	SEC	31/3/2017	Open	organise a meeting by VC
VARIOUS Discussion forum on implementation of Reg. 619/2011	SEC	15/03/2017	0	No volunteer to moderate. Maybe Nina?
Discussion forum on CRISPR			Open	Contact moderator for a report for the plenary april
	SEC	28/02/2017	Open	Contact moderator for a report to rithe pienary april
Share list of members of WGs	SEC	28/2/2017	Open	
Setup a WG on multiplex methods	SEC	31/03/2017	Open	Lutz to draft a mandate
New WG on good practice/quality of sequencing data	SEC	30/04/2017	Open	Define a mandate (Esther, Malcolm, Lutz)
Setup forum for identitying research topics	SEC	15/3/2017	Open	need a moderator, ask for volunteers
Update the list of observers with contacts of regional networks	SEC	28/2/2017	Open	
Send out the table to the ENGL	SEC	28/2/2017	Open	Deadline end of april