



31st ENGL STEERING COMMITTEE (SC) MEETING

21-22 June 2016 Ispra, Italy

Report

1.1 Welcome, apologies

The Secretary welcomed the participants and SANTE (connected via video-link). He announced that the Chair would be able to join the meeting at a later stage. The following Member States (MS) were excused: Czech Republic, Croatia, Estonia, Finland, Greece, Ireland, Lithuania, Romania and Portugal.

1.2 Approval of the agenda

The Secretary informed that an additional point had been added to the agenda regarding the EURL GMFF validation reports, in particular a discussion on parameters and their impact on the performance of the methods. The Agenda (Annex 1) was approved with this modification.

1.3 Approval of the report of the SC30 meeting

The report of the SC30 meeting, previously circulated, was approved without changes.

1.4 Review of Dynamic Action List (DAL SC30)

The Secretary reviewed the Dynamic Action List (DAL) of the previous meeting. There was no discussion on the points presented.

1.5 Update from SANTE

DG SANTE informed that the report of a technical study concerning needs for harmonisation was distributed for comments to Member States Competent Authorities and will be discussed in July at the Standing Committee on Plants, Animals, Food and Feed (PAFF) meeting.

The German representative remarked the difficulty in implementing the performance level at the 0.1%, as required by Regulation (EU) No 619/2011, because of lack of certified reference materials (CRM) at this percentage level. Other members expressed the same opinion and remarked that technical difficulties in the preparation of the material were leading to high uncertainty values. They all agreed to establish a discussion forum to collect methodological problems in the implementation of Regulation (EU) No 619/2011 and draft a final report proposing technical solutions. DG SANTE agreed on the proposal but reminded that according to EU legislation the applicants are not obliged to provide CRM at the 0.1% level.

Upon a request by one of the SC members, DG SANTE explained that a questionnaire on seeds had been launched many months before but that the analysis of the results has been kept on hold because of other priorities.

2 Progress reports ENGL working groups

2.1 WG-UpMeth (Update of methods): update

The WG chair explained that the JRC is preparing a template for collecting raw data on methods performance from the laboratories. The data would help verifying if the methods are still fit for the purpose. The WG is also investigating new definitions of "core PCR method", "PCR method/module procedure or method protocol" and "equivalent method/module procedure" according to ISO guidelines. Future activities will regard the provision of a template and guidance to laboratories for submitting existing in-house validation data and establishment of connections with relevant ENGL WGs (i.e. AG-SMV, new WG on method verification and on digital PCR). A meeting is planned in October 2016 for the finalisation of the document.

The Chair remarked that the technical role of the ENGL in defining the parts of the protocols that are not modifiable is very important for the entire control system. He suggested sharing the draft document with SC members for incorporating feedback and comments before the presentation to the ENGL plenary. A final document could then be completed and approved by the SC in February 2017.

2.2 WG-dPCR (Digital PCR): update

The WG chair informed that a fourth meeting had been organised in April for the drafting sub-group. The group had long discussions on a case by case transferring of a validated method with all its specificity testing into a dPCR format. A second meeting for the drafting sub-group is planned in July for discussing the section on the *in-house* validation/verification of a dPCR and revision of the condensed technical part. The draft document will be then circulated for comments to the entire WG.

2.3 WG-UoM (Unit of Measurement): update

No update was provided.

2.4 WG-Mvrf2 (Method Verification): update

The WG chair explained that the mandate of the group includes the definition of verification criteria for techniques not currently covered, alignment with the new Method Performance Requirements (MPR) document and review of the terminology. The chair reported that the group had a kick-off meeting and two web-meetings in April while a fourth and fifth web-meetings were planned respectively in June and July. The final document is almost completed and should be finalised for the ENGL plenary in September. The Secretary suggested anticipating the last web-meeting for submitting the final draft to the SC members and receiving feedback before the ENGL plenary.

2.5 WG-Proc (ENGL Procedures): update

The mandate of the group does not entail a modification of the ENGL Consortium Agreement (CA) but the definition of the internal operational procedures and routine activities. The group, constituted by few members, had its first meeting on the 13th of April 2016 but that it is still lacking a chair. The Secretary asked for volunteers. The work plan includes a gap analysis of the CA, agreement on the procedures to be defined and a working draft by the Secretariat describing the *status quo* which could be used as a starting point for further developments. The following gaps were identified in the first meeting:

- Formal approval and publication of ENGL documents
- Observers/invited speakers
- Functioning of WGs
- Request of membership to the Secretariat
- Participation of industry/private companies/other stakeholders to ENGL meetings
- Partners in liaison to the ENGL (foreseen in the CA)

Members suggested defining procedures for addressing new topics or technical developments; input and advice from other stakeholders during the meetings could be useful but underlined that invitations should be clearly based on personal expertise and discussions should be purely scientific and technical. Moreover, separate sections at the plenary should be dedicated to participation of external members. The Secretary commented that participation of non-ENGL members to ENGL meetings is currently approved by the SC on a case by case approach. He proposed defining a procedure for the invitation leaving the final approval to the SC.

2.6 AG SMV (Advisory Group on Selection of Methods for Validation): update

The WG chair informed that no additional methods have been submitted since the last meeting. IPH (BE) could propose two construct-specific methods for validation: one for detecting the AquaBounty GM salmon and another for identifying the GMM *B. Subtilis* overproducing Vitamin B2. SANTE informed that the Commission received from the U.S. Food and Drug Administration (FDA) the GM salmon samples and the relative detection method but not CRM. This was an issue for the possible validation of the method since the Commission cannot approach the applicant directly. The German representative informed that the German national network received the protocol for a multiplex gel-based conventional PCR method from AquaBounty and that the company was willing to send material to be distributed to the laboratories. Members suggested coordinating the work to avoid duplication of efforts.

The Chair encouraged SC members in proposing methods to the AGSMV WG. Participants suggested validating dPCR methods and having discussions on best NGS platforms.

3. Future Working groups

The Chair remarked that new breeding techniques (NBT) are evolving very rapidly and asked if this technology should be discussed in a proper WG. Members suggested monitoring the field and waiting for later developments.

Regarding implementation of Regulation (EU) 619/2011 the Secretary suggested having an electronic forum and requested to submit questions that could trigger discussion. The Chair asked for volunteer moderators.

The Chair launched a tour de table for collecting points of interest to the entire network. Participants suggested categorization of food matrixes and DNA extraction methods, guidance on the development and validation of multiplex methods in the MPR document. The Secretary suggested launching a survey on DNA extraction and deciding later if a WG would be necessary. A representative from Slovenia informed that an article on a matrix-based DNA extraction approach was recently published (http://bijh-s.zrc-sazu.si/ABS/SI/ABS/Cont/58_2/61_Zel%20et%20al_ABS%2058_2.pdf ?). Members finally suggested more visibility and participation as a network at standardization bodies meetings (i.e. ISO and CEN).

4. Progress on the validation of the pCambia method.

The EURL GMFF reported that all the results from the laboratories have been received and that the data analysed. The performance parameters could be considered in line with the ENGL MPR criteria except than for the 20 copies GM level. Members suggested including the method in the GMOMETHODS database without waiting for the publication of the article on the collaborative study. This approach could speed up the availability of the method to laboratories for performing the analysis.

5. JRC reorganization

The Chair explained the strategy and the structure upon the JRC reorganization foreseen for the 1st of July 2016. The Institute for Health and Consumers Protection, within which was operating the EURL GMFF will be merged with the Institute for Reference Materials in the new Directorate F – Health, Consumers and Reference Materials with headquarters in Geel (Belgium). All EURLs including the EURL GMFF will be combined in the new Unit JRC-F.5 "Food and Feed Compliance" under the responsibility of Prof. Hendrik Emons. The Chair remarked that the colleagues interacting with ENGL members will remain mainly in Ispra in that unit. The Bioinformatics group will be splitted in two units, JRC-F.4 "Fraud Prevention and Detection" headed by Mr. Franz Hubert and the JRC-F.7 "Knowledge for Health and Consumer Safety" under the responsibility of Mr. Guy Van den Eede. He finally announced to be moving to Bruxelles in the role of Adviser for Bio-Economy. He assured the participants on the continuation of the ENGL role and the commitment of the JRC in maintaining the activities serving two legal mandates. The Secretary added that in future work programs the ENGL will be linked to the EURL GMFF.

Participants expressed their concern on the continuing provision of bioinformatics support and availability of tools existing on the EURL GMFF web pages, such as the JRC-GMO Matrix and JRC Event Finder which are very much appreciated by official control laboratories. In addition, concern was expressed on the support for BCH activities and collaboration on common vocabulary for genetic elements between the GMOMETHODS database and EUginius database groups. Participants requested further clarifications on the capacity building activities which in their opinion have a direct impact on their work. The Secretary informed that a new Administrative Arrangement has been signed with SANTE to continue those activities and that for the time being the EURL GMFF will still be responsible for their provision.

6. Roadmap for the Network on Species Identification

The Chair explained that species identification is covered in the mandate of unit JRC-F.4 but that a new network linked to these activities could be organised and the ENGL could play a role also in this field. The Secretary could brief the new unit heads on the species identification workshop hosted by the JRC the previous year.

7. Dates of 2017 meetings

The following dates were proposed for the following SC and ENGL meetings in 2017: February (SC), April (ENGL Plenary), June (SC), September (NRLs WS + ENGL plenary). The Secretary will investigate if the dates overlap with other events.

8. Other ENGL matters

The EURL GMFF presented the results of the collaborative trials for detecting the events cotton MON88701, soybean MON87751 and maize VCO-01981-5. All three methods exhibited performance values in line with the ENGL method acceptance criteria in the preliminary in-house testing conducted by the EURL GMFF (step 3). The data from the collaborative studies instead did not entirely fulfil the ENGL performance requirements for some variables.

The bias values for the 0.1% level resulted to be outside the $\leq 25\%$ limit for the cotton MON88701 and soybean MON87751 methods. The PCR efficiencies for both the GM and reference gene systems for cotton event MON88701 resulted to be outside the 90%-110% interval required. In the collaborative study for detecting maize event VCO-01981-5 the RSDr values for the 0.1% test level resulted to be higher than the acceptable limit. Further tests were later performed by the EURL GMFF to investigate these findings and confirmed the variability of the results.

The EURL GMFF wished to verify if the SC members were still considering those methods fit for the intended purpose. Some participants expressed concern on accepting methods that do not fit the established criteria fearing that this could lead to a relaxed application of the requirements for all methods. Others remarked that

control laboratories may face difficulties with the results if they are not in line with their internal control system. After the discussion all SC members agree on drafting the reports carefully alerting laboratories on the problem and on monitoring their performance. Participants further suggested submitting the test samples again to some laboratories on a voluntary basis to perform a small ring-trial. The Chair commented that the acceptance criteria for the 0.1% level was defined without appropriate testing experience at that low level and proposed starting a discussion on the issue. These results confirmed the idea that CRM at the 0.1% level would be helpful for harmonising the analyses.

9. Preparation of the 26th ENGL plenary (21-22 September 2016, including the NRLs annual workshop)

The Secretary presented the draft agenda. The following topics were suggested by the SC members:

- 1) Training needs for NRLs
- 2) Workflow for detecting non-authorised GMOs
- 3) Presentation of the outcomes of the "Technical Meeting on the impact of Whole Genome Sequencing (WGS) on food safety management" organised by FAO in May
- 4) Presentation from the JRC advisor for bio-economy
- 5) Presentation of multiplex digital PCR
- 6) Presentation/update from SANTE on the report on sampling
- 7) Presentation on DNA extraction: quality control, impact on quantification and decision support systems

The Secretary requested submitting eventual additional proposals.

10. Participation of representatives of West African Countries to the ENGL plenary on the occasion of a study visit

The JRC explained that representatives from eight West African countries will visit the JRC Ispra in September on the same dates of the ENGL Plenary meeting. The SC thus agreed on asking the African delegation to present their activities at the plenary.

11. Any other business

The Secretary requested suggestions for breakout group's topics. Members suggested the following items:

- 1) Future analytical challenges for the ENGL resulting from New Breeding Techniques (NBT) and Synbio products
- 2) How to handle increasing analytical demands

Participants commented that discussions on these topics should be restricted to ENGL members.

12. Review of Dynamic Action List (DAL SC31)

The Secretary informed that the DAL will be shared shortly after the meeting via ENGLnet (see Annex 2). He requested to identify the moderator for the electronic forum on the CRISPR/Cas technology and on the implementation of Regulation (EU) No 619/2011. The Secretary provided a week for submitting proposals and further announced that the table on DNA extraction to be used for a web-based exchange of information on DNA extraction procedures will be sent for feedback to all members.

13. Conclusions and end of meeting

The Chair thanked the participants and closed the meeting

Annex 1: agenda



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit



31th ENGL STEERING COMMITTEE MEETING

21-22 June 2016, building 36/B, room 3, Ispra, Italy

Draft Agenda

Day 1 – 21 June 2016

9:30 Start of meeting

Welcome, apologies, quorum
Approval of the agenda
Approval of the report of the SC30 meeting
Review of Dynamic Action List (DAL SC30)
Update from SANTE

10:30 Coffee break

11:00 Progress reports ENGL working groups

WG-UpMeth (Update of methods)
WG-dPCR (Digital PCR)
WG-UoM (Unit of Measurement)
WG-Mvrf Ω (Method Verification)
WG-Proc (ENGL Procedures)
AG SMV (Advisory Group on Selection of Methods for Validation)

12:30 Buffet lunch

Future Working groups
Roadmap for the Network on Species Identification

15:30 Coffee break

Dates of 2017 meetings
Other ENGL matters

17:00 End of Day 1

19:30 Social dinner at "Ristorante Belvedere", Ranco

Day 2 – 22 June 2016

9:30 Start of meeting

Preparation of the 26th ENGL plenary (21-22 September 2016, includes the NRLs annual workshop)
Participation of representatives of West African Countries to the ENGL plenary on the occasion of a study visit

10:45 Coffee break

Any other business
Review of Dynamic Action List (DAL SC31)
Conclusions and end of meeting

12:30 Sandwich lunch

Meeting documents are available at:

<https://englnet.jrc.ec.europa.eu/steering/31st%20Steering%20Committee%20meeting/default.aspx?InstanceID=1>

Annex 2: action list

31st ENGL STEERING COMMITTEE ACTION LIST 22/6/2016				
ACTIONS	Resp.	Timelines	Status	Comments
ENGL GENERAL				
Report of 31st ENGL SC	SEC	31/7/2016	Open	
Organise 27th ENGL Plenary in Ispra	SEC	Jun-16	Open	21-22 SEptember 2016. Send draft agenda
2017 meetings	SEC		Open	will be in February, April, June and September 2017 in Ispra
WORKING GROUPS				
Advisory Group on "selection of methods for validation" (SMV)				
Coordinate with DE, SANTE, BE for method on GM salmon	SEC	31/07/2016	Open	
Proceed with pCAMBIA reporting	EURL	31/07/2016	Open	Add method to the dbase of ref methods, then paper for publication
WG-UpMethod				
Prepare template for data collection from ENGL labs	EURL + WG	31/07/2016	Open	JRC is working on it
Organise last physical meeting	SEC	31/07/2016	Open	September, early or back to plenary
Circulate document to other WGs	SEC	30/6/2016	Open	For information and alignment
WG-UoM				
Ask chair on the progress and timeline	SEC	30/06/2016	Open	
WG-dPCR				
Present the final report at the next plenary meeting	SEC	20/09/2016	Open	
WG-MV/rf2				
Organise final web meeting	SEC	30/06/2016	Open	End of august
Circulate final draft to the SC	SEC	09/10/2016	Open	After the august meeting, for comments before the Plenary in September. Plenary for approval
WG-Proc				
Consider adding internal rule on "formal way for considering new topics"	SEC	31/07/2016	Open	
VARIOUS				
Discussion forum on implementation of Reg. 619/2011	SEC	31/07/2016	Open	No volunteer to moderate. Maybe Nancy?
Discussion forum on CRISPR (detection of)	SEC	31/07/2016	Open	Will be moderated by colleague of Markus
Circulate DIR report to the SC for update	SEC	30/06/2016	Open	
Setup a WG on multiplex methods	SEC	31/03/2016	Open	put on hold and reconsider at the next SC meeting
Send new JRC organigramme to the SC	SEC	30/06/2016	Open	
Send out the table on DNA extraction to the SC for comments and then to the ENG	SEC	30/06/2016	Open	
Discussion forum on cutoff in ENGLnet	SEC	29/02/2016	Open	try to activate, with a moderator