EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit

29th ENGL STEERING COMMITTEE MEETING

24-25 June 2015, Ispra, Italy

Meeting Report

1.1 Welcome, apologies
The Chair welcomed the participants and informed that representative from Romania, Czech Republic, Finland, Greece, Ireland, Malta, Norway, Croatia, Latvia, Lithuania, Estonia, Slovenia were excused.

1.2 Approval of the agenda
The Chair asked anticipating the discussion of the points requiring input from SANTE (i.e. GMM) to the conference call organised in the morning with the colleagues from Brussels and postponing the progress reports of the ENGL working groups to the following day. In addition he requested adding an agenda point on "preparation of an ENGL position paper on the need of CRMs at different mass fraction (including 0.1%) for implementing Regulation (EC) 619/2011" because this point was discussed at a break-out group at the last ENGL plenary.

The agenda (Annex 1) was approved with these modifications.

1.3 Approval of the report of the SC28 meeting
The report of the last meeting had been circulated prior to the meeting and was approved without changes.

1.4 Review of Dynamic Action List (DAL SC28)
The Secretary reviewed the DAL of the previous meeting. Several points are addressed by the agenda of the current meeting, others have been closed. There was no discussion on the DAL SC28.

1.5 Update from SANTE
DG SANTE reported that for imports of microorganisms and enzymes Turkish authorities will no longer require certificates of GMO freeness for products derived from, but no longer containing GMOs.

The progress of the independent scientific committees on synthetic biology was presented. Three opinions were prepared: the first and second opinion respectively on definition and risk assessment of synthetic biology had just been published. The committees are now working on the third opinion concerning required research activities. DG SANTE remarked that according to the definition, current applications of synthetic biology shall fall under the EU legislation on GMOs but it is difficult to foresee all implications for future products of synthetic biology.

2 Progress reports ENGL working groups

2.1 AG SMV (Advisory Group on Selection of Methods for Validation): update
The speaker explained the workflow of method proposal and summarised the actions taken; materials and design for the validation of the pCambia T 35S detection method are being prepared; the AG SMV performed a new survey in 2014 and decided to validate in 2016 a qualitative multiplex covering five GM events not detected by commonly used screening approaches. The Secretary mentioned that the ring-trial on pCambia should be completed by end of September.

ENGL members are encouraged to submit new methods covering analytical gaps; the submission form is available on the EURL GMFF website, page of the GMOMETHODS database. The methods proposed will be evaluated according to the minimum performance criteria as defined by ENGL or by a case by case approach, if necessary.

The EURL GMFF launched a survey for identifying methods and target reference genes commonly used in GMO analysis by control laboratories and invited the ENGL members to respond to this survey as it would provide useful input also for the AG SMV. Depending on the results of the survey the group may organise a physical meeting in December.

In order to encourage participation to the activities of the group, the ENGL secretariat will send an e-mail encouraging membership to the group and submission of new methods proposals.

2.2 WG-DIR (Detection Interpretation Reporting): progress
The speaker reported that the last comments were addressed and that the report is only missing the revision of the section on next generation sequencing and final editorial work. The document will be finalised soon.

2.3 WG-ST (Seed Testing): progress
DG SANTE informed that the Seed Testing report will be discussed with the MS at the PAFF (Plants, Animals, Food and Feed) committee meeting in September or October. It was suggested distributing the report to Competent Authorities to favour discussion without waiting for the PAFF meeting. This proposal was supported and will be discussed with DG SANTE.

2.4 WG-UpMeth (Update of methods): update
The kick-off meeting of the WG took place on 27-28 of May. The following points were agreed:

a. All methods (including taxon-specific) must comply with the new MPR guidelines
b. For the time being, only the real-time PCR module will be considered
c. General criteria for controlling performance parameters should be defined
d. Recommended actions should be provided

The WG-UpMeth will review the MPR criteria and discuss which deviations would require updating the official SOP of the reference method, and when a re-validation would be required.

The group will consider the results of the survey launched by the EURL GMFF on reference methods used by laboratories.

The first document produced will describe which deviation of a method from the originally validated protocol would require specific actions for ensuring the continued validity of the published reference method.

The WG plans to have one physical meeting a year and electronic exchange of information during the remaining periods. At the meeting the authorisation renewals expected for the next year will be reviewed.

During the discussion on known deviations, participants commented that the GMOMethods database and the EURL GMFF validation reports do not provide a clear warning against the use of *adh1* taxon-specific methods in GMO analysis. The Secretariat assured to correct the problem.

2.5 WG-dPCR (Digital PCR): update
The first meeting for that WG is planned for early July.

2.6 WG-UoM (Unit of Measurement): update
The purpose of this WG is to produce a practical guidance for how to deal with the conversion of copy-number based quantification into mass/mass quantification, as required by Regulation (EC) No 619/2011. The first meeting of the WG is planned for end of June.

3 New activities

3.1 Interpretation of results at the limit of detection
The Secretary explained that the WG DIR could not find consensus on the question of interpreting PCR results at the limit of detection. The part of the document describing approaches to establish decision criteria for these situations was therefore removed from the final document. The SC was invited to discuss this point and to decide if and how the issue should be followed-up.

While the DIR document could be a starting point for this, participants remarked that more data was needed for comparing "a priori" versus "a posteriori" approaches. The approach chosen would have an impact on the laboratory workflow and the result would be very dependent on PCR machines, method and reagents used. As such it was questioned if any solution found in one laboratory would be transferable to other laboratories.

The Secretary remarked that a harmonised approach should nevertheless be developed for reliable, consistent, and reproducible results at the LOD level. The Secretary proposed using a break-up session at the next ENGL plenary for discussing the issue and invited participants to share their results at that occasion. The proposal was accepted.

3.2 Possible ENGL activities on genetically modified microorganisms

The Secretary remarked that at the last SC meeting a new WG was proposed on GMM whose mandate awaited clarifications in light of the new legislative initiatives from the Commission.

DG SANTE provided the following explanations:

- For additives, enzymes and flavourings produced with GMM for food use, the applicant has to demonstrate, among other things, the absence of the GMM in the product and that the newly introduced genes have been removed. The method for testing the presence of recombinant DNA should be documented in detail according to EFSA guidance but no official validation is required. Specifications including purity are also provided by the applicant. The risk management is based on the EFSA's assessment.
  In the context of food enzymes, there is a framework regulation in place. However, the positive list has not yet been established as the enzymes are currently being evaluated by EFSA. The entry of a GMM-derived food enzyme in the Union list, will include, among other requirements, the origin and the strain of the GM microbe.

- For feed additives produced by GMM the applicant has to provide the description of the genetic modification and the unique identifier to EFSA. For the description of the genetic modification the applicant must provide the data in accordance with the EFSA Guidelines for GMM intended for food and feed. Risk management is based on the assumption that no DNA is present in the additive. If no recombinant DNA is present in the feed additive the method of analysis is not mandatory and does not undergo any official validation. However, the applicant must demonstrate the purity of the product and must describe the method of analysis used to determine this purity.
  For certain feed additives the authorisation is granted to a specific authorisation holder while for others the authorisations are generic. There is the obligation in both cases to indicate the production strains in the decision for authorisation. The production strains are also described in the EFSA opinion. There are few generic authorisations (i.e. vitamins or amino acids) for which the production strains are not indicated in the decision for authorisation because they undergo a re-evaluation process that will be completed soon. Once the re-evaluation will be completed the information on the production strains will be included in all the decisions for authorisation.

Participants underlined the difficulty in distinguishing recombinant DNA from its natural counterpart and the lack of harmonised criteria for defining purity. These facts could generate discrepancies in the results. Participants also remarked that laboratories need information on the genetic target for controlling the products and identifying recombinant DNA that accidentally remained in a product that should not contain any DNA.

4 Scientific / technical topics

4.1 Collaboration ENGL-other networks

Participants suggested inviting representatives from other networks (e.g. custom laboratories) to present their activities. One participant raised concerns about coexistence between ISTA and ISO 17025 accreditation but other participants declared not to be affected by the problem since most GMO laboratories are anyway already accredited under ISO 17025. They suggested inviting ISTA representatives for addressing issues of accreditation and GMO testing on seeds to the ENGL plenary.

4.2 DNA extraction from difficult food and feed matrices, possible role of ENGL labs

The Secretary summarised the results of a breakout group discussion at the ENGL plenary meeting of December 2014 on DNA extraction from difficult matrices and explained that its final output was a proposal of activating a discussion on the web with a moderator. The SC endorsed this idea and one member recommended expanding the discussion to measurement of DNA recovery, which has a large uncertainty.
The Secretariat volunteered to post questions on the web for stimulating discussion. The outcome could be summarised at the forthcoming ENGL plenary (September 2015).

4.3 Modifications to validated methods during method verification

The Secretary remarked that laboratories implementing variations in the official procedure should perform a full verification to assure that the modified method provides the same or a higher performance of the protocol originally validated. If that is appropriately demonstrated, the accreditation body should accept the modification. The new WG on update of methods will provide guidance consisting of general criteria and a simple experimental design for testing performance of modified methods in alignment with the ENGL verification document.

Participants suggested reactivating the WG on verification and providing guidance also on verification criteria for multiplex methods. This proposal was accepted by the SC. The representative from Denmark accepted to chair the reactivated WG, together with the representative from Slovenia. New members could be accepted provided that the group remains of manageable size.

A new mandate with an appropriate timeline will be defined by the Chair and co-chair of the WG in cooperation with the secretariat and submitted for acceptance to the SC. An invitation for joining the group will be launched by the secretariat as soon as the mandate is ready.

5 ENGL topics

5.1 Organisational matters

The Chair explained that the Commission needs to streamline activities and that the unit, hosting the EURL-GMFF and supporting the ENGL has been asked to expand its expertise to other areas.

In this context the chair explained the intention of the JRC to initiate other networks addressing the use of DNA-analysis in other fields, including species identification, and invited ENGL members to join these other networks. Enlarging the ENGL mandate would not be an option and the ENGL shall continue to fulfil its mandate as before.

However, in an environment of stable or even shrinking budgets, this implies that resources might be needed to be re-allocated to these new activities.

One way of streamlining the ENGL activities could be reducing the number of ENGL plenaries and of ENGL SC meetings to one per year; this has the advantage of optimising travelling costs and time for members, also considering that the meeting's agenda is not always full and a certain degree of repetitiveness in the discussions undoubtedly exists.

This proposal was intensively discussed and, while the SC may agree on one ENGL plenary per year, many members insisted on keeping two ENGL-SC meetings per year. The Secretariat decided to launch a written procedure for taking the decision since the participants did not express a unanimous opinion.

The issue of network activity between meetings was brought up and the chair stated concern about the minimal response the Secretariat receives to its requests. It seems that the vast majority of the ENGL members do not actively participate in any networking other than the meetings. However, the discussion on ways and means to stimulate the network activities between meetings did not lead to any concrete proposals.

5.2 Preparation of the 24th ENGL plenary (22-23 September 2015)

The Chair presented a draft agenda for the 24th ENGL plenary and the 10th annual workshop of NRLs nominated under Regulation (EC) No 882/2004.

The draft agenda was discussed; regarding training needs for NRLs, members suggested organising small break-up groups to favour discussions among laboratories. It was also proposed to ask experts to offer personal coaching on specific issues, in order to allow less experienced laboratories to clarify points they would not raise in a larger group.

Other points suggested for the agenda are the results of the EURL GMFF survey on reference methods and a presentation on the new JRC decision supporting tools available on the web.

For the Break-out Groups (BOG) the following topics were suggested:

1) DNA extraction
2) Multitarget methods and their verification
3) Digital PCR (WG may use the BOG to enlarge discussion)
4) Interpretation of results at the limit of detection

The participants agreed to organise the 24th ENGL plenary meeting on the 22-23rd of September 2015.

6 AOB

No other business was proposed.

7 DAL SC29 and End of Meeting

The Secretariat presented the updated dynamic action list, which was agreed by the participants (Annex 2).

The chair thanked the participants and closed the meeting.

Annex 1: agenda

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29th ENGL STEERING COMMITTEE MEETING

24-25 June 2015, building 36/B, room 3, Ispra, Italy

Draft Agenda

AP	Time	Topic	Documents in ENGLnet
	Day 1		
1.1	09:30	▪ Welcome, apologies	
1.2		▪ Approval of the agenda	Agenda
1.3		▪ Approval of the report of the SC28 meeting	Report SC28
1.4		▪ Review of Dynamic Action List (DAL SC28)	DAL SC28
1.5		▪ Update from SANTE	
	10:30	*Coffee Break*	
2	11:00	*Progress reports ENGL working groups*	
2.1		▪ AG SMV (Advisory Group on Selection of Methods for Validation): update	
2.2		▪ WG-DIR (Detection Interpretation Reporting): progress	
2.3		▪ WG-ST (Seed Testing): progress	
2.4		▪ WG-UpMeth (Update of methods): update	
2.5		▪ WG-dPCR (Digital PCR): update	
2.6		▪ WG-UoM (Unit of Measurement): update	
	12:30	*Buffet lunch*	
3	14:00	*New activities*	
3.1		▪ Interpretation of results at the limit of detection	Draft from WG DIR
3.2		▪ Possible ENGL activities on genetically modified microorganisms	Report of the BOG on GMM
	15:15	*Coffe Break*	
4	15:45	*Scientific / technical topics*	
4.1		▪ Collaboration ENGL-other networks	
4.2		▪ DNA extraction from difficult food and feed matrices, possible role of ENGL labs	
		▪ Modifications to validated methods during method verification	
	17:15	*End of day 1*	
	19:30	*Social dinner at Restaurant Vecchia Angera (Hotel Pavone)*	
	Day 2		
5	09:30	*ENGL topics*	
5.1		▪ Organisational matters	
5.2		▪ Preparation of the 24th ENGL plenary (22-23 September 2015)	
	10:45	*Coffee Break*	
6	11:15	▪ AOB	
7	12:00	*DAL SC29 and End of Meeting (12:10)*	DAL SC29
	12:15	*Sandwich lunch*	

Annex 2: dynamic action list (DAL)

29th ENGL STEERING COMMITTEE ACTION LIST 25/6/2015				
ACTIONS	**Resp.**	**Timelines**	**Status**	**Comments**
ENGL GENERAL				
Report of 29th ENGL SC	SEC	Jul-15	Open	
Organise 24rd ENGL Plenary in Ispra	SEC	30/06/2015	Open	send draft agenda and ask for coaching topics. Define BOG mandates
Organise 30th ENGL SC	SEC		Open	dates to be decided
WORKING GROUPS				
Advisory Group on "selection of methods for validation" (SMV)				
Organise meeting (VC or physical)	SEC	30/09/2015	Open	December 2015 or January 2016
WG-UpMethod				
Organise 2nd meeting	SEC		Open	Dates ? Once a year? Maybe an informal meeting at the Plenary in September
WG-UoM				
Organise 2nd meeting	SEC	Sep-15	Open	Autumn 2015
WG-dPCR				
Organise 2nd meeting	SEC	30/09/2015	Open	Autumn 2015
VARIOUS				
Organise meeting of the WG on ENGL procedures	SEC	30/9/2015	Open	Gimara, Lotte, Esther, by VC
Launch written procedure for plenaries 2016	SEC	31/7/2015	Open	
Send email to ENGL for AGMSV	SEC	30/06/2015	Open	Invite submission of methods and call for members
Finalise the DIR report	SEC	15/08/2015	Open	
Ask SANTE to circulate the ST report to MS	SEC	30/06/2015	Open	to allow MS evaluating the report before the next PAFF
Ask labs to bring data to the BOG on interpretation of results at the LOD	SEC	30/7/2015	Open	
Consider training for labs on cutoff	SEC	Sep-15	Open	ask during the BOG at the Sept 2015 plenary
Reactivate WG Verification	SEC	Jul-15	Open	Mandate and call for members