



34th ENGL STEERING COMMITTEE MEETING

20-21 February 2018, Ispra (Italy)

MEETING REPORT

1. Welcome, apologies, quorum

The Chairman welcomed the participants and announced that the representatives from Germany and Belgium were not able to attend the meeting. He asked for a tour de table presentation of the participants.

2. Approval of the Agenda

The draft agenda (Annex 1) was approved. The member from Slovenia proposed to also discuss the procedures for maintenance/validation of large equipment in the laboratory, as laboratories are using various approaches (according to the manufacturer or using in-house procedures). The Chairman suggested that this should be discussed at the Annual meeting in October.

3. Approval Report of the 33rd ENGL SC meeting

The report previously circulated for comments was endorsed without modifications.

4. Review of Dynamic Action List (DAL SC33)

The Secretariat reviewed the open points on the list and informed the participants that the discussion on the issues with the implementation of Regulation (EC) No 619/2011 is still open and that this topic will be addressed later in this meeting. He also mentioned that no new elements are available on GM Petunia and that no further guidance seems necessary, and that the list of observers to the Annual meeting, including from other Regional Networks, is still to be decided and links to the discussion on the ENGL Procedures later during the day.

5. Update from SANTE

DG SANTE mentioned that 33 GMOs were authorised and 3 renewals were finalised last year. The Decisions on three cultivation files were finally voted, but not yet adopted (1507, Bt11 and MON810 renewal). In October 2017 the new EFSA environmental risk assessment guidance was published, but this is still awaiting further comments from the European Parliament and Council; if final, Dir. 2001/18 would need to be updated in line with the EFSA Guidance.

Regarding NPBTs (New Plant Breeding Techniques), the European Court of Justice' ruling on mutagenesis techniques is expected in April at the earliest; the Advocate General has issued his opinion on the case, stating that plants developed by both conventional and new mutagenesis techniques (e.g CRISPR-CAS), as long as no recombinant DNA has been used, should be considered exempted from the GMO Regulations. The Commission is waiting for the legal interpretation of the Court, but even after that, further interpretation will be needed. The Chairman added that also the General Food Law of 2002 is in the process of being reviewed; this is a primary legislation, meaning that afterwards also secondary legislation will be reviewed, including Regulation 1829/2003 (and 1831/2003 on feed additives). DG SANTE also explained that the options regarding the NPBT include re-opening the current legislation or developing a specific legislation to deal with such products.

6. Progress of ENGL working groups

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

The Secretariat, on behalf of the Chair of the WG, reported on the last VC meeting in December. The EURL GMFF has in-house tested the pentaplex method, which revealed issues with the robustness (instrument-specific). A small trial will be organised with a few NRL volunteers to test if a different mastermix could solve the issue. The WG will also assess the in-house data collected by CRA-W on a new low-copy potato endogenous reference gene before starting a collaborative validation trial. The next meeting of this WG is planned for March. One of the agenda points of that meeting will be to brainstorm on future analytical needs, e.g. for the detection of unauthorised GMOs. In order to avoid the problems with the pentaplex method it was

proposed that any method submitted for validation to the EURL should have been tested by at least two independent laboratories.

6.2 WG-UpMeth (Update of methods)

The Secretariat, on behalf of the Chair of the WG, explained that the group has been working on a new draft report, containing definitions e.g. on what is a method, and a new flowchart following clarification with DG SANTE on the requirements for the detection method at the time of the renewal of a GM event authorisation. The new draft is to be reviewed by end February, then a final VC may be organised before sending the draft to the SC for comments.

The ENGL Chair proposed to include a list of important definitions on ENGLnet to avoid that different guidance documents would develop their own definitions.

6.3 WG-Proc (ENGL Procedures)

The Chair of this WG apologises for the delay in sending a draft of the new procedures to the SC. There are 4 main procedures drafted:

- 1). On the working of the ENGL, the procedure for adoption of documents needs to be clarified (WG to SC, then back to WG, then final approval by SC before discussion and approval by entire ENGL), and an alternative approval cycle was suggested (from WG directly to whole ENGL). The SC presented different views on this proposal, e.g. that the SC should at least check if the guidance is in line with the mandate, however, also the timing needs to be respected. The ENGL Chair also proposed to apply an obligatory revision cycle to all guidance documents, e.g. a consultation after 5 years in which it should be decided if a revision is needed or not.
- 2). On the establishment of new WGs, it is clarified that the SC decides this, and a Chair and drafting team (new) and rapporteur (new) should be appointed.
- 3). The participation of non-ENGL members to the annual meetings (at least to the open part of these) has to be approved by the SC, and different categories may be distinguished (observers, speakers and experts invited for one meeting).
- 4). For the purpose of increasing the participation of ENGL members to discussions on ENGLnet, the tasks of responsible for the fora are better clarified.

6.4 WG-dPCR (Digital PCR)

The Chair of the WG reported (by telephone on day 2) that the final draft of the guidance has been approved by the WG and is ready to be sent to the SC for review. The ENGL Chair suggested instead sending the draft directly to the whole ENGL for review. For reviewing the dPCR guidance draft, a commenting table will be distributed into which the comments, as specific as possible, should be entered. Comments would need to be discussed by the WG first, before approval of a new version by the SC. The guidance describes also briefly applications to fields different from GMOs, however, without providing guidelines for these. One issue for further discussion is that the measurement uncertainty estimations mentioned may not be suitable for samples analysed in routine controls. The ENGL Chair suggested addressing this issue, which is not only relevant for dPCR, in the measurement uncertainty document that is now under revision.

6.5 New WGs

The three new WGs that were approved by the SC have been set up and a large interest from ENGL members was noted. The WG on DNA extraction (WG-DNAex) will have its kick-off meeting after the current SC meeting; the WG on multiplex PCR (WG-mpPCR) will start off on 21-22 March and for the WG on Sequencing (WG-Seq) a meeting date, probably in April, has to be decided.

7. Role of ENGL on capacity building

The JRC explained the capacity building activities that started in 2000 (with DG SANTE support in 2009) and which partially overlap with the EURL mandate under Regulation 1829/2003, and which include meetings with regional networks and trainings (e.g. on practical aspects of regulatory GMO control implementation in Geel on 6-8 March 2018). There is now a large global network in place that could be a source of contacts and first-hand information. There is a wish to continue (at least part of) these activities, however, the EURL GMFF or the JRC cannot continue to operate this on the longer term. A possible role of the ENGL was discussed in managing a platform for coordination of such capacity building activities occurring at national and European level. A survey will be organised to collect interest and expertise from ENGL members in supporting such a platform. The ENGL may then be proposed as a source of expertise to DG SANTE under the Better Training for Safe Foods programme.

8. ENGL membership

The ENGL Chair explained that the Consortium Agreement sets boundary conditions on the membership to the ENGL. In dependence on the outcome of the EU negotiations with the UK, the future participation of UK experts and their continued support to the work of the ENGL will have to be arranged.

9. ENGL Annual meeting

The structure of the 2018 Annual meeting was discussed. This would be a 2.5 days meeting, starting with the NRL workshop (0.5 d), followed by a closed ENGL meeting (0.5 d) to discuss ENGL matters (progress of WGs etc.), then 0.5 day of brainstorming on 1 or 2 selected topics, e.g. discussion on the outcome of the workshop in May on GMO screening strategies, then 1 full science day with invited speakers, invited guests from regional networks outside the EU, etc. The SC agrees with this proposal. Proposals for topics (and speakers) for the science day are requested.

10. Training workshop on GMO screening strategies

The 2018 training workshop for NRLs and OCLs will take place in Gembloux (CRA-W) on 23-25 May and is being co-organised with F. Debode (CRA-W) and E. Kok (RIKILT). The draft programme was presented and some further suggestions were made. A questionnaire will be distributed to the ENGL to collect information on current screening practices in ENGL laboratories. Further information will be provided in the announcement letter for this workshop.

11. Reference materials/ positive controls

- For the detection of GM salmon, no further information or reference material has been received from the Company AquaBounty.
- CRMs for stacked GMOs: there is one CRM available from the JRC (MON810xMON863), however, there is no requirement for such CRMs in the legislation. It was clarified again that in case of two or more GMOs of the same species, their mass fractions need to be summed up in order to assess compliance to the labelling threshold.
- AOCS CRMs: the German BVL has sent a letter to the EURL requesting CRMs at 1 and 0.1 m/m % for enforcement of the control legislation. The EURL agreed to raise this issue during the meeting with EuropaBio in March. DG SANTE is also aware of the issue.

12. RASFF notification

GM *E. coli* in feed: RASFF 2017.1544. Tests in Italy in Nov. 2017 have shown that some feed batches contained living GM bacteria. As no method or reference material was available, a synthetic sequence was used by the Italian NRL for validation of two detection methods. A few other Member States have also addressed the issue, but in a different way, e.g. the product was declared as GMO, therefore no further testing was needed.

13. Seed testing

DG SANTE reported on the results of a questionnaire sent to Member States on the interpretation of the zero tolerance in seed. Some Member States see this as a tolerance limit (< 0.1 % is OK), not as an analytical limit of testing. In case there is a need for action, DG SANTE will ask the ENGL to provide its technical expertise in the matter. This may require a guidance document on a technically feasible approach in line with Regulation 619/2011, taking also sampling into account. The SC agrees to provide such guidance.

14. New activities

14.1 Update of "Guidance document on measurement uncertainty for GMO testing laboratories"

The Chair informed the ENGL that the mentioned guidance document will be revised, and a team of contributors, under the leadership of the original corresponding author of the document, S. Trapmann, has been identified. An additional ENGL member volunteered to join the team. The revised guidance will also address uncertainty estimation for dPCR methods and other new approaches, the application of proposed approaches to routine samples, and uncertainty contributions in case of the unavailability of CRMs at low mass fractions.

14.2 GM "arctic" apple

The Chair informed the ENGL on the deregulation of two GM apple varieties in the US and Canada, sold under the brand name "Arctic apple". These apples have been modified by gene-silencing the expression of the polyphenol oxidase gene resulting in fruits with retarded browning reaction upon cutting or bruising. They are intended for the fresh-cut market (fresh fruit salads). There is at the moment no information that these apples would have entered the European market. It is agreed to search for the transgene sequence in patent databases and to send a letter to the owner of the company to request more information and a reference material.

14.3 Chinese rice methods

The Dutch NRL reported on experimental work showing that SYBR Green methods for Chinese rice may also amplify a sequence in conventional rice. Other issues with false positive reactions have also been signaled. Not many instances of GM rice from China have been found recently. The SC agrees to collect some false-positive samples from ENGL members and three NRLs have volunteered to test on these samples the validated method in a small collaborative trial.

14.4 Joint EURL GMFF – EURL FA activity on GMM in feed additives

The Secretariat reported on a joint activity between two JRC-led EURLs to develop guidance on minimum performance criteria for the presence of genetically modified microorganisms in feed additives. This is based on a request from DG SANTE to assist in the revision of Regulation 429/2008 on feed additives.

15. Method repeatability and enforcement of thresholds

The Secretariat was informed on issues with some Accreditation Bodies who are not accepting that the precision at the level of 0.1 % mass fraction may be for a specific method in a specific laboratory higher than mentioned in the MPR guidance. However, other Accreditation Bodies accepted this relaxation of the requirements. The unavailability of some of the CRMs (i.e. from AOCS) at this low level adds to the problem. The Chair mentioned that such information and guidance on how to address the issue should be added to the revised guidance on measurement uncertainty estimation.

16. AOB

The Italian NRL reported that the DNA extraction kit from the original protocol for the detection of GM flaxseed from Canada is not available anymore; he proposed several options to resolve this. It is important to put the emphasis on the quality of the extracted DNA, rather than prescribing a specific DNA extraction method. Quality criteria should be proposed by the WG DNAex.

The EURL reported on the outcome of the "Hands-on training on digital PCR" in Ljubljana end of last year. This was well appreciated by the 20 participants, and most of the presentations are available on ENGLnet. A similar training was organised by NIB in January 2018 in the frame of the capacity building programme.

The Finnish NRL reported on a question received on insects which are allowed as food in Finland: what if they had been fed with GMO feed (which may remain in their stomachs)? The discussion will be followed up.

17. DAL SC34 and End of Meeting

The Secretariat reviewed the new DAL (Annex 2) and announced that the Annual ENGL meeting will take place in the first week of October. The next Steering Committee meeting is planned for the 12th (morning) -13th (noon) of June 2018. The Chairman thanked the participants for the interesting and productive discussions and closed the meeting.

Annex 1: agenda



EUROPEAN COMMISSION
DIRECTORATE GENERAL
JOINT RESEARCH CENTRE
Directorate F - Health, Consumers and Reference Materials
Food & Feed Compliance



34th ENGL STEERING COMMITTEE MEETING

20-21 February 2018, Ispra (Italy)
Room 3

Draft Agenda

Day 1 – 20 February 2018

	Time	Topic	Documents in ENGLnet
1	09:30	▪ Welcome, apologies, quorum	Draft agenda Report SC33 DAL SC33
2		▪ Approval of the agenda	
3		▪ Approval of the report of the SC33 meeting	
4		▪ Review of Dynamic Action List (DAL SC33)	
5		▪ Update from SANTE	
	10:45	<i>Coffee Break</i>	
6	11:15	<i>Progress ENGL working groups</i>	Progress report
6.1		▪ AG SMV (Advisory Group on Selection of Methods for Validation)	
6.2		▪ WG-UpMeth (Update of methods)	
6.3		▪ WG-dPCR (Digital PCR)	
6.4		▪ WG-Proc (ENGL Procedures)	
6.5		▪ WG-mpPRC (multiplex PCR methods)	
6.6		▪ WG-seq (good practice/quality of DNA sequencing data)	
6.7	▪ WG-DNAex (DNA extraction)		
	12:30	<i>Buffet lunch</i>	
7	14:00	▪ ENGL membership	
8		▪ Discussion on ENGL Annual Meeting October 2018	
9		▪ ENGL and capacity building activities	
10		▪ Workshop on "GMO screening approaches"	
	15:30	<i>Coffee Break</i>	
11	16:00	▪ Reference materials/positive controls - availability (GM salmon, stacked events, GM <i>E. coli</i> etc.) and application (AOCS CRMs)	
12		▪ RASFF 2017.1544 on <i>E. coli</i> in feed	
13		▪ Questionnaire of the Commission and replies of Member States concerning seed testing	
	17:15	<i>End of day 1</i>	
	19:30	<i>Dinner at Hotel Lido, Angera</i>	

Day 2 – 21 February 2018

14	09:15	<i>New activities</i>	
14.1		▪ Update of document "Guidance Document on Measurement Uncertainty for GMO Testing Laboratories"	
14.2		▪ GM apple "Artic" sold in the USA	
14.3		▪ Joint EURL GMFF-EURL FA activity on GMM in feed additives	
	10:45	<i>Coffee Break</i>	
15	11:15	▪ Methods repeatability and enforcement of thresholds	
16		▪ AOB	
17	12:15	<i>DAL SC34 and End of Meeting (12:30)</i>	DAL SC34
	12:30	<i>Sandwich lunch</i>	

Meeting documents available at:

<https://englnet.jrc.ec.europa.eu/steering/34th%20ENGL%20SC%20meeting/default.aspx?InstanceID=1>

Annex 2: action list

34th ENGL STEERING COMMITTEE ACTION LIST 21/2/2018				
ACTIONS	Resp.	Timelines	Status	Comments
ENGL GENERAL				
Report of 34th ENGL SC	SEC	Mar-18	Open	
Annual meeting October	SEC	15/3/2018	Open	ask SC for proposals on topics/speakers
WORKING GROUPS				
Advisory Group on "selection of methods for validation" (SMV)				
Organise next meeting	SEC	28/2/2018	Open	Web meeting in March; discuss procedures on acceptance of methods (test second lab?)
WG-UpMethod				
Prepare template for data collection from ENGL labs	EURL + WG	30/4/2018	Open	
Organise next meeting	SEC	15/3/2018	Open	web meeting date to be decided
WG-dPCR				
Send doc to the ENGL for comments	SEC	22/2/2018	Open	deadline 4 weeks
Send draft to the drafting group for the MU doc	SEC	22/2/2018	Open	
WG-seq				
Organise kick-off meeting	SEC	28/02/2018	Open	april
WG-Proc				
Send doc to the SC for comments	SEC	15/03/2018	Open	
VARIOUS				
Prepare list of terms and definitions used by the ENGL	SEC	31/5/2018	Open	publish on ENGLnet
Survey on equipment management	SEC+NIB	31/3/2018	Open	in preparation to the Annual Meeting/with Jana
Survey on capacity building	SEC	Mar-18	Open	with JRC F7
Arctic apple	EURL-SEC	15/03/2018	Open	collect info - send request for samples to company
Sybr Cry1Ab/Ac method	SEC	15/03/2018	Open	Send request to ENGL on +ve samples availability
Discussion forum on implementation of Reg. 619/2011	SEC	30/04/2018	Open	
Discussion forum on CRISPR	SEC	31/3/2018	Open	Contact moderator for a report
Update the list of observers with contacts of regional networks	SEC	31/3/2018	Open	