



## 33<sup>rd</sup> ENGL STEERING COMMITTEE MEETING

20-21 June 2017, Ispra (Italy)

### Report

#### 1. Welcome, apologies, quorum

The Chairman welcomed the participants.

#### 2. Approval of the agenda

The agenda (Annex 1) was approved without modifications.

#### 3. Approval of the report of the SC32 meeting

The report previously circulated for comments was endorsed without modifications.

#### 4. Review of Dynamic Action List (DAL SC32)

The Secretariat reviewed the open points of the action list.

#### 5. Update from SANTE

DG SANTE explained that information to be provided by the applicant on fermentation products for the authorisation of feed additives is specified under Regulation 429/2008. SANTE informed also that the EFSA's Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has prepared draft guidance to applicants for the preparation and presentation of applications for authorisation of a feed additive. DG SANTE explained that the requirements of Regulation 429/2008 should not be confused with the risk assessment requisites specified in the EFSA guidance. EFSA has launched an open consultation on the document published on its web site (see <http://www.efsa.europa.eu/en/consultations/call/170615>). DG SANTE invited to provide comments within the 15<sup>th</sup> of September 2017. SANTE asked to receive assistance in drafting guidance on detection of recombinant DNA in feed additives produced through fermentation. This guidance should define specific performance requirements for the DNA detection methods provided by the applicant in compliance to the GM part of the EU Regulation. DG SANTE explained that the proposal should be received by the end of year 2017. Upon request from the participants DG SANTE agreed in submitting in two weeks all information.

The Chairman suggested creating an ad-hoc task force coordinated by the two EURLs concerned (GMOs and Feed additives) and preparing a document for the next ENGL meeting. He proposed including a break-out section at the next plenary for discussing the proposal. The final document should be communicated to SANTE by the end of the year. All participants agreed to the proposal.

DG SANTE announced that a Scientific Advise Mechanism will publish on the 28<sup>th</sup> of April an explanatory note on the techniques used in agriculture, including new technologies. The explanatory note will be presented at a Forum on the 28<sup>th</sup> of September. SANTE invited ENGL members to register to the Forum.

DG SANTE informed that the JRC presented the report on unit of measurement to the Member States, which requested to include conversion factors for the different crops.

#### 6. Progress ENGL working groups

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

The Secretary presented the activities on behalf of the WG chair. In 2016 the WG received two new methods proposed for validation: a qPCR method for the detection of a potato reference gene and a multiplex ddPCR method for the identification of all soybean GM events approved in EU. A web meeting was organised on the 1<sup>st</sup> of June 2017 to discuss the two proposals. All members agreed in considering the potato method as a good candidate for a collaborative study, provided that its performance is in line with the ENGL method acceptance criteria. Experimental data were requested to the authors for a thoroughly evaluation.

The second method is considered not filling an analytical gap but nonetheless is regarded as a good candidate for optimising the analytical workflow. Members decided that performance criteria were needed for the validation of the ddPCR method and proposed waiting for the guidance document on dPCR developed by the dedicated ENGL working group. The speaker finally remarked that a survey to identify gaps will be organised in cooperation with the EURL GMFF and that a list of species-specific detection methods still needs to be finalized.

## **6.2 WG-UpMeth (Update of methods)**

The Secretary reported on the status of the activities on behalf of the chair. At the previous meeting ENGL members proposed organising a discussion forum on the definition of method. The chair posted three proposals in ENGLnet but received limited feedback, therefore proposed eliminating the definition from the document.

In the following discussion the participants agreed on considering the WG not the right forum for addressing the issue of the definition of method. The Chairman proposed drafting a preparatory document on the definition of method and presenting the WG proposal at the plenary meeting for discussion.

## **6.3 WG-Mvrf2 (method verification)**

The document has been finalised and it has been circulated for comments. Publication process is pending.

## **6.4 WG-dPCR (Digital PCR)**

The Secretary informed that the final version of the document will be distributed to the Steering Committee within the upcoming two weeks. The document will be then presented at the ENGL plenary in September.

It was suggested that in the document a simplex ddPCR rather than a multiplex method should be included.

## **6.5 WG-Proc (ENGL Procedures)**

The Secretary informed that the last meeting of the WG was held in March. The members of the group asked to discuss within the steering committee the draft procedure on establishing formal liaisons between the ENGL and external organisations. DG SANTE expressed its concern on having other external organisations influencing the activities of the ENGL network which is operating the European Union legislation and suggested employing temporary observers in place of permanent liaison.

The Chairman confirmed that liaison members in ISO committees have the right to comment and permanently attend meetings. Participants approved the idea of extending the role of observers to international organisations without giving the right to permanently participate to the ENGL activities.

## **7. New activities**

### **7.1 Draft mandate WG on multiplex real-time PCR Methods (WG-mpPCR)**

The Secretary explained that some comments on the mandate have been already incorporated and remarked that the tasks were well defined and ambitious.

It was suggested using software for analyzing the primers and probe sequences to avoid internal or self-annealing primers; the Secretariat agreed in adding bioinformatics analysis in the document.

It was also suggested removing the "real-time" specification from the title; after discussing the difficulty of covering in the same document the real-time and digital PCR technologies the participants agreed in keeping the title more general and addressing both technologies in the document.

### **7.2 Draft mandate WG on sequencing**

It was commented that the draft mandate was missing concrete tasks; different members expressed their interest in joining the group and informed that guidelines on generation of DNA sequences for GMO analysis are being prepared by EFSA and were discussed within the Decathlon project as well as by ISO and CEN committees. The Secretary reminded that guidelines for submission of DNA sequences derived from genetically modified organisms and associated annotations are also available on the EURL GMFF website.

It was suggested dividing the document in two parts, one establishing general guidelines on the generation and analyses of sequences and the second regarding fast technological developments which could be timely updated. The Secretary proposed submitting comments in writing to redraft the mandate.

## **8. ENGL topics**

### **8.1 Preparation of the 28<sup>th</sup> ENGL plenary (20-21 September 2017)**

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

- Proposals by on definition of method (WG on Update of Methods)
- Presentation of the final document on digital PCR (WG digital PCR)
- Presentation of the mandate of the two new WGs (on PCR multiplexing and sequencing)
- Authentication including species identification (by the JRC Food and Fraud Unit F.4)
- NGS-based species identification (Decathlon project) by RIKILT
- GMO analysis in Japan
- Method Performance Parameters developed by the Decathlon project
- Update from the Allergen Detection Laboratory Network (JRC)

- Report on GM petunia with focus on detection methods and recommendation
- Report on glow fish (summary of information available and possible guidance or recommendation)
- Update on CEN and ISO activities
- Presentation of the outcome of the DNA extraction workshop

For the break-out groups the following topics were suggested:

- 1) (GM) DNA in feed additives
- 2) Homogeneity of lab samples preparation and sample homogenization and controls
- 3) Design of Pre-spotted plates

## 8.2 GM Petunia

DG SANTE summarised the issues discussed at the Member States Standing Committee on 12<sup>th</sup> of June and reported that at least 10 Member States (MS) were monitoring the market by targeting the trade names of GM petunia already identified (approximately 50).

DG SANTE reported that the environmental risk assessment performed by the scientific bodies of the MS concluded that there were limited or negligible environmental hazards from GM petunia. USDA issued a guideline on testing and extraction methods for GM petunia and provided the list of trade names to be monitored. The Australian authorities reported identification of GM petunia in the market while a white GM petunia was also reported in China. A petunia GM event had been authorised in China but no information was available on the commercialisation.

DG SANTE is planning to ask harmonised information on GM petunia and Member States will be requested to submit a report in September 2017

The German member presented a table showing the different GM petunia hybrid lines and the related genetic targets according to plasmid maps and publications; information on sequences and experimental data are also reported, together with a decision tree for detection.

Since the p35S promoter is present in all GM petunia described so far, the initial screening step is targeting this genetic element; following positive detection of the P-35S promoter, additional tests for detection of P-nos, T-nos and T-ocs elements are used for identifying the different GM petunia events. The insert and flanking sequences of GM petunia were provided by Mayer (the author of the first event described in literature) and are available in the Euginius database; the German competent authorities have decided testing also other varieties of ornamental flowers starting from the following year.

The Belgian member informed that a pCambia vector may have been used for the development of some GM petunia events and suggested using the method targeting the element as a possible screening test.

The Secretariat remarked that the EURL GMFF guidance on GM petunia screening will be updated with the information newly available.

## 8.3 GM fish

DG SANTE received a notification from one MS on detection of GM glofish and is monitoring the situation. A case of detection of GM fish was reported in Denmark; Deboode *et al.* developed some primer sets for the detection green, red and yellow GM glofish using PCR; it was reported that the methods function in a satisfactory manner. The Belgian NRL developed several methods using the TaqMan chemistry which are specific for the different fish colours. More structured information on detection methods and positive controls was requested.

## 8.4 Report on the DNA extraction workshop

The UK member presented a summary of the DNA extraction workshop organized at the JRC on the 7<sup>th</sup>-9<sup>th</sup> of June 2017. The aim of the workshop was to identify issues, collate and share best practice and guidance on DNA extraction. The workshop had different presentations but also interactive sections focusing on issues and possible solutions. Nineteen EU MS participated but also laboratories from Mexico, Ecuador and Brazil. Power point predefined presentations were distributed to the participants for recording their experience. Malcom Burns presented a summary of trends obtained by analyzing the participant replies.

The agreed outcome of the workshop was to collate those presentations and publish a summary document. M. Burns developed and presented a database for performing fast searches on DNA extraction issues and solutions.

The Chairman thanked UK for the excellent organisation of the workshop and remarked that all information collected should be exploited. Summarising the suggestions from the participants the Chairman proposed an ENGL guidance document on DNA extraction with a stable part covering the principles and a dynamic part including recommendations from laboratories with positive and negative examples; he recommended preparing a mandate proposal for a new WG to be discussed at the ENGL plenary in September 2017. He further suggested offering a new workshop in the future to monitor new developments.

### **8.5 Method's repeatability and enforcement of thresholds**

Esther Kok, absent, will be asked preparing a background document for consideration at the next meetings

### **8.6 Pre-spotted plates: current layout, labs needs, future (JRC)**

The JRC provided an update on the Pre-spotted plates (PSP) commercialisation project. In April 2017 the EURL GMFF invited partners possibly interested in developing the PSP at commercial level; five companies showed interest. The selection will be performed in July-November 2017 according to the offered prices; the decision will be finalised in December 2017. Four layouts will be offered, one screening plate with 16 assays and other three plate layouts specific for GM maize, GM soya and GM canola. The ENGL could support the project by revising and /or modifying these layouts, identifying needs for addition/removal of assays and update/modification of the GMO matrix.

It was commented that it would be very important providing plastic plates, having a price quotation and information on product liability (responsible for the performance of the PSP). Members also enquired on the shelf life of the product which could be very important for accreditation. The EURL GMFF asked input on the layout required by the laboratories: members suggested a break-out group at the next ENGL plenary on user needs.

### **8.7 ENGL guidance doc on EURL GMFF web site**

It was commented that the ENGL guidance documents are hidden under the WG structure. It was proposed moving the final documents to the upper level in the main EURL GMFF web page under ENGL guidance documents to make them more visible. The proposal was accepted.

### **8.8. AOCS CRMs: actions pending**

The EURL GMFF should collect information on issues with the AOCS CRM and prepare a note in concertation with SANTE.

### **8.9 SPECENZYM project: purity aspects of food enzymes**

The Belgian competent authority asked to verify the purity of food enzymes, also with regards to the presence of transgenic DNA. About 300 food enzymes and GMM are listed by EFSA. It is proposed to employ a generic approach for testing for the presence of microorganism species using methods for detection of 16S and 18S elements and sequencing (NGS) for GMM characterisation.

The Chairman commented that the approach could be presented to the NRL workshop as a proposal for a research project.

### **9. AOB**

The member from Slovenia announced that a workshop for NRLs on digital PCR will be organised in Ljubljana on the second week of November, in collaboration with the EURL GMFF; the workshop will include laboratory training.

### **10. DAL SC33 and End of Meeting**

Due to lack on time, the Secretary provided the action list (Annex 2) by email and ENGLnet.

The Chairman thanked the participants for their good contributions and ideas and closed the meeting.

## Annex 1 – Agenda



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

33<sup>rd</sup> ENGL STEERING COMMITTEE MEETING

20-21 June 2017, Ispra (Italy)  
Building 101

## Draft Agenda

Day 1 – 20 June 2017  
Room 1302

	12:00	Buffet lunch	
	Time	Topic	Documents in ENGLnet
1	13:00	<ul style="list-style-type: none"> <li>▪ Welcome, apologies, quorum</li> <li>▪ Approval of the agenda</li> <li>▪ Approval of the report of the SC32 meeting</li> <li>▪ Review of Dynamic Action List (DAL SC32)</li> <li>▪ Update from SANTE</li> </ul>	Agenda Report SC32 DAL SC32
2			
3			
4			
5			
6	14:30	<i>Progress ENGL working groups</i> <ul style="list-style-type: none"> <li>▪ AG SMV (Advisory Group on Selection of Methods for Validation)</li> <li>▪ WG-UpMeth (Update of methods)</li> <li>▪ WG-Mvrf2 (method verification)</li> <li>▪ WG-dPCR (Digital PCR)</li> <li>▪ WG-Proc (ENGL Procedures)</li> </ul>	
6.1			
6.2			
6.3			
6.4			
6.5			
	15:45	Coffee Break	
7	16:15	<i>New activities</i> <ul style="list-style-type: none"> <li>▪ Draft mandate WG on multiplex real-time PCR Methods (WG-mpPCR)</li> <li>▪ Draft mandate WG on sequencing</li> </ul>	Draft mandate  Draft mandate
7.1			
7.2			
	17:30	End of day 1	
	19:30	Dinner at Ristorante Corner 08 Monate	

Day 2 – 21 June 2017  
Room 1302

8	09:30	<i>ENGL topics</i> <ul style="list-style-type: none"> <li>▪ Preparation of the 28<sup>th</sup> ENGL plenary (20-21 September 2017)</li> <li>▪ GM Petunia</li> <li>▪ GM fish (glowfish)</li> <li>▪ Report from the DNA extraction workshop</li> <li>▪ Method's repeatability and enforcement of thresholds</li> </ul>	Draft Agenda
8.1			
8.2			
8.3			
8.4			
8.5			
	10:45	Coffee Break	
8.6	11:15	<ul style="list-style-type: none"> <li>▪ Pre-spotted plates: current layout, labs needs, future (JRC)</li> <li>▪ ENGL Guidance Documents on EURL Website</li> <li>▪ AOCS CRMs: actions pending</li> <li>▪ SPECENZYM project: purity aspects of food enzymes</li> <li>▪ AOB</li> </ul>	
8.7			
8.8			
8.9			
9			
10	12:15	DAL SC33 and End of Meeting (12:30)	DAL SC33
	12:30	Sandwich lunch	

Meeting documents available at:

<https://englnet.jrc.ec.europa.eu/steering/33rd%20SC%20meeting/default.aspx?InstanceID=1>

## Annex 2 – Action List

33rd ENGL STEERING COMMITTEE ACTION LIST 21/6/2017				
ACTIONS	Resp.	Timelines	Status	Comments
<b>ENGL GENERAL</b>				
Report of 33rd ENGL SC	SEC	15/7/2017	Open	
Organise 28th ENGL Plenary in Ispra	SEC	31/8/2017	Open	20-21 september. Send draft agenda for input
<b>WORKING GROUPS</b>				
<b>Advisory Group on "selection of methods for validation" (SMV)</b>				
Organise next meetings	SEC	28/2/2017	Open	a web meeting when info on potato received and the annual meeting towards the end of the year
<b>WG-UpMethod</b>				
Prepare template for data collection from ENGL labs	EURL + WG	31/12/2017	Open	
Organise next meeting	SEC	28/2/2017	Open	web meeting July; physical meeting on 21 or 22 September
Propose draft definitions to the ENGL plenary (presentation)	WG chair	31/7/2017	Open	Reminder to provide comments on the forum
<b>WG-dPCR</b>				
Circulate final WG draft to the SC	SEC	15/7/2017	Open	
Present the final report at the next plenary in September	WG chair	20/9/2017	Open	
<b>WG-MVrf2</b>				
Circulate final WG draft to SC for comments	SEC	30/6/2017	Open	
Present the final doc at the plenary in September	WG chair	20/9/2017	Open	
<b>WG-Proc</b>				
Organise next meeting	WG chair and SEC	31/3/2017	Open	August or early september. Circulate next draft before the meeting
<b>VARIOUS</b>				
Discussion forum on implementation of Reg. 619/2011	SEC	30/06/2017	Open	
Discussion forum on CRISPR	SEC	30/06/2017	Open	Contact moderator for a report
Update EURL guidance on GM petunia	EURL	30/6/2017	Open	
Prepare doc for SC on MPR for GMM detection in feed additives	EURL	31/7/2017	Open	coordinate between EURLs (GMO and FA) after receiving info from SANTE.
Prepare a template for WG reporting to the meetings	SEC	31/08/2017	Open	one page
WG sequencing mandate: collect comments from SC by 7 July	SEC	25/6/2017	Open	send email to SC to provide comments
WG on guidance for DNA extraction	SEC + SC	31/7/2017	Open	draft a mandate
WG multiplexing: prepare final draft of mandate	SEC	30/6/2017	Open	circulate to SC for final approval
Ask German network about AOCS survey	SEC	30/06/2017		
Update the list of observers with contacts of regional networks	SEC	28/2/2017	Open	