



30th ENGL STEERING COMMITTEE MEETING

3-4 February 2016, Ispra, Italy

Meeting Report

1.1 Welcome, apologies

The Chair welcomed the participants and announced that a video-link with SANTE will be maintained during the entire meeting.

1.2 Approval of the agenda

The Agenda (Annex 1) was approved without modifications

1.3 Approval of the report of the SC29 meeting

The report of the last meeting had been circulated before the meeting and was approved without changes.

1.4 Review of Dynamic Action List (DAL SC29)

The Secretary reviewed the DAL of the previous meeting. There was no discussion on the points presented.

1.5 Update from SANTE

SANTE informed that a legal interpretation document on new breeding techniques (NBT) is under preparation by the Commission and is expected to be finalised by March/April 2016 and presented to stakeholders before final adoption. The elements considered for the analysis are the definition of GMOs according to article 2 of Directive 2001/18/EC and the conditions for exemption set out in Annex 1B of the same Directive.

SANTE informed that the work of the three Scientific Committees on an operational definition of synthetic biology, related risk assessment methodology and safety aspects and research priorities has been finalised. The three opinions are publicly available.

An Open-ended Online Forum and an ad hoc technical expert group on synthetic biology established under the Convention on Biological Diversity (CBD) took on board the operational definition proposed by the three scientific committee of the European Commission. Two peer-reviewed reports on the outcome of the process were submitted for consideration and published on line by CBD. The SC members requested to receive the hyperlinks of the documents, now available at: <https://englnet.jrc.ec.europa.eu/steering/30th-Steering/Shared%20Documents/1/CBDlinksSynbio.pdf>

SANTE finally informed that the report of the ENGL WG on seed testing and sampling was presented to MS. The document was appreciated by the MS Competent Authorities and SANTE thanked the ENGL for the valuable input.

The new Head of Unit Biotechnology at DG SANTE briefly intervened and introduced herself.

2. Progress reports ENGL working groups

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

The Secretary informed, on behalf of the WG leader, that no methods proposals for validation had been submitted during 2015 and encouraged a more active participation from the network members. He suggested reviewing the document recently published describing the GMOs placed in the commercial pipeline and the GMOs submitted for field trials for identifying possible analytical gaps. The SC agreed to this proposal and asked the secretary to go ahead.

2.2 WG-UpMeth (Update of methods): update

The WG leader informed that after a kick-off meeting in May 2015 a second meeting took place in November 2015 when the WG members agreed on the general structure of the planned guideline.

In a third meeting organised in February 2016 the group was informed by the EURL GMFF about the results of a survey on methods used by official laboratories, and how these are modified in practice. The WG discussed this information and took it into account for further development of the document.

ENGL SC members discussed whether the modification of a method is leading to a new method and agreed on considering the primers and probes sequences as its core characteristics. SANTE asked if the WG could consider Regulation (EU) No 503/2013 and in particular Annex III for providing a clear definition of method and protocol. These two terms could help defining when the method or the protocol is modified and a new validation is required.

2.3 WG-dPCR (Digital PCR): update

The WG chair explained that the task of the WG is to explore transferability of existing real-time PCR methods to digital PCR platforms, investigate applicability of dPCR methods to difficult matrices, deal with accreditation issues, and define method performance requirements.

The outline of the report as decided at the first meeting of the WG on the 30th of June/1st July 2015 was presented. At a second meeting in December 2015 the WG discussed comments and contributions and agreed on developing a technical document with practical recommendations for the transfer of qPCR protocols to dPCR format.

The representative from Slovenia, informed that a Webinar for implementing dPCR on analysis of organisms other than GMOs was planned on the 11th of February and that an introductory regional workshop on detection and identification of GMOs by dPCR was being organised by the CBD on 7th-11th of March.

The WG met for the 3rd meeting in March 2016 and made progress on the main issues still open. It was decided that a drafting group will work on the document (two Webex conferences will be held in April 2016) and will provide an advanced draft for comments by the WG members within the first half of May 2016.

2.4 WG-UoM (Unit of Measurement): update

The WG chair, explained the strategy defined by the WG for establishing the conversion factors for converting copy numbers results into mass fraction results and vice versa. Since the conversion factor is linked to the CRMs used, the WG proposed the CRMs as anchoring point for traceability and comparability of results. A final draft providing a table with conversion factors is expected by June 2016 for consideration by the Steering Committee.

3. New activities

3.1 Survey on DNA extraction

Following a recommendation from an ENGL break-out group, the EURL GMFF drafted a table to be used for a survey to collect information on DNA extraction from different matrices. The Chair asked the participants to comment the table by the end of February and announced that the EURL GMFF will provide a web page for sharing the adopted version and harvesting further experience from the network.

3.2 Future Working groups (including reactivation of WG "verification" and WG on ENGL procedures, MPR)

WG Verification 2

The Secretary presented the mandate for reactivating the WG on Method Verification. The WG will update the current document, adding in particular guidance for multiplex PCR and multi target approaches (PSP). Participants suggested updating the terminology to the new ISO standard and commented that dPCR should also be addressed. The mandate was modified and approved (see Annex 2 for the mandate)

WG on ENGL procedures

The Secretary asked if members supported the establishment of a WG on ENGL procedures. The WG should propose to the SC streamlined ENGL operational procedures for aspects that are currently not defined. The Chair remarked, as an example, that presently the ENGL plenary does not have a clear function and proposed assigning to the Steering Committee a managerial and a first-approval function and to the ENGL plenary a final approval role to more involve the entire network in the decision-making process. The Consortium Agreement should not be changed. The SC agreed to the proposal and provided input on the following topics that might be addressed:

- 1) Participation of observers
- 2) Confidentiality
- 3) Industry participation to ENGL meetings
- 4) Functions of the ENGL plenary
- 5) Reimbursements
- 6) Formal approval process of ENGL documents.

The Secretary concluded that a WG on operational procedures for the ENGL will be created (see Annex 3 for the mandate).

WG on Method Performance Requirements (MPR)

The Secretary invited reflecting on a possible reopening of the WG on MPR. The MPR document has a central role and a legal impact on the functioning of the entire system and therefore needs to be constantly updated, while keeping it as stable as possible. Performance criteria on dPCR and further guidance on robustness testing could be added.

It was suggested waiting for the closure of the activities of the WGs on dPCR and Update of Methods to see the conclusions and their possible impact on the MPR document. Minimum performance parameters for Next Generation Sequencing are being discussed within the Decathlon project, therefore also these could be included in the document.

The Chair proposed inviting a NGS expert and organizing a breakout group discussion on NGS (with focus on data quality control) at the following ENGL plenary. The SC agreed.

WG on interpretation of results at the limit of detection

The Secretary asked if the proposal of creating a WG on interpretation of results at the limit of detection should be finally approved or rejected. A break-out session at the previous ENGL plenary concluded that it would not be advisable to establish numerical decision criteria (the so-called “cutoff”) but acknowledged that advice on procedures for interpreting the results could be useful, especially for new laboratories. In the following discussion, proposals included an online discussion forum, provision of an ENGL orientation document instead of a guidance and further discussion at the ENGL plenary. No final decision was taken.

4. Scientific / technical topics

4.1 EURL GMFF survey on use of reference methods

The purposes of the survey launched in June 2015 by the EURL GMFF and the main results were presented. Almost all official control laboratories use EU reference methods for performing quantitative identification of GMOs and a lower number employ them for qualitative purposes. A significant part of the laboratories declared to occasionally or frequently exploit the two decision supporting tools JRC GMO-Matrix and JRC Event-Finder. Finally almost half of the method protocols were found to be somehow modified by most laboratories, mainly with regard to the master mix and the reaction volume of the PCR reactions. The SC commented on the survey report and agreed that the data should be taken into account by the WG on dPCR and Update of Methods. However, the SC members were not surprised and offered adaptation to technical progress as well as to standard approaches of the respective laboratories as possible reasons for the modification. They also agreed that this is not posing any problem for the overall functioning of GMO controls in the EU.

5. ENGL topics

5.1 Preparation of the 25th ENGL plenary (13-14 April 2016)

The following topics were suggested by the SC for the next ENGL plenary meeting:

- 1) Inviting the secretariat of the CBD (Convention on Biodiversity) or more precisely of the BCH (Biosafety Clearing House) to present their activities
- 2) Update on CEN and ISO activities
- 3) Inform about the use of Probability of Detection (POD) modelling for single-laboratory validation of qualitative real-time PCR methods
- 5) Update on progress of the European Network on Species Identification (ENSI)
- 6) Update from SANTE
- 7) Presentation on new breeding technologies (plants and animals), synthetic biology, gene editing technologies
- 8) Update on the oilseed rape OXY-235

Participants also proposed organising a breakout group on NGS.

The ENGL secretariat took note and will integrate the requests into the draft agenda for the ENGL plenary. The secretary invited the SC to come up with more topics for breakout groups.

5.2 Discussion on optimisation of ENGL

This point is covered by the upcoming activity of the WG on ENGL Procedures.

6. AOB

The Chair invited suggestions for topics to be included in the call for Horizon 2020. Participants proposed the following points:

- 1) New breeding techniques and detection strategies
- 2) Development of new screening approaches for detection of GMM
- 3) Non-targeted detection methods (e.g. NGS)

The Secretary invited the SC to provide additional proposals within 2 weeks.

7 DAL SC30 and End of Meeting (12:10)

The Secretary informed that the dynamic action list (DAL) will be shared shortly after the meeting via ENGLnet (see annex 4).

The Chair thanked the participants and closed the meeting.

The next meeting is planned for June 2016, to prepare the ENGL plenary meeting of September 2016.

Annex 1 – Agenda



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit

30th ENGL STEERING COMMITTEE MEETING

3-4 February 2016, building 36/B, room 3, Ispra, Italy

Draft Agenda

AP	Time	Topic	Documents in ENGLnet
	Day 1		
1.1	09:30	<ul style="list-style-type: none"> ▪ Welcome, apologies 	Agenda Report SC29 DAL SC29
1.2		<ul style="list-style-type: none"> ▪ Approval of the agenda 	
1.3		<ul style="list-style-type: none"> ▪ Approval of the report of the SC29 meeting 	
1.4		<ul style="list-style-type: none"> ▪ Review of Dynamic Action List (DAL SC29) 	
1.5		<ul style="list-style-type: none"> ▪ Update from SANTE 	
	10:30	<i>Coffee Break</i>	
2	11:00	<i>Progress reports ENGL working groups</i>	
2.1		<ul style="list-style-type: none"> ▪ AG SMV (Advisory Group on Selection of Methods for Validation): update 	
2.2		<ul style="list-style-type: none"> ▪ WG-UpMeth (Update of methods): update 	
2.3		<ul style="list-style-type: none"> ▪ WG-dPCR (Digital PCR): update 	
2.4		<ul style="list-style-type: none"> ▪ WG-UoM (Unit of Measurement): update 	
	12:30	<i>Buffet lunch</i>	
3	14:00	<i>New activities</i>	Draft table Draft mandates
3.1		<ul style="list-style-type: none"> ▪ Survey on DNA extraction 	
3.2		<ul style="list-style-type: none"> ▪ Future Working groups (including reactivation of WG "verification" and WG on ENGL procedures, MPR) 	
	15:15	<i>Coffee Break</i>	
4	15:45	<i>Scientific / technical topics</i>	JRC Report on survey
4.1		<ul style="list-style-type: none"> ▪ EURL GMFF survey on use of reference methods 	
	17:15	<i>End of day 1</i>	
	19:30	<i>Social dinner at "Corner 08", Monate</i>	
	Day 2		
5	09:30	<i>ENGL topics</i>	
5.1		<ul style="list-style-type: none"> ▪ Preparation of the 25th ENGL plenary (13-14 April 2016) 	
5.2		<ul style="list-style-type: none"> ▪ Discussion on optimisation of ENGL 	
	10:45	<i>Coffee Break</i>	
6	11:15	<ul style="list-style-type: none"> ▪ AOB 	
7	12:00	<i>DAL SC30 and End of Meeting (12:10)</i>	DAL SC30
	12:15	<i>Sandwich lunch</i>	

Annex 2 – Mandate of the WG-MVrf2**Mandate for an ENGL Working Group on "Update of Method Verification Document" (WG-MVrf2)**

Approved by the ENGL Steering Committee of 3-4 February 2016

Background

The ENGL document "Verification of analytical methods for GMO testing when implementing inter-laboratory validated methods" is a guidance developed by the ENGL working group on "Method Verification" and was published in 2011 (see <http://gmo-crl.jrc.ec.europa.eu/ENGL/docs/WG-MV-Report.pdf>).

The guidance document aims at harmonizing the in-house verification of inter-laboratory validated methods for the qualitative and quantitative detection of GMOs, including element-, construct-, and event-specific methods.

The document has been widely used and proved to be very successful in fostering harmonization in the way methods are implemented by control laboratories.

After five years it is however felt necessary to review the guidance document and update it taking into technology and methodology developments and other guidance texts produced from 2011 to date.

Tasks

The WG will:

- 1) Update the document to include verification criteria for techniques not currently covered, to be first identified by the WG.
- 2) Align the document to the new version of the MPR (see [http://gmo-crl.jrc.ec.europa.eu/doc/MPR%20Report%20Application%202010 2015.pdf](http://gmo-crl.jrc.ec.europa.eu/doc/MPR%20Report%20Application%202010%202015.pdf)).
- 3) Review the terminology, also considering the new ISO 16577.

While focusing in the specific point listed above, the WG should review the document in its entirety and improve it if and where necessary.

Timeline

The working group will be formed by the end of February 2016 and is expected to meet in March/April. The WG shall report to the ENGL SC in June 2016 in view of a possible final report to be approved by the ENGL plenary in September 2016.

Annex 3 – Mandate of the WG-Proc



Mandate for an ENGL Working Group on "ENGL Procedures" (WG-Proc)

Approved by the ENGL Steering Committee of 3-4 February 2016

Background

The functioning of the ENGL is regulated by a Consortium Agreement (see <http://gmo-crl.jrc.ec.europa.eu/ENGL/docs/2009-05-19%20Consortium%20Agreement%20Final.pdf>) signed by all ENGL Members.

The Consortium Agreement provides rules and procedures for all main aspects of the ENGL, like membership, work program and confidentiality. It does not, however, include detailed procedures that are needed for the routine activity of the network, e.g. approval workflow of documents, management of observers, participation to meetings of non-ENGL members etc.

It is therefore deemed useful that an ENGL working group is formed to deal with these aspects.

The new procedures, one approved by the entire ENGL, will become applicable. It is not foreseen that they will become integral part of the Consortium Agreement, which will not be modified.

Tasks

The WG will:

- 1) Identify and agree on the procedures to be drafted, in consultation with the ENGL Presidency and the ENGL Secretariat
- 2) Produce procedures that should be streamlined and easily implementable

Timeline

The working group will be formed by the end of February. The first meeting will take place in March/April. Draft procedures should be provided to the ENGL SC for discussion in June 2016 for a possible approval by the ENGL plenary in September 2016.

Annex 4 – Dynamic Action List (DAL)

30th ENGL STEERING COMMITTEE ACTION LIST 04/02/2016				
ACTIONS	Resp.	Timelines	Status	Comments
ENGL GENERAL				
Report of 30th ENGL SC	SEC	14/02/2016	Open	
Organise 25th ENGL Plenary in Ispra	SEC	29/02/2016	Open	13-14 April 2016. Send draft agenda
Organise 31st ENGL SC	SEC	30/04/2016	Open	June 2016 Send draft agenda
WORKING GROUPS				
Advisory Group on "selection of methods for validation" (SMV)				
Organise meeting (VC)	SEC	15/02/2016	Open	Set on 25/02/2016. Status of ref genes methods selection? Provide pipeline paper
WG-UpMethod				
Prepare template for data collection from ENGL labs	EURL + WG	31/03/2016	Open	
Work on definition of "method" versus "protocol"	WG	31/03/2016	Open	Refer to Regulation 503/2013 - suggested by SANTE
WG-UoM				
3rd meeting ?	SEC	10/02/2016	Open	Ask Philippe C.
WG-dPCR				
Organise 3rd meeting	SEC	29/02/2016	Open	9-10 March 2016
VARIOUS				
Share ppt of the NRLs workshop on dPCR done in Slovenia	SEC	29/02/2016	Open	Ask authors for OK
Share paper on global pipeline	SEC	10/02/2016	Open	Relevant also for the AG-SMV
Finalise the DIR report	SEC	29/02/2016	Open	
Adapt table on DNA extraction after comments received from SC	SEC	31/03/2016	Open	comments by the SC by end of February
WG procedures	SEC	15/03/2016	Open	get input from SC (by 15 March) - send mandate and ask for EOI to SC members
WG verification 2	SEC	15/02/2016	Open	send mandate and EOI to ENGL members
discussion forum on cutoff in ENGLnet	SEC	29/02/2016	Open	try to activate, with a moderator
ENGL: European Network of GMO Laboratories SEC: ENGL Secretariat EURL: European Union Reference Laboratory for GM food feed				