



25th ENGL STEERING COMMITTEE MEETING

10-11 September 2013, Ispra, Italy

MEETING REPORT

1. Introductory activities

1.1 Welcome, quorum, apologies

The President welcomed the participants, apologised for the late finalisation of the report of the previous Steering Committee (SC) meeting and officially opened the 25th SC meeting.

1.2 Approval of the agenda

The President asked if additional points needed to be inserted in the agenda (see agenda in annex 1). SC members enquired on the progress of the survey on Certified Reference Materials (CRMs). The President informed that a direct collection of issues from individual laboratories was finally considered preferable by SANCO to avoid undermining trust in the official control capabilities.

It was further remarked by the participants that AOCS does not always guarantee the quantity (DNA) dispatched and that the amount indicated on the label often does not correspond to the one measured by the laboratory.

It was suggested addressing an EU-RL GMFF note directly to AOCS and to the owner of the corresponding GM event (i.e. Bayer CropScience); issues with CRMs to be mentioned in the note should be forwarded to the Secretary. The agenda was finally approved.

1.3 Approval of the report SC24 meeting

The Secretary summarised the main points of the report. The SC24 report was approved.

1.4 Review of Dynamic Action List (DAL SC24)

The Secretary presented the DAL and asked for comments. A new meeting of the Advisory Group on Selection of Methods for Validation (AGSMV) was requested for finalising the list of methods proposed for validation. It was noted that objective methods selection criteria should be pre-defined.

2. Progress reports ENGL working groups

2.1 WG MPR (Method Performance Requirements): final draft of the MPR document

The WG leader reminded that members were asked to provide comments on the final draft and that more time is necessary to address all of them. The final document should be finalised for comments by the ENGL members, later provided to the industry for comments and finally approved by the Steering Committee.

2.2 WG SPP (Sample Preparation Procedure)

It was announced that a final draft will be presented at the ENGL plenary meeting in December 2013.

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

The AG chair summarised the outcome of the last discussions. It was reminded that from a review analysis fourteen methods and five targets had been selected and that a matrix was generated between methods validated or under validation and the corresponding detected GMOs.

A dynamic priority list was produced including the three primary targets having a higher GMO coverage. It was highlighted that some primers and probes presented miss-match sequences in the targets of certain GMO. Regular surveys should be performed to maintain the list updated, to be decided by whom. The GMOseek algorithm developed by the GMOseek project could be a helpful tool to identify additional targets having relevant coverage.

The President informed that a budget request will be presented to SANCO for running two validation trials. SC members recommended using a new list based on objective pre-defined quality criteria and demands of the ENGL.

It was further suggested to update the matrix with input from experimental analysis when new GMOs are approved.

The President added that information on selected primers could be forwarded to EU-RL GMFF for performing similarity searches against new GMO sequences and that the resulting matrix results could be shared among SC members without providing confidential information.

2.4 WG DIR (Detection Interpretation Reporting)

The WG leader summarised the conclusions and remarked that different procedures were identified and are described in the draft document for establishing a cut-off value. As a joint initiative with the AG SMV, a draft “European screening matrix” considering methods adopted in Belgium, Germany, Italy and The Netherlands has been prepared. Donor organism methods were also discussed. It was remarked that botanical impurities could be addressed (microscopy methods).

3. New activities/issues

3.1 Identification of stacked GMOs

The President reported that SANCO requested assistance of the EU-RL and ENGL to develop approaches for discriminating stacked events from single events in a mixture. This analytical gap is undermining the approval process and the official control since it is not possible to distinguish an authorised single event from an un-authorised stacked event containing it.

The President proposed creating a working group for investigating technical solutions. The WG should review the state of the art approaches and analyse which ones could be feasible.

Different approaches were discussed, such as methods detecting second insertion sites, fluorescence hybridisation of intact cells, statistical analysis distribution of amplification products for stacked events and single events by digital PCR. The option involving next generation sequencing was not considered momentarily feasible in Europe since the technology is not yet widely used by and available to the control laboratories.

The SC members expressed some scepticism on the feasibility of the project but finally approved the EU-RL proposal.

A draft mandate (see annex 2) and related timeline for the WG was prepared and finally approved. The title of the WG is “Identification of stacked GM events” (WG-IGSE). The first meeting is planned for October, followed by two more meetings and final reporting to the SC26 in March/April 2014.

3.2 Verification of methods – ENGL activity concerning documentation, guidance and/or validation of “donor” organisms specific methods (CaMV, FMV, A. tumefaciens etc.) and concerning control samples keeping

Methods of detection of donor organisms sequences (e.g. CaMV) are available but not validated, and their application seems not to be harmonised, as laboratories implement different methods.

It was reminded that a review of available methods for donor organisms is currently ongoing within the WG DIR.

The President suggested compiling a summary of the available methods with a related priority list to harmonise approaches among ENGL laboratories. The ENGL activities could be strengthened by validating the methods or having them verified by the EU-RL GMFF. Control samples as plasmids could be provided by the EU-RL GMFF once the methods are selected and the sequence information are made available.

3.3 Proposal for a questionnaire to gain experience with ENGL guidance documents:

i) UGM document: application e.g. in decision taking at the 2x LODabs

ii) Verification document: application for qualitative (screening) methods

It was commented that the guidance document for verification does not cover screening methods. It would be also useful to have feedback on the implementation of the 2 x LOD approach (table 2) of the UGM guidance document. The SC members asked the German member to draft a questionnaire for the next ENGL plenary meeting in December 2013. This first survey will focus on the experiences of ENGL members with the UGM document and on additional needs requested. The outcome could be discussed during the same plenary meeting, if the evaluation would be available in short-term.

4. Scientific / technical issues

4.1 GM wheat testing

The Secretary presented a summary on the GM wheat issue. He informed that a revised method proposed by Monsanto was undergoing investigation by the EU-RL GMFF and that the sensitivity has been confirmed to be around 0.1%. Feedback was requested to the laboratories on the performance of the methods for GM wheat detection. Apparently little testing activities are carried out at the moment for GM wheat.

4.2 Revised EU-RL GMFF guidance on Chinese rice analysis

A summary on tests performed on rice products derived from China was presented by two ENGL members. They reported that quite a few of the positive results were contested by a second private laboratory performing counter analyses.

In addition, variations of the order of magnitude of two Ct values were observed between different PCR platforms, which could be reduced with the use of an internal control. Most of the samples tested by the NL were positive only for the Cry1Ab/Ac target (35S and T-nos not detected) and re-testing of the positive Cry1Ab/Ac with the TaqMan Cry1Ab/Ac method validated by DE gave negative results.

It was remarked that the 38 Ct cut-off value suggested in the draft revised guideline proposal can be adequate only when a single peak is present. In the presence of many peaks it was suggested to reduce the Ct cut-off value to 33-35. It was commented that when working below the LOD value the probability of getting variable results increases strongly.

It was reminded that literature reviews have revealed that a Cry1Ab/AC method would not cover all GM rice events containing the Cry element; the President suggested speeding up the publication under preparation so that scientific data could be used for revising decisions and approaches. It was asked to circulate the draft revised guidance document to the ENGL members and finalise it by October to eventually prompt revision of the law.

4.3 GM papaya from Thailand

The genetics and commercial distribution of several GM papaya events were reviewed by the EU-RL GMFF. It was remarked that the sequences of the GM papayas used in the bioinformatics analysis were reconstructed *in silico* from available information provided on patents, publications and relative methods of detection.

It was noted that very few construct or event-specific methods are available for distinguishing different papaya- events but also that since there is no authorised GM papaya on the market, the simple detection of any GM-element in a consignment by an element-specific method would be sufficient for rejection. On the basis of available information, currently available screening methods should be able to detect most of the GM-Papayas possibly present on the market.

SC members reminded that a qualitative construct-specific method for detection of GM 55-1 papaya has been finally published in the amendment of ISO standard 21569 and should be included into the EU-RL GMFF GMO reference methods database.

5. Scientific / technical issues

5.1 Unit of measurement and conversion: pragmatic guidance (linked to 5.2)

IRMM reminded the SC of the training on proper use of CRMs and measurement uncertainty organised in November in Geel. Regarding the request previously formulated of providing a table with the information on CRMs zygosity, it was highlighted that such a table would need to be maintained and that IRMM would have difficulties ensuring this. As an alternative, IRMM decided to provide this information in all CRM certificates.

It was pointed out that such a table, created by the German network of GMO-laboratories, could be shared on the ENGL net, with the caveat that the table is not dynamically updated and does not include information on the maternal/paternal origin of the GMOs. In the near future the EUGinius database could provide such information on CRMs and maintain it updated.

5.2 Free access to GMOseek algorithm

The National Institute of Biology (NIB, Slovenia) announced that free access of the GMOseek algorithm developed by the GMOseek project is now available and proposed to present the project to the ENGL plenary.

5.3 Updated GMO CRM certificates (linked to 5.1)

See point 5.1 above

5.4 Invitation of an expert on breeding (e.g. Brassica) to the 20th ENGL Plenary (linked to the issue of unit of measurement and conversion factors).

Members were encouraged to submit proposals for topics and speaker(s) to be invited to the ENGL plenary meeting beginning of December. In the discussion about possible topics, it was suggested to cover also wheat and new breeding technologies in general.

6. General ENGL issues

6.1 Croatian member of the SC

The Secretary stated that Mrs. Ivana Ferencak was contacted but that no decision has been communicated yet to the ENGL Secretariat.

6.2 Process to share information on testing screening methods on new GM events

It was discussed if an ENGL- platform for sharing analytical results obtained by laboratories when testing screening methods on newly approved GM events would be considered useful, and the SC agreed that it would be very valuable. It was suggested to use an existing platform rather than developing a new one. The representative from Germany informed that similar data are being entered into the EUginus database.

It was decided that the type and source of the platform will be discussed at a later stage as various aspects need to be considered (e.g. finances). The EU-RL stated that the point will be added to the agenda of the upcoming meeting between EUginus partners and the EU-RL GMFF (to be held in October 2013).

6.3 Process of consultation of the ENGL SC on guidance documents

The discussion focused on the procedure to be followed when guidance documents prepared by the EU-RL GMFF are drafted; it was remarked that NRLs implementing the guidance document should be involved in the revision process and should be included into the e-mail list of reviewers. It was agreed that on a case by case basis the final recipient of the document should be involved into the revision process.

6.4 Preparation of the 20th ENGL plenary meeting

The date of 4-5th of December was selected for the next ENGL plenary meeting. The SC members suggested some agenda points and will provide additional agenda points by e-mail to the ENGL-secretariat. A request will be e-mailed to the ENGL members by the Secretariat.

6.5 Preparation of the 9th Workshop of NRLs Reg. (EC) No 882/2004

The date of 4th and 5th of December was decided, only the first half day on issues exclusively of interest to NRL-882. The SC members suggested some agenda points and will provide additional agenda points to the Secretariat by email. A specific email requesting contributions will be sent to NRLs by the Secretariat.

7. AOB

A question was raised on the ENGL working groups reporting. WG chairs are regularly requested to provide a progress report both at the ENGL plenary meetings and at the Steering Committee meetings, with the risk that the ENGL members not sitting in the SC may miss the information provided during the SC meeting. It was therefore suggested and agreed to upload the progress reports presented at the SC meetings on the ENGLnet.

8. DAL SC25 and next meeting

The ENGL Secretary presented the DAL SC 25 (see annex 3) that includes the updated appropriate follow-up actions.

The next meeting (SC26) will be held in March-April 2014. The secretariat will set-up a doodle well in advance to identify the most convenient date.

List of Annexes:

- 1) Agenda
- 2) Mandate for the WG-IGSE (see 3.1)
- 3) DAL (Dynamic Action List) SC 25

Annex 1: agenda

EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit

**25th ENGL STEERING COMMITTEE MEETING**

10-11 September 2013, Ispra, Italy

DRAFT Agenda
(Version 6/9/2013)

AP	Time	Topic	Documents in ENGLnet
	Day 1		
1.1	09:30	<ul style="list-style-type: none"> ▪ Welcome, quorum, apologies 	
1.2		<ul style="list-style-type: none"> ▪ Approval of the agenda 	Agenda
1.3		<ul style="list-style-type: none"> ▪ Approval of the report SC24 meeting 	Report SC24
1.4		<ul style="list-style-type: none"> ▪ Review of Dynamic Action List (DAL SC24) 	DAL SC24
	10:45	<i>Coffee Break</i>	
2	11:15	<i>Progress reports ENGL groups</i>	
2.1		<ul style="list-style-type: none"> ▪ WG MPR (Method Performance Requirements): final draft of the MPR document 	
2.2		<ul style="list-style-type: none"> ▪ WG SPP (Sample Preparation Procedure) 	V10 – final draft
2.3		<ul style="list-style-type: none"> ▪ AG SMV (Advisory Group on Selection of Methods for Validation) 	Report from the chair + AP2.3
2.4		<ul style="list-style-type: none"> ▪ WG DIR (Detection Interpretation Reporting) 	DIR update
	12:30	<i>Buffet Lunch</i>	
3	14:00	<i>New activities / issues</i>	
3.1		<ul style="list-style-type: none"> ▪ Identification of stacked GMOs 	
3.2		<ul style="list-style-type: none"> ▪ Verification of methods – ENGL activity concerning documentation, guidance and/or validation of “donor” organisms specific methods (CaMV, FMV, <i>A. tumefaciens</i> etc.) and concerning control samples keeping 	AP3.2
3.3		<ul style="list-style-type: none"> ▪ Proposal for a questionnaire to gain experience with ENGL guidance documents: <ul style="list-style-type: none"> i) UGM document: application e.g. in decision taking at the 2x LODabs ii) verification document: application for qualitative (screening) methods 	AP3.3
	15:15	<i>Coffee Break</i>	
4	15:45	<i>Scientific / technical issues</i>	
4.1		<ul style="list-style-type: none"> ▪ GM wheat testing 	
4.2		<ul style="list-style-type: none"> ▪ Revised EU-RL GMFF guidance on Chinese rice analysis 	Draft of revised guidance
4.3		<ul style="list-style-type: none"> ▪ GM papaya from Thailand 	
	17:30	<i>End of Meeting, day one</i>	
	19:30	<i>Social dinner Hotel Lido</i>	
5	Day 2	<i>Scientific / technical issues</i>	
5.1	09:30	<ul style="list-style-type: none"> ▪ Unit of measurement and conversion: pragmatic guidance (linked to 5.2) 	Example of table (BVL)
5.2		<ul style="list-style-type: none"> ▪ Updated GMO CRM certificates (linked to 5.1) 	
5.3		<ul style="list-style-type: none"> ▪ Free access to GMOseek algorithm 	
5.4		<ul style="list-style-type: none"> ▪ Invitation of an expert on breeding (e.g. Brassica) to the 20th ENGL Plenary (linked to the issue of unit of measurement and conversion factors) 	
	10:45	<i>Coffee Break</i>	

6	11:15	<i>General ENGL issues</i>	
6.1		▪ Croatian member of the SC	
6.2		▪ Process to share information on testing screening methods on new GM events	
6.3		▪ Process of consultation of the ENGL SC on guidance documents	
6.4		▪ Preparation of the 20 th ENGL plenary meeting (Nov-Dec 2013)	Draft agenda 20 th ENGL Plenary
6.5		▪ Preparation of the 9 th Workshop of NRLs Reg. (EC) No 882/2004	Draft agenda WS NRLs 882/2004
7	12:00	<i>AOB</i>	
8	12:15	<i>DAL SC25 and End of Meeting (12:30)</i>	DAL SC25
	12:30	<i>Sandwich Lunch</i>	

Annex 2: Mandate of ENGL WG-IGSE



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Molecular Biology and Genomics Unit



Mandate for an ENGL-WG for identification of stacked GM events (WG-IGSE)

This mandate was approved by the ENGL SC25 on 11 September 2013

No methodology exists to discriminate between GM stacked events and individual events in a sample.

Currently, GM stacked events are authorised according to Regulation (EC) No 1829/2003 based on methods validated for single events.

The ENGL was asked to provide technical advice on this topic, as some are questioning the current practice.

Hence, the ENGL WG for “identification of stacked GM events” was formed to draft a report to the 26th ENGL Steering Committee by March-April 2014:

The remit of the WG-IGSE is to:

- review the current state of play (e.g. by literature search)
- explore the feasibility of novel approaches under routine analytical conditions
- propose research strategies
- provide recommendation(s)

Timeline: First meeting: October 2013
 Second meeting: December 2013
 Third meeting: February 2014

Annex 3: DAL (Dynamic Action List) SC 25

ACTIONS	Resp.	Timelines	Status	Comments
ENGL CONSORTIUM AGREEMENT				
Circulate report of 25th ENGL SC	SEC	Oct-13	Open	
Organise 20th ENGL Plenary in Ipsra	SEC	Nov-13	Open	4-5 December
Organise 26th ENGL SC	SEC	Mar-14	Open	
Invite SC members to propose points for the ENGL plenary and 882	SEC	Sep-13	Open	
Organise the 9th workshop NRLs 882/2004	SEC	Nov-13	Open	04-Dec
ENGL WORKING GROUPS				
WG Detection Interpretation Reporting (DIR)				
Organise 4th meeting	SEC	Nov-13	Open	in connection to the Plenary 20th- 2-3 december
Provide last results of the survey on matrices	SEC	Mar-13	Open	
WG Method Performance Requirements (MPR)				
Check with SANCO on the procedure	SEC	Oct-13	Open	
Prepare final draft of the document for ENGL comments	WG chair	Oct-13	Open	
Consult the industry	WG chair	15-11-13	Open	
Prepare final draft for adoption by the SC26	SEC	Feb-14	Open	adoption at the SC26
WG Sample Preparation Procedure (SPP)				
Prepare final draft (V10) for ENGL comments	SEC and WG chair	Oct-13	Open	
Prepare final draft for adoption by the SC26	SEC and WG chair	Feb-14	Open	
Advisory Group on "selection of methods for validation"				
Analyse methods for donor organisms	SMV AG	31/3/2014	Open	
Share the bioinfo analysis with the SC	AG chair	31-12-13	Open	
Organise a meeting of the group	SEC	Nov-13	Open	Ipsra, date to be decide after doodle
OTHERS				
Send the call for interest for the new WG-IGSE	SEC	15-09-13	Open	
Organise the first meeting of the WG-IGSE	SEC	15-10-13	Open	
Revise the EU-RL GMFF guidance document on chinese rice	EURL	Sep-13	Open	draft to be discussed by Stand Committee October 2013
Prepare an ENGL note to BCS and AOCS	EURL	Oct-03	Open	
	SEC	Sep-13	Open	
Gather information on issues with CRMs to support the note	SEC	Sep-13	Open	send a reminder
Ask for control samples for wheat MON71800	EURL	Sep-13	Open	
Seek for info on target sequences CaMV	SEC	Oct-13	Open	for the preparation of plasmid control samples by the EURL
Invite expert(s) on breeding and NBT to the 20th ENGL plenary	SEC	Oct-13	Open	Send reminder to SC to propose names
Ask MPR working group to check/approve criteria for inclusion of methods in the GMOMETHODS database	SEC	ASAP	Open	After alignment of criteria to MPR doc send the doc to the ENGL for comments
Questionnaire on UGM doc	SEC	Oct-13	Open	Lutz to provide a draft, then circulated to the SC by email
explore a suitable way to provide a platform to share info on testing screening methods; link to EUGINIUS?	SEC	Nov-13	Open	collaboration JRC-EUGINIUS?