



46th ENGL Steering Committee Meeting

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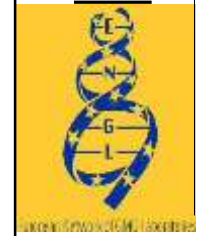
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46th ENGL Steering Committee Meeting

Report of the meeting - 14 March 2024



1. Welcome, apologies, quorum

The Chair welcome the participants. The Secretariat informed that of the 31 participants were connected.

2. Approval of the agenda

The participants approved the agenda (Annex 1). The representative of Italy requested to include in the agenda a discussion on authorship for documents drafted by ENGL working groups.

3. Update from SANTE

SANTE informed that most of its activities since the previous ENGL meeting regarded the NGT proposal. The European Parliament reached a common position on the NGT proposal. This was not the case in the Council representing the Member States. SANTE hopes that the NGT proposal will continue its legal progression without significant modifications. The Commission will need the support of the ENGL for establishing the implementing measures once the proposal is adopted by the EP and Council.

Regarding SANTE other recent activities, the Commission was requested by Germany to define the legal status of analysis performed by digital PCR. In a survey performed four years ago, many Member States expressed interest in addressing topics on seed testing. The Member States requested an information exchange system for communicating non-compliance on seed since they cannot use the rapid alert system for food and feed (RASFF). SANTE is evaluating other solutions for communicating results of seeds analysis. SANTE also launched a new survey for Member States to verify the topics they want to address in relation to seed testing.

The representative from Germany requested clarifications on the EP amendment aiming at introducing a requirement for labelling of category 1 products in the current NGT proposal. SANTE informed that the NGT proposal considers the labelling of these products as not necessary but negotiations are still open.

The representative from Italy requested an update on the adventitious presence of GMMs (and DNA thereof) in food/feed products; SANTE remarked the complexity of the issue and acknowledged that different views exist.

A JRC representative requested an update on harmonisation issues concerning botanical impurities. SANTE clarified that as long as the determination and expression of the total fraction of botanical impurities is not harmonised in the applicable sectorial legislation, it would be useless to start harmonisation of the GM fraction of these impurities. The speaker reminded a suggestion expressed during the previous meeting to create a small WG. The Secretary added that a small WG could review the chapter 7 of the JRC Technical Report "Recommendation for the unit of measurement and the measuring system to report traceable and comparable results expressing GM content in accordance with EU legislation". This point could be discussed under the AOB section of the agenda.

The representative from Poland asked if patent copyrights on natural plants or feed/food would be prohibited. SANTE explained that it is difficult to modify the EU patents regulation because it is

aligned to the rest of the world. Patents also are not necessarily negative for small and medium-sized enterprises (SMEs).

4. Progress ENGL Working Groups

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

The Chair of the WG informed that the JRC conducted analyses on reference genes for maize, soy, cotton and rapeseed and their method performance to identify the most suitable taxon systems for GMO analysis. Since this information needed to be updated, the JRC performed a new bioinformatics analysis to estimate the copy number of these genes in the available genomes from the same species, as well as to predict expected and unexpected amplifications using *in silico* PCR simulations. The report will be published on the EURL GMFF web site. Information on the reagent mixes used in the different validation studies has also been updated. A concise summary report will be drafted in summer, covering the reference genes copy number and a summary of the method performance data obtained from the EURL GMFF validation reports. It will also provide alternative PCR reagents if those used in the validation are no longer available. The group will have two additional meetings for discussing the document on reference genes and other points.

The representative from Germany enquired on the purpose of the new bioinformatics analysis since the reference systems have been already validated. The chair of the WG explained that multiple reference systems have been validated for each crop but that not all of them are optimal; some have been published more than 10 years ago, others use reagents no longer available or have copy number and primer sequences issues. The report is expected to identify optimal reference systems, so that laboratories can select a single taxon method per crop for their analysis and reduce the cost of maintaining different systems in place. A concise document summarising data from several dossiers can help laboratories in the selection of the best analytical system or be very useful for new laboratories in the field, or for laboratories that have less experience.

4.2 WG-GMM (Detection of genetically modified microorganisms in food and feed)

The speaker explained that the group has drafted an extensive document but it is currently silent while awaiting legal clarification from SANTE. Some WG members proposed to draft a new mandate to avoid legal references and focus on the analytical aspects. Others consider the political interpretation very important for the scope of the WG. SANTE is planning to reconvene the Member States to find a solution. The Secretariat requested suggestions on how to proceed with the document and the group activities.

The Chair underlined that the document has been pending for quite a while and that the information included in the report could be very useful for the laboratories.

The representative from Germany requested a clarification on the Commission expectations for the deliverable of the WG; it is commented that the report covers technical challenges on GMM detection and the legal uncertainties should not stop its publication.

4.3 WG-NMT (New Mutagenesis Techniques)

The Chair reminded that the mandate of the group is to evaluate whether the report produced for NGT plants could be extended to animals and if other specific aspects should be considered. So far, the group discussed a definition of NGT animals and mutations occurrence in animals, verified published guidance on detection of NGT animals and summarised the retrieved information. EFSA has published in 2023 a guidance on risk assessment of NGT animals. In this

document, almost 200 applications on commercialised and pre-commercialised NGT animals are considered. Food and feed purposes regard 75 % of the applications, with 10 % of them introduced by SDI, 79 % by a CRISPR/Cas system and the remaining by TALEN technology.

The main task of the group is to look for challenges in differentiating conventional and NGTs animals and signal issues specific for the latter. These may concern sampling, taxon-specific markers, mitochondrial versus nuclear targets and the impact of tissue targets. The group will discuss and decide which aspects should be included in the report.

Another group will cover GMMs produced by NGTs. This group needs to provide a clear definition of NGT GMMs for category 3 products containing only recombinant DNA (lack of viability) and category 4 products containing GMMs capable of replication and gene transfer, i.e. capable to survive (persist) and proliferate in specific environments. EFSA published in December 2023 a horizon-scanning document on products obtained by NGTs, which highlights the type of GMMs that may be authorised in the future and the expected type of modifications. The analytical challenges regard the selection of reference genes, the existence of multiple modifications and their stability, the differentiation of NGT GMMs from the other strains, the identification of natural variants and of mutations introduced by mutagenesis techniques.

The Chair clarified that the 195 NGT animal applications mentioned in the EFSA document do not regard applications for authorisations but research applications that could be developed in the future for food and feed purposes. He underlined that the scope of the WG is also to verify if the ENGL method performance requirements can be applied to current NGTs products and especially to those harbouring point mutations.

SANTE remarked that the deliverable on NGT GMMs should be prioritised, because these products will be probably marketed first but that a document on NGT animals could also be immediately required if the latter are approved outside the EU. SANTE does not consider controls on the factory bioreactors as a problem in EU, since they are already in place.

4.4 WG-GMA (GM animals)

The main task of the group is to draft a report addressing challenges related to detection of authorised and non-authorised GM animals used in food and feed ingredients. The scope covers GM animals obtained by conventional techniques, but not NGT animals.

Some of the members contribute also to the WG on new mutagenesis techniques. Since some parts are overlapping these two groups will have to liaise with each other to minimize duplication of work. A kick-off meeting is planned in May 2024.

5. Preparation ENGL Annual Meeting 2024/NRL training/NRL workshop

The Secretary proposed 12-14 November as the dates for the 20th NRL workshop and the 35th ENGL plenary meeting. He also announced the celebration of the 20th anniversary of the launch of the EURL GMFF.

The Chair requested to share ideas for the celebration of the anniversary. The Secretary requested suggestions for the ENGL meeting.

A JRC representative suggested presenting as usual, an update of the EURL GMFF activities. These include three proficiency tests (PTs) reports, since the second PT of year 2023 was not finalized at the time of the last NRL workshop. He further proposed to include in the agenda an update from SANTE and the results of a survey among laboratories on the occurrence of GMOs in samples. The JRC report on reference genes could be presented either at the NRLs workshop or at the ENGL plenary.

The ENGL report on sequencing, which is almost finalised, could be presented. Involved ENGL partners could present the EU Horizon projects “DETECTIVE” and “DARWIN” while the WG AGSMV could summarise results from the reference genes report. The Secretary proposed to invite speakers from non-EU regions as in the previous ENGL plenaries. He asked to identify network representatives for having an update on new NGT organisms or new research projects i.e. from China or Middle East network regions. Other members suggested inviting representatives from Japan because they have an authorised NGT tomato on the market and other organisms.

It was also suggested to discuss extraction methods for high processed food samples and to have presentations of Horizon Europe projects from ENGL members involved.

6. Update on NRL training activities

The Secretary requested input for the EURL GMFF training activities. The representative from Netherland suggested offering basic training on classical polymerase chain reaction (PCR) analysis. The representative from Denmark advised to organise a workshop on laboratory implementation of reference methods. A JRC representative proposed discussions and exchange of experiences on DNA extraction and use of conversion factors, since they have been identified as important items in PTs follow-up.

The Chair suggested demonstrating the use of conversion factors and tools on the EURL GMFF web site according to laboratory interest. The representative from Italy supported the idea of covering basic GMO analytical aspects.

7. New activities

A discussion took place on the need to update the existing ENGL document “Guidelines for sample preparation procedures in GMO analysis”.

The representative from Denmark remarked that laboratories are not responsible nor able to influence sampling performed on the field, but supported a discussion on sampling and harmonisation between grains and food and feed. The representative from Italy proposed to involve ENGL colleague’s expert on sampling.

The Secretary requested to prepare a mandate proposal for this activity.

A JRC representative remarked that the new NGT proposal will also require implementing acts and new procedures and possibly modifications in the ENGL method performance requirements (MPR). He suggested starting discussing the analytical implications of the proposal.

SANTE supported the idea of starting a discussion on the subject and clarified that the NGT proposal would be implemented after two years from its adoption.

The Secretary asked if it was necessary to activate a new WG or wait for the approval of the NGT proposal. The Chair suggested starting discussing possible options.

The representative from Belgium agreed in investigating more cost-efficient strategies for performing official controls (e.g. checking quality of labels or data processing in combination with testing). In 2010, a knowledge-based approach for official control was developed, starting with data analysis, definition of a hypothesis and then the performance of analytical tests.

A representative from JRC underlined that similar approaches are being discussed in the Horizon Europe projects, specifically for NGT products. It is a valuable discussion to reduce the amount of work involved in the validation of methods of analysis of classical GMOs and potential future NGT products.

The Secretary remarked that in the NGT proposal the EURL GMFF has the possibility to adapt its own procedures for implementing new measures. If the validation approach for NGT products is changed, the entire paradigm could be modified also for conventional GMOs. The Secretary commented that the possibility of defining alternative procedure needs to be evaluated first at the legal level but that could be discussed also at the ENGL level.

8. AOB

For the DNA extraction report recently published, the authorship was restricted to the drafting group, while the other members were included in the acknowledgment section. The representative from Italy remarked that this approach was never followed before and requested if it would be applied also to the documents prepared by the other WGs.

A JRC representative explained that the term “ENGL” cannot be longer used as a reference and that a list of authors needs to be provided for the submission in PUBSY (the JRC internal publication depository). In line with international guidelines, only members that provided a substantial contribution to the drafting of the document and to ideas were recognised as authors.

The representative from Netherland remarked that the approach for recognising authorship and the list of authors should be known in advance. The representative from Italy added that it could be difficult to weight the impact of every single member of a WG to the final deliverable.

The Secretary remarked that the new approach would stimulate members in contributing more significantly to the activities of the WG. The Chair underlined that the new guidelines established by the ENGL are identical to those of general publications.

The Secretary and the Chair thanked the participants for the enriching discussions and the suggestions and closed the meeting.

Annex 1 – Agenda

46th ENGL Steering Committee Meeting

Online meeting – 14 March 2024



Time	Topic	Documents in CIRCABC
From 09:30 till 10:30	1. Welcome, apologies, quorum 2. Approval of the agenda 3. Update from SANTE	Draft agenda
From 10:30 till 11:00	Coffee break	
From 11:00 till 12:15	4. Progress ENGL Working Groups 4.1 AG SMV (Advisory Group on Selection of Methods for Validation) 4.2 WG-GMM (Detection of genetically modified microorganisms in food and feed) 4.3 WG-NMT (New Mutagenesis Techniques) 4.4 WG-GMA (GM animals)	Progress reports
From 12:15 till 14:00	Lunch break	
From 14:00 till 15:00	5. Preparation ENGL Annual Meeting 2024/NRL training/NRL workshop	
From 15:00 till 16:00	6. New activities 7. Update on NRL training activities 8. AOB	
16:00	Closure of the meeting	

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