European Commission

Report

# 39th ENGL Steering Committee Meeting

Webex meeting

23 June 2020

**The European Commission's science and knowledge service**

Joint Research Centre

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# JRC Ispra, 23 June 2020

## 1 Welcome, apologies, quorum

The Chair welcomed the participants and informed them that the meeting would be recorded to avoid missing any information during the notes taking process. He ensured that the tapes would be erased after the minutes were finalised. The participants did not raise any objections. The Chair noted that according to the presence list, there were 26 colleagues registered, of which 22 were representatives from MS. He concluded that the number reached the quorum established for the meeting. The Chair apologised on behalf of the Unit Head for their absence and presented the agenda.

The Secretary explained that the main purpose of the meeting was to monitor the progress of the WGs and to re-connect with the members. He informed participants that two additional points, proposed by the representative from Germany, would be addressed in the AOB section and asked whether other items needed to be included in the agenda. The representative from Belgium proposed a topic on food enzymes.

## 2 Approval of the agenda

The draft agenda was approved. The Secretary apologised for not having yet published the report of the 38th SC meeting, which was previously circulated among members and approved remotely via electronic means. He informed that the new procedure for endorsing the SC reports would be maintained for the present meeting.

## 3 Review of Dynamic Action List (DAL SC38)

The Secretary reviewed the open points of the list. He informed that the speakers previously proposed for the annual ENGL meeting were not contacted because of the COVID-19 pandemic.

## 4 Update from SANTE

SANTE informed that the seed-testing document had been endorsed on the 4th of June after meetings with the Regulatory Committee 2001/18. The document will be included as an Annex to the minutes of the meeting and distributed by early July. The document will also be submitted to the Secretary for distribution to the ENGL members.

The drafting of the document on new genomic techniques was also progressing. The input received from the MS was being consolidated. The stakeholders consultation (51 contributions received) had been concluded. Many organisations were late in replying to the survey. The drafting of the document covered parts on enforcement, ethics and one on research to which the JRC is contributing. The project was still on track but some delays could be expected for the summer. The final document should be ready by December 2020 to provide to political

partners sufficient time to decide.

The representative from Slovenia enquired on the ruling of the French Conseil d'Etat on mutagenesis techniques. SANTE had discussed the issue with MS without reaching a clear outcome. An update will be provided at a later stage.

## 5 Progress ENGL working groups

### ▪ 5.1 WG- MPR (Minimum Performance Requirements)

The speaker explained that the mandate of the group concerned the review and definition of method performance requirements (MPR) for digital PCR methods, detection of products generated by new mutagenesis techniques and of food and feed from GM animals. The group consists of 18 members organised in three subgroups according to the different sections of the mandate. He informed that the physical meeting previously planned for the 26 th and 27th of February 2020 had been cancelled and replaced by videoconferences organised in March for the different subgroups. The speaker presented a summary of the acceptance and performance criteria reviewed by the group for the application of digital PCR. Most of the performance criteria for real-time PCR are applicable to digital PCR. However, for some of them the adaptation and definition to the new technology requires further discussion, For instance, the number of partitions that should be positive for claiming a positive result and the conversion of the results of digital PCR into mass fractions. The members were reviewing also the factors involved in robustness and evaluating the transferability of the procedure on different platforms. The subgroup expressed concern on the practicability of the digital PCR technology because only a limited number of laboratories are currently equipped with the relevant instrumentation.

The second subgroup analysed the possible genetic variations generated by new breeding techniques and agreed on performing a preliminary categorisation by grouping them in three classes (i.e. variations with up to 3 nucleotides, small insertions or deletions, and big deletions/insertions). The subgroup agreed that only real-time PCR, digital PCR and potentially NGS approaches might be useful for detecting these products. The subgroup also concluded that its current input could only be regarded as theoretical, since it did not have experience in analysing these types of GMOs.

The third subgroup collected information on existing GM animals and concentrated on those developed for human consumptions or pet companionship. The members considered the performance parameters described in the MPR document as already applicable to GM animals. They proposed describing a minimum panel of species for verification of specificity. A draft conclusion on MPR for detection of GM animals will be circulated for comments within the subgroup and will be proposed to the working group by September 2020. The representative from Germany suggested reviewing an ISO standard recently approved for detection of animal food products (https://www.iso.org/obp/ui/#iso:std:iso:20813:ed-1:v1:en). A participant asked to share the reference to the SC members.

A JRC representative informed that a guideline article on digital PCR had been accepted in the journal Clinical Chemistry and will be provided to the ENGL members as soon as it will be published.

SANTE enquired over a gene-edited line of tilapia that has been exempted from GMO regulation in Argentina. The Secretary asked to provide information, if available, on the tilapia GM line to the EURL GMFF, which will then submit it to SANTE.

- **5.2 AG SMV (Advisory Group on Selection of Methods for Validation)**

The speaker reminded that two methods accepted for validation, a pentaplex and a potato reference method respectively, were undergoing further experimental steps and awaiting specificity tests at the JRC. She reminded that the group had proposed to the JRC some optimisation of the JRC GMO-Matrix web application. The group was preparing a list of most suitable reference genes for GM plants while it had already provided a list of reference genes for detection of GM animals. It will perform a gap analysis by December 2020 for verifying if new GM events authorised outside Europe are covered by the GMOMETHODS database. The speaker informed that digital PCR methods could be considered by the WG as possible candidates for validation.

The Secretary remarked that the list of suitable reference genes for detection of GM plants would be completed by September 2020. He notified that the validation of a digital PCR method detecting maize event MON810 had been halted in March by the COVID-19 emergency and that the researcher following the project had concluded her contract. The project would be resumed as soon as the EURL GMFF would be able to restart its laboratory activities. The JRC will contact the participants and the ENGL members again to verify if other laboratories are interested in participating in the study.

The representative from Belgium notified the publication of a new method for detection of an antibiotic resistance gene. The method will be accredited under a flexible scope. The Secretary encouraged the Belgian laboratory in providing information on the method to the advisory group so that it could analyse the data and identify if it is filling a gap and is of general interest for the ENGL. He did not foresee interference problems with the WG GMM since the latter defines criteria for detection of GMM not its acceptance for validation by the EURL GMFF.

The representative from Belgium requested to discuss a general strategy on GMM at the SC level. Representatives from other MS expressed interest in discussing a possible monitoring of GMM contamination in food and feed. The Secretary suggested discussing the issue at the following advisory group meeting.

The representative from Germany received from its national network the request of validating a multiplex method for detection of reference genes for soy, maize and rice because of their relevance in routine GMO testing. A method duplex for soy and maize was published recently (*K. Dolch, M. Judas, F. Schwägele, D.A. Brüggemann: Development and validation of two triplex real-time PCR systems for the simultaneous detection of six cereal species in processed meat products. Food Control 101 (2019) 180-188*). In the screening phase, this method could reduce the workload of the laboratories.

The WG chair suggested submitting the multiplex method for the forthcoming AG SMV meeting.

- **5.3 WG-mpPCR (multiplex PCR methods)**

The speaker informed that in April 2020, the Chair and the Secretary attempted resolving the comments provided to the draft document and distributed a new advanced version to the members. A physical meeting, previously planned in Strasbourg, was cancelled because of the

COVID-19 pandemic and was substituted by a web meeting. The group will decide how to finalise the document at the following meeting planned for the 21st of June. The Chair underlined that some contributions were still missing and that the document is already more than 50 pages long. He hoped to share a new version of the document at the following SC meeting.

- **5.4 WG-seq (good practice/quality of DNA sequencing data)**

The Chair notified her future contribution to the guideline as a private member and not as a representative of her MS institution. She remarked that the WG had a limited number of participants. The Chair informed that the entire group had reviewed the first draft of the document in October 2019. The coordinators of the subchapters had further discussed the guideline in a videoconference. The group had a meeting in January 2020 and drafted the section on testing the quality of DNA sequences. They identified three possible scenarios for the analysis depending on whether the samples were containing known GMOs, unknown GMOs or a mix of both.

The group had a considerable delay but the first two chapters were in a good status. An additional meeting was deemed necessary for discussing the quality aspects of DNA sequencing. The group agreed at the January meeting in Bruxelles to include the technical aspects of the different platforms in an Annex, though the information could soon become outdated. The group is planning to organise an additional meeting and provide the final draft in September-October 2020. The document will include information on detection of small changes related to gene editing focusing on qualitative aspects.

The representative from Germany reminded that a draft document of ISO/TC 276 – Biotechnology/ WG3 on analytical methods was evaluating the quality of massive parallel sequencing data (ISO/FDIS 20397-2). This document will be published soon.

The Secretary thanked the Chair for continuing the activity as external expert and appreciated her contribution to the group.

- **5.5 WG-DNAex (DNA extraction)**

The speaker provided an update on behalf of the chair of the WG. He informed that the group including 19 members had a physical meeting in November 2019 where the three mandates were organised under six subtasks associated with task leaders. The speaker commented that all the subtasks were in an advanced stage. He informed that in February 2020 a table on issues and solutions covering subtask 1 had been uploaded on the ENGL-net. In the previous three months, a document on trend analysis and recommendations for keeping the table active had been submitted for feedback to the members. Discussions for consolidating subtasks four and five had been held. A number of the subtasks had been delayed slightly due to the COVID-19 situation.. The WG members had also been discussing aspects of verification/validation of DNA extraction methods that could be relevant for the MPR document.

The speaker informed that the WG Chair was planning a videoconference for verifying progress with the drafting teams, collecting comments from members and finalising the document. He needed to verify if a physical meeting could be organised after the summer.

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

The Secretary notified that the kick-off meeting of the new WG on GMM had been cancelled

because of the coronavirus pandemic. The chair of the group from the JRC had been and is heavily involved in COVID-19 projects and has not been able to organise any activity. The Secretary informed that the WG included only 10 members and enquired whether other experts could be interested in joining or leading the group or follow the activities at least for the first meeting.

The representative from Belgium offered to help in the organisation of the first meeting.

- **5.7 WG-Proc (ENGL Procedures)**

The Secretary informed that the section on additional procedures needed still to be drafted.

The Secretary requested provision of the presentations from the SC meeting for publication on the ENGL-net

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## 6 Guidance document on Measurement Uncertainty for GMO Testing Laboratories - 3rd Edition

The speaker explained that the third version of the document on measurement uncertainty (MU) published in 2020 takes into account further EU legislation (2017/625 and 619/2011), the mandatory accreditation to ISO/IEC 17025 and the availability of validated methods and accepted GMO CRMs. It also includes a new section on digital PCR. The document provides guidance for laboratories in estimating the MU using data obtained on routine samples and, if those are not available, using matrix CRMs. When both approaches could not be applied due to the lack of samples and matrix CRMs, the laboratories may assume a relative standard uncertainty of 25 % for measured values larger than 2 g/kg and a relative standard uncertainty of 35 % for mass fractions between the LOQ and 2 g/kg. Upon the availability of routine samples, the MU should be estimated using these. She warned that the internet link to the document in the EU legislation still was not updated, but after the ENGL SC meeting the web link from (EU) 619/2011 to the 3rd edition of the MU guidance document will be established. The document has been made available on 25/06/2020 via the EURL GMFF website together with the other guidance documents and the CRM webpage of the JRC.

Representatives from different MS appreciated the work but remarked obtaining some time higher MU values. The speaker explained that in the absence of samples, MUs were established from the minimum performance criteria set in the MPR document and were including the uncertainty originating from the DNA extraction step.

## 7 Preparation ENGL Annual Meeting 29 September-1 October 2020/NRL training/NRL workshop

The Secretary requested feedback on the organisation of the NRL workshop, the training for the NRLs and the annual ENGL meeting. He informed that the NRL workshop could be organised at the date planned but as a Webex meeting because under Commission guidelines physical meetings had to be avoided at least until October 2020. The training could not be organised as a hands-on workshop for the same reason. A JRC representative previously sent an e-mail to NRLs representatives proposing a two-hours training section and requesting ideas on the subjects to be covered. Respondents suggested addressing use of conversion factors, guidance on measurement uncertainty estimation in line with the publication of the new guidance from agenda point 6, trouble-shooting for DNA extraction or explanations on the supporting web tools. The Secretary invited proposing other topics or to indicate if the activities

should be postponed to a different date.
Many participants remarked that a digital training of two hours could be attended by a wider number of participants and be easier to follow than a one-day training workshop. They proposed, as additional topics, networking for accreditation and detection of SNPs by qPCR.
A JRC representative indicated October-November 2020 as a possible date for the training. The Secretary considered the topics of measurement uncertainty and guidance on the solution table for DNA extraction posted on the ENGL-net as more suitable for a digital training.

He then offered different options for organising the ENGL plenary such as skipping the meeting, organising one-day digital event as planned in October or a physical meeting later in 2021. He considered also alternative solutions for conducting the meeting. Many participants suggested organising a physical meeting early in 2021. The Secretary warned that for a physical meeting, arrangements need to be made well in advance and that, given the uncertainty of the pandemic situation, he could not predict when it would be possible to organise the event. The unit secretary informed that from an administrative point of view the JRC could organise a physical ENGL meeting starting as of May-June 2021. After discussion, it was finally proposed to organise a one-day virtual meeting on the date previously planned, involving experts also from other fields and providing scientific presentations. It was also suggested to have digital "informal rooms" where participants could have discussions and exchange ideas as during coffee breaks and to offer YouTube presentations for a wider audience.

The Secretary requested submitting topics, proposals for experts and contacts points to the EURL GMFF functional mailbox. He need to consult the JRC press contact to see if a YouTube option is feasible.

## 8 Discussion on the current situation and way forward for ENGL activities 2020

The Secretary explained the working situation at the JRC during the Coronavirus pandemic. The majority of the colleagues in the entire Commission, except a number with critical on-site functions, were teleworking. The EURL GMFF had set up a COVID-19 testing facility, but the GMO laboratory activities had to be stopped since March 2020. He forecasted a gradual return to a new normality and a slow resumption of the GMO activities. The COVID-19 lockdown had a limited impact on the ENGL activities thanks to the efforts of the WG members. The Secretary requested information on the situation from the participants. All activities of the official laboratories were halted or heavily reduced during the COVID-19 lockdown, but they were gradually resuming their experimental functions using masks and by maintaining social distancing. Some laboratories had been also involved in the detection of SARS-CoV-2 in wastewaters, testing and validation of diagnostic kits, verifying masks for their microorganism filtering efficacy or studying virus diversity in water.
The Secretary appreciated how quickly ENGL laboratories had converted to other activities.

## 9 AOB

The representative from the Netherlands enquired on a re-evaluation of the Commission Implementing Decision 2011/884/EU on GM rice originating from China; according to Netherlands authorities, still GM positive samples are found in products imported from China. SANTE informed that the Chinese government had not formally requested to stop testing for GM rice in rice products and therefore there was no reason for reviewing that Decision. He

further clarified that according to a programme developed for extracting information on measures taken at European level there were no non-authorised GMOs in rice shipments from China to the EU.

The representative from Germany highlighted that according to the EURL GMFF webpage only the CRMs from AOCS were officially listed for GA21 detection even though CRMs from the JRC were also available for the same purpose. The Secretary clarified that for the Commission the CRMs to be used in official EU controls are those mentioned in the authorisation Decision. Some participants using the JRC material for its higher quality declared not to be aware of this requirement. A JRC representative further explained that the JRC would continue providing CRMs for GA21 analysis to other parts of the world until the stock is exhausted. He will verify the copy numbers in the JRC and AOAC CRMs to ascertain whether the use of one or the other reference material for detection of GA21 may have affected the results of the last proficiency test.

The representative from Belgium reported that almost 60% of the samples taken to analyse for presence of GMM DNA or GMM were positive for antibiotic resistance genes. The Belgian official laboratory sequenced the products to develop detection methods and was further investigating their specificity. She considered these findings an important safety issue and urged the monitoring of these products in food and feed. She informed that the Belgian authorities had launched rapid alert notifications.
The Secretary commented that alpha-amylase is present in many types of products originating from different MS.

SANTE informed that the rapid alert notifications from the Belgium Authorities were just validated and that other five or six cases have been already notified. The notified products were originating from different countries.

Other participants requested sharing information on the detection methods. The representative from Belgium informed that the protease method had been published but not validated while the method for detection of the alpha-amylase could be provided before publication within a formal data transfer agreement.

The Secretary appreciated the information provided and thanked all members for their active participation.

## JRC Mission

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