42nd ENGL Steering Committee Meeting

Meeting report

24 February 2022

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

Joint Research Centre

42nd ENGL Steering Committee 24 February 2022

1 Welcome, apologies, quorum

The new Unit Head of JRC F.5 welcomed the participants. The Secretary informed that the points suggested by the participants will be discussed under AOB.

2 Approval of the agenda

The draft agenda (Annex 1) was approved.

3 Review of Dynamic Action List (DAL SC41)

The Secretary reviewed the open points of the list. He informed that the coordinator of the Working Group (WG) on sequencing is no longer available and suggested appointing a new chair for finalising the report. The proposal of collecting terminologies from the different documents of the European Network of GMO Laboratories (ENGL) could not be addressed by the Secretariat alone. He asked whether a new WG should be established for that purpose. He finally suggested defining a mandate for the WG on GM animals.

A member from the Joint Research Centre (JRC) explained that the methods developed by the Belgian laboratory for detection of Genetically Modified Microorganisms (GMM) are published under the section "Unauthorised Genetically Modified Microorganisms (GMM)" of the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) website.

4 Update from SANTE

SANTE presented the recent developments on New Genomic Techniques (NGT) and GM presence in feed/ food additives/enzymes.

NGTs

The conclusion of the NGT study is that the European Union (EU) legislation on GMOs is not suited to certain NGT products and needs to be adapted to scientific and technological developments. Furthermore, regulatory and risk assessment requirements need to be tailored to diverse risk profiles. Finally, the technology could contribute to the Green Deal, to sustainability objectives and to a more competitive economy without being detrimental to organic agriculture. The Commission will evaluate policy actions on plants derived from targeted mutagenesis and cis-genesis while for other technologies it will need to acquire more expertise. The use of NGTs in medicinal products will be addressed in the Commission's Pharmaceutical Strategy. A high-level event on "New genomic techniques – way forward for safe and sustainable innovation in the agri-food sector" was organised on 29 November 2021. The presentations are still available.

SANTE explained that the objectives of the new policy action are:

- to maintain a high level protection of human and animal health and of the environment,
- contribute to the innovation and sustainability objectives of the European Green Deal and of the Farm-to-Fork and Biodiversity strategies,
- enhance the competiveness of the EU agri-food sector,

- ensure a level-playing field for its operators as well as an effective functioning of the internal market.

SANTE underlined that in the new policy the risks assessment and approval requirements should be proportionate to the risk involved in line with the risk profiles on a case-by-case basis. A sustainability analysis should examine whether and in which way these products contribute to sustainability and sustainability-related requirements or incentives. SANTE remarked that the concept of sustainability is complex and is yet to be defined. The new policy should include appropriate traceability and labelling provisions and mechanisms for rapidly adjusting to scientific and technological progress.

As a main step for the preparation of the new policy, the Commission organised a four-week public consultation, which was open until 22 October 2021. The consultation received 70894 contributions, of which a large majority were identified as coming from organised campaigns asking to maintain the NGT products under the current legislative framework on GMOs and the remaining part from non-campaign replies asking the Commission to proceed with the announced policy actions. The contributions originated from 91 countries including the 27 MS of the EU.

As an additional step, the Commission has delivered the inception impact assessment, including an open consultation. Further work will focus on the problem definition, setting of the objectives, developing of policy options and assessment of their impacts at economic, environmental, social, administrative, civil rights levels, and is including concerns expressed during the earlier consultation. The output will again be submitted to an open consultation during 2022. The actual policy initiative is possibly expected for the second quarter of 2023.

The assessment will be further supported by a fact-finding study in two MS. The fact-finding study will gather information on the practical implementation of official controls on NGTs under the current GMO legislation and identify good practices or difficulties. It will be organised in a virtual format for five consecutive half days in two MS, and involve SANTE experts assisted by four national experts. The findings will be later presented to MS.

GM presence in feed/food additives/enzymes

SANTE recalled that DNA of unauthorised GMOs have been detected in food and feed ingredients resulting from fermentation. The problem has been discussed with MS at the Standing Committee on Plants, Animals, Food and Feed (SC PAFF) on 20 September 2021. The discussion is still ongoing because MS have diverging views on how to address the problem.

On a general point, SANTE remarked that the valuable work performed by the ENGL and the EURL GMFF should be more visible and better communicated from the onset of the projects.

Questions:

The Chair thanked SANTE for the very informative presentation. A representative from Italy requested information on the role of the fact-finding study in the policy roadmap and remarked the importance of sharing information on NGT detection strategies in different MS.

SANTE explained that the fact-finding study is performed only in two MS because of limited human resources and highlighted that all MS have nonetheless provided their comments in the survey launched by the Commission. SANTE also ensured that the results of the study would be shared with all MS.

A representative from Belgium requested to avoid the word "traces" in relation to the GM presence in feed/food additives/enzymes because in some cases million copies of full size antibiotic genes had been detected in the samples. She further enquired on the definition of traces and its legal reference in the EU legislation. The representative from Belgium suggested using the term "presence" instead of "traces" and requested clarification on detection of live GMOs in the samples.

SANTE agreed to refer to "presence" instead of "traces" and recalled that living GMM in such products clearly need an authorisation under Regulation (EC) No 1829/2003. SANTE noted a lack of harmonised enforcement in the MS causing uncertainty to food operators. SANTE is further analysing the legal situation and will revert to the ENGL group when this is finalised.

A representative from the EURL GMFF reminded that the publication of the ENGL report on detection of NGT plant products has been mainly based on theoretical principles and requested whether SANTE was expecting an update of the report also at the experimental level.

SANTE commented that the ENGL statement on the Chhalliyil et al. article already substantiated the ENGL report. A broader literature review however, could further strengthen the ENGL conclusions on detection of NGT plant products.
A representative from Germany thanked SANTE for sharing the roadmap and highlighted the lack of experience and reference material for NGT detection. He announced the future publication in collaboration with the EURL GMFF of the experimental verification of the method developed by Chhalliyil et al. He noted that after submission of their article the authors of the Cibus detection method have incorporated directly in their original publication a correction of the protocol, which was therefore, not addressed in their evaluation. To his dismay, it will be then difficult to defend their results and have clear answers on NGT detection issues.
A representative of the EURL GMFF suggested publishing the article as drafted and then a separate reaction to the experimental correction of the Cibus paper. The German representative expressed his willingness to collaborate with the EURL GMFF for a common reaction and sharing the link to the publication with ENGL members.

5 Progress ENGL working groups

5.1 WG-MPR (Minimum Performance Requirements)

The group has finalised the MPR document dealing with NGT products, digital PCR and GM animals. The document was submitted for feedback to stakeholders in February. The comments received are being addressed and the document will be finalised and published in the near future.

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

The EURL GMFF has finalised the list of best endogenous targets per species. The evaluation was based on validation data of the respective reference methods and on other sources. The group will discuss in the next meeting how to share this list with the ENGL. The GMM methods developed by the Belgium National Reference Laboratory were published in the section on unauthorised GMOs of the EURL GMFF website. The group decided to publish on the same website other new methods detecting antimicrobial resistance (AMR) genes and GMM construct specific targets. The members will evaluate whether to perform a validation study for a potato reference gene method previously submitted. The WG will also decide whether to validate a digital PCR method previously submitted since the assessment criteria for digital PCR methods have been defined in the MPR2 document. A gap analysis performed by the WG in 2021 did not identify missing analytical targets and concluded that the existing EU reference methods are providing a sufficient coverage for the EU authorised GMOs.

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

The chair of the group is not in a position to continue following the activities; an advanced draft of the document is available and was circulated to the WG members for comments.

The Secretary requested whether the members could consider the document completed and if a new chair needs to be appointed. It was recommended to identify a new chair for following-up and bring to conclusion the document.

The Secretary identified as future actions for the group 1) a call for the chair vacancy 2) a request for a second round of comments and 3rd) the organisation of a WG meeting.

5.4 WG-DNAex (DNA extraction)

The chair of the group informed that some chapters of the report on DNA extraction have been merged to harmonise the text. A final draft has been submitted for comments to members with a

17 March 2022 deadline. The members will discuss also whether organising a DNA extraction workshop as described in the mandate.

The Secretary offered to provide the latest JRC template to finalise the report.

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

The WG chair informed that the four chapters of the document including introduction, general consideration on genetically modified microorganisms (GMM), strategy and scientific tools, have been merged and reviewed twice. The members will introduce the last comments by the 15th of March 2022 but will need feedback from SANTE on two parts of the document. The last chapter on conclusion and future perspectives is not yet completed.

The Chair enquired over ongoing activities on GMM detection in the different MS.

A representative from Slovenia informed having implemented the Belgian methods but to be uncertain on the implementing actions for positive samples.

The Belgian laboratory has been monitoring food additives and enzymes to verify the level of contamination. It has tested 50 samples received from the companies. There is a strong presumption of GMM contamination in many samples since multiple antibiotic resistance (Sciensano) genes were detected, but given the complexity of the results, it was not possible to confirm the strains possibly present. The laboratory also detected live pathogenic bacteria, not GMM, inducing diarrhoea, and is performing whole genome sequencing of the isolates. The laboratory has contacted the Belgian authorities but it is still uncertain on how to proceed in terms of risk evaluation and considering the legal bases). A new laboratory Belgian project will start in 2022; it will focus on metagenomics and will extent the survey to additional fermentation products (not only food enzymes but also food complement); it will also consider fungal GMM. The results of the metagenomics study on food enzyme samples showing the presence of additional GMM contamination, including GMM with CRISPR/CAs sequence motifs, were submitted for publication (D'aes *et al*., submitted). The Belgian laboratory has received additional FE samples (with focus on protease and amylase) and 50% of the tested samples contain DNA of GM protease or amylase.

A representative from France confirmed using the Belgian methods for analysing 30 samples. Some of the samples were not compliant. The French competent authorities (CA) are expecting a legislation in this field.

Monitoring activities on GMM have not been introduced yet in the Italian national network. Denmark laboratories are not planning to start any activity on GMM detection.

The Chair thanked the participants for their comments.

6 Preparation ENGL Annual Meeting 2022/NRL training/NRL workshop and ENGL annual meeting

The ENGL meeting could be organised as a one day on line meeting or as a two days physical meeting, depending on the Covid-19 situation. The Secretary underlined that the decision was probably premature and suggested keeping both options open. He announced the organisation of the meeting for the 17th of October 2022 and requested feedback on topics to be covered and possible speakers.

Many participants supported the organisation of a hybrid event to allow physical interactions between ENGL members but also online participation of colleagues not able to attend the meeting. The three areas covered in the previous ENGL plenary (NGT, GMM and digital PCR) have remained at the centre of discussions and were included as topics for the following meeting. Participants further suggested covering new GMOs coming to the market, multiplex PCR and related laboratory experiences. The Secretary suggested collecting information on multiplex PCR practice through a survey. SANTE offered to provide an update and anticipated the crucial discussion on the EU GMO legislation. A representative from Germany requested whether new

screening strategies were available for increasing official control efficiency. The Chair requested to submit suggestions for possible speakers to the Secretariat. The Secretary proposed presenting research projects initiated in the MS on NGT detection.

NRL workshop

A JRC speaker suggested extending the NRL workshop to a full day event to allow longer discussions on proficiency tests (PT) results, on future planning and on issues encountered by the laboratories.

He suggested considering discussion on implementing a risk-based screening strategy and collecting information on GM event incidences in official control analyses. He further requested if the discussion on detection of NGT products should be included in the workshop or the ENGL meeting and finally informed that the format of the meeting (online or physical) will depend on the Covid-19 situation.

He reminded that at the previous NRL workshop the participants expressed interest in training in bioinformatics and next generation sequencing (NGS) technologies. The Belgian NRL proposed to coordinate, together with the EURL GMFF, a practical training for the analysis of sequencing data.

Some members informed having encountered difficulties in the accreditation of analytical approaches when outsourcing sequencing. The Belgian NRL offered to present its strategy for accreditation of different workflows and further proposed organising a practical training on sequencing for 15-20 people. The speaker further requested to define the needs and the number of interested participants. The training could be organised in the Belgian NRL in September 2022 and possibly also online for not attending members.

The Chair thanked the Belgian NRL for the offer and requested to define a program in collaboration with the EURL GMFF. Given the work involved in the organisation of the training, the Belgian speaker requested having a confirmation for at least 10-15 interested participants and a definition of their level of experience in sequencing. The Chair considered the request reasonable.

An Italian representative requested a training on the organisation of proficiency tests since those organised by the EURL GMFF are too challenging for some members of the Italian network. The Chair recalled that the JRC organises internal training on ISO standards, including on ISO 17043, but needed more details for eventually helping on that issue.

7 New activities

SANTE noted the value of updating the ENGL document on NGT detection to confirm the validity of its conclusions. A JRC representative reminded the finalisation of the new MPR guidance including criteria for detection of NGT products, which could be referenced in the updated document and suggested collecting experiences on detection of NGT products in the different MS. The participants agreed to review the ENGL document. The Chair proposed to establish a WG with a clear mandate, to verify if the original authors of the report could be involved in the revision process and to launch a call for new members.

The Secretary shared a draft mandate for a new working group on detection of GM animals. The WG should cover the analytical challenges, the screening strategies and scientific tools for detection of non-authorised GM animals including NGT animals in food and feed and as food and feed. The Secretary requested to identify additional experts for performing the task. Participants suggested covering also non-food/feed commercial products, e.g. glow-fish, and species-specific identification tests. According to a representative from Germany, the report should not be restricted to food and feed but cover also living organisms as e.g. GM insects. It was suggested to further extend the scope of the report to control samples and reference materials. Another member from Netherland proposed including sampling strategies.

The Chair agreed to include the suggestions in the mandate and to further distribute the draft to ENGL members.

8 AOB

The Chair requested suggestions for highlighting the work of the ENGL or for other points of discussion. A representative from Germany suggested proposing an ENGL research project under the EU horizon program for detection of NGT products. SANTE confirmed the availability of funding under this program and encouraged the submission of research proposals by an ENGL consortium. A representative from Poland supported the suggestion while a JRC representative reminded that a survey was launched on NGT detection activities in the MS.

A representative from Germany highlighted the lack of reference material for commercial products possibly imported into the EU and asked support to the Commission.
The Commission has asked the authorities to provide official detection methods for those products but has not received any reply from the companies.

A representative from Netherland asked whether the legislation on GM rice imports from China would be further extended. SANTE informed that positives samples were still being detected in products imported from China and that therefore the control activities will be continued.

The Secretary announced that the date previously agreed for the organisation of the next meeting has been subsequently blocked for an audit. He apologised for the short notice and proposed alternative options. The participants agreed in organising the next meeting on 10th of June 2022.

The Chair thanked the participants for their contributions and closed the meeting.

Annex 1: agenda

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	Time	Topic	Documents in CIRCABC
1	9:00	• Welcome, apologies, quorum	
2		• Approval of the agenda	Draft agenda
3		• Review of Dynamic Action List (DAL SC41)	DAL SC41
4		• Update from SANTE	
	10:00	*Break*	
5	10:30	Progress ENGL working groups	
5.1		• WG-MPR (Minimum Performance Requirements)	Progress reports
5.2		• AG SMV (Advisory Group on Selection of Methods for Validation)	
5.3		• WG-seq (good practice/quality of DNA sequencing data)	
5.4		• WG-DNAex (DNA extraction)	
5.5		• WG-GMM (Detection of genetically modified microorganisms in food and feed)	
	12:00	*Break*	
6	14:00	• Preparation ENGL Annual Meeting 2022/NRL training/NRL workshop	
7	15:00	• New activities	
8		• AOB	
	16:00	End of meeting	

JRC Mission

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