GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 146th MEETING

Held on 29-30 September 2021, TELE/WEB

(Agreed on 14 October 2021)

Participants

- Panel Members:

Jean-Louis Bresson, Tamas Dalmay, Ian Dewhurst, Michelle Epstein, Leslie George Firbank, Philippe Guerche, Francisco Javier Moreno, Ewen Mullins, Hanspeter Naegeli, Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano, Giovanni Savoini, Eve Veromann and Fabio Veronesi

- European Commission:

DE SANTE : Alexandre Huchelmann and Juliette-Marie Margueritte Anastasia Pagida

- EFSA:

GMO Unit: Ana Afonso, Michele Ardizzone, Giuseppe Condorelli, Giacomo De Sanctis, Silvia Federici, Antonio Fernández Dumont, Andrea Gennaro, Tilemachos Goumperis, Paschalina Grammatikou, Dafni Maria Kagkli, Anna Lanzoni, Paolo Lenzi, Aleksandra Lewandowska, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, and Franz Streiss

DATA Unit: José Ángel Gómez Ruiz

SCER Unit: Yann Devos (item 6.2)

REPRO Department: Head of REPRO Department Guilhem de Seze (9.1)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jan Hejatko and Jose Juan Sanchez Serrano (Day 2 only)

2. Adoption of agenda

The agenda was adopted without changes.

[1] As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Report on written procedures since the 145th GMO Plenary meeting

Since the 145th Plenary meeting, one output has been adopted by written procedure:

4.2 The minutes of the 145th Plenary meeting

The minutes of the 145th Plenary meeting were adopted by written procedure and published on 2 August 2021.

5. Scientific topics for discussion

5.1. Application for authorisation of genetically modified maize NK603 x T25 x DAS-40278-9 and subcombinations, for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by Pioneer Overseas Corporation (EFSA-GMO-NL-2019-164)[4]

Maize NK603 x T25 x DAS-40278-9 was produced by conventional crossing to combine three single maize events: NK603 expressing CP4 EPSPS and CP4 EPSPS L214P to confer tolerance to glyphosate -containing herbicides, T25 expressing PAT to confer tolerance to glufosinate -ammonium based herbicides and DAS-40278-9 expressing AAD-1 to catalyse the degradation of the general class of herbicides known as aryloxyphenoxypropionates (AOPP) and to confer tolerance to 2,4-D herbicides. The scope of the application EFSA-GMO-NL-2019-164 is for food and feed uses, import and processing and does not include cultivation in the European Union (EU).

The GMO Panel revised the current text, where appropriate and questions were raised and addressed throughout the different sections of the draft opinion. It was agreed that, once the missing information will be provided (bioinformatic analyses and a request to provide clarifications on cited additional studies), the GMO Panel will assess it and, where appropriate, amend the text of the draft opinion.

A revised draft opinion will be circulated via email to the GMO Panel and, if no further questions will be identified during the revision, the opinion will be proposed for adoption by written procedure.

5.2. Application for authorisation of genetically modified maize DP-202216-6, for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by Pioneer Overseas Corporation (EFSA-GMO-NL-2019-159)[5]

Maize event DP2022166 expresses the phosphinothricin acetyltransferase enzyme (PAT) which confers tolerance to glufosinate-ammonium-containing herbicides. In addition, maize DP2022166 has been developed to extend and increase the expression of the ZMM28 protein, a MADS-box transcription factor, which can provide an opportunity for a potential yield enhancement (PYE) under field

[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[4] https://open.efsa.europa.eu/questions/EFSA-Q-20219-00808
[5] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00419

conditions. The scope of application EFSAGMONL2019159 is for food and feed uses, import and processing and does not include cultivation in the European Union (EU).

The GMO Panel discussed outstanding issues related to the PYE trait. In particular, the variability in the expression of the PYE trait at the different field trials sites and the possibility to identify an alternative and more consistent endpoint to confirm the expression of the PYE trait.

Further discussion is needed at the different GMO panel expert working groups.

5.3. Scientific opinion on *in vitro* random mutagenesis techniques[6]

The discussion on the scientific content of the mandate took place in the GMO Panel's Molecular Characterisation WG.[7]

The draft scientific opinion as well as the public comments were discussed at the GMO Panel meeting on 7 July 2021.[8] Subsequently the Molecular Characterisation Working Group revised the draft opinion in light of the comments received.

The GMO Panel revised the draft text. The opinion was adopted by the GMO panel and will be published on the EFSA website and EFSA Journal. A technical report on the public consultation will be made available.

5.4. Evaluation of existing guidelines for their adequacy for the food and feed (FF) risk assessment (RA) of genetically modified plants (GMP) obtained through synthetic biology (SynBio)[9]

The activities of the working group (WG) on SynBio GMP – FF[10] were presented. The activities of the WG are in the context of the overarching mandate and considering the conclusions of the previous WG on molecular characterisation and environmental risk assessment of SynBio Plants[11]. The methodology used by the FF Synbio WG was presented as well as the structure of the scientific opinion. It was also explained that in the initial phases of the SynBio GMP – FF activities the WG considered it important to expand the pool of case studies with an additional example (case study 4) representing a food/feed product likely to come on the market in the next decade and challenging even more the applicability of the food and feed risk assessment guidelines. Case study 4 refers to a case of *de novo* domestication of the wild tomato *Solanum pimpinellifolium* via genome editing. The main challenge posed by this additional case study is the lack of history of safe use (HoSU) for the *S. pimpinellifolium* and the magnitude of the introduced changes that alter substantially the crop from a phenotypic, agronomic and compositional point of view. The presentation was followed by a general discussion.

The scientific opinion will be submitted for possible endorsement for public consultation at 147th GMO Plenary meeting (1–2 December 2021).

6. New Mandates

6.1 Applications under Regulation (EC) No 1829/2003

Since the last meeting of the GMO Panel, EFSA has not received any new applications.

[6] https://open.efsa.europa.eu/questions/EFSA-Q-2020-00445
[7] Minutes of the WG meetings are available at: https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo#working-groups
[8] https://www.efsa.europa.eu/sites/default/files/2021-07/145th-plenary-meeting-gmo-panel-minutes.pdf
[9] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00052
[10] https://www.efsa.europa.eu/sites/default/files/2021-03/synbio-gm-plants-foodfeed-risk-assessment-minutes.pdf
[11] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6301

6.2 Upcoming mandate to update the EFSA technical report on the occurrence of teosinte in EU.

On the 30 September 2021, the EC mandated[12] EFSA to update its technical report (2016)[13] on the relevance of new scientific evidence on the occurrence of teosinte in maize fields in Spain and France for previous environmental risk assessment conclusions and risk management recommendations on the cultivation of maize events MON810, Bt11, 1507 and GA21. The mandate has a timeline of six months.

6.3 Other Requests and Mandates

On 28 September 2021, EC mandated EFSA to consider the new sequencing information of genetically modified soybean 40-3-2, provided by Bayer.

7 Feedback from the Scientific Committee/the Scientific Panels, EFSA, the European Commission

7.1 Scientific Committee and other Scientific Panel(s) including their Working Groups

The Panel Chair reported on discussions at the last Scientific Committee meeting.[14]

7.2 EFSA including its Working Groups/ Task Forces

None

7.3 European Commission

The representatives of the European Commission (EC) informed the GMO Panel on their on-going activities, including approval procedures for applications for which the GMO Panel has delivered a scientific opinion.

8 Other scientific topics for information and/or discussion

8.1 Scientific Opinion of the GMO Panel with recommendations for future development of allergenicity risk assessment

An update of the Allergenicity Working Group activities was presented to the Panel members. In 2021, the GMO Panel published a statement on *in vitro* protein digestion [15] and EFSA organised a dedicated workshop on allergenicity assessment aimed at collecting feedback on the topic. An EFSA event report containing details of such a workshop were recently published[16]. The outcome of the workshop will guide the Allergenicity Working Group in the preparation of the Scientific Opinion on recommendations for future development that is currently ongoing. The scientific opinion will focus on 1) improving the allergenicity risk assessment for products derived from biotechnology, 2) defining knowledge gaps, 3) determining how new basic research findings and technological developments can improve the current risk assessment methodology, and 4) prioritizing basic research funding.

[12] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00557
[13] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2016.EN-1094
[14] https://www.efsa.europa.eu/en/events/event/105th-plenary-meeting-scientific-committee
[15] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6350
[16] https://www.efsa.europa.eu/en/efsajournal/pub/en-6826

The scientific opinion will be presented at the 147th GMO Panel plenary meeting (1st-2nd December 2021) for discussion and possible adoption.

9 Any other business

9.1 Update on ART Programme – organigramme, RA workflow, DOI issues

The Head of the REPRO Department, Guilhem de Seze, explained the reasons behind EFSA's new organisational structure. In order to implement the new obligations and new processes required by the Transparency Regulation (TR), the ART Programme designed a harmonised high-level Risk Assessment (RA) process divided in four main steps: Mandate & dossier intake, Preliminary activities to Risk Assessment, Risk Assessment, and Output publication & dissemination. To best support the changes triggered by the TR, the next step was to redesign EFSA's internal structure: among other changes, EFSA will have one department focusing on RA production (Assess Department), and one focusing on services in support of RA production (Enable Department). The final organigramme, with all Heads of Unit, Teams and most Team Leaders, will be confirmed by the EFSA Management Team on 24 September, after which all staff (and experts) will be informed.

Guilhem also gave an overview of the most recent DOI issues, explaining that while the technical Task Force is working on the issues reported, the automatic request for expert DOI submission will be disabled from 18 September. Experts will be asked to use the alternative workflow described in the EFSA Competing Interest Management rules. More info will follow via email.

9.2 Transversal Working Group (WG) of the GMO Panel

The GMO Panel discussed the establishment of a GMO transversal working group. The remit of the WG is to provide a mechanism for trans-disciplinary discussions among experts during the risk assessment of GMO applications as needed. Meetings of the *transversal WG* shall be held on an *ad hoc* case-by-case basis. The Chair of the GMO Panel appointed Tamas Dalmay as Chair of the *Transversal WG*.

10 Adoption of the minutes and next meeting

The minutes of the current meeting will be adopted by written procedure and will be published at: https://www.efsa.europa.eu/en/events/event/146th-plenary-meeting-gmo-panel

The 147th GMO Plenary meeting will be held on 1–2 December 2021 online and will be open to observers.