SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
Minutes of the 157th Plenary meeting

10 May 2023
MINUTES - Agreed on 29 May 2023

Location: Webconference

Attendees:

- **Panel Members:**

  Jean Louis Bresson, Tamas Dalmay, Michelle Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Ewen Mullins (chair), Hanspeter Naegeli, Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano, Giovanni Savoini and Fabio Veronesi

- **European Commission:**

  DG SANTE:

  Olga Orlova

- **EFSA**:

  NIF Unit:

  Michele Ardizzone, Giacomo De Sanctis, Antonio Fernández Dumont, Andrea Gennaro, Tilemachos Goumperis, Paschalina Grammatikou, Aleksandra Lewandowska, Ana Martin Camargo, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Reinhilde Schoonjans and Kyriaki Xiftou

  FDP Unit:

  Silvia Federici (for item 5.2)

  MESE Unit:

  Jose Ángel Gómez Ruiz (for item 5.2)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ian Dewhurst and Eve Veromann.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

4. Report on written procedures since the 156th Plenary meeting

4.1 Minutes of the 156th Plenary meeting

The minutes of the 156th Plenary meeting were agreed by written procedure on the 29 March 2023[3].

4.2 Application for authorization of genetically modified maize Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Syngenta Crop Protection NV/SA (EFSA-GMO-DE-2018-149)[4]

Maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 was produced by crossing to combine six single maize events: expressing Cry1Ab, Cry1A.105, Cry2Ab2 and Vip3Aa20 proteins to confer resistance to certain lepidopteran pests, eCry3.1Ab and mCry3A proteins to confer resistance to certain coleopteran pests, mEPSPS protein to confer tolerance to glyphosate-containing herbicides, PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and PMI protein used as a selectable marker. The scope of the application EFSA-GMO-DE-2018-149 is for food and feed uses, import and processing and does not include cultivation within the EU.

The draft opinion was submitted for adoption at the 156th Plenary meeting held on 15-16 March 2023. It was agreed to adopt the opinion by written adoption after fine-tuning some of the sections. A revised text of the scientific opinion has been circulated and was adopted by written procedure on 18 April 2023. The scientific opinion was published on the EFSA website and in the EFSA Journal.

5. Scientific topics for discussion and possible adoption

5.1 Application for authorization of genetically modified cotton COT102 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Syngenta Crop Protection N.V./S.A. (EFSA-GMO-DE-2017-141)[5]

Cotton event COT102 was obtained by *Agrobacterium*-mediated transformation of *Gossypium hirsutum* L. cv. Coker 312 to introduce the gene *vip3Aa19* to confer resistance to certain coleopteran pests and the gene *aph4* that was used as a selectable marker during product development and that confers resistance to hygromycin B. The scope of the application EFSA-GMO-DE-2017-141 is for food and feed uses, import and processing and does not include cultivation in the European Union.

The GMO Panel revised the draft opinion, and where appropriate, questions were raised and addressed throughout the different sections. The GMO Panel adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

5.2 Request for placing on the market of genetically modified maize DP-202216submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2019-159)[6]

Maize event DP-202216expresses the phosphinothricin acetyltransferase enzyme (PAT) which confers tolerance to glufosinate-ammonium-containing herbicides. In addition, maize DP-202216 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)

[3] https://www.efsa.europa.eu/sites/default/files/2023-04/minutes-156th-gmo-plenary.pdf
[4] https://open.efsa.europa.eu/questions/EFSA-Q-2018-00292
[5] https://open.efsa.europa.eu/questions/EFSA-Q-2017-00271
[6] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00419

under field conditions. The scope of application EFSA-GMO-NL-2019-159 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 and the history of safe consumption for the ZMM28 protein in farmed and companion animals. The GMO Panel also made progress on drafting the scientific opinion.

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

6. Other scientific topics for information and/or discussion

6.1 Guidance review

An internal standard operation procedure requests a regular review of validity and possible revisions of cross-cutting and sectoral guidance documents. The Unit presented the current list of applicable GMO Guidance documents, Technical notes and Statements associated with an indicative need for possible revision. This state of play proposal was based on discussions that took place in the last years in the GMO Panel or in its working groups.

It was recognised the major impact a guidance document revision might have on the workload of the GMO Panel. It was also recognised the ultimate goal of increasing the quality of the dossiers and make them updated to the scientific progresses and to streamline the assessment of dossiers. The GMO Panel discussed the possibility to identify alternative tools to achieve these goals.

6.2 Risk assessment of stacks and subcombinations

The GMO Panel discussed the requirements for risk assessment of stacked events and subcombinations. About stacked events it was discussed the differences between assessment strategies for segregating vs. non-segregating crops as indicated in Regulation (EU) No. 503/2013. In case of segregating crops, the applications shall include all subcombinations independently of their origin which have not yet been authorised, while for non-segregating crops the subcombinations shall not be included. About subcombinations, the GMO Panel discussed the current approaches followed to reflect the different types of information that an application contains to support the assessment of subcombinations. Further discussion is needed at the different GMO Panel expert working groups.

7. New Mandates

No new application under Regulation (EC) No 1829/2003 or EC mandates were received.

8. Feedback from the Scientific Committee/the Scientific Panels, EFSA, European Commission

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

The Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting and ongoing EFSA activities[7]. Connections were identified between the item 7.1 (Speed risk assessment) discussed at the Scientific committee and item 6.1 discussed during this Plenary meeting.

8.2 Upcoming Mandates

None

[7] https://www.efsa.europa.eu/pl/events/113th-plenary-meeting-scientific-committee

8.3 European Commission

The representatives of the EC informed the GMO Panel on their ongoing activities, including approval procedures for applications for which the GMO Panel has delivered a scientific opinion.

9. Any Other Business

None

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/157th-plenary-meeting-gmo-panel

The next meeting will be held on 29 June 2023, online and open to observers.