SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

159th Panel Plenary meeting

27 - 28 September 2023
14:00-17:00 / 09:00-12:00
MINUTES - Agreed on 11 October 2023

Location: Teleconference

Attendees:

- **Panel Members**

Jean-Louis Bresson, Tamas Dalmay, Ian Dewhurst, 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, Eve Veromann and Fabio Veronesi

- **European Commission**

DG SANTE: Alexandre Huchelmann, Irene Sacristan (item 8.1), Olga Orlova

- **EFSA**

NIF Unit:

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

FDP Unit:

Silvia Federici and Claudia Parisi (both for item 8.1)

MESE Unit:

Jose Ángel Gómez Ruiz (for item 5.3)

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

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.

4. Report on written procedures since the 158th Plenary 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

4.1 Agreement of the minutes of the 158th GMO Panel Plenary meeting held on 29 June 2023, via teleconference

The minutes of the 158th Panel plenary meeting were agreed by written procedure on 18 July 2023.

5. Scientific outputs submitted for discussion and possible adoption

5.1 Application for renewing the authorisation for the placing on the market of food products (including pollen) and feed products containing, consisting of or produced from genetically modified maize MON 810 and products other than food and feed containing or consisting of it, with the exception of cultivation, authorised under Regulation (EC) No 1829/2003 (Commission Decision 2013/649/EU and 2017/1207/EU) submitted by Bayer Agriculture BV (GMFF-2022-9450, EFSA-Q-2022-00867)

Maize MON 810 was developed to provide protection against certain lepidopteran target pests (such as the European corn borer (*Ostrinia nubilalis*) and species belonging to the genus *Sesamia*) by the introduction of a part of a *Bacillus thuringiensis* gene encoding the insecticidal Cry1Ab protein.
Following the submission of applications EFSA-GMO-RX-MON810 and EFSA-GMO-NL-2012-107, and the publication of the EFSA scientific opinions[3,4], the placing on the market of maize MON 810 for products containing, consisting of, or produced from this GM maize, including pollen, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2013/649/EU and 2017/1207/EU. In 2022 the applicant asked the European Commission to renew the authorisation for the placing on the market of maize MON 810 and submitted dossier GMFF-2022-9450 in support of their request. The GMO Panel assessed the application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines.
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 the GMO Panel will assess the recently received additional information in the relevant working groups. If no other questions are identified during the assessment, the opinion will be proposed for possible adoption by written procedure or during one of the next GMO Plenary meetings.

5.2 Application for renewing the authorisation for the placing on the market of food and feed products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 and its subcombinations, authorised under Regulation (EC) No 1829/2003 (Commission Decision 2013/650/EU) jointly submitted by Bayer Agriculture BV and Corteva Agriscience (GMFF-2022-9170, EFSA-Q-2022-00845)

Maize MON 89034 × 1507 × MON 88017 × 59122 contains *cry1A.105*, *cry2Ab2*, *cry1F*, *pat*, *cry3Bb1*, CP4 *epsps*, *cry34Ab1* and *cry35Ab1* genes conferring resistance against certain lepidopteran and coleopteran target pests and tolerance to glufosinate-ammonium- and glyphosate-based herbicides.
Following the submission of applications EFSA-GMO-CZ-2008-62 and the publication of the EFSA scientific opinion[5], the placing on the market of maize MON 89034 × 1507 × MON 88017 × 59122 and 8 out of 10 of its subcombinations for products containing, consisting of, or produced from this GM maize, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2013/650/EU. In 2022 the applicants asked the European Commission

[3] https://doi.org/10.2903/j.efsa.2009.1149
[4] https://doi.org/10.2903/j.efsa.2012.3022
[5] https://doi.org/10.2903/j.efsa.2010.1781

to renew the authorisation for the placing on the market of maize MON 89034 × 1507 × MON 88017 × 59122 and submitted dossier GMFF-2022-9170 in support of their request. The GMO Panel assessed the application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines.
The GMO Panel revised the draft opinion, and where appropriate, questions were raised and addressed throughout the different sections.
It was agreed that the GMO Panel will assess the missing information in the relevant working groups once it is provided. If no other questions are identified during the assessment, the opinion will be proposed for discussion and possible adoption at one of the upcoming GMO Plenary meetings.

5.3 Application for authorisation of LBFLFK canola import in the European Union submitted under Regulation (EC) No 1829/2003 by BASF Agriculture Solutions (EFSA-GMO-DE-2019-157, EFSA-Q-2019-00394)

Oilseed rape event LBFLFK was produced by *Agrobacterium*-mediated transformation of the conventional cv. Kumily using a single transformation vector to introduce genes encoding fatty acid desaturase and elongase proteins to allow for the synthesis of omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs), including EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid), from oleic acid, as well as an AHAS (acetohydroxyacid synthase) protein to confer tolerance to imidazolinone-containing herbicides. The scope of the application EFSA-GMO-DE-2019-157 is for food and feed uses, import and processing and does not include cultivation in the European Union.

The Panel discussed the spontaneous information provided by the applicant (protein structure and history of safe use) and defined the next steps to progress the risk assessment of oilseed rape LBFLFK. Further discussion is needed.

5.4 Application for authorization of genetically modified cotton GHB614 x T304-40 x GHB119 x COT102 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience N.V. (EFSA-GMO-ES-2017-147, EFSA-Q-2017-00505)

Cotton GHB614 x T304-40 x GHB119 x COT102 was produced by crossing to combine four single cotton events: expressing Cry1Ab, Cry2Ae and Vip3Aa19 proteins to confer resistance to certain lepidopteran pests, 2mEPSPS protein to confer tolerance to glyphosate-containing herbicides, PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and APH4 protein used as a selectable marker. The scope of the application EFSA-GMO-ES-2017-147 is for food and feed uses, import and processing and does not include cultivation within the EU.
The Panel discussed the information provided by the applicant (characteristics of the tested GM line) and defined the next steps to progress the risk assessment of cotton GHB614 x T304-40 x GHB119 x COT102. Further discussion is needed.

5.5 Application for authorisation of genetically modified cotton T304-40 x GHB119 x COT102 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by BASF Agriculture Solutions (EFSA-GMO-BE-2018-155, EFSA-Q-2018-00809)

Cotton T304-40 x GHB119 x COT102 was produced by crossing to combine three single cotton events: expressing Cry1Ab, Cry2Ae and Vip3Aa19 proteins to confer resistance to certain lepidopteran pests, PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and APH4 protein used as a selectable marker. The scope of the application

EFSA-GMO-BE-2018-155 is for food and feed uses, import and processing and does not include cultivation within the EU.
The Panel discussed the information provided by the applicant (characteristics of the tested GM line) and defined the next steps to progress the risk assessment of cotton T304-40 x GHB119 x COT102. Further discussion is needed.

6. Other scientific topics for discussion

6.1 Guidance review

The GMO Panel was informed of the follow-up activities that the Unit took after the discussion held during the 157th GMO Plenary.[6] A further proposal was discussed, aiming at the unification of the applicable scientific GMO guidance documents, technical notes and scientific statements into one document to avoid duplication and improve clarity The new guidance document would not include novel requirements or scientific updates, but would consist in a re-assembling of the existing documents. The GMO Panel discussed the possibility to engage in this activity starting in 2024.

7. New mandates

7.1 Applications

Since the last meeting of the GMO Panel, EFSA received the following application:

- GMFF-2023-1739 Application for authorisation of genetically modified MON 94313 x MON 89788 soybean in accordance with Regulation (EC) No. 1829/2003 [7]

7.2 Mandates

None

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

8.1 Commission proposal on plants obtained by certain new genomic techniques

The representative of EC presented to the GMO Panel their proposal for a new Regulation on plants produced by certain new genomic techniques (NGT). The presentation was followed by a discussion between EC and the GMO Panel. In particular, the following were discussed:

1) The verification criteria that allow NGT plants to be classified as belonging to category 1 (i.e. NGT plants that could occur naturally or could have been obtained by conventional breeding methods).
2) The risk assessment principles and the autorisation procedure of NGT plants belonging to category 2 (i.e. NGT plants not equivalent to conventional) as well as the specific provision for category 2 NGT plants featuring traits that can contribute to sustainability goals.
3) The need for future guidance and secondary legislation in case the proposal, following the ordinary legislative procedure, will become law.

8.2 European Commission

The representatives of the EC informed the GMO Panel on their ongoing activities, including

6 https://www.efsa.europa.eu/sites/default/files/2023-06/Minutes%20of%20157th%20GMO%20plenary.pdf
7 https://open.efsa.europa.eu/questions/EFSA-Q-2023-00641

approval procedures for applications for which the GMO Panel has delivered a scientific opinion.

8.3 Upcoming mandates

In the last years it became evident that there is the need to define new approaches to conduct the risk assessment of GM crops expressing high number of new proteins and/or that are difficult to characterise and test (e.g. membrane-bound proteins).
To move forward the field of protein safety and advance the safety assessment of complex products, the GMO Panel identified the need to develop a scientific opinion reflecting on current practice, challenges and future opportunities of protein safety in GMOs.[8] A self-task mandate of the GMO Panel was proposed to develop a scientific opinion regarding protein safety assessment. In case, the GMO panel self-task is approved, the chair of the GMO panel and the NIF head of Unit agreed that there is no need to establish a new working group (WG), since the activities can be conducted within the Food and Feed WG. The foreseen output is a scientific opinion to be completed by the end of 2024.

9. Any other business

None

10. 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/159th-plenary-meeting-gmo-panel

The next meeting will be held on 29-30 November 2023, in Parma.

8 https://www.efsa.europa.eu/sites/default/files/2023-04/minutes-156th-gmo-plenary.pdf