SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

160th Panel Plenary meeting

29-30 November 2023
09:00-17:00 / 09:00-13:00
MINUTES - Agreed on 19 December 2023

Location: EFSA, Parma

Attendees:

- Panel Members:

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

- Hearing Experts[1]:

Not Applicable

- European Commission and/or Member States representatives:

EC: Alexandre Huchelmann, Olga Orlova (by tele)

- EFSA:

NIF Unit:

Ana Afonso, Giacomo De Sanctis, Antonio Fernández Dumont, Andrea Gennaro, Aina Belen Gil Gonzalez, 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, Marta Rodrigues and Reinhilde Schoonjans

IDATA Unit:

Adrián César Razquin (for items 6.4, 6.5)

MESE Unit:

Jose Ángel Gómez Ruiz (for item 5.2)

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[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.

[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
[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. Report on written procedure since the 159th Plenary

4.1 Minutes of the 159th Plenary meeting held from 27th to 28th September 2023, by teleconference

The minutes of the 159th Panel plenary meeting were agreed by written procedure on 11 October 2023.

5. Scientific output(s) submitted for discussion/adoption

5.1 Application for authorisation of maize DP23211 for placing on the EU market submitted under Regulation (EC) No 1829/2003 by Corteva Agriscience (EFSA-GMO-NL-2019-163, EFSA-Q-2019-00807)

Maize event DP23211 expresses the IPD072Aa protein and DvSSJ1 double-stranded RNA (dsRNA) to confer resistance to certain coleopteran pests, phosphinothricin acetyltransferase (PAT) protein to confer tolerance to glufosinate-ammonium-containing herbicides and phosphomannose isomerase (PMI) protein used as a selectable marker. The scope of application EFSA-GMO-NL-2019-163 is for food and feed uses, import and processing and does not include cultivation in the EU.
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 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 draft scientific opinion, and in particular the food and feed assessment. Further discussion is needed.

5.3 Application for authorisation of soybean DBN9004 for placing on the EU market submitted under Regulation (EC) No 1829/2003 by Beijong DaBeiNong Biotechnology (EFSA-GMO-BE-2019-165, EFSA-Q-2020-00013)

Soybean event DBN9004 expresses the CP4 EPSPS protein to confer tolerance to glyphosate and phosphinothricin acetyltransferase (PAT) protein to confer tolerance to glufosinate-ammonium-containing herbicides. The scope of application EFSA-GMO-BE-2019-165 is for food and feed uses, import and processing and does not include cultivation in the EU.
The progress made in the risk assessment by all working groups was presented. Further discussion is needed.

5.4 Application for authorisation of soybean DBN8002 for placing on the EU marker submitted under Regulation (EC) No. 1829/2003 by Beijong DaBeiNong Biotechnology (GMFF-2022-11530, EFSA-Q-2023-00103)

Soybean event DBN8002 expresses the Vip3Aa protein to confer resistance to certain lepidopteran pests and phosphinothricin acetyltransferase (PAT) protein to confer tolerance to glufosinate-ammonium-containing herbicides. The scope of application GMFF-2022-11530 is for food and feed uses, import and processing and does not include cultivation in the EU.
The application has been recently validated and the main characteristics of the submitted dossier were discussed. The application will be tabled for discussion once all the working groups will progress on the risk assessment.

5.5 Application for renewal of the authorisations for continued marketing of genetically modified MON 810 maize for food and feed uses (including pollen), excluding cultivation submitted under Regulation (EC) No. 1829/2003 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[4][5] , the placing on the market of maize MON 810 for food and feed uses (including pollen), excluding cultivation in the EU, was authorised by Commission Implementing Decisions 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 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.

5.6 Application for authorisation of genetically modified maize DP915635 in accordance with Regulation (EC) No. 1829/2003 (EFSA-GMO-NL-2020-172, EFSA-Q-2020-00834)

Maize event DP915635 expresses the IPD079Ea protein to confer resistance to certain coleopteran pests, phosphinothricin acetyltransferase (PAT) protein to confer tolerance to glufosinate-ammonium-containing herbicides and phosphomannose isomerase (PMI) protein used as a selectable marker. The scope of application EFSA-GMO-NL-2020-172 is for food and feed uses, import and processing and does not include cultivation in the EU.

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.

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

5.7 Application for authorisation of genetically modified maize MON 95275 in accordance with Regulation (EC) No. 1829/2003 (GMFF-2022-5890, EFSA-Q-2022-00330)

Maize event MON 95275 expresses the Mpp75Aa1.1 and Vpb4Da2 proteins and DvSnf7 dsRNA to confer resistance to certain coleopteran pests. The scope of application GMFF-2022-5890 is for food and feed uses, import and processing and does not include cultivation in the EU.

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.

5.8 Application for authorisation of genetically modified maize MON 94804 in accordance with Regulation (EC) No. 1829/2003 (GMFF-2022-10651, EFSA-Q-2023-00106)

Maize event MON 94804 contains the GA20ox_SUP suppression cassette expressing a miRNA that suppresses the expression of the targeted maize endogenous gibberellin 20 oxidase (ZmGA20ox) genes, ZmGA20ox3 and ZmGA20ox5. This results in the reduction of gibberellic acid/gibberellin (GA) levels predominantly in the stalk, leading to a reduction of internode length and consequently reduced overall plant height. Maize MON 94804 does not express any newly expressed proteins. The scope of application GMFF-2022-10651 is for food and feed uses, import and processing and does not include cultivation in the EU.

The application has been recently validated and a first draft of the draft opinion was presented. Questions were raised and addressed throughout the different sections. It was agreed that the GMO Panel will assess the additional 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.

6. Other scientific topics for information/discussion

6.1 Plants produced via new genetic techniques (NGTs)

The Panel had a discussion on the challenges plants obtained through NGTs poses to the risk assessment. The six criteria identified by EFSA (2022) were applied to several hypothetical case studies. The Panel discussed the relevance of the information as by the current data requirements for GM plants for the identified NGT case studies. The Panel identified the need to further discuss the implication on RA the NGT plants might have.

6.2 The scrutiny of patents on GM events: implications for the risk assessment

The Panel discussed the relevance of patents for informing the risk assessment of GM plants. The main limitations of patents compared with peer-reviewed publications or with studies were discussed. In addition, the Panel discussed the relevance to request applicant to provide relevant patents.

6.3 Scientific opinion on GMM-NGT

In August 2022 EC mandated EFSA to produce an opinion on new developments in biotechnology applied to microorganisms.[6] The mandate was assigned to the GMM-WG[7] that in line with the EC mandated worked on two deliverables. The first consisting of the horizon scanning on microorganisms and their products obtained by new developments in biotechnology and that was commissioned to a contractor and the second consisting in the EFSA opinion on potential novel hazards/risks from new developments in biotechnology applied to microorganisms and adequacy of the current EFSA risk assessment guidance. The Chair of the GMM-WG introduced to the Panel the current draft of the opinion as well as the main outcomes of the horizon scanning. In the upcoming months the GMM-WG will progress with the finalisation of the draft that will be presented at the upcoming GMO Plenary with the aim of endorsing the draft for the public consultation.

6.4 Technical Note on sequencing

EFSA reported on the update of the 2018 Technical Note on sequencing[8] and presented the introduced modification and its rationale. The aim remains data harmonization and quality that will contribute to a faster processing of the application. To this end, EFSA will also make available a script to be used on a voluntary basis to check the quality of the submitted sequencing data in accordance with the EFSA Technical note. This script will be the same as the one that EFSA uses for internal quality control of the submitted sequencing data. In addition, EFSA shared with the Panel members the comments received by the applicants[9] on the draft Technical Note. The EFSA Technical Note will be further finalised and published at the beginning of 2024.

6.5 EFSA Project on GM Plant sequences (GMPSeq)

EFSA updated the GMO Panel on the recently launched Genetically Modified Plant Sequences (GMPSeq) portal. The portal provides secure access to EFSA staff and experts to the confidential DNA sequences from GMO applications and allows EFSA to perform sequence quality check analysis. Due to the confidentiality of the database, the access is limited to authorised users following dedicated training.

7. Update on new Mandates

7.1 Applications

None

7.2 Mandates

EFSA informed the GMO Panel of the self-task mandate of the GMO panel on a scientific opinion regarding protein safety[10] . The GMO identified the need to publish a scientific opinion reflecting on current practice, challenges and future opportunities of protein safety in GMOs. The scientific opinion is expected to be completed by December 2024 and should cover:

1. Lessons learned from experiences in the assessment of newly expressed proteins in the last 20 years, including more recent complex cases.

2. Building on the experience and issues identified, develop a critical appraisal of new methodologies available with the potential to be used as complementary/alternative testing strategies to current methodologies described in legal frameworks.

[6] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00508
[7] https://www.efsa.europa.eu/sites/default/files/2023-01/gmm-ngt-minutes.pdf
[8] https://www.efsa.europa.eu/en/efsajournal/pub/5345
[9] https://www.efsa.europa.eu/en/events/ad-hoc-meeting-industry-representatives-gmo-applicants
[10] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00664

3. Road map for future implementation of such complementary/alternative methods in risk assessment strategies.

4. Recommendations for further research to address methodological development needs.

In frame of the mandate, on 19 December 2023 EFSA is organizing a webinar intended for all interested stakeholders with expertise in the area of protein safety assessment. Registration is open until 18 December 2023 (12.00 CET) at this link. The webinar aims to provide clarity on the mandate and to introduce an open survey to collect input on the topic from stakeholders. The survey will be launched on 19th December and will be open till 18th February 2024.

8. Feedback from the Scientific Committee/ Scientific Panels/EFSA/ EC

8.1 Scientific Committee

The Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting and ongoing EFSA activities[11].

8.2 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.

8.3 Scientific Panel(s) including their Working Groups

- **GMA-NGT WG**

The Chair of the GMA-WG[12] update the Panel on the progresses made on the mandate to produce an opinion on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques).[13]

- **EFSA guidance on the assessment of microorganisms**

The GMO Panel was informed about the on-going work to develop a guidance document for microorganism characterisation. EFSA conducts the risk assessment of microorganisms that are used in the food chain for different purposes. The assessments are linked to requests for authorisation of the products under the applicable Regulations; the products evaluated may contain the microorganism, be prepared from, or obtained with the microorganism, and the microorganisms can be genetically modified or not. EFSA considers it necessary to have one scientific guidance document detailing the requirements for the risk assessment of microorganisms that could be applied across sectors. The Scientific Committee plays a major role in harmonising practices across areas; therefore, it was proposed that the Scientific Committee prepares a guidance document on the risk assessment of microorganisms used in the food chain to be applied across sectors. The Scientific Committee agreed on the proposal and a self-task will be prepared. At this regard, it is intended that the WG on microbiology from the FEEDAP Panel with experts from other Panels will prepare the draft guidance for the consideration of the relevant EFSA Panels and finally for the endorsement and adoption by the Scientific Committee.

9. Any other business

None

[11] https://www.efsa.europa.eu/en/events/116th-plenary-meeting-scientific-committee
[12] https://www.efsa.europa.eu/sites/default/files/2023-07/minutes-gma-ngt.pdf
[13] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00050

10. Next meeting

The next meeting will be held on 7th-8th February 2024 via teleconference.