

**SCIENTIFIC PANEL ON
GENETICALLY MODIFIED ORGANISMS
Minutes of the 158th Plenary meeting**



29 June 2023

MINUTES - Agreed on 18 July 2023

Location: Webconference

Attendees:

- **Panel Members:**

Jean Louis Bresson, Tamas Dalmay, Ian Dewhurst, Michelle Epstein,
Leslie George Firbank, Philippe Guerche, Jan Hejatk, 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:

Alexandre Huchelmann, Juliette-Marie Margueritte, Olga Orlova and Mara Sgroi

- **EFSA:**

NIF Unit:

Ana Afonso (Head of NIF Unit), Michele Ardizzone, Giacomo De Sanctis,
Antonio Fernández Dumont, Andrea Gennaro, Tilemachos Goumperis,
Paschalina Grammatikou, Dafni Maria Kagkli, Paolo Lenzi, Aleksandra Lewandowska,
Ana Martin Camargo, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli,
Reinhilde Schoonjans and Kyriaki Xiftou

FDP Unit:

Sara De Berardis (for item 9.1), Silvia Federici (for items 6.1, 9.1) and Claudia Parisi (for item 9.1)

OBSERVERS:

Stefano Brizzi (BASF), Alexandra Chanoca (Corteva Agriscience), Mariassunta Ciccone (Università degli Studi di Ferrara), Fabiola Cuevas Bustamante (Corteva Agriscience), Adinda De Schrijver (Sciensano, Belgium), Marion Dolezel (Environment Agency, Austria), Alvaro Eseverri-Sabate (BASF), Miroslava Feketová (CCTIA in Bratislava), Michał Giziński (Ministry of Climate and Environment, Poland), Elisa Gómez (Student, Spain), Luis Gramacho (Portuguese Environment Agency), Ana Guillem (Syngenta), Ulrike Hahn (NHU-Europe GmbH), Taha Hosni (Nuseed (Nufarm)), Gijs Kleter (Wageningen Food Safety Research, Netherlands), Petra Kostolaniova (CropLife Europe), Veronika Kyrova (National Institute of Public Health in Prague, Centre for health, nutrition and food in Brno), Emily Macdougald (Federal Agency for the Safety of the Food Chain (FASFC), Belgium), Maica Martinez Parrilla (Corteva Agriscience), Nina McCormick (Bayer CropScience), Alessandro Nicolia (Council for Agricultural Research and Economics (CREA-OF), Italy), Concepción Novillo (Bayer CropScience), Maria Pilar Iñiguez Ortega (University of Alicante), Eva-Theresa Pyl (Federal Office of Consumer Protection and Food Safety (BVL), Germany), Kelly Seligman (Chr Hansen), Heike Sprenger (German Federal Institute for Risk Assessment (BfR)), Ine Criel (BASF), Pavol Viktorinova (The Central Control and Testing Institute in Agriculture in Bratislava (ÚKSÚP)), Nancy Podevin (Corteva Agriscience), Cecilia Primo Planta (Syngenta), Romain Raemaekers (Syngenta), Diego Rodriguez Manzano (Corteva Agriscience), Valerie Sert (Corteva Agriscience), Marta Schiller (Citizen, Poland), Zbigniew Sieradzki (National Veterinary Research Institute, Poland), Andreas Voloudakis (Agricultural University of Athens), Andrzej Kowalczyk (Plant Health and Seed Inspection, Poland), Sasi Wilhelmi (BASF),



Aleksandra Wolnicka (Provincial Inspectorate of Plant Health and Seed Inspection in Katowice), Kamila Zdenkova (UCT Prague) Luise Zühl (German Federal Agency for Nature Conservation (BfN)).

1. Welcome and apologies for absence

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

2. Presentation of the Guidelines for Observers

The Head of NIF Unit presented the guidelines for observers for open plenary meetings.¹

3. Adoption of agenda

The agenda was adopted without changes

4. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, 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.

5. Report on written procedures since the 157th Plenary meeting

5.1 Minutes of the 157th Plenary meeting

The minutes of the 157th Plenary meeting were agreed by written procedure on the 29 May 2023⁴.

6. Scientific topics for discussion and possible adoption

6.1 Request for placing on the market of genetically modified maize DP-202216 submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2019-159)⁵

Maize event DP-202216 expresses 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) 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 requested additional information was discussed in the relevant GMO Panel expert working groups (WGs). It was not possible to present the draft scientific opinion at the current Plenary meeting for discussion and possible adoption.

Further discussion is needed at the relevant GMO Panel expert WGs.

¹ <https://www.efsa.europa.eu/sites/default/files/observersguidelines.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 <https://www.efsa.europa.eu/sites/default/files/2023-06/Minutes%20of%20157th%20GMO%20plenary.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00419>



6.2 Request for placing on the market of genetically modified maize DP-915635-4 for food and feed uses, import, processing, excluding cultivation (EFSA-GMO-NL-2020-172)⁶

Maize event DP-915635-4 expresses the IPD079Ea protein to confer resistance to certain coleopteran pests, 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.

It was agreed that the GMO Panel will assess in the relevant working groups the missing information once it is provided (determination of the newly expressed protein levels and the update of the literature searching). 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.

7. New Mandates

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

- GMFF-2023-14732 Application for authorisation to place on the EU market food and feed produced from sugar beet KWS20-1⁷

Since the last meeting of the GMO Panel, the following applications were made valid:

- GMFF-2022-11530 Application for authorisation to place soybean DBN8002 on the EU market⁸
- GMFF-2022-10651 Application for authorisation to place maize MON 94804 on the EU market⁹
- GMFF-2022-6232 Application for authorisation to place maize DP202216 x NK603 x DAS-40278-9 and its sub-combinations on the EU market¹⁰

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 activities¹¹.

8.2 Upcoming Mandates

None

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.

⁶ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00834>

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00378>

⁸ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00103>

⁹ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00106>

¹⁰ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00197>

¹¹ <https://www.efsa.europa.eu/pl/events/114th-plenary-meeting-scientific-committee-open-observers>



8.4 Feedback on the GMO Network meeting

The Unit briefly summarised the items presented at the 15th GMO Network meeting held in Prague on the 8th June 2023¹².

9. Any Other Business

9.1 Post-TR (transparency regulation) application: major changes for the EFSA risk assessment

Representatives of the FDP (Front-Desk and workforce Planning) Unit and NIF Unit, summarised the main changes since the entry into force of the TR. Information on the pre-submission advice for applications and renewals as well as on the notification of studies (NoS) was provided. Changes during the RA phase such as the possibility to access the public version of dossiers after validation, the tool to submit public comments and the activities required to conduct the assessment of the confidentiality requests submitted by applicants were summarised. The main features of the OpenEFSA portal (<https://open.efsa.europa.eu/>) were also presented.

10. Questions from and answers to Observers

Observers were invited to submit questions to the GMO Panel at the time of registration. EFSA received the following questions ahead of the meeting:

NUMBER	QUESTION	ANSWER
1	<p>1) What has the Panel's experience been with EFSA's new transparency approach? For example, have there been any more inputs from the public, media, etc.?</p> <p>2) Which prospects are there of having more frequent (partially) open sessions?</p> <p>3) What was the reason for changing the titles of assessment outcomes from "opinion" to "assessment"?</p> <p>4) The Panel has started and/or completed various reviews of previously published documents (for example SDN-3, GM animals, synbio, allergenicity). Which other documents might there be up for review shortly?</p>	<p>1) To date, the Public Consultation of only one GMO dossier was completed. Via the AsKEFSA portal in 2022 a significant number of requests were received from EU citizens. EFSA implemented interactive tools to enhance the proactive disclosure of information relating to the GMO Risk Assessment Process</p> <p>2) Since the first open Plenary of the GMO Panel held in 2014 no partially open sessions were organized. The frequency of the open plenary is currently of one per year.</p> <p>3) No specific reason, only an editorial decision.</p> <p>4) In the short term EFSA does not foresee reviews of previously published documents.</p>

¹² Agenda, minutes and presentations of the GMO Network meeting are available at the following link: <https://www.efsa.europa.eu/en/events/15th-meeting-gmo-network>



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/158th-plenary-meeting-gmo-panel-open-observers>

The next meeting will be held on 27-28 September 2023, online.
