



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 135th MEETING

Held on 29-30 January 2020, Parma

(Agreed on 11 February 2020)

Participants

■ Panel Members:

Jean-Louis Bresson, Tamas Dalmay, Ian Dewhurst, Michelle Epstein¹, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Ewen Mullins², Hanspeter Naegeli, Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano, Giovanni Savoini, Eve Veromann and Fabio Veronesi

■ Hearing experts: Michael Bonsall, John Mumford, Ernst Wimmer³

■ European Commission and/or Member States representatives:

Ilaria Ciabatti and Beatrice Marquez-Garrido (DG SANTE)

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Anna Lanzoni, Sylvie Mestdagh, Franco Maria Neri, Konstantinos Paraskevopoulos, Nikoletta Papadopoulou, Tommaso Raffaello and Elisabeth Waigmann

Other Unit:

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ Attended the first day of the meeting and by teleconference second day.

² Attended second day by teleconference.

³ Attended first day by teleconference.

⁴ 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. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management, 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 134th GMO Plenary meeting

The minutes of the 134th Plenary meeting were adopted by written procedure and published on 18 December 2019.

5. Scientific topic(s) for discussion

5.1 Application for authorization of genetically modified soybean MON 87705 x MON 87708 x MON 89788 for food and feed uses submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V (EFSA-GMO-NL-2015-126) ([EFSA-Q-2015-00548](#))

The three-event stack soybean MON 87705 x MON 87708 x MON 89788 was obtained by conventional crossing of three single transformation events MON 87705, MON 87708 and MON 89788. The three single events produce newly expressed proteins conferring herbicide tolerance to dicamba (from MON 87708) and glyphosate (from MON 89788). In addition, the three-event stack has a different seed fatty acid biosynthetic pathway obtained by down-regulating two key enzymes, FATB and FAD2. Application EFSA-GMO-NL-2015-126 was submitted by Monsanto for the placing of soybean MON 87705 x MON 87708 x MON 89788 on the EU market for food/feed uses, import and processing under Regulation (EU) No 503/2013.

A scientific officer of the GMO Unit led the GMO Panel through the text of the draft opinion. Questions were raised and addressed throughout the reading of the different sections of the draft opinion. The GMO Panel revised the draft text, where appropriate. Some sections of the draft opinion were not discussed pending additional data from the applicant. Further discussion is needed and will take place with the Working Groups of the GMO Panel. When ready, a revised draft opinion will be presented to the GMO Panel for adoption.

5.2 Application for renewal of authorisation of food and feed containing, consisting of or produced from GM maize MON 88017 and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation 1829/2003 (EFSA-GMO-RX-014) ([EFSA-Q-2018-00672](#))



Maize MON 88017 was developed to confer resistance to certain coleopteran pests and tolerance to glyphosate-based herbicides. Following a thorough risk assessment by EFSA, maize event MON 88017 was authorized for food/feed uses, import and processing in the European Union in 2009 (see Commission Decision 2009/814/EC). In 2018 the applicant asked the European Commission to renew the authorisation for the placing on the market of maize MON 88017 and submitted application EFSA-GMO-RX-014 in support to their request. The GMO Panel assessed application EFSA-GMO-RX-014 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines.

In this meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the opinion, which will be published on the EFSA website and in the [EFSA Journal](#).

5.3 Mandate for assessment of genetically modified organisms engineered with gene drives (gene drive modified organisms) and their implications for risk assessment methodologies (EFSA-Q-2018-00619)

The European Commission mandated EFSA to deliver a scientific opinion on gene drive modified organisms and their implications for risk assessment methodologies. According to the mandate specifications, EFSA was requested to identify potential risks in terms of impact on human and animal health and the environment that gene drive modified organisms could pose, including potential novel hazards of gene drive modified organisms, considering relevant comparators, where appropriate; to determine whether the existing guidelines for risk assessment are adequate and sufficient for gene drive modified organisms or whether there is a need for updated guidance. In case where a need for an updated guidance is found, EFSA was requested to identify the specific areas where such updated guidance is needed. Under the present mandate, EFSA is not requested to develop guidelines for the risk assessment of gene drive modified organism. EFSA is also requested to provide technical and scientific expertise on risk assessment of gene drive modified organisms to support the EU in the work under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

At the Panel meeting last November, a scientific officer of the GMO Unit presented the draft opinion prepared by the ad hoc WG (<http://www.efsa.europa.eu/en/gmo/working-groups>) established to address this mandate. After a first review of the available text, it was agreed that further discussion was needed at the WG level.

At this meeting, the GMO Panel scrutinized and, where appropriate, edited the revised text of the draft opinion before endorsing it. The output will be open for comments from the public through a dedicated consultation that will be launched in the coming weeks.

5.4 Mandate for assessment of SDN Scientific opinion on plants developed using type 1 and type 2 Site-Directed Nuclease and Oligonucleotide Directed Mutagenesis (EFSA-Q-2019-00297)

A scientific officer of the GMO Unit presented the terms of reference and provided background information on the mandate from the European Commission. EFSA is tasked to advise whether the assessment methodology described in the 2012 scientific opinion of the GMO Panel addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function³, may be applicable, in whole or in part, to plants developed with type 1 and type 2 Site-Directed Nucleases and with oligonucleotide directed mutagenesis. If the answer is yes, EFSA is requested to advise whether the conclusions of the 2012 scientific opinion are valid, in whole or in

³ The scientific opinion is available at: <https://www.efsa.europa.eu/en/efsajournal/pub/2943>



part, to plants developed with type 1 and type 2 Site-Directed Nucleases and with oligonucleotide directed mutagenesis.

The discussion on the scientific content of the mandate took place in the GMO Panel's Molecular Characterisation WG⁴. At the present meeting, the draft text of the scientific opinion on SDN-1 and -2 and ODM was presented to and discussed with the GMO Panel for the first time. Further discussion is needed at the WG level.

At this next meeting, the GMO Panel will be asked to endorse the final draft opinion prior to a public consultation expected in spring 2020.

5.5 Mandate for assessment of Synthetic Biology developments in plants, environmental risk assessment aspects (ERA) ([EFSA-Q-2018-01000](#))

The European Commission tasked EFSA to issue scientific opinions on synthetic biology developments in plants (for agri-food uses) to inform the EU position in international negotiations for synthetic biology (e.g. Convention on Biological Diversity). EFSA and its GMO Panel shaped their work considering agri/food/feed products about to enter the EU market over the next decade. EFSA established two multidisciplinary *ad hoc* Working Groups (WGs) to address the terms of reference: one focusing on microorganisms within the remit of the EFSA Scientific Committee and the other addressing plants falling under the GMO Panel ([EFSA website](#)).

At the Panel meeting last November, a scientific officer of the GMO Unit presented the draft opinion prepared by the *ad hoc* WG (<http://www.efsa.europa.eu/en/gmo/working-groups>) established to address this mandate. After a first review of the available text, it was agreed that further discussion was needed at the WG level.

At this meeting, the GMO Panel scrutinized and, where appropriate, edited the revised text of the draft opinion before endorsing it. The output will be open for comments from the public through a dedicated consultation that will be launched in spring 2020.

6. New Mandates

6.1 Applications under Regulation (EC) No 1829/2003

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

- Application EFSA-GMO-NL-2019-163 for placing on the market of genetically modified DP-023211-2 Maize ([EFSA-Q-2019-00807](#))
- Application EFSA-GMO-NL-2019-164 for placing on the market of genetically modified NK603xT25xDAS-40278-9 Maize ([EFSA-Q-2019-00808](#))
- Application EFSA-GMO-BE-2019-165 for placing on the market of Genetically Modified soybean DBN-09004-6 for food and feed uses, import and processing ([EFSA-Q-2020-00013](#))

6.2 Annual Post-market environmental monitoring reports of GM plants

No new mandate was received.

⁴ Minutes of the WG meetings are available at: <http://www.efsa.europa.eu/sites/default/files/wgs/gmo/gmomc2019.pdf>



6.3 Other Requests and Mandates

Since the last meeting of the GMO Panel, EFSA received from the European Commission:

- the request for technical and scientific assistance on the internal review under Regulation (EC) No 1367/2006 of the Commission's decisions renewing the authorisation for the placing on the market of soybean MON 89788 and soybean A2704-12

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

Not applicable

7.2 EFSA including its Working Groups/ Task Forces

Not applicable

7.3 European Commission

The representative of the European Commission provided feedback on recent meetings held at the European Commission.

8 Any other business

8.1 Application for authorization of genetically modified *Brassica napus* MS11 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-BE-2016-138) ([EFSA-Q-2016-00857](#))

Application EFSA-GMO-BE-2016-138 was submitted by Bayer CropScience for the placing on the market of *Brassica napus* Ms11 for food and feed uses, import and processing under Regulation (EC) No 1829/2003.

At the 130th meeting of the GMO Panel on 3rd April 2019, two scientific officers of the GMO Unit had introduced the peculiarities of this male sterile rapeseed event and the subsequent technical limitations (e.g. suitable test material, herbicide treatment, comparator) encountered by the applicant to perform field trials in line with the applicable guidelines. In addition, the GMO Panel discussed the 'inconsistency' between the scope of this application for food/feed uses of the male sterile event Ms11 and the intended use of this event (i.e. for breeding purpose only). The Ms11 event is of commercial interest in combination with the restorer line Rf3. The GMO Panel was informed that some EU Member States already raised comments on the intended use of Ms11 event. The GMO Panel considered different scenarios for completing the risk assessment of Ms11 event in the light of the considerations listed above. The Working Groups were tasked to supplement the draft opinion accordingly.

At this meeting the GMO Panel scrutinized and, where appropriate, edited the revised text of the draft opinion. Further discussion is needed.



8.2 EFSA Activities: update by Head of Department

The Head of the EFSA Department on Regulated Products (REPRO HoD) joined the meeting to update the Panel on new rules, ongoing and forthcoming EFSA initiatives.

8.3 Feedback from observers from the Open GMO Panel 134th meeting, 27-28 November 2019

A scientific officer of the GMO Unit updated the GMO Panel on the outcome of the online survey following the meeting open to the public (27-28 November 2019).

Adoption of the minutes and next meeting

The minutes of the current meeting were adopted by written procedure and will be published at:

<https://www.efsa.europa.eu/en/events/event/135th-plenary-meeting-gmo-panel>

The 136th GMO Plenary meeting will be held on 01-02 April in Parma.