GENETICALLY MODIFIED ORGANISMS UNIT

# SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

## Minutes of the 136th Meeting

**Held on 01-02 April 2020, TELE/WEB**

**(Agreed on 14 April 2020)**

## Participants

- Panel Members:

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

- Hearing experts: none

- European Commission and/or Member States representatives: Ilaria Ciabatti, Beatrice Marquez-Garrido and Alexandre Huchelmann (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, Dafni Maria Kagkli, Anna Lanzoni, Sylvie Mestdagh, Franco Maria Neri, Lorenz Oberkofler, Konstantinos Paraskevopoulos, Nikoletta Papadopoulou, Tommaso Raffaello, Riccardo Vriz and Elisabeth Waigmann

  Other Unit: none

## 1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies received.

This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

[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. 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, 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 135th GMO Plenary meeting

The minutes of the 135th Plenary meeting were adopted by written procedure and published on 11 February 2020.

## 5. Scientific topic(s) for discussion and/or possible adoption

### 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 and MON 87705). 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 reminded the Panel members about the peculiarity of this application, i.e. that the applicant did not provide a 90-day study on MON87705 in line with the applicable legal requirements in the context of this three-event stack soybean application (i.e. no treatment with the intended herbicide was applied to MON 87705 soybean used to produce the test material).

Most of the draft scientific opinion was already discussed at the 135th Plenary meeting. Pending missing information and further discussion with the Working Groups of the GMO Panel, related sections of the draft opinion were put on hold.

In the meantime, EFSA has received the missing information addressing all pending questions; Consequently, the Working Groups assessed the information and finalised the text of the draft opinion.

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, and subsequently adopted the output, which will be published on the EFSA website and in the EFSA Journal.

### 5.2 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.

The risk assessment of this application was discussed by the GMO Panel at several occasions owing to 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 past meetings, the GMO Panel has also 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. Following the agreement of the GMO Panel to develop different scenarios taking into account the intended use in the scientific opinion, the Working Groups were tasked to draft text accordingly.

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, and subsequently adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

## 6. Mandate for discussion

### 6.1. 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 briefly 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 function[2], 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 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 WG[3].

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 to comments from the public through a dedicated consultation that will be launched in the coming weeks.

[2] The scientific opinion is available at: https://www.efsa.europa.eu/en/efsajournal/pub/2943
[3] Minutes of the WG meetings are available at: https://www.efsa.europa.eu/en/gmo/working-groups

### 6.2 Applications under Regulation (EC) No 1829/2003

Since the last meeting of the GMO Panel, EFSA has not received new applications.

### 6.3 Annual Post-market environmental monitoring reports of GM plants

A scientific officer of the GMO Unit informed that the mandate to assess the annual post-market environmental monitoring report on GM maize MON 810 in 2018 was received from the European Commission. The deadline to finalise the mandate is end of August 2020.

### 6.4 Other Requests and Mandates

Since the last meeting of the GMO Panel, EFSA has not received new mandates.

## 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

The Chair and vice-Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting, on new mandates and ongoing EFSA activities.

### 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 Digital collaboration

A scientific officer of the GMO Unit updated the Panel members on new digital tools to be used by staff and experts throughout the development of scientific outputs.

## 9. 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/topics/topic/gmo

The 137th GMO Plenary meeting will be organised remotely on 27-28 May, 2020 (am).