GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 133rd MEETING

Held on 25-26 September 2019, Parma

(Agreed on 2 October 2019)

Participants

- Panel Members:

  Jean-Louis Bresson, Tamas Dalmay, Michelle Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Ewen Mullins, Hanspeter Naegeli, Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano[1], Giovanni Savoini[2], Eve Veromann and Fabio Veronesi
- Hearing expert: -
- European Commission and/or Member States representatives:

  Hans Moons (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, Ana Martin Camargo, Sylvie Mestdagh, Franco Maria Neri, Irina Olaru, Konstantinos Paraskevopoulos, Nikoletta Papadopoulou, Tommaso Raffaello and Elisabeth Waigmann

  TS Unit: Claudia Paoletti, Ingrid Miliute

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ian Dewhurst.

2. Adoption of agenda

The agenda was adopted without changes.

[1] Attended the first day of the meeting.
[2] Attended the first day (pm) and second day in full.
[3] 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

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[4] and the Decision of the Executive Director on Competing Interest Management[5], 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 131st GMO Plenary meeting

The minutes of the 132nd Plenary meeting were adopted by written procedure and published on 18 July 2019.

5. Scientific topic(s) for discussion

5.1. Application for authorization of genetically modified soybean MON 87751 x MON 87701 x MON 87708 x MON 89788 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V. (EFSA-GMO-NL-2016-128) (EFSA-Q-2016-00009)

The four-event stack soybean MON 87751 x MON 87701 x MON 87708 x MON 89788 was obtained by conventional crossing of GM soy lines MON 87751, MON 87701, MON 87708 and MON 89788. Soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 inherited the traits as present in the parental lines, i.e. protection against certain lepidopteran pests (from MON 87751 and MON 87701) and tolerance to dicamba (from MON 87708) and glyphosate (from MON 89788). The scope of application EFSA-GMO-NL-2016-128 includes the four-event stack soybean MON 87751 × MON 87701 × MON 87708 × MON 89788 for food/feed uses, import and processing in the European Union.

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.

5.2. Application for renewal of authorisation of food and feed containing, consisting of or produced from genetically modified maize MIR604 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-013 (EFSA-Q-2018-00644)

Maize MIR604 was developed to confer resistance to some coleopteran pests. Following a thorough risk assessment by EFSA, maize event MIR604 was authorized for food/feed uses, import and processing in the European Union in 2009 (see Commission Decision 2009/866/EC). In 2018 the applicant asked the European Commission to renew the authorisation for the placing on the market of maize MIR604 and submitted application EFSA-GMO-RX-013 in support to their request.

The GMO Panel assessed application EFSA-GMO-RX-013 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines.

[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[5] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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. Application for renewal of authorisation of food and feed containing, consisting of or produced from genetically modified maize MON 89034 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-015) (EFSA-Q-2018-00673)

Maize MON 89034 was developed to confer resistance to some lepidopteran pests. Following a thorough risk assessment by EFSA, maize event MON 89034 was authorized for food/feed uses, import and processing in the European Union in 2009 (see Commission Decision 2009/813/EC). In 2018 the applicant asked the European Commission to renew the authorisation for the placing on the market of maize MON 89034 and submitted application EFSA-GMO-RX-015 in support to their request.

The GMO Panel assessed application EFSA-GMO-RX-015 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.

5.4. Mandate for assessment of additional information related to the application for authorisation of food and feed containing, consisting and produced from genetically modified maize 3272 (EFSA-GMO-UK-2006-34) (EFSA-Q-2017-00341)

Maize 3272 was already subject to previous risk assessment by the GMO Panel in 2013. The 2013 scientific opinion of the GMO Panel was inconclusive owing to data gaps identified for comparative analysis and safety of the thermostable alpha-amylase AMY797E. Late 2017, EC tasked EFSA and its GMO Panel to assess new datasets on comparative analysis and *de novo* sensitisation to alpha-amylases to supplement its previous risk assessment of maize 3272.

At its last meeting on 3rd July 2019, a scientific officer of the GMO Unit presented the peculiarities of the GM maize event and clarified that, notwithstanding the full scope of application EFSA-GMO-UK-2006-34, maize 3272 is mainly intended for ethanol production. The GMO Panel and its Food/Feed Working Group took into consideration the additional information package in support to the intended uses of maize 3272 for ethanol production and of its by-products for feed purpose (i.e. dried distiller grains with solubles (DDGS)). The GMO Panel discussed the way forward, including the proposal to highlight and, when possible, to conclude on different exposure scenarios (i.e. full scope vs intended uses of maize 3272).

In response to the initial data gap related to the comparative analysis, the GMO Panel assessed the additional information provided by the applicant and concludes that the agronomic and phenotypic characteristics as well as forage and grain composition of maize 3272 do not give rise to concerns regarding food and feed safety, and nutritional concerns when compared to non-GM maize. Considering the full scope of this application and the characteristics of the trait introduced in this GM maize, the effect of processing and potential safety implications of specific food or feed products remain to be further investigated.

In relation to the allergenic potential of AMY797E protein and considering all possible food and feed uses of maize 3272, the GMO Panel concludes that the information provided does not fully address the concerns previously raised by the GMO Panel in 2013. Owing to the nature and the knowledge available on this protein family (or functional class of enzymes), it is still unclear whether under specific circumstances the alpha-amylase AMY797E has the capacity to sensitise certain individuals and to cause adverse effects. In addition, the applicant provided thorough information relevant for the allergenicity assessment of a specific product, the dried distiller grains with solubles (DDGS) which is the main product of interest for importation into the European Union. Having considered the information provided on this product, the GMO Panel is of the opinion that under the specific conditions of use described by the applicant, DDGS produced from maize 3272 does not raise concerns when compared to DDGS from non-GM maize.

At the present meeting, the GMO Panel scrutinized and revised the text of the draft statement, where appropriate. The GMO Panel subsequently adopted the statement, which will be published on the EFSA website and in the EFSA Journal.

5.5. Application for authorization of genetically modified maize MON 87427 x MON 89034 x MIR162 x MON 87411 and all its subcombinations for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V. (EFSA-GMO-NL-2017-144) (EFSA-Q-2016-00009)

The four-event stack maize MON 87427 x MON 89034 x MIR162 x MON 87411 was obtained by conventional crossing to combine four single maize events: MON 87427 (expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein), MON 89034 (expressing the Cry1A.105 and Cry2Ab2 proteins), MIR162 (expressing the Vip3Aa20 and phosphomannose isomerase (PMI) proteins)), and MON 87411 (expressing the Cry3Bb1 and CP4EPSPS proteins, and the DvSnf7 dsRNA) to confer resistance to certain lepidopteran and coleopteran pests and tolerance to glyphosate-containing herbicides.

The scope of application EFSA-GMO-NL-2017-144 includes the four-event stack maize MON 87427 x MON 89034 x MIR162 x MON 87411 and all its sub-combinations, independently of their origin, for food/feed uses, import and processing. In case of an application on a stack event of a segregating crop (e.g. maize, rapeseed), some sub-combinations falling within the scope might not be supported by a specific dataset. The risk assessment strategy of such sub-combinations was discussed and endorsed by the GMO Panel at its 115th plenary meeting. The risk assessment of these sub-combinations is conducted following a weight of evidence approach that takes as a starting point results of the assessments of the single events, the comprehensive dataset produced for the four-event stack maize, and all the data available for sub-combinations previously assessed by the EFSA GMO Panel as stand-alone dossiers.

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. New Mandates

6.1. Applications under Regulation (EC) No 1829/2003

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

- EFSA-GMO-NL-2019-159 - Request for placing on the market of genetically modified maize DP-202216-6;
- EFSA-GMO-NL-2019-160 - Request for placing on the market of genetically modified oilseed rape NS-B5ØØ27-4.

6.2. Annual Post-market environmental monitoring reports of GM plants

Not applicable

6.3. Other Requests and Mandates

Not applicable

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 Chairs of the ad hoc Working Groups on Synthetic Biology (link to minutes) and GMOs engineered with Gene Drives (link to minutes) updated the GMO Panel about the progress made with these two mandates received from the European Commission.

A scientific officer of the GMO Unit updated the GMO Panel on the progress made with the request from the European Commission to issue a scientific opinion on plants developed using type 1 and type 2 Site-Directed Nucleases and Oligonucleotide Directed Mutagenesis.

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. Other scientific topics for information and/or discussion

Not applicable

9. Any other business

9.1. New 'Transparency' Regulation

The EFSA manager of the ARchitecture Transformation (ART) Programme joined the meeting to present the implementation of the new Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the

food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. This new Regulation will enter into force in March 2021. The ART programme initially focuses on getting EFSA ready for when the Transparency Regulation will enter into force, closing critical gaps in what the EFSA Strategy 2020 promises, and leaning all EFSA core and enabling processes. The ART programme will design and implement the new measures focusing on (1) transparency and confidentiality, (2) engagement and risk communication, (3) sustainability of the scientific production model and (4) governance. Following a detailed presentation, the EFSA ART manager addressed the questions raised by Panel members.

10. 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/133rd-plenary-meeting-gmo-panel

The 134th GMO Plenary meeting will be held on 27-28 November in Parma.