Scientific Panel on GMO

Minutes of the 127th plenary meeting

Held on 28 – 29 November 2018, Parma (Italy)

(Agreed on 29 November 2018)

Participants

- Panel Members:

  Jean-Louis Bresson, Tamas Dalmay, Ian Crawford Dewhurst, Michelle M. Epstein, Leslie George Firbank, Philippe Guerche, Francisco Javier Moreno, Ewen Mullins, Hanspeter Naegeli, Fabien Nogué[1], Nils Rostoks, Giovanni Savoini, Jose Juan Sanchez Serrano, Eve Veromann, Fabio Veronesi

- Hearing Experts[2]:

  None

- European Commission representatives:

  Beatriz Marquez-Garrido[1], Alexandre Huchelmann[1] and Hans Moons (DG SANTE)

- EFSA:

  GMO Unit: Fernando Álvarez, Michele Ardizzone, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Andrea Gennaro, José Ángel Gomez Ruiz, Marina Koukoulanaki, Anna Lanzoni, Ana Martin Camargo, Sylvie Mestdagh, Franco Maria Neri, Irina Olaru, Claudia Paoletti, Konstantinos Paraskevopoulos, Nikoletta Papadopoulou, Tommaso Raffaello, Matthew Ramon and Elisabeth Waigmann.

  Other EFSA Units/Directorates: none

- Observers (in application of the guidelines for observers[3]): None

- Others: Marco Daniele Parenti, Aurelia Santoro, Alberto Del Rio, Claudio Franceschi, Innovamol (for Item 8.1 only)

[1] Remote attendance

[2] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.

[3] http://www.efsa.europa.eu/en/stakeholders/observers.html

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jan Hejatko who could not attend the two-day meeting. Giovanni Savoini presented his apologies for the afternoon of 28 November. Fabien Nogué who joined remotely presented his apologies for the afternoon of both days.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[4] and the Decision of the Executive Director on Declarations of Interest[5], EFSA screened the Annual Declarations of Interest filled in by the experts invited to the present meeting. No conflicts of interest related to the issues discussed in this meeting have been identified during the screening process or at the oral declaration of interest at the beginning of this meeting.

4. Report on written adoption procedure since 126th Plenary meeting

None.

5. Scientific outputs submitted for discussion and/or possible adoption

5.1. Assessment of genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (application EFSA-GMO-NL-2013-112) (EFSA-Q-2013-00079)

Maize MON 89034 × 1507 × NK603 × DAS-40278-9 (hereafter referred to as the 'four-event stack maize') was produced by conventional crossing to combine four single transformation events. The applicant Dow AgroSciences submitted application EFSA-GMO-NL-2013-112 for the placing on the market of the four-event stack maize and all its sub-

[4] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[5] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

combinations, independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003.

A member of the EFSA GMO Unit informed the GMO Panel that application EFSA-GMO-NL-2013-112 was submitted prior to the entry into force of Regulation (EU) No 503/2013.

In this meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The sections of the scientific opinion on (1) the single transformation events and (2) the expression of the inserts were subject to detailed discussions. The EFSA GMO Unit confirmed that the sequence of maize transformation event 1507, as present in the four-event stack maize, was previously assessed in the context of applications EFSA-GMO-DE-2010-86[6] and EFSA-GMO-RX-008[7]. It was also clarified that, in order to assess changes in protein expression levels which may result from potential interactions between the events, the field trials included maize DAS-40278-9 and maize MON 89034 × 1507 × NK603, which is in line with the EFSA GMO Panel's Guidance for risk assessment of food and feed from GM plants[8]. Text of the sections on toxicological and nutritional assessment was also revised to better reflect the available datasets.

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

5.2. Assessment of genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow Agrosciences (application EFSA-GMO-NL-2013-113) (EFSA-Q-2013-00210)

Maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 (hereafter referred to as the 'five-event stack maize') was produced by conventional crossing to combine five single transformation events. The applicant Dow AgroSciences submitted application EFSA-EFSA-GMO-NL-2013-113 for the placing on the market of the five-event stack maize and all its sub-combinations, independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003.

The GMO Panel acknowledged the high similarity between application EFSA-EFSA-GMO-NL-2013-113 and application EFSA-GMO-NL-2013-112 discussed under agenda item 5.1, above. Previous discussions and amendments to the scientific opinion on the four-event stack maize also apply to the five-event stack maize.

[6] https://www.efsa.europa.eu/en/efsajournal/pub/5309
[7] https://www.efsa.europa.eu/en/efsajournal/pub/5347
[8] https://www.efsa.europa.eu/en/efsajournal/pub/2150

Furthermore, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the draft opinion, which will be published on the EFSA website and on the EFSA Journal.

5.3. Assessment of genetically modified soybean A2704-12 for its authorisation renewal for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-009) (EFSA-Q-2017-00721)

Soybean A2704-12 was developed to confer herbicide tolerance. With the submission of application EFSA-GMO-RX-009 under Regulation (EC) No 1829/2003, the applicant Bayer requested the renewal of the initial authorisation for food and feed uses, import and processing of soybean A2704-12 within the European Union.

In June 2018, the European Commission requested EFSA to analyse new nucleic acid sequencing data and updated bioinformatics data for GM soybean A2704-12 and to indicate whether the previous conclusions of the GMO Panel on the risk assessment of GM soybean A2704-12 remain valid. This data was assessed in the context of a separate mandate to EFSA, for which EFSA has published a statement[9], indicating that the new data did not give rise to safety issues and, consequently, the original risk assessment of soybean A2704-12 remains valid.

In this meeting, the GMO Panel scrutinized and revised the draft text, where appropriate. The GMO Panel subsequently adopted the draft 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 (initial application EFSA-GMO-UK-2006-34) (EFSA-Q-2017-00341)

The GMO Panel was informed that maize 3272 was already subject to previous risk assessments by the GMO Panel[10]. The 2013 scientific opinion of the GMO Panel was inconclusive.

Late 2017 EC tasked EFSA and its GMO Panel to assess new datasets on comparative analysis and *de novo* sensitisation to alpha- amylases in order to supplement its previous risk assessments of maize 3272. Upon request the applicant provided a scoping review on the sensitisation potential of alpha-amylases.

[9] https://www.efsa.europa.eu/en/efsajournal/pub/5496

[10] Scientific Opinion on application (EFSA-GMO-UK-2006-34) for the placing on the market of genetically modified maize 3272 with a thermotolerant alpha-amylase, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG and Additional information (I) and (II) provided by the applicant on application for authorization of GM maize 3272 submitted under Regulation (EC) No 1829/2003 (EFSA-GMO-UK-2006-34):

The Food/Feed Working Group reported that it met the applicant[11] to discuss the additional information submitted in light of the scope of application EFSA-GMO-UK-2006-34, i.e. for food and feed uses.

It was concluded that further information is needed prior to completion of this mandate.

6. New Mandates

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

The following application was received:

- Application EFSA-GMO-NL-2018-155 from BASF on cotton T304-40 x GHB119 x COT102

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

EFSA expects to receive the annual post-market environmental monitoring (PMEM) report from Bayer for the 2017 growing season of maize MON 810 in the European Union.

6.3. Other Requests and Mandates

EFSA recently received the following mandate from the European Commission:

- For the assessment of additional information in relation to application EFSA-GMO-NL-2009-75.

A member of the GMO Unit presented to the GMO Panel the context of this mandate: the scientific opinion on application EFSA-GMO-NL-2009-75[12] was inconclusive for products rich in protein, such as rapeseed protein isolates in feed; the European Commission has mandated EFSA to assess a 28-day study provided by the co-applicants BASF and Monsanto. This study is currently under assessment by the GMO Panel's FF WG.

7. Feedback from the Scientific Committee/Scientific Panels, EFSA and the European Commission

7.1. Scientific Committee and other Scientific Panel(s) including their Working Groups

A Vice-Chair of the GMO Panel reported on the 91st plenary meeting of the Scientific Committee. The minutes of this meeting can be found here.

In response to mandates from the European Commission, EFSA established two *ad hoc* Working Groups (WGs), i.e. on GMOs engineered

[11] More details will be available in the minutes of the Food & Feed Working group at https://www.efsa.europa.eu/sites/default/files/wgs/gmo/gmoffminutes2018.pdf

[12] https://www.efsa.europa.eu/en/efsajournal/pub/4466

with Gene Drives, and on Synthetic Biology[13]. The Chairs of these two WGs were appointed by the Chair of the GMO Panel in consultation with the EFSA GMO Unit:

- Leslie Firbank as Chair of the 'Gene Drive' WG;
- Ewen Mullins as Chair of the 'Synthetic Biology' WG.

7.2. EFSA including its Working Groups /Task Forces

None

7.3. European Commission

The representative of the European Commission provided feedback on recent meetings held at the European Commission and informed the GMO Panel that next PAFF meeting will take place on 3 December 2018. At this forthcoming PAFF meeting, the EFSA GMO Unit will present four scientific opinions recently adopted by the GMO Panel.

8. Other scientific topics for information and/or discussion

8.1. Procurement on adjuvanticity/ immunogenicity assessment of proteins: presentation by contractor

Early 2017 EFSA launched a call for tender to conduct a literature review in support to adjuvanticity/immunogenicity assessment of proteins. The external contractor appointed to that task presented the final report that will be published on the EFSA website.

The contractor addressed the questions from the GMO Panel and EFSA GMO Unit on the literature review itself and on considerations for the risk assessment of food allergens. The discussion also touched upon the following issues: the research to be conducted in the future that could contribute to the field of immunogenicity and adjuvanticity; the use of animal models; the factors defining an immunological response; the use of artificial intelligence in processing data from humans; the possibilities to improve predictability of an immune response.

The GMO Panel and Unit discussed also the next steps and certain details of the report that are directly relevant for the work of the GMO Panel.

8.2. Strategy for the risk assessment of GM oilseed rape Ms11, and Ms11xRf3 (applications EFSA-GMO-BE-2016-138, EFSA-GMO-NL-2017-143)

A member of the Unit presented to the GMO Panel the background of these applications, the scientific peculiarities of male sterile oilseed rape Ms11, the minimum data requirements for field trial, the technical limitations related to the suitability of test material for comparative

[13] For further details, please consult the minutes of the 126th plenary meeting of the GMO Panel

analysis and for feeding studies, and possible scenarios for proceeding with the risk assessment.

According to Regulation (EU) No 503/2013, all single transformation events of a higher stack should be risk assessed before starting the risk assessment of the stack. However, applicants may derogate to the aforementioned Regulation provisions subject to technical or scientific justifications; the European Commission confirmed that the single rapeseed Ms11 needs to be evaluated first and independently from the double stack Ms11xRf3.

The GMO Panel agreed that further consideration is needed.

9. Any other business

9.1. Feedback from the *ad hoc* annual meeting with industry representatives (24-25 October 2018)

The meeting provided an opportunity for open dialogue and the discussion focussed on:

- Technical topics such as e.g. the quality of DNA sequencing for the molecular characterisation of genetically modified plants (GMPs), the assessment of human dietary exposure in the context of marketing applications for GM food and feed, and the evaluation of 90-day toxicological studies with rodents; as well as
- Recent EFSA's experiences pertaining to the administrative processing of marketing applications for GM food and feed in the European Union.

The meeting took place in a constructive atmosphere and marks an important step in enhanced dialogue among the parties. The slides presented by EuropaBio and EFSA are now published online at https://www.efsa.europa.eu/en/events/event/181024-1.

9.2. Feedback from the GMO Network meeting

A member of the GMO Unit provided feedback from the meeting with MS representatives, held on 8-9 November. The topics discussed comprised: EFSA activities on GMOs, recent explanatory notes and technical guidance published EFSA, and activities conducted in MS on gene drive and synthetic biology. The minutes of the meeting and the presentations are available on the EFSA website.

9.3. Upcoming training in ERA for Panel members

A member of the EFSA GMO Unit informed the Panel of an upcoming training on PLH/GMO environmental risk assessment. The training will be held by an external contractor and dates still need to be confirmed (likely first half of February). Expression of interest should be sent to the Unit.

10. Adoption of the minutes of the current meeting

The minutes of the current meeting were adopted on 29 November 2018.