GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 141st MEETING

Held on 25-26 November 2020, TELE/WEB

(Agreed on 4th December 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

- European Commission and/or Member States representatives:

Alexandre Huchelmann, Juliette Margueritte and Olga Orlova (DG SANTE)

- EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Federica Ceriani, Giacomo De Sanctis, Yann Devos, Silvia Federici, Antonio Fernández Dumont, Andrea Gennaro, José Ángel Gomez Ruiz, Dafni Kagkli, Anna Lanzoni, Paolo Lenzi, Sylvie Mestdagh, Franco Maria Neri, Lorenz Oberkofler, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Franz Streissl, Riccardo Vriz

Other Unit: none

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

[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

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], 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 140th GMO Plenary meeting

The minutes of the 140th Plenary meeting were adopted by written procedure and published on 12 November 2020.

5. Scientific topic(s) for discussion

5.1 Application for renewal of authorisation of food and feed containing, consisting of or produced from GM maize Bt11 and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation 1829/2003 (Commission Decision 2010/419/EU) (EFSA-GMO-RX-016) (GMO-EFSA-Q-2018-00799).

Maize Bt11 was developed to confer resistance to certain lepidopteran pests and tolerance to glufosinate ammonium-based herbicides. Maize event Bt11 was authorized for products containing, consisting of, or produced from this GM maize, excluding cultivation in the EU, in the European Union in 2010 (see Commission Decision 2010/419/EU). In 2018 the applicant asked the European Commission to renew the authorisation for the placing on the market of maize Bt11 and submitted application EFSA-GMO-RX-016 in support to its request.

The applicant provided a set of information, including a *de novo* 90-day oral repeated dose toxicity study in rat with maize Bt11, that was collected or commissioned during the authorization period. The GMO Panel assessed application EFSA-GMO-RX-016 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines.

The GMO Panel 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.

5.2 Application for authorization of genetically modified maize 1507 x MON810 x MIR162 x NK603 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Pioneer Hi-Bred International Inc. (EFSA-GMO-NL-2015-127) (GMO-EFSA-Q-2015-00841).

The four-event stack maize 1507 x MON810 x MIR162 x NK603 was obtained by conventional crossing of four single transformation events 1507, MON810, MIR162 and NK603. The scope of application

[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

EFSA-GMO-NL-2015-127 is for food and feed uses, import and processing in the European Union (EU) of the herbicide-tolerant and insect-resistant maize 1507 x MIR162 x MON 810 x NK603 and all its sub-combinations independently of their origin.

Questions were raised and addressed throughout 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.

5.3 Application for authorization of genetically modified maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 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-2017-139) (GMO-EFSA-Q-2017-00115).

The six-event stack maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 was obtained by conventional crossing of six single transformation events MON 87427, MON 87460, MON 89034, 1507, MON 87411 and 59122. The scope of application EFSA/GMO/NL/2017/139 is for import, processing, and food and feed uses within the European Union (EU) of maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 and all its subcombinations independently of their origin.

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.

5.4 Statement of the GMO Panel on *in vitro* protein digestibility test in allergenicity and protein safety assessment of GM plants (GMO-EFSA-Q-2020-00314)

The GMO Panel issued in 2017 a guidance document on the allergenicity assessment of GM plants[4]. The guidance document addressed the following topics, i.e. non-IgE-mediated adverse immune reactions to foods, *in vitro* protein digestibility tests and endogenous allergenicity. In relation to the *in vitro* protein digestibility tests, the GMO Panel considered that additional investigations were needed before any updated recommendations and guidance for applicants could be provided. EFSA launched an external contract to investigate a refined protocol for *in vitro* protein digestion. The final report was recently published[5].

The Chair of the ad hoc Working group on allergenicity, Javier Moreno, explained the criticisms on pepsin resistance test and the findings of recent research, including the outcome of the external report 'Refined Protocol for *in vitro* digestion of proteins for allergenicity assessment'[5].

Questions were raised and addressed throughout the reading of the different sections of the draft statement. The GMO Panel revised the draft text, where appropriate, and subsequently adopted the statement, which will be published on the EFSA website and in the EFSA Journal. The GMO Panel acknowledged the work of the dedicated ad hoc Working Group. Furthermore, it was highlighted the

[4] https://www.efsa.europa.eu/en/efsajournal/pub/4862

[5] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2019.EN-1765

efforts made on stakeholders' engagement[6] and the valuable input received from the consultative group.

In response to the internal mandate, the GMO Panel will work on a Scientific Opinion providing recommendations for future developments, including research needs, in the field of allergenicity assessment, and protein safety in general. The scientific output from the GMO Panel is expected by the last quarter of 2021.

6. New Mandates

6.1 Applications under Regulation (EC) No 1829/2003

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

- EFSA-GMO-NL-2020-169 on oilseed rape MON 94100 for all food and feed uses, import and processing **(GMO-EFSA-Q-2020-00749)**

6.2 Annual Post-market environmental monitoring reports of GM plants

No new mandate was received.

6.3 Other Requests and Mandates

No new mandate was received.

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 Panel Chair, Hanspeter Naegeli, 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 progress with GMO authorisations and recent meetings with Member States (MS). EFSA presented the recently adopted scientific opinions on gene drive, synthetic biology and SDN/ODM at the regulatory committee – Directive 2001/18/EC on 12 November. Member States called for an in-depth EU debate on these new techniques. The European Commission is in contact with EFSA for discussion on possible future work.

8. Other scientific topics for information and/or discussion

- none

[6] https://www.efsa.europa.eu/en/news/allergenicity-assessment-gm-plants-stakeholders-support-working-group

9. Any other business

9.1 Protocol development for EC mandate on in vitro random mutagenesis

A protocol is to be developed by scientific Panels when they receive from European Commission, European Parliament or Member States, the so called "generic mandates". At its last meeting on 9th November, the GMO Panel addressed the recommendations to EFSA Scientific Panels for the protocol development for non-applications scientific assessments.

The GMO Panel will implement this approach to the mandate on *in vitro* random mutagenesis received from the European Commission. The Working Group of the GMO Panel on Molecular Characterisation discussed the protocol development on 13 November. Representatives of the European Commission participated to the meeting for joint discussion and decision on the scope of the mandate at stake.

9.2 Follow up to previous plenary discussion on EFSA-GMO-RX-017

At its meeting on 14-15 October 2020, the GMO Panel reviewed the draft text of the scientific opinion on application EFSA-GMO-RX-017 except the section on the evaluation of literature pending additional information. EFSA has received additional information requested and revised the text of the opinion accordingly. The draft scientific opinion will be proposed to Panel members for adoption by written procedure.

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/141st-plenary-meeting-gmo-panel

The 142nd GMO Plenary meeting will be held on 27-28 January 2021, online.