European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 98th Plenary meeting of the Scientific Panel on GMO

Held on 27-29 May 2015, Parma

(Agreed on 24 June 2015)

Participants

- **Panel members**:

Salvatore Arpaia, Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Huw Jones, József Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Hanspeter Naegeli, Kaare Nielsen, Jaroslava Ovesná, Joe Perry, Nils Rostoks and Christoph Tebbe.

- **Hearing experts**: none.
- **EFSA:**

GMO Unit: Fernando Alvarez, Michele Ardizzone, Herman Broll, Yann Devos, Zoltán Divéki, Antonio Fernández Dumont, Andrea Gennaro, Viola Ghio, Ana Gomes, Anna Lanzoni, Yi Liu, Sylvie Mestdagh, Franco Neri, Irina Olaru, Claudia Paoletti, Konstantinos Paraskevopoulos, Matthew Ramon and Elisabeth Waigmann.

- **Other EFSA Units/Directorates:** none.
- **European Commission observers:** Maria Mirazchiyska (DG SANTE).
- **Observers (in application of the guidelines for observers)**: none.
- **Others:** none.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hilde-Gunn Hoen-Sorteberg for the entire duration of the meeting; Andrew Chesson, Jürgen Gropp, Lieve Herman, Hanspeter Naegeli apologised for 29 May 2015.

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[1] and the Decision of the Executive Director implementing this Policy regarding

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

Declarations of Interests[2], EFSA screened the Annual Declarations of Interest (ADoIs) and the Specific Declarations of Interest (SDoIs) filled in by the experts invited to the present meeting. No conflicts of interests relating to the issues discussed in this meeting were identified during the screening process or in the Oral Declaration of Interest (ODoI) at the beginning of this meeting.

4. Agreement of the minutes of the 97th Plenary meeting held on 15-16 April 2015, Parma

The minutes of the 97th GMO Plenary meeting (15-16 April 2015) were adopted and will be published on the EFSA website at: EFSA Event: 97th plenary meeting of GMO Panel

5. Scientific outputs submitted for discussion and possible adoption

5.1 Application for authorisation of genetically modified soybean MON 87708 x MON 89788 for all food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2012-108) (EFSA-Q-2012-00442)

Single events MON 87708 and MON 89788 were combined to produce the stack two-event soybean MON 87708 × MON 89788. The EFSA GMO Panel previously assessed the two single events and did not identify safety concerns in the context of their scope. No new data on single soybean events leading to a modification of the original conclusions on their safety were identified. Agronomic and phenotypic characteristics, as well as compositional data of soybean MON 87708 × MON 89788, did not give rise to food/feed and environmental safety concerns. The EFSA GMO Panel considers that there is no reason to expect interactions between the single events that could impact on the food and feed safety and the nutritional properties of soybean MON 87708 × MON 89788. There are no indications of an increased likelihood of establishment and spread of feral soybean plants. Considering the scope of application EFSA-GMO-NL-2012-108, potential interactions with the biotic and abiotic environment were not considered to be a relevant issue. The unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87708 × MON 89788 to environmental bacteria does not give rise to any safety concern. The post-market environmental monitoring plan and reporting intervals are in line with the scope. In conclusion, the EFSA GMO Panel considers that the information available for soybean MON 87708 × MON 89788 addresses the scientific comments raised by Member States and that the soybean MON 87708 × MON 89788, as described in this application, is as safe as its non-GM comparator and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of its scope.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: EFSA GMO Panel publications.

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

5.2 Application for authorisation of genetically modified maize MON 87427 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-BE-2012-110) (EFSA-Q-2012-00692)

Maize MON 87427 was developed by *Agrobacterium tumefaciens*-mediated transformation to express the CP4 5-enolpyruvyl-shikimate-3-phosphate synthase (EPSPS) protein, in all tissues except for the male reproductive tissues, conferring tissue-selective tolerance to glyphosate. The molecular characterisation of maize MON 87427 did not give rise to safety issues. Agronomic and phenotypic characteristics as well as compositional data of maize MON 87427 did not raise food/feed and environmental safety concerns. No differences in the compositional data requiring further safety assessment were identified. There were no concerns regarding the potential toxicity and allergenicity of the newly expressed CP4 EPSPS protein. The nutritional value of maize MON 87427 is not expected to differ from that of non-genetically modified (GM) maize varieties. There are no indications of an increased likelihood of establishment or spread of feral maize plants. Given its intended use in food and feed, interactions with the biotic and abiotic environment were not considered an issue. Risks associated with an unlikely, but theoretically possible, horizontal gene transfer from maize MON 87427 to bacteria have not been identified. The monitoring plan and reporting intervals are in line with the scope of the application for maize MON 87427. In conclusion, the EFSA Panel on Genetically Modified Organisms considers that the information available for maize MON 87427 addresses the scientific comments raised by Member States and that the maize MON 87427, as described in this application, is as safe as its conventional counterpart and non-GM reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of the application.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: EFSA GMO Panel publications.

5.3 Application for authorisation of genetically modified oilseed rape MS8 x RF3 x GT73 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2009-75) (EFSA-Q-2009-00890)

The Panel discussed the draft scientific opinion. Further discussion, pending arrival of additional information, is needed.

5.4 Application for authorisation of genetically modified maize Bt11 x MIR162 x MIR604 x GA21 for food and feed uses, import and processing, submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2009-66) (EFSA-Q-2009-00444)

The Panel discussed the draft scientific opinion. Further discussion, pending arrival of additional information, is needed.

5.5 Guidance Document for the agronomic and phenotypic characterisation of genetically modified plants (EFSA-Q-2013-00606)

This document provides guidance for the agronomic and phenotypic characterisation of genetically modified (GM) plants and clarifies the EFSA GMO Panel's view on how agronomic and phenotypic data support the risk assessment of GM plants. Specific recommendations are given on (1) the selection of sites and test materials; (2) the quality and design of field trials; (3) the selection of relevant agronomic and phenotypic endpoints; and (4) data analysis. The guidance proposes a comprehensive and harmonised approach for the agronomic and phenotypic characterisation of GM plants, which should ensure the best use of agronomic and

phenotypic data for the comparative analysis of GM plants and derived food and feed products, and for their food and feed and environmental risk assessment.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: EFSA GMO Panel publications.

5.6 Guidance Document for the risk assessment of the renewal of GM plant products authorised under Regulation (EC) No 1829/2003 (EFSA-Q-2013-00684)

According to Articles 11(6) and 23(6) of Regulation (EC) No 1829/2003 on genetically modified food and feed, the European Food Safety Authority should publish detailed guidance to assist applicants in the preparation and presentation of their applications for the renewal of authorisations of that genetically modified food and feed. This guidance document describes the data requirements for renewal applications, which should contain a copy of the authorisation, post-market monitoring and post-market environmental monitoring reports, systematic search and evaluation of literature, updated bioinformatics and any additional documents or studies performed by or on behalf of the applicant during the authorisation period. The applicant is requested to assess the collected information and conclude whether the previous risk assessment remains valid. The applicant can also propose amending or complementing the original conditions of the authorisation, including the monitoring plan(s).

The opinion was adopted by the Panel and will be published on the EFSA website at: EFSA GMO Panel publications.

5.7 Proposal from the GMO for a self-task activity to supplement its previous risk mitigation measures reducing exposure of non-target Lepidoptera to maize MON 810, Bt11 or 1507 pollen (EFSA-Q-2015-00059)

Using mathematical modelling, the EFSA GMO Panel has previously quantified the risk to non-target (NT) Lepidoptera of conservation concern, potentially occurring within protected habitats, associated with the ingestion of Bt-maize pollen deposited on their host plants. To reduce the estimated larval mortality to a negligible level, an isolation distance of 20 and 30 m was recommended between protected habitats and the nearest fields of maize MON 810/Bt11 and 1507, respectively. Here, the EFSA GMO Panel refines its model predictions, accounting for newly reported information on maize pollen deposition over long distances. For its calculations, the EFSA GMO Panel considered three exposure scenarios at a range of isolation distances, at two protection levels and for a range of lepidopteran species, including hypothetical ones, with a wide spectrum of sensitivities to Bt toxins. An analysis of various sources of uncertainties affecting the exposure of NT Lepidoptera to Bt-maize pollen was conducted, in order to provide quantitative estimates of realistic exposure levels. The EFSA GMO Panel therefore provides risk managers with a tool to estimate and mitigate the risk for NT Lepidoptera of conservation concern. In contrast to its previous outcomes obtained for unrealistically large levels of exposure that would not be expected in practice, the EFSA GMO Panel reports here mortality estimates for a more realistic level of exposure. The EFSA GMO Panel concludes that its previous recommendation for a 20 m isolation distance around protected habitats, within which maize MON810/Bt11 should not be cultivated, remains valid. New calculations show that the previously recommended isolation distance of 30 m from the nearest maize 1507 field would still protect NT Lepidoptera with known levels of sensitivity, including the 'highly-sensitive' *Plutella xylostella*. Should hypothetical species with greater sensitivities exist, larger isolation distances would be needed to ensure the desired level of protection.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: EFSA GMO Panel publications.

6 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

One application was received:

Application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-RX_1_1507(2)) (EFSA-Q-2015-00342)

6.2 Annual post-market environmental monitoring reports of GM plants

None.

6.3 Other requests and mandates

Two mandates were received:

Mandate for the assessment of scientific elements in publication Transgene Expression and Bt protein content in transgenic Bt maize (MON 810) under optimal and stressful environmental conditions by Trtikova et al., 2015 (EFSA-Q-2015-00382)

Mandate for the RA of the GMO "Arsenic Biosensor", a derivative of Bacillus subtilis 168 trpC2, for the purpose of its inclusion in Part C Annex II of Council Directive 2009/41/EC (EFSA-Q-2015-00383)

EFSA also informed the Panel on the call for tender “Literature review of baseline information to support the risk assessment of RNAi-based GM plants (OC/EFSA/GMO/2015/01)”, which was published on the EFSA website.

7 Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA and the European Commission

7.1 Scientific Committee and other Scientific Panels

None.

7.2 EFSA including its Working Groups/Task Forces

None.

7.3 European Commission

The European Commission (EC) representative updated the Panel on applications that are undergoing authorisation procedures and on generic mandates.

8 Other scientific topics for information and/or discussion

None.

9 Any other business

9.1 Panel Members reporting on meetings / conferences they attended on behalf of EFSA

A Panel member reported on a meeting held in the Austrian Agency for Health and Food Safety (AGES), where he presented the EFSA GMO Panel’s work.

9.2 Feedback from the GMO Network meeting

EFSA and Panel members who had attended the GMO Network meeting (12-13 May 2015) provided feedback to the Panel on the discussions. The meeting minutes will be published at EFSA: Events.