European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 85th Plenary meeting of the Scientific Panel on GMO

Held on 23–24 October 2013, Parma

(Agreed on 4 December 2013)

Participants

- **Panel members**:

Salvatore Arpaia, Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Hilde-Gunn Opsahl Hoen-Sorteberg, Huw Jones[1], Jozsef Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Hanspeter Naegeli, Kaare Nielsen[1], Jaroslava Ovesná, Joe Perry, Nils Rostoks and Christoph Tebbe.

- **Hearing experts**:

Clare Mills[2] and Justin Marsh.[2]

- **EFSA:**

GMO Unit: Jaime Aguilera, Herman Broll, Yann Devos, Zoltán Divéki, Anders Falk, Antonio Fernandez Dumont, Andrea Gennaro, Ana Gomes, Anna Lanzoni, Yi Liu, Sylvie Mestdagh, Irina Olaru, Claudia Paoletti, Matthew Ramon and Elisabeth Waigmann.

- **Other EFSA Units/Directorates:** none
- **European Commission observers:** Kaja Kantorska (DG SANCO); Marco Mazzara[3], Alex Patak[3] and Mauro Petrillo[3] (JRC-ISPC).
- **Observers (in application of the guidelines for observers)**: none.
- **Others:** none.

1. Welcome and apologies for absence

The Chair welcomed the participants.

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 implementing this Policy regarding

[1] Attended via teleconference.
[2] Attended for item 8.b) only.
[3] Attended via teleconference for item 8.a) only.

Declarations of Interests[5], EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI please refer to Annex I.

4. Agreement of the minutes of the 84th Plenary meeting held on 11–12 September 2013, Parma

The minutes of the 84th GMO Plenary meeting (11–12 September 2013) were adopted and will be published at: EFSA Event: 84th plenary meeting of GMO Panel

5. Scientific outputs submitted for discussion and possible adoption

5.1 Scientific Opinion on a request from the European Commission for the assessment of the new scientific elements supporting the prolongation of prohibition of the placing on the market of maize MON 863 for food and feed purposes in Austria (EFSA-Q-2013-00310)

Austria notified the European Commission of its new scientific elements justifying the prolongation for three additional years of the implementation of a national safeguard measure prohibiting the placing on the market of genetically modified maize MON 863 in Austria. Subsequently, the European Commission asked the European Food Safety Authority (EFSA) to assess the new scientific information supporting the prolongation of the prohibition. Having considered the information provided by Austria and all relevant scientific publications, the EFSA Panel on Genetically Modified Organisms (GMO Panel) concluded that the new scientific elements submitted by the Austrian Authorities do not lead EFSA to reconsider the conclusions in its opinions on maize MON 863.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: http://www.efsa.europa.eu/en/publications.htm

5.2 Statement supplementing the environmental risk assessment conclusions and risk management recommendations on genetically modified insect-resistant maize 59122 for cultivation in the light of new scientific information on non-target organisms and regionally sensitive areas (EFSA-Q-2013-00607)

Following a request from the European Food Safety Authority (EFSA), the Panel on Genetically Modified Organisms (GMO Panel) was asked to supplement its environmental risk assessment conclusions and risk management recommendations on maize 59122 for cultivation in the light of new scientific information on non-target organisms and regionally sensitive areas. Having considered additional information relevant to the assessment of potential adverse effects of maize 59122 on non-target organisms, the Panel must revise two of its previous environmental risk assessment conclusions, invalidating its earlier statement on the environmental safety of maize 59122 in its 2013 Scientific Opinion. A gap in the event-specific data on the honeybee study performed by Maggi (2001) was identified, as a result of which uncertainty over the occurrence of adverse effects on pollinators due to potential unintended changes in maize 59122 remains. Therefore, the Panel is no longer in a position to complete its assessment on the occurrence of adverse effects on pollinators. The Panel reassessed the available dataset on ladybirds, including the Califf and Ostrem (2009) study, and considers the latter study does not enable resolving the remaining

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

scientific uncertainty on the potential toxicity of the binary Cry34Ab1/Cry35Ab1 proteins on *Coccinella septempunctata* or other ladybirds. In both cases, the Panel recommends that an additional laboratory study is performed prior to authorisation. The Panel considered regionally sensitive areas in its assessment, but regards it as premature to recommend specific risk management strategies for susceptible insect species potentially found within and nearby such areas owing to the inconclusive nature of the assessment of potential adverse effects of maize 59122 on non-target organisms

The GMO Panel also supported the advisability of continued collaboration with the Member State performing the initial environmental risk assessment of a cultivation application, after the submission of its environmental risk assessment report. This would allow the GMO Panel to invite that Member State to appraise the additional information requested by the GMO Panel, and to consider these appraisals before finalising its scientific opinion. In addition, a revision of the template table offering a schematic summary of NTO studies outlined in EFSA's Submission guidance[6] was discussed and was recommended for implementation when appropriate.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: http://www.efsa.europa.eu/en/publications.htm

5.3 Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from BASF Plant Science Company GmbH on genetically modified potato EH92-527-1 in 2012 (EFSA-Q-2013-00439)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) assessed the monitoring report, provided by BASF, on the genetically modified (GM) potato EH92-527-1 (variety Amflora) for the 2012 growing season. Because of the discontinuation of the GM potato cultivation in the European Union in 2012, the 2012 monitoring report contained a limited information package, mainly the results of the 2012 monitoring study for volunteers within and around the fields cropped with the GM potato in 2010. The EFSA GMO Panel concludes that GM potato volunteers can be controlled by the applied weed control practices but cannot conclude on the absence of enhanced fitness of the GM potato due to data limitations and flaws in the study design. Hence, the EFSA GMO Panel makes appropriate recommendations. Accounting for the biology of the crop, the GM trait and the common management practices in potato cropping, the EFSA GMO Panel considers it is unlikely that a potential change in fitness or persistence would significantly alter the ability of GM volunteers to establish. Moreover, the EFSA GMO Panel does not consider the occurrence of potato volunteers as an environmental concern but rather as a crop management issue. Therefore, the EFSA GMO Panel concludes that the information provided in the 2012 monitoring report does not indicate any adverse effects of potato EH92-527-1 on the environment or human and animal health. Therefore, the outcomes of the 2012 monitoring report do not invalidate the conclusions of the EFSA GMO Panel's previous opinions on potato EH92-527-1.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: http://www.efsa.europa.eu/en/publications.htm

[6] EFSA Guidance on the submission of applications for authorisation of genetically modified food and feed and genetically modified plants for food and feed uses under Regulation (EC) 1829/2003. EFSA Journal 2001;9(7):2311. 27 pp. doi:10.2903/j.efsa.2011.2311.

5.4 Request to assess maize MON 810 monitoring report for the 2011 cultivation season provided by Monsanto (EFSA-Q-2013-00440)

The EFSA GMO Panel discussed the maize MON 810 monitoring report for the 2011 cultivation season. The draft scientific opinion will be discussed in the following GMO Panel Plenary meeting (4-5 December 2013).

5.5 Application for authorisation of genetically modified Soybean 305423 for food and feed uses, submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2007-45) (EFSA-Q-2007-122)

The EFSA GMO Panel discussed the draft scientific opinion, with a particular focus on comparative analysis and food/feed safety assessment. Further discussion is needed.

6. New mandates

6.1 Applications under Regulation (EC) No 1829/2003

None.

6.2 Annual post-market environmental monitoring reports of GM plants

None.

6.3 Other requests and mandates

None.

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

7.1 Scientific Committee and other Scientific Panels

A member of the GMO Panel provided feedback from a meeting of the Emerging Risks WG of the Scientific Committee and suggested it would be useful for the Panel to learn more about the activities of this WG. EFSA will schedule a presentation on this subject at a future meeting.

7.2 Working Groups

The GMO Panel discussed a proposal from the Food and Feed Safety WG regarding the structure of scientific opinions for GM stacked events. Further discussion is needed.

7.3 EFSA

The GMO Panel was informed that Bernhard Url had been appointed as Acting Executive Director of EFSA at the 58th meeting of the EFSA Management Board on 24 October.

7.4 European Commission

A member of the European Commission informed the GMO Panel about applications that are undergoing authorisation procedures and on other activities.

8. Other scientific topics for information and/or discussion

8.1 Sequencing of stacked events

Representatives of the European Union Reference Laboratory for GM Food and Feed, JRC, presented to the GMO Panel their activities in relation to applications submitted for authorisation under Regulation (EC) No 1829/2003, in particular to applications for GM stacked events. Considering that the Implementing Regulation (EC) No 503/2013 requires the resequencing of events in the GM stack, the JRC representatives explained their approach to sequencing stacked events and possible changes following the coming into force of the aforementioned Regulation.

8.2 Allergenicity literature reviews

An external contractor presented to the GMO Panel the outcome of the EFSA procurement on "Literature reviews on non-IgE-mediated adverse reactions to foods and *in vitro* digestibility tests for allergenicity assessment of food and feed". The two reports prepared by the contractor in the context of this procurement will be published on the EFSA website upon finalisation.

9. Any other business

9.1 Panel members reporting on meetings and/or conferences they attended on behalf of the EFSA

None.

9.2 Comparison between EC's IR 503/2013 and EFSA's Guidance on the RA of food and feed from GM plants

A member of the EFSA GMO Unit informed the Panel of the new requirements of the Implementing Regulation (EC) No 503/2013, in comparison with the EFSA Guidance for the risk assessment of food and feed from GM plants, published in 2011. The differences between these two documents were explained, together with how the new Regulation would influence the evaluation of applications for GM plants. The Panel was informed of the EFSA Task Force[7] set up to provide clarity concerning the objectives of the mandatory 90-day rodent feeding study in GM risk assessment and more detailed instructions on how to apply existing EFSA Guidance.

9.3 Feedback from the GMO Technical meeting with applicants

The Head of the GMO Unit provided feedback from the GMO Technical meeting with applicants, which took place on EFSA premises on 15 October 2013. This meeting was organised by EFSA's APDESK Unit, in collaboration with the GMO Unit, and aimed at promoting an exchange of views on administrative and scientific issues related to the preparation, submission and risk assessment of GMO applications.

10. Questions from and answers to observers (in application of the Guidelines for observers)

As there were no observers attending the meeting, other than representatives from DG SANCO, European Commission, this item is not applicable.

[7] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00718

Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)[8]

CONFLICT OF INTEREST: With regard to this meeting, Mr Kaare Nielsen declared the following interest: He participated as an external advisor in a research project on the Prevalence of Antibiotic Resistance for the Austrian Agency for Health and Food Safety. He will also co-author a paper on the research results. Results derived from this project are included in the data package supporting the Austrian Safeguard Clause. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of interest.

This results in it being impossible for the expert to be present when agenda item 5.1, "Scientific Opinion on a request from the European Commission for the assessment of the new scientific elements supporting the prolongation of prohibition of the placing on the market of maize MON 863 for food and feed purposes in Austria (EFSA-Q-2013-00310)", is discussed, voted on or in any way processed by the scientific group concerned.

CONFLICT OF INTEREST: With regard to this meeting, Mr Christoph Tebbe declared the following interest: The applicant company for the Amflora potato, BASF, has previously commissioned a study on potato from the expert's institute, in which the expert participated. Consequently, as stated in the expert's ADOI, he declared an interest for all potato and for all BASF applications and linked activities. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of interest.

This results in it being impossible for the expert to be present when agenda item 5.3, "Scientific Opinion on the annual Post-Market Environmental Monitoring (PMEM) report from BASF Plant Science Company GmbH on genetically modified potato EH92-527-1 in 2012 (EFSA-Q-2013-00439)", is discussed, voted on or in any way processed by the scientific group concerned.

[8] The Annual Declarations of Interests were screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.