European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 77th Plenary meeting of the Scientific Panel on GMO

Held on 17–18 October 2012, Parma

(Agreed on 5 December 2012)

Participants

- **Panel members**:

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

- **Hearing experts**:

Josep Casacuberta.[2]

- **EFSA:**

GMO Unit: Anna Christodoulidou, Yann Devos, Zoltán Divéki, Antonio Fernández Dumont, Andrea Gennaro, Yi Liu, Sylvie Mestdagh, Irina Olaru, Claudia Paoletti, Nancy Podevin, Stefano Rodighiero and Elisabeth Waigmann.

- **Other EFSA Units/Directorates:** none.
- **European Commission observers:** Dorothée André and Sabine Pelsser, European Commission.
- **Observers (in application of the guidelines for observers[3]**: none.
- **Others:** none

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Huw Jones.

2. Adoption of agenda

The agenda was adopted without changes.

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[1] Present only on 17 October.
[2] Present via teleconference for item 6.4 only.
[3] http://www.efsa.europa.eu/en/stakeholders/observers.htm

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[4] and the Decision of the Executive Director implementing this Policy,[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. No conflicts of interests related to the issues discussed in this meeting have been 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 76th Plenary meeting held on 5–6 September 2012, Parma

The minutes of the 76th GMO Plenary meeting (5–6 September 2012) were adopted and will be published at: EFSA Event: 76th Plenary meeting of GMO Panel.

5. Report on written procedures since the 76th Plenary meeting

The Scientific Opinion on an application for the placing on the market of herbicide-tolerant, increased oleic acid genetically modified soybean MON 87705 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto (EFSA-GMO-NL-2010-78) (EFSA-Q-2010-00165) was unanimously adopted by written procedure on 28 September 2012 and will be published on the EFSA website at: http://www.efsa.europa.eu/en/publications.htm

6. Scientific outputs submitted for discussion and possible adoption (use as appropriate)

6.1 Scientific Opinion on a request to gather all available information related to the environmental risk assessment of maize 1507 for cultivation (EFSA-Q-2012-00712)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) compiled its previous risk assessment conclusions and risk management recommendations on the genetically modified insect-resistant maize 1507, and considered their validity in the light of new relevant scientific publications published from 2005 onwards. The EFSA GMO Panel performed a search of the scientific literature published between 2005 and September 2012, and identified 61 peer-reviewed publications containing evidence specific to the risk assessment and/or management of maize 1507, of which two publications were relevant for the food and feed safety assessment and 34 were relevant for the environmental risk assessment and/or risk management. None of these publications reported new information that would invalidate the previous conclusions on the safety of maize 1507 made by the EFSA GMO Panel. Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize 1507, as well as its previous recommendations on risk mitigation measures and monitoring, remain valid and applicable.

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

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

6.2 Scientific Opinion on a request for additional evidence to support elements of the EFSA Scientific Opinion, updating the evaluation of the environmental risk assessment and risk management recommendations on the mortality of non-target Lepidoptera where maize 1507 is cultivated (EFSA-Q-2012-00819)

The EFSA GMO Panel was asked by the European Commission to apply its mathematical model to simulate and assess potential adverse effects resulting from the exposure of non-target Lepidoptera to maize 1507 pollen under hypothetical agricultural conditions, and to provide information on the factors affecting the insect resistance management plan, additional to that in its 2011 Scientific Opinion updating the conclusions of the environmental risk assessment and risk management recommendations on maize 1507. Here, risk managers are provided with additional evidence and further clarifications to those previous conclusions and risk management recommendations. This Scientific Opinion provides background scientific information to inform the decision-making processes; the EFSA GMO Panel reiterates that risk managers should choose risk mitigation and management measures that are proportionate to the level of identified risk according to the protection goals pertaining to their regions.

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

6.3 Application for authorisation of genetically modified maize MON 87460 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2009-70) (EFSA-Q-2009-00661)

Maize MON 87460 was developed through *Agrobacterium*-mediated transformation and expresses the cold shock protein B (CspB) from *Bacillus subtilis* and neomycin phosphotransferase II (NPTII) from *Escherichia coli* to reduce yield loss under water-limited conditions. Maize MON 87460 contains a single copy of the *csp*B and *npt*II expression cassettes. Bioinformatic analysis of the flanking sequences and the open reading frames spanning the junctions created by the transformation did not raise safety issues. Comparative analyses established that, besides the expression of the CspB and NPTII proteins, some differences were observed in the composition of forage and grain produced from maize MON 87460 compared with its conventional counterpart, when grown under well-watered conditions. Given the magnitude of these changes and the characteristics of these endpoints, the EFSA GMO Panel concluded that the observed differences do not raise safety concerns for humans and animals. Under stressful conditions, maize MON 87460 can show enhanced agronomic performance characteristics and some differences in chemical composition in comparison with its conventional counterpart. Given the intended trait, the observed differences were not unexpected, and raised no safety concerns. The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the CspB and NPTII proteins, or of maize MON 87460. Maize MON 87460 is as nutritious as any other maize and can be used in the same way. In cases of spillage, there are no indications of increased likelihood of the establishment or survival of feral maize plants MON 87460. Risks associated with a theoretically possible horizontal gene transfer from maize MON 87460 to bacteria have been analysed in detail, including different scenarios of integration, and did not raise safety concerns for the intended uses of maize MON 87460. The post-market environmental monitoring plan and reporting intervals are in line with the intended uses of maize MON 87460.

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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

6.4 Request for an opinion on the adequacy of EFSA guidelines to perform a risk assessment of plants developed through a number of new techniques: zinc finger nuclease 3 (ZFN-3) (EFSA-Q-2012-00241)

The European Commission requested that the EFSA Panel on Genetically Modified Organisms deliver a scientific opinion related to risk assessment of plants developed using the zinc finger nuclease 3 technique (ZFN-3), which allows the integration of gene(s) in a predefined insertion site in the genome of the recipient species. Since other nucleases with a similar function to ZFN are considered in this opinion, the term site-directed nuclease 3 (SDN-3) is used to describe the technique rather than ZFN-3 specifically. The EFSA GMO Panel considers that its guidance documents are applicable for the evaluation of food and feed products derived from plants developed using the SDN-3 technique and for performing an environmental risk assessment. However, on a case-by-case basis fewer event-specific data may be needed for the risk assessment of plants developed using the SDN-3 technique. The EFSA GMO Panel compared the hazards associated with plants produced by the SDN-3 technique with those obtained by conventional plant breeding techniques and by currently used transgenesis. With respect to the genes introduced, the SDN-3 technique does not differ from transgenesis or from the other genetic modification techniques currently used, and can be used to introduce transgenes, intragenes or cisgenes. The main difference between the SDN-3 technique and transgenesis is that the insertion of DNA is targeted to a predefined region of the genome. Therefore, the SDN-3 technique can minimise hazards associated with the disruption of genes and/or regulatory elements in the recipient genome. Whilst the SDN-3 technique can induce off-target changes in the genome of the recipient plant, these would be fewer than those occurring with most mutagenesis techniques. Furthermore, where such changes occur they would be of the same types as those produced by conventional breeding techniques.

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

7. New mandates

7.1 Applications under Regulation (EC) No 1829/2003

None.

7.2 Annual post-market environmental monitoring reports of GM plants

None.

7.3 Other requests and mandates

None.

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

8.1 Scientific Committee and other Scientific Panels

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8.2 Working Groups

- **Potential effects of the specific genetic background of comparators**

A Panel member gave a presentation on the potential implications of interactions between the GM event and the genetic background on the risk assessment and the recommendations that could be made to risk managers in case of such interaction.

- **Analysis of agronomic and phenotypic datasets**

A Panel member gave a presentation on the analysis of agronomic and phenotypic datasets, possible effect of genetic background and implications for the assessment of potential unintended effects. Several issues, such as the need to establish a list of relevant endpoints for yield components of crops and a database of reference values and to provide further guidance on the analysis of yield components, were discussed by the GMO Panel.

8.3 EFSA

- **Séralini et al. (2012) paper**

The Head of the GMO Unit informed the Panel that following receipt of an official request from the European Commission in relation to the Séralini et al. (2012) paper, EFSA published an initial review of the Seralini *et al*. publication[6] on 4 October as well as a FAQ page. EFSA has requested further information on open issues from the authors. EFSA expects to publish a second paper on this issue, taking on board the reviews performed by Member States and the answers of the authors, if any become available. The GMO Panel was also informed of the request by Professor Gilles-Eric Séralini to have access to the full dossier of application EFSA-GMO-NL-2005-22. It was clarified that in the frame of EU legislation, public access is granted following a written request.

8.4 European Commission

The Head of E1 Unit of EC SANCO, Dorothée André, presented to the GMO Panel the Commission's point of view on several key elements to be followed in order to ensure that quality opinions are produced and that Member State comments are addressed. The importance of networking with Member States and organising bilateral meetings, when needed, was underlined. The issue of conflict of interest concerning EFSA's experts, on which the Commission had received several questions, was also discussed, reminding the importance of EFSA's independence during the risk assessment process. In closing, it was highlighted that EFSA's scientific advice was crucial for the Commission to allow strong risk management decisions.

9. Other scientific topics for information and/or discussion

a) Update on "Software development in support of EFSA statistical requirements for GMO dossiers"

The complete first version was received and comments were sent to the contractor. The full version is expected by December and a presentation to the Panel is expected to take place

[6] Séralini G-E, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D and de Vendômois JS, 2012. Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. Food and Chemical Toxicology, 50 (11), 4221-4231

at the January Plenary meeting. The GMO Environment WG will discuss the relevance of including environmental field trials in the software at its next meeting.

b) Update on the SAS Unit's work on equivalence testing for compositional assessment

The GMO Panel was informed about the EFSA SAS Unit's work supporting the GMO Unit in the evaluation of statistical data submitted with applications received under the new guidance for the risk assessment of GM plants, and establishing alternative methods to estimate equivalence limits.

10. Any other business

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

None.

b) EFSA10 year anniversary scientific conference (7–8 November 2012)

Presentations will be given by a Panel member, as well as by Harry Kuiper, the former Chair of the GMO Panel.

c) Feedback from applicant meeting (12 October 2012, Parma)

Representatives from the industry met with EFSA staff with the aim of openly discussing key issues such as the enhancement of communication between applicants and the Authority, streamlining the application process and reducing the timeline involved. Ways of fostering greater understanding of the application process and the essential scientific requirements under the risk assessment phase of GMO applications were also covered.

d) EuropaBio Workshop (24-25 October 2012, Brussels)

EuropaBio and CropLife International are organising a workshop on the risk assessment requirements for GM food and feed with respect to toxicology and allergenicity. GMO Panel members and other experts will attend this meeting, together with representatives of the EFSA's GMO Unit.

e) COGEM–EFSA NTO Workshop (29–30 November 2012, Amsterdam)

The EFSA and the Netherlands Commission on Genetic Modification (COGEM) are organising a joint workshop to discuss the latest scientific insights on *Bt* proteins, the selection of non-target organisms, modelling and the experimental design of laboratory and field experiments, in the context of environmental risk assessment. The aim of this workshop is to provide an overview of the most recent scientific knowledge on these aspects of *Bt* proteins, and to identify related issues for which further research might be needed in support of the risk assessment of GM crops.

11. Questions from and answers to observers (in application of the guidelines for Observers[3])

As there were no observers attending the meeting, this item is not applicable.