European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 81st Plenary meeting of the Scientific Panel on GMO

Held on 17–18 April 2013, Parma

(Agreed on 29 May 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, Jozsef Kiss, Gijs Kleter, Martinus Løvik,[1] Antoine Messéan,[2] Hanspeter Naegeli, Kaare Nielsen, Joe Perry, Nils Rostoks and Christoph Tebbe.

- **Hearing experts**:

John Mumford[3] and Fredrik Sundström.[4]

- **EFSA:**
  - **GMO Unit:** Jaime Aguilera, Anna Christodoulidou, Yann Devos, Zoltán Divéki, Anders Falk, Antonio Fernández Dumont, Andrea Gennaro, Ana Gomes, Yi Liu, Sylvie Mestdagh, Irina Olaru, Claudia Paoletti, Matthew Ramon, Stefano Rodighiero and Elisabeth Waigmann.
  - **Other EFSA Units/Directorates**: Per Bergman (REPRO[5]), Dirk Detken, Simone Gabbi (LRA/RESU[6]), Laura Smillie (COMMS[7]), Andras Szoradi (P&M/SCISTRAT[8]).
- **European Commission observers:** Sarah Brown (DG SANCO).
- **Observers (in application of the Guidelines for Observers[9])**: see Annex I.
- **Others:** None.

1. Welcome and apologies for absence

The Chair welcomed the participants, and gave observers the opportunity to introduce themselves. The Chair also expressed his pleasure at having a broad range of observers,

[1] Present via teleconference.
[2] Present on 17 April only.
[3] Member of the GM Insect Working Group, present only for agenda item 7.1.
[4] Member of the GM Fish Working Group, present only for agenda item 7.1.
[5] Scientific Evaluation of Regulated Products (REPRO) Directorate.
[6] Legal and Regulatory Affairs (LRA) Unit of the Resources and Support (RESU) Directorate.
[7] Communications Directorate.
[8] Planning and Monitoring (P&M) Team of the Science Strategy & Coordination (SCISTRAT) Directorate.
[9] http://www.efsa.europa.eu/en/stakeholders/observers.htm

including overseas risk assessment experts from Malaysia, representatives of industry and non-governmental organisations.

Apologies were received from Jaroslava Ovesna from the GMO Panel.

2. Adoption of agenda

The agenda was adopted with a minor editorial change.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs)[10] and the Decision of the Executive Director implementing this Policy[11], 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 were identified during the screening process or at in the Oral Declaration of interest (ODoI) at the beginning of this meeting.

4. Presentation of the 'Guidelines for Observers'

A member of the P&M Team presented the EFSA Guidelines on attendance of Observers in open plenary meetings.

5. Agreement of the minutes of the 80th Plenary meeting held on 6–7 March 2013, Parma

The minutes of the 80th GMO Plenary meeting (6–7 March 2013) were adopted and will be published at: EFSA Event: 80th plenary meeting of GMO Panel

6. Report on written procedures since the 80th Plenary meeting

There have been no written adoptions since the 80th Plenary meeting.

7. Scientific outputs submitted for discussion and possible adoption

7.1 EFSA environmental risk assessment guidance on genetically modified animals (EFSA-Q-2011-00919)

This document provides guidance for the environmental risk assessment (ERA) of living genetically modified (GM) animals, namely fish, insects and mammals and birds, to be placed on the European Union (EU) market in accordance with Regulation (EC) No 1829/2003 or Directive 2001/18/EC. It provides guidance for assessing potential effects of GM animals on animal and human health and the environment and the rationales for data requirements for a comprehensive ERA. The ERA should be carried out on a case-by-case basis, following a step-by-step assessment approach. This document describes the six sequential steps for the ERA of GM animals, as indicated in Directive 2001/18/EC: (1) problem formulation including hazard and exposure identification; (2) hazard

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

characterisation; (3) exposure characterisation; (4) risk characterisation; (5) risk management strategies; and (6) an overall risk evaluation. The Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority follows Annex II of Directive 2001/18/EC, considering specific areas of risk to be addressed by applicants and risk assessors during the ERA of GM fish, GM insects and GM mammals and birds. Each specific area of risk is considered in a structured and systematic way following the aforementioned six steps. In addition, this Guidance Document describes several generic cross-cutting considerations (e.g. choice of comparators, use of non-GM surrogates, experimental design and statistics, long-term effects, uncertainty analysis) that need to be accounted for throughout the whole ERA.

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

The Panel also endorsed the Technical report on the Outcome of the public consultation on the draft Scientific Opinion of the GMO Panel providing guidance on the environmental risk assessment of genetically modified animals, which will be published on the EFSA website at: http://www.efsa.europa.eu/en/publications.htm

7.2 Scientific opinion on a mandate for the assessment of the new scientific elements supporting the prolongation of prohibition of the placing on the market of GM oilseed rape GT73 for food and feed purposes in Austria (EFSA-Q-2013-00230)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) evaluated the documentation provided by Austria to support the prolongation of the safeguard clause measure prohibiting the placing on the market of the genetically modified oilseed rape event GT73 for import, processing and feed uses in Austria. The EFSA GMO Panel assessed whether the submitted documentation comprised new scientific information that would change or invalidate the conclusions of its previous risk assessments on oilseed rape GT73. The EFSA GMO Panel also considered the relevance of the concerns raised by Austria in the light of the most recent data published in the scientific literature. The authorised uses of oilseed rape GT73 exclude cultivation, but data on gene flow, persistence and invasiveness derived from cultivation were considered as a worst case, representing conditions where exposure and potential impact are expected to be the highest, to assess possible environmental impacts resulting from seed import spills. In the documentation provided by Austria and in the scientific literature, the EFSA GMO Panel could not identify new scientific evidence that indicates that the import, processing and feed uses of oilseed rape GT73 in the EU pose a significant and imminent risk to the environment. The EFSA GMO Panel does not consider the occurrence of occasional feral oilseed rape GT73 plants, pollen dispersal and consequent cross-pollination as environmental harm in itself. In conclusion, the EFSA GMO Panel considers that, based on the documentation supplied by Austria and a review of recent scientific literature, there is no specific scientific evidence in terms of risk to the environment that would support the notification of a safeguard clause measure under Article 23 of Directive 2001/18/EC nor its prolongation, and that would invalidate its previous risk assessments of oilseed rape GT73.

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

7.3 Scientific opinion on a mandate for the assessment of the new scientific elements supporting the prolongation of prohibition of the placing on the market of GM oilseed rapes Ms8, Rf3 and Ms8xRf3 for food and feed purposes in Austria (EFSA-Q-2013-00233)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) evaluated the documentation provided by Austria to support the prolongation of the safeguard clause measure prohibiting the placing on the market of the genetically modified oilseed rape events Ms8, Rf3 and Ms8 x Rf3 for import, processing and feed uses in Austria. The EFSA GMO Panel assessed whether the submitted documentation comprised new scientific information that would change or invalidate the conclusions of its previous risk assessments on oilseed rape Ms8, Rf3 and Ms8 x Rf3. The EFSA GMO Panel also considered the relevance of the concerns raised by Austria in the light of the most recent data published in the scientific literature. The authorised uses of oilseed rape Ms8, Rf3 and Ms8 x Rf3 exclude cultivation, but data on gene flow, persistence and invasiveness derived from cultivation were considered as a worst case, representing conditions where exposure and potential impact are expected to be the highest, to assess possible environmental impacts resulting from seed import spills. In the documentation provided by Austria and in the scientific literature, the EFSA GMO Panel could not identify new scientific evidence that indicates that the import, processing and feed uses of oilseed rape Ms8, Rf3 and Ms8 x Rf3 in the EU pose a significant and imminent risk to the environment. The EFSA GMO Panel does not consider the occurrence of occasional feral oilseed rape Ms8, Rf3 and Ms8 x Rf3plants, pollen dispersal and consequent cross-pollination as environmental harm in itself. In conclusion, the EFSA GMO Panel considers that, based on the documentation supplied by Austria and a review of recent scientific literature, there is no specific scientific evidence in terms of risk to the environment that would support the notification of a safeguard clause measure under Article 23 of Directive 2001/18/EC nor its prolongation, and that would invalidate its previous risk assessments of oilseed rape Ms8, Rf3 and Ms8 x Rf3.

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

7.4 Application for authorisation of genetically modified soybean MON87708 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2011-93) (EFSA-Q-2011-00122)

The draft opinion was presented to the Panel for a first reading. The discussions mainly focused on the sections dealing with the compositional, agronomic and phenotypic analysis, the repeated-dose 90-day oral toxicity study and the potential for gene transfer.

8. New mandates

8.1 Applications under Regulation (EC) No 1829/2003

One new mandate was received as follows:

Application for the authorisation of genetically modified soybean DAS-68416-4 × MON-89788-1 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2013-115) (EFSA-Q-2013-00281).

8.2 Annual post-market environmental monitoring reports of GM plants

None.

8.3 Other requests and mandates

Three new mandates were received as follows:

a) Mandate 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).

b) Request to complement EFSA's scientific opinion on oilseed rape GT73 (application EFSA-GMO-NL-2010-87) (EFSA-Q-2013-00360).

c) Mandates for the risk assessment of the genetically modified carnation lines EFD-25958-3 and IFD-26407-2 from Florigene for the only purpose of import, under Part C of Directive 2001/18/EC (notifications C/NL/09/01 and C/NL/09/02 respectively). (EFSA-Q-2013-00327) (EFSA-Q-2013-00328).

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

9.1 Scientific Committee and other Scientific Panels

The Chair of the GMO Panel informed the Panel members about the content of the 61st Scientific Committee Plenary meeting. Among the items discussed at this meeting were: update on prioritisation of research proposals for consideration in the context of Horizon 2020, exposure to multiple chemicals, and consideration of new data available just before or after adoption of opinions.

9.2 Working Groups

None.

9.3 EFSA

- Harmonised timelines for submitting information to EFSA within the stop-the-clock mechanism

The Director of the REPRO Directorate presented a proposal for the harmonisation of timelines for submitting information to EFSA within the stop-the-clock mechanism. He noted that different timelines for submission of additional information during the risk assessment process are applied by the scientific panels of EFSA. In order to harmonise the stop-the-clock mechanism, standardised timelines for certain data submissions are proposed by EFSA.

The timelines currently observed for submitting additional information to EFSA were discussed by the GMO Panel during the meeting and feedback was provided to the Director of REPRO.

9.4 European Commission

- **Possible generic mandates**

The GMO Panel was informed that EFSA would receive the post-market environmental monitoring (PMEM) report for Amflora potato cultivation in 2012.

10. Other scientific topics for information and/or discussion

- **Mandate to complement the opinion on MON 87705**

The GMO Panel was updated on the proceedings related to the mandate received from European Commission, requesting EFSA to complement its opinion related to MON 87705 soybean in order to cover the safety of oil for commercial frying.

- **GMO Network meeting**

A draft Agenda for the 4th Meeting with Member State experts of the EFSA scientific network on risk assessment of GMOs that will take place in Parma on 22–23 May 2013 was presented to the GMO Panel.

- **Workshop on software for statistical evaluation of compositional and agronomic data**

The GMO Panel was updated about a workshop that will take place on 30 – 31 May2013, in EFSA premises, where participants will test the software and provide feedback on its functions.

- **Call on bioinformatic support**

The GMO Panel was informed about the call for preparatory support on bioinformatics for the evaluation of the risk assessment of GMO dossiers. The call was published in the Official Journal on 3 April 2013. The deadline for submission of offers is 27 May 2013.

- **Call on statistical support**

The GMO Panel was informed about an ongoing call for support in the assessment of statistical data packages included in GM plant applications.

- **Call on food enzymes support**

The Panel was informed about an EFSA call on preparation of summary reports from dossiers on food enzymes. The deadline for submission of offers is 28 June 2013.

11. Questions from Observers

See Annex II. The Chair of the GMO Panel answered the written questions received prior to the Plenary meeting, irrespective of whether the registrants who put the questions were able to attend or not.

12. Any Other Business

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

None.

b) Specialised courses for Panel members

The GMO Panel members were reminded about the specialised training courses organised by EFSA on variability and uncertainty, and exposure assessment.

c) Feedback from the OECD meeting

EFSA participated in the 2013 OECD Task Force meeting for Novel Foods and Feed and presented a summary report produced by EFSA and the Austrian and Norwegian Competent Authorities, in which scientific issues on endogenous allergenicity were discussed. The OECD Task Force invited EFSA, Austria, Norway and other interested delegations to gather additional information relevant for the endogenous allergenicity assessment and to report back for further discussion at the 2015 OECD Task Force meeting.

Annex I

LIST OF OBSERVERS

1. Ms Pascale Delzenne (FR), Monsanto, Belgium (no questions)
2. Dr Arnaud Apoteker (FR), GMO Adviser to the Greens/EFA Group in the European Parliament, Belgium (no questions)
3. Dr Celmira Susana Sousa (PT), BASF Italia SpA, Italy (no questions)
4. Dr Annlisa Bacchi (IT), Barilla, Italy (no questions)
5. Dr Maria del Carmen Martinez Parrilla (ES), Bayer CropScience (no questions)
6. Dr Manuel Gomez Barbero (ES), EuropaBio, Belgium (three questions)
7. Professor Niklaus Ammann (CH), PRRI, ASK-FORCE, Switzerland (one question)
8. Mr Jamal Khair Hashim (Malaysian), Ministry of Health, Malaysia (no questions)
9. Mr Laila Rabaah Ahmad Suhaimi (Malaysian), Ministry of Health, Malaysia (no questions)
10. Ms Nur Hidayah Jamaludin (Malaysian), Ministry of Health, Malaysia (no questions)
11. Dr Donald Prater (US), US-FDA, US (no questions)
12. Dr Dara Corrigan (US), Director of the FDA Europe Office, US-FDA, US (no questions)

Annex II

Questions submitted by Observers registered to attend the GMO Panel Plenary meeting

17–18 April 2013

Ms Camilla Beech (UK), Oxitec Ltd, United Kingdom

1. "What is the timeframe for the adoption of the Guidance on GM animals?"

The Chair of the GMO Panel indicated that the Guidance on the environmental risk assessment of GM Animals is on the Agenda, for discussion and possible adoption, in this current Plenary meeting. As soon as any adopted Guidance is published on the EFSA website it is immediately effective, in the sense that any application made after the date of publication will be assessed in accordance with the new Guidance.

2. "What, if any, consideration has been given, when revising the Guidance document to the publication by the World Health Organisation on the Guidance Framework for Testing Genetically Modified Mosquitoes, and how might a developer use multiple frameworks for the ERA of genetically modified insects?"

The Chair of the GMO Panel replied that members of the GMO Panel are aware of the document referred to, which is currently a draft for public consultation. The regulations for release of GMOs within the EU are laid out in Directive EC 2001/18 and these differ from those in other world regions. Guidance issued by EFSA is specifically tailored to satisfy the requirements of EU legislation.

An applicant is free to bring forward any evidence considered relevant. However, dossiers submitted to accompany applications for release of GMOs within the EU should follow the Guidance adopted by the EFSA GMO Panel. This details requirements for data for risk assessment, and it is against these requirements that the application will be assessed.

Dr Manuel Gomez Barbero (ES), EuropaBio, Belgium

1. "Would not be possible more transparent to publish the GMO Panel meeting minutes in a more detailed manner rather than opening them to stakeholders once in a while?"

The Chair of the GMO Panel explained that the initiative under which EFSA is giving access to some scientific plenary meetings in its 2012/2013 programme is a pilot scheme, which will be reviewed later in 2013. The initiative forms part of EFSA's commitment to openness and transparency, and this process is expected to develop further in the future. However, at present, there are no plans to make the minutes more detailed than is currently the case. The minutes are accurate; they are designed to capture the major issues agreed by the Panel at the meeting.

2. "Would it be possible to ask clarification on certain discussions if applicants cannot understand the specifics just by reading the GMO Panel meetings?"

The Chair of the GMO Panel answered that EFSA welcomes feedback and answers questions from any party interested in EFSA's work. All questions sent to EFSA receive an individual response. Please use the 'Ask EFSA' service (http://www.efsa.europa.eu/en/contact/askefsa.htm)

3. "Would the GMO Panel be open for scientific discussions to get familiarity with new technologies that will be the key for the new products under development?"

The Chair of the GMO Panel replied that EFSA is an independent organisation and its Panel members fill out detailed Declarations of Interest to ensure transparency. GMO Panel members represent EFSA regularly at scientific meetings, as long as these are open to academics from independent institutions such as universities and publicly funded research institutes. Such meetings may also include stakeholders from industry and NGOs. New technologies are discussed at these and other meetings. The GMO Panel has already adopted Scientific Opinions on relevant topics such as cisgenesis and zinc-finger techniques, in response to questions from DG SANCO. In addition, EFSA organises stakeholder meetings, colloquia and workshops on topics of interest. If appropriate, hearing experts with expertise in specific topics may be invited to Plenary meetings for particular agenda items, to share their expertise with the Panel.

Professor Niklaus Ammann (CH), PRRI, ASK-FORCE, Switzerland

1. "My question which I already asked at the plenary 10years meeting 'What progress can be expected for a general shift in the biosafety research strategy from process-oriented to product-oriented regulation in the future?' I would also be ready to serve as an external expert on those matters."

The Chair of the GMO Panel answered that the EFSA GMO Panel issues its Scientific Opinions and Guidance in line with Directive EC 2001/18 and Regulation 1829 EC. In the European legislation, the requirement for a safety assessment is based on the technology used to produce a GMO, rather than the trait expressed by that GMO. The GMO Panel is aware that traits such as herbicide tolerance may be generated either by genetic modification or by conventional breeding (as in the 'Clearfield' system). The GMO Panel is also aware that in different world regions different regulatory systems exist; for example, Canada assesses the safety of 'plants with a novel trait' using identical regulations, whether these traits are introduced using biotechnology, mutagenesis or conventional breeding techniques.

However, although the GMO Panel advises, elected representatives decide. Hence, this question is better directed to bodies with more influence on these matters than the Panel. Only through a change in legislation, voted on by Member States, could a change from process-oriented regulation to product-oriented GMO regulation come about within the EU.

Dr Helen Wallace (UK), GeneWatch UK (NGO), United Kingdom

1. "Does EFSA intend to respond to and comply with the European Ombudsman's investigation regarding conflicts of interest on the GM Insects Working Group and its failure to consult on GM insects on the food chain before finalising its guidance on environmental risk assessment of GM animals?"

The Chair of the GMO Panel indicated that this question was not of scientific nature and invited EFSA LRA representatives to respond. An LRA officer indicated that EFSA has received the administrative complaint brought by GeneWatch UK regarding an alleged

maladministration arising from not having prevented certain conflicts of interest in the WG on GM insects ERA Guidance Document and other aspects. The Regulation establishing the European Ombudsman lays down the procedure that should be followed by the Ombudsman and the institution concerned when dealing with such administrative complaints. EFSA will respond to the complaint in question in accordance with these rules and by the deadlines foreseen therein. In this case, this means that EFSA will have to issue its opinion on the complaint by 30 June 2013.

2. "What is EFSA's position on including the European Parliament in the process of developing Guidance for deliberate release of GM animals, including insects, fish, birds and mammals?"

The Chair of the GMO Panel indicated that, similarly to the question above, this question should be answered by EFSA, since it is not of a scientific nature.

An officer of the LRA replied that when an EFSA document is published for public consultation, any individual or official body can contribute by sending comments or suggestions for the document, within the specified timelines. Therefore, in the context of public consultation, any Member of the European Parliament could send comments on an EFSA document.