European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 97th Plenary meeting of the Scientific Panel on GMO

Held on 15-17 April 2015, Parma

(Agreed on 27 May 2015)

Participants

- **Panel members**:

Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Hilde-Gunn Opsahl Hoen-Sorteberg, Huw Jones, József Kiss, Martinus Løvik, Antoine Messéan, Kaare Nielsen, Jaroslava Ovesná, Joe Perry, Nils Rostoks, Christoph Tebbe.

- **Hearing experts**: Andrew Hart (Scientific Committee Working Group on Uncertainty in Risk Assessment).
- **EFSA:** none.

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:** Reinhilde Schoonjans (SCER Unit, SCISTRAT Department).
- **European Commission observers:** Kaja Kantorska (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 Salvatore Arpaia, Gijs Kleter and Hanspeter Naegeli.

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 96th Plenary meeting (Open Plenary) held on 4-5 March 2015, Parma

The minutes of the 96th GMO Plenary meeting (4-5 March 2015) were adopted and will be published on the EFSA website at: EFSA Event: 96th plenary meeting of GMO Panel

5. Scientific outputs submitted for discussion and possible adoption

5.1 Application for authorisation of genetically modified maize 5307 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2011-95) (EFSA-Q-2011-00310)

Maize 5307 was developed by *Agrobacterium tumefaciens*-mediated transformation to express two proteins: eCry3.1Ab, conferring resistance to certain coleopteran pests, and phosphomannose isomerase (PMI), used as selection marker. The molecular characterisation showed relevant similarities between the amino acid sequence of PMI and a known allergen, and between the amino acid sequence of eCry3.1Ab and a potential toxin. Some agronomic and phenotypic differences between maize 5307 and its conventional counterpart were observed (higher 'heat units to 50 % pollen shed', grain moisture, plant height, grain yield); however, the EFSA GMO Panel considered that these do not give rise to food/feed or 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 PMI protein. The EFSA GMO Panel could not conclude on the safety of the eCry3.1Ab protein due to the inadequate 28-day toxicity study provided. The outcome of a broiler feeding study with maize 5307 was not assessed by the EFSA GMO Panel, due to study weaknesses. There are no indications of an increased likelihood of the establishment and spread of feral maize plants. Interactions with the biotic and abiotic environment were not considered to be a relevant issue. Risks associated with the unlikely but theoretically possible horizontal gene transfer of recombinant genes from maize 5307 to bacteria were not identified. The post-market environmental monitoring plan and reporting intervals are in line with the scope of the application. In conclusion, in the absence of an appropriate assessment of eCry3.1Ab, the EFSA GMO Panel is not in a position to complete its food/feed risk assessment of maize 5307. However, the EFSA GMO Panel concludes that the maize 5307 is unlikely to have any adverse effect on 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 - Scientific Opinion of the GMO Panel: Scientific Opinion on genetically modified maize 5307

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

5.2 Application for authorisation of genetically modified maize DAS-40278-9 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2010-89) (EFSA-Q-2010-01326)

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

5.3 Application for authorisation of genetically modified soybean DAS-68416-4 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2011-91) (EFSA-Q-2011-00052)

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

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

The Panel discussed the draft guidance focusing on the changes introduced to address the comments received during the previous plenary meeting. Further discussion is needed.

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

The Panel discussed the draft guidance, focusing on the changes introduced to address the input received during the previous plenary meeting. 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

- Request for scientific assistance on the arguments provided by Monsanto with regards to EFSA's opinion on Monsanto's Insect Resistance Management Strategy

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

7.2.1 Feedback from the Scientific Committee's Overarching ERA Working Group

A member of the SCER Unit (SCISTRAT Department) presented the GMO Panel with the draft guidance documents prepared by the WG on Overarching ERA. As specified in the mandate, the WG developed separate draft opinions on harmonising the approach to setting protection goals and the two specific elements of environmental

risk assessment (ERA) within the remit of EFSA, i.e. coverage of endangered non-target species, and recovery of non-target species. Public consultation for these documents is foreseen to start at the end of June 2015.

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

8.1 Uncertainty analysis

Andrew Hart, Chair of the Scientific Committee Working Group on Uncertainty in Risk Assessment presented the GMO Panel with an overview on the discussions held in the Molecular Characterisation WG and the Food-Feed Safety WG on uncertainty analysis.

9 Any other business

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

None.

9.2 Feedback from the 96th GMO Plenary (Open plenary)

A member of the GMO Unit presented an overview of the feedback received from observers attending the 96th GMO Plenary meeting.

9.3 GMO Network meeting

The meeting will take place in Parma on 12-13 May. The draft agenda was presented to the GMO Panel and will be made available at EFSA: Events