European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 93rd Plenary meeting of the Scientific Panel on GMO

Held on 22-23 October 2014, Parma

(Agreed on 3 December 2014)

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, József Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Hanspeter Naegeli, Jaroslava Ovesná, Kaare Nielsen, 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, Ana Gomes, Anna Lanzoni, Yi Liu, Sylvie Mestdagh, Irina Olaru, Claudia Paoletti, Matthew Ramon and Elisabeth Waigmann.

- **Other EFSA Units/Directorates:** Per Bergman (REPRO Department).
- **European Commission observers:** Kaja Kantorska (DG SANCO).
- **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 Lieve Herman for October 22nd.

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 92nd Plenary meeting held on 10-11 September 2014, Parma

The minutes of the 92nd GMO Plenary meeting (10-11 September 2014) were adopted and will be published on the EFSA website at: EFSA Event: 92nd plenary meeting of GMO Panel.

5. Scientific outputs submitted for discussion and possible adoption

5.1 Scientific Opinion on objections of a Member State to a notification (Reference C/NL/13/01) for the placing on the market of the genetically modified carnation SHD-27531-4 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Suntory Holdings Limited (EFSA-Q-2014-00446)

The European Commission asked the EFSA GMO Panel to address the objections of Cyprus to the placing on the market of the genetically modified (GM) carnation SHD-27531-4. The GM carnation cut flowers, with a modified petal colour, are intended to be imported and distributed in the European Union for ornamental use only. The EFSA GMO Panel responded to the objections of Cyprus, taking into account the limited intended use of carnation SHD-27531-4 and the information available. First, the EFSA GMO Panel concludes that the propagation of carnation SHD-27531-4 by individuals cannot be excluded. However, should this occur, carnation SHD-27531-4 would not show any potential for increased survival, fitness or weediness compared with its parental line. Second, the EFSA GMO Panel is of the opinion that the potential spread of pollen of the GM carnation SHD-27531-4 by Lepidoptera to wild Dianthus species cannot be eliminated but is highly unlikely to occur and, if it did occur, it is very unlikely that viable hybrids would be produced, survive and result in adverse environmental effects. Third, considering the very low potentials for hybridisation and/or seed production of (GM) carnations, the EFSA GMO Panel concludes that plant-to-plant gene transfer of the introduced genes is very unlikely and, if it did occur, it is unlikely to result in viable seed production leading to adverse environmental effects.

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 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 EFSA GMO Panel endorsed the draft guidance document for the risk assessment of the renewal of GM plant products authorised under Regulation (EC) No 1829/2003.

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

The draft guidance will be placed at EFSA Call: Public consultation on the draft Guidance for Renewal Applications of Genetically Modified Food and Feed authorised under Regulation (EC) No. 1829/2003 on 4 November 2014 for a 6-week public consultation.

5.3 Application for authorisation of genetically modified maize Bt11 x MIR162 x 1507 x GA21 for food and feed uses, import and processing and and the ten other combinations of the individual events submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2010-86) (EFSA-Q-2010-01087)

The Panel discussed the draft scientific opinion, focusing on possible interactions between the Bt proteins, in the context of the three risk assessment areas: molecular characterization, food/feed safety and environmental safety.

5.4 Mandate for the identification of existing monitoring networks suitable to provide datasets to support post market environmental monitoring (PMEM) of GMOs (EFSA-Q-2014-00583)

Following a request from the European Commission, a set of assessment criteria was developed to support the selection of existing environmental surveillance networks for post-market environmental monitoring (PMEM) of genetically modified plants (GMPs). In compliance with these criteria, some networks and associated programmes were identified as being of potential use subject to further case-by-case analysis. When considering PMEM of GMPs, the approach would also require comparing sites monitored by the networks and the locations where GMPs are cultivated. The reporting of the sites surveyed by networks and locations of cultivated GMPs should thus follow the same standards in order to ensure interoperability and to potentially establish a causal link between a change observed and the GMPs. In this respect, technical support might be required by networks to transform their data records into workable standards. Moreover, the EFSA GMO Panel was asked by the European Commission to examine the sensitivity of statistical analyses used by the networks to detect change. A decision tree is provided for selecting the optimal method for statistical analysis based on the study design and the datasets from networks. Sufficient statistical power needs to be ensured to detect an effect for a particular indicator. Sample size is one of the main contributing factors in determining the power of any network to detect an effect of a product release into the environment. Increasing the sample size implies variable extra-costs depending on whether data are collected by volunteers or professionals. A more powerful statistical analysis can also be achieved by pooling datasets collected by different networks; this needs further investigation because of important covariates leading to differentiated responses. In general, PMEM would benefit from a move towards ‘open data’ policies for re-analysis or pooling data collected by different networks.

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 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

Two new applications were received:

Application for authorisation of genetically modified soybean MON 87751 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto S.A./N.V. (EFSA-GMO-NL-2014-121) (EFSA-Q-2014-00719)

Application for authorisation of genetically modified cotton GHB614 x T304-40 x GHB119 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience N.V. (EFSA-GMO-NL-2014-122) (EFSA-Q-2014-00721).

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

The Chair of the GMO Panel reported on the issues discussed during the 69th Plenary meeting of the Scientific Committee, such as: guidance documents under public consultation, the PPR Guidance on terrestrial ecotoxicology, EFSA work in the area of contaminants, production and consumption of insects as food and feed, EFSA Scientific Cooperation Roadmap.

7.2 Working Groups

- Unintended effects

The GMO Panel discussed the concept of unintended effects, as defined by the guidance documents on environmental risk assessment of GM plants and on risk assessment of food and feed from GM plants, respectively.

7.3 EFSA

- Increasing efficiency in dossier evaluation

The Head of the GMO Unit presented to the Panel a series of alternative actions that could lead to an increase in efficiency of evaluation of application dossiers submitted to EFSA, as a continuation of the discussion held during the 92nd Plenary meeting of the GMO Panel on the same topic.

- New DOI rules

Per Bergman, Head of the REPRO Department presented the new rules for Declarations of Interests to be submitted by experts involved in EFSA scientific activities.

7.4 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

- Uncertainty analysis

The GMO Panel discussed the possibility of performing uncertainty analyses for stacked GM events. EFSA Opinions on such stacks depends critically on the assessment of potential interactions between the events and their impact on to human/animal/environmental safety. The Panel were updated on the work of the

Scientific Committee Working Group in this area. Since every risk assessment involves uncertainty, the Panel felt that a formal uncertainty analysis might add clarity in the case of assessments of stacks for which experimental data were limited for certain sub-combinations. It was reported that the ongoing work of the Working Group towards the development of harmonised uncertainty analysis could facilitate the work of risk managers in interpretation of EFSA Opinions and subsequent incorporation into the decision-making process. Further discussion is necessary.

- Selection of comparators

The GMO Panel discussed the selection of appropriate non-GM comparators for the comparative compositional/agronomic/phenotypic assessment of GM stacked events when a near-isogenic conventional counterpart is not available. The Panel acknowledged the difficulties raised by this issue, as outlined in the Guidance on selection of comparators for the risk assessment of genetically modified plants and derived food and feed[3]. Further discussion is needed.

9 Any other business

- Technical meeting with applicants

The Head of the GMO Unit presented the agenda of the Info Session on GMO Applications – Technical meeting with applicants, scheduled for October 28th, 2014, Parma.

- Update on GRACE Project

A member of the GMO Panel provided feedback on the GRACE project.

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 of the European Commission, this item is not applicable.

[3] EFSA Panel on Genetically Modified Organisms (GMO), 2011. Guidance document on Selection of Comparators for the Risk Assessment of GM Plants. EFSA Journal 2011; 9(5):2149. [20 pp.] doi:10.2903/j.efsa.2011.2149. Available online: www.efsa.europa.eu/efsajournal.htm