Scientific Panel on GMO

Minutes of the 99th Plenary meeting of the Scientific Panel on GMO

24-25 June 2015, Parma

(Agreed on 21 August 2015)

Participants

- **Panel members**:

Salvatore Arpaia, Andrew Nicholas Edmund Birch, Andrew Chesson (on 25 June 2015), Patrick du Jardin, Achim Gathmann, Lieve Herman, Huw Jones, József Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Kaare Nielsen, Jaroslava Ovesná, Joe Perry and Nils Rostoks.

- **Hearing experts**: Hildegard Przyrembel (for item 5.2).
- **EFSA:**

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:** none.
- **European Commission observers:** Maria Mirazchiyska (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 Jürgen Gropp, Hilde-Gunn Hoen-Sorteberg, Hanspeter Naegeli and Christoph Tebbe for both days, and from Andrew Chesson for 24 June 2015.

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

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

Policy regarding 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 98th Plenary meeting held on 27-29 May 2015, Parma

The minutes of the 98th GMO Plenary meeting (27-29 May 2015) were adopted and will be published on the EFSA website at: EFSA Event: 98th plenary meeting of GMO Panel.

5 Scientific outputs submitted for discussion and possible adoption

5.1 Application for authorisation of genetically modified maize NK603 x T25 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2010-80) (EFSA-Q-2010-00880)

Single events NK603 and T25 were combined to produce the stack two-event maize NK603 × T25. The EFSA GMO Panel previously assessed the two single events and did not identify safety concerns in the context of their scope. No new data on single maize events leading to a modification of the original conclusions on their safety were identified. Agronomic and phenotypic characteristics, as well as compositional data of maize NK603 × T25, did not give rise to food/feed and environmental safety concerns. The EFSA GMO Panel considers that there is no reason to expect interactions between the single events that could impact on the food and feed safety and the nutritional properties of maize NK603 × T25. There are no indications of an increased likelihood of establishment and spread of feral maize plants. Considering the scope of application EFSA-GMO-NL-2010-80, potential interactions with the biotic and abiotic environment were not considered to be a relevant issue. The unlikely but theoretically possible transfer of the recombinant genes from maize NK603 × T25 to environmental bacteria does not give rise to any safety concern. The post-market environmental monitoring plan and reporting intervals are in line with the scope. In conclusion, the EFSA GMO Panel considers that the information available for maize NK603 × T25 addresses the scientific comments raised by Member States and that maize NK603 × T25, as described in this application, is as safe as its non-GM comparator and non-GM conventional maize varieties with respect to potential effects on human and animal health and 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 GMO Panel publications.

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

5.2 Application for authorisation of genetically modified soybean MON 87705 x MON 89788 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2011-100) (EFSA-Q-2011-00954)

The EFSA GMO Panel previously assessed the two single events combined to produce soybean MON 87705 × MON 89788 and did not identify safety concerns. No new data on the single events affecting the previous conclusions were identified. No differences in composition requiring further assessment were observed between soybean MON 87705 × MON 89788 and its comparator, except for the intended trait i.e. an altered fatty acid profile. Nutritional assessment on soybean MON 87705 × MON 89788 oil and oil-containing food products did not identify concerns on human health and nutrition. There are no concerns regarding the use of feedingstuffs from defatted soybean meal MON 87705 × MON 89788. The EFSA GMO Panel is of the opinion that soybean MON 87705 × MON 89788 is as safe, and at least as nutritious, as its comparator and commercial soybean varieties. There is no reason to expect interactions between the single events that could impact on the food and feed safety and the nutritional properties of soybean MON 87705 × MON 89788. There are no indications of an increased likelihood of establishment and spread of feral soybean plants. Potential interactions with the biotic and abiotic environment were not considered to be a relevant issue. The unlikely but theoretically possible transfer of the recombinant genes from soybean MON 87705 × MON 89788 to environmental bacteria does not give rise to any safety concern. The post-market environmental monitoring plan and reporting intervals are in line with the scope of the application. The EFSA GMO Panel considers that the information available for soybean MON 87705 × MON 89788 addresses the scientific comments raised by Member States. The EFSA GMO Panel concludes, considering the scope of the application, that soybean MON 87705 × MON 89788 is as safe as its comparator and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment. The GMO Panel recommends a post-market monitoring plan, focusing on import data and, if needed, on consumption data for the European population, for the marketed foods and feed.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: EFSA GMO Panel publications.

5.3 Application for authorisation of genetically modified soybean FG72 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer (EFSA-GMO-BE-2011-98) (EFSA-Q-2011-00848)

Soybean FG72 was developed by biolistic transformation to express the HPPD W336 and 2mEPSPS proteins, which confer tolerance to isoxaflutole- and glyphosate-based herbicides. The molecular characterisation of soybean FG72 did not give rise to safety issues. The agronomic and phenotypic characteristics of soybean FG72 tested under field conditions revealed no biologically relevant differences between soybean FG72 and its conventional counterpart that would give rise to any food and 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 newly expressed proteins HPPD W336 and 2mEPSPS, and no evidence that the genetic modification might significantly change the overall allergenicity of soybean FG72. The nutritional characteristics of soybean FG72 is not expected to differ from that of non-GM soybean varieties. There are no indications of an increased likelihood of establishment and spread of feral soybean plants. Considering the scope of this application, interactions with the biotic and abiotic environment were not considered to be an issue. Risks associated with an unlikely but theoretically possible horizontal gene transfer from soybean FG72 to bacteria have not been identified. The monitoring plan and reporting intervals are in line with the scope of the application. In conclusion, the EFSA GMO Panel considers that the information available for soybean FG72 addresses the scientific comments raised by Member States and that soybean FG72, as described in this application, is as safe as its conventional counterpart and non-GM soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of the scope of this application.

The opinion was unanimously adopted by the Panel and will be published on the EFSA website at: EFSA GMO Panel publications.

6 New 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 issues discussed during the 73rd plenary meeting of the Scientific Committee. These included the draft opinion on environmental risk assessment, the draft guidance on uncertainty in risk assessment and the draft opinion on production and consumption of insects as food and feed.

7.2 EFSA including its Working Groups/Task Forces

None.

7.3 European Commission

The European Commission representative updated the Panel on applications that are undergoing authorisation procedures and on generic mandates.

8 Other scientific topics for information and/or discussion

None.

9 Any other business

None.