

## Scientific Panel on GMO

### Minutes of the 104th Plenary meeting of the Scientific Panel on GMO

**27-28 January 2016, Parma**

**(Agreed on 9 March 2016)**

#### Participants

- **Panel members:**

Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Achim Gathmann, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Elsa Nielsen, Hanspeter Naegeli, Fabien Nogue, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli, Jean-Michel Wal.

- **EFSA:**

**GMO Unit:** Fernando Alvarez, Michele Ardizzone, Herman Broll, Yann Devos, Zoltán Divéki, Antonio Fernández Dumont, Niccolò Franceschi, Andrea Gennaro, Ana Gomes, Anna Lanzoni, Sylvie Mestdag, Franco Neri, Irina Olaru, Claudia Paoletti, Konstantinos Paraskevopoulos, Matthew Ramon, Regina Selb, and Elisabeth Waigmann.

**Other EFSA Units/Directorates:** Zoltan Diveki (FIP Unit / REPRO Directorate) for item 5.1, Yi Liu (FIP Unit / REPRO Directorate) for item 5.3, and Elisa Aiassa (AMU Unit / RASA Directorate) for item 7.2.2.

- **European Commission observers:** Maria Mirazchiyska (DG SANTE).
- **Observers (in application of the guidelines for observers):** none.
- **Others:** Hildegard Przyrembel and Thomas Frenzel for item 5.3.

#### 1 Welcome and apologies for absence

The Chair of the GMO Panel welcomed the participants.

#### 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<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, 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. For further details on the outcome of the screening of the ADoI and SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

### 4 Agreement of the minutes of the 103rd Plenary meeting held on 9-10 December 2015, Parma

The minutes of the 103rd GMO Plenary meeting (9-10 December 2015) were adopted and will be published on the EFSA website at: [Event: 103rd plenary meeting of GMO Panel](#)

### 5 Scientific outputs submitted for discussion and/or possible adoption

#### **5.1 Application for authorisation of genetically modified oilseed rape MS8 x RF3 x GT73 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2009-75) ([EFSA-Q-2009-00890](#))**

The Panel discussed the application. Further discussion is needed, pending the assessment of spontaneously received information.

#### **5.2 Application for authorisation of genetically modified cotton 281-24-236 x 3006-210-23 x MON88913 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No. 1829/2003 by Mycogen Seeds c/o Dow Agroscience LLC (EFSA-GMO-NL-2009-68) ([EFSA-Q-2009-00491](#))**

The Panel discussed the application. Further discussion is needed, pending the arrival of additional information.

#### **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 all sub-combinations independently of their origin submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2010-86) ([EFSA-Q-2010-01087](#))**

The Panel discussed the application, focusing on the compositional analysis and nutritional assessment. Further discussion is needed.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf>

## **6 New mandates**

### **6.1 Applications under Regulation (EC) No 1829/2003**

Three new applications were received as follows:

Application for authorization of genetically modified maize 1507 x MON 810 x MIR162 x NK603 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Pioneer Hi-Bred International Inc. (EFSA-GMO-NL-2015-127);

Application for authorization of genetically modified soybean MON 87751 x MON 87701 x MON 87708 x MON 89788 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V. (EFSA-GMO-NL-2016-128);

Application for authorization of genetically modified soybean MON 87751 x MON 87701 x MON 89788 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V. (EFSA-GMO-NL-2016-129).

### **6.2 Annual PMEM reports**

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**

None.

### **7.2 EFSA including its Working Groups/Task Forces**

#### **AP125 suitability of test material and representativeness of sites**

The GMO Panel discussed the suitability of the test material used for the comparative assessment and the representativeness of sites where the field trials were performed for application EFSA-GMO-BE-2015-125.

#### **Prometheus Project**

A scientific officer of the AMU Unit presented to the GMO Panel and Unit a survey in the context of the EFSA Prometheus project. Both Panel and Unit members were invited to fill in the survey.

### **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**

None.

## **9 Any other business**

### **9.1 Criteria to assess studies performed in other countries**

The GMO Panel members agreed that discussion of the criteria to assess studies performed in other countries should take place in each standing WG (MC, FF and ERA) before reaching a plenary agreement.

### **9.2 NDA GDs**

The GMO Panel members were informed of the public consultation that would be launched for two draft guidance documents of the EFSA Panel on Dietetic Products, Nutrition and Allergies (The NDA Panel): the draft guidance for novel foods applications and the draft guidance on notifications for authorisation of traditional foods from third countries.

## Annex I

### Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

**CONFLICT OF INTEREST:** In the SDoI filled for the present meeting, Philippe Guerche declared the following interest: Mr Guerche commented on Application for authorisation of genetically modified oilseed rape MS8 x RF3 x GT73 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2009-75) as member of the French High Council for Biotechnology, which advises the French government on GMOs. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of the agenda item 5.1.

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<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>