

# Scientific Panel on Genetically Modified Organisms Minutes of the 36<sup>th</sup> meeting of the Working Group on Annual Post-Market Environmental Monitoring (PMEM) reports

# Held on 13 April 2018 (TELE/WEB) (Agreed on 16 April 2018)

# Participants

• Working Group Members:

Salvatore Arpaia, Barbara Manachini, Antoine Messéan (chair) and Jeremy Sweet

• Hearing Experts<sup>1</sup>:

Not applicable

- European Commission and/or Member States representatives: Anastasia Pagida
- EFSA:

GMO Unit: Fernando Álvarez AMU Unit: Marios Georgiadis and Alexandra Papanikolau

• Others:

Not applicable

# 1. Welcome and apologies for absence

The chair welcomed the participants. No apologies for absence were received.

# 2. Adoption of agenda

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group member invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

## 4. Agreement of the minutes of the 35<sup>th</sup> Working Group meeting held on 10 May 2017

The minutes of the 35<sup>th</sup> Working Group meeting held on 10 May 2017 were agreed on 10 May 2017.<sup>4</sup>

### **5.** Scientific topics for discussion

#### 5.1. Annual 2016 PMEM report on maize MON 810 <u>EFSA-Q-2017-00817</u>

The working group discussed the information provided by the consent holder in its 2016 PMEM report on maize MON 810. Upon request of the European Commission, the Working Group assessed the findings of the monitoring activities and the appropriateness of the methodology taking into account the comments received from Member States. Further discussion is needed.

#### 6. Any Other Business

Not applicable.

# 7. Next meeting

Not applicable.

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

<sup>&</sup>lt;sup>4</sup> <u>http://www.efsa.europa.eu/en/gmo/working-groups</u>



# Scientific Panel on Genetically Modified Organisms Minutes of the 35<sup>th</sup> meeting of the Working Group on Annual Post-Market Environmental Monitoring (PMEM) reports

# Held on 10 May 2017 (TELE/WEB) (Agreed on 10 May 2017)

# Participants

• Working Group Members:

Salvatore Arpaia, Barbara Manachini, Antoine Messéan (chair) and Jeremy Sweet

• Hearing Experts<sup>1</sup>:

Not applicable

- European Commission and/or Member States representatives: Anastasia Pagida
- EFSA:

GMO Unit: Fernando Álvarez AMU Unit: Marios Georgiadis and Laura Martino

• Others:

Not applicable

# 1. Welcome and apologies for absence

The chair welcomed the participants. No apologies for absence were received.

# 2. Adoption of agenda

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.</u>



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group member invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

### 4. Agreement of the minutes of the 34<sup>th</sup> Working Group meeting held on 27 April 2017

The minutes of the 34<sup>th</sup> Working Group meeting held on 27 April 2017 were agreed on 27 April 2017.<sup>4</sup>

### **5. Any Other Business**

The Working Group discussed the implementation of the EFSA's draft uncertainty guidance in the assessment of annual PMEM reports of genetically modified plants. Further discussion is needed.

#### 6. Next meeting

Not applicable.

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

<sup>&</sup>lt;sup>4</sup> <u>http://www.efsa.europa.eu/en/gmo/working-groups</u>



# Scientific Panel on **Genetically Modified Organisms** Minutes of the 34<sup>th</sup> meeting of the Working Group on Annual Post-Market Environmental Monitoring (PMEM) reports

#### Held on 27 April 2017 (TELE/WEB)

(Agreed on 27 April 2017)

#### **Participants**

- **Working Group Members** 
  - Salvatore Arpaia, Antoine Messéan (chair), Barbara Manachini and Jeremy Sweet

#### Hearing Experts<sup>1</sup>

- None
- **European Commission and/or Member States representatives** 
  - Anastasia Pagida (DG SANTE)
- **EFSA** 
  - GMO Unit: Fernando Álvarez
  - AMU Unit: Marios Georgiadis and Laura Martino

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.

#### 2. Adoption of agenda

The agenda was adopted without changes.

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interests,<sup>3</sup> EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:

http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

 <sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
<sup>3</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

# 4. Agreement of the minutes of the 33<sup>rd</sup> Working Group meeting held on 3 April 2017 (Parma)

The minutes of the  $33^{rd}$  Working Group meeting held on 3 April 2017 were agreed by written procedure on 5 April 2017.<sup>4</sup>

#### 5. Any Other Business

The Working Group discussed the implementation of the EFSA's draft uncertainty guidance in the assessment of annual PMEM reports of genetically modified plants. Further discussion is needed.

#### 6. Next meetings

- 10 May 2017 (TELE/WEB)

<sup>&</sup>lt;sup>4</sup> <u>http://www.efsa.europa.eu/sites/default/files/gmopmemreports2017.pdf</u>



# Scientific Panel on Genetically Modified Organisms Minutes of the 33<sup>rd</sup> meeting of the Working Group on Annual Post-Market Environmental Monitoring (PMEM) reports

### Held on 3 April 2017 (Parma)

(Agreed on 5 April 2017)

#### Participants

- Working Group Members
  - Salvatore Arpaia, Antoine Messéan (chair), Barbara Manachini and Jeremy Sweet
- Hearing Experts<sup>1</sup>
  - None
- European Commission and/or Member States representatives
  - Anastasia Pagida (DG SANTE)
- EFSA
  - GMO Unit: Fernando Álvarez
  - AMU Unit: Marios Georgiadis and Laura Martino

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

# 2. Adoption of agenda

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</u>



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interests,<sup>3</sup> EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

# 4. Agreement of the minutes of the 32<sup>nd</sup> Working Group meeting held on 9 March 2017 (TELE/WEB)

The minutes of the of the 32<sup>nd</sup> Working Group meeting held on 9 March 2017 were agreed by written procedure on 10 March 2017.<sup>4</sup>

### **5.** Scientific topics for discussion

#### 5.1 Annual 2015 PMEM report on maize MON 810<sup>5</sup>

The Working Group discussed the information provided by the consent holder in its 2015 PMEM report on maize MON 810. Upon request of the European Commission, the Working Group assessed the findings of the monitoring activities and the appropriateness of the methodology taking into account the comments received from Member States. The scientific opinion can proceed to finalisation.

#### 6. Any Other Business

The Working Group discussed the implementation of the EFSA's draft uncertainty guidance in the assessment of annual PMEM reports of genetically modified plants. Further discussion is needed.

#### 7. Next meetings

- 27 April 2017 (TELE/WEB)

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

<sup>&</sup>lt;sup>4</sup> <u>http://www.efsa.europa.eu/sites/default/files/gmopmemreports2017.pdf</u>

<sup>&</sup>lt;sup>5</sup> http://registerofquestions.efsa.europa.eu/rogFrontend/questionLoader?question=EFSA-Q-2016-00690



# Scientific Panel on Genetically Modified Organisms

# Minutes of the 32<sup>nd</sup> meeting of the Working Group on Annual Post-Market Environmental Monitoring (PMEM) reports

# Held on 9 March 2017 (TELE/WEB)

# (Agreed on 10 March 2017)

# Participants

- Working Group Members
  - Salvatore Arpaia, Antoine Messéan (chair), Barbara Manachini and Jeremy Sweet
- Hearing Experts<sup>1</sup>
  - None
- European Commission and/or Member States representatives
  - Anastasia Pagida (DG SANTE)
- EFSA
  - GMO Unit: Fernando Álvarez
  - AMU Unit: Marios Georgiadis

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

# 2. Adoption of agenda

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</u>



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interests,<sup>3</sup> EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

#### 4. Agreement of the minutes of the 31<sup>st</sup> Working Group meeting held on 7 February 2017 (Parma)

The minutes of the of the 31<sup>st</sup> Working Group meeting held on 27 February 2017 were agreed by written procedure on 3 March 2017.<sup>4</sup>

# 5. Any Other Business

The Working Group discussed the implementation of the EFSA's draft uncertainty guidance in the assessment of annual PMEM reports of genetically modified plants. Further discussion is needed.

#### 6. Next meetings

- 3 April 2017 (Parma)

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u> 3 <u>http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf</u>

http://www.efsa.europa.eu/sites/default/files/gmopmemreports2017.pdf



# Scientific Panel on Genetically Modified Organisms Minutes of the 31st meeting of the Working Group on Annual Post-Market Environmental Monitoring (PMEM) reports

# Held on 27 February 2017 (Parma)

# (Agreed on 3 March 2017)

# Participants

- Working Group Members
  - Salvatore Arpaia, Antoine Messéan (chair) and Jeremy Sweet
- Hearing Experts<sup>1</sup>
  - None
- European Commission and/or Member States representatives
  - Anastasia Pagida (DG SANTE)
- EFSA
  - GMO Unit: Fernando Álvarez and Yann Devos
  - AMU Unit: Marios Georgiadis

# 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Barbara Manachini

# 2. Adoption of agenda

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</u>



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interests,<sup>3</sup> EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

# 4. Agreement of the minutes of the 30<sup>th</sup> Working Group meeting held on 7 February 2017 (Parma)

The minutes of the of the 30<sup>th</sup> Working Group meeting held on 7 February 2017 were agreed by written procedure on 8 February 2017.<sup>4</sup>

# **5.** Scientific topics for discussion

# 5.1 Annual 2015 PMEM report on maize MON 810<sup>5</sup>

The Working Group revised the draft text of the scientific opinion. Further discussion might be needed.

# 6. Any Other Business

- 7. Next meetings
  - 9 March 2017 (Parma)

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

<sup>&</sup>lt;sup>4</sup> <u>http://www.efsa.europa.eu/sites/default/files/gmopmemreports2017.pdf</u>

<sup>&</sup>lt;sup>5</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00690</u>



# Scientific Panel on Genetically Modified Organisms Minutes of the 30th meeting of the Working Group on Annual Post-Market Environmental Monitoring (PMEM) reports

### Held on 7 February 2017 (Parma)

(Agreed on 8 February 2017)

#### Participants

- Working Group Members
  - Salvatore Arpaia, Barbara Manachini, Antoine Messéan (chair) and Jeremy Sweet
- Hearing Experts<sup>1</sup>
  - Gema Farinós (Centro de Investigaciones Biológicas) and Thomas Thieme (Bio-Test lab)
  - Liesselot Bertho, Ivo Brants, Graham Head and Conchi Novillo (Monsanto)
- European Commission and/or Member States representatives
  - Anastasia Pagida (DG SANTE)
- EFSA
  - GMO Unit: Fernando Álvarez and Yann Devos
  - AMU Unit: Marios Georgiadis and Laura Martino

# **1. Welcome and apologies for absence**

The Chair welcomed the participants.

# 2. Adoption of agenda

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</u>



## 3.Hearing Expert(s)

Ms. Gema Farinós and Mr. Thomas Thieme were invited to present their views for agenda item 5.1. Ms. Liesselot Bertho, Mr. Ivo Brants, Mr. Graham Head and Ms. Conchi Novillo were invited to elaborate on the specific questions they were called upon for agenda item 5.1 of the present meeting on behalf of the applicant Monsanto. All hearing experts attended the meeting on 7 February 2017 from 09:30 to 13:30 (CET time).

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interests<sup>3</sup>, EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

# 4. Agreement of the minutes of the 29<sup>th</sup> Working Group meeting held on 23 January 2017, Parma

The minutes of the of the 29<sup>th</sup> Working Group meeting held on 23 January 2017 were agreed by written procedure on 24 January 2017<sup>4</sup>.

#### **5.** Scientific topics for discussion

#### 5.1 Annual 2015 PMEM report on maize MON 810<sup>5</sup>

Upon request from EFSA, the applicant was given the opportunity to present at a hearing the additional information related to its 2015 PMEM report. After the hearing was finished, and the hearing expert(s) left the room/teleconference, the WG/Panel discussed the clarifications provided by the applicant. EFSA will follow up by providing the applicant with a written summary of the points discussed as well as of the next steps and relative timelines.

#### **6.** Any Other Business

#### 7. Next meetings

- 27 February 2017 (Parma)

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

<sup>&</sup>lt;sup>4</sup> <u>http://www.efsa.europa.eu/sites/default/files/gmopmemreports2016.pdf</u>

<sup>&</sup>lt;sup>5</sup> <u>http://registerofguestions.efsa.europa.eu/rogFrontend/guestionLoader?guestion=EFSA-Q-2016-00690</u>



# Scientific Panel on Genetically Modified Organisms Minutes of the 29th meeting of the Working Group on Annual Post-Market Environmental Monitoring (PMEM) reports

### Held on 23 January 2017 (Parma)

(Agreed on 24 January 2017)

#### **Participants**

- Working Group Members
  - Salvatore Arpaia, Barbara Manachini, Antoine Messéan (chair) and Jeremy Sweet
- Hearing Experts<sup>1</sup>
  - None
- European Commission and/or Member States representatives
  - Anastasia Pagida (DG SANTE)
- EFSA
  - GMO Unit: Fernando Álvarez
  - AMU Unit: Marios Georgiadis and Laura Martino

# 1. Welcome and apologies for absence

The Chair welcomed the participants.

# 2. Adoption of agenda

<sup>&</sup>lt;sup>1</sup> As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <u>http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</u>



In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interests,<sup>3</sup> EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

# 4. Agreement of the minutes of the 28<sup>th</sup> Working Group meeting held on 20 December 2016 (TELE/WEB)

The minutes of the of the 28<sup>th</sup> Working Group meeting held on 20 December 2016 were agreed by written procedure on 20 December 2016.<sup>4</sup>

#### 5. Scientific topics for discussion

#### **5.1 Annual 2015 PMEM report on maize MON 810<sup>5</sup>**

The Working Group discussed the information provided by the consent holder in its 2015 PMEM report on maize MON 810. Further discussion is needed.

#### **6.** Any Other Business

The Working Group discussed the implementation of the EFSA's draft uncertainty guidance in the assessment of annual PMEM reports of genetically modified plants. Further discussion is needed.

#### 7. Next meetings

- 7 February 2017 (Parma)

<sup>&</sup>lt;sup>2</sup> <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

<sup>&</sup>lt;sup>4</sup> <u>http://www.efsa.europa.eu/sites/default/files/gmopmemreports2016.pdf</u>

<sup>&</sup>lt;sup>5</sup> <u>http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00690</u>