



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 229th MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 28 September 2021, Tele/WEB
(Agreed on 28 September 2021)**

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
DG SANTE: Juliette-Marie Margueritte
- EFSA:
GMO Unit: Giacomo De Sanctis, Andrea Gennaro, Franco Maria Neri, and Franz Streissl
SCER Unit: Yann Devos (for items 6.3 and 7.1)
- Others:
None

1. Welcome and apologies for absence

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

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 228th Working Group meeting held on 6 July 2021, Tele/WEB.

The minutes of the 228th Working Group meeting held on 6 July 2021 were agreed on the 8 July 2021.⁴

5. Scientific topics on applications for discussion

5.1. EFSA-GMO-NL-2018-151 (Maize MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9)⁵

The Working Group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-DE-2019-157 (Canola LBFLFK)⁶

The Working Group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁷

The Working Group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-NL-2020-171 (Maize DP4114 x MON89034 x MON87411 x DAS-40278-9)⁸

The Working Group discussed the application. Further discussion is needed.

5.1. EFSA-GMO-NL-2020-172 (Maize DP-915635-4)⁹

The Working Group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00457>

⁶ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00394>

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00419>

⁸ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00833>

⁹ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00834>



6. Scientific topics for discussion

6.1. Assessment of additional information on oilseed rape MS11 (EFSA-GMO-BE-2016-138)¹⁰

The working group discussed the mandate. Further discussion is needed.

6.2. Food and feed risk assessment of SynBio-derived plants¹¹

The working group was updated on the progresses made with the drafting of the scientific opinion with particular attention on the comparative analysis of such plants.

6.3. Discussion of the «Marotti et al. (2020) » publication¹²

The working group reviewed the Marotti et al. (2020) publication and discussed its possible implication for the environmental risk assessment of plant-to-plant gene transfer in *Brassica napus* applications.

7. Any other business

7.1. Update on upcoming mandate on teosinte

8. Next meeting

30 November 2021, Tele/WEB

¹⁰ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00044>

¹¹ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00052>

¹² Marotti et al., 2020 Evaluation of the propensity of interspecific hybridization between oilseed rape (*Brassica napus* L.) to wild-growing black mustard (*Brassica nigra* L.) displaying mixoploidy. Plant Science 296: 110493.
<https://doi.org/10.1016/j.plantsci.2020.110493>

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 228th MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 6 July 2021, Tele/WEB
(Agreed on 8 July 2021)**

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
DG SANTE: Juliette-Marie Margueritte and Anastasia Pagida (for item 6.1)
- EFSA:
DATA Unit: Jose Ángel Gómez Ruiz (for item 7.1) and Giovanni Iacono (for item 5.1)
GMO Unit: Giacomo De Sanctis, Andrea Gennaro, Franco Maria Neri, Pietro Piffanelli (for item 5.2) and Franz Streissl
SCER Unit: Yann Devos (for item 6.1)
- Others:
None

1. Welcome and apologies for absence

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

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 227th Working Group meeting held on 25 June 2021, Tele/WEB.

The minutes of the 227th Working Group meeting held on 25 June 2021 were agreed on the 25 June 2021.⁴

5. Scientific topics on applications for discussion

5.1. EFSA-GMO-DE-2019-157 (Canola LBFLFK)⁵

The Working Group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁶

The Working Group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-BE-2019-165 (Soybean DBN-09004-6)⁷

The Working Group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-NL-2020-169 (Oilseed rape MON 94100)⁸

The Working Group discussed the application. Further discussion is needed.

5.5. EFSA-GMO-NL-2020-170 (Maize MON 95379)⁹

The Working Group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00394>

⁶ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00419>

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00013>

⁸ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00749>

⁹ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00786>



6. Scientific topics for discussion

6.1. Teosinte

The Working Group reviewed and discussed the publication by Lohn et al. (2021), entitled “*Transgene behaviour in genetically modified teosinte hybrid plants: transcriptome expression, insecticidal protein production and bioactivity against a target insect pest*”.¹⁰

The evidence reported in the publication indicates that:

- (1) Spanish teosinte plants (#9) hand-pollinated by maize MON810 (variety LG30490YG) pollen under controlled conditions (i.e. climate chambers, with removal of immature tassels from female plants) produced 2.7% viable F₁ seeds (in contrast to 92.8% when maize MON810 plants [#6 plants] were hand-pollinated by Spanish teosinte pollen);
- (2) *cry1Ab* mRNA and Cry1Ab protein were stably and consistently expressed in all leaf samples taken from teosinte hybrids (#6 leaf samples of teosinte [female]×maize MON810 [male] plants, #15 leaf samples of maize MON810 [female]×teosinte [male] plants) grown under controlled conditions (i.e. climate chambers). It was also observed that:
 - a. mRNA levels of the *cry1Ab* transgene in the Spanish teosinte F₁ hybrid plants do not appear to determine directly, in any measurable way, the concentration of the produced Cry1Ab protein;
 - b. The concentration of Cry1Ab protein in the leaf samples of Spanish teosinte F₁ hybrids is similar to that of maize MON810 plants;
- (3) Toxicity on second instar larvae of European corn borers (ECB) *Ostrinia nubilalis*, presumably due to Cry1Ab, was observed, with mortality rates of 95% or higher after only 4 days exposure. Similar mortality rates were observed for larvae fed leaves of Spanish teosinte F₁ hybrids and maize MON810, while the mean larval mortality rate of ECB fed plant material from Spanish teosinte was 27%.

The Working Group notes that the information reported in the scientific publication is insufficient to adequately appraise the scientific quality of the data and methods as reported by the authors.

The Working Group is of the opinion that, contrary to the authors’ claims, the findings reported by Lohn et al. (2021) do not invalidate the assumptions made in EFSA (2016) and associated environmental risk assessment conclusions and risk management recommendations for maize MON810 made by the GMO Panel. On the contrary, the findings are consistent with the previously hypothesised pathways to harm for the cultivation of maize MON810.

Lohn et al. (2021) write that one of the conclusions of EFSA (2016) was “*that gene flow rates from maize to Spanish teosinte would be “too low” to allow significant gene flow to occur “even if teosinte is abundant”*”. The Working Group notes that nowhere in EFSA (2016) has such a statement been made. Instead, EFSA (2016) considered that “*while gene flow from maize to teosinte can be observed in field trials designed to maximise the probability of hybridisation, actual rates of gene flow from maize to mexicana are probably quite low, even when teosinte is abundant*”.

The Working Group notes that the findings reported by Lohn et al. (2021) do not support the authors’ claim that “*First, we show that crop/weed hybridization in fields where maize and teosinte exist sympatrically can lead to potentially catastrophic transfer of resistance traits into an already noxious weed*”. This is because Lohn et al. (2021) did not: (1) quantify actual rates of vertical gene flow from maize to Spanish teosinte under field conditions (instead the experimental design implemented by Lohn et al. (2021) was tailored to maximise hybridisation rates, and so overestimated actual real-life

¹⁰ <https://enveurope.springeropen.com/articles/10.1186/s12302-021-00506-x>



hybridisation rates); and (2) investigate the potential of viable F₁ teosinte hybrid seeds to germinate, establish and persist in and near maize fields.

To ensure the risk of Cry1Ab resistance evolving in corn borer populations is further minimised, the Working Group reiterates its previous recommendation (see webminutes of the 225th meeting) that:

- (1) Maize MON810 cultivation be restricted in fields where teosinte or teosinte hybrid plants occur;
- (2) Refuges of non-Cry1Ab-expressing maize are not planted where teosinte or teosinte hybrid plants are found.

7. Any other business

7.1. Update in the upcoming implementation of the requirements of the statement on human dietary exposure assessment to newly expressed proteins in GM food

The Working Group discussed the technicalities in sampling pollen for protein expression data from oilseed rape and soybean plants.

8. Next meeting

28 September 2021, Tele/WEB



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 227th MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 25 June 2021, Tele/WEB

(Agreed on 25 June 2021)

Participants

- Working Group Members:
Antoine Messéan and Ewen Mullins
- Hearing Experts¹:
Paolo Bàrberi, Ian Dewhurst, Thomas Frenzel, Javier Moreno, Nils Rostoks and Jose Juan Sanchez Serrano
- European Commission and/or Member States representatives:
DG SANTE: Juliette-Marie Margueritte
- EFSA:
GMO Unit: Michele Ardizzone, Giacomo De Sanctis, Silvia Federici, Andrea Gennaro, Tilemachos Goumperis, Franco Maria Neri, Dafni Maria Kagkli, Anna Lanzoni, Nikoletta Papadopoulou, Pietro Piffanelli and Tommaso Raffaello
- Others:
None

1. Welcome and apologies for absence

EFSA welcomed the participants. No apologies for absence were received.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 226th Working Group meeting held on 11 May 2021, Tele/WEB.

The minutes of the 226th Working Group meeting held on 11 May 2021 were agreed by written procedure on the 17 May 2021.⁴

5. Hearing Experts

Paolo Bàrberi, Ian Dewhurst, Thomas Frenzel, Javier Moreno, Nils Rostoks and Jose Juan Sanchez Serrano were invited to present their views for the items of the present meeting.

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA invited Paolo Bàrberi, Ian Dewhurst, Thomas Frenzel, Javier Moreno, Nils Rostoks and Jose Juan Sanchez Serrano to submit an Annual Declaration of Interest. Their participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e. not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

6. Scientific topics for discussion

6.1. EFSA-GMO-NL-2019-154 (Cotton GHB811)⁷

The working group discussed the application. Further discussion is needed.

6.2. EFSA-GMO-NL-2019-158 (*Brassica juncea* CQ RF3)⁸

The working group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00808>

⁸ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00412>



6.3. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁹

The working group discussed the application. Further discussion is needed.

7. Any other business

None.

8. Next meeting

6 July 2021, Tele/WEB

⁹ <https://open.efsa.europa.eu/questions/EFSA-O-2019-00419>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 226th MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 11 May 2021, Tele/WEB

(Agreed on 17 May 2021)

Participants

- Working Group Members:
Antoine Messéan
- Hearing Experts¹: None
- European Commission and/or Member States representatives: Anastasia Pagida
- EFSA:
GMO Unit: Franz Streissl
PREV Unit: Fernando Alvarez
SCER Unit: Yann Devos (for discussion on recommendations)
- Others: None

1. Welcome and apologies for absence

The chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 225th Working Group meeting held on 3-4 May 2021, Tele/WEB.

The minutes of the 225th Working Group meeting held on 3-4 May 2021 were agreed on 7 May 2021.⁴

5. Scientific topics for discussion

5.1. Request from the European Commission to assess the annual 2019 post-market environmental monitoring (PMEM) report on maize MON 810)⁵

The working group discussed the draft statement on the annual PMEM report. The recommendation section was agreed and the answers to MSs comments were discussed.

6. Any Other Business

None

7. Next meeting

6 June, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/qmo/working-groups>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00029>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 225th MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 3-4 May 2021, Tele/WEB
(Agreed on 7 May 2021)**

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins (chair), Christoph Tebbe (items 7.1 and 7.2)
Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Paolo Bàrberi (item 7.3) and Boet Glandorf (item 7.1)
- European Commission and/or Member States representatives:
Juliette-Marie Margueritte and Anastasia Pagida
- EFSA:
GMO Unit: Giacomo De Sanctis, Andrea Gennaro, Franco Maria Neri and Franz Streissl
SCER Unit: Yann Devos
- Others:
None

1. Welcome and apologies for absence

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

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 224th Working Group meeting held on 8 April 2021, Tele/WEB.

The minutes of the 224th Working Group meeting held on 8 April 2021 were agreed by written procedure on the 9 April 2021.⁴

5. Hearing Experts

Prof. Paolo Bàrberi was invited to present his views for item 7.3 and Dr. Debora Glandorf to present her view for item 7.1 of the present meeting.

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA invited Prof. Paolo Bàrberi and Dr. Debora Glandorf to submit an Annual Declaration of Interest. Their participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e. not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

6. Scientific topics on applications for discussion

6.1. EFSA-GMO-DE-2017-141 (Cotton COT102)⁷

The working group discussed the application. Further discussion is needed.

6.2. EFSA-GMO-NL-2019-154 (Cotton GHB811)⁸

The working group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ <https://open.efsa.europa.eu/questions/EFSA-Q-2017-00271>

⁸ <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00808>



6.3. EFSA-GMO-NL-2019-158 (*Brassica juncea* CQ RF3)⁹

The working group discussed the application. Further discussion is needed.

7. Scientific topics for discussion

7.1. Exposure of soil organisms to *Bt* proteins via manure

The working group discussed the topic. Further discussion is needed.

7.2. Post-market environmental monitoring (PMEM) report on the cultivation of maize MON810 for 2019¹⁰

The working group was updated on the assessment of relevant publications identified in the frame of the 2019 PMEM report, and discussed the relevance and quality of specific publications.

7.3. Genetically modified plants with tolerance to multiple herbicides

The working group discussed different strategies to assess genetically modified plants tolerant to more than one herbicide. Further discussion is needed.

7.4. Teosinte¹¹

In line with the request of the European Commission (DG SANTE), the working group assessed the information on teosinte supplied by the Competent Authorities of France and Spain, existing scientific literature and any other pertinent information. The outcome of the assessment performed by the working group is reported in the Annex of the webminutes (see Annex).

7.5. External scientific report by Baudrot et al. (2021)¹²

The working group discussed the external scientific report by Baudrot et al. (2021). Further discussion is needed on model applicability.

7.6. Assessment of additional information on oilseed rape MS11 (EFSA-GMO-BE-2016-138)¹³

The working group discussed the mandate. Further discussion is needed.

⁹ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00412>

¹⁰ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00029>

¹¹ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00266>

¹² <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6443>

¹³ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00044>



8. Any other business

None.

9. Next meeting

11 May 2021, Tele/WEB (annual PMEM report on MON810 only)



Annex – Update on teosinte | Report on the outcome of the assessment performed by the COMPERA Working Group at its meeting of 3-4 May 2021

Background

In its 2016 technical report on teosinte (EFSA, 2016)¹⁴, EFSA assessed the possible consequences of vertical gene flow from the genetically modified (GM) maize events MON810, Bt11, 1507 and GA21 for cultivation through the pathway to potential harm approach. While vertical gene flow and introgression between maize and *Zea mays* subsp. *mexicana* may occur under field conditions, it is expected to occur at low rates. The possible introgression of transgenes from maize MON810, Bt11, 1507 and GA21 into weedy teosinte may provide a selective advantage to hybridising teosinte progeny only under high infestation of target pests and/or when glufosinate-ammonium- and/or glyphosate-containing herbicides are applied. Therefore, it was concluded that the overall environmental exposure to teosinte hybrid plants, bearing either the insect resistance or herbicide tolerance trait or both, would remain low compared to exposure to GM maize, provided that measures are employed to control and/or eradicate weedy teosintes and their progeny in infested agricultural areas.

Based on the available evidence, the impact of insect resistance and/or herbicide tolerance in teosinte hybrid plants on other organisms (including target and non-target organisms), the abiotic environment or biogeochemical cycles was considered to be very low under EU conditions.

EFSA (2016) also concluded that the use of glyphosate-containing herbicides on maize GA21 may enhance the fitness of glyphosate tolerant maize × teosinte hybrids, should they occur within the confines of a managed field environment where glyphosate is applied. To ensure effective long-term management of weedy teosinte and teosinte hybrid plants that may acquire glyphosate tolerance through vertical gene flow from maize GA21, and avoid exacerbating weed problems, EFSA recommended integrated weed management reliant on multiple tactics (e.g. alternative chemistry mixtures, mechanical, rotational) be deployed, should maize GA21 be grown in areas where teosinte occurs.

Assessment of new relevant scientific publications

The COMPERA Working Group previously assessed the publications by Díaz et al. (2020)¹⁵ and Le Corre et al. (2020)¹⁶ at its 218th and 219th meetings¹⁷, respectively. The Working Group concluded that:

- Owing to limitations associated with the design and resulting conclusions of the study conducted and reported by Díaz et al. (2020), no reliable scientific deductions can be drawn from it;
- The evidence reported by Le Corre et al. (2020) demonstrates that:
 - Weedy teosinte found both in France and Spain derive from *Zea mays* ssp. *mexicana*, suggesting a single geographical origin for teosinte plants found in Europe;
 - French teosinte is adapted to European temperate latitude growing conditions (i.e. early flowering), compared to *Zea mays* ssp. *mexicana*;

¹⁴ <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2016.EN-1094>

¹⁵ <https://link.springer.com/article/10.1007/s10722-019-00828-z>

¹⁶ <https://www.pnas.org/content/117/41/25618>

¹⁷ <https://www.efsa.europa.eu/sites/default/files/wqs/qmo/qmocompera2019.pdf>



- Some characteristics/phenotypic traits of conventional maize (i.e. high latitude dent maize) varieties, including herbicide tolerance (i.e. a mutant herbicide-target gene (*ACC1*)), have successfully introgressed in French teosintes, confirming the occurrence of vertical gene flow from conventional maize varieties to weedy teosinte when maize and weedy teosintes grow sympatrically.

Overall, the COMPERA Working Group concluded that the evidence reported by Le Corre et al. (2020) does not indicate the need to revise the previous environmental risk assessment conclusions and risk management recommendations for maize MON810, Bt11, 1507 and GA21 made by the GMO Panel. This is primarily because, based on the available evidence, the potential for vertical gene flow between maize and *Zea mays* subsp. *mexicana* under field conditions has been considered previously by EFSA, and the environmental consequences thereof assessed through the pathway to potential harm approach.

Nevertheless, the Working Group considered that further discussion is required on the potential need to update the post-market environmental monitoring (PMEM) plan for maize MON810.

Request from the European Commission

Following the publication of the scientific papers by Díaz et al. (2020) and Le Corre et al. (2020) and their assessment by the COMPERA Working Group, the European Commission (DG SANTE) approached the Competent Authorities of the Member States affected by teosinte occurrence in their territory (i.e. France and Spain), with the purpose of obtaining relevant information on teosinte gathered by them.

Based on the information supplied by the Competent Authorities of France and Spain, existing scientific literature and any other pertinent information, EFSA has been asked in a letter of the European Commission (dated 20 April 2021; Ares(2021)2647635) to assess whether there is a need to update:

1. The PMEM plan for maize MON810;
2. The EFSA (2016) technical report on teosinte.

Documents supplied by the Competent Authorities of France and Spain

Along with its request, the European Commission provided the following documents to EFSA:

1. Documents provided by the Competent Authority of France
 - a. Note on the teosinte situation in France from the authorities (original document in French);
 - b. Annex – Teosinte: A weed that requires special vigilance (original document in French).
2. Documents provided by the Competent Authority of Spain
 - a. Report of the National Biosafety Committee (CNB) on the presence of teosinte in Europe (official translation in English);
 - b. Reply to the request for information on the teosinte situation in Catalonia (official translation in English);
 - c. Report on the teosinte (*Zea mays* subsp.) situation in the autonomous community of Aragon, 2020 (official translation in English).



Information reported in the documents supplied by the Competent Authorities of France and Spain

Information relevant for the environmental risk assessment of maize MON810 reported in the documents supplied by the Competent Authorities of France and Spain is briefly summarised below.

The observations reported on the occurrence of teosinte in France are based on field surveys conducted by Arvalis in 2012, FREDON de Nouvelle Aquitaine in 2019 and INRAE between 2017 and 2020. The observations on teosinte reported in Spain are based on systematic field surveys conducted in Aragon between 2014 and 2020 and in Catalonia between 2015 and 2020.

Endpoints	France (no cultivation of maize MON810)	Spain (cultivation of maize MON810)
Occurrence/density of teosinte and its progeny in and near maize fields (in-field, field margins, off-field)	<ul style="list-style-type: none"> -Teosinte is mostly found in maize fields (more than 80% of the observations), and less in soybean fields (ca. 10%) and other fields (sunflower, cereal stubble or sorghum) -The occurrence of teosinte did not expand since 2012 -Teosinte is rarely found in field margins or off-field (2 plants were observed). No teosinte populations were observed in non-cropped land -Hybrid-like teosinte spikes were rarely observed in maize fields (in less than one out of 10 fields, each time on a single plant or a small number of plants; see also Figure 10 in the supplementary material reported by Le Corre et al., 2020) 	<ul style="list-style-type: none"> -Both in Aragon and Catalonia, teosinte is mainly found in maize fields -Overall, the occurrence of teosinte tends to be stable or even lower since it was detected in 2014 -Teosinte is not found in field margins or further away because teosinte is unable to survive under these conditions -Typically, teosinte has not been found in <i>Bt</i> maize fields, except in Bujaraloz (Aragon) in 2014
Hybridisation potential between maize and teosinte	<ul style="list-style-type: none"> -A preliminary hybridisation experiment carried out by INRAE suggests that the spontaneous hybridisation rate of maize by teosinte pollen is an order of magnitude higher than that of teosinte by maize pollen (less than 0.1%) -In 2021 and 2022, INRAE will continue molecular genetics work to further characterise introgression between French teosinte and maize 	<ul style="list-style-type: none"> -A preliminary hybridisation study performed under greenhouse conditions in 2016 and repeated in 2017 failed to detect the Cry1Ab protein in the progeny (grains) derived from the artificial crosses -Research by INIA and CSIC is ongoing to determine levels of Cry1Ab expression in hybrids of <i>Bt</i> maize and <i>Zea mays</i> subsp. <i>mexicana</i> and <i>Zea mays</i> subsp. <i>parviglumis</i> and in their progeny



		-The ability of teosinte from the Ebro Valley to cross with <i>Bt</i> maize is being studied. The progeny will be subject to Cry1Ab expression analyses
Occurrence/density of teosinte and its progeny in non- <i>Bt</i> maize refuge areas	Not investigated/monitored as there is no cultivation of maize MON810	No teosinte has been found in non- <i>Bt</i> maize refuges in Aragon and Catalonia
Host plant suitability of teosinte and its progeny for European and Mediterranean corn borers	-Not investigated/monitored systematically as there is no cultivation of maize MON810 -In the plots sampled by INRAE, the presence of larvae was occasionally observed on teosinte plants and/or in their ears or stem. However, they have not been identified	-Not investigated/monitored systematically -Larvae of both corn borer species were observed at various larval stages in teosinte plants in the Ebro Valley -During visits of infested sites over the course of all the years (2014 to 2020) corn borer infestations of teosinte were observed -At present, it is still not known whether corn borer larvae are able to complete their development cycle on the plant. Research efforts are ongoing to address the matter
Host plant suitability of teosinte and its progeny for non-target Lepidoptera larvae	Not investigated/monitored	-Not investigated/monitored -Studies in Central America and Mexico suggest that maize and teosinte host similar insects (see report for references)
Occurrence of Cry1Ab protein in teosinte and its progeny	Not investigated/monitored systematically as there is no cultivation of maize MON810	-Not investigated/monitored systematically in Aragon and Catalonia -In a preliminary study performed by INIA in Aragon, qualitative analyses using lateral-flow immunoassays for Cry1Ab presence were performed on plant material derived from teosinte sampled in fields of conventional maize or refuge areas close to fields of <i>Bt</i> maize. No Cry1Ab was detected -In the future, monitoring efforts may focus on testing for Cry1Ab protein presence in teosinte plants and their progeny potentially found in <i>Bt</i>



		maize fields in Aragon and Catalonia
Cry1Ab expression levels in teosinte and its progeny	Not investigated/monitored systematically as there is no cultivation of maize MON810	Not investigated/monitored

Assessment of the information supplied by the Competent Authorities of France and Spain

The COMPERA Working Group wishes to thank the Competent Authorities of France and Spain for sharing the additional information gathered on teosinte and supplied to EFSA via the European Commission (DG SANTE).

The documents provided by the Competent Authorities of France and Spain do not report on the materials and methods used to gather and analyse the data. Moreover, no details are provided about sampling efforts. Consequently, the COMPERA Working Group is not in a position to fully appraise the quality of the data reported and conclusions drawn by the respective authorities.

Nevertheless, the field observations, mostly on the occurrence of teosinte, reported by the Competent Authorities of France and Spain do not invalidate the assumptions made in EFSA (2016). On the contrary, the observations deliver evidence to further test specific risk hypotheses of the previously devised pathways to potential harm for the cultivation of maize MON810. In particular, the field surveys conducted suggest that the occurrence of teosinte did not increase substantially in the affected regions. Moreover, teosinte is mostly found in maize fields and less in soybean fields, whilst it is rarely observed in non-cropped land (e.g. field margins, off-field). The preliminary results of the hybridisation studies are consistent with previously reported evidence, which indicates that vertical gene flow and introgression between maize and *Zea mays* subsp. *mexicana* may occur under field conditions at low rates, while the hybridisation rate between maize and *Zea mays* subsp. *parviglumis*, where incompatibility is absent, is much higher. Overall, the field survey observations suggest that the environmental exposure to potential Cry1Ab-expressing teosinte hybrid plants would remain extremely low compared to exposure to maize MON810.

While this pathway to potential harm is most unlikely, theoretically potential patches of Cry1Ab-expressing teosinte hybrid plants (if they do not express the Cry1Ab protein at sufficiently high dose to kill corn borer larvae) occurring in maize MON810 fields or non-*Bt* maize refuges could contribute to resistance evolution. Therefore, to ensure the risk of Cry1Ab resistance evolving in corn borer populations is further minimised, the COMPERA Working Group recommends maize MON810 cultivation be restricted in fields where teosinte or teosinte hybrid plants occur, and refuges of non-Cry1Ab-expressing maize are not planted where teosinte or teosinte hybrid plants are found.

Relevant existing scientific literature and any other relevant information

Besides the previously considered peer-reviewed publications by Trtikova et al. (2017)¹⁸, Devos et al. (2018)¹⁹, Bauer-Panskus et al. (2020)²⁰, Díaz et al. (2020), EFSA (2020)²¹ and Le Corre et al. (2020), the COMPERA Working Group is not aware of any other information on teosinte relevant for the environmental risk assessment and risk management of maize MON810.

¹⁸ <https://www.nature.com/articles/s41598-017-01478-w>

¹⁹ <https://www.sciencedirect.com/science/article/abs/pii/S0167880918301075>

²⁰ <https://enveurope.springeropen.com/articles/10.1186/s12302-020-00301-0>

²¹ <https://www.efsa.europa.eu/en/supporting/pub/en-1890>



Conclusion and recommendations

The COMPERA Working Group **considers** that the observations reported in the documents of the Competent Authorities of France and Spain, together with relevant existing scientific literature and any other relevant information, do not invalidate the assumptions made in EFSA (2016) and associated environmental risk assessment conclusions and risk management recommendations for maize MON810 made by the GMO Panel. In addition, based on the assessment of the available evidence, the COMPERA Working Group **concludes** that:

1. The practical implementation of the PMEM plan for maize MON810 through annual PMEM reports needs to address teosinte more explicitly in the future;
2. The EFSA (2016) technical report on teosinte needs to be updated to integrate and report the most recent and relevant information on teosinte for the environmental risk assessment and risk management of maize MON810, Bt11, 1507 and GA21.

More specifically, the COMPERA Working Group **recommends** that for:

1. Future annual PMEM reports on maize MON810
 - a. All scientific evidence relevant for the environmental risk assessment and risk management of maize MON810 be considered explicitly by the consent holder;
 - b. The farmer questionnaires be revised to include the reporting of both the occurrence of teosinte and teosinte hybrid plants and the corresponding level of infestation;
 - c. The consent holder and the Competent Authorities where maize MON810 is grown ensure robust information systems are in place to promote the sharing of relevant information on teosinte;
2. The EFSA (2016) technical report on teosinte
 - a. The most recent and relevant scientific evidence be integrated and referred to since its publication;
 - b. The insect risk management recommendations be expanded to ensure that:
 - i. Maize MON810 cultivation be restricted in fields where teosinte or teosinte hybrid plants occur;
 - ii. Refuges of non-Cry1Ab-expressing maize are not planted where teosinte or teosinte hybrid plants are found;
3. Activities performed by the Competent Authorities of France and Spain
 - a. Further details on the materials and methods used to gather and analyse the valuable data (including sampling efforts) presented in the documents provided by the Competent Authorities of France and Spain be reported;
 - b. The research/monitoring activities pertaining to teosinte performed/commissioned by the Competent Authorities of France and Spain be continued and expanded. This will be critical for the generation of empirical data on teosinte and potential teosinte hybrid plants that could be used to further test specific risk hypotheses of the previously devised pathways to potential harm for the cultivation of maize MON810.



GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 224th MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 8 April 2021, Tele/WEB
(Agreed on 9 April 2021)**

Participants

- Working Group Members:
Antoine Messéan
- Hearing Experts¹: None
- European Commission and/or Member States representatives: None
- EFSA:
GMO Unit: Franz Streissl
PREV Unit: Fernando Alvarez
- Others: None

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

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 223rd Working Group meeting held on 16 March 2021, Tele/WEB.

The minutes of the 223rd Working Group meeting held on 16 March 2021 were agreed on the 18 March 2021.⁴

5. Scientific topics for discussion

5.1. Request from the European Commission to assess the annual 2019 post-market environmental monitoring (PMEM) report on maize MON 810)⁵

The working group discussed the methodology and outcomes of the general surveillance and case specific monitoring activities provided by the consent holder in the 2019 PMEM report. Further discussion is needed.

6. Any Other Business

None

7. Next meeting

3-4 May, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <https://open.efsa.europa.eu/questions/EFSA-O-2021-00029>

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 223rd MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 16 March 2021, Tele/WEB
(Agreed on 18 March 2021)**

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹ for item 6.1 only:
Salvatore Arpaia and Jörg Romeis
- European Commission and/or Member States representatives:
Juliette-Marie Margueritte and Anastasia Pagida
- EFSA:
GMO Unit: Giacomo De Sanctis, Andrea Gennaro, Franco Maria Neri, Lorenz Oberkofler and Franz Streissl
SCER Unit: Yann Devos
- Others:
None

1. Welcome and apologies for absence

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

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 222nd Working Group meeting held on 26 January 2021, Tele/WEB.

The minutes of the 222nd Working Group meeting held on 26 January 2021 were agreed on the 29 January 2021.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-BE-2019-165 (Soybean DBN-09004-6)⁵

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Testbiotech's media release on *Bt* protein toxicity potentiated by protease inhibitors

The working group assessed the claims made by Testbiotech in a media release entitled "*Are GE plants with Bt toxins 20 times more toxic than previously known?*"⁶ and the scientific publication by MacIntosh et al. (1990)⁷ cited therein.

In the media release, Testbiotech argued that "*Bt [Bacillus thuringiensis] proteins expressed in GM [genetically modified] plants are significantly more toxic than natural Bt toxins [...] if mixed with plant material from, e.g. soybeans, cotton and maize, toxicity could be up to 20 times higher*". Testbiotech attributed this effect "*to enzymes [enzyme inhibitors] naturally present in the tissues of many crop plants*". Testbiotech also stated that "*These findings were never considered by EFSA [European Food Safety Authority]. It seems as if EFSA simply overlooked the relevant publication. EFSA routinely accepts tests with isolated Bt proteins produced by bacteria to assess the risks of GM plants*". Finally, Testbiotech claimed that "*The toxicity and immunogenicity of Bt proteins produced in plants, such as maize, cotton and soybean, must be assumed to be much higher compared to the naturally occurring*

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00013>

⁶ <https://www.testbiotech.org/en/press-release/are-ge-plants-bt-toxins-20-times-more-toxic-previously-known>

⁷ <https://pubs.acs.org/doi/abs/10.1021/1f00094a051>



Bt toxins. These problems relate to all Bt plants approved for import or cultivation in the EU and mixtures in food and feed”.

The working group reviewed the stated publication and the associated comments from Testbiotech. In summary, the working group determined that the generic nature of the claims made, combined with a deficit in supporting data, raise no valid concerns related to the food and feed safety or environmental risk assessment of *Bt*-expressing GM plants for import or cultivation. In support of this, the working group noted that:

- For the food and feed safety assessment of *Bt*-expressing GM plants, the food and feed safety working group of the EFSA GMO Panel previously concluded that the information reported in the media release by Testbiotech does not raise any concerns for human and animal health.⁸
- For the environmental risk assessment of previously risk assessed *Bt*-expressing GM plants for import, the potential interactions of *Bt*-expressing GM soybean, cotton and maize events with non-target organisms (NTOs) are not considered by the EFSA GMO Panel to raise any environmental safety concerns due to the limited level of exposure.⁹
- For the environmental risk assessment of *Bt*-expressing GM plants for cultivation, the concerns raised by Testbiotech are invalid given the mandatory requirement for applicants to supply NTO studies using *Bt*-expressing plant material as test substance (see below).

In regard to the claims made by Testbiotech, there is no clarity presented to support/define the use of “natural” or “naturally occurring” *Bt* proteins, and whether reference is implicitly made to inactive protoxins present in *Bacillus thuringiensis*, in contrast to the activated *Bt* proteins expressed in GM plants that are typically truncated and/or codon optimised.

The claim that EFSA has overlooked the publication by McIntosh et al. (1990) is false. The publication was not cited in EFSA GMO Panel outputs covering the environmental risk assessment of *Bt*-expressing GM plants for cultivation, because the experiments reported in the publication are not considered representative of the expected, real-world exposure to such plants under field conditions. This is primarily due to: (1) the use of *Escherichia coli* derived *Bt* proteins in the insect bioassays, which are not functionally and structurally similar to the those expressed in GM plants; (2) the inclusion in the artificial insect diets of some protease inhibitors (PIs) from plant seed extracts which are known to confer natural host plant resistance; (3) the lack of characterisation of the naturally occurring PIs in the GM tobacco plant extracts expressing a *Bt* protein; and (4) the testing of target (lepidopteran and coleopteran) insect pests which are known to be sensitive to the *Bt* proteins, while this may not necessarily be the case for all NTOs. Therefore, the working group reaffirms that the findings reported by McIntosh et al. (1990) do not specifically refer, nor relate to *Bt*-expressing GM plants. At present, none of the GM plants assessed by the EFSA GMO Panel have been genetically modified to express PIs in combination of *Bt* proteins for enhanced efficacy against target insect pests.

The working group notes that the “up to 20 times higher” toxicity claimed by Testbiotech is not aligned with the evidence reported by McIntosh et al. (1990). In most of the experiments performed by McIntosh et al. (1990), PIs potentiated the activity of *Bt* proteins by 1.3 to 13-fold, measured as (larval) weight reduction. Moreover, results from the existing scientific literature do not offer univocal results: they range from variable potentiation levels to no such effects observed, depending on the target species and concentrations and types of PI tested (e.g. Tabashnik et al., 1992; Morris et al., 1995; Liu and Tabashnik, 1997; Santos et al., 1997; Shao et al., 1998; Zhang et al., 2000; Winterer

⁸ <https://www.efsa.europa.eu/sites/default/files/wqs/gmo/wq-applications-foodfeed-2018-2021.pdf>

⁹ <https://efsa.onlinelibrary.wiley.com/journal/18314732>



and Bergelson, 2001; Mesén-Porras et al., 2020).^{10,11,12,13,14,15,16,17} While PIs might enhance the toxicity of *Bt* proteins in NT species sensitive to them, there is no evidence suggesting that they may change target specificity or widen their range.

The recurrent claim of Testbiotech that "*EFSA routinely accepts tests with isolated Bt proteins produced by bacteria to assess the risks of GM plants*" is outdated and false. As clarified previously to Testbiotech and the RAGES consortium,¹⁸ the NTO risk assessment of *Bt*-expressing GM plants for cultivation considers different sources and lines of evidence in a weight of evidence approach. In the EU, such assessments cover potential adverse environmental effects on NTOs due to intended and unintended changes in the GM plant. The GMO Panel guidance document on the ERA of GM plants¹⁹ introduced the concept of the whole GM plant as the environmental stressor to be evaluated for the environmental risk assessment of GM plants for cultivation, in addition to the risk assessment of the newly expressed proteins in GM plants. Accordingly, laboratory bioassays with plant material are mandatory for all GM plants for which authorisation for cultivation is in the scope of the application (Tier 1b studies), to capture potential unintended effects, unknown complexities and variability in GM plants compounds, irrespective of the intended traits. In this respect, applicants are required to submit *in planta* data on a range of NTOs belonging to different functional groups and that are potentially exposed to GM plants under field conditions for any applications for authorisation of *Bt*-expressing GM plants for cultivation.

The working group considers that the NTO risk assessment approach followed by the EFSA GMO Panel is robust and fit for purpose, and that the claims made in the Testbiotech media release fail to provide verifiable evidence to the contrary. NT insect bioassays with purified *Bt* proteins supplied in applications for authorisation of GM plants typically have a margin of safety that is at least 10 times the expected environmental concentration.²⁰ This margin is higher than the potentiation effects of PIs normally detected according to existing experimental evidence obtained even with purified proteins during *in vitro* tests. Moreover, numerous NTO studies conducted by applicants or available in the scientific literature, covering a broad range of taxa and functional groups, with *Bt*-expressing GM plant material as test substance (in laboratory and field studies) have not found evidence of unexpected adverse effects on NTOs. Overall, this confirms that the tiered approach followed for NTO risk assessments is accurate and conservative to detect harmful effects that may manifest in the field.

In conclusion, the working group considers that the information reported in Testbiotech's media release does not raise any legitimate concerns for the environmental risk assessment of *Bt*-expressing GM plants for import or cultivation.

¹⁰ <https://academic.oup.com/je/article-abstract/85/6/2082/846372>

¹¹ <https://academic.oup.com/je/article-abstract/88/4/815/806320>

¹² <https://academic.oup.com/je/article-abstract/90/2/287/806463>

¹³ <https://link.springer.com/article/10.1023/A:1009603101549>

¹⁴ <https://www.sciencedirect.com/science/article/abs/pii/S0022201198947577>

¹⁵ <https://www.sciencedirect.com/science/article/abs/pii/S002220110094936X>

¹⁶ <https://onlinelibrary.wiley.com/doi/full/10.1046/j.1365-294X.2001.01239.x>

¹⁷ https://www.scielo.sa.cr/scielo.php?script=sci_arttext&pid=S1659-13212020000200461&lng=pt&nrm=iso

¹⁸ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1890>

¹⁹ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1879>

²⁰ Note that such tests are typically performed with the activated *Bt* protein that is functionally and structurally similar to that expressed in the *Bt*-expressing GM plant



6.2. Assessment of additional information related to the application for authorisation of food and feed containing or consisting of and produced from genetically modified oilseed rape MS11²¹

The working group discussed the mandate. Further discussion is needed.

7. Next meeting

4 May 2021, Tele/WEB

²¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2021-00044>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 222nd MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 26 January 2021, Tele/WEB

(Agreed on 29 January 2021)

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan (except agenda item 6.1), Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹: None
- European Commission and/or Member States representatives:
DG SANTE: Marta Cubria Radio, Olga Orlova and Anastasia Pagida (for item 6.1 and 6.2 only)
- EFSA:
GMO Unit: Giacomo De Sanctis, Yann Devos, Andrea Gennaro, Franco Maria Neri, Lorenz Oberkofler and Franz Streissl
- Others: None

1. Welcome and apologies for absence

The chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 221st Working Group meeting held on 14 December 2020, Tele/WEB.

The minutes of the 221st Working Group meeting held on 14 December 2020 were agreed on the 14 December 2020.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2019-161 (Maize DP-202216-6, EFSA-Q-2019-00628⁵)

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2019-164 (Maize NK603 × T25 × DAS-40278-9, EFSA-Q-2019-00628⁶)

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Discussion on the « Baudrot et al. (2021) » publication⁷

The publication by Baudrot et al. was discussed. The authors describe a modelling exercise that seeks to quantify the risk of genetically modified *Bt* maize pollen to non-target lepidopteran larvae at landscape scale, using a spatially explicit model, based on a real landscape. The model suggests that risk of mortality to larvae of the butterfly *Aglais io* is the highest for susceptible individuals within 10m of the crop edge. Moreover, model predictions show that an average estimate of risk can mask differences in risk to individual organisms. These findings are consistent with approaches currently used for the environmental risk assessment of genetically modified plants for cultivation.

The publication is interesting as it applies toxicokinetic and toxicodynamic processes at the individual organism level to help estimate impacts at larger spatial and temporal scales. However, the model has not been validated with an independent dataset on *A. io* collected in the field. It is acknowledged that it would be difficult to validate the model with field data because of the large number of parameters.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00628>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00808>

⁷ Baudrot V, Walker E, Lang A, Stefanescu C, Rey JF, Soubeyr S, Messéan A, 2020. When the average hides the risk of *Bt*-corn pollen on non-target Lepidoptera: Application to *Aglais io* in Catalonia, *Ecotoxicology and Environmental Safety*, 207, 111215. <https://doi.org/10.1016/j.ecoenv.2020.111215>



Recent scientific developments (EFSA GMO panel 2020⁸ and EFSA Scientific committee 2020⁹) and ongoing discussions on environmental protection goals highlight the potential role for modelling approaches in environmental risk assessment. The model described by Baudrot et al. (2021) could be useful to quantify protection goals and to evaluate risk mitigation options for different protection goals. However, it is premature to suggest that the current version of the model would be able to achieve these goals, as it has not yet been validated. Overall, the COMPERA WG concludes that previous environmental risk assessment conclusions and risk management recommendation for maize MON810 are not affected by the findings reported by Baudrot et al. (2021).

6.2. Update on teosinte

The COMPERA WG was updated on the steps taken by DG SANTE on teosinte. DG SANTE has contacted the relevant competent authorities in France and Spain to seek new relevant data on teosinte since the publication of EFSA's technical report on teosinte in 2016. Depending on the availability and relevance of data generated, further actions may be taken.

7. Next meeting

16 March 2021, Tele/WEB

⁸ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Bresson J-L, Dalmay T, Dewhurst IC, Epstein MM, Guerche P, Hejatko J, Moreno FJ, Mullins E, Nogue F, Rostoks N, Sanchez Serrano JJ, Savoini G, Veromann E, Veronesi F, Bonsall MB, Mumford J, Wimmer EA, Devos Y, Paraskevopoulos K and Firkbank LG, 2020. Scientific Opinion on the adequacy and sufficiency evaluation of existing EFSA guidelines for the molecular characterisation, environmental risk assessment and post-market environmental monitoring of genetically modified insects containing engineered gene drives. EFSA Journal 2020;18(11):6297, 90 pp. <https://doi.org/10.2903/j.efsa.2020.6297>

⁹ EFSA Scientific Committee, More S, Bampidis V, Benford D, Bragard C, Halldorsson T, Hernandez-Jerez A, Hougaard Bennekou S, Koutsoumanis K, Machera K, Naegeli H, Nielsen SS, Schlatter J, Schrenk D, Silano V, Turck D, Younes M, Glandorf B, Herman L, Tebbe C, Vlak J, Aguilera J, Schoonjans R and Cocconcilli PS, 2020. Scientific Opinion on the evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of microorganisms obtained through synthetic biology. EFSA Journal 2020;18(10):6263, 50 pp. <https://doi.org/10.2903/j.efsa.2020.6263>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 221TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 14 December 2020, Tele/WEB
(Agreed on 14 December 2020)**

Participants

- Working Group Members:
Christoph Tebbe
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
None
- EFSA:
GMO Unit: Andrea Gennaro and Lorenz Oberkofler
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 220th Working Group meeting held on 30 November 2020, Tele/WEB.

The minutes of the 220th Working Group meeting held on 30 November 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2017-140 (Maize MON 87419)⁵

The working group discussed the potential to microorganism gene transfer of this application. Further discussion is needed.

5.2. EFSA-GMO-DE-2017-141 (Cotton COT102)⁶

The working group discussed the potential to microorganism gene transfer of this application. Further discussion is needed.

5.3. EFSA-GMO-ES-2018-154 (Cotton GHB811)⁷

The working group discussed the potential to microorganism gene transfer of this application. Further discussion is needed.

5.4. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁸

The working group discussed the potential to microorganism gene transfer of this application. Further discussion is needed.

5.5. EFSA-GMO-NL-2019-161 (Maize MON 87429)⁹

The working group discussed the potential to microorganism gene transfer of this application. Further discussion is needed.

5.6. EFSA-GMO-NL-2019-163 (Maize DP-023211-2)¹⁰

The working group discussed the potential to microorganism gene transfer of this application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00263>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00271>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00808>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00419>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00628>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00807>



6. Any Other Business

None.

7. Next meeting

26 January 2021, Tele/WEB

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE JOINT MEETING OF THE WORKING GROUPS ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT AND ON THE FOOD & FEED SUB-WORKING GROUP ON NUTRITIONAL ASSESSMENT

**Held on 30 November 2020, Tele/WEB
(Agreed on 30 November 2020)**

Participants

- Working Group Members:
Comparative analysis and ERA: Antoine Messéan and Ewen Mullins
Food and Feed: Thomas Frenzel and Javier Moreno
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
GMO Unit: Federica Ceriani, Yann Devos, Andrea Gennaro, Anna Lanzoni, Franco Maria Neri and Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 219th Working Group meeting held on 24 November 2020, Tele/WEB.

The minutes of the 219th Working Group meeting on comparative analysis and environmental risk assessment held on 24 November 2020 were agreed.⁴

5. Scientific topics for discussion

None

6. Any Other Business

6.1. Comparative analysis of agronomic, phenotypic and compositional data gathered from male sterile plants

The working group discussed the item. Further discussion is needed.

7. Next meeting

14 December 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/qmo/working-groups>

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 219TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 24 November 2020, Tele/WEB
(Agreed on 24 November 2020)**

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
DG SANTE: Juliette-Marie Margueritte and Anastasia Pagida (for item 6.1 only)
- EFSA:
GMO Unit: Giacomo De Sanctis, Yann Devos, Andrea Gennaro, Franco Maria Neri, Lorenz Oberkofler and Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

The chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 218th Working Group meeting held on 10 September 2020, Tele/WEB.

The minutes of the 218th Working Group meeting held on 13 October 2020 were agreed on the 13 October 2020.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2019-163 (Maize DP-023211-2)⁶

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2019-164 (Maize NK603 × T25 × DAS-40278-9)⁷

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Discussion on the « Le Corre et al. (2020) » publication⁸

The working group reviewed and discussed the publication by Le Corre et al. (2020). The evidence reported in the publication demonstrates that:

- (1) The weedy teosintes found in France and Spain derive from *Zea mays* ssp. *mexicana*, suggesting a single geographical origin for teosintes found in Europe;
- (2) French teosintes adapted to European temperate latitude growing conditions (i.e. early flowering), compared to *Zea mays* ssp. *mexicana*;

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00419>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00807>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00808>

⁸ Le Corre V, Siol M, Vigouroux Y, Tenaillon MI, and Délye C, 2020. Adaptive introgression from maize has facilitated the establishment of teosinte as a noxious weed in Europe. Proceedings of the National Academy of Sciences of the United States of America, 117, 25618–25627. <https://doi.org/10.1073/pnas.2006633117>



- (3) Some characteristics/phenotypic traits of conventional maize (i.e. high latitude dent maize) varieties, including herbicide tolerance (i.e. a mutant herbicide-target gene (*ACC1*)), have successfully introgressed in the French teosintes, confirming the occurrence of vertical gene flow from conventional maize varieties to weedy teosinte when maize and weedy teosintes grow sympatrically.

The potential for vertical gene flow between maize and *Z. mays* subsp. *mexicana* under field conditions has been acknowledged previously by EFSA based on the available evidence then. In EFSA (2016)⁹, the possible consequences of such vertical gene flow from the genetically modified (GM) maize events MON810, Bt11, 1507 and GA21 were assessed through the pathways to harm approach. It was concluded that the possible introgression of transgenes from maize MON810, Bt11, 1507 and GA21 into weedy teosinte may provide a selective advantage to hybridising teosinte progeny only under high infestation of target pests and/or when glufosinate-ammonium- and/or glyphosate-containing herbicides are applied. The overall environmental exposure to maize × teosinte hybrids, bearing either the insect resistance or herbicide tolerance trait or both, would remain low compared to exposure to GM maize, provided that measures are employed to control and/or eradicate weedy teosintes and their progeny in infested agricultural areas. Based on the available evidence, the impact of insect resistance and/or herbicide tolerance in maize × teosinte hybrids on other organisms (including target and non-target organisms), the abiotic environment or biogeochemical cycles can be considered very low under EU conditions at present. EFSA (2016) also concluded that the use of glyphosate-containing herbicides on maize GA21 may enhance the fitness of glyphosate tolerant maize × teosinte hybrids, should they occur within the confines of a managed field environment where glyphosate is applied. To ensure effective long-term management of weedy teosinte and maize × teosinte hybrids that may acquire glyphosate tolerance through vertical gene flow from maize GA21, and avoid exacerbating weed problems, EFSA recommended that integrated weed management reliant on multiple tactics (e.g. alternative chemistry mixtures, mechanical, rotational) must be deployed, should maize GA21 be grown in areas where weedy teosinte occurs.

The working group concludes that the evidence reported by Le Corre et al. (2020) does not indicate the need to revise the previous environmental risk assessment conclusions and risk management recommendations for maize MON810, Bt11, 1507 and GA21 made by the GMO Panel. On the contrary, Le Corre et al. (2020) justifies the pathway to harm approach taken as reported in EFSA (2016). Nevertheless, the working group considers that further discussion is required on the potential need to update the post-market environmental monitoring for maize MON 810.

7. Next meeting

30 November 2020, Tele/WEB

⁹ EFSA (European Food Safety Authority), 2016. Relevance of new scientific evidence on the occurrence of teosinte in maize fields in Spain and France for previous environmental risk assessment conclusions and risk management recommendations on the cultivation of maize events MON810, Bt11, 1507 and GA21. EFSA supporting publication, 13, EN-1094. 13 pp. doi:[10.2903/sp.efsa.2016.EN-1094](https://doi.org/10.2903/sp.efsa.2016.EN-1094)

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 218TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 13 October 2020, Tele/WEB
(Agreed on 13 October 2020)**

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
None
- EFSA:
GMO Unit:
Fernando Álvarez, Giacomo De Sanctis, Yann Devos, Andrea Gennaro, Franco Maria Neri, Lorenz Oberkofler and Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

The chair welcomed the participants.

2. Adoption of agenda

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 217th Working Group meeting held on 10 September 2020, Tele/WEB.

The minutes of the 217th Working Group meeting held on 10 September 2020 were agreed on the 10 September 2020.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-DE-2019-157 (Canola LBFLFK)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2019-158 (*Brassica juncea* CQ RF3)⁶

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2019-161 (Maize MON 87429)⁷

The working group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-NL-2019-163 (Maize DP 023211)⁸

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Discussion on the Díaz et al. (2020) publication⁹

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00394>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00412>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00628>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00807>

⁹ Díaz A, Taberner A and Vilaplana L, 2020. The emergence of a new weed in maize plantations: characterization and genetic structure using microsatellite markers. Genetic Resources and Crop Evolution, 67, 225–239.



The working group reviewed and discussed the Díaz et al. (2020) publication. Owing to limitations associated with the design and resulting conclusions of the study, the working group considers that no reliable scientific deductions can be drawn from it.

6.2. Discussion on the analysis of agronomic and phenotypic endpoints across applications

6.3. Discussion on the EFSA opinion on evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology¹⁰

7. Next meeting

24 November 2020, Tele/WEB

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01000>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 217TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 10 September 2020, Tele/WEB
(Agreed on 10 September 2020)**

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
None
- EFSA:
GMO Unit: Giacomo De Sanctis, Yann Devos, Andrea Gennaro, Lorenz Oberkofler and Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

The chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 216th Working Group meeting held on 7 September 2020, Tele/WEB.

The minutes of the 216th Working Group meeting held on 7 September 2020 were agreed on the 8 September 2020.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2016-132 (Soybean DAS-81419-2 × DAS-44406-6)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2017-139 (Maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122)⁶

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-DE-2017-141 (Cotton COT102)⁷

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Discussion on the EFSA opinion on genetically modified organisms engineered with gene drives (gene drive modified organisms) and their implications for risk assessment methodologies⁸

7. Next meeting

13 October 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00195>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00115>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00271>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00619>



GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 216TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 7 September 2020, Tele/WEB
(Agreed on 8 September 2020)**

Participants

- Working Group Members:
Christoph Tebbe
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
None
- EFSA:
GMO Unit: Andrea Gennaro and Lorenz Oberkofler
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 215th Working Group meeting held on 30 June 2020, Tele/WEB.

The minutes of the 215th Working Group meeting held on 30 June 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-DE-2017-141 (Cotton COT102)⁵

The working group discussed the potential to microorganism gene transfer of this application. Further discussion is needed.

6. Any Other Business

None.

7. Next meeting

10 September 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00271>

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 215TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 30 June 2020, Tele/WEB

(Agreed on 30 June 2020)

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
None
- EFSA:
GMO Unit: Giacomo De Sanctis, Andrea Gennaro, Franco Maria Neri and Lorenz Oberkofler
ALPHA Unit: Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

The chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 214th Working Group meeting held on 26 June 2020, Tele/WEB.

The minutes of the 214th Working Group meeting held on 26 June 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2015-127 (Maize 1507 x MIR162 x MON 810 x NK603)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-RX-002 (oilseed rape GT73)⁶

The working group discussed the application. No further discussion is needed.

6. Any Other Business

None.

7. Next meeting

10 September 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00841>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00478>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 214TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 26 June 2020, Tele/WEB

(Agreed on 26 June 2020)

Participants

- Working Group Members:
Antoine Messéan
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
GMO Unit: Fernando Álvarez and Franz Streissl
AMU Unit: Valeria Ercolano, Marios Georgiadis
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 213th Working Group meeting held on 22 June 2020, Tele/WEB.

The minutes of the 213th Working Group meeting held on 22 June 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. Request from the European Commission to assess the annual 2018 post market environmental monitoring (PMEM) report on maize MON 810⁵

The working group discussed the mandate. Further discussion is still needed.

6. Any Other Business

6.1. Discussion on the Bertho et al. (2020) publication⁶

The working group discussed different aspects related to the pooled-analysis of the farmer questionnaires and the implications of their results for future general surveillance activities of genetically modified maize MON 810.

7. Next meeting

30 June 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/qmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00184>

⁶ Bertho et al., 2020. Results from ten years of post-market environmental monitoring of genetically modified MON 810 maize in the European Union. PLoS ONE 15(4): e0217272. <https://doi.org/10.1371/journal.pone.0217272>



GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 213TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 22 June 2020, Tele/WEB

(Agreed on 22 June 2020)

Participants

- Working Group Members:
Antoine Messéan and Ewen Mullins
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Béatrice Marquez-Garrido
- EFSA:
GMO Unit: Andrea Gennaro and Franco Maria Neri
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 212th Working Group meeting held on 27 May 2020, Tele/WEB.

The minutes of the 212th Working Group meeting held on 27 May 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2019-161 (Maize MON 87429)⁵

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. None

7. Next meeting

30 June 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00628>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 212ND MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 27 May 2020, Tele/WEB

(Agreed on 27 May 2020)

Participants

- Working Group Members:
Antoine Messéan
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
GMO Unit: Fernando Álvarez, Franz Streissl
AMU Unit: Valeria Ercolano, Marios Georgiadis
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 210th Working Group meeting held on 24 April 2020, Tele/WEB.

The minutes of the 211th Working Group meeting held on 26 May 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. Request from the European Commission to assess the annual 2018 post market environmental monitoring (PMEM) report on maize MON 810⁵

The working group discussed the mandate. Further discussion is still needed.

6. Any Other Business

6.1. Discussion on the Bertho et al. (2020) publication⁶

The working group discussed different aspects related to the pooled-analysis of the farmer questionnaires and the implications of their results for future general surveillance activities of genetically modified maize MON 810.

7. Next meeting

30 June 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00184>

⁶ Bertho et al., 2020. Results from ten years of post-market environmental monitoring of genetically modified MON 810 maize in the European Union. PLoS ONE 15(4): e0217272. <https://doi.org/10.1371/journal.pone.0217272>



GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 211TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 26 May 2020, Tele/WEB

(Agreed on 26 May 2020)

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins, Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
None
- EFSA:
GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Andrea Gennaro, Franco Maria Neri and Lorenz Oberkofler
ALPHA Unit: Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

The chair welcomed the participants.

2. Adoption of agenda

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 210th Working Group meeting held on 24 April 2020, Tele/WEB.

The minutes of the 210th Working Group meeting held on 24 April 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2015-127 (Maize 1507 x MIR162 x MON 810 x NK603)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-ES-2018-154 (Cotton GHB811)⁶

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2019-163 (Maize DP023211-2)⁷

The working group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-NL-2019-164 (Maize NK603 x T25 x DAS-40278-9)⁸

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Discussion of Pott et al. (2019) publication⁹

7. Next meeting

27 May 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00841>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00808>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00807>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00808>

⁹ <https://www.nature.com/articles/s41598-020-62055-2?draft=collection>

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 210TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 24 April 2020, Tele/WEB

(Agreed on 24 April 2020)

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins, Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
DG SANTE: Béatrice Marquez Garrido
- EFSA:
GMO Unit: Giacomo De Sanctis, Andrea Gennaro, Franco Maria Neri and Lorenz Oberkofler
ALPHA Unit: Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 209th Working Group meeting held on 31 March 2020, Tele/WEB.

The minutes of the 209th Working Group meeting held on 31 March 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2018-150 (Maize DP4114 x MON810 x MIR604 x NK603)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-ES-2018-154 (Cotton GHB811)⁶

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2019-161 (Maize MON 87429)⁷

The working group discussed the application. Further discussion is needed.

6. Any Other Business

None

7. Next meeting

26 May 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00370>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00808>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00628>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 209TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 31 March 2020, Tele/WEB

(Agreed on 31 March 2020)

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan, Ewen Mullins, Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Andrea Gennaro, Franco Maria Neri and Lorenz Oberkofler
ALPHA Unit: Franz Streissl

1. Welcome and apologies for absence

EFSA welcomed the participants.

This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 208th Working Group meeting held on 24 March 2020, Tele/WEB.

The minutes of the 208th Working Group meeting held on 24 March 2020 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-ES-2018-154 (Cotton GHB811)⁵

The working group did not discuss the application because it was not possible to collect the received additional information.⁶

5.2. EFSA-GMO-DE-2019-157 (LBFLFK canola)⁷

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁸

The working group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-NL-2019-164 (Maize NK603 × T25 × DAS-40278-9)⁹

The working group discussed the application. Further discussion is needed.

6. Any Other Business

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00808>

⁶ Access to EFSA building is currently limited in line with the measures established to reduce the risk of COVID-19 infection.

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00394>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00419>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00808>



- 6.1. Discussion of mandate to provide assistance on new scientific information in relation to the risk assessment of GM crops in the EU and Switzerland (RAGES project reports)¹⁰**
- 6.2. Discussion of the mandate to assess the 2018 PMEM report on maize MON 810¹¹**

7. Next meeting

26 May 2020, Tele/WEB

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00808>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00184>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 208TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 24 March 2020, Tele/WEB

(Agreed on 24 March 2020)

Participants

- Working Group Members:
Antoine Messéan
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
GMO Unit: Fernando Álvarez, Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Declarations of Interest of Hearing experts

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA invited Paolo Bàrberi to submit an Annual Declaration of Interest. His participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e., not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

5. Agreement of the minutes of the 207th Working Group meeting held on 28 January 2020, Parma.

The minutes of the 208th Working Group meeting held on 28 January 2020 were agreed on that date.⁴

6. Scientific topics for discussion

6.1. Request from the European Commission to assess the annual 2018 post-market environmental monitoring (PMEM) report on maize MON 810⁵

The working group discussed the methodology and outcomes of the general surveillance and case specific monitoring activities provided by the consent holder in the 2018 PMEM report. Further discussion is needed.

7. Any Other Business

Not applicable

8. Next meeting

31 March 2020, Tele/WEB

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00184>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 207TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 28 January 2020, Parma

(Agreed on 28 January 2020)

Participants

- Working Group Members:
Leslie Firbank, Antoine Messéan (by tele), Ewen Mullins (chair) (by tele), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Paolo Bàrberi (by tele for item 7.1 only)
- European Commission and/or Member States representatives:
DG SANTE: Béatrice Marquez-Garrido (by tele for item 7.1 only)
- EFSA:
GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Yann Devos, Andrea Gennaro and Franco Maria Neri
PLH Unit: Franz Streissl
- Others:
Not applicable

1. Welcome and apologies for absence

The chair welcomed the participants.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Declarations of Interest of Hearing experts

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA invited Paolo Bàrberi to submit an Annual Declaration of Interest. His participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e., not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

5. Agreement of the minutes of the 206th Working Group meeting held on 18 December 2019, Tele/WEB.

The minutes of the 206th Working Group meeting held on 18 December 2019 were agreed on that date.⁴

6. Scientific topics for discussion

6.1. EFSA-GMO-NL-2015-126 (Soybean MON 87705 × MON 87708 × MON 89788)⁵

The working group discussed the application. Further discussion is needed.

6.2. EFSA-GMO-NL-2016-132 (Soybean DAS-81419-2 × DAS-44406-6)⁶

The working group discussed the application. Further discussion is needed.

6.3. EFSA-GMO-NL-2018-153 (Soybean GMB151)⁷

The working group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00548>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00781>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00394>



6.4. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁸

The working group discussed the application. Further discussion is needed.

6.5. EFSA-GMO-NL-2019-161 (Maize MON 87429)⁹

The working group discussed the application. Further discussion is needed.

7. Any Other Business

7.1. Discussion of Miyazaki et al. (2019) publication¹⁰

8. Next meeting

31 March 2020, Parma

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00419>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00628>

¹⁰ <https://enveurope.springeropen.com/articles/10.1186/s12302-019-0274-1>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 206TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 18 December 2019, Tele/WEB

(Agreed on 18 December 2019)

Participants

- Working Group Members:
Ewen Mullins, Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Andrea Gennaro and Franco Maria Neri
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants. Apologies for absence were received from Leslie Firbank.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 205th Working Group meeting held on 26 November 2019, Parma.

The minutes of the 205th Working Group meeting held on 26 November 2019 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-DE-2019-157 (Canola LBFLFK)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁶

The working group discussed the application. Further discussion is needed.

5.3. Mandate on plants developed using type 1 and type 2 Site-Directed Nucleases and Oligonucleotide Directed Mutagenesis ⁷

The working group was updated on the progress of the mandate. Further discussion is needed.

6. Any Other Business

Discussion of EPA Network technical report "Monitoring of spontaneous populations of GM plant species in the environment"⁸

7. Next meeting

28 January 2020, Parma

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00394>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00419>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00297>

⁸ [Link to the report](#)



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 205TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 26 November 2019, Parma
(Agreed on 26 November 2019)**

Participants

- Working Group Members:
Leslie Firbank (tele), Antoine Messéan (tele), Ewen Mullins, Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Anastasia Pagida (agenda item 7.2)
- EFSA:
GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Yann Devos, Andrea Gennaro and Franco Maria Neri
PLH Unit: Franz Streissl (agenda item 7.1)
- Others:
Not applicable

1. Welcome and apologies for absence

EFSA welcomed the participants. No apologies for absence were received.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 204th Working Group meeting held on 22 October 2019, Parma.

The minutes of the 204th Working Group meeting held on 22 October 2019 were agreed on that date.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2016-132 (Soybean DAS-81419-2 x DAS-44406-6)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-BE-2016-138 (Oilseed rape MS11)⁶

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-ES-2018-154 (Cotton GHB811)⁷

The working group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)⁸

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Environmental risk assessment of SynBio-derived plants⁹

6.2. Discussion on the Chvátalová (2019) publication¹⁰

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00195>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00857>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00808>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00419>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01000>

¹⁰ <https://enveurope.springeropen.com/articles/10.1186/s12302-019-0238-5>



7. Next meeting

18 December 2019, Tele-meeting

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 204TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 22 October 2019, Tele/WEB

(Agreed on 22 October 2019)

Participants

- Working Group Members:
Ewen Mullins, Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
none
- European Commission and/or Member States representatives:
None
- EFSA:
GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Yann Devos, (agenda items 6.2 and 7.1)
Andrea Gennaro, Franco Maria Neri and Tommaso Raffaello (agenda item 7.2)
- Others:
None

1. Welcome and apologies for absence

EFSA welcomed the participants. Apologies for absence were received from Les Firbank and Antoine Messéan.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Declarations of Interest of Hearing experts

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management⁴, EFSA invited Adinda De Schrijver to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e., not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

5. Agreement of the minutes of the 203rd Working Group meeting held on 24 September 2019, Parma.

The minutes of the 203rd Working Group meeting held on 24 September 2019 were agreed on that date.⁴

6. Scientific topics for discussion

6.1. EFSA-GMO-DE-2012-111 (Soybean SYHT0H2)⁵

The working group discussed the application. Further discussion is needed.

6.2. EFSA-GMO-BE-2016-138 (Oilseed rape MS11)⁶

The working group discussed the application. Further discussion is needed.

6.3. EFSA-GMO-ES-2018-154 (Cotton GHB811)⁷

The working group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00753>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00857>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00808>



7. Any Other Business

- 7.1. Environmental risk assessment of SynBio-derived plants⁸**
- 7.2. Plants developed using type 1 and type 2 Site-Directed Nucleases and Oligonucleotide Directed Mutagenesis⁹**

8. Next meeting

26 November 2019, Parma

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01000>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00297>



GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 203RD MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 24 September 2019, Parma
(Agreed on 24 September 2019)**

Participants

- Working Group Members:
Les Firbank, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Adinda De Schrijver (by tele for item 7.1 only)
- European Commission and/or Member States representatives:
None
- EFSA:
GMO Unit: Fernando Álvarez, Ana Martin Camargo, Giacomo De Sanctis, Yann Devos and Andrea Gennaro
- Others:
None

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Antoine Messéan.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Declarations of Interest of Hearing experts

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management⁴, EFSA invited Adinda De Schrijver to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e., not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

5. Agreement of the minutes of the 202nd Working Group meeting held on 2 July 2019, Parma.

The minutes of the 202nd Working Group meeting held on 2 July 2019 were agreed.⁴

6. Scientific topics for discussion

6.1. EFSA-GMO-DE-2016-137 (Maize GA21 x T25)⁵

The working group discussed the application. Further discussion is needed.

6.2. EFSA-GMO-BE-2016-138 (Oilseed rape MS11)⁶

The working group discussed the application. Further discussion is needed.

6.3. EFSA-GMO-DE-2018-149 (Maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21)⁷

The working group discussed the application. Further discussion is needed.

6.4. EFSA-GMO-NL-2018-150 (Maize DP4114 x MON810 x MIR604 x NK603)⁸

The working group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00775>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00857>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00292>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00370>



6.5. EFSA-GMO-NL-2018-153 (Soybean GMB151)⁹

The working group discussed the application. Further discussion is needed.

6.6. EFSA-GMO-NL-2019-159 (Maize DP-202216-6)¹⁰

The working group discussed the application. Further discussion is needed.

7. Any Other Business

7.1. Environmental risk assessment of SynBio-derived plants¹¹

8. Next meeting

22 October 2019, Tele/WEB

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00781>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00419>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01000>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 202ND MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 2 July 2019, Parma

(Agreed on 2 July 2019)

Participants

- Working Group Members:
Les Firbank (by tele), Antoine Messéan, Ewen Mullins (chair) (by tele), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Adinda De Schrijver (by tele for item 7.2 only)
- European Commission and/or Member States representatives:
DG SANTE: Alexandre Hucklemann (by tele) and Ilaria Ciabatti (by tele for item 7.2 only)
- EFSA:
GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Yann Devos, Andrea Gennaro and Franco Maria Neri
SCER Unit: Caterina Barrasso (for item 7.2 only)
- Others:
Not Applicable

1. Welcome and apologies for absence

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

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



2. Adoption of agenda

The agenda was adopted with one change – the removal of application EFSA-GMO-DE-2016-137.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Declarations of Interest of Hearing experts

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management⁴, EFSA invited Adinda De Schrijver to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e., not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

5. Agreement of the minutes of the 199th Working Group meeting held on 8 April 2019, WEB/TELE-conference.

The minutes of the 201st Working Group meeting held on 11 June 2019 were agreed.⁴

6. Scientific topics for discussion

6.1. EFSA-GMO-NL-2017-144 (Maize MON 87427 x MON 89034 x MIR162 x MON 87411)⁵

The working group discussed the application. Further discussion is needed.

6.2. EFSA-GMO-DE-2018-149 (Maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21)⁶

The working group discussed the application. Further discussion is needed.

6.3. EFSA-GMO-NL-2018-150 (Maize DP4114 x MON810 x MIR604 x NK603)⁷

The working group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00442>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00292>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00370>



6.4. EFSA-GMO-NL-2018-153 (Soybean GMB151)⁸

The working group discussed the application. Further discussion is needed.

7. Any Other Business

7.1. Maize MON 810 PMEM report for 2017⁹

7.2. Environmental risk assessment of SynBio-derived plants¹⁰

8. Next meeting

24 September 2019, Parma

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00781>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01001>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01000>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 201ST MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 11 June 2019, Tele/WEB

(Agreed on 11 June 2019)

Participants

- Working Group Members:
Ewen Mullins, Christoph Tebbe
- Hearing Experts¹:
Salvatore Arpaia
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
GMO Unit: Fernando Álvarez
- Others:
Not Applicable

1. Welcome and apologies for absence

EFSA welcomed the participants. No apologies for absence were received.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Declarations of Interest of Hearing experts

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management⁴, EFSA invited Adinda De Schrijver to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e., not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

5. Agreement of the minutes of the 200th Working Group meeting held on 21 May 2019

The minutes of the 200th Working Group meeting held on 21 May 2019 were agreed on 21 May 2019.⁴

6. Scientific topics for discussion

Not applicable.

7. Any Other Business

7.1. Mandate to provide scientific assistance on three publications in relation to the risk assessment of genetically modified maize MON 810⁵

The Working Group discussed the scientific publications by Paula and Andow (2015)⁶, Paula et al. (2015)⁷ and Tomaszewski et al. (2012).⁸

8. Next meeting

2 July 2019, Parma

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00373>

⁶ Uptake and bioaccumulation of Cry toxins by an aphidophagous predator. Environmental Pollution, 209: 164–168.

⁷ Sequestration and transfer of Cry entomotoxin to the eggs of a predaceous ladybird beetle. PLoS ONE 10(12): e0144895.

⁸ Adsorption of insecticidal Cry1Ab protein to humic substances. 2. Influence of humic and fulvic acid charge and polarity characteristics. Environmental Science & Technology, 46: 9932–9940.



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 200TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 21 May 2019, Parma

(Agreed on 21 May 2019)

Participants

- Working Group Members:
Les Firbank, Antoine Messéan, Ewen Mullins (chair), Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Adinda De Schrijver (item 7.2)
- European Commission and/or Member States representatives:
Hans Moons: (DG SANTE by tele)
- EFSA:
GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Yann Devos, Andrea Gennaro,
Franco Maria Neri and Nikoletta Papadopoulou (item 7.2)
SCER Unit: Caterina Barrasso (item 7.2)
- Others:
Not Applicable

1. Welcome and apologies for absence

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

2. Adoption of agenda

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Declarations of Interest of Hearing experts

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management⁴, EFSA invited Adinda De Schrijver to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e., not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework.

5. Agreement of the minutes of the 199th Working Group meeting held on 8 April 2019, WEB/TELE-conference.

The minutes of the 199th Working Group meeting held on 8 April 2019 were agreed.⁴

6. Scientific topics for discussion

6.1. EFSA-GMO-BE-2016-138 (Oilseed rape MS11)⁵ and EFSA-GMO-NL-2017-143 (Oilseed rape MS11×RF3)⁶

The working group discussed the applications. Further discussion is needed.

6.2. EFSA-GMO-NL-2017-144 (Maize MON87427 × MON89034 × MIR162 × MON8741)⁷

The working group discussed the application. Further discussion is needed.

6.3. EFSA-GMO-NL-2018-148 (Soybean DP305423 × MON87708 × MON89788)⁸

The working group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00857>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00424>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00442>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00146>



6.4. EFSA-GMO-NL-2018-153 (Soybean GMB151)⁹

The working group discussed the application. Further discussion is needed.

6.5. EFSA-GMO-ES-2018-154 (Cotton GHB811)¹⁰

The working group discussed the application. Further discussion is needed.

7. Any Other Business

7.1. Discussion on the reporting of exceptional weather events across GMO applications

7.2. Environmental risk assessment of SynBio-derived plants¹¹

8. Next meeting

11 June 2019, Tele/WEB

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00781>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00808>

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01000>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 199TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 8 April 2019, Tele/WEB
(Agreed on 8 April 2019)**

Participants

- Working Group Members:
Antoine Messéan
- Hearing Experts:¹
Salvatore Arpaia
- European Commission and/or Member States representatives:
Anastasia Pagida (DG SANTE)
- EFSA:
GMO Unit: Fernando Álvarez; Ana Martín Camargo

1. Welcome and apologies for absence

EFSA staff welcomed the participants.

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 199th Working Group meeting

The minutes of the 198th Working Group meeting held on 5 April 2019 were agreed on 5 April 2019.⁴

5. Scientific topics for discussion

5.1. Request from EC to assess the annual 2017 post market environmental monitoring (PMEM) report on maize MON 810⁵

The working group discussed the methodology and outcomes of the general surveillance and case specific monitoring activities provided by the consent holder in the 2017 PMEM report. Further discussion is needed.

6. Any Other Business

Not applicable

7. Next meeting(s)

21 May 2019, Parma

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01001>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 198th MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 5 April 2019, Tele/WEB
(Agreed on 5 April 2019)¹**

Participants

- Working Group Members:²
Julie Glanville
- Hearing Experts:³
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
GMO Unit: Fernando Álvarez
- Others:
Not Applicable

¹ Minutes should be published within 15 working days of the final day of the relevant meeting.

² Indicate first full name and then surname (John Smith) all throughout the document.

³ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>



1. Welcome and apologies for absence

EFSA staff welcomed the participant.

No apologies were received.

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 Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 197th Working Group meeting held on 2 April 2019

The minutes of the 197th Working Group meeting held on 2 April 2019 were agreed.⁶

5. Scientific topics for discussion

5.1. EFSA-GMO-DE-2017-142 (Maize MZIR098)⁷

The working group discussed the application. Further discussion on the literature search is needed.

5.2. EFSA-GMO-DE-2018-149 (Bt11 × MIR162 × MIR604 × MON 89034 × 5307 × GA21)⁸

The working group discussed the application. Further discussion on the literature search is needed.

5.3. EFSA-GMO-NL-2018-150 (Maize DP4114 × MON810 × MIR604 × NK603)⁹

The working group discussed the application. Further discussion on the literature search is needed.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00398>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00292>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00370>



5.4. EFSA-GMO-RX-015 (Maize MON 89034)¹⁰

The working group discussed the application. Further discussion on the literature search is needed.

6. Any Other Business

Not applicable

7. Next meeting(s)

8 April 2019, Tele/WEB

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00673>

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 197TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 2 April 2019, TELE-meeting

(Agreed on 2 April 2019)

Participants

- Working Group Members:
Les Firbank; Ewen Mullins (chair); Eve Veromann and Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Hans Moons: (DG SANTE by tele)
- EFSA:
GMO Unit: Fernando Álvarez; Giacomo De Sanctis; Andrea Gennaro and Franco Maria Neri
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Antoine Messéan

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 196th Working Group meeting held on 15 March 2019, WEB/TELE-conference.

The minutes of the 196th Working Group meeting held on 15 March 2019 were agreed.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-DE-2018-149 (Maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2017-139 (Maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122)⁶

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2018-150 (Maize DP4114 x MON 810 x MIR604 x NK603)⁷

The working group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-NL-2016-136 (Cotton DAS-81910-7)⁸

The working group discussed the application. Further discussion is needed.

5.5. EFSA-GMO-NL-2018-153 (Soybean GMB151)⁹

The working group discussed the application. Further discussion is needed.

6. Any Other Business

None

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00292>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00115>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00370>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00707>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00781>

7. Next meeting(s)

8 April 2019, TELE-meeting



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 196TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 15 March 2019, Parma

(Agreed on 15 March 2019)

Participants

- Working Group Members:
Christoph Tebbe
- EFSA:
GMO Unit: Andrea Gennaro

1. Welcome and apologies for absence

EFSA staff welcomed the participants.

No apologies were received.

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



4. Agreement of the minutes of the 195th Working Group meeting held on 26 February 2019, WEB/TELE-conference.

The minutes of the 195th Working Group meeting held on 26 February 2019 were agreed.³

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2016-135 (Soybean MON 87708 x MON 89788 x A5547-127)⁴

The working group discussed the potential to microorganism gene transfer of this application. Further discussion is needed.

6. Any Other Business

6.1. Discussion on the risk assessment of horizontal gene transfer

7. Next meeting(s)

28 March 2019, TELE-meeting

³ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00688>

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 195TH MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

Held on 26 February 2019, Parma

(Agreed on 26 February 2019)

Participants

- Working Group Members:
Les Firbank; Antoine Messéan; Ewen Mullins (chair); Eve Veromann; Fabio Veronesi
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Hans Moons: (DG SANTE by tele)
- EFSA:
GMO Unit: Giacomo de Sanctis; Yann Devos; Andrea Gennaro; Franco Maria Neri; Irina Olaru (item 5.1 only)
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies were received.

2. Adoption of agenda

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 194th Working Group meeting held on 22 February 2019, WEB/TELE-conference.

The minutes of the 194th Working Group meeting held on 22 February 2019 were agreed.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2012-109 (Oilseed rape 73496)⁵

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2016-128 (Soybean MON 87751 × MON 87701 × MON 87708 × MON 89788)⁶

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2016-136 (Cotton DAS-81910-7)⁷

The working group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-DE-2016-137 (Maize GA21 × T25)⁸

The working group discussed the application. Further discussion is needed.

5.5. EFSA-GMO-BE-2016-138 (Oilseed rape MS11)⁹

The working group discussed the application. Further discussion is needed.

5.6. EFSA-GMO-NL-2017-143 (Oilseed rape MS11 × RF3)¹⁰

The working group discussed the application. Further discussion is needed.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁵ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00617>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00009>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00707>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00775>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00857>

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00424>



5.7. EFSA-GMO-NL-2017-145 (Maize MON 87427 x MON 89034 x 1507 x MON 87411 x 59122 x DAS-40278-9)¹¹

The working group discussed the application. Further discussion is needed.

5.8. EFSA-GMO-DE-2018-149 (Maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21)¹²

The working group discussed the application. Further discussion is needed.

5.9. EFSA-GMO-NL-2018-150 (Maize DP4114 x MON 810 x MIR604 x NK603)¹³

The working group discussed the application. Further discussion is needed.

5.10. EFSA-GMO-NL-2018-151 (Maize MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9)¹⁴

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Discussion on the herbicide treatments across applications

7. Next meeting(s)

2 April 2019, TELE-meeting

¹¹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00487>

¹² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00292>

¹³ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00370>

¹⁴ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00457>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 194th MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 22 February 2019, Tele/WEB
(Agreed on 22 February 2019)¹**

Participants

- Working Group Members:²
Julie Glanville
- Hearing Experts:³
Not applicable
- European Commission and/or Member States representatives:
Not applicable
- EFSA:
GMO Unit: Fernando Álvarez
AMU Unit: Irene Muñoz Guajardo
- Others:
Not Applicable

¹ Minutes should be published within 15 working days of the final day of the relevant meeting.

² Indicate first full name and then surname (John Smith) all throughout the document.

³ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



1. Welcome and apologies for absence

EFSA staff welcomed the participants.

No apologies were received.

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 Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 193rd Working Group meeting held on 20 February 2019

The minutes of the 193rd Working Group meeting held on 20 February 2019 were agreed on 20 February 2019.⁶

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2016-136 (Cotton DAS-81910-7)⁷

The working group discussed the application. Further discussion on the literature search is needed.

5.2. EFSA-GMO-NL-2017-143 (Oilseed rape MS11 × RF3)⁸

The working group discussed the application. Further discussion on the literature search is needed.

5.3. EFSA-GMO-NL-2017-145 (Maize MON 87427 × MON 89034 × 1507 × MON 87411 × 59122 × DAS-40278-9)⁹

The working group discussed the application. Further discussion on the literature search is needed.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00707>

⁸ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00424>

⁹ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00487>



5.4. EFSA-GMO-ES-2018-154 (Cotton GHB811)¹⁰

The working group discussed the application. Further discussion on the literature search is needed.

6. Any Other Business

Not applicable

7. Next meeting(s)

26 February 2019, Parma

¹⁰ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00808>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 193rd MEETING OF THE WORKING GROUP ON COMPARATIVE ANALYSIS AND ENVIRONMENTAL RISK ASSESSMENT

**Held on 20 February 2019, Tele/WEB
(Agreed on 20 February 2019)¹**

Participants

- Working Group Members:²
Antoine Messéan
- Hearing Experts:³
Salvatore Arpaia
- European Commission and/or Member States representatives:
Anastasia Pagida (DG SANTE)
- EFSA:
GMO Unit: Fernando Álvarez; Ana Martín Camargo
- Others:
Not Applicable

¹ Minutes should be published within 15 working days of the final day of the relevant meeting.

² Indicate first full name and then surname (John Smith) all throughout the document.

³ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



1. Welcome and apologies for absence

EFSA staff welcomed the participants.

No apologies were received.

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 Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 192nd Working Group meeting held on 1 February 2019

The minutes of the 192nd Working Group meeting held on 1 February 2019 were agreed on 1 February 2019.⁶

5. Scientific topics for discussion

5.1. Request from EC to assess the annual 2017 post-market environmental monitoring (PMEM) report on maize MON 810⁷

The working group discussed the methodology and outcomes of the general surveillance and case-specific monitoring activities provided by the consent holder in the 2017 PMEM report as well as scientific comments submitted by EU Member States. Further discussion is needed.

6. Any Other Business

Not applicable

7. Next meeting(s)

22 February 2019, Tele/WEB

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-01001>

Scientific Panel on Genetically Modified Organisms Minutes of the 192nd meeting of the Working Group on Comparative Analysis and Environmental Risk Assessment

**Held on 1 February 2019, Tele/WEB
(Agreed on 1 February 2019)**

Participants

- **Working Group Members:**

Julie Glanville

- **Hearing Experts¹:**

Not applicable

- **European Commission and/or Member States representatives:**

Not applicable

- **EFSA:**

GMO Unit: Fernando Álvarez

AMU Unit: Irene Muñoz Guajardo

- **Others:**

Not Applicable

¹ 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>.

1. Welcome and apologies for absence

EFSA staff welcomed the participant. No apologies for absence were received.

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 Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened Interests declared by the working group member invited for the present meeting. No conflicts related to the issues discussed in this meeting have been identified.

4. Agreement of the minutes of the 191st Working Group meeting held on 22 January 2019

The minutes of the 191st Working Group meeting, held on 22 January 2019, were agreed on 22 January 2019.⁴

5. Scientific topics for discussion

5.1 EFSA-GMO-NL-2012-109 (Oilseed rape 73496)

[EFSA-Q-2012-00617](#)

The working group discussed the application. Further discussion on the literature search is needed.

5.2 EFSA-GMO-DE-2012-111 (Soybean SYHT0H2)

[EFSA-Q-2012-00753](#)

The working group discussed the application. Further discussion on the literature search is needed.

5.3 EFSA-GMO-NL-2017-139 (Maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122)

[EFSA-Q-2017-00115](#)

The working group discussed the application. Further discussion on the literature search is needed.

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

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

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

5.4 EFSA-GMO-NL-2017-144 (Maize MON 87427 × MON 89034 × MIR162 × MON 87411)

[EFSA-Q-2017-00442](#)

The working group discussed the application. Further discussion on the literature search is needed.

5.5 EFSA-GMO-RX-014 (Maize MON 88017)

[EFSA-Q-2018-00672](#)

The working group discussed the application. Further discussion on the literature search is needed.

6. Any Other Business

none

7. Next meeting

20 February 2019, Tele/WEB

Scientific Panel on Genetically Modified Organisms Minutes of the 191st meeting of the Working Group on Comparative Analysis and Environmental Risk Assessment

**Held on 22 January 2019, Parma
(Agreed on 22 January 2019)**

Participants

- **Working Group Members:**

Ewen Mullins (chair), Les Firbank, Antoine Messéan, Eve Veromann and Fabio Veronesi

- **Hearing Experts¹:**

Not applicable

- **European Commission and/or Member States representatives:**

DG SANTE: Hans Moons (by tele)

- **EFSA:**

GMO Unit: Fernando Álvarez, Giacomo De Sanctis, Yann Devos, Andrea Gennaro and Franco Maria Neri

- **Others:**

Not Applicable

1. Welcome and apologies for absence

EFSA staff welcomed the participant. No apologies for absence were received.

¹ 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>.

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 Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened Interests declared by the working group member invited for the present meeting. No conflicts related to the issues discussed in this meeting have been identified.

4. Agreement of the minutes of the 190th Working Group meeting held on 11 January 2019

The minutes of the 190th Working Group meeting, held on 11 January 2019, were agreed on 11 January 2019.⁴

5. Scientific topics for discussion

5.1. EFSA-GMO-NL-2012-109 (Oilseed rape 73496)

[EFSA-Q-2012-00617](#)

The working group discussed the application. Further discussion is needed.

5.2. EFSA-GMO-NL-2016-131 (Maize MON 87427 x MON 89034 x MIR162 x NK603)

[EFSA-Q-2016-00148](#)

The working group discussed the application. Further discussion is needed.

5.3. EFSA-GMO-NL-2016-132 (Soybean DAS-81419-2 x DAS-44406-6)

[EFSA-Q-2016-00195](#)

The working group discussed the application. Further discussion is needed.

5.4. EFSA-GMO-NL-2016-134 (Maize MON 87427 x MON87460 x MON 89034 x MIR162 x NK603)

[EFSA-Q-2016-00686](#)

The working group discussed the application. Further discussion is needed.

5.5. EFSA-GMO-BE-2016-138 (Oilseed rape MS11)

[EFSA-Q-2016-00857](#)

The working group discussed the application. Further discussion is needed.

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

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

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

5.6. EFSA-GMO-NL-2017-143 (Oilseed rape MS11×RF3)

[EFSA-Q-2017-00424](#)

The working group discussed the application. Further discussion is needed.

5.7. EFSA-GMO-NL-2017-144 (Maize MON 87427 x MON 89034 x MIR162 x MON 87411)

[EFSA-Q-2017-00442](#)

The working group discussed the application. Further discussion is needed.

5.8. EFSA-GMO-NL-2018-148 (Soybean DP305423 x MON87708 x MON89788)

[EFSA-Q-2018-00146](#)

The working group discussed the application. Further discussion is needed.

5.9. EFSA-GMO-ES-2018-154 (Cotton GHB811)

[EFSA-Q-2018-00808](#)

The working group discussed the application. Further discussion is needed.

6. Any Other Business

6.1. Discussion on the herbicide treatments across applications

7. Next meeting

1 February 2019, Parma

Scientific Panel on Genetically Modified Organisms Minutes of the 190th meeting of the Working Group on Comparative Analysis and Environmental Risk Assessment

**Held on 11 January 2019, Tele/WEB
(Agreed on 11 January 2019)**

Participants

- **Working Group Members:**

Julie Glanville

- **Hearing Experts¹:**

Not applicable

- **European Commission and/or Member States representatives:**

Not applicable

- **EFSA:**

GMO Unit: Fernando Álvarez, Yann Devos

AMU Unit: Irene Muñoz Guajardo

- **Others:**

Not Applicable

1. Welcome and apologies for absence

EFSA staff welcomed the participant. No apologies for absence were received.

¹ 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>.

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 Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened Interests declared by the working group member invited for the present meeting. No conflicts related to the issues discussed in this meeting have been identified.

4. Agreement of the minutes of the 189th Working Group meeting held on 13 December 2018

The minutes of the 189th Working Group meeting, held on 13 December 2018, were agreed on 13 December 2018.⁴

5. Scientific topics for discussion

5.1 EFSA-GMO-NL-2016-131 (Maize MON 87427 × MON 89034 × MIR162 × NK603)

[EFSA-Q-2016-00148](#)

The working group discussed the application. Further discussion on the literature search is needed.

5.2 EFSA-GMO-DE-2016-137 (Maize GA21 × T25)

[EFSA-Q-2016-00775](#)

The working group discussed the application. Further discussion on the literature search is needed.

5.3 EFSA-GMO-NL-2017-140 (Maize MON 87419)

[EFSA-Q-2017-00263](#)

The working group discussed the application. Further discussion on the literature search is needed.

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

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

⁴ <http://www.efsa.europa.eu/en/gmo/working-groups>

5.4 EFSA-GMO-RX-002 (Oilseed rape GT73)

[EFSA-Q-2016-00478](#)

The working group discussed the application. Further discussion on the literature search is needed.

5.5 EFSA-GMO-RX-012 (Oilseed rape T45)

[EFSA-Q-2018-00229](#)

The working group discussed the application. Further discussion on the literature search is needed.

6. Any Other Business

6.1. Revision of EFSA 2017 Explanatory note on literature searching⁵

The working group discussed the revision of the explanatory note. Further discussion is needed.

7. Next meeting

22 January 2019, Parma

⁵ <https://www.efsa.europa.eu/en/supporting/pub/en-1207>