



GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 6th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED PLANTS – FOOD and FEED

**Held on 3 September 2021, TELE/WEB
(Agreed on 1 October 2021)**

Participants

- Working Group Members:
 - Josep Casacuberta, Ian Dewhurst, Javier Moreno, Ewen Mullins, Hanspeter Naegeli (Chair) and Matias Zurbriggen
- Ad hoc Experts¹:
 - None
- European Commission and/or Member States representatives:
 - Ilaria Ciabatti
- EFSA:
 - GMO Unit: Antonio Fernandez Dumont, Andrea Gennaro, Jose Angel Gomez, Tilemachos Goumperis, Anna Lanzoni and Nikoletta Papadopoulou

1. Welcome and apologies for absence

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>.



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.

3. Agreement of the minutes of the 5th Working Group meeting held on 20 July 2021 via TELE/WEB.

The minutes of the 5th Working Group meeting held on 20 July 2021 were agreed.⁴

4. Scientific topic(s) for discussion

5.1 EC Mandate on GMOs developed through synthetic biology and their implications for risk assessment methodologies⁵

The Working Group discussed the preliminary draft text of the Scientific Opinion. The interpretation of the Terms of Reference was discussed and, following clarification with EC, adapted to the specific working package of the mandate (WP4). Case studies were used to discuss the adequacy and applicability of the guidelines for the risk assessment of food and feed from Synbio Genetically Modified Plants (addressing Term of Reference 3). Various interpretations were discussed for the case study representing a *de novo* domestication Synbio GMP (case study 4), in particular as regards the adequacy and sufficiency of the comparative analysis guidelines. Finally, a scientific officer of the GMO Unit presented examples of nutritional assessment of GMPs, highlighting the driving role of comparative analysis.

The draft scientific opinion will be presented to the GMO Panel at the September 2021 Plenary meeting and the Working Group decided to present and discuss in that forum the case study 4. Further discussion is needed.

5. AOB

None

6. Next meeting

11 November 2021, 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 <https://www.efsa.europa.eu/sites/default/files/2021-03/synbio-gm-plants-foodfeed-risk-assessment-minutes.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00052>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 5th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED PLANTS – FOOD and FEED (Sub Working Group)

**Held on 20 July 2021, TELE/WEB
(Agreed on 20 July 2021)**

Participants

- Working Group Members:
 - Hanspeter Naegeli
- Ad hoc Experts¹:
 - None
- European Commission and/or Member States representatives:
 - None
- EFSA:
 - GMO Unit: Anna Lanzoni

1. Welcome and apologies for absence

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the

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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



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 4th Working Group meeting held on 17 June 2021 via TELE/WEB.

The minutes of the 4th Working Group meeting held on 17 June 2021 were agreed.⁴

5. Scientific topic(s) for discussion

5.1 EC Mandate on GMOs developed through synthetic biology and their implications for risk assessment methodologies⁵

The sub Working Group discussed the structure of the draft opinion and developed preliminary text. Further drafting and discussion are needed.

6. AOB

None

7. Next meeting

3 September 2021, TELE/WEB

⁴ <https://www.efsa.europa.eu/sites/default/files/2021-03/synbio-gm-plants-foodfeed-risk-assessment-minutes.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00052>



GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 4th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED PLANTS – FOOD and FEED

**Held on 17 June 2021, TELE/WEB
(Agreed on 1st July 2021)**

Participants

- Working Group Members:
 - Josep Casacuberta, Ian Dewhurst, Javier Moreno, Ewen Mullins, Hanspeter Naegeli (Chair) and Matias Zurbriggen
- Ad hoc Experts¹:
 - None
- European Commission and/or Member States representatives:
 - None
- EFSA:
 - GMO Unit: Antonio Fernandez Dumont, Andrea Gennaro, Anna Lanzoni and Nikoletta Papadopoulou
 - SCER Unit: Reinhilde Schhonsjans

1. Welcome and apologies for absence

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 3rd Working Group meeting held on 17 May 2021 via TELE/WEB.

The minutes of the 3rd Working Group meeting held on 17 May 2021 were agreed.⁴

5. Scientific topic(s) for discussion

5.1 EC Mandate on GMOs developed through synthetic biology and their implications for risk assessment methodologies⁵

The Working Group discussed the ongoing activities on Safe by Design at EU and OECD level and agreed that these may be of interest in the context of Synbio products and their risk assessment. The Working Group discussed the structure of the draft opinion and developed preliminary text on the text cases identified. Further drafting and discussion are needed.

A representative of the Synbio GMM Food and Feed working group presented the ongoing activities. Alignment on various aspects of the draft documents were discussed, these including for example nutritional assessment of Synbio products. Further discussion is needed.

6. AOB

None

7. Next meeting

3 September 2021, 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 <https://www.efsa.europa.eu/sites/default/files/2021-03/synbio-gm-plants-foodfeed-risk-assessment-minutes.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00052>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 3rd MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED PLANTS – FOOD and FEED

**Held on 11 May 2021, TELE/WEB
(Agreed on 19 May 2021)**

Participants

■ Working Group Members:

- Josep Casacuberta, Ian Dewhurst, Javier Moreno, Ewen Mullins, Hanspeter Naegeli (Chair) and Matias Zurbriggen

■ Ad hoc Experts¹:

none

■ European Commission and/or Member States representatives:

- DG SANTE: Alexandre Huchelmann

■ EFSA:

- GMO Unit: Antonio Fernandez Dumont, Andrea Gennaro, Tilemachos Goumperis, Anna Lanzoni and Nikoletta Papadopoulos
- NUTRI Unit: Wolfgang Gelbmann

1. Welcome and apologies for absence

No apologies were received. Josep Casacuberta attended the half of the meeting duration.

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 2nd Working Group meeting held on 13th April 2021 via TELE/WEB.

The minutes of the 2nd Working Group meeting held on 13 April 2021 were agreed.⁴

5. Scientific topic(s) for discussion

5.1 EC Mandate on GMOs developed through synthetic biology and their implications for risk assessment methodologies⁵

Synbio products could offer challenges in the implementation of comparative analysis with regards to the choice of the comparator, the availability of reference varieties and the selection of endpoints (EFSA GMO Panel, 2021). As indicated in Regulation (EU) No. 503/2013, *where no appropriate conventional counterpart can be identified, a comparative safety assessment cannot be made and consequently a safety and nutritional assessment of the genetically modified food or feed shall be carried out as for novel foods falling within the scope of Regulation (EC) No 258/97 of the European Parliament and of the Council that do not have conventional counterparts (such as where the genetically modified food or feed is not closely related to a food or feed with a history of safe use or where a specific trait or specific traits are introduced with the intention of bringing complex changes in the composition of the genetically modified food or feed)*. A scientific officer from the EFSA NUTRI Unit presented the risk assessment of Novel Foods in the EU, presenting various scientific opinions as examples. The Working group discussed elements of relevance for the discussion on the food and feed risk assessment of the identified Synbio test cases. Further discussion is needed.

The Working Group discussed aspects related to the food and feed risk assessment of Synbio test case 1 (GM sweet maize engineered to produce vitamin B12) and 2 (gluten-free wheat). The working group noted the large number of proteins newly expressed in the Synbio maize and noted that, in accordance to the EFSA guidance and Reg. (EU) No 503/2013, these should be tested one-by-one in case of absence of history of consumption. The Working Group reflected on practicalities to obtain the proteins to test and on ethical considerations on the use of a large number of animals. Further discussion is needed. The appropriateness of the compositional analysis requested by Reg. (EU) No. 503/2013 for the Synbio wheat was discussed. Further discussion is needed.

In general, the Working group highlighted that information on the design and modelling applied to obtain Synbio products can be of relevance to feed the risk assessment of such products. The applicability of the safe-by-design approach to the Synbio process and its relevance for food and feed risk assessment considerations was also discussed.

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 <https://www.efsa.europa.eu/sites/default/files/2021-03/synbio-gm-plants-foodfeed-risk-assessment-minutes.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00052>



The working group discussed the draft text prepared by one expert to introduce the fourth Synbio test case, and the structure of the draft scientific opinion. Further discussion is needed.

AOB

None

Next meeting

17 June 2021, 11.00-18.00, TELE/WEB



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 2nd MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED PLANTS – FOOD and FEED

**Held on 13 April 2021, TELE/WEB
(Agreed on 24 April 2021)**

Participants

■ Working Group Members:

- Josep Casacuberta, Ian Dewhurst, Javier Moreno, Ewen Mullins, Hanspeter Naegeli (Chair) and Matias Zurbriggen

■ Ad hoc Experts¹:

none

■ European Commission and/or Member States representatives:

- DG SANTE: Ilaria Ciabatti

■ EFSA:

- GMO Unit: Antonio Fernandez Dumont, Anna Lanzoni and Nikoletta Papadopoulou

1. Welcome and apologies for absence

No apologies were received. The WG welcomed Matias Zurbriggen, new member of the Working Group.

2. Adoption of agenda

The agenda was adopted without changes.

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<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 1st Working Group meeting held on 9 March 2021 via TELE/WEB.

The minutes of the 1st Working Group meeting held on 9 March 2021 were agreed.⁴

5. Scientific topic(s) for discussion

5.1 EC Mandate on GMOs developed through synthetic biology and their implications for risk assessment methodologies⁵

The working group discussed the outcome of the preparatory exercise conducted on the three test cases proposed in the EFSA GMO Panel, 2020 opinion (Synbio MC and ERA). The target of the exercise was to preliminarily verify the adequacy of requirements from Regulation (EU) 503/2013 and relevant EFSA guidance documents to address the risk assessment of the above test cases, and to identify challenging aspects needing discussion.

The WG identified as areas deserving further discussion the comparative assessment (compositional analysis) and the assessment of the newly expressed proteins. Further discussion will continue in the next WG meetings.

One expert presented a potential additional test case (domesticated tomato). The working group noted that this case is very different from the other three cases, since it re-introduces commercial varieties genes (known) into an unknown background (wild type). As such it will open the discussion to aspects not covered by the other test cases. The WG agreed therefore to introduce this case and to discuss it in the next meetings.

AOB

None

Next meeting

11 May 2021, 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 <https://www.efsa.europa.eu/sites/default/files/2021-03/synbio-gm-plants-foodfeed-risk-assessment-minutes.pdf>

⁵ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00052>



SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 1st MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED PLANTS – FOOD and FEED

**Held on 9 March, TELE/WEB
(Agreed on 16 March 2021)**

Participants

- Working Group Members:
 - Hanspeter Naegeli (Chair), Ian Dewhurst, Javier Moreno, Josep Casacuberta and Ewen Mullins
- Ad hoc Experts¹:
 - none
- European Commission and/or Member States representatives:
 - Ilaria Ciabatti (DG SANTE)
- EFSA:
 - GMO Unit: Andrea Gennaro, Nikoletta Papadopoulou, Antonio Fernandez and Anna Lanzoni.
- Others:
 - Matias Zurbriggen (hearing expert)

1. Welcome and apologies for absence

No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

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<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. Scientific topic(s) for discussion

4.1 EC Mandate on GMOs developed through synthetic biology and their implications for risk assessment methodologies⁴

Continuation of the Mandate M-2018-0205: Further to publication of the SynBio GMP MC and ERA opinion by the EFSA GMO Panel, EFSA and the Commission agreed to continue with the second opinions on FF risk assessment aspects of SynBio products (see EFSA register of questions queried with the Keyword Synthetic Biology <http://registerofquestions.efsa.europa.eu/roqFrontend/login?0>). An ad hoc WG SynBio was set up for the working package dedicated to the evaluation of the adequacy of the Food and Feed (FF) risk assessment guidance documents to SynBio Genetically Modified plants (GMPs).

Scope of the opinion: The GMP food and feed guidance documents will be scrutinised to initiate the checking of the adequacy for FF aspects. The scope of the exercise is limited to GMPs. Areas to be assessed include: comparative analysis, toxicology, allergenicity, dietary exposure and nutrition.

Composition of the WG: Naegeli was appointed Chair of this WG by the GMO Panel in the plenary meeting of January 2021. Experts from the standing working groups of the GMO panel were appointed in accordance EFSA SOP 06. A future recruitment of a Synbio expert is foreseen.

Work program: The working group discussed the plan and the working strategy for addressing the Working Package regarding the FF risk assessment of GMPs in the context of the above mandate. It was confirmed that the WG will base its work on the Scientific Opinion EFSA GMO Panel, 2021⁵, and the same test cases will be used to evaluate the adequacy of GMP FF risk assessment guidance documents. A hearing expert was involved to present the state-of-the-art regarding SynBio GMPs of relevance for the FF risk assessment. The WG agreed to explore the opportunity to introduce one additional test case, further discussion is needed. Preparatory scrutiny of FF requirements in assessment guidance documents and their adequacy to the identified test cases will initiate offline and will be the basis for the discussion at the next WG meeting.

AOB

None

Next meeting

13 April 2021, 13.30-17.30

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://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2021-00052>

⁵ EFSA GMO Panel, 2021 "Evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology (<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6301>)