



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.

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 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.

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

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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>)