



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 13th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – FOOD and FEED

TELE-conference, 13 June 2022

(Agreed on 13 June 2022)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
FEED Unit: Joana Revez
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Ilaria Ciabatti (DG SANTE) and Anna Lanzoni (PREV Unit)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/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 12th Working Group meeting held per TELE-conference.

The minutes of the 12th Working Group meeting held on 16 May 2022 were agreed on 16 May 2022.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM prepares a draft opinion on FF aspects. In this meeting, the WG finalised the processing of the comments received from the public consultation and finalized all sections of the opinion. Each comment is being responded in the Technical Report and where needed the draft opinion has been amended. The Technical Report shall be published together with the finalised opinion as supporting document.

Next steps: This work will be completed by 20 June, after which the draft opinion will be sent to the Scientific Committee for adoption in the plenary meeting of 5/6 July. The technical report will also be completed and sent for endorsement to the Scientific Committee, together with the opinion.

7. Any Other Business

None

8. Next meetings in 2022

None for SynBioM. The continuation of the mandate for SynBio Animals is to be decided.

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/wqs/cross-cutting-science/wq-SynBio.pdf>



SCIENTIFIC COMMITTEE

MINUTES OF THE 12th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – FOOD and FEED

TELE-conference, 16 May 2022

(Agreed on 16 May 2022)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Olga Orlova (pm) and Ilaria Ciabatti (am) (DG SANTE)
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
FEED Unit: Joana Revez
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Alexandre Huchelmann (DG SANTE) and Anna Lanzoni (PREV)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/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 11th Working Group meeting held per TELE-conference.

The minutes of the 11th Working Group meeting held on 12 April 2022 were agreed on 12 April 2022.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM prepares a draft opinion on FF aspects. In this meeting, the WG continued to process the comments received from the public consultation. Each comment is being responded and where needed the draft opinion is being amended. The comments and responses shall be published together with the finalised opinion.

Next steps: The finalisation of the draft opinion will continue in the next WG meeting of 13 June 2022.

7. Any Other Business

None

8. Next meetings in 2022

June 13: TC

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/wgs/cross-cutting-science/wg-SynBio.pdf>



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 11th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – FOOD and FEED

TELE-conference, 12 April 2022

(Agreed on 12 April 2022)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Ilaria Ciabatti (DG SANTE)
- EFSA:
SCER Unit: Reinhilde Schoonjans
FEED Unit: Joana Revez
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Jaime Aguilera (FIP Unit), Anna Lanzoni (PREV Unit) and Alexandre Huchelmann (DG SANTE)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/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 10th Working Group meeting held per TELE-conference.

The minutes of the 10th Working Group meeting held on 21 March 2022 were agreed on 21 March 2022.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM prepares a draft opinion on FF aspects. In this meeting, the WG continued to process the comments received from the public consultation. Each comment is being responded and where needed the draft opinion is being amended. The comments and responses shall be published together with the finalised opinion.

Next steps: This work will continue in the next WG meeting of 16 May 2022.

7. Any Other Business

None

8. Next meetings in 2022

May 16: physical meeting in Parma

June 13: TC

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/wqs/cross-cutting-science/wq-SynBio.pdf>



SCIENTIFIC COMMITTEE

MINUTES OF THE 10th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – FOOD and FEED

TELE-conference, 21 March 2022

(Agreed on 21 March 2022)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann (pm) and Ilaria Ciabatti (am) (DG SANTE)
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
PREV Unit: Anna Lanzoni
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Joana Revez (FEED Unit)

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/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 9th Working Group meeting held per TELE-conference.

The minutes of the 9th Working Group meeting held on 14 December 2021 were agreed on 14 December 2021.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM has prepared a draft opinion on FF aspects. The draft opinion was endorsed by Scientific Committee for public consultation, which took place online for 8 weeks from 19 Jan until 20 March 2022.

In this meeting, the WG started processing the comments received from the public consultation and agreed on a task division. Each comment will be responded in the Annex to the opinion with the Outcome of the public consultation. Where needed the draft opinion shall be amended.

Next steps: This work will continue in the next WG meeting of 12 April 2022.

7. Any Other Business

None

8. Next meetings in 2022

April 12: TC

May 16: physical meeting in Parma (tbc)

June 13: TC

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/wqs/cross-cutting-science/wq-SynBio.pdf>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 9th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – FOOD and FEED

TELE-conference, 14 December 2021

(Agreed on 14 December 2021)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann (am), Ilaria Ciabatti (pm) and Anastasia Pagida (agenda item 7) (DG SANTE)
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
GMO Unit: Anna Lanzoni
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Joana Revez (FEED Unit).

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.

4. Agreement of the minutes of the 8th Working Group meeting held per TELE-conference.

The minutes of the 8th Working Group meeting held on 30 September 2021 were agreed on 30 September 2021.³

5. Hearing Expert(s)

Not Applicable.

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM continued the preparatory work for the opinion on FF aspects. In this context a preparatory work with the Chair and Lieve Herman took place on 21 October 2021 to pool the conclusions from the various sections together and streamline them. The draft opinion was prepared to be presented to the Scientific Committee in the November plenary meeting for endorsement for public consultation.

In this meeting, the WG addressed the suggestions received from the Scientific Committee upon their endorsement on 17 November 2021. All sections were further revised with improvements and agreed for public consultation.

Next steps: The draft opinion will be prepared for public consultation to be launched end January – early February 2022.

7. Update from the EC on international negotiations

Work under the Convention of Biological Diversity (CBD) is ongoing. Anastasia Pagida (SG SANTE) presented to the WG members the convention and its protocols, the CBS portal on Synthetic Biology (<https://bch.cbd.int/synbio/>), the background and issues discussed at the 24th meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA-24).

8. Any Other Business

None.

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

³ <https://www.efsa.europa.eu/sites/default/files/wqs/cross-cutting-science/wg-SynBio.pdf>

9. Next meetings

Meetings for 2022 were agreed as follows:

- 21 March 2022: TC
- 12 April 2022: TC
- 16 May 2022: physical meeting in Parma (TBC)
- 7 June 2022: TC



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 8th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – FOOD and FEED

TELE-conference, 30 September 2021

(Agreed on 30 September 2021)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Ilaria Ciabatti DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
FEED Unit: Joana Revez
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Alexandre Huchelmann (DG SANTE) and Anna Lanzoni (GMO Unit).

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/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 7th Working Group meeting held per TELE-conference.

The minutes of the 7th Working Group meeting held on 23 June 2021 were agreed on 23 June 2021.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM continued the preparatory work for the opinion on FF aspects. The WG addressed the comments received from the Scientific committee upon their first reading on 23 September 2021. All sections under the assessment part were revisited for addressing outstanding actions and comments. The conclusions from each section were revisited and the WG has started to compile them in the conclusion section. This work needs to continue.

Next steps: additional tasks will be addressed in October. The draft opinion will be prepared for submission to the Scientific Committee in the November plenary meeting for endorsement for public consultation.

7. Any Other Business

None

8. Next meetings

- Nov 17-18: scheduled SC endorsement for public consultation (tbc)
- 14 December (TC 10.00am – 17.00pm)

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/wqs/cross-cutting-science/wq-SynBio.pdf>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 7th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – FOOD and FEED

TELE-conference, 23 June 2021

(Agreed on 23 June 2021)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann (absent), Ilaria Ciabatti (absent) DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
GMO Unit: Anna Lanzoni
FEED Unit: Joana Revez
- Others:
Not Applicable

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Alexandre Huchelmann and Ilaria Ciabatti as well as from Jaime Aguilera.

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 6th Working Group meeting held per TELE-conference.

The minutes of the 6th Working Group meeting held on 10-11 June 2021 were agreed on 11 June 2021.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM continued the preparatory work for the opinion on FF aspects. The WG worked on the sections of nutritional assessment, exposure, impact on gut microbiome, including phase 1 evaluations and the respective phase 2 evaluations of the guidances against the selected cases studies. The outlook section (phase 3) was revisited. The draft Opinion was further elaborated in all sections to clarify remaining issues. The WG drafted the conclusions in line with the ToRs.

Next steps: Tasks will be addressed in July and the draft opinion will be prepared for submission to the Scientific committee for first reading in the September plenary meeting.

7. 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 <https://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-SynBio.pdf>

8. Next meetings

- *September 22-23: scheduled first reading by SC (tbc)*
- September 30 (TC 10.00am – 17.00pm)
- *November 17-18: scheduled SC endorsement for public consultation (tbc)*
- December 14 (TC 10.00am – 17.00pm)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

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

TELE-conference, 10 – 11 June 2021

(Agreed on 11 June 2021)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann (absent), Ilaria Ciabatti (am 11 June) DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
FEED Unit: Joana Revez
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Alexandre Huchelmann.

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/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 5th Working Group meeting held per TELE-conference.

The minutes of the 5th Working Group meeting held on 8 April 2021 were agreed by written procedure on 15 April 2021.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM continued the preparatory work for the opinion on FF aspects. The WG worked on the phase 2 evaluation of the guidances against the selected cases studies. The draft Opinion was further elaborated and finetuned in all sections. The WG reviewed the ToRs and prepared for drafting of conclusions in each section.

Next steps: a first full review is programmed in the second week of June. For the June 23 meeting the conclusions will be further elaborated as well as the outlook section.

7. Any Other Business

None

8. Next meetings

- June 23 (TC 10.00am – 17.00pm)
- *September 22-23: scheduled first reading by SC (tbc)*
- September 30 (TC 10.00am – 17.00pm)
- *November 17-18: scheduled SC endorsement for public consultation (tbc)*
- *November 30 to be postponed on 14 December (TC 10.00am – 17.00pm)*

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/wgs/cross-cutting-science/wg-SynBio.pdf>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 5th MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – FOOD and FEED

TELE-conference, 8 April 2021

(Agreed on 15 April 2021)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
DG SANTE Ilaria Ciabatti (am) Alexandre Huchelmann (pm),
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
FEED Unit: Joana Revez (am)
GMO Unit: Anna Lanzoni
- Others:
Not Applicable

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair 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 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 4th Working Group meeting held per TELE-conference.

The minutes of the 4th Working Group meeting held on 18 March 2021 were agreed by written procedure on 18 March 2021.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM continued the preparatory work for the opinion on FF aspects. The draft Opinion was reviewed in the sections molecular characterisation incl. QPS evaluation, product/process information, comparative approach, toxicity, allergenicity, microbiome, nutrition, immune system. These sections were further developed by evaluating cross-referenced existing GMM guidance documents of the GMO Panel (2011), FEEDAP Panel (2018) and NDA Panel (2016) and by adding conclusions or recommendations for future guidance updates.

The WG selected and described near future SynBioM cases to be used in "agri-food" as per the mandate ToRs: the table of selected cases is ready for incorporation into the draft opinion. The selection covers the range of cat 1-4, type of organisms (phages, microbes, microalgae; viable and non-viable), the range of use applications (novel food, feed, food additives, flavourings, biomass) and allow to evaluate if there could be new potential hazards.

The next step is that the WG will continue the phase 2 evaluation of the case studies into the opinion. The structure of the opinion will be mapped against the prevailing guidance structure and placeholders will be introduced for sections yet to be addressed.

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/wgs/cross-cutting-science/wg-SynBio.pdf>

7. Any Other Business

None

8. Next meetings

- May 25 (TC 10.00am – 17.00pm): conclude phase 2 evaluation
- June 23 (TC 10.00am – 17.00pm)
- *Sept 22_23: scheduled first reading by SC (tbc)*
- September 30 (TC 10.00am – 17.00pm)
- *Nov 17-18: scheduled SC endorsement for public consultation (tbc)*
- November 30 (TC 10.00am – 17.00pm)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

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

TELE-conference, 18 March 2021

(Agreed on 18 March 2021)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann (pm), Ilaria Ciabatti (am) DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; no apologies were received.

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/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 3rd Working Group meeting held per TELE-conference.

The minutes of the 2nd Working Group meeting held on 24 February 2021 were agreed by written procedure on 24 February 2021.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM continued the preparatory work for the opinion on FF aspects. The draft Opinion was further compiled with inputs from the members on the sections microbiome, nutrition, allergenicity and immune system. The next step is to elaborate more the section on toxicology and product/process information.

The WG continued checking the existing GMM guidance documents of the GMO Panel (2011), FEEDAP Panel (2018) and NDA Panel (2016).

The WG discussed near future SynBioM cases to be used in "agri-food" as per the mandate ToRs: a table of potential cases was presented to span the range of organisms (phages, microbes, microalgae; viable and non-viable), the range of use applications (novel food, feed, food additives, biomass). The next step will be to determine for the cases the potential new hazards.

The WG will continue the appraisal of the guidances.

7. Any Other Business

None

8. Next meetings

- April 8 (TC 10.00am – 17.00pm)

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/wqs/cross-cutting-science/wq-SynBio.pdf>

- May 25 (TC 10.00am – 17.00pm)
- June 23 (TC 10.00am – 17.00pm)
- *Sept 22_23: scheduled first reading by SC (tbc)*
- September 30 (TC 10.00am – 17.00pm)
- *Nov 17-18: scheduled SC endorsement for public consultation (tbc)*
- November 30 (TC 10.00am – 17.00pm)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

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

TELE-conference, 24 February 2021

(Agreed on 24 February 2021)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren, Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann and Marta Cubria Radio, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
FEED Unit: Joana Revez (pm only)
- Others:
Not Applicable

1. Welcome and apologies for absence

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

The Chair welcomed the participants; apologies were received, from Ilaria Ciabatti (DG SANTE), Anna Lanzoni (GMO Unit) and Annamaria Rossi (NDA Unit).

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 2nd Working Group meeting held per TELE-conference.

The minutes of the 2nd Working Group meeting held on 2 February 2021 were agreed by written procedure on 18 February 2021.⁴

5. Hearing Expert (s)

Not Applicable

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBioM continued the preparatory work for the opinion on FF aspects. A first draft Opinion was compiled in the recent EFSA template and the previous matrix file was incorporated. This matrix file was expanded with more comments to the relevant sections of the guidance documents to be checked for adequacy.

The WG continued to check the existing GMM guidance document of the GMO Panel (2011) and provided further comments.

The chair of the working group refined the scheme to illustrate which use applications are to be covered (e.g. novel food, feed, food additives) and which potential hazards can be identified *a priori* though not specific for SynBioMs (e.g. nutrition, (protein) toxicity, allergenicity impact on microbiome). This was incorporated in the draft opinion.

The WG discussed near future SynBioM cases to be used in "agri-food" as per the mandate ToRs.

The next steps are to keep providing input on the matrix, on the case studies and on the first guidance to be checked for adequacy.

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/wqs/cross-cutting-science/wq-SynBio.pdf>

7. Any Other Business

None

8. Next meetings

- March 18 (TC 10.00am – 17.00pm)
- April 8 (TC 10.00am – 17.00pm)
- May 25 (TC 10.00am – 17.00pm)
- June 23 (TC 10.00am – 17.00pm)
- *Sept 22_23: scheduled first reading by SC (tbc)*
- September 30 (TC 10.00am – 17.00pm)
- *Nov 17-18: scheduled SC endorsement for public consultation (tbc)*
- November 30 (TC 10.00am – 17.00pm)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

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

Teleconference, held on 2 February 2021

(Agreed on 18 February 2021)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (Chair), Lieve Herman, Hendrik van Loveren (am only), Carmen Pelaez, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Ilaria Ciabatti (30 min pm only), Alexandre Huchelmann (pm only) and Marta Cubria Radio, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
GMO Unit: Anna Lanzoni
NDA Unit: Annamaria Rossi
FIP Unit: Jaime Aguilera
FEED Unit: Joana Revez
- Others:
Not Applicable

¹ As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair 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 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 18 December 2020 per TELE-conference.

The minutes of the 1st Working Group meeting held on 18 December 2020 were agreed by written procedure on 15 January 2021.⁴

5. Hearing Expert (s)

Not Applicable.

6. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Under mandate M-2018-0205 the WG SynBio was updated (<https://ess.efsa.europa.eu/doi/doiweb/wg/685310>) to continue with the second opinions on FF aspects of SynBioM. Extra expertise was recruited for toxicology and for effects on gut microbiome. The chair explained the context of the mandate, the *modus operandus* of the WG and the work-program under this mandate.

The guidance documents to be checked for adequacy are mapped in a matrix table. The WG began to check the existing GMM guidance document of the GMO Panel (2011) and provided initial comments. The chair of the working group revisited the scheme to illustrate which use applications are to be covered (e.g. novel food, feed, food additives) and which potential hazards can be identified *a priori* though not specific for SynBioMs (e.g. nutrition, (protein) toxicity, allergenicity impact on microbiome). The WG will look for near future SynBioM cases to be used in "agri-food" as per the mandate ToRs; the case studies should try to reflect the range of organisms groups to be covered (e.g. bacteria, microalgae, virus/phages and fungi). EMA was contacted to learn about experiences with microorganisms used for medicinal purposes (i.e. viral or bacterial oral vaccines) and related documents are inspected for relevance to this EFSA WG.

The next steps are to keep providing input on the matrix and on the first guidance to be checked for adequacy.

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/wgs/cross-cutting-science/wg-SynBio.pdf>

7. Any Other Business

None.

8. Next meetings

- February 24 (TC 10.00am – 17.00pm)
- March 18 (TC 10.00am – 17.00pm)
- April 8 (TC 10.00am – 17.00pm)
- May 25 (TC 10.00am – 17.00pm)
- June 23 (TC 10.00am – 17.00pm)
- *September 22-23: scheduled first reading by SC (tbc)*
- September 30 (TC 10.00am – 17.00pm)
- *November 17-18: scheduled SC endorsement for public consultation (tbc)*
- November 30 (TC 10.00am – 17.00pm)



SCIENTIFIC COMMITTEE

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

Teleconference, held on 18 December 2020

(Agreed on 15 January 2020)

Participants

- Working Group Members:
Pier Sandro Cocconcilli (Chair), Lieve Herman, Hendrik van Loveren, Just Vlak
- Hearing Experts¹:
none
- European Commission and/or Member States representatives:
Ilaria Ciabatti, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
GMO Unit: Anna Lanzoni
NDA Unit: Annamaria Rossi
FIP Unit: Jaime Aguilera
FEED Unit: Joana Revez
- Others:
Not Applicable

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>.



1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Alexandre Huchelmann (DG SANTE).

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 15th Working Group meeting held on 28 September 2020

Not applicable. The minutes of the Working Group meetings for the SynBioM ERA aspects were agreed per written procedure and published on the EFSA website.⁴

5. Scientific topic(s) for discussion (EFSA-Q-2020-00768)

Continuation of the Mandate M-2018-0205: Further to publication of the SynBioM MC and ERA opinion by the Scientific Committee, EFSA and the Commission agreed to continue with the second opinions on FF aspects of SynBioM and SynBioP (see EFSA register of questions queried with the Keyword Synthetic Biology <http://registerofquestions.efsa.europa.eu/roqFrontend/login?0>). The existing WG SynBio was allocated for this work.

Scope of the opinion and mapping of domains to be covered: The guidance documents to be checked will be mapped in a matrix table. The GMM guidance document will be used to initiate the checking of the adequacy for FF aspects. The use applications as novel food, feed, food additives are to be covered. Potential hazards regarding nutrition, (protein) toxicity, allergenicity are to be checked. Organisms groups of bacteria, algae, virus and fungi are to be covered.

New composition of the WG: The Chair of the WG was reconfirmed by the SC in the plenary meeting of September 2020 (see minutes item 4.2

<https://www.efsa.europa.eu/sites/default/files/event/2020/100th-plenary-meeting-scientific-committee-minutes.pdf>). An additional need for expertise was identified regarding the impact of living microorganisms when ingested on the gut microbiome. Recruitment procedures for a WG member will start following the EFSA SOP 06. Also, for microalgae used as food or feed additional

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/sites/default/files/wgs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



expertise is foreseeable, as well as expertise with SynBioM for medicinal applications. Both will be covered in the future by the recruitment of (hearing) experts.

Table for content of the Opinion: Problem formulations and technical aspects that are important to be addressed in the draft opinion for SynBio M food/feed aspects were mapped in a preliminary Table of contents that is following the main structure of the previous opinion on MC and ERA aspects.

Work program: The WG discussed the strategies and work-program under this mandate. The utility of case studies was discussed and confirmed.

6. Any Other Business

None

7. Next meetings

- February 2 (TC 10.00am – 17.00pm)
- February 24 (TC 10.00am – 17.00pm)
- April 8 (TC 10.00am – 17.00pm)
- May 25 (TC 10.00am – 17.00pm)
- June 23 (TC 10.00am – 17.00pm)
- *Sept 22_23: scheduled first reading by SC (tbc)*
- September 30 (TC 10.00am – 17.00pm)
- *Nov 17-18: scheduled SC endorsement for public consultation (tbc)*
- November 30 (TC 10.00am – 17.00pm)



SCIENTIFIC COMMITTEE

MINUTES OF THE 15TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Teleconference, held on 28 September 2020

(Agreed on 7 October 2020)

Participants

- Working Group Members:
Pier Sandro Cocconcetti (Chair), Boet Glandorf, Christoph Tebbe, Lieve Herman, Just Vlak
- Hearing Experts¹:
none
- European Commission and/or Member States representatives:
Ilaria Ciabatti, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
GMO Unit: Nikoletta Papadopoulou, Anna Lanzoni (for item 5, workprogram)
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; no apologies 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 14th Working Group meeting held on 3 July June 2020.

The minutes of the 14th Working Group meeting were agreed per written procedure and published on the EFSA website.⁴

5. Scientific topic(s) for discussion

Further to adoption of the SynBioM MC and ERA opinion by the Scientific Committee on 16 September, the WG addressed the outstanding comments and approved the suggestions made by the Scientific Committee. The opinion is now finalized and will be prepared for publication together with the technical report of the public consultation that was also finalised. The WG was invited to brainstorm on the next step of the work-program under this mandate and to share views on the strategies, problem formulations and technical aspects that are important to be addressed in the next opinion for SynBio M food/feed aspects.

6. Any Other Business

None

7. Next meetings

- To be decided in December 2020

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/sites/default/files/wqs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



SCIENTIFIC COMMITTEE

MINUTES OF THE 14TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Teleconference, held on 3 July 2020

(Agreed on 10 July 2020)

Participants

- Working Group Members:
Pier Sandro Cocconcetti (Chair), Boet Glandorf, Christoph Tebbe, Lieve Herman, Just Vlak
- Hearing Experts¹:
Vitor Martins Dos Santos
- European Commission and/or Member States representatives:
Alexandre Huchelmann, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants; apologies were received from Ilaria Ciabatti and Hans Moons (DG SANTE), as well as from Victor De Lorenzo.

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 13th Working Group meeting held on 22-23 June 2020.

The minutes of the 13th Working Group meeting were agreed per written procedure and published on the EFSA website.⁴

5. Scientific topic(s) for discussion

Further to the work done in the 13th meeting, the WG continued to wherever appropriate, take comments into account for finalisation of the draft Opinion. All sections of the draft Opinion were revised, while writing and finalising the abstract and summary. The Technical report of the public consultation as well as the Opinion are ready for submission to the Scientific Committee for adoption in the September plenary meeting.

6. Any Other Business

None

7. Next meetings

- 28 September (9.00am – 17.00am), converted in teleconference: address SC comments on the final (adopted) Opinion and the Technical Report of the public consultation

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/sites/default/files/wqs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



SCIENTIFIC COMMITTEE

MINUTES OF THE 13TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Teleconference, held on 22-23 June 2020

(Agreed on 1 July 2020)

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.

Participants

- Working Group Members:
Pier Sandro Cocconcilli (Chair), Boet Glandorf, Christoph Tebbe, Lieve Herman, Just Vlak
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Ilaria Ciabatti, Hans Moons, Alexandre Huchelmann, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
GMO Unit: Nikoletta Papadopoulou
- Others:
Not Applicable

1. Welcome and apologies for absence

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 Chair welcomed the participants; no apologies were received. Hans Moons (DG SANTE) is joining the meeting in view of supporting the EU work under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety (as per the mandate of the EC).

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 12th Working Group meeting held on 4-5 June 2020.

The minutes of the 12th Working Group meeting were agreed per written procedure and published on the EFSA website.⁴

5. Scientific topic(s) for discussion

Further to the work done in the 12th meeting, the WG continued to respond in the Table of comments received during the public consultation of the draft Opinion during the period 31 March – 4 June. The Technical Report of the public consultation was established. Wherever appropriate, comments were taken into account for finalisation of the draft opinion. All sections of the draft Opinion were revised, and conclusions aligned. The summary will be prepared in the next meeting.

6. Any Other Business

None

7. Next meetings

- 3 July TC (13.00 – 17.00pm)
- 28 September (9.00am – 17.00am), converted in teleconference: address SC comments on the final (adopted) Opinion and the Technical Report of the public consultation

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/sites/default/files/wqs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



SCIENTIFIC COMMITTEE

MINUTES OF THE 12TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Teleconference, held on 4-5 June 2020

(Agreed on 17 June 2020)

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.

Participants

- Working Group Members:
Pier Sandro Cocconcelli, Boet Glandorf, Christoph Tebbe, Lieve Herman, Just Vlak
- Hearing Experts¹:
Vitor Martins dos Santos, Victor de Lorenzo (both on 4 June pm only and 5 June)
- European Commission and/or Member States representatives:
Alexandre Huchelmann, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans (Chair of this meeting)
FIP Unit: Jaime Aguilera
- Others:
Not Applicable

1. Welcome and apologies for absence

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 Chair welcomed the participants and apologies were received from Ilaria Ciabatti (DG SANTE), Tommaso Raffaello and Nikoletta Papadopoulou (GMO Unit).

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.

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 11th Working Group meeting held on 2-3 March 2020.

The minutes of the 11th Working Group meeting were agreed per written procedure and published on the EFSA website.⁴

5. Hearing Expert (s)⁵

The hearing experts, Prof. dr. Victor de Lorenzo and Prof.dr.ir. Vitor Martins dos Santos, were invited to express their views on specific aspects of synthetic Biology, when they occurred in the comments received under item 6 of the present meeting. Such comments mainly occurred in section 3 and section 5 of the draft Opinion.

6. Scientific topic(s) for discussion

The public consultation period was extended with one week due to the Corona virus lock down situation in many countries and ended on 4 June 23.00pm instead of the planned 26 May 2020. The comments received during the public consultation were duly evaluated (in 2 batches, received until 29 May and received until 5 June) by the WG and EFSA responses were directly inserted in the table that will be published in the technical report of the public consultation. Wherever appropriate, comments were taken into account for finalisation of the draft opinion. This work will continue in the next meeting.

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/sites/default/files/wgs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>

⁵



7. Any Other Business

None

8. Next meetings

- 22-23 June, converted in teleconference: to address the public comments
- 3 July (13.00pm – 17.00pm): teleconference to finalise addressing the public comments and technical report
- 28 – 29 September, converted in teleconference: to address the comments from the SC on the final Opinion and the technical report of the public consultation.



SCIENTIFIC COMMITTEE

MINUTES OF THE 11TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Teleconference, held on 2-3 March 2020

(Agreed on 10 March 2020)

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.

Participants

- Working Group Members:
Pier Sandro Cocconcilli (Chair), Boet Glandorf, Christoph Tebbe, Lieve Herman
- Hearing Experts¹:
Vitor Martins dos Santos
- European Commission and/or Member States representatives:
Alexandre Huchelmann, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
- Others:
Not Applicable

1. Welcome and apologies for absence

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 Chair welcomed the participants and apologies were received from Ilaria Ciabatti (DG SANTE), Tommaso Raffaello and Nikoletta Papadopoulou (GMO Unit), Victor Di Lorenzo and Just Vlak.

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.

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 10th Working Group meeting held on 14 15 January 2020.

The minutes of the 10th Working Group meeting were agreed and published on the EFSA website.⁴

5. Scientific topic(s) for discussion

The comments from the Scientific Committee during the plenary of 19 February 2020 were addressed directly in the Opinion. The draft opinion was finalized in all sections and prepared for going into public consultation.

6. Any Other Business

Communication planning: The public consultation is now scheduled from 31 March till end 26 May 2020 and the context of this mandate will be communicated on EFSA's website, as well as in the EFSA Journal. The scheduled meeting for 14-15 May is cancelled. The Opinion is scheduled for submission to the SC in September, for possible adoption in the plenary meeting of 16-17 September.

7. Next meetings

4-5 June, Parma: to address the public comments

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/sites/default/files/wqs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



22-23 June, Parma: to address the public comments

3 July (9.00 am – 13.00pm): teleconference to finalise addressing the public comments

28 – 29 September, Parma: to address the comments from the SC on the final (adopted) Opinion and the technical report of the public consultation.



SCIENTIFIC COMMITTEE

MINUTES OF THE 10TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Held on 14-15 January 2020, Parma

(Agreed on 24 January 2020)

Participants

- Working Group Members:
Pier Sandro Cocconcetti (Chair), Boet Glandorf, Christoph Tebbe, Lieve Herman, Just Vlak (first day)
- Hearing Experts¹:
Vitor Martins dos Santos, Victor Di Lorenzo (TC first day)
- European Commission and/or Member States representatives:
Alexandre Huchelmann (TC first day), DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
FIP Unit: Jaime Aguilera
COMMS Unit: Francesca Matteuci
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants and apologies were received from Ilaria Ciabatti (DG SANTE) and Tommaso Raffaello (GMO Unit).

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 9th Working Group meeting held on 4 November 2019.

The minutes of the 9th Working Group meeting, per teleconference, were agreed and published on the EFSA website.⁴

5. Scientific topic(s) for discussion

The comments from the Scientific Committee during the first reading at the plenary of 5 December 2019 were addressed. The Opinion was further finetuned in all sections and the conclusions were revisited in detail. The Working Group decided on the content of the glossary, abstract and summary. New tasks were identified before finalising this draft version that will be submitted for endorsement by the Scientific Committee on 19 February.

6. Any Other Business

Communication planning: The public consultation is now scheduled from 31 March till end May 2020 and the context of this mandate will be communicated on EFSA's website, as well as in the EFSA Journal.

7. Next meetings

2 March 2020 (14.00pm – 18.00pm) and 3 March 2020 (8.30 am – 17.00pm)

14-15 May, Parma: placeholder (probably to be cancelled)

4-5 June, Parma: to address the public comments

22-23 June, Parma: to address the public comments

3 July (9.00 am – 13.00pm): teleconference to finalise addressing the public comments

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/sites/default/files/wqs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



The Opinion is scheduled for submission to the SC in September, for possible adoption in the plenary meeting of 16-17 September.



SCIENTIFIC COMMITTEE

MINUTES OF THE 9TH TELE-MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Held on 4 November 2019, Teleconference

(Agreed on 11 November 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcelli, Boet Glandorf, Christoph Tebbe, Lieve Herman, Just Vlak
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
GMO Unit: Tommaso Raffaello
FEED Unit: Jaime Aguilera
- 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. Agreement of the minutes of the 8th bis Working Group meeting held on 14 October 2019.

The minutes of the 8th bis Working Group meeting were agreed on 29 October and published on the EFSA website.⁴

5. Scientific topic(s) for discussion

The draft conclusions of opinion were formulated during this meeting and the foundations of the conclusions within the body text were checked. All members were asked to revisit now the recommendations section.

6. Any Other Business

None.

7. Next meeting

4-5 December 2019 SC plenary meeting for first reading

14-15 January 2020

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/sites/default/files/wqs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



SCIENTIFIC COMMITTEE

MINUTES OF THE 8TH-bis TELE-MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Held on 14 October 2019, Parma

(Agreed on 29 October 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcelli, Boet Glandorf, Christoph Tebbe, Lieve Herman
- Hearing Experts¹:
None
- European Commission and/or Member States representatives:
Alexandre Huchelmann, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
GMO Unit: Tommaso Raffaello
- 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. Agreement of the minutes of the 8th Working Group meeting held on 7-8 October 2019.

The minutes of the 8th Working Group meeting were agreed and published on the EFSA website.⁴

5. Scientific topic(s) for discussion

The opinion was further developed in the sections 5, 6, 7, and 8.

6. Any Other Business

None.

7. Next meeting

4th November 2019, TC.

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/sites/default/files/wqs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



SCIENTIFIC COMMITTEE

MINUTES OF THE 8TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Held on 7-8 October 2019, Parma

(Agreed on 14 October 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcelli, Boet Glandorf, Christoph Tebbe, Lieve Herman
- Hearing Experts¹:
Vitor Martins dos Santos
- European Commission and/or Member States representatives:
Alexandre Huchelmann, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
GMO Unit: Tommaso Raffaello
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants and apologies were received from Victor de Lorenzo (hearing expert).

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 after adjusting the timing and rank order of the topics.

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 7th Working Group meeting held on 2-3 September 2019.

The minutes of the 7th Working Group meeting were agreed and published on the EFSA website.⁴

5. Hearing Experts

Prof. Vítor Martins dos Santos was invited to present his views on modelling approaches, microbiome assessment and systems approaches.

The expertise for SynBio viruses was not covered in the current WG. Just Vlak, who can cover this expertise was asked to become member and has now been included as a working group member.

6. Scientific topic(s) for discussion

The opinion was further developed in the sections on ERA, recommended options, and overarching gap analysis.

7. Any Other Business

7.1. Meetings

The WG meetings in 2020 were agreed.

8. Next meeting

14 October 2019, TC

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/sites/default/files/wqs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>

SCIENTIFIC COMMITTEE

MINUTES OF THE 7TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Held on 2-3 September 2019, Parma

(Agreed on 13 September 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcelli, Boet Glandorf, Christoph Tebbe, Lieve Herman
- Hearing Experts¹:
Victor de Lorenzo (TC)
Vitor Martins dos Santos (2 Sept)
- European Commission and/or Member States representatives:
Alexandre Huchelmann, DG SANTE
- EFSA:
SCER Unit: Reinhilde Schoonjans
GMO Unit: Tommaso Raffaello
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants and apologies were received from Ilaria Ciabatti (DG SANTE).

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 after adjusting the timing and rank order of the topics.

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 6th Working Group meeting held on 16-17 July 2019.

The minutes of the 6th Working Group meeting were agreed and published on the EFSA website.⁴

5. Hearing Experts

Prof. Vítor Martins dos Santos was invited to present his views on RA challenges of SynBio microalgae. Prof. Victor de Lorenzo was shortly available to follow up on the previous meeting.

6. Scientific topic(s) for discussion

Outstanding comments were addressed in the opinion, and the format/content development of each subchapter agreed. In order to fully address the ToR, new chapters were created to reflect identified lack of guidance and how they can be addressed in the future.

7. Any Other Business

7.1. Next WG meetings

The WG meetings in 2020 were agreed.

8. Next meeting

7-8 October 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/sites/default/files/wgs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



SCIENTIFIC COMMITTEE

MINUTES OF THE 6TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Held on 16-17 July 2019, Parma

(Agreed on 30 July 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcetti, Boet Glandorf, Christoph Tebbe
- Hearing Experts¹:
Victor de Lorenzo
Vitor Martins dos Santos (pm 16 July)
- European Commission and/or Member States representatives:
Ilaria Ciabatti, DG SANTE (am 16, am 17 July)
Alexandre Huchelmann, DG SANTE (pm 16 July)
- EFSA:
SCER Unit: Caterina Barrasso, Reinhilde Schoonjans
GMO Unit: Tommaso Raffaello
- Others:
Not Applicable

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>.



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on 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 5th Working Group meeting held on 13-14 June 2019, Parma and TELE-conference on 28 June 2019.

The minutes of the 5th Working Group meeting held on 13-14 June and on 28 June 2019 were agreed.⁴

5. Hearing Experts

Prof. Victor de Lorenzo was invited to share knowledge on safe implementation of SynBio in microorganisms, new issues and criteria for a safe chassis, standardization and domestication. Prof. Vítor Martins dos Santos was invited to present his views on the risk assessment challenges of microalgae SynBio developments.

6. Scientific topic(s) for discussion

6.1. ERA sections

The experts discussed the ERA section in the draft scientific opinion in terms of structure, content and complexity.

6.2. New issues

Upon the presentation of Prof. Victor de Lorenzo, the WG discussed some new insights regarding SynBio developments, new risk assessment issues and the safe implementation of SynBio.

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 Please add here the link to the respective minutes published on the EFSA website



6.3. MC sections

The experts continued the discussion on the MC in the draft scientific opinion and developed in depth one section as a style and content model to be applied by all WG members.

6.4. Recommendation section

The experts started the discussion on the development of the recommendation section in the draft of the scientific opinion.

7. Any Other Business

7.1. Next WG meetings

The WG meetings in 2020 were agreed for the months of January and March. The further planning towards the end of the mandate as discussed.

8. Next meeting

2-3 September 2019, Parma



SCIENTIFIC COMMITTEE

MINUTES OF THE 5TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Held on 13-14 June 2019, Parma and TELE-conference, 28 June 2019

(Agreed on 4 July 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (chair)¹, Boet Glandorf, Lieve Herman^{1 2}, Christoph Tebbe
- Hearing Experts³:
Vítor Martins dos Santos (am 14 July)
- European Commission and/or Member States representatives:
Ilaria Ciabatti, DG Santé
- EFSA:
SCER Unit: Caterina Barrasso, Reinhilde Schoonjans
GMO Unit: Tommaso Raffaello
FIP Unit: Jaime Aguilera
- Others:
Not Applicable

¹ 13-14 June only

² Chair (pm) 13 June

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

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes. The sub-meeting was confirmed for the 28th June to deepen out the ERA subsections of the draft opinion and the way forward on how to structure the ERA.

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 4th Working Group meeting held on 10 May 2019, TELE-conference.

The minutes of the 4th Working Group meeting held on 10th May 2019 were agreed on 24th May 2019.⁶

5. Scientific topics for discussion

5.1.Draft Scientific GMM SynBio Opinion

The working group worked on each chapter of the draft of the scientific opinion.

5.2.SynBio developments in microalgae

The hearing expert presented micro-algae SynBio developments and the molecular techniques used for these developments. Potential safety issues and challenges for the risk assessment of micro-algae SynBio developments were discussed with the working group members.

5.3.Toxicological testing methods with living microorganisms

The toxicological testing methods for living microorganisms is necessary in the areas of NDA, FIP, FEED, and PPP. The current practices (inside and outside EFSA) were mapped and presented to the experts of the working group. The experts will consider this information while developing the toxicity chapter in the draft of the scientific opinion.

5.4.Reference EFSA guidances to be analysed

The working group further addressed the ToR4 while identifying further EFSA guidances to be checked for adequacy. The need to related expertise was also discussed.

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/sites/default/files/wgs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



5.5.ERA sections state of play (TELE-conference 28th of June)

Boet Glandorf and Christoph Tebbe discussed how to structure the ERA section in the Scientific Opinion, in order to fully reflect the approach of the ERA as stipulated in Directive 2001/18. The overall re-structuring of the scientific opinion was also discussed in order to create a subchapter on phenotypic characterisation, forming the bridge between the molecular characterisation and the ERA sections of the opinion. This proposal will be reviewed by the entire WG and to be implemented by the next meeting in July.

6. Any Other Business

Technical issues with the common workspace were addresses with the experts that have encountered difficulties in accessing the common work file.

7. Next meetings

16-17 July Parma
2-3 September Parma
7-8 October Parma
14 October Teleconference
14-15 January Parma (to be discussed)
2-3 March Parma (to be discussed)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 4TH MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

TELE-conference (09.00-13.00), 10 May 2019

(Agreed on 24 May 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcetti (chair), Boet Glandorf, Lieve Herman, Christoph Tebbe
- European Commission and/or Member States representatives:
Ilaria Ciabatti, DG Santé
- EFSA:
SCER Unit: Caterina Barrasso, Reinhilde Schoonjans
GMO Unit: Nikoletta Papadopoulou, Tommaso Raffaello
FIP Unit: Jaime Aguilera
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on 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.

4. Agreement of the minutes of the 3rd Working Group meeting held on 16 April 2019, Parma.

The minutes of the 3rd Working Group meeting held on 16 April 2019 were agreed on 26 April and published on the EFSA website.³

5. Scientific topic(s) for discussion

5.1. Last comments on the final report of the procurement

The experts were asked to provide a last round of feedbacks to be included in the final report developed by the contractor RIVM.

5.2. Feedbacks in the Assessment section of the Scientific Opinion

The feedbacks developed by the experts on the adequacy of the guidances' chapters during phase 1 (without the defined case studies in mind) were discussed in the working group. The work will continue in the next physical meeting.

5.3. Selection of case studies

Case studies were selected by the experts in order to cover different aspects of complexity to be addressed under the mandate: new organism used for SynBio GMM, different routes of exposure to the SynBio GMM, high extent of genetic modification.

6. Next meeting

13-14 June, physical meeting, Parma

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

³ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 3RD MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS- ENVIRONMENTAL RISK ASSESSMENT

TELE-conference (13.00 – 17.00pm), 16 April 2019

(Agreed on 26 April 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (chair), Boet Glandorf, Lieve Herman, Christoph Tebbe
- Hearing Experts¹:
Victor de Lorenzo
- European Commission and/or Member States representatives:
Alexandre Huchelmann, DG Santé
- EFSA:
SCER Unit: Caterina Barrasso, Reinhilde Schoonjans
GMO Unit: Tommaso Raffaello
FIP Unit: Jaime Aguilera
- 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. Agreement of the minutes of the 2nd Working Group meeting held on 18-19 March 2019, Parma.

The minutes of the 2nd Working Group meeting held on 18-19 March 2019 were agreed on 29 March and published on the EFSA website.⁴

5. Hearing Expert

Prof. Victor de Lorenzo was invited to present his views on the list of case studies presented during the meeting.

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA invited Prof. Victor de Lorenzo 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 framework⁷.

6. Scientific topic(s) for discussion

6.1. Procurement – List of case studies

Literature screens during the Horizon scanning by the contractor RIVM were explained and the listing of the case studies that met the inclusion criteria were presented to the working group.

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/sites/default/files/wqs/cross-cutting-science/wq-Synbio-GMM-ERA-2018-2020.pdf>

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 Decision of the Executive Director on Competing Interest Management, Article 9:

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



6.2. Views of the hearing expert

The hearing expert showed his views on the case studies presented by the contractor and on some issues to be addressed for SynBio safety.

6.3. Selection case studies

The working group started the discussion for the selection of the case studies to frame the questions to be addressed under the mandate.

7. Any Other Business

7.1. Not Applicable

8. Next meeting

10 May 2019 (Teleconference)



SCIENTIFIC COMMITTEE

MINUTES OF THE 2ND MEETING OF THE WORKING GROUP ON SYNTHETIC BIOLOGY OF GENETICALLY MODIFIED MICRO-ORGANISMS – ENVIRONMENTAL RISK ASSESSMENT

Held on 18-19 March 2019, Parma

(Agreed on 29 March 2019)

Participants

- Working Group Members:
Pier Sandro Cocconcelli (chair), Boet Glandorf, Lieve Herman, Christoph Tebbe
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Ilaria Ciabatti, DG SANTE
- EFSA:
SCER Unit: Caterina Barrasso, Reinhilde Schoonjans
GMO Unit: Tommaso Raffaello
FIP Unit: Jaime Aguilera
- Others:
Not Applicable

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>.



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on 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 4-5 February 2019, Parma.

The minutes of the 1st Working Group meeting held on 4-5 February 2019 were agreed on 15th February 2019.⁴

5. Scientific topic(s) for discussion

5.1.Chapters of EFSA guidance relevant for the mandate

The working group identified relevant chapters of EFSA guidance to be checked for their adequacy under the mandate.

5.2.Preliminary case studies

Preliminary case studies listed by the contractor were shown during the working group. The experts started a preliminary discussion for their selection.

6. Any Other Business

6.1.Not Applicable

7. Next meeting

16 April 2019, Teleconference

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/sites/default/files/wgs/cross-cutting-science/wg-Synbio-GMM-ERA-2018-2020.pdf>

Scientific Committee and Emerging Risks Unit

Minutes of the 1st meeting of the Working Group on Synthetic Biology of Genetically Modified Micro-Organisms - Environmental Risk Assessment

Held on 4-5 February 2019, Parma (Italy)

(Agreed on 15 February 2019)

Participants

- **Working Group Members:**

Pier Sandro Cocconcetti (Chair), Boet Glandorf, Lieve Herman, Christoph Tebbe

- **Hearing Experts¹:**

Victor de Lorenzo (for item 5.1)

- **European Commission:**

Ilaria Ciabatti (DG SANTE)

- **EFSA:**

SCER Unit: Caterina Barrasso, Reinhilde Schoonjans

GMO Unit: Nikoletta Papadopoulou, Tommaso Raffaello

FIP Unit: Jaime Aguilera

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/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair 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 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. Hearing Expert

Prof. Victor de Lorenzo was invited to present his views for item 5.1 – Listing of relevant Case studies of the present meeting.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA invited Prof. Victor de Lorenzo 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 framework⁶.

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/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 Decision of the Executive Director on Competing Interest Management, Article 9:

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

5. Scientific topic(s) for discussion

5.1. Introduction of the Mandate

EFSA staff introduced the [mandate](#) and its scope, as well as the associated timeline and expected deliverables.

5.2. GMM SynBio developments within the remit of this working group

The Experts discussed the working context of SynBio developments in the frame of this working group for case-study selection, particularly those intended for agri-food use as mentioned in the mandate and intended for deliberate release into the environment.

5.3. Possible GMM SynBio applications in the next 10 years

Experts discussed the possibility of GMM SynBio developments and the likelihood of commercial/practical applications within the next 10 years.

6. Any Other Business

The digital working environment was explored together with the experts. Useful conferences were listed.

7. Next meetings

2nd WG: 18-19 March

3rd WG: 16 April (pm, half day TelConf)

4th WG: 10 May (am, half day TelConf)

5th WG: 13-14 June

6th WG: 16-17 July

7th WG: 2-3 September

8th WG: 7 October or 14 October (pm, half day TelConf)

9th WG: 29-30 October or 12-13 November