



# SCIENTIFIC PANEL ON Genetically Modified Organisms (GMO)

5<sup>th</sup> working group meeting on new biotechnology applied to  
animals (GMA-NGT WG)



29-30 January 2024

09:00-17:00 (day 1) / 09:00-13:00 (day 2)

MINUTES - Agreed on 30 January 2024

**Location:** Web conference

## **Attendees:**

### ○ **Working Group Members:**

Leslie Firbank, Thomas Frenzel, Debora Glandorf, Mette S. Herskin, Simon Lillico, Javier Moreno, Fabien Nogué, Robin Ornsrud, Anna Troedsson-Wargelius, Giovanni Savoini (chair).

### ○ **Hearing Experts<sup>1</sup>:**

Mike McGrew.

### ○ **European Commission and/or Member States representatives:**

Frank Swartenbroux, DG Sante E.3 (Biotechnology).

### ○ **EFSA:**

Nutrition and Food Innovation (NIF) Unit: Michele Ardizzone, Paschalina Grammatikou, Paolo Lenzi, Ana Martin Camargo.

Biological Hazards & Animal Health and Welfare (BIOHAW) Unit: Marika Vitali.

### ○ **Others**

None

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

The Chair welcomed the participants.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## IV. Agreement of the minutes of the 4<sup>th</sup> Working Group meeting held on 11-12 December 2023, via web

The minutes of the 4<sup>th</sup> Working Group meeting were agreed by written procedure on 17 December 2023<sup>4</sup>

## V. Scientific and administrative topic(s) for discussion

### a. Mandate M-2018-0205 with EFSA-Q-2023-00050<sup>5</sup>

The working group discussed several topics related to new biotechnologies, including NGT and SynBio, applicable to farmed animals and aquaculture, refining the work carried out in previous meetings, as regards: the comprehensive definition of NGTs applicable to the scope of the mandate; identification of process and product-related novel hazards; the criteria applicable to the selection of appropriate comparator(s) for NGT animals; the translatability of concepts familiar in crops and plants for NGT animals; and the criteria for the selection of case studies. Furthermore, according to the Terms of Reference of the mandate, the working group continued the assessment of the adequacy of the EFSA guidances covering all aspects of molecular characterisation, food feed safety & welfare, and environmental impact of genetically modified animals, for the risk assessment of animals produced by new biotechnologies for agri-food and feed purposes. Further discussion is needed in future meetings.

## VI. Any Other Business

Not Applicable

## VII. Preparatory meetings

Since the 4<sup>th</sup> WG meeting, the following preparatory meetings chaired by EFSA staff also were held:

- **Preparatory meeting on Molecular Characterisation**

Date: 09/01/2024

**Working Group Members:** Simon Lillico, Fabien Nogu  , Anna Troedsson-Wargelius.

**Hearing Experts:** Mike McGrew.

EFSA:

- Nutrition and Food Innovation Unit: Michele Ardizzone, Paolo Lenzi

Topic for discussion: Applicability of Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects (EFSA,2012)

AOB: None

- **Preparatory meeting on food and feed**

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<sup>4</sup> <https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo>

<sup>5</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00050>



Date: 10/01/2024

Working Group Members: Javier Moreno, Robin Ornsrud, Giovanni Savoini.

Hearing Experts: none

EFSA:

- Nutrition and Food Innovation Unit: Michele Ardizzone, Paschalina Grammatikou

Topic for discussion: Applicability of Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects (EFSA,2012)

AOB: none

- **Preparatory meeting on the comparator**

Date: 11/01/2024

Working Group Members:

Leslie Firbank, Thomas Frenzel, Mette S. Herskin, Robin Ornsrud

Hearing Experts: none

EFSA:

- Nutrition and Food Innovation Unit: Michele Ardizzone

Topic for discussion: Applicability of Guidance on the risk assessment of food and feed from genetically modified animals and on animal health and welfare aspects (EFSA,2012)

AOB: None

- **Preparatory meeting on environmental risk assessment**

Date: 11/01/2024

Working Group Members: Mette S. Herskin

Hearing expert: None

EFSA:

- Nutrition and Food Innovation Unit: Ana Martin Camargo
- Biological Hazards & Animal Health and Welfare (BIOHAW) Unit: Marika Vitali.

Topic for discussion: Applicability of the section Animal Welfare of the Guidance on the ERA of GM animals (EFSA, 2013) for NGT-animals

AOB: None

- **Preparatory meeting on environmental risk assessment**

Date: 22/01/2024

Working Group Members:

Leslie Firbank, Debora Glandorf, Anna Troedsson-Wargelius.

Hearing expert: None

EFSA:

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- Nutrition and Food Innovation Unit: Ana Martin Camargo, Reinhilde Schoonjans

Topic for discussion: Applicability of the Guidance on the ERA of GM animals (EFSA, 2013) for NGT-animals

AOB: None

## **VIII. Next meeting**

The next meeting will be held on 18<sup>th</sup> and 19<sup>th</sup> March 2024, via web-conference.



# SCIENTIFIC PANEL ON Genetically Modified Organisms (GMO)

4<sup>th</sup> working group meeting on new biotechnology applied to  
animals (GMA-NGT WG)



11-12 December 2023

09:00-17:00 (day 1) / 09:00-13:00 (day 2)

MINUTES - Agreed on 17 December 2023

**Location:** Web conference

**Attendees:**

○ **Working Group Members:**

Leslie Firbank, Thomas Frenzel, Debora Glandorf (only Day 1), Mette S. Herskin, Simon Lillico, Javier Moreno (only Day 1), Fabien Nogué, Robin Ornsrud, Anna Troedsson-Wargelius, Giovanni Savoini (chair).

○ **Hearing Experts<sup>1</sup>:**

Mike McGrew.

○ **European Commission and/or Member States representatives:**

Frank Swartenbroux, DG Sante E.3 (Biotechnology).

○ **EFSA:**

Nutrition and Food Innovation (NIF) Unit: Michele Ardizzone, Paschalina Grammatikou, Paolo Lenzi, Ana Martin Camargo.

Biological Hazards & Animal Health and Welfare (BIOHAW) Unit: Marika Vitali.

○ **Others**

None

## I. Welcome and apologies for absence

The Chair welcomed the participants.

## II. Adoption of agenda

The agenda was adopted without changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the 3<sup>rd</sup> Working Group meeting held on 23-24 October 2023, in Parma**

The minutes of the 3<sup>rd</sup> Working Group meeting were agreed by written procedure on 31 October 2023<sup>4</sup>

#### **V. Scientific and administrative topic(s) for discussion**

##### **a. Mandate M-2018-0205 with EFSA-Q-2023-00050<sup>5</sup>**

The working group discussed several topics related to new biotechnologies, including NGT and SynBio, applicable to farmed animals and aquaculture, refining the work carried out in previous meetings, as regards: the comprehensive definition of NGTs applicable to the scope of the mandate; the different methods available for producing NGT animals; the criteria applicable to the selection of appropriate comparator(s) for NGT animals; the translatability of concepts familiar in crops and plants for NGT animals; the methodologies used in EFSA for the animal welfare risk assessment. Furthermore, according to the Terms of Reference of the mandate, the working group started the assessment of the adequacy of the EFSA guidances covering all aspects of molecular characterisation, food feed safety & welfare, and environmental impact of genetically modified animals, for the risk assessment of animals produced by new biotechnologies for agri-food and feed purposes. Further discussion is needed in future meetings.

#### **VI. Any Other Business**

Not Applicable

#### **VII. Next meeting**

The next meeting will be held on 29<sup>th</sup> and 30<sup>th</sup> January 2024, via web-conference.

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<sup>4</sup> <https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo>

<sup>5</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00050>



## **Annex**

### **Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting**

With regard to this meeting, Dr. Debora Glandorf declared the following interest: "Working Group Microbiële Gewasbeschermingsmiddelen", which provides input to the Dutch Ministry of Agriculture regarding scientific aspects of the new data requirements for microbial protection products. The role of Debora Glandorf in this Working group consists of providing input on the methodology and data requirements for the environmental risk assessment of GMOs, such as the use of problem formulation approach in the environmental risk assessment. In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the Expert concerned.



SCIENTIFIC PANEL ON  
Genetically Modified Organisms (GMO)  
3<sup>rd</sup> working group meeting on new biotechnology applied to  
animals (GMA-NGT WG)



23-24 October 2023  
09:00-17:00 (day 1) / 09:00-13:00 (day 2)  
MINUTES - Agreed on 31 October 2023

**Location:** Parma

**Attendees:**

- **Working Group Members:**  
Leslie Firbank, Thomas Frenzel (only Day 2), Debora Glandorf, Mette S. Herskin, Simon Lillico, Javier Moreno, Fabien Nogué (only Day 1), Robin Ornsrud, Anna Troedsson-Wargelius, Giovanni Savoini (chair).
- **Hearing Experts<sup>1</sup>:**  
Mike McGrew.
- **European Commission and/or Member States representatives:**  
Frank Swartenbroux, DG Sante E.3 (Biotechnology).
- **EFSA:**  
Nutrition and Food Innovation (NIF) Unit: Michele Ardizzone, Paschalina Grammatikou, Paolo Lenzi, Ana Martin Camargo.  
Biological Hazards & Animal Health and Welfare (BIOHAW) Unit: Marika Vitali.
- **Others**  
None

## I. Welcome and apologies for absence

The Chair welcomed the participants.

## II. Adoption of agenda

The agenda was adopted without changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### **IV. Agreement of the minutes of the 2<sup>nd</sup> Working Group meeting held on 12-13 September 2023, via web-conference**

The minutes of the 2<sup>nd</sup> Working Group meeting were agreed by written procedure on 27 September 2023<sup>4</sup>

#### **V. Scientific and administrative topic(s) for discussion**

##### **a. Mandate M-2018-0205 with EFSA-Q-2023-00050<sup>5</sup>**

The working group discussed several topics related to new biotechnologies, including NGT and SynBio, applicable to farmed animals and aquaculture, including: a comprehensive definition of NGTs applicable to the scope of the mandate; the different methods available for producing NGT animals; the criteria applicable to the selection of appropriate comparator(s) for NGT animals; the translatability of concepts familiar in crops and plants, also for NGT animals; the methodologies used in EFSA for the animal welfare risk assessment; the potential role of NGT insects for agri-food-feed purposes. Furthermore, the working group discussed also possible interpretation of the ToRs of the mandate and the proposal for an informative webinar to present the project to stakeholders. Finally, the structure of the scientific opinion was presented. Further discussions are needed in future meetings.

#### **VI. Any Other Business**

Not Applicable

#### **VII. Next meeting**

The next meeting will be held on 11<sup>th</sup> and 12<sup>th</sup> December 2023, via web-conference.

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<sup>4</sup> <https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo>

<sup>5</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00050>



**SCIENTIFIC PANEL ON**  
**Genetically Modified Organisms (GMO)**  
**2<sup>nd</sup> working group meeting on new biotechnology applied to**  
**animals (GMA-NGT WG)**



12-13 September 2023

09:00-17:00 (day 1) / 09:00-13:00 (day 2)

MINUTES - Agreed on 27 September 2023

**Location:** Web conference

**Attendees:**

- **Working Group Members:**  
Leslie Firbank, Thomas Frenzel, Debora Glandorf, Mette S. Herskin, Javier Moreno, Fabien Nogué, Robin Ornsrud, Giovanni Savoini (chair).
- **Hearing Experts<sup>1</sup>:**  
Simon Lillico, Anna Troedsson-Wargelius, Diane Wray-Cahen (for Agenda Item #7 only).
- **European Commission and/or Member States representatives:**  
Frank Swartenbroux, DG Sante E.3 (Biotechnology).
- **EFSA:**  
Nutrition and Food Innovation (NIF) Unit: Michele Ardizzone, Paschalina Grammatikou, Paolo Lenzi, Ana Martin Camargo.  
Biological Hazards & Animal Health and Welfare (BIOHAW) Unit: Marika Vitali.
- **Others**  
Alison Van Eenennaam – contractor (for Agenda Item #9 only)

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

The Chair welcomed the participants. Apologies were received from Mike McGrew.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **IV. Agreement of the minutes of the 1<sup>st</sup> Working Group meeting held on 17-18 July 2023, via web-conference**

The minutes of the 1<sup>st</sup> Working Group meeting were agreed by written procedure on 26 July 2023<sup>4</sup>

#### **V. Scientific and administrative topic(s) for discussion**

##### **a. Mandate M-2018-0205 with EFSA-Q-2023-00050<sup>5</sup>**

The working group discussed the potential risks related to new genomic techniques (NGTs) applied to farmed animals and aquaculture, and the possible approach to adequately address the EC mandate. The criteria necessary for an effective selection of potential case studies were assessed, as well as the need for further clarification on the terms of reference. Finally, the results of the gathering report of knowledge on NGTs applied to farmed animals and aquaculture or their agri/food/feed products, and a global overview of regulatory policies for animal biotechnology were presented. Tasks were distributed to all members of the Working Group. Further discussions are needed in future meetings.

#### **VI. Any Other Business**

Not Applicable

#### **VII. Next meeting**

The next meeting will be held on 23<sup>rd</sup> and 24<sup>th</sup> October 2023 in Parma.

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<sup>4</sup> <https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo>

<sup>5</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00050>



SCIENTIFIC PANEL ON  
Genetically Modified Organisms (GMO)  
1<sup>st</sup> working group meeting on new biotechnology applied to  
animals (GMA-NGT WG)



17-18 July 2022

10:00-13:00 (day 1) / 14:00-17:00 (day 2)

MINUTES - Agreed on XX Month202X

**Location:** Web conference

**Attendees:**

- **Working Group Members:**  
Leslie Firbank, Thomas Frenzel, Debora Glandorf, Mette S. Herskin, Javier Moreno, Fabien Nogu  , Robin Ornsrud, Giovanni Savoini (chair).
- **Hearing Experts<sup>1</sup>:**  
Ian Cowx, Simon Lillico, Mike McGrew.
- **European Commission and/or Member States representatives:**  
Frank Swartenbroux, DG Sante E.3 (Biotechnology).
- **EFSA:**  
Nutrition and Food Innovation (NIF) Unit: Michele Ardizzone, Paschalina Grammatikou, Paolo Lenzi, Ana Martin Camargo, Nikoletta Papadopoulou, Reinhilde Schoonjans.  
Biological Hazards & Animal Health and Welfare (BIOHAW) Unit: Marika Vitali.  
Risk Assessment Logistic (RAL): Bianca Bottoni, Rita Faria Pontes Figueiras

## I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Anna Troedson Wargelius.

## II. Adoption of agenda

The agenda was adopted without changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

## IV. Agreement of the minutes of the 1<sup>st</sup> Working Group meeting held on 17-18 July 2023, via web-conference

The minutes of the 1<sup>st</sup> Working Group meeting were agreed by written procedure on 26 July 2023

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## V. Scientific and administrative topic(s) for discussion

### a. WG composition and set-up and Tour the Table

The Chair of the meeting invited all participants to present themselves focusing on the relevance of their expertise to the scope of the GMA-NGT mandate.

### b. Administrative information

Information relevant to the activities of the experts was provided regarding administrative aspects, use of the Teams channel platform used for sharing documents and on the role and duties of the expert.

### c. EC Mandate on new developments in biotechnology applied to animals for agri-food uses.

The content of the EC mandate received by DG SANTE was presented. The discussion focused on the scope, background, Terms of Reference and deadlines.

### d. Knowledge gathering on known cases of animals (and their food and feed products) obtained by new developments in biotechnology.

An update of the activities related to the knowledge gathering on known cases of animals (and their food and feed products) obtained by new developments in biotechnology was presented.

### e. EFSA guidance for the risk assessment of GM animals: EFSA GMO & AHAW Panels 2012<sup>4</sup> and EFSA GMO Panel 2013<sup>5</sup>

The principles underlying the risk assessment of GM animals, as outlined in EFSA GMO & AHAW Panels 2012 and in EFSA GMO Panel 2013 were presented, highlighting the main concepts covering comparative assessment, molecular characterisation, food and feed safety, animal welfare, and environmental impact.

### f. Approach to deal with the task of the mandate

In order to set up the discussion foreseen in subsequent meetings on the preferred approach to tackle the mandate, some examples of approaches used in the context of other mandates with a similar scope were presented (e.g. EFSA GMO Panel 2020<sup>6</sup>; EFSA GMO Panel 2021<sup>7</sup>; VKM report on genome editing 2021<sup>8</sup>).

### g. Dates for the next GMA-NGT WG meetings

Dates were agreed for the next four GMA-NGT WG meetings.

### h. Tasks assignments for the next GMA-NGT WG meetings

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<sup>4</sup> <https://www.efsa.europa.eu/it/efsajournal/pub/2501>

<sup>5</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/3200>

<sup>6</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/6297>

<sup>7</sup> <https://pubmed.ncbi.nlm.nih.gov/33598046/>

<sup>8</sup> <https://imr.brage.unit.no/imr-xmlui/handle/11250/2992217>



Tasks were assigned in preparation of the next GMA-NGT WG meeting.

## **VI. Any Other Business**

Not Applicable

## **VII. Next meeting**

The next meeting will be held on 12<sup>th</sup> and 13<sup>th</sup> September 2023 via web conference.