16th Working Group meeting on New Approach Methodologies (NAMs)



21 November 2025 14:00-17:00 MINUTES – Agreed on 28 November 2025

Location: Web conference

Attendees:

- Working Group (WG) Members:
 Maria Bastos, Jacqueline Castenmiller, Qasim Chaudhry, Roland Franz, Henriqueta Louro
- European Chemical Agency (ECHA):
 Camelia Constantin
- Organisation for Economic Co-operation and Development (OECD): Eugene Choi
- European Commission Joint Research Centre (EC JRC):
 Susanne Bremer-Hoffmann, Alessia Bogni, Joao Barroso, Deborah Stanco
- National Institute of Standards and Technology (NIST):
 Elijah Petersen
- o U.S. Food and Drug Administration (US FDA): Anil Patri
- o EFSA

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Mina Ristovska, Claudia Roncancio-Peña EFSA Feed and Contaminant Unit (FEEDCO) Unit: Chantra Eskes

I. Welcome and apologies for absence

EFSA 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 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 these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf

MEETING MINUTES – 21 November 2025 16th Working Group on NAMs



IV. Agreement of the minutes of the 15th Working Group meeting held on 21 and 22 July 2025, in EFSA (Parma)

The minutes of the 15th Working Group meeting were agreed by written procedure on 1 August 2025.

V. Scientific topic(s) for discussion

In the context of the EFSA NAMs4NANO Project (GP/EFSA/MESE/2022/01) "Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations", the WG on NAMs was requested to provide input on Lot 1 Draft Deliverable 3 on a 'Draft implementation plan for a qualification system for NAMs within EFSA's remit'. The input provided will be considered by the grant holder to prepare a final draft of the deliverable and resubmit it for EFSA's approval.

VI. Next WG meeting

15th Working Group meeting on New Approach Methodologies (NAMs)



21 and 22 July 2025
Day 1 14:00-18:00 / Day 2 09:00-13:00
MINUTES - Agreed on 1 August 2025

Location: Parma (Day 1 M05 / Day 2 M06a)

Attendees:

- Working Group (WG) Members:
 Maria Bastos, Jacqueline Castenmiller, Qasim Chaudhry, Roland Franz, Henriqueta Louro
- European Chemical Agency (ECHA):
 Camelia Constantin, Virginia Rodriguez Unamuno
- European Medicines Agency (EMA):
 Polly Paul, Stefano Ponzano
- Organisation for Economic Co-operation and Development (OECD):
 Mar Gonzalez, Eugene Choi, Anne Gourmelon
- European Commission Joint Research Centre (EC JRC):
 Susanne Bremer-Hoffmann, Alessia Bogni, Deborah Stanco
- National Institute of Standards and Technology (NIST):
 Elijah Petersen
- EFSA

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Ana Diges, Claudia Roncancio-Peña EFSA Food Ingredients and Packaging (FIP) Unit: Ana Maria Rincon, Daniele Comandella EFSA Feed and Contaminant Unit (FEEDCO) Unit: Chantra Eskes EFSA Pesticide Peer Review (PREV) Unit: Sofia Batista Leite

Welcome and apologies for absence

EFSA welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

MEETING MINUTES – 21 and 22 July 2025 15th Working Group meeting on NAMs



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 these meetings 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 14th Working Group meeting held on 20 and 21 May 2025, via web-conference

The minutes of the 14th Working Group meeting were agreed by written procedure on 27 May 2025.

V. Scientific topic(s) for discussion

In the context of the EFSA NAMS4NANO Project (GP/EFSA/MESE/2022/01)³ "Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations", the WG on NAMs was requested to support EFSA at a workshop with the project grant holder to brainstorm on Lot 1 'Draft implementation plan for a qualification system for NAMs within EFSA's remit'. The input provided will be considered for the scientific direction of the deliverable, which will be finalised by the grant holders and submitted for EFSA's approval.

In the first part of the meeting, a summary of the NAMs4NANO <u>Qualification System Proposal</u>, including its methodology, input received during the consultation process and dissemination activities, and next steps was presented by the grant holders. The second part of the meeting was then focused on gathering input from the audience on the qualification proposal and upcoming implementation plan. In particular, following a presentation on the experience with the implementation of EMA's qualification system, input was requested from attending WG members, EU agencies, and other organisations on the NAMs4NANO Qualification System proposal. A perspective on Partnership for the Assessment of Risks from Chemicals (PARC) activities promoting NAMs development and possible collaboration on a case study was also discussed. Lastly, the grant holders presented proposals of possible NAMs to be selected for testing the qualification proposal, in view of the preparation of an implementation plan. Further consultation with experts and EFSA will follow to reach agreement on the NAMs to be prioritized for internal testing of the qualification criteria.

VI. Next WG meeting

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf
 https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf
 https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf
 https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf
 https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf

SCIENTIFIC COMMITTEE (PREV Unit)

14th Working Group meeting on New Approach Methodologies (NAMs)



20-21 May 2025

MINUTES - agreed on 27th May 2025

Location: Webconference

Attendees:

Working Group (WG) Members:

Emilio Benfenati Romualdo Benigni Qasim Chaudry Glenn Lurman Eva Bay Wedebye Agnes Stier

Hearing experts¹

Syngenta: Katy BRIDGWOOD and Mark GARROD

BASF: Monika BROSS, Monika KEMENY, Christian SPANGLER

o EFSA:

EFSA Pesticide Peer Review (PREV) Unit: Juan Manuel Parra Morte (Chair), Martina Panzarea. EFSA Integrated Data (IDATA) Unit: Andrea Gissi, Edoardo Carnesecchi.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies from Agnes Stier. Glenn Lurman attended the 20th of May.

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 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. The following interests were declared orally by the members at the beginning of this meeting: Qasim Chaudhry is part of the Advisory Board of an ECHA funded project on NAMs (not paid) and Glenn Lurman is supporting WHO on groundwater metabolites toxicology assessment.

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 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



IV. Agreement of the minutes of the 12th Working Group held on 3 December 2024, via web-conference

The minutes of the Working Group meeting were agreed upon by written procedure on 19 December 2024.

V. Scientific topic(s) for discussion

a. Support to the EFSA Project: Practical implementation of NAMs into the risk assessment of pesticide metabolites (lead by PREV Unit)

In the context of the Project, lead by PREV Unit and contracted out, on "Practical implementation of NAMs into the risk assessment of pesticide metabolites" (EFSA-Q-2023-00211), the WG on NAMs was requested to support EFSA PREV Unit in the revision of the deliverables of the project.

The WG discussed deliverable 3. The input provided will be considered for the revision of the deliverable that will be finalised by the contractor.

VI. Hearing experts

The hearing experts had one hour to present their replies to the following questions from the Working Group.

- What are industry's views on integrating the following lines of evidence for grouping and read across for Ames mutagenicity?, considering that expert review would be needed in any case.
 - o Similarity in regard to Phys-chem properties. Please give specific criteria.
 - Molecular Structural Similarity. Please give specific criteria.
 - o Organic functional Groups similarity. Please give specific criteria.
 - Similarity in regard to alerts by Profilers (mechanistic and/or endpoint specific) for Ames mutagenicity. Please give specific criteria.
 - Other: Please give specific criteria.
- What are industry's views on the use of at least two independent QSAR prediction results for Ames mutagenicity? Please give specific criteria. Expert review would be needed in any case.
- We would also like to hear from industry on the application of the proposed conceptual framework to the substance and their metabolites under consideration for the case studies.

Hearing experts did not propose specific criteria and highlighted the importance of experts' review. EFSA highlighted that although specific criteria will be proposed, experts' review of the outcome of the workflow is needed.

VII. Preliminary meetings

Preliminary meetings were held on 24th March 2025 and 19th May 2025 between EFSA (Juan Parra, Andrea Gissi and Martina Panzarea) with Romualdo Benigni to prepare the discussion during the WG.

VIII. Next meeting

SCIENTIFIC COMMITTEE (PREV Unit)

13th Working Group meeting on New Approach Methodologies (NAMs)



21 and 24 February 2025 14:00-18:00 MINUTES - Agreed on 6 March 2025

Location: Web conference

Attendees:

Working Group Members
 Qasim Chaudhry
 Maria Bastos
 Jacqueline Castenmiller
 Roland Franz
 Henriqueta Louro

European Chemical Agency (ECHA)
 Camelia Constantin
 Virginia Rodriguez Unamuno

European Commission Joint Research Centre (EC JRC)
 Susanne Bremer Hoffmann
 Alessia Bogni
 Deborah Stanco
 João Barroso

US Food and Drug Administration (US FDA):
 Anil Patri
 Suzanne Fitzpatrick

National Institute of Standards and Technology (NIST):
 Elijah Petersen

o EFSA

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Ana Diges, Claudia Roncancio-Peña

EFSA Food Ingredients and Packaging (FIP) Unit: Ana Maria Rincon EFSA Feed and Contaminant Unit (FEEDCO) Unit: Paola Manini EFSA Integrated Data (IDATA) Unit: Edoardo Carnesecchi

I. Welcome and apologies for absence

EFSA welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

MEETING MINUTES – 21 and 24 February 2025 13th Working Group meeting on NAMs



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 and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings 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 12th Working Group meeting held on 3 December 2024, via web-conference

The minutes of the 12th Working Group meeting were agreed by written procedure on 19 December 2024.

V. Scientific topic(s) for discussion

In the context of the EFSA NAMS4NANO Project (GP/EFSA/MESE/2022/01)³ "Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations", the WG on NAMs was requested to support EFSA at the Interim Meeting of the NAMs4NANO Project organised to discuss the 3rd deliverable of Lot 2 on 'Interim report with first set of experimental results and updated Integrated Approach to Testing and Assessment (IATA) of risk assessment case studies' and Lot 3 'Interim report with first set of experimental results of methodological case studies'. The input provided will be considered for the revision of the deliverables that will be finalised by the grant holders and re-submitted to EFSA for approval.

VI. Next WG meeting

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/competing interest management

thtp://www.efsa.europa.eu/sites/default/files/corporate_bublications/files/competing_interest_management_17.pdf

https://www.efsa.europa.eu/en/art36grants/article36/gpefsamese202201-nams4nano-integration-new-approach-methodologies-results

SCIENTIFIC COMMITTEE (PREV Unit)

12th Working Group meeting on New Approach Methodologies (NAMs)



03 December 2024 09:30-16:30 MINUTES – agreed on 19th <u>December 2024</u>

Location: Webconference

Attendees:

o Working Group (WG) Members:

Emilio Benfenati Romualdo Benigni Qasim Chaudry Glenn Lurman Eva Bay Wedebye Agnes Stier

o FFSA:

EFSA Pesticide Peer Review (PREV) Unit: Juan Manuel Parra Morte (Chair), Martina Panzarea. EFSA Methodology and Scientific Support (MESE) Unit: Lucian Farcal. EFSA Integrated Data (IDATA) Unit: Andrea Gissi, Edoardo Carnesecchi, Alison Hunt.

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 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.

IV. Agreement of the minutes of the 11th Working Group meeting held on 26 April 2024, via web-conference

The minutes of the 11^{th} Working Group meeting were agreed upon by written procedure on 26 April 2024.

V. Scientific topic(s) for discussion

a. Support to the EFSA Project: Practical implementation of NAMs into the risk assessment of pesticide metabolites (lead by PREV Unit)

¹ 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/competing_interest_management_17.pdf

MEETING MINUTES – 3 December 2024 12th Working Group meeting on NAMs



In the context of the Project, lead by PREV Unit and contracted out, on "Practical implementation of NAMs into the risk assessment of pesticide metabolites" (EFSA-Q-2023-00211), the WG on NAMs was requested to support EFSA PREV Unit in the revision of the deliverables of the project.

The WG discussed the task 3 (creation of a decision scheme for toxicological assessment of metabolites) and task 3.1 (proof-of-concept studies for a decision scheme on toxicological assessment of metabolites) of the 3rd Deliverable of Objective 1 of the Project. The input provided will be considered for the revision of the deliverable that will be finalised by the contractor.

VI. Next meeting

SCIENTIFIC COMMITTEE (PREV Unit)

11th Working Group meeting on New Approach Methodologies (NAMs)



23 April 2024 09:00-16:00 MINUTES – agreed on 26 April 2024

Location: Webconference

Attendees:

o Working Group (WG) Members:

Emilio Benfenati Romualdo Benigni Qasim Chaudry Glenn Lurman Eva Bay Wedebye Agnes Stier

o European Chemicals Agency (ECHA):

Andrea Gissi

o EFSA:

EFSA Pesticide Peer Review (PREV) Unit: Juan Manuel Parra Morte (Chair), Martina Panzarea. EFSA Methodology and Scientific Support (MESE) Unit: Lucian Farcal.

Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted with changes, Item No. 3.4 of the agenda was discussed first followed by Items No. 3.2, 3.1 and 3.2.

III. 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.

IV. Agreement of the minutes of the 9th Working Group meeting held on 14 March 2024, via web-conference

The minutes of the 9th Working Group meeting were agreed upon by written procedure on 26 March 2024.

¹ 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/competing_interest_management_17.pdf

MEETING MINUTES – 23 April 2024 10th Working Group meeting on NAMs



V. Scientific topic(s) for discussion

a. Support to the EFSA Project: Practical implementation of NAMs into the risk assessment of pesticide metabolites (lead by PREV Unit)

In the context of the Project, lead by PREV Unit and contracted out, on "Practical implementation of NAMs into the risk assessment of pesticide metabolites" (EFSA-Q-2023-00211), the WG on NAMs was requested to support EFSA PREV Unit in the revision of the deliverables of the project.

The WG discussed the 2nd Deliverable of Objective 1 of the Project. The input provided will be considered for the revision of the deliverable that will be finalised by the contractor.

VI. Next meeting

10th Working Group meeting on New Approach Methodologies (NAMs)



15 April 2024 12:30 - 18:00 MINUTES - Agreed on 23 April 2024

Location: Parma & Webconference

Attendees:

o Working Group (WG) Members:

Maria Bastos, Jacqueline Castenmiller, Qasim Chaudhry, Henriqueta Louro, Alicja Mortensen.

o EC JRC:

Joao Barroso, Alessia Bogni, Susanne Bremer-Hoffmann, Silvia Casati, Effrosyni Katsanou, Milena Mennecozzi, Monica Piergiovanni, Deborah Stanco, Maurice Whelan.

o EMA:

Michael Empl

o US FDA:

Anil Patri

o US NIST:

Elijah Petersen

o ECHA:

Camelia Constantin, Marianne Matzke.

o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Lucian Farcal, Claudia Roncancio-Peña, Adriana Scattareggia Marchese.

EFSA Feed and Contaminant Unit (FEEDCO): Chantra Eskes, Paola Manini.

EFSA Nutrition and Food Innovation Unit (NIF): Reinhard Ackerl, Irene Nuin, Annamaria Rossi, Francesco Suriano.

EFSA Pesticides Peer Review Unit (PREV): Sofia Batista Leite, Dimitra Kardassi, Andrea Terron.

EFSA Chief Scientist Office (CSO): Jean-Lou Christian Michel Dorne.

EFSA Enable Departement Office: Claudia Paoletti.

I. Welcome and apologies for absence

EFSA welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

MEETING MINUTES – 15 April 2024 10th Working Group meeting on NAMs



III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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 9th Working Group meeting held on 14th March 2024, via web-conference

The minutes of the 9th Working Group meeting were agreed by written procedure on 26 March 2024.

V. Scientific topic for discussion

a. Support to the EFSA NAMs4NANO Project (GP/EFSA/MESE/2022/01)

In the context of the EFSA NAMS4NANO Project (GP/EFSA/MESE/2022/01)³ "Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations", the WG on NAMs was requested to support EFSA at the Interim Meeting of the NAMs4NANO Project to discuss the 2nd Deliverable of Lot 1 'Proposal for a fit for purpose qualification system for NAMs in the food and feed sector'. The input provided will be considered for the revision of the deliverable that will be finalised by the grant holder and re-submitted to EFSA for approval. As a next step, the deliverable will be published in the EFSA Journal as External Scientific Report.

VI. Next meeting

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

 $^{{}^2 \}overline{\text{http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf}$

³ https://www.efsa.europa.eu/en/art36grants/article36/gpefsamese202201-nams4nano-integration-new-approach-methodologies-results

SCIENTIFIC COMMITTEE (PREV Unit)

9th Working Group meeting on New Approach Methodologies (NAMs)



14 March 2024 09:00-16:00 MINUTES – agreed on 26 March 2024

Location: Webconference

Attendees:

o Working Group (WG) Members:

Emilio Benfenati Romoualdo Benigni Qasim Chaudry Glenn Lurman Eva Bay Wedebye Agnes Stier

European Chemicals Agency (ECHA):

Andrea Gissi

o EFSA:

EFSA Pesticide Peer Review (PREV) Unit: Juan Manuel Parra Morte (Chair), Martina Panzarea, Sofia Batista Leite.

EFSA Methodology and Scientific Support (MESE) Unit: Lucian Farcal.

EFSA Integrated Data (IDATA) Unit: Edoardo Carnesecchi.

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 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.

IV. Agreement of the minutes of the 8th Working Group meeting held on 09 February 2024, via web-conference

The <u>minutes of the 8^h Working Group meeting</u> were agreed upon by written procedure on 19 February 2024.

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

MEETING MINUTES - 14 March 2024 9th Working Group meeting on NAMs



V. Scientific topic(s) for discussion

a. Support to the EFSA Project: Practical implementation of NAMs into the risk assessment of pesticide metabolites (lead by PREV Unit)

In the context of the Project, lead by PREV Unit and contracted out, on "Practical implementation of NAMs into the risk assessment of pesticide metabolites" (EFSA-Q-2023-00211), the WG on NAMs was requested to support EFSA PREV Unit in the revision of the deliverables of the project. The WG will provide advice on how in silico tools (e.g., QSARs and read across) could be implemented in the OECD QSAR Toolbox for a decision scheme for mutagenicity assessment (bacterial gene mutation) of pesticide metabolites. The advice will be shared with the contractor who will explore its technical applicability.

VI. Next meeting

The next meeting of	f the WG	supportina FF	SA PRFV Uni	t is schedule	d for 23	April 2023.
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8th Working Group meeting on New Approach Methodologies (NAMs)



09 February 2024 14:00 - 16:15 MINUTES - Agreed on 19 February 2024

Location: Webconference

Attendees:

o Working Group (WG) Members:

Maria Bastos Birgit Dusemund Dieter Schrenk Johannes Westendorf

o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Alicia Paini, Adriana Scattareggia Marchese.

EFSA Feed and Contaminant Unit (FEEDCO): Paola Manini.

I. Welcome and apologies for absence

EFSA welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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 7th Working Group meeting held on 18th January 2024, via web-conference

The <u>minutes of the 7th Working Group meeting</u> were agreed by written procedure on 26 January 2024.

V. Scientific topic for discussion

¹ 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/competing_interest_management_17.pdf

MEETING MINUTES – 18 January 2024 7th Working Group meeting on NAMs



a. Support to the EFSA Project on the use of NAMs to explore interspecies metabolic differences on essential oils as feed additives (OC/EFSA/SCER/2021/14)

In the context of the EFSA Project on the use of NAMs to explore interspecies metabolic differences on essential oils as feed additives (OC/EFSA/SCER/2021/14), the WG on NAMs was requested to support EFSA during the final meeting of the Project, which was organised to discuss the final results presented by the contractor. The input provided will be considered for the preparation of the Final Report that will be re-submitted to EFSA for approval. As a next step, the deliverable will be published in the EFSA Journal as External Scientific Report.

VI. Next meeting

7th Working Group meeting on New Approach Methodologies (NAMs)



18 January 2024 14:00 - 18:00 MINUTES - Agreed on 26 January 2024

Location: Webconference

Attendees:

o Working Group (WG) Members:

Tanja Schwerdtle

o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Jean-Lou Dorne, Adriana Scattareggia Marchese.

EFSA Feed and Contaminant Unit (FEEDCO): Chantra Eskes.

Welcome and apologies for absence

EFSA welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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 6th Working Group meeting held on 1st December 2023, via web-conference

The minutes of the 6th Working Group meeting were agreed by written procedure on 8 December 2023.

V. Scientific topic for discussion

a. Support to the EFSA Project on the use of NAMs to explore the immunotoxicity of the contaminant PFAS (OC/EFSA/SCER/2021/13)

In the context of the EFSA Project on the use of NAMs to explore the immunotoxicity of the contaminant PFAS (OC/EFSA/SCER/2021/13), the WG on NAMs was requested to support EFSA during the final meeting of the Project, which was organised to discuss the draft final report submitted by the contractor. The input provided will be considered for the preparation of the Final

¹ 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/competing_interest_management_17.pdf

MEETING MINUTES – 18 January 2024 7th Working Group meeting on NAMs



Report that will be re-submitted to EFSA for approval. As a next step, the deliverable will be published in the EFSA Journal as External Scientific Report.

VI. Next meeting

The next meeting will be decided by written proce

SCIENTIFIC COMMITTEE (PREV Unit)

6th Working Group meeting on New Approach Methodologies (NAMs)



1 December 2023 09:00-13:00 MINUTES – agreed on 8 December 2023

Location: Webconference

Attendees:

o Working Group (WG) Members:

Emilio Benfenati

Romoualdo Benigni

Qasim Chaudry

Glenn Lurman

Eva Bay Wedebye

Agnes Stier

European Chemicals Agency (ECHA):

Andrea Gissi

o EFSA:

EFSA Pesticide Peer Review (PREV) Unit: Juan Manuel Parra Morte (Chair), Martina Panzarea, Sofia Batista Leite

EFSA Methodology and Scientific Support (MESE) Unit: Alexis Nathanail, Lucian Farcal

EFSA Food Ingredients & Packaging (FIP) Unit: Carla Martino

Integrated Data (IDATA) Unit: Edoardo Carnesecchi

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted with the following changes:

- break moved before item 5 instead of being after item 5.1 according to schedule.

III. 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 Management^{2,} 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.

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/competing_interest_management_17.pdf

MEETING MINUTES - 1 December 2023 6th Working Group meeting on NAMs



IV. Agreement of the minutes of the 5th Working Group meeting held on 15 November 2023, via web-conference

The <u>minutes of the 5th Working Group meeting</u> were agreed by written procedure on 21 November 2023.

V. Scientific topic(s) for discussion

a. Support to the EFSA Project: Practical implementation of NAMs into the risk assessment of pesticide metabolites (lead by PREV Unit)

In the context of the Project, led by PREV Unit and contracted out, on "Practical implementation of NAMs into the risk assessment of pesticide metabolites" (EFSA-Q-2023-00211), the WG on NAMs was requested to support EFSA PREV Unit in the revision of the deliverables of the project. The WG will provide advice on how in silico tools (e.g., QSARs and read-across) could be implemented in the OECD QSAR Toolbox for a decision scheme for mutagenicity assessment (bacterial gene mutation) of pesticide metabolites. The advice will be shared with the contractor who will explore its technical applicability.

VI. Next meeting





15 November 2023 14:00 - 17.00 MINUTES - Agreed on 21 November 2023

Location: Webconference

Attendees:

o Working Group (WG) Members:

Jacqueline Castenmiller Qasim Chaudry Roland Franz Maria Henriqueta Louro

Joint Research Centre (JRC):

Susanne Bremer-Hoffmann Deborah Stanco Alessia Bogni

National Institute of Standards and Technology (NIST):

Elijah Petersen

o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Djien Liem, Claudia Roncancio-Pena, Adriana Scattareggia Marchese.
EFSA Food Ingredients and Packaging Unit (FIP): Ana Maria Rincon
EFSA Feed and Contaminant Unit (FEEDCO): Chantra Eskes

Welcome and apologies for absence

EFSA welcomed the participants. Apologies were received by Maria Bastos, Alicja Mortensen (WG Members), Anil Patri (US FDA), Marianne Matzke and Camelia Constantin (ECHA).

II. Adoption of agenda

The agenda was adopted with minor changes on the time schedule.

III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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

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

MEETING MINUTES – 15 November 2023 5th Working Group meeting on NAMs



IV. Agreement of the minutes of the 4th Working Group meeting held on 30-31 October 2023, via web-conference

The <u>minutes of the 4th Working Group meeting</u> were agreed by written procedure on 21 November 2023.

V. Scientific topic for discussion

a. Support to the EFSA NAMS4NANO Project

In the context of the EFSA NAMS4NANO Project (GP/EFSA/MESE/2022/01)³ "Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations", the WG on NAMs was requested to support EFSA at the Interim Meeting of the NAMs4NANO Project to discuss the 1st Deliverable of Lot 1 'Review on NAM-based tools and methods for the toxicity assessment of nanoparticles'. The input provided will be considered for the revision of the deliverable that will be finalised by the grant holders and re-submitted to EFSA for approval. As a next step, the deliverable will be published in the EFSA Journal as External Scientific Report.

VI. Next meeting

³ https://www.efsa.europa.eu/en/art36grants/article36/gpefsamese202201-nams4nano-integration-new-approach-methodologies-results





30 and 31 October 2023 13:30 - 18.30 MINUTES - Agreed on 21 November 2023

Location: Webconference

Attendees:

o Working Group (WG) Members:

Maria Bastos Jacqueline Castenmiller Qasim Chaudry Roland Franz Maria Henriqueta Louro Alicja Mortensen

o European Chemicals Agency (ECHA):

Camelia Constantin Marianne Matzke

Joint Research Centre (JRC):

Alessia Bogni Susanne Bremer Hoffmann Deborah Stanco

US Food and Drug Administration (US FDA):

Anil Patri

o National Institute of Standards and Technology (NIST):

Elijah Petersen

o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Djien Liem¹, Claudia Roncancio-Pena, Adriana Scattareggia Marchese. EFSA Feed and Contaminant Unit (FEDCO) Unit: Paola Manini EFSA Food Ingredients and Packaging Unit (FIP): Ana Maria Rincon

I. Welcome and apologies for absence

EFSA welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

Participated only on Day 1.

MEETING MINUTES – 30 and 31 October 2023 4th Working Group meeting on NAMs



III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} 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 3rd Working Group meeting held on 18 September 2023, via web-conference

The minutes of the 3rd Working Group meeting were agreed by written procedure on 18 September 2023.

V. Scientific topic for discussion

a. Support to the EFSA NAMS4NANO Project

In the context of the EFSA NAMS4NANO Project (GP/EFSA/MESE/2022/01)⁴ "Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations", the WG on NAMs was requested to support EFSA at the Interim Meeting of the NAMs4NANO Project organised to discuss the 2nd Deliverable of Lot 2 'updated IATA on risk assessment case studies and related study protocols' and Lot 3 'updated study protocols on the methodological case studies' (L2-3, D2). The input provided will be considered for the revision of the deliverables that will be finalised by the grant holders and re-submitted to EFSA for approval.

VI. Next meeting

The next meeting will be held on 15 November 2023.

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

 $^{^3\ \}underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf}$

⁴ https://www.efsa.europa.eu/en/art36grants/article36/gpefsamese202201-nams4nano-integration-new-approach-methodologies-results

3rd Working Group meeting on New Approach Methodologies (NAMs)



18 September 2023 14:00-15.30 MINUTES - Agreed on 19 September 2023

Location: Webconference

Attendees:

o Working Group (WG) Members:

Maria Bastos Birgit Dusemund

o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Jean

EFSA Feed and Contaminant Unit (FEEDCO) Unit: Paola Manini EFSA Pesticide Peer Review (PREV) Unit: Jochem Louisse

I. Welcome and apologies for absence

EFSA welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} 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. Scientific topic for discussion

a. Support to the EFSA NAMs Project on Essential Oils

In the context of the EFSA Pilot Project on the use of New Approach Methodologies (NAMs) to explore interspecies metabolic differences on essential oils as feed additives (OC/EFSA/SCER/2021/14)³, the WG on NAMs was requested to support EFSA during the 4th Interim Meeting, which was organised to discuss the approach and preliminary results of the project. The input provided will be considered by the contractor for the preparation of the next deliverable.

V. Next meeting

 $^{{}^{1}\,\}underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf}$

 $^{^2 \ \}underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf}$

https://etendering.ted.europa.eu/cft/cft-document.html?docId=100581





26-27 June 2023 13:30-17.30/09:00-13:00 MINUTES - Agreed on 14 July 2023

Location: Webconference

Attendees:

o Working Group (WG) Members:

Maria Bastos Jacqueline Castenmiller Qasim Chaudry Roland Franz¹ Henriqueta Louro Alicja Mortensen

Joint Research Centre (JRC):

Susanne Bremer-Hoffman Alessia Bogni Deborah Stanco

European Medicines Agency (EMA):

Michael Empl

o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Claudia Roncancio-Pena, Djien Liem, Maria Chiara Astuto, Irene Cattaneo

EFSA Food Ingredients and Packaging (FIP) Unit: Eric Barthélémy, Ana Rincon

Welcome and apologies for absence

EFSA welcomed the participants. Apologies were received from Camelia Constantin and Marianne Matzke (ECHA).

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} 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.

 $^2 \ \underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf}$

¹ Participated only on Day 1

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

MEETING MINUTES – 26 and 27 June 2023 2nd Working Group meeting on NAMs



IV. Scientific topic(s) for discussion

a. Support to the EFSA NAMS4NANO Project

In the context of the EFSA NAMS4NANO Project (GP/EFSA/MESE/2022/01)⁴ "Integration of New Approach Methodologies results in chemical risk assessments: case studies addressing nanoscale considerations", the WG on NAMs was requested to support EFSA at the NAMs4NANO EFSA/JRC Workshop organised to discuss study proposals from Lot 2 and 3 grant holders. The input provided will be considered for the revision of the study proposals that will be presented at the next meeting.

V. Next meeting

The next meeting is tentatively scheduled for 30-31 October 2023.

 $^{^{4} \ \}text{https://www.efsa.europa.eu/en/art36grants/article36/gpefsamese202201-nams4nano-integration-new-approach-methodologies-results}$

1st Working Group meeting on New Approach Methodologies (NAMs)



4-5 April 2023 14:00-17.00/09:00-13:00

Location: Webconference

Attendees:

o Working Group (WG) Members:

Maria Bastos Roland Franz Alicia Mortensen

o European Commission:

Susanne Bremer-Hoffman (JRC) Alessia Bogni (JRC) Deborah Stanco (JRC)

o ECHA:

Camelia Constantin

o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Claudia Roncancio-Pena, Djien Liem, Maria Chiara Astuto, Irene Cattaneo

I. Welcome and apologies for absence

EFSA welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Group 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.

IV. Internal mandate and Terms of Reference

EFSA is establishing a new **Working Group (WG) on New Approach Methodologies (NAMs)** and the Terms of Reference are reported below:

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

The WG will provide transversal support to EFSA NAMs activities to identify areas of implementation that will derive from the execution of case studies or from other ongoing EFSA projects on NAMs. Areas of contribution can include (but not limited to):

- development of guidance or best practices, tailored validation processes, identification of operational fit for purpose frameworks,
- educational needs for EFSA staff and risk assessors at MSs level and support to the internal and external communication,

In addition, the WG will provide support and advice on:

- expansion of the NAMs network,
- identification and participation to events related to NAMs,
- questions from the EFSA Knowledge Innovation Community on NAMs.

V. Scientific topic(s) for discussion

a. Support to the EFSA NAMS4NANO Project

In the context of the EFSA NAMS4NANO Project (GP/EFSA/MESE/2022/01)³ "Integration of New Approach Methodologies results in Chemical risk assessments: case studies addressing nanoscale considerations" the WG on NAMs was requested to support EFSA at the kickoff meeting of the project.

VI. Next meeting

The next meeting will be communicated in due course by written procedure.

³ https://www.efsa.europa.eu/en/art36grants/article36/gpefsamese202201-nams4nano-integration-new-approach-methodologies-results