16th Working Group meeting on FOLLOW-UP TOX



3 June 2024 09:30-13:30 MINUTES - Agreed on 19/06/2024

Location: Web-conference.

Attendees:

- Working Group Members: Ursula Gundert-Remy (Chair), Maria Bastos, Rex FitzGerald, Alicja Mortensen, Sabina Passamonti, Agnes Oomen, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.
- EFSA: FIP Unit: Stefania Barmaz, Borana Dino, Elena Mazzoli, Josef Daniel Rasinger, Ana Maria Rincon, Laura Ruggeri, Camila Smeraldi.
- EMA: Francisca van Doesum-Wolters.
- o DG-SANTE: Katleen Baert.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were sent by Emanuela Corsini.

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 15th Working Group meeting

The minutes of the 15th Working Group meeting were agreed on 3rd June 2024.

V. Scientific topic(s) for discussion

a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

The scientific draft opinion was finalized by the WG and will be transmitted to the FAF Panel plenary for possible adoption at a forthcoming meeting.

MEETING MINUTES – 3 June 2024 16th Working Group meeting on Follow-up Tox



VI. Any Other Business

None.

VII. Next meeting

No future meetings are scheduled for the moment.

15th Working Group meeting on FOLLOW-UP TOX





Location: Hybrid meeting

Attendees:

- Working Group Members: Ursula Gundert-Remy (Chair), Maria Bastos, Emanuela Corsini, Rex FitzGerald, Alicja Mortensen, Sabina Passamonti, Agnes Oomen, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.
- EFSA: FIP Unit: Stefania Barmaz, Borana Dino, Elena Mazzoli, Josef Daniel Rasinger, Ana Maria Rincon, Laura Ruggeri, Camila Smeraldi.
- EMA: Corinne De Vries* , Francisca van Doesum-Wolters*.

Welcome and apologies for absence

The Chair welcomed the participants. Matthew Wright sent apologies for being absent on the $21^{\rm st}$ of May; Maria Bastos and Ine Waalkens-Berendsen sent apologies for being absent for part of the meeting on the $22^{\rm nd}$ of May; Ruud Woutersen sent apologies for being absent on the $23^{\rm rd}$ 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 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 14th Working Group meeting

The minutes of the 14th Working Group meeting were agreed on 30th April 2024.

V. Scientific topic(s) for discussion

^{*}participated only on the 21st of May.

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

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

MEETING MINUTES – 21-23 May 2024 15th Working Group meeting on Follow-up Tox



a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

The WG advanced on the draft opinion, revising mainly the sections on the biological and toxicological studies, discussion, and conclusion.

The draft opinion will be further revised for a future meeting.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on the 3rd of June 2024, web-conference.

14th Working Group meeting on FOLLOW-UP TOX





Location: Web-conference

Attendees:

- Working Group Members: Ursula Gundert-Remy (Chair), Maria Bastos, Emanuela Corsini, Rex FitzGerald, Alicja Mortensen, Sabina Passamonti, Agnes Oomen, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.
- EFSA: FIP Unit: Stefania Barmaz, Borana Dino, Ana Maria Rincon, Laura Ruggeri, Camila Smeraldi.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were sent by Beate Ulbrich.

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 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 13th Working Group meeting

The minutes of the 13th Working Group meeting were agreed on 12th April 2024.

V. Scientific topic(s) for discussion

a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

The WG discussed the chronic toxicity study and the findings in the Weight of Evidence (WoE) table.

The WG confirmed that the old studies submitted by the IBO during the re-evaluation will not be re-assessed.

The draft opinion will be further revised for a future 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 – 23 April 2024 14th Working Group meeting on Follow-up Tox



VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 21st-23rd May 2024, physical meeting in Parma.

13th Working Group meeting on FOLLOW-UP TOX





Location: Web-conference

Attendees:

- Working Group Members: Ursula Gundert-Remy (Chair), Maria Bastos, Emanuela Corsini, Rex FitzGerald, Alicja Mortensen, Sabina Passamonti, Agnes Oomen, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.
- EFSA: FIP Unit: Stefania Barmaz, Borana Dino, Elena Mazzoli, Josef Daniel Rasinger, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were sent by Alicja Mortensen for the 11^{th} of April.

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.

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 I.

IV. Agreement of the minutes of the 12th Working Group meeting

The minutes of the 12th Working Group meeting were agreed on 18th March 2024.

V. Scientific topic(s) for discussion

a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

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 – 11 and 12 April 2024 13th Working Group meeting on Follow-up Tox



The draft opinion was discussed by the WG. The methodology section was agreed, and it will be forwarded to the FAF Panel for endorsement.

The WG discussed the findings in the Weight of Evidence (WoE) table.

The WG received an update on the most recent literature search.

The draft opinion will be further revised for a future meeting.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 23^{rd} April via web conference, and on 21^{st} - 23^{rd} May 2024, physical meeting in Parma.

MEETING MINUTES – 11 and 12 April 2024 13th Working Group meeting on Follow-up Tox



Annex I

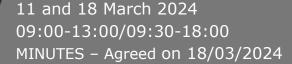
Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Prof. Agnes Oomen declared the following interest in relation to the agenda item 4.2: authorship or co-authorship of a part of the publications that the mandate requires to review. The review of the expert's work was not on the agenda of the present meeting, and measures have been taken in the preparation of the draft output to avoid that the expert assesses, rates or reviews her own work. In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, 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.

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

ttp://www.eisa.europa.eu/sites/derault/files/corporate_publications/files/competing_interest_management_17.pdf

12th Working Group meeting on FOLLOW-UP TOX





Location: Web-conference

Attendees:

- Working Group Members: Ursula Gundert-Remy (Chair), Maria Bastos, Emanuela Corsini**, Rex FitzGerald, Alicja Mortensen, Sabina Passamonti, Agnes Oomen, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.
- EFSA: FIP Unit: Stefania Barmaz, Borana Dino, Elena Mazzoli, Josef Daniel Rasinger, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi.

MESE Unit: Sara Levorato*, Alexis Nathanail*.

* participated only on the 11th of March; ** participated only on the 18th of March

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were sent by Emanuela Corsini.

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 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 11th Working Group meeting

The minutes of the 11th Working Group meeting were agreed on 16th February 2024.

V. Scientific topic(s) for discussion

 a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

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 – 11 and 18 March 2024 12th Working Group meeting on Follow-up Tox



The WG discussed on the findings in the Weight of Evidence (WoE) table and the way forward.

The WG will provide an update on the ongoing assessment to the FAF Panel at the plenary meeting in March. The draft opinion will be further revised for a future meeting.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 11th and 12th April 2024, via web conference.

11th Working Group meeting on FOLLOW-UP TOX





Location: Web-conference

Attendees:

- Working Group Members: Ursula Gundert-Remy (Chair), Maria Bastos, Emanuela Corsini, Rex FitzGerald, Alicja Mortensen, Sabina Passamonti, Agnes Oomen, Beate Ulbrich, Ruud Woutersen and Matthew Wright.
- EFSA: FIP Unit: Stefania Barmaz, Borana Dino, Elena Mazzoli, Josef Daniel Rasinger, Ana Maria Rincon, Laura Ruggeri.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were sent by Ine Waalkens-Berendsen.

II. Adoption of agenda

The agenda was adopted without change.

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 10th Working Group meeting

The minutes of the 10th Working Group meeting were agreed on 24th January 2024.

V. Scientific topic(s) for discussion

a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

A preparatory meeting was held on the 15th of February 2024 among Ursula Gundert-Remy, Maria Bastos, Alicja Mortensen, Agnes Oomen and Jan Mast (as hearing expert) to discuss

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 – 16 February 2024 11th Working Group meeting on Follow-up Tox



the advice provided by the Scientific Committee Cross-cutting Working Group Nanotechnologies.

The WG discussed and agreed to update the literature search.

The WG members continued the assessment of the toxicity studies, and the draft opinion will be further revised for a future meeting.

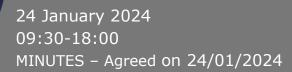
VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 11th and 18th March 2024, via web conference.

10th Working Group meeting on FOLLOW-UP TOX





Location: Web-conference

Attendees:

- Working Group Members: Ursula Gundert-Remy (Chair), Maria Bastos, Emanuela Corsini, Rex FitzGerald, Alicja Mortensen, Sabina Passamonti, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.
- EFSA: FIP Unit: Stefania Barmaz, Valeriu Curtui, Borana Dino, Elena Mazzoli, Josef Daniel Rasinger, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi.

MESE Unit: Maria Chiara Astuto, Sara Levorato, Alexis Nathanail.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were sent by Agnes Oomen.

II. Adoption of agenda

The agenda was adopted without change.

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

The minutes of the 9th Working Group meeting were agreed on 19th December 2023.

V. Scientific topic(s) for discussion

a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

The WG discussed and confirmed the reliability assessment of different toxicity studies.

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

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

MEETING MINUTES – 24 January 2024 10th Working Group meeting on Follow-up Tox



An update from ccWG Genotoxicity, ccWG Nanotechnologies and Applicant technical hearing of the FAF WG Specifications was provided to the WG.

The WG members will continue the assessment of the toxicity studies and the draft opinion will be further revised for a future meeting.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 16th February 2024, via web conference.

9th Working Group meeting on FOLLOW-UP TOX





Location: Web-conference

Attendees:

- Working Group Members: Ursula Gundert-Remy (Chair), Maria Bastos, Emanuela Corsini, Francesco Cubadda, Rex FitzGerald, Agnes Oomen, Sabina Passamonti, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.
- EFSA: FIP Unit: Stefania Barmaz, Borana Dino, Elena Mazzoli, Josef Daniel Rasinger, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi.

Welcome and apologies for absence

The Chair welcomed the participants. Apologies were sent by Alicja Mortensen.

II. Adoption of agenda

The agenda was adopted without change.

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.

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.

IV. Agreement of the minutes of the 8th Working Group meeting

The minutes of the 8th Working Group meeting were agreed on 23rd November 2023.

V. Scientific topic(s) for discussion

 a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (<u>EFSA Q-2018-00526</u>)

The IBO informed the WG on the *in vitro* testing programme to generate additional data for the ongoing risk assessment of synthetic amorphous silica (SAS) as an ingredient in cosmetics products by the Scientific Committee on Consumer Safety (SCCS).

The IBO indicated the intention to provide -this information -to EFSA by mean of a spontaneous

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 – 5 December 2023 9th Working Group meeting on Follow-up Tox



submission around the end of February 2024. The WG acknowledged this upcoming spontaneous submission of newly generated *in vitro* data.

The WG discussed the ADME (absorption, distribution, metabolism, and excretion) studies, including the nanoscale considerations. The repeated dose studies were also assessed. Moreover, discussions on the reliability of the studies took place.

VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 24th January 2024, via web conference.

MEETING MINUTES - 5 December 2023 9th Working Group meeting on Follow-up Tox



Annex

With regard to this meeting, Prof. Agnes Oomen declared the following interest in relation to the agenda item 4.2: authorship or co-authorship of a part of the publications that the mandate requires to review. The review of the expert's work was not on the agenda of the present meeting, and measures have been taken in the preparation of the draft output to avoid that the expert assesses, rates or reviews her own work. In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴,—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 and -participation was allowed to the meeting.

With regard to this meeting, Dr. Francesco Cubadda declared the following interest in relation to the agenda items 4.2 and 4.3: authorship or co-authorship of a part of the publications that the mandate requires to review. Measures have been taken in the preparation of the draft output to avoid that the expert assesses, rates or reviews his own work. In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, 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 (CoI) participation was allowed to the meeting.

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

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

8th Working Group meeting on FOLLOW-UP TOX



06 November 2023 09:30-18:00 MINUTES – Agreed on 23 November 2023

Location: Web-conference

Attendees:

o Working Group Members:

Ursula Gundert-Remy (Chair), Maria Bastos, Emanuela Corsini, Francesco Cubadda, Rex FitzGerald, Alicja Mortensen, Agnes Oomen, Sabina Passamonti, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.

o EFSA: FIP Unit: Stefania Barmaz, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi, Vasantha Palaniappan.

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence.

II. Adoption of agenda

The agenda was adopted without change.

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.

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.

IV. Agreement of the minutes of the 7th Working Group meeting

The minutes of the 7th Working Group meeting were agreed on 18th September 2023.

V. Scientific topic(s) for discussion

 a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (<u>EFSA Q-2018-00526</u>)

The WG discussed the criteria for assessing - the nano consideration of toxicological studies including studies on absorption, distribution, metabolism, and excretion. A first overview was given on the ADME studies. The WG will provide feedback to the FAF Panel at the plenary meeting in November.

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 – 6 November 2023 8th Working Group meeting on Follow-up Tox



VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 5^{th} December 2023, via web conference.

MEETING MINUTES - 6 November 2023 8th Working Group meeting on Follow-up Tox



Annex

With regard to this meeting, Prof. Agnes Oomen declared the following interest in relation to the agenda item 5.1: authorship or co-authorship of a part of the publications that the mandate requires to review. In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI).

This results in the exclusion of the expert from any discussion, voting or other processing of item 5.1 by the concerned scientific group.

With regard to this meeting, Prof. Francesco Cubadda declared the following interest in relation to the agenda item 5.1: authorship or co-authorship of a part of the publications that the mandate requires to review. In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI).

This results in the exclusion of the expert from any discussion, voting or other processing of item 5.1 by the concerned scientific group.

³ 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 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

7th Working Group meeting on FOLLOW-UP TOX



18 September 2023 09:30-18:00 MINUTES - Agreed on 18/09/2023

Location: Web-conference

Attendees:

Working Group Members:

Ursula Gundert-Remy (Chair), Rex FitzGerald, Alicja Mortensen, Agnes Oomen, Sabina Passamonti, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen and Matthew Wright.

o EFSA: FIP Unit: Stefania Barmaz, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies sent by Francesco Cubadda.

II. Adoption of agenda

The agenda was adopted without change.

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.

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.

IV. Agreement of the minutes of the 6th Working Group meeting

The minutes of the 6th Working Group meeting were agreed on 28th June 2023.

V. Scientific topic(s) for discussion

a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

The WG discussed the toxicokinetic data and the related nanoscale considerations. The assessment by the experts will be further discussed in the next WG. The need for requesting a clarification to the Interest Business Operator was identified by the WG.

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 September 2023 7th Working Group meeting on Follow-up Tox



VI. Any Other Business

The WG was informed that a preparatory meeting took place on 13 September on the "Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)". The topic of the meeting was the data extraction of the information related to the nanoscale considerations.

VII. Next meeting

The next meeting will be held on 6th November2023, via web conference.

MEETING MINUTES – 18 September 2023 7th Working Group meeting on Follow-up Tox



Annex I

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

With regard to this meeting, Prof. Agnes Oomen declared the following interest in relation to the agenda item 4.2: authorship or co-authorship of a part of the publications that the mandate requires to review. Because the review of the expert's work was not on the agenda of the present meeting, and measures have been taken in the preparation of the draft output to avoid that the expert assesses, rates or reviews her own work. In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, 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.

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

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

6th Working Group meeting on FOLLOW-UP TOX





Location: EFSA - Parma Web-conference

Attendees:

o Working Group Members:

Ursula Gundert-Remy (Chair), Francesco Cubadda, Rex FitzGerald, Alicja Mortensen, Agnes Oomen, Sabina Passamonti, Beate Ulbrich, Ine Waalkens-Berendsen.

Hearing expert: Jan Mast

o EFSA:

FIP Unit: Stefania Barmaz, Vasantha Palaniappan, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies sent by Ruud Woutersen and Matthew Wright.

II. Adoption of agenda

The agenda was adopted without change.

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.

IV. Agreement of the minutes of the 5th Working Group meeting held on 16 and 23 June 2023 via web-conference

The minutes of the 5th Working Group meeting were agreed on 8th June 2023.

V. Scientific topic(s) for discussion

a. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (EFSA Q-2018-00526)

The WG discussed and agreed the criteria for the appraisal of relevance and reliability of the studies together with specific criteria for the nanoscale considerations. The assessment by the experts will be discussed in the next WG.

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 – 12 June 2023 6th Working Group meeting on Follow-up Tox



b. Follow up on the re-evaluation of gold (E 175) (EFSA-Q-2021-00562)

EFSA presented the mandate received from EU Commission and the assessment of the technical part performed by the FAF WG Specifications. The criteria for the literature search have been agreed.

VI. Any Other Business

EFSA will plan additional meetings in 2023 and inform the WG members on the exact dates.

VII. Next meeting

The next meeting will be held on 18th September 2023, via web conference.

5th Working Group meeting on FOLLOW-UP TOX



16 & 23 May 2023 09:30-18:00 MINUTES – Agreed on 08/06/2023

Location: EFSA - Parma Web-conference

Attendees:

- Working Group Members:
- Ursula Gundert-Remy (Chair), Rex FitzGerald, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Wouterersen.
- o Hearing experts: Laurence Castle, Peter Fürst.
- o EFSA FIP Unit: Camilla Smeraldi, Vasantha Palaniappan, Ana Maria Rincon, Laura Ruggeri.

Welcome and apologies for absence

The Chair welcomed the participants. Apologies received from Alicja Mortensen.

II. Adoption of agenda

The agenda was adopted without change.

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 4th Working Group meeting held on 27 March 2023 via web-conference

The minutes of the 4th Working Group meeting (include link) were agreed on 27th March 2023.

V. Scientific topic(s) for discussion

a. Opinion on the follow-up of the re-evaluation of Indigo Carmine (E 132) (EFSA-Q-2021-00180)

The draft opinion was finalised by the WG and will be transmitted to the FAF Panel for discussion and possible adoption.

b. Opinion on the follow-up of the re-evaluation Glycerol esters of wood rosin (E 445) <u>EFSA-Q-2021-00564</u>

The draft opinion was finalised by the WG and will be transmitted to the FAF Panel for discussion and possible adoption.

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 – 16 & 23 May 2023 5th Working Group meeting on Follow-up Tox



VI. Any Other Business

None.

VII. Next meeting

The next meeting will be held on 12th June 2023, via web conference.

4th Working Group meeting on FOLLOW-UP TOX





Location: Web-conference

Attendees:

- Working Group Members:
 Ursula Gundert-Remy (Chair), Francesco Cubadda, Rex FitzGerald, Alicja Mortensen, Agnes
 Oomen, Sabina Passamonti, Beate Ulbrich, Ine Waalkens-Berendsen, Ruud Woutersen.
- EFSA:
 FIP Unit: Camilla Smeraldi, Vasantha Palaniappan, Ana Maria Rincon, Laura Ruggeri,
 Stefania Barmaz.

I. Welcome and apologies for absence

The Chair welcomed the participants. Matthew Wright sent apologies for absence.

II. Adoption of agenda

The agenda was adopted without change.

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.

IV. Agreement of the minutes of the 3rd Working Group meeting held on 23 November 2022 via web-conference

The minutes of the 3rd Working Group meeting were agreed on 23 November 2022.

V. Scientific topic(s) for discussion

 Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups (<u>EFSA Q-2018-00526</u>)

The assessment was presented to the Working Group and the members discussed the work plan for the literature search on silicon dioxide (E 551). The members discussed and agreed the criteria for appraising the relevance and the reliability of toxicity studies that will be included in the assessment. Tasks were allocated to the experts in advance to the next discussion at a forthcoming meeting.

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

² http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

MEETING MINUTES – 27th March 2023 4th Working Group meeting on Follow up Tox



VI. Any Other Business

The WG discussed the plan for finalising the opinions on E132 and E445.

VII. Next meeting

The next meeting will be held on 16^{th} and 23^{rd} May, via web conference.





FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS

MINUTES OF THE 3RD MEETING OF THE WORKING GROUP ON FOLLOW-UP TOX

WEB-conference, 23 November 2022

(Agreed on 23 November 2022)¹

Participants

■ Working Group Members:²

Ursula Gundert-Remy (Chair), Francesco Cubadda, Rex FitzGerald, Alicja Mortensen, Agnes Oomen, Sabina Passamonti, Beate Ulbrich, Ine Waalkens-Berendsen, Matthew Wright

EFSA:

FIP Unit: Ana Maria Rincon, Camilla Smeraldi

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Ruud Woutersen.

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 Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by

 $^{^{1}}$ Minutes should be published within 15 working days of the final day of the relevant meeting.

² Indicate first full name and then surname (John Smith) all throughout the document.

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

⁴ http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

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 06 October 2022.

The minutes of the 2nd Working Group meeting were agreed by written procedure on 17 October 2022⁵

5. Scientific topic(s) for discussion

5.1. Opinion on the re-evaluation of silicon dioxide (E 551) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additive for uses in foods for all population groups.

EFSA-Q-2018-00526

The Working Group members received an update on the assessment of the data related to the characterisation of the material used as a food additive currently ongoing with the FAF Panel WG on Food Additives Specifications. Based on the preliminary assessment of the data, it has been confirmed that the safety assessment of the food additive E 551 will have to be complemented with the nanospecific considerations, in accordance with the 2021 EFSA SC "Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health". To this end, advice has been sought from the EFSA Crosscutting WG Nanotechnologies on the elements specific to silicon dioxide that will have to be taken into consideration for appraising the data available. The advice from the Cross-cutting WG Nanotechnologies was presented to the Working Group members and it will be used to inform the data extraction from both the published and unpublished data that will be included in this updated assessment.

The Working Group members discussed the plan for the literature search that will be performed to update the database on silicon dioxide (E 551) and agreed on a set of criteria to be applied to the screening steps (Title and Abstract; Full Text) for inclusion and exclusion of the studies.

Finally, the Working Group members discussed and agreed on some preliminary criteria for appraising the relevance and the reliability of toxicity studies that will be included in the assessment.

As a next step, EFSA will proceed with performing the literature search and is planning to outsource the initial steps of the screening to an external contractor. The Working Group members will be consulted during this process and tasks were allocated in advance to the next discussion at a forthcoming meeting.

6. Any Other Business

EFSA provided an update on status of the other ongoing and planned assessments allocated to this Working Group.

⁵ Please add here the link to the respective minutes published on the EFSA website

7. Next meeting(s)

Tentative dates for the next year were agreed.





FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF)

MINUTES OF THE 2nd MEETING OF THE WORKING GROUP FOLLOW-UP TOX

web-conference, 6 October July 2022 (09:30-16:30)

(Agreed on 17/10/2022)

Participants

Working Group Members:

Ursula Gundert-Remy (Chair), Rex FitzGerald, Alicja Mortensen, Sabina Passamonti, Beate Ulbrich, Dina Waalkens-Berendsen, Ruud Woutersen.

■ EFSA:

FIP Unit: Laura Ruggeri, Camilla Smeraldi, Alkiviadis Stagkos-Georgiadis, Stefania Barmaz.

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 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

4. Instructions for accessing Teams

EFSA provided instructions on how to access the EFSA environment in Microsoft Teams.

5. Scientific topic(s) for discussion

Follow-up of the re-evaluation of Glycerol esters of wood rosin E445 Q-2021-00564

The draft opinion encompassing the information submitted in the call for data launched by the EU Commission was presented to the Working Group. The WG members assess the toxicological data and drafted provisional conclusions pending the assessment in the FAF Working Group on the Specifications of Food Additives.

Follow-up of the re-evaluation of Indigo Carmine Q-2021-00180

The draft opinion encompassing the information submitted in the call for data launched by the EU Commission was presented to the Working Group. The WG members concluded the assessment of the toxicological data.

Presentation of the work and planning

EFSA provided a presentation on the workplan for 2022 and beginning of 2023.

6. Any Other Business

None

7. Next meeting(s)

Next meeting will take place before the end of the year, depending on the outcome of the discussions at the FAF Working Group on the Specifications of Food Additives. The exact date of the next meeting will be defined according to the availability of the experts.





FOOD INGREDIENTS AND PACKAGING UNIT

SCIENTIFIC PANEL ON FOOD ADDITIVES AND FLAVOURINGS (FAF)

MINUTES OF THE 1st MEETING OF THE WORKING GROUP FOLLOW-UP TOX

web-conference, 13 July 2022 (09:00-10:30)

(Agreed on 20 July 2022)

Participants

Working Group Members:

Ursula Gundert-Remy (Chair), Francesco Cubadda, Rex FitzGerald, Alicja Mortensen, Agnes Oomen, Sabina Passamonti, Beate Ulbrich, Dina Waalkens-Berendsen, Ruud Woutersen, Matthew Wright.

■ EFSA:

FIP Unit: Valeriu Curtui, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi, Alkiviadis Stagkos-Georgiadis,

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 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

4. Tour the table for introducing the WG members

The WG members introduced themselves to the group.

5. Scientific topic(s) for discussion

Presentation of the work and planning

EFSA provided a presentation on the workplan of the new WG for 2022. The WG will focus on the toxicological data submitted in the context of the follow-up of the re-evaluation of the food additives, data from literature search and will provide considerations on the safety of food additive in the nanoform when relevant.

6. Any Other Business

None

7. Next meeting(s)

Next meeting is provisionally scheduled in October 2022. The exact date of the next meeting will be set according to the availability of the experts.