

22 April 2024

10:00 - 17:00

MINUTES - Agreed on 13 May 2024

Location: Parma & Webconference**Attendees:**

- Working Group (WG) Members:

Maria Bastos
Jacqueline Castenmiller¹
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
David Gott
Jan Mast²
Alicja Mortensen
Agnes Oomen
Eveline Verleysen

- European Commission:

Takis Daskaleros (DG SANTE)

- EFSA:

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

EFSA Food Ingredients and Packaging (FIP) Unit: Agnieszka Mech, Ana Maria Rincon³.

EFSA Feed and Contaminants (FEEDCO) Unit: Anna Dioni¹, Orsolya Holczknecht.

EFSA Nutrition and Food Innovation (NIF) Unit: Marcello Laganaro, Annamaria Rossi⁴.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from the WG member Henriqueta Louro and the EC representative Hubert Rauscher (EC JRC).

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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, 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 Did not participate to Item Va

² Did not participate to Item Vd

³ Participated to Item Va

⁴ Participated to Item VI and VII

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



IV. Agreement of the minutes of the 51th Working Group meeting held on 22 March 2024, via web-conference

The [minutes of the 51st Working Group meeting](#) were agreed by written procedure on 04 April 2024.

V. Scientific topics for discussion

a) Request for advice from the Food Ingredients and Packaging (FIP) Unit on Silicon dioxide (E 551) (EFSA-Q-2018-00526)

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements⁷ and Guidance on Nano – Risk Assessment⁸) the ccWG Nano was requested for assistance from the EFSA Food Ingredients and Packaging (FIP) Unit on Silicon dioxide (E 551) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as food additive (EFSA-Q-2018-00526). During the present meeting, the ccWG continued the discussion on the Appendix to the SiO₂ draft Opinion summarising the advice provided by this WG in the context of this assessment.

b) Request for advice from the Feed and Contaminants (FEEDCO) Unit on Cobalt Carbonate (EFSA-Q-2022-00792)

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements⁷ and Guidance on Nano – Risk Assessment⁸), the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Cobalt Carbonate (EFSA-Q-2022-00792). Previous advice on this application was submitted to the FEEDCO Unit at past WG meetings. During the present meeting, the WG was presented with the preliminary assessment of the new data submitted by the applicant. After a discussion, the WG agreed on an advice for submission to the FEEDCO Unit.

c) Request for advice from the Feed and Contaminants (FEEDCO) Unit on Perlite (E599) (EFSA-Q-2023-00704)

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements⁷), the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Perlite (E599) (EFSA-Q-2023-00704). After being presented with the background information and the data submitted by the applicant, the WG discussed and agreed on an advice for submission to the FEEDCO Unit.

d) Request for advice from the Feed and Contaminants (FEEDCO) Unit on the Exception list

In the context of the implementation of its Guidance on Particle – Technical Requirements⁷, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on an exception list of active substances used in feed additives with the aim to exclude those for which, with the current status of implementation⁹, there is no need to characterise the possible presence of a fraction of small particles including nanoparticles. A preliminary discussion was held during the present meeting.

VI. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements⁷ and Guidance on Nano – Risk Assessment⁸), the ccWG Nano continued the discussion

⁷ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

⁸ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

⁹ [171st Plenary Meeting of the Scientific Panel on Additives and Products or Substances used in Animal Feed \(europa.eu\)](#)



started at previous meetings on the lessons learnt from the pilot phase of their implementation, considering possible next steps and actions with the aim to provide further indication to applicants.

During the meeting, the WG was presented with the status of the surveys aimed at collecting feedback from the different stakeholders involved in the implementation of the Nano Guidances to be considered for their update. The WG was presented with the results of the survey dedicated to EFSA Panels, Units and WGs and was updated on the extension of the deadline for the survey dedicated to external stakeholders¹⁰ (30th April 2024).

VII. Any Other Business

- **Update on the review of the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283**

The WG was updated on the status of the activities to revise the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283¹¹ by the Commission Expert Group on Nanomaterials in Food. This revision is following the adoption of the Commission Recommendation on nanomaterial, published in June 2022.

VIII. Next meetings

The next meetings are scheduled for:

- 27 May 2024
- 8-9 July 2024
- 16 September 2024
- 21-22 October 2024
- 25 November 2024

¹⁰ https://ec.europa.eu/eusurvey/runner/Nanotech_Survey_2024

¹¹ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283>

22 March 2024

9:00 - 16:00

MINUTES - Agreed on 04 April 2024

Location: Parma & Webconference**Attendees:**

- Working Group (WG) Members:

Maria Bastos¹
Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
David Gott
Henriqueta Louro
Jan Mast
Alicja Mortensen
Agnes Oomen
Eveline Verleysen

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Claudia Cascio¹, Irene Cattaneo, Adriana Scattareggia Marchese.

EFSA Food Ingredients and Packaging (FIP) Unit: Stefania Barmaz², Daniele Comandella, Blanka Halamoda³, Agnieszka Mech⁴, Ana Maria Rincon².

EFSA Feed and Contaminants (FEEDCO) Unit: Anna Dioni⁵, Orsolya Holczknecht⁵, Maria Vittoria Vettori³.

EFSA Nutrition and Food Innovation (NIF) Unit: Reinhard Ackerl⁶, Wolfgang Gelbmann⁷, Marcello Laganaro, Emanuela Turla⁸.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros (DG SANTE) and Hubert Rauscher (EC JRC).

II. Adoption of agenda

The agenda was adopted with minor changes.

III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence⁹ and the Decision of the Executive Director on Competing Interest Management¹⁰, 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

1 Participated to items Vc and Vd

2 Participated to item Vc

3 Participated to item Vd

4 Participated to item Vb, Vc and Vd

5 Participated to item, Vc, and Vd and VI

6 Did not participate to item Vd

7 Participated to item Vb

8 Participated to item Va

⁹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁰ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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 50th Working Group meeting held on 26-27 February 2024, via web-conference

The minutes of the 50th Working Group meeting were agreed by written procedure on 21 March 2024.

V. Scientific topics for discussion

a) Request for advice from the Nutrition and Food Innovation (NIF) Unit on Urolithin A (EFSA-Q-2018-00724)

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹¹ and Guidance on Nano – Risk Assessment¹²), the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was requested for support from the EFSA Nutrition and Food Innovation (NIF) Unit on Urolithin A (EFSA-Q-2018-00724). Previous advice on this application was submitted to the NIF Unit at past WG meetings. During the present meeting, the WG was presented with the preliminary assessment of the new data submitted by the applicant. After a discussion, the WG agreed on an advice for submission to the NIF Unit.

b) Request for advice from the Nutrition and Food Innovation (NIF) Unit on Algal meal and oleoresin of Haematococcus pluvialis containing Astaxanthin (EFSA-Q-2021-00319)

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹¹ and Guidance on Nano – Risk Assessment¹²) the ccWG Nano was requested for assistance from the Nutrition and Food Innovation (NIF) Unit on Algal meal and oleoresin of Haematococcus pluvialis containing Astaxanthin (EFSA-Q-2021-00319). Previous advice on this application was submitted to the NIF Unit at past WG meetings. During the present meeting the ccWG was presented with the preliminary assessment of the new data submitted by the applicant. After a discussion the WG agreed on an advice for submission to the NIF Unit.

c) Request for advice from the Food Ingredients and Packaging (FIP) Unit on Silicon dioxide (E 551) (EFSA-Q-2018-00526)

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹¹ and Guidance on Nano – Risk Assessment¹²) the ccWG Nano was requested for assistance from the EFSA Food Ingredients and Packaging (FIP) Unit on Silicon dioxide (E 551) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as food additive (EFSA-Q-2018-00526). During the present meeting, the ccWG discussed the structure of the Appendix to the SiO₂ draft Opinion summarising the advice provided by this WG in the context of this assessment. Further discussion on this topic will continue at the next meetings.

d) Request for advice from the Feed and Contaminants (FEEDCO) Unit on Canthaxanthin (EFSA-Q-2021-00149; EFSA-Q-2021-00150; EFSA-Q-2023-00485)

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹¹ and Guidance on Nano – Risk Assessment¹²), the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Canthaxanthin (EFSA-Q-2021-00149; EFSA-

¹¹ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769> 12

¹² EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>



Q-2021-00150; EFSA-Q-2023-00485). The WG continued the discussed started at the 50th ccWG meeting and agreed on a final advice for submission to the FEEDCO Unit.

VI. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹¹ and Guidance on Nano – Risk Assessment¹²), the ccWG Nano continued the discussion started at previous meetings on the lessons learnt from the pilot phase of their implementation, considering possible next steps and actions with the aim to provide further indication to applicants.

VII. Any Other Business

The WG was informed about the launch of the survey on the EFSA Nano Guidances^{11,12} with external Stakeholders. Applicants, IBOs, researchers and experts in the field are invited to provide their feedback via the dedicated link¹³ by 15 April 2024. WG members were also informed that the survey with EFSA Panels, Units and WGs has been closed.

VIII. Next meetings

The ccWG was updated about the change of date of the July meeting, which was re-scheduled on 8-9 July 2024 as physical meeting in Parma. WG members were also informed about the 2024 Annual meeting of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed (NanoNetwork), tentatively scheduled for the last week of November 2024.

The next meetings are scheduled for:

- 22 April 2024
- 27 May 2024
- 8-9 July 2024
- 16 September 2024
- 21-22 October 2024
- 25 November 2024

¹³ https://ec.europa.eu/eusurvey/runner/Nanotech_Survey_2024

26-27 February 2024

14:00-18:00 and 9:00- 16:00

MINUTES - Agreed on 21 March 2024

Location: Parma & Webconference

Attendees:

- Working Group (WG) Members:

Maria Bastos
Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
David Gott
Henriqueta Louro
Jan Mast
Alicja Mortensen
Agnes Oomen¹
Eveline Verleysen

- European Commission:

Takis Daskaleros² (DG SANTE)
Hubert Rauscher³ (EC JRC)

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Claudia Cascio, Irene Cattaneo, Sara Levorato⁴, Daniela Maurici⁵, Claudia Roncancio-Pena⁶, Adriana Scattareggia Marchese.

EFSA Food Ingredients and Packaging (FIP) Unit: Stefania Barmaz⁷, Daniele Comandella⁸, Agnieszka Mech⁹, Ana Maria Rincon¹⁰, Laura Ruggeri⁴, Camilla Smeraldi³.

EFSA Feed and Contaminants (FEEDCO) Unit: Angelica Amaduzzi¹¹, Mary Bridget Gilsean⁴, Anna Dioni, Jaume Galobart I Cots⁵, Orsolya Holczknecht, Jordi Ortuño Casanova⁶, Anita Radovnikovic¹⁰, Joana Revez⁶, Maria Vittoria Vettori⁵.

EFSA Nutrition and Food Innovation (NIF) Unit: Marcello Laganaro.

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of agenda

The agenda was adopted with changes in the timeschedule and with the addition of item VIIIb.

¹ Did not participate to Items VI d and to part of VII.

² Did not participated to Items V, VI b, VI d and part of VII.

³ Participated to Items VI b and VI c.

⁴ Participated to Item VI b.

⁵ Participated to Item VIII b.

⁶ Did not participated to Items VI a and part of VII.

⁷ Participated to Item VI b and VIII b.

⁸ Participated to Items V and VI a.

⁹ Did not participated to part of Item VII.

¹⁰ Did not participated to Items VI c, VI d and part of item VII.

¹¹ Participated to Items VI b, VI c and VI d.



III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence¹² and the Decision of the Executive Director on Competing Interest Management¹³, 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 49th Working Group meeting held on 16 January 2024, via web-conference

The [minutes of the 49th Working Group meeting](#) were agreed by written procedure on 1 February 2024.

V. Feedback from 117th Scientific Committee Plenary

The cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was informed about the outcome of the 117th Scientific Committee (SC) Plenary held on 5 February 2024¹⁴, where EFSA presented the proposed way forward for the update of the 2021 Nano Guidances (Guidance on Particle – Technical Requirements¹⁵ and Guidance on Nano – Risk Assessment¹⁶). The EFSA SC was provided with an overview of the roadmap for the revision of the Guidances, aimed at providing further clarification to applicants and risk assessors. Modalities and clear timelines for the update will be communicated subsequently.

VI. Scientific topics for discussion

a) Request for advice from the Food Ingredients and Packaging (FIP) Unit on Clarification on the use of DLS and other light scattering methods for characterisation of particle size distribution (PSD)

In the context of the implementation of its Guidance on Particle – Technical Requirements (TR)¹⁵, the ccWG Nano was requested for support from the EFSA Food Ingredients and Packaging (FIP) Unit to further clarify to Applicants and Interested Business Operators (IBOs) the provisions of the Guidance on Particle-TR on the use of Dynamic Light Scattering (DLS) and other light scattering methods. During the meeting, the ccWG discussed and agreed on a text which clarifies that DLS and other light scattering methods are not a suitable methodology for the identification and characterisation of a fraction of small particles including nanoparticles according to the Guidance on Particle - TR. The integral statement together with relevant references are reported in **Annex I**.

b) Request for advice from the Food Ingredients and Packaging (FIP) Unit on Silicon dioxide (E 551) (EFSA-Q-2018-00526)

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹⁴ and Guidance on Nano – Risk Assessment¹⁵) the ccWG Nano was requested for assistance from the EFSA Food Ingredients and Packaging (FIP) Unit on Silicon dioxide (E 551) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as food additive (EFSA-Q-2018-00526). During the present meeting, the FIP Unit presented the state of progress of the assessment and the additional requests to the WG. After a discussion, the WG agreed on a text to clarify

¹² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

¹⁴ https://www.efsa.europa.eu/sites/default/files/2024-02/Minutes_117th%20plenary_3.pdf

¹⁵ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

¹⁶ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>



the input provided during previous meetings on how to address nano specific considerations for the appraisal of toxicokinetic, toxicological and genotoxicity studies. Further discussion on this topic will be continued at the next meetings.

c) Request for advice from the Feed and Contaminants (FEEDCO) Unit on Canthaxanthin (EFSA-Q-2021-00149; EFSA-Q-2021-00150; EFSA-Q-2023-00485)

In the context of the implementation of the Guidance on Particle – Technical Requirements¹⁵, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Canthaxanthin (EFSA-Q-2021-00149; EFSA-Q-2021-00150; EFSA-Q-2023-00485). After being presented with the background information and the preliminary assessment of the data submitted by the applicant, the WG discussed and agreed on an advice for submission to the FEEDCO Unit.

d) Request for advice from the Feed and Contaminants (FEEDCO) Unit on Clinoptilolite (EFSA-Q-2022-00474).

In the context of the implementation of the Guidance on Particle – Technical Requirements¹⁵, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Clinoptilolite (EFSA-Q-2022-00474). After being presented with the background information of this assessment and with the outcome of the discussion held at previous meetings, the WG agreed on an advice for submission to the FEEDCO Unit.

e) Request for advice from the Feed and Contaminants (FEEDCO) Unit on Lutein-rich extract of Tagetes erecta for turkeys for fattening (EFSA-Q-2023-00483).

In the context of the implementation of the Guidance on Particle – Technical Requirements¹⁵, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Lutein-rich extract of Tagetes erecta for turkeys for fattening (EFSA-Q-2023-00483). After being requested to provide comments to the assessment of the data provided by the applicant, the WG agreed on an advice for submission to the FEEDCO Unit.

f) Request for advice from the Feed and Contaminants (FEEDCO) Unit on Pantothenic acid as calcium-D-pantothenate and D-panthenol for all animal species (EFSA-Q-2023-00518).

In the context of the implementation of the Guidance on Particle – Technical Requirements¹⁵, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Pantothenic acid as calcium-D-pantothenate and D-panthenol for all animal species (EFSA-Q-2023-00518). After being requested to provide comments to the assessment of the data provided by the applicant, the WG agreed on an advice for submission to the FEEDCO Unit.

g) Request for advice from the Feed and Contaminants (FEEDCO) Unit on Vitamin B2 (Riboflavin produced by Saccharomyces cerevisiae CEN.PK113-7D) for all animal species (EFSA-Q-2022-00846).

In the context of the implementation of the Guidance on Particle – Technical Requirements¹⁵, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Vitamin B2 (Riboflavin produced by Saccharomyces cerevisiae CEN.PK113-7D) for all animal species (EFSA-Q-2022-00846). After being requested to provide comments to the assessment of the data provided by the applicant, the WG agreed on an advice for submission to the FEEDCO Unit.

VII. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹⁵ and Guidance on Nano – Risk Assessment¹⁶), the ccWG Nano continued the discussion started at previous meetings on the lessons learnt from the pilot phase of their implementation, considering possible next steps and actions with the aim to provide further indication to applicants.

During the meeting, the WG was presented with the status of the surveys aimed at collecting feedback from the different stakeholders involved in the implementation of the Nano Guidances to be considered



for their update. The WG was presented with the preliminary results of the survey dedicated to the members and observers of the EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed (NanoNetwork) and was informed about the launch of the survey targeted to EFSA Units, Panels and their WGs. The next step will be the launch of a survey dedicated to external stakeholders.

VIII. Any Other Business

a) New publication on TiO₂ genotoxicity

The ccWG was requested from the EFSA Food Ingredients and Packaging (FIP) Unit to evaluate the relevance of a recently published study on TiO₂ genotoxicity, focusing specifically on the methodology that the authors used to determine the dispersibility and stability of the test material in the suspensions. After a discussion, the WG agreed to draft an advice to be submitted to the FIP Unit.

b) Assessment of feed additives consisting of or containing nanoparticles

Upon request from the FEEDCO Unit, the item "Assessment of feed additives consisting of or containing nanoparticles" was added to the agenda of the meeting. The WG was informed about the outcome of the discussion held at the 171st Plenary meeting of the FEEDAP Panel¹⁷ on the implementation of the EFSA Nano Guidances to the assessment of feed additives.

IX. Next meetings

The next meetings are scheduled for:

- 22 March 2024
- 22 April 2024
- 27 May 2024
- 5 July 2024
- 16 September 2024
- 21-22 October 2024
- 25 November 2024

Annex I

Clarification on the use of Dynamic Light Scattering (DLS) and other light scattering methods for characterisation of particle size distribution

DLS (and other light scattering methods) is not a suitable methodology for identification and characterization of a fraction of small particles including nanoparticles according to the Guidance on Particle – Technical Requirements (TR)¹⁵, because:

1. It measures the hydrodynamic diameter, therefore it is not useful to measure the size distribution of particles which are not spherical in shape;
2. It cannot distinguish between constituent particles, agglomerates and aggregates;
3. The measured light scattering intensity is proportional to d^6 therefore the detection is strongly biased to larger sizes. Therefore, it is not well suited to measure (very) polydisperse size distributions.

DLS can be used as a screening technique indicating the presence of small particles (including nanoparticles) in a dispersion but cannot be used to exclude their presence. Detailed size characterisation then needs to be performed by a confirmatory method (e.g., electron microscopy).

Therefore, according to the Guidance on Particle - TR, DLS can only be useful for determining the stability of particle dispersions, as it can provide information on whether or not particles have remained dispersed over a period of time or have clustered together in the form of larger-sized aggregates/agglomerates.

The technique is based on measurement of the light scattered and therefore works better for materials that have a relatively higher refractive index (i.e., are 'shiny'), such as metals/metal oxides, and may

¹⁷ https://www.efsa.europa.eu/sites/default/files/2024-02/feedap_240130-0201_m.pdf



have limitations for particles made of organic materials that generally have a low refractive index. This means that for polydisperse materials and/or materials made of organic substances, data generated by DLS are particularly uncertain.

It is also notable that reliable DLS measurements have to be carried out in a pure, simple liquid medium and cannot be applied to complex liquid matrices where multiple particles or other light-scattering objects of different origin (e.g., protein) may be present. The conditions of the measurement have to be stated (e.g., medium, temperature, dilution) and the performance of the instrument has to be verified and documented by measurement of a suitable size standard (e.g., polystyrene latex particles).

In summary, DLS is not a suitable methodology for identification and characterization of a fraction of small particles including nanoparticles according to the Guidance on Particle TR. An overview of DLS is given in the NanoDefine Methods Manual - Part 2: Evaluation of methods (Mech et al., 2020)¹⁸.

¹⁸ Mech A, Rauscher H, Rasmussen K, Babick F, Hodoroaba VD, Ghanem A, Wohlleben W, Marvin H, Brungel R and Friedrich CM, 2020. The NanoDefine Methods Manual. Part 2: Evaluation of methods, EUR 29876 EN, Publications Office of the European Union, Luxembourg, 2020, ISBN 978-92-76-11953-1. <https://doi.org/10.2760/071877>, JRC117501

SCIENTIFIC COMMITTEE
49th cross-cutting Working Group meeting on
Nanotechnologies



16 January 2024

09:00-17:00

MINUTES - Agreed on 01 February 2024

Location: Web-conference

Attendees:

- Working Group (WG) Members:

Maria Bastos
Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
David Gott
Maria Henriqueta Louro
Jan Mast
Alicja Mortensen
Agnes Oomen
Eveline Verleypsen

- European Commission:

Kirsten Rasmussen (JRC)¹

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Claudia Cascio, Irene Cattaneo, Claudia Roncancio-Pena², Adriana Scattareggia Marchese.

EFSA Food Ingredients and Packaging (FIP) Unit²: Stefania Barmaz, Daniele Comandella, Valeriu-Gheorghe Curtui, Ana Maria Rincon, Laura Ruggeri, Camilla Smeraldi.

EFSA Feed and Contaminants (FEEDCO) Unit: Anna Dioni, Orsolya Holczknecht, Jordi Ortuño Casanova².

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Hubert Rauscher (EC JRC) and Takis Daskaleros (DG SANTE).

II. Adoption of agenda

The agenda was adopted with some adaptations due to lack of time.

III. Declarations of Interest of Working Group 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

¹ Participated to agenda item VII

² Participated to agenda item IV

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



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 48th Working Group meeting held on 27 November 2023, via web conference

The [minutes of the 48th Working Group meeting](#) were agreed by written procedure on 12 December 2023.

V. Scientific topic(s) for discussion

a. Request for advice from the Food Ingredients and Packaging (FIP) Unit on Silicon dioxide (E 551) ([EFSA-Q-2018-00526](#))

In the context of the implementation of the Guidance on Nano – Risk Assessment⁵, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was requested for assistance from the EFSA Food Ingredients and Packaging (FIP) Unit on Silicon dioxide (E 551) as a food additive in foods for infants below 16 weeks of age (EFSA-Q-2018-00526). During the present meeting, the FIP Unit presented the state of progress of the draft Opinion and the specific question to the WG. After a discussion, the WG agreed on an advice for submission to the FIP Unit.

b. Request for advice from the Feed and Contaminants (FEEDCO) Unit on Canthaxanthin ([EFSA-Q-2021-00149](#), [EFSA-Q-2021-00150](#), [EFSA-Q-2023-00485](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements⁶, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Canthaxanthin (EFSA-Q-2021-00149, EFSA-Q-2021-00150, EFSA-Q-2023-00485). After being presented with the background information and the data submitted by the applicant, the WG agreed on tasks allocation. Further discussion will continue at the next meeting.

c. Request for advice from the Feed and Contaminants (FEEDCO) Unit on Clinoptilolite ([EFSA-Q-2022-00474](#)).

In the context of the implementation of the Guidance on Nano – Risk Assessment⁴, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Clinoptilolite (EFSA-Q-2022-00474). Due to lack of time at the present meeting, this item has been postponed to the next meeting.

⁵ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

⁶ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769> 12



- d. Request for advice from the Feed and Contaminants (FEEDCO) Unit on dossiers of clays: Bentonite 1m558i for all animal species ([EFSA-Q-2022-00801](#)), Bentonite for ruminants, poultry and pigs ([EFSA-Q-2022-00799](#)), Phyllite for all animal species ([EFSA-Q-2022-00424](#)), Argile du Périgord (natural mixture of illite-illite/smectite mixed layer) for all animal species ([EFSA-Q-2022-00840](#)).**

In the context of the implementation of the Guidance on Particle – Technical Requirements⁹, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on four dossiers of clays: Bentonite 1m558i for all animal species (EFSA-Q-2022-00801), Bentonite for ruminants, poultry and pigs (EFSA-Q-2022-00799), Phyllite for all animal species (EFSA-Q-2022-00424), Argile du Périgord (natural mixture of illite-illite/smectite mixed layer) for all animal species (EFSA-Q-2022-00840). Due to lack of time at the present meeting, an advice on these dossiers will be agreed by written procedure.

VI. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

Due to lack of time, this agenda item has been postponed to the next meeting.

VII. Any Other Business

- **Update on ongoing OECD activities on sample preparation/dosimetry and solubility/dissolution rate.**

The WG was presented with an update on the ongoing activities at OECD on the revision of the Guidance on Sample Preparation and Dosimetry (GSPD) and on the preparation of the new Guidance document on determination of solubility and dissolution rate of nanomaterials in water and biologically relevant simulant fluids.

VIII. Next meetings

The next meetings are scheduled for:

- 26-27 February
 - 22 March 2024
 - 22 April 2024
 - 27 May 2024
 - 27 June 2024
 - 16 September 2024
 - 21-22 October 2024
 - 25 November 2024
-



SCIENTIFIC COMMITTEE

48th cross-cutting Working Group meeting on Nanotechnologies



27 November 2023

09:30-17:00

MINUTES - Agreed on 12 December 2023

Location: Web-conference

Attendees:

- Working Group (WG) Members:

Maria Bastos
Qasim Chaudhry (WG Chair)
Francesco Cubadda
David Gott
Henriqueta Louro
Jan Mast
Alicja Mortensen
Agnes Oomen¹
Eveline Verleysen

- European Commission:

Takis Daskaleros² (DG SANTE)

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Claudia Cascio, Irene Cattaneo, Adriana Scattareggia Marchese
EFSA Food Ingredients and Packaging (FIP) Unit: Eric Barthélémy³, Agnieszka Mech⁴, Ana Maria Rincon¹
EFSA Feed and Contaminants (FEEDCO) Unit: Angelica Amaduzzi⁵, Anna Dioni, Jaume Galobart I Cots⁶, Orsolya Holczknecht, Alberto Navarro Villa⁷, Jordi Ortuño Casanova⁸.
EFSA Nutrition and Food Innovation (NIF) Unit: Marcello Laganaro⁹.

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from WG members Jacqueline Castenmiller, Roland Franz, and Hubert Rauscher (EC JRC).

II. Adoption of agenda

The agenda was adopted without changes.

¹ Did not participate in part of agenda item VI.

² Participated in agenda item VI.

³ Did not participate in part of agenda item Va

⁴ Did not participate in agenda item Vb

⁵ Participated in part of agenda item Va and Vb.

⁶ Participate in part of agenda item Vb.

⁷ Participated in agenda item Vb.

⁸ Did not participate in agenda item VI

⁹ Participated in part of agenda item VI.



III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence¹⁰ and the Decision of the Executive Director on Competing Interest Management¹¹, 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 47th Working Group meeting held on 18 October 2023, via web-conference

The [minutes of the 47th Working Group meeting](#) were agreed by written procedure on 30 October 2023.

V. Scientific topics for discussion

a. Request for advice from the Feed and Contaminants (FEEDCO) Unit on Clinoptilolite (EFSA-Q-2022-00474)

In the context of the implementation of the Guidance on Particle – Technical Requirements¹², the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was requested for assistance from the EFSA Feed and Contaminants (FEEDCO) Unit on Clinoptilolite (EFSA-Q-2022-00474). Previous advice on this application was submitted to the FEEDCO Unit at past WG meetings. During the present meeting, the WG was presented with the new data submitted by the applicant. After a discussion, the WG agreed on an advice for submission to the FEEDCO Unit.

b. Request for advice from the Feed and Contaminants (FEEDCO) Unit on Cobalt Carbonate as trace element (EFSA-Q-2022-00792) and (EFSA-Q-2022-00745)

In the context of the implementation of the Guidance on Particle – Technical Requirements¹², the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Cobalt Carbonate used as trace element (EFSA-Q-2022-00792 and EFSA-Q-2022-00745). After being presented with the background information and the data submitted by the applicant, the WG discussed and agreed on an advice for submission to the FEEDCO Unit.

c. Request for advice from the Feed and Contaminants (FEEDCO) Unit on Lanthanum carbonate octahydrate (EFSA-Q-2023-00440)

In the context of the implementation of the Guidance on Particle – Technical Requirements¹², the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Lanthanum carbonate octahydrate (EFSA-Q-2023-00440). After being presented with the background information and the data submitted by the applicant, the WG discussed and agreed on an advice for submission to the FEEDCO Unit.

¹⁰ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

¹² EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>



VI. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹² and Guidance on Nano – Risk Assessment¹³), the ccWG Nano continued the discussion started at previous meetings on the lessons learnt from the pilot phase of the implementation, considering possible next steps and actions to provide further guidance to applicants.

In order to collect additional feedback from the different stakeholders involved in the implementation of the Nano Guidances, EFSA is launching *ad hoc* surveys to gather input and collect comments. A first survey dedicated to the members and observers of the EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed (NanoNetwork) was launched. As a next step, EFSA will collect and elaborate the feedback received and will share other two surveys dedicated to External Stakeholders and to EFSA Staff, Panels and Working Groups.

VII. Any Other Business

- **Update on the review of the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283**

The WG was updated on the status of the activities to revise the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283¹⁴ by the Commission Expert Group on Nanomaterials in Food. This revision is following the adoption of the Commission Recommendation on nanomaterial¹⁵, published in June 2022. On 30 November 2023, the draft act has been launched for public consultation¹⁶.

VIII. Next meetings

The next meetings are scheduled for:

- 16 January 2024
- 26-27 February 2024
- 22 March 2024
- 22 April 2024
- 27 May 2024
- 27 June 2024
- 16 September 2024
- 21-22 October 2024
- 25 November 2024

¹³ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

¹⁴ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods. Available at: <https://eurlex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283>

¹⁵ Nanomaterial definition of Commission Recommendation C(2022)3689. Available at: https://ec.europa.eu/environment/chemicals/nanotech/pdf/C_2022_3689_1_EN_ACT_part1_v6.pdf

¹⁶ [Revision of the definition of engineered nanomaterial in food \(europa.eu\)](https://ec.europa.eu/environment/chemicals/nanotech/pdf/C_2022_3689_1_EN_ACT_part1_v6.pdf)



SCIENTIFIC COMMITTEE

47th cross-cutting Working Group meeting on Nanotechnologies



18 October 2023

09:00-16:00

MINUTES - Agreed on 30 October 2023

Location: Parma & Webconference

Attendees:

- Working Group (WG) Members:

Maria Bastos
Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Henriqueta Louro
Agnes Oomen
Alicja Mortensen
Eveline Verleysen

- European Commission

Takis Daskaleros (DG SANTE)¹
Hubert Rauscher (EC JRC)

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Adriana Scattareggia Marchese
EFSA Food Ingredients and Packaging (FIP) Unit: Ana Rincon², Agnieszka Mech
EFSA Feed and Contaminants (FEEDCO) Unit³: Angelica Amaduzzi, Anna Dioni, Matteo Lorenzo Innocenti, Orsolya Holczknecht, Jordi Ortuño Casanova, Maria Vittoria Vettori
EFSA Nutrition and Food Innovation (NIF) Unit: Emanuela Turla⁴, Reinhard Ackerl⁵

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Claudia Cascio.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Group members

¹ Did not participate in agenda items Vb, Vc, Vd

² Did not participate in agenda item Va

³ Participated in agenda items Vb, Vc, Vd

⁴ Participated in agenda item Va

⁵ Participated in agenda item Va



In accordance with EFSA's Policy on Independence⁶ and the Decision of the Executive Director on Competing Interest Management⁷, 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 46th Working Group meeting held on 29 September 2023, via web-conference

The [minutes of the 46th Working Group meeting](#) were agreed by written procedure on 16 October 2023.

V. Scientific topic(s) for discussion

a. Request for advice from the Nutrition and Food Innovation (NIF) Unit on Urolithin A (EFSA-Q-2018-00724)

In the context of the implementation of the Guidance on Particle – Technical Requirements⁸, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was requested for assistance from the EFSA NIF Unit on Urolithin A ([EFSA-Q-2018-00724](#)). Previous advice on this application was submitted to the NIF Unit at past WG meetings. During the present meeting, the WG was presented with the newly data submitted by the applicant in response to a clock stop letter. After a discussion, the WG agreed on an advice to be submitted to the NIF Unit.

b. Request for advice from the Feed and Contaminants (FEEDCO) Unit on Mixture (artificial) of sepiolite (90%) and diatomaceous earth (kieselguhr, silica) (10%) (EFSA-Q-2019-00301)

In the context of the implementation of the Guidance on Nano – Risk Assessment⁹, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the Mixture (artificial) of sepiolite (90%) and diatomaceous earth (kieselguhr, silica) (10%) ([EFSA-Q-2019-00301](#)). After being presented with the background information and the data submitted by the applicant, the WG discussed and agreed on an advice for submission to the FEEDCO Unit.

c. Request for advice from the Feed and Contaminants (FEEDCO) Unit on Kaolinitic clay (EFSA-Q-2019-00527)

In the context of the implementation of the Guidance on Particle – Technical Requirements⁸, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the Kaolinitic clay ([EFSA-Q-2019-00527](#)). After being presented with the background information and the data submitted by the applicant, the WG discussed and agreed on an advice for submission to the FEEDCO Unit.

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁸ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769> 12

⁹ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>



d. Request for advice from the Feed and Contaminants (FEEDCO) Unit on Natrolite-phonolite (EFSA-Q-2014-00888)

In the context of the implementation of the Guidance on Nano – Risk Assessment⁹, the ccWG Nano was requested for assistance from the EFSA FEEDCO Unit on Natrolite-phonolite ([EFSA-Q-2014-00888](#)). During the present meeting, the WG finalised the discussion held at previous WG meetings.

VI. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements⁸ and Guidance on Nano – Risk Assessment⁹), the ccWG Nano continued the discussion started at previous meetings on the lessons learnt from the pilot phase of the implementation, considering possible next steps and actions to provide further guidance to applicants. The discussion will further continue at the next WG meetings.

VII. Next meetings

The next meetings are scheduled for:

- 27 November 2023
- 16 January 2024
- 26-27 February 2024
- 22 March 2024
- 22 April 2024
- 27 May 2024
- 27 June 2024
- 16 September 2024
- 21-22 October 2024
- 25 November 2024



SCIENTIFIC COMMITTEE
46th cross-cutting Working Group meeting on
Nanotechnologies



29 September 2023

09:00-15:30

MINUTES - Agreed on 16 October 2023

Location: Parma & Webconference

Attendees:

- Working Group (WG) Members:

Maria Bastos
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Agnes Oomen
Alicja Mortensen

- European Commission

Takis Daskaleros (DG SANTE)

- EFSA:

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

EFSA Food Ingredients and Packaging (FIP) Unit: Eric Barthélémy¹, Ana Rincon, Agnieszka Mech

EFSA Feed and Contaminants (FEEDCO) Unit: Angelica Amaduzzi², Montserrat Anguita Freixa², Orsolya Holczknecht³, Jordi Ortuño Casanova², Maria Vittoria Vettori⁴

EFSA Nutrition and Food Innovation (NIF) Unit: Reinhard Ackerl⁵, Marcello Laganaro⁵

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Jacqueline Castenmiller, Henriqueta Louro, Eveline Verleysen (WG members) and Hubert Rauscher (EC JRC).

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 Independence⁶ and the Decision of the Executive Director on Competing Interest Management⁷, EFSA screened the Annual Declarations of Interest filled

¹ Did not participate in agenda items Va and Vb

² Participated in agenda items Va and Vb

³ Participated in agenda item V and part of agenda item VI

⁴ Participated in agenda items Va, Vb and VII

⁵ Participated in agenda item V and part of agenda item VI

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



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 45th Working Group meeting held on 11 July 2023, via web-conference

The [minutes of the 45th Working Group meeting](#) were agreed by written procedure on 24 July 2023.

V. Scientific topic(s) for discussion

a. Request for advice from the Feed Additives and Contaminants (FEEDCO) Unit on Natrolite-phonolite (EFSA-Q-2014-00888)

In the context of the implementation of the Guidance on Nano – Risk Assessment⁸, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was requested for assistance from the EFSA FEEDCO Unit on Natrolite-phonolite ([EFSA-Q-2014-00888](#)). During the present meeting, the WG continued the discussion held at previous WG meetings and agreed on an advice to be submitted to the FEEDCO Unit.

b. Kieselgur (diatomaceous earth, purified) (EFSA-Q-2019-00662)

In the context of the implementation of the Guidance on Particle – Technical Requirements⁹, the ccWG Nano was requested for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Kieselgur (diatomaceous earth, purified) ([EFSA-Q-2019-00662](#)). A first advice on this application was agreed at the 43rd ccWG Nano meeting. During the present meeting, the WG discussed the preliminary assessment on the data submitted by the applicant and agreed on further input to be shared with the FEEDCO Unit.

c. Request for advice from the Nutrition & Food Innovation (NIF) Unit on the Novel Food Guidance update

In the context of the implementation of the EFSA Nano Guidances (Guidance on Particle – Technical Requirements⁹ and Guidance on Nano – Risk Assessment⁸), the ccWG Nano was requested for assistance from the EFSA Nutrition & Food Innovation (NIF) Unit in light of the current update of the EFSA Novel Food Guidance¹⁰.

VI. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements⁹ and Guidance on Nano – Risk Assessment⁸), the ccWG Nano continued the discussion started at previous meetings on the lessons learnt from the pilot phase of the implementation, considering possible next steps and actions to provide further guidance to applicants. The discussion will further continue at the next WG meetings.

⁸ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

⁹ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769> 12

¹⁰ [Meeting minutes of the Working Group \(WG\) on Novel Foods \(europa.eu\)](#)



VII. Any Other Business

- **Update on EMA's Committee for Veterinary Medicinal Products (CVMP) activities in the field of nanomaterials' safety assessment**

The WG was updated on the status of the activities of EMA's Committee for Veterinary Medicinal Products (CVMP) in the field of nanomaterials' safety assessment¹¹, that EFSA is following as observer.

VIII. Next meetings

The next meetings are scheduled for:

- 18 October 2023
- 27 November 2023
- 16 January 2024
- 26-27 February
- 22 March
- 22 April
- 27 May 2024
- 27 June 2024
- 16 September 2024
- 21-22 October 2024
- 25 November 2024

¹¹ https://www.ema.europa.eu/en/documents/work-programme/cvmp-work-plan-2022_en.pdf



SCIENTIFIC COMMITTEE

45th cross-cutting Working Group meeting on Nanotechnologies



11 July 2023

10:00-17.00

MINUTES - Agreed on 24 July 2023

Location: Webconference

Attendees:

- Working Group (WG) Members:

Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
Henriqueta Louro
Agnes Oomen
Alicja Mortensen
Eveline Verleysen
Stefan Weigel

- European Commission

Takis Daskaleros¹ (DG SANTE)

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Claudia Cascio²

EFSA Food Ingredients and Packaging (FIP) Unit: Eric Barthélémy³, Ana Rincon

EFSA Feed and Contaminants (FEEDCO) Unit: Orsolya Holczknecht⁴, Revez Joana⁵, Maria Vittoria Vettori⁶

EFSA Nutrition and Food Innovation (NIF) Unit: Reinhard Ackerl⁷, Marcello Laganaro⁸

I. Welcome and apologies for absence

The Chair welcomed the participants and the EFSA Staff Claudia Cascio, who joined the Working Group (WG). The Chair thanked for his support and contribution the WG member Stefan Weigel, who will leave the WG starting from the next meeting. Apologies for absence were received from Maria Bastos, David Gott, Jan Mast (WG members) and Hubert Rauscher (EC JRC).

II. Adoption of agenda

The agenda was adopted with minor changes.

¹ Participated in agenda items Vd, VII and VIII

² Did not participate in agenda item VIII

³ Participated in agenda items VII and VIII

⁴ Participated in agenda items Va, Vb and Vc

⁵ Participated in agenda items Va and Vb

⁶ Participated in agenda items Va, Vb and Vc

⁷ Participated in agenda item Vd

⁸ Did not participate in agenda item VIII



III. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence⁹ and the Decision of the Executive Director on Competing Interest Management¹⁰, 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 44th Working Group meeting held on 31 May 2023, via web-conference

The [minutes of the 44th Working Group meeting](#) were agreed by written procedure on 15 June 2023.

V. Scientific topic(s) for discussion

a. Request for advice from the Feed Additives and Contaminants (FEEDCO) Unit on Cylactin®, with Shellac ([EFSA-Q-2020-00391](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements¹¹, the cross-cutting WG on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Feed Additives and Contaminants (FEEDCO) Unit on Cylactin®, with Shellac (EFSA-Q-2020-00391). After being presented with the background information and preliminary assessment, the WG discussed and agreed on an advice for submission to the FEEDCO Unit.

b. Request for advice from the Feed Additives and Contaminants (FEEDCO) Unit on Dicopper chloride trihydroxide (Intellibond C) ([EFSA-Q-2021-00547](#)) and Zinc Chloride Hydroxide Monohydrate (Intellibond Z) ([EFSA-Q-2021-00548](#))

In the context of the implementation of the of the Guidance on Particle – Technical Requirements¹¹, the ccWG Nano was asked for support from the EFSA FEEDCO Unit on Dicopper chloride trihydroxide (Intellibond C) (EFSA-Q-2021-00547) and on Zinc Chloride Hydroxide Monohydrate (Intellibond Z) (EFSA-Q-2021-00548). After being presented with the reply from the applicant to EFSA's request for supplementary information, the WG submitted an advice to the FEEDCO Unit.

c. Request for assistance from the FEEDCO Unit on Natrolite-phonolite ([EFSA-Q-2014-00888](#))

In the context of the implementation of the Guidance on Nano – Risk Assessment¹², the ccWG Nano was asked for assistance from the EFSA FEEDCO Unit on Natrolite-phonolite (EFSA-Q-2014-00888), following a previous advice from this WG provided at the 43rd WG meeting. Further discussion will continue at the next meeting.

d. Request for advice from the Nutrition and Food Innovation (NIF) Unit on the Novel Food Guidance update

In the context of the implementation of the EFSA Nano Guidances (Guidance on Particle – Technical Requirements¹¹ and Guidance on Nano – Risk Assessment¹²), the ccWG Nano was

⁹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

¹⁰ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

¹¹ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

¹² EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>



requested for assistance from the EFSA Nutrition & Food Innovation (NIF) Unit in light of the current update of the EFSA Novel Food Guidance¹³. Further discussion will be held at the next meeting.

VI. Discussion on lessons learnt from the first implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹¹ and Guidance on Nano – Risk Assessment¹²), the ccWG Nano continued the discussion started at previous meetings on the lessons learnt from the pilot phase of the implementation, considering possible next steps and actions to provide further guidance to applicants. The discussion will continue at the next WG meetings.

VII. SCCS Guidance on the safety assessment of nanomaterials in cosmetics

The ccWG Nano was presented by the Chair with the recently published 2nd revision of the “SCCS Guidance on the safety assessment of nanomaterials in cosmetics”¹⁴. The WG was provided with an overview of the recent state of the art for the assessment of nanomaterials in the cosmetics’ regulatory framework and appreciated the increased readiness in using New Approach Methodologies (NAMs) (i.e. non-animal methods) for the risk assessment of these materials.

VIII. Any Other Business

○ Update on EMA’s Committee for Veterinary Medicinal Products (CVMP) activities in the field of nanomaterials’ safety assessment

The WG was informed that EFSA has been invited to follow the ongoing activities of EMA’s Committee for Veterinary Medicinal Products (CVMP) in the field of nanomaterials’ safety assessment¹⁵.

○ SCHEER Scientific Opinion on the safety of titanium dioxide in toys

The ccWG Nano was informed about the recently published SCHEER Scientific Opinion on the safety of titanium dioxide in toys¹⁶.

○ OECD work on Guidance for sample preparation and dosimetry

The WG was informed about the ongoing activities at OECD for the development of a guidance document on sample preparation and dosimetry. Experts are invited to contribute, to be aligned with their national delegates.

○ Preparatory meeting

Since the last WG meeting, a preparatory meeting was held on 30 June 2023 to discuss the following agenda items:

- **Va.** Request for advice from the Feed Additives and Contaminants (FEEDCO) Unit on Cylactin®, with Shellac (EFSA-Q-2020-00391)

¹³ [Meeting minutes of the Working Group \(WG\) on Novel Foods \(europa.eu\)](#)

¹⁴ https://health.ec.europa.eu/publications/sccs-guidance-safety-assessment-nanomaterials-cosmetics-2nd-revision_en

¹⁵ https://www.ema.europa.eu/en/documents/work-programme/cvmp-work-plan-2022_en.pdf

¹⁶ [SCHEER - Scientific Opinion on the safety of titanium dioxide in toys \(europa.eu\)](#)



- **Vb.** Request for advice from the Feed Additives and Contaminants (FEEDCO) Unit on Dicopper chloride trihydroxide (Intellibond C) (EFSA-Q-2021-00547) and Zinc Chloride Hydroxide Monohydrate (Intellibond Z) (EFSA-Q-2021-00548)

IX. Next meetings

The next meetings are scheduled for:

- 29 September 2023 (Parma, all day)
 - 18 October 2023 (webconference, all day)
 - 21 November 2023 (webconference, all day)
-



SCIENTIFIC COMMITTEE

44th cross-cutting Working Group meeting on Nanotechnologies



31 May 2023

10:00-17.00

MINUTES - Agreed on 15 June 2023

Location: Webconference

Attendees:

- Working Group (WG) Members:

Maria Bastos
Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
David Gott
Jan Mast
Agnes Oomen
Eveline Verleysen

- European Commission

Takis Daskaleros (DG SANTE)
Hubert Rauscher (JRC)

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Claudia Cascio, Lucian Farcas¹

EFSA Food Ingredients and Packaging (FIP) Unit: Eric Barthélémy², Ana Rincon³

EFSA Feed and Contaminants (FEEDCO) Unit: Orsolya Holczknecht⁴

EFSA Nutrition and Food Innovation (NIF) Unit: Reinhard Ackerl⁵, Marcello Laganaro⁶

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from WG members Roland Franz, Henriqueta Louro, Alicja Mortensen and Stefan Weigel.

II. Adoption of agenda

The agenda was adopted with minor changes in the timeschedule.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁷ and the Decision of the Executive Director on Competing Interest Management⁸, 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

¹ Participated in agenda item VII

² Participated in agenda items Vd, VII and VII

³ Did not participate in agenda item Va

⁴ Participated in agenda items Vc and VI

⁵ Did not participate in agenda item Vc

⁶ Participated in agenda item Va

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Agreement of the minutes of the 43rd Working Group meeting held on 28 April 2023, via web-conference

The [minutes of the 43rd Working Group meeting](#) were agreed by written procedure on 23 May 2023.

V. Scientific topic(s) for discussion

a. Request for advice from the NIF Unit on Bacterial Cellulose ([EFSA-Q-2018-00294](#))

In the context of the implementation of the Guidance on Nano – Risk Assessment⁹, the ccWG Nano was asked for support from the EFSA Nutrition and Food Innovation (NIF) Unit on Bacterial Cellulose (EFSA-Q-2018-00294). The ccWG Nano was previously consulted for advice on this case, and after being presented with the new data submitted by the applicant agreed on an advice to be submitted to the NIF Unit.

b. Presentation on the follow up of the re-evaluation of Gold (E 175) ([EFSA-Q-2021-00562](#))

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹⁰ and Guidance on Nano – Risk Assessment⁹), the ccWG Nano was asked for support from the EFSA Food Ingredients and Packaging (FIP) Unit on the follow up of the re-evaluation of Gold (E 175) (EFSA-Q-2021-00562). After being presented with the background information of the European Commission mandate, the ccWG was requested to provide input to refine the literature search to be performed for the safety assessment of this food additive.

c. Request for advice from the FEEDCO Unit on examples of generic feed additives

In the context of the implementation of the Guidance on Particle – Technical Requirements¹⁰, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the implementation of the Guidance on Particle-TR for some generic feed additives. After being presented with the background information, the WG agreed on an advice to be submitted to the FEEDCO Unit.

d. Request for assistance from the FIP Unit on the 'Proposal for the safety assessment of the use of substances from renewable biological origin to manufacture food contact materials' ([EFSA-Q-2023-00256](#))

In the context of the implementation of the EFSA Guidance on Particle – Technical Requirements¹⁰, the ccWG was asked from the EFSA Food Ingredients and Packaging (FIP) Unit to provide input on the draft Technical Report "Proposal for the safety assessment of the use of substances from renewable biological origin to manufacture food contact materials" (EFSA-Q-2023-00256), under development by the EFSA CEP WG on Food Contact Materials. After being presented with the background information, the ccWG provided advice on the draft text proposed on how to address the presence of small particles including nanoparticles according to the EFSA Guidance on Particle – Technical Requirements⁴.

⁹ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

¹⁰ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>



VI. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements¹⁰ and Guidance on Nano – Risk Assessment⁹), the ccWG Nano continued the discussion started at previous meetings on the lessons learnt from the pilot phase of the implementation, considering possible next steps and actions to provide further guidance to applicants. The discussion will further continue at the next WG meetings.

VII. Any Other Business

o Update on ongoing activities

The ccWG Nano was updated on a number of EU ongoing activities in the field of Nanotechnologies. In particular, the WG was presented with the 'Guidance on the implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial', published by Rausher et al., 2023¹¹. The WG members were also informed on the recent call for the adoption of a more protective definition for nanomaterials published by ANSES in May 2023¹². Lastly, the WG was updated on the organisation of the next NanoNetwork¹³ meeting on 26 September 2023, which will be held in Parma as joint session of the 13th Global Summit on Regulatory Science (GSRS23)¹⁴.

VIII. Next meetings

The next meetings are scheduled for:

- 11 July 2023
- 29 September 2023
- 18 October 2023
- 21 November 2023

¹¹ <https://publications.jrc.ec.europa.eu/repository/handle/JRC132102>

¹² <https://www.anses.fr/en/content/ANSES-calls-adoption-more-protective-definition-nanomaterials>

¹³ <https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/scientific-committee#networks>

¹⁴ <https://qcrsr.net/2023-qsr/>



SCIENTIFIC COMMITTEE

43rd cross-cutting Working Group meeting on Nanotechnologies



28 April 2023

9:00-17.00

MINUTES - Agreed on 23 May 2023

Location: Webconference

Attendees:

- Working Group (WG) Members:

Maria Bastos
Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
David Gott
Henriqueta Louro
Jan Mast
Alicja Mortensen
Agnes Oomen
Eveline Verleysen
Stefan Weigel

- European Commission

Takis Daskaleros (DG SANTE)

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Claudia Cascio, Lucian Farcial
EFSA Food Ingredients and Packaging (FIP) Unit: Eric Barthelemy, Carla Martino, Agnieszka Mech, Multari Salvatore, Ana Rincon
EFSA Feed and Contaminants (FEEDCO) Unit: Angelica Amaduzzi, Jordi Ortuño Casanova, Orsolya Holczknecht, Barbara Rossi, Maria Vittoria Vettori
EFSA Nutrition and Food Innovation (NIF) Unit: Wolfgang Gelbmann

I. Welcome and apologies for absence

The Chair welcomed the participants and welcomed the new WG member to cover the expertise in physico-chemical characterisation.

Apologies for absence were received by Hubert Rauscher.

Stefan Weigel did not participate in part of agenda item VI and in agenda items VII and VIII
Jan Mast did not participate in agenda items VII and VIII.

Alicja Mortensen did not participate in part of agenda item V.

Multari Salvatore and Martino Carla participated in agenda item Va.

Lucian Farcial participated in part of agenda item Va.

Claudia Cascio participated in part of agenda items V, and VI.

Wolfgang Gelbmann participated in agenda item Ve.

Eric Barthelemy participated in part of agenda items VI and VII.

Angelica Amaduzzi, Jordi Ortuño Casanova, Orsolya Holczknecht, Barbara Rossi participated in agenda items Vb, Vc, Vd.

Maria Vittoria Vettori participated in part of agenda item V.

Orsolya Holczknecht participated in agenda items Va, Vb, Vc, Vd.



Takis Daskaleros did not participate in agenda item Vb, Vc and Vd.

II. Adoption of agenda

The agenda was adopted with minor changes in the timeschedule.

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 42nd Working Group meeting held on 20 March 2023, via web-conference

The [minutes of the 42nd Working Group meeting](#) were agreed by written procedure on 4 April 2023.

V. Scientific topic(s) for discussion

a. Request for advice from the FIP Unit on Smoke flavourings

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Food Ingredients and Packaging (FIP) Unit on the assessment of the data submitted related to smoke flavourings under assessments by the FAF Panel: Scansmoke SEF7525 (SF-004) ([EFSA-Q-2022-00421](#)), proFagus SMOKE R714 (SF-001) ([EFSA-Q-2022-00423](#)), proFagus SMOKE R709 (SF-008) ([EFSA-Q-2022-00422](#)), Zesti Smoke Code 10 (SF-002) ([EFSA-Q-2022-00415](#)), SmokEz C-10 (SF-005) ([EFSA-Q-2022-00416](#)), SmokEz Enviro-23 (SF-006) ([EFSA-Q-2022-00417](#)). After being presented with the data submitted by the applicant, the WG provided advice to the FIP Unit.

b. Request for advice from the FEEDCO Unit on Chlorophyllin copper complex ([EFSA-Q-2022-00232](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Chlorophyllin copper complex (EFSA-Q-2022-00232). After being presented with the data submitted by the applicant, the WG agreed on an advice to be submitted to the FEEDCO Unit.

c. Request for advice from the FEEDCO Unit on Kieselgur (diatomaceous earth, purified) ([EFSA-Q-2019-00662](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Kieselgur (diatomaceous earth, purified) (EFSA-Q-2019-00662). After being presented

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

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

³ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>



with the data submitted by the applicant, the WG agreed on an advice to be submitted to the FEEDCO Unit.

d. Request for advice from the FEEDCO Unit on Natrolite-phonolite ([EFSA-Q-2014-00888](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on Natrolite-phonolite (EFSA-Q-2014-00888). After being presented with the data submitted by the applicant, the WG agreed on an advice to be submitted to the FEEDCO Unit.

e. Request for advice from the NIF Unit on Algal meal and oleoresin of Haematococcus pluvialis containing astaxanthin as a novel food ([EFSA-Q-2021-00319](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Nutrition and Food Innovation (NIF) Unit on the Algal meal and oleoresin of Haematococcus pluvialis containing astaxanthin as a novel food (EFSA-Q-2021-00319). After being presented with the data submitted by the applicant, the WG agreed on an advice to be submitted to the NIF Unit.

VI. Discussion on lessons learnt from the implementation phase of the Nano Guidances and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements³ and Guidance on Nano – Risk Assessment⁴), the ccWG Nano continued the discussion started at previous meetings on the lesson learnt from the pilot phase of the implementation, considering possible next steps and actions to provide further guidance to applicants. The discussion will further continue at the next WG meetings.

VII. Any Other Business

○ **Update on the review of the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283**

The WG was updated on the on the status of the activities to revise the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283⁵ by the Commission Expert Group on Nanomaterials in Food. This revision is following the adoption of the Commission Recommendation on nanomaterial⁶, published in June 2022. The WG will be kept informed on further developments.

○ **ECHA draft Guidance on the Drinking Water Directive (DWD)**

The WG discussed input to be provided to ECHA on the draft Guidance on Drinking Water Directive (DWD).

VIII. Next meeting

The next meetings are scheduled for:

- 31 May 2023

⁴ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

⁵ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods. Available at: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283>

⁶ Nanomaterial definition of Commission Recommendation C(2022)3689. Available at: https://ec.europa.eu/environment/chemicals/nanotech/pdf/C_2022_3689_1_EN_ACT_part1_v6.pdf



- 11 July 2023
- 29 September 2023
- 18 October 2023
- 21 November 2023



SCIENTIFIC COMMITTEE

42nd cross-cutting Working Group meeting on Nanotechnologies



20 March 2023

09:30-17.00

MINUTES - Agreed on 4 April 2023

Location: Parma

Attendees:

- o Working Group (WG) Members:

Maria Bastos
Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
Henriqueta Louro
Jan Mast
Alicja Mortensen
Agnes Oomen

- o European Commission

Takis Daskaleros (DG SANTE)
Hubert Rauscher (JRC)

- o EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo
EFSA Food Ingredients and Packaging (FIP) Unit: Agnieszka Mech, Ana Rincon
EFSA Feed and Contaminants (FEEDCO) Unit: Orsolya Holczknecht, Maria Vittoria Vettori
EFSA Nutrition and Food Innovation (NIF) Unit: Reinhard Ackerl, Marcello Laganaro
EFSA Knowledge, Innovation and Partnership Management (KNOW) Unit: Georgia Gkrintzali

I. Welcome and apologies for absence

The Chair welcomed the participants. Francesco Cubadda, Roland Franz (WG Members) and Takis Daskaleros (DG SANTE) participated online.
Apologies were received from David Gott and Stefan Weigel (WG Members).
Orsolya Holczknecht and Maria Vittoria Vettori were present for agenda item V.
Agnieszka Mech, Ana Rincon, Georgia Gkrintzali were present for agenda item VI and VII.
Hubert Rauscher was absent for agenda item VII.

II. Adoption of agenda

The agenda was adopted with minor 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

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



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 41st Working Group meeting held on 21 February 2023, via web-conference

The [minutes of the 41st Working Group meeting](#) were agreed by written procedure on 10 March 2023.

V. Scientific topic(s) for discussion

a. Request for advice from the FEEDCO Unit on Stenorol® (halofuginone hydrobromide) for chickens for fattening and turkeys ([EFSA-Q-2021-00321](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the coccidiostat feed additive Stenorol® (halofuginone hydrobromide) for chickens for fattening and turkeys (EFSA-Q-2021-00321). After a discussion on the data submitted by the applicant, the WG agreed an advice for submission to the FEEDCO Unit.

b. Request for advice from the FEEDCO Unit on a list of coccidiostat feed additives⁴

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on a list of coccidiostat applications⁴. The WG continued the discussion started at the previous meeting and provided input on the new data submitted by the applicants for this list coccidiostat feed additives.

c. Request for advice from the FEEDCO Unit on 25-hydroxycholecalciferol ([EFSA-Q-2021-00641](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the feed additive 25-hydroxycholecalciferol for all pigs, all poultry for fattening and ornamental birds, and other poultry species. After a short discussion, the WG agreed to finalise by written procedure the advice to be submitted to the FEEDCO Unit.

VI. Discussion on lesson learnt from the implementation phase of the Nano Guidances and next steps

³ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

⁴ Elancoban (monensin sodium) ([EFSA-Q-2021-00537](#))
Clinacox 0.5% (diclazuril) ([EFSA-Q-2020-00201](#) and [EFSA-Q-2020-00203](#))
Monteban G100 (narasin) ([EFSA-Q-2020-00557](#))
Coxiril (diclazuril) ([EFSA-Q-2021-00472](#) and [EFSA-Q-2021-00669](#))
Maxiban (narasin+nicarbazin) ([EFSA-Q-2019-00739](#))
Nicacox (nicarbazin) ([EFSA-Q-2021-00259](#))
Quinox (decoquinate) ([EFSA-Q-2021-00428](#))



In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements³ and Guidance on Nano – Risk Assessment⁵), the ccWG Nano continued the discussion started at the previous meeting on the lesson learnt from the pilot phase of the implementation, considering possible next steps and actions to provide further guidance to applicants. The discussion will further continue at the next WG meetings.

VII. Any Other Business

- **EFSA Environmental Scanning: detecting weak signals in the area of new food, feed sources and production technologies**

The WG was presented with the EFSA's innovation project (identification of weak signals related to new food/feed sources and production techniques), focusing on the signals related to nanotechnology. Additionally, it was referred to the outcomes of the breakout session of nanotechnology during EFSA's Food/Feed Lab that took place on the 7th and 8th of March in Milan⁶.

- **Update on the review of the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283**

The WG was updated on the on the status of the activities to revise the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283⁷ by the Commission Expert Group on Nanomaterials in Food. This revision is following the adoption of the Commission Recommendation on nanomaterial⁸, published in June 2022. The WG will be kept informed on further developments.

VIII. Next meeting

The next meetings are scheduled for:

- 28 April 2023
- 31 May 2023
- 11 July 2023
- 29 September 2023
- 18 October 2023
- 21 November 2023

⁵ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp.
<https://doi.org/10.2903/j.efsa.2021.6768>

⁶ <https://www.efsa.europa.eu/en/events/future-food-and-feed-lab-stakeholder-workshop-new-foodfeed-sources-and-technologies>

⁷ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods. Available at: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283>

⁸ Nanomaterial definition of Commission Recommendation C(2022)3689. Available at: https://ec.europa.eu/environment/chemicals/nanotech/pdf/C_2022_3689_1_EN_ACT_part1_v6.pdf



SCIENTIFIC COMMITTEE

41st cross-cutting Working Group meeting on Nanotechnologies



21 February 2023

10:00-17.00

MINUTES - Agreed on 10 March 2023

Location: Webconference

Attendees:

- Working Group (WG) Members:

Maria Bastos
Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
Henriqueta Louro
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

- European Commission

Takis Daskaleros (DG SANTE)
Hubert Rauscher (JRC)

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Claudia Cascio, Irene Cattaneo
EFSA Food Ingredients and Packaging (FIP) Unit: Eric Barthelemy, Agnieszka Mech, Ana Rincon
EFSA Feed and Contaminants (FEEDCO) Unit: Angelica Amaduzzi, Orsolya Holczknecht, Maria Vittoria Vettori
EFSA Nutrition and Food Innovation (NIF) Unit: Reinhard Ackerl, Eirini Kouloura, Marcello Laganaro

I. Welcome and apologies for absence

The Chair welcomed the participants. A tour the table was held to introduce the new WG members.

Apologies were received from David Gott (WG Member).

Maria Bastos (WG Member) participated in agenda items VI and VII.

Claudia Cascio did not participate in the agenda item VII.

Eric Barthelemy participated in part of the agenda item VI and in the item VII.

Agnieszka Mech did not participate in part of the agenda items V and VI.

Ana Ricon participated in the agenda item V and in part of the item VII.

Angelica Amaduzzi participated in the agenda item V.a.

Orsolya Holczknecht participated in the agenda item V.

Orsolya Holczknecht participated in part of the agenda item V.

Reinhard Ackerl and Marcello Laganaro participated in the agenda items V and in part of the agenda item VI.

Eirini Kouloura participated in the agenda item V.



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. 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 40th Working Group meeting held on 18 January 2023, via web-conference

The [minutes of the 40th Working Group meeting](#) were agreed by written procedure on 1 February 2023.

V. Discussion on the input received from EFSA Units on Nano Guidances implementation, lesson learnt and next steps

In the context of the implementation of its Nano Guidances (Guidance on Particle – Technical Requirements³ and Guidance on Nano – Risk Assessment⁴), a dedicated meeting was organised with EFSA Units to exchange on the current status of the implementation and identify difficulties emerged from the implementation process. Based on the feedback received from the EFSA Units, the WG members discussed the lesson learnt from the pilot phase of the implementation and considered possible next steps and actions to provide further guidance to applicants. The discussion will continue at the next WG meetings.

VI. Scientific topic(s) for discussion

a. Request for advice from the FEEDCO Unit on Clinoptilolite of sedimentary origin ([EFSA-Q-2022-00474](#))

In the context of the implementation of the Nano Guidances (Guidance on Particle – Technical Requirements³ and Guidance on Nano – Risk Assessment⁴), the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the technological feed additive Clinoptilolite of sedimentary origin (EFSA-Q-2022-00474).

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

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

3 EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

4 EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>



After being presented with the data submitted by the applicant, the WG discussed and agreed on the advice to be submitted to the FEEDCO Unit.

b. Request for advice from the FEEDCO Unit on Elancoban® (monensin sodium) for chickens for fattening, chickens reared for laying and turkeys ([EFSA-Q-2021-00537](#))

In the context of the implementation of the Guidance on Particulate Matter – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the coccidiostat feed additive Elancoban® (monensin sodium) for chickens for fattening, chickens reared for laying and turkeys (EFSA-Q-2021-00537). During its 35th and 36th meeting the ccWG Nano discussed and agreed on a first advice on Elancoban® (monensin sodium) that was submitted to the FEEDCO Unit. After being presented with the new data submitted by the applicant, the WG started a discussion that will be continued at the next meeting.

c. Request for advice from the FEEDCO Unit on Clinacox 0.5% (diclazuril) for chickens for fattening ([EFSA-Q-2020-00201](#)) and for chickens reared for laying ([EFSA-Q-2020-00203](#))

In the context of the implementation of the Guidance on Particulate Matter – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the coccidiostat feed additive Clinacox 0.5% (diclazuril) for chickens for fattening (EFSA-Q-2020-00201) and for chickens reared for laying (EFSA-Q-2020-00203). After being presented with the data submitted by the applicant, the WG started a discussion that will be continued at the next meeting.

d. Request for advice from the FEEDCO Unit on Monteban® G100 (narasin) for chickens for fattening ([EFSA-Q-2020-00557](#))

In the context of the implementation of the Guidance on Particulate Matter – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the coccidiostat feed additive Monteban® G100 (narasin) for chickens for fattening (EFSA-Q-2020-00557). After being presented with the data submitted by the applicant, the WG started a discussion that will be continued at the next meeting.

e. Request for advice from the FEEDCO Unit on Stenorol® (halofuginone hydrobromide) for chickens for fattening and turkeys ([EFSA-Q-2021-00321](#))

In the context of the implementation of the Guidance on Particulate Matter – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the coccidiostat feed additive Stenorol® (halofuginone hydrobromide) for chickens for fattening and turkeys (EFSA-Q-2021-00321). After being presented with the data submitted by the applicant, the WG started a discussion that will be continued at the next meeting.

VII. Any Other Business

o **Update on ongoing activities**

The WG was updated on a number of EU ongoing activities in the field of Nanotechnologies. In particular, on 7 February 2023 EFSA participated to the online thematic workshop, organised by Plastics and CUSP WG on Risk assessment to investigate and discuss the



applicability of existing risk assessment frameworks related to Micro and Nano Particles⁵. The WG was also updated on the status of the EFSA NAMS4NANO project⁶.

VIII. Next meeting

The next meetings are scheduled for:

- 20 March 2023
- 28 April 2023
- 31 May 2023
- 11 July 2023
- 26 September 2023
- 29 September 2023
- 18 October 2023
- 21 November 2023

Annex I

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

With regard to this meeting, Agnes Oomen declared the following interest: new interest as Chair of the OECD Expert Group on the Development of new Test Guideline/Guidance Document on toxicokinetics to accommodate testing of nanoparticles, not declared in her previous ADOI (validity until 16th June 2023). In accordance with EFSA's Policy on Independence⁷ and the Decision of the Executive Director on Competing Interest Management⁸, 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.

5 <https://cusp-research.eu/cusp-workshop-series-on-human-risk-assessment-of-mnps/>

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

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

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

SCIENTIFIC COMMITTEE
40th cross-cutting Working Group meeting on
Nanotechnologies



18 January 2023

09:00-13.30

MINUTES - Agreed on 1 February 2023

Location: Webconference

Attendees:

- Working Group (WG) Members:

Jacqueline Castenmiller
Qasim Chaudhry (WG Chair)
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen

- EFSA:

EFSA Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo
EFSA Food Ingredients and Packaging (FIP) Unit: Eric Barthelemy
EFSA Feed and Contaminants (FEEDCO) Unit: Orsolya Holczknecht, Jordi Tarrés Call
EFSA Nutrition and Food Innovation (NIF) Unit: Eirini Kouloura, Marcello Laganaro, Alejandra Munoz, Annamaria Rossi

I. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Stefan Weigel (WG Member), Takis Daskaleros (DG SANTE) and Hubert Rauscher (JRC).

Orsolya Holczknecht did not participate in agenda point VIII and IX.

Jordi Tarrés Call participated only for agenda points Va and Vb.

Marcello Laganaro did not participate in agenda point VII, VIII and IX.

Eric Barthelemy did not participate in agenda point VII, VIII and IX.

Eirini Kouloura, Annamaria Rossi and Alejandra Munoz participated only for agenda point V(c).

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. Certain interests were declared orally by the members before the beginning of the

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. 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 39th Working Group meeting held on 30 November 2022, via web-conference

The [minutes of the 39th Working Group meeting](#) were agreed by written procedure on 16 December 2023.

V. Scientific topic(s) for discussion

a. Request for advice from the FEEDCO Unit on Vitamin B2 (Riboflavin) produced by *Bacillus subtilis* for all animal species ([EFSA-Q-2020-00637](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the nutritional feed additive Vitamin B2 (Riboflavin) produced by *Bacillus subtilis* for all animal species (EFSA-Q-2020-00637). During its 39th meeting the WG on Nanotechnologies discussed and agreed on a first advice on Vitamin B2 that was submitted to the FEEDCO Unit. After being presented with additional data, further discussion was held during the present meeting and the WG agreed on a second advice to be submitted to the FEEDCO Unit.

b. Request for advice from the FEEDCO Unit on Vitamin B12 (cyanocobalamin) for all animal species ([EFSA-Q-2021-00571](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the nutritional feed additive Vitamin B12 (cyanocobalamin) produced by fermentation with non-genetically modified *Ensifer adhaerens* CGMCC 19596 for all animal species (EFSA-Q-2021-00571). After being presented with the data submitted by the applicant, the WG discussed and agreed on the advice to be submitted to the FEEDCO Unit.

c. Request for advice from the NIF Unit on 99% CBD powder as a NF ([EFSA-Q-2021-00405](#)) and extract containing around 84% CBD as NF ([EFSA-Q-2021-00404](#))

In the context of the implementation of the Guidance on Particle – Technical Requirements³, the ccWG Nano was asked for support from the EFSA Nutrition and Food Innovation (NIF) Unit on 99% CBD powder as a novel food (EFSA-Q-2021-00405) and extract containing around 84% CBD as novel food (EFSA-Q-2021-00404). After being presented with the data submitted by the applicant, the WG discussed a general advice that will be agreed by written procedure and then submitted to the requesting unit.

VI. Discussion on the presentation given by FEFANA at the Info Session on applications for feed additives

The WG was provided with the presentation given by FEFANA on the 'Industry's views on the implications of the EFSA Nano guidance documents in feed additives applications' at the 'Info session on applications for feed additives'⁴, where the EFSA Nano Guidances^{3,5} (i.e. the Guidance on Particle – Technical Requirements³ and the Guidance on Nano – Risk

³ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

⁴ <https://www.efsa.europa.eu/en/events/info-session-applications-feed-additives>



Assessment⁵) were presented. A dedicated discussion on the presentation by FEFANA was held during the present meeting. The WG appreciated the useful input received and agreed that more detailed recommendations could be developed in order to further support applicants on how to interpret the Nano Guidances^{3,5} for the evaluation of certain aspects related to feed additives. Further discussion will be held at the next meetings to agree on the best way forward.

VII. Discussion EFSA/ANSES on nanomaterials assessment strategy

Following the previous exchange with ANSES, the WG was informed that a discussion will continue among the two agencies to reflect on opportunities for further cooperation to find ways for a consistent and harmonised approach to risk assessment of nanomaterials.

VIII. Any Other Business

○ Workplan for 2023 and new WG composition

The WG was updated on the workplan expected for 2023, which will be focused to continue supporting EFSA Panels and Units in the implementation of the EFSA Nano Guidances^{3,5}. In view of such requests for support, the WG was informed that two new experts will be invited to join the WG as from the next meeting to cover the expertise in nanogenotoxicity and feed additives risk assessment.

○ Input from EFSA Units on EFSA Nano Guidances^{3,5} implementation

The WG was informed about the ongoing activities organised internally to facilitate a smooth and harmonised implementation of the Nano Guidances across different EFSA sectors. A dedicated meeting with the different EFSA Units was organised to clarify the current status of the implementation of the Nano Guidances across different sectors, gather input on the Nano Guidances applicability domain and identify any issues and difficulties in the implementation process. Discussion on the inputs received will be held at the next WG meeting.

IX. Next meeting

The next meetings are scheduled for:

- 21 February 2023
- 20 March 2023
- 28 April 2023
- 31 May 2023
- 11 July 2023
- 29 September 2023
- 18 October 2023
- 21 November 2023

⁵ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>



Annex I

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

With regard to this meeting, Jan Mast declared the following interest: new interest as membership of a scientific advisory entity and new research funding not declared in his previous ADOI (validity until 25th February 2023). In accordance with EFSA's Policy on Independence⁶ and the Decision of the Executive Director on Competing Interest Management⁷, 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.

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 39TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 30 November 2022
(Agreed on 16 December 2022)**

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry (Chair)
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel¹

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)
Takis Daskaleros (DG SANTE)
Bruno Teste (ANSES, NanoNetwork Representative of France)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Djien Liem²
Feed and Contaminants (FEEDCO) Unit³: Jordi Tarres Call, Alberto Navarro Villa, Anita Radovnikovic, Maria Vittoria Vettori
Food Ingredients and Packaging (FIP) Unit⁴: Eric Barthelemy, Ana Rincon

¹ Present for agenda items 5, 7, 8

² Present for agenda item 5

³ Present for agenda item 6

⁴ Present for agenda item 5

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 38th Working Group meeting held on 7 November 2022, by WEB-conference.

The minutes of the 38th Working Group meeting were agreed by written procedure on 21 November 2022⁷.

5. Discussion EFSA/ANSES on nanomaterials assessment strategy

Following the presentation given at the 12th meeting of the EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed (NanoNetwork)⁸, ANSES was invited to present its recent activities in the field of nanotechnology and nanomaterials risk assessment and to exchange views on the respective assessment strategies, and to discuss possibilities for mutual improvements and harmonisation. Further exchanges to reflect on the discussions and to find opportunities for further cooperation will follow.

6. Scientific topic(s) for discussion

6.1. Requests for advice from the FEEDCO Unit on dicopper chloride trihydroxide for all animal species (EFSA-Q-2021-00547⁹)

In the context of the implementation of the Guidance on Particle – Technical Requirements¹⁰, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the nutritional feed additive under renewal dicopper chloride trihydroxide for all animal species (EFSA-Q-2021-00547¹⁰). After being presented with the new data submitted by the applicant, the WG discussed an advice that will be finalised and agreed by written procedure, before submission to the FEEDCO Unit.

6.2. Request for assistance from the FEEDCO Unit on Vitamin B2 (Riboflavin) produced by *Bacillus subtilis* for all animal species (EFSA-Q-2020-00637¹¹)

In the context of the implementation of the Guidance on Particle – Technical Requirements¹², the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the

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

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

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

8 <https://www.efsa.europa.eu/en/events/12th-meeting-efsa-scientific-network-risk-assessment-nanotechnologies-food-and-feed>

9 <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00547>

10 EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp.

<https://doi.org/10.2903/j.efsa.2021.6769>

11 <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00637>

12 EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp.

<https://doi.org/10.2903/j.efsa.2021.6769>

nutritional feed additive Vitamin B2 (Riboflavin) produced by *Bacillus subtilis* for all animal species (EFSA-Q-2020-00637). After being presented with the data submitted by the applicant, the WG discussed and agreed on the advice to be submitted to the FEEDCO Unit.

6.3. Request for assistance from the FEEDCO Unit on Phenylcapsaicin, a synthetic analogue of capsaicin (EFSA-Q-2022-00355)¹³

In the context of the implementation of the Guidance on Particle – Technical Requirements¹¹, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the zootechnical feed additive Phenylcapsaicin, a synthetic analogue of capsaicin (EFSA-Q-2022-00355). After being presented with the data submitted by the applicant, the WG discussed an advice that will be finalised and agreed by written procedure before submission to the FEEDCO Unit.

7. Annex on 'Degradation/dissolution rate under acidic conditions', produced to update the recently published Guidance on Particle – TR⁶

The Annex on 'Degradation/dissolution rate under acidic conditions' has been produced to provide further clarifications regarding the application of the Guidance on Particle – Technical Requirements¹¹ to substances that only meet the dissolution/degradation rate threshold under acidic conditions. After a period of internal consultation with EFSA Panels and Units and external consultation with the Nano Network¹⁴, based on the input received, a final draft was prepared and presented for discussion at the November Scientific Committee (SC) Plenary Meeting, held on 16 and 17 November 2022. The SC adopted unanimously the Annex and advanced few suggestions to improve clarity. During the present meeting, the WG refined the Annex accordingly and agreed on a final version for publication. The Annex will be published in the EFSA Journal as supporting publication to the Guidance on Particle – Technical Requirements¹¹ by the end of the year¹⁵.

8. Any Other Business

8.1. Feedback on the '8th meeting of the FCM Network'¹⁷ and on the 'Info session on applications for feed additives'¹⁸

With the aim of promoting a smooth and harmonised implementation of its Nano Guidances across EFSA sectors, EFSA was invited to participate to the '8th meeting of the FCM Network'¹⁶ and the 'Info session on applications for feed additives'¹⁷, both held on 24 November 2022 in Parma. The WG was updated on the outcome of both events and on the feedback received by Stakeholders. A dedicated discussion on the presentation given by FEFANA on the "Industry's views on the implications of the EFSA Nano guidance documents in feed additives applications" will be held at the next meetings.

8.2. Update on the review of the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283

Takis Daskaleros (DG SANTE) updated the WG on the status of the activities to revise the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283¹⁸ by the Commission Expert Group on Nanomaterials in Food. This revision is following the adoption of the Commission Recommendation on nanomaterial¹⁹, published in June 2022. The WG will be kept informed on further developments.

8.3. Confirmation of next meeting dates and workplan

The WG discussed and agreed the workplan and next meeting dates.

13 <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00355>

14 <https://www.efsa.europa.eu/it/science/scientific-committee-and-panels/scientific-committee#networks>

15 Published on 9 December 2022. Available at:

https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2021.6769&file=efs26769-sup-0001-Annex_A.pdf

16 <https://www.efsa.europa.eu/en/events/8th-meeting-fcm-network>

17 <https://www.efsa.europa.eu/en/events/info-session-applications-feed-additives>

18 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods. Available at: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283>

19 Nanomaterial definition of Commission Recommendation C(2022)3689. Available at:

https://ec.europa.eu/environment/chemicals/nanotech/pdf/C_2022_3689_1_EN_ACT_part1_v6.pdf

9. Next meetings

The next meetings are tentatively scheduled for:

- 18 January 2023, WEB-conference
- 21 February 2023, WEB-conference
- 20 March 2023 (Parma)
- 28 April 2023, WEB-conference
- 31 May 2023, WEB-conference
- 11 July 2023, WEB-conference
- 29 September 2023, WEB-conference
- 18 October 2023, WEB-conference
- 21 November 2023, WEB-conference



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 38TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 07 November 2022
(Agreed on 21 November 2022)**

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry (Chair)
Francesco Cubadda
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen¹
Stefan Weigel²

■ European Commission and/or Member States representatives:

Hubert Rausher (JRC)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo
Feed and Contaminants (FEEDCO) Unit: Orsolya Holczknecht
Food Ingredients and Packaging (FIP) Unit: Ana Rincon
Nutrition and Food Innovation (NIF) Unit: Reinhard Acker³

¹ Absent from agenda item 7

² Present from agenda item 6

³ Present from agenda item 6

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Roland Franz and Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted. The item on the 'Update on the revision of the definition of engineered nanomaterial in the Novel Food Regulation' was postponed to the next meeting.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 37th Working Group meeting held on 10 October 2022, by WEB-conference.

The minutes of the 37th Working Group meeting were agreed by written procedure on 24 October 2022⁶.

5. Scientific topic(s) for discussion

5.1. Requests for advice from the FEEDCO Unit on zinc chloride hydroxide monohydrate for all animal species (EFSA-Q-2021-00548⁷)

In the context of the implementation of its Guidance on Particle – Technical Requirements⁸, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the nutritional feed additives under renewal (i.e. trace elements) zinc chloride hydroxide monohydrate for all animal species (EFSA-Q-2021-00548⁷). After being presented with the new data submitted by the applicant, the WG discussed an advice that will be finalised and agreed by written procedure, before submission to the FEEDCO Unit.

5.2. Request for assistance from the FIP Unit on the re-evaluation of silicon dioxide (E 551) as a food additive (EFSA-Q-2018-00526⁹)

In the context of the implementation of its Nano Guidances^{6,10}, the ccWG Nano was asked for support from the EFSA Food Ingredients and Packaging (FIP) Unit on the re-evaluation of silicon dioxide (E 551) as food additive for infants below 16 weeks of age and as a follow-up to the 2018 ANS Panel Opinion¹¹ on the re-evaluation of silicon dioxide as a food additive (EFSA-Q-2018-00526).

During the present meeting, the WG revised the advice on nanoscale considerations for the assessment of the study design and study results of relevant toxicological evidence on E 551. The advice includes a summary table of the key elements produced to further support in the assessment of toxicological studies. A final version of the advice was agreed for submission to the FIP Unit.

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

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

6 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

7 <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00548?search=EFSA-Q-2021-00548>

8 EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp.

<https://doi.org/10.2903/j.efsa.2021.6769>

9 <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00526>

10 EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

11 <https://www.efsa.europa.eu/en/efsajournal/pub/5088>

6. Draft Annex on 'Degradation/dissolution rate under acidic conditions', produced to update the recently published Guidance on Particulate – TR⁶

The draft Annex on 'Degradation/dissolution rate under acidic conditions' has been produced to provide further clarifications regarding the application of the Guidance on Particulate – Technical Requirements to substances that only meet the dissolution/degradation rate threshold under acidic conditions. After formal endorsement at the April Scientific Committee (SC) plenary meeting, the draft document was subjected to a period of internal consultation with EFSA Panels and Units. The comments submitted were considered and an updated version of the draft Annex was presented for discussion and possible endorsement by the SC in July 2022 for an external consultation with the Nano Network. The comments received were discussed during the 12th Nano Network meeting, held on 24 and 25 October 2022. Based on the comments received, the ccWG Nano further refined the draft Annex and agreed on a final draft to be presented for discussion and possible adoption at the November 2022 EFSA SC Plenary Meeting.

7. Any Other Business

7.1. Feedback from the 12th NanoNetwork meeting

The ccWG Nano was updated on the outcome of the 12th meeting of the Network on Nanotechnologies in Food and Feed (NanoNetwork), which was held in the mornings of 24-25 October 2022 by WEB-conference¹². The WG was informed on the topics discussed and possible follow up activities.

7.2. Info session on applications for feed additives, questions on nano aspects submitted by stakeholders

In the context of promoting the smooth and harmonised implementation of its Nano Guidances EFSA is organising an 'Info session on applications for feed additives'¹³, which will take place on 24 November 2022. The WG discussed the questions submitted by Stakeholders on the Nano Guidances and elaborated on possible replies to be presented at the info session.

7.3. Confirmation of next meeting dates and workplan

The WG discussed and agreed the workplan and next meeting dates.

8. Next meetings

The next meeting is scheduled for:

- 30 November 2022, WEB-conference (from 9.00 to 13.00)

¹² <https://www.efsa.europa.eu/en/events/12th-meeting-efsa-scientific-network-risk-assessment-nanotechnologies-food-and-feed>

¹³ <https://www.efsa.europa.eu/it/events/info-session-applications-feed-additives>



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 37TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 10 October 2022
(Agreed on 24 October 2022)**

Participants

■ Working Group Members:

Jacqueline Castenmiller¹
Qasim Chaudhry
Francesco Cubadda
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel²

■ European Commission and/or Member States representatives:

Hubert Rausher (JRC)
Panagiotis Daskaleros (DG SANTE)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: Maria Chiara Astuto, Irene Cattaneo, Djien Liem.
Food Ingredients and Packaging (FIP) Unit: Ana Rincon, Camilla Smeraldi³, Stefania Barmaz³, Agnieszka Mech, Laura Ruggeri³.

¹ Absent for agenda item 7

² Present for agenda items 6 and 7

³ Present for agenda items 5 and 6

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 36th Working Group meeting held on 16 September 2022, by WEB-conference.

The minutes of the 36th Working Group meeting were agreed by written procedure on 3 October 2022⁶.

5. Scientific topic(s) for discussion

5.1. Request for assistance from the FIP Unit on the re-evaluation of silicon dioxide (E 551) as a food additive (EFSA-Q-2018-00526⁷)

In the context of the implementation of its Nano Guidances^{8,9}, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Food Ingredients and Packaging (FIP) Unit on the re-evaluation of silicon dioxide (E 551) as food additive for infants below 16 weeks of age and as a follow-up to the 2018 ANS Panel Opinion¹⁰ on the re-evaluation of silicon dioxide as a food additive (EFSA-Q-2018-00526).

The WG continued to progress on the preparation of an advice on nanoscale considerations for the assessment of the study design and study results of relevant toxicological evidence on E 551. After the delivery of the tasks allocated at the last meeting, the WG revised a summary table of the key elements of the advice produced to further support in the assessment of toxicological studies. A final version of the draft advice will be finalised by written procedure. If needed, further discussion will be held at the next WG meeting.

5.2. Discussion on the applicability of the Nano Guidances to certain hydrocolloids/macromolecular polysaccharides/gums

In relation to the agenda item presented at the previous ccWG Nano meeting in September, the WG was informed on the approach discussed at the 31st Panel on Food Additives and Flavourings (FAF) meeting with respect to the re-evaluation of sodium carboxy methyl cellulose (E 466) as a food additive in foods for infants below 16 weeks of age and follow up of its re-evaluation as food additive for uses in foods for all population groups (EFSA-Q-2018-00099¹¹) based on the data submitted by the applicant on the 'Safety evaluation strategy and corresponding testing strategy'. Suggestions for improvement by the WG members were noted and the outcome of the discussion will be submitted for further consideration by the FAF Panel.

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

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

6 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

7 <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00526>

8 <https://www.efsa.europa.eu/it/efsajournal/pub/6768>

9 <https://www.efsa.europa.eu/en/efsajournal/pub/6769>

10 <https://www.efsa.europa.eu/en/efsajournal/pub/5088>

11 <https://https://open.efsa.europa.eu/questions/EFSA-Q-2018-00099>

6. Examples of implementation of the Nano Guidances to biological substances

The WG discussed lessons learnt and experience gained from the application of its Nano Guidances to biological substances. A document is being produced to collect lessons learnt from all requests for assistance received and cases analysed so far. The idea is to keep it as a 'living document' and to be shared with EFSA Units to further promote the smooth and harmonised implementation of the Nano Guidances.

7. Any Other Business

7.1. Review of the European Commission definition of Nanomaterial

The ccWG Nano was informed on the ongoing activities to revise the definition of engineered nanomaterial of the Novel Food Regulation (EU) 2015/2283¹² by the Commission Expert Group on Nanomaterials in Food. This revision is following the adoption of the Commission Recommendation on nanomaterial¹³, published in June 2022. The ccWG Nano will be kept informed on relevant developments and discussions.

7.2. Update on the Nano Network organisation

The WG was informed on the ongoing activities to organise the 12th meeting of the Network on Nanotechnologies in Food and Feed (NanoNetwork), which will be held in the mornings of 24-25 October 2022 by WEB-conference.

7.3. Update on the Review of titanium dioxide as a food additive from the Food Standards Australia New Zealand (FSANZ)

The ccWG Nano was informed on the recently published Review of titanium dioxide as a food additive from the Food Standards Australia New Zealand (FSANZ)¹⁴.

7.4. Update on NANOCULTURE event

The WG was updated on the outcome of the NANOCULTURE Final Event held on 22 September 2022, where EFSA participated with a presentation on "EFSA 2021 guidance documents on risk assessment of nanoparticles and nanomaterials in food and feed chain". During the event, the result of the NANOCULTURE Project (Risk assessment and mitigation of the presence of engineered NANOmaterials in Atlantic aquaCULTURE), an Interreg Atlantic Area project, were presented.

7.5. Update on dissemination activities

In the context of promoting the smooth and harmonised dissemination of its Nano Guidances, the WG was informed of two upcoming activities, the EFSA Food Contact Materials (FCM) Network¹⁵ and the EFSA Info session on applications for feed additives¹⁶, which will take place in November 2022.

7.6. First commenting round on the draft new Study Report on applicability of the key event-based OECD TG 442D for *in vitro* skin sensitisation testing of nanomaterials

The ccWG Nano was informed that the first version of the draft new OECD Study Report on applicability of the key event-based TG 442D for *in vitro* skin sensitisation testing of nano-materials¹⁷, compiled by Switzerland, is ready for the first commenting round.

12 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods. Available at: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32015R2283>

13 Nanomaterial definition of Commission Recommendation C(2022)3689. Available at: https://ec.europa.eu/environment/chemicals/nanotech/pdf/C_2022_3689_1_EN_ACT_part1_v6.pdf

14 <https://www.foodstandards.gov.au/consumer/foodtech/Pages/Review-of-titanium-dioxide-as-a-food-additive.aspx>

15 <https://www.efsa.europa.eu/en/events/8th-meeting-fcm-network>

16 <https://www.efsa.europa.eu/it/events/info-session-applications-feed-additives>

17 <https://www.oecd.org/chemicalsafety/testing/draft-study-report-test-guideline-442D-in-vitro-skin-sensitisation-nanomaterials.pdf>

7.7. Confirmation of next meeting dates and workplan

The WG discussed and agreed the workplan and next meeting dates.

8. Next meetings

The next meetings are scheduled for:

- 7 November 2022, WEB-conference (from 9.00 to 13.00)
- 30 November 2022, WEB-conference (from 9.00 to 13.00)



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 36TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 16 September 2022
(Agreed on 3 October 2022)**

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
David Gott
Jan Mast
Alicja Mortensen¹
Agnes Oomen
Stefan Weigel

■ European Commission and/or Member States representatives:

Panagiotis Daskaleros (DG SANTE)

■ Hearing Expert²

Georges Bories (Member of the WG on Toxicology of the FEEDAP Panel)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: José Tarazona (Chair), Djien Liem³, Maria Chiara Astuto, Irene Cattaneo.
Feed and Contaminants (FEEDCO) Unit: Orsolya Holczknecht⁴ and Maria Vittoria Vettori⁵.
Food Ingredients and Packaging (FIP) Unit: Ana Rincon⁶.
Nutrition and Food Innovation (NIF) Unit: Tilemachos Goumperis, Emanuela Turla⁷.

1 Present from agenda item 6.4

2 As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:

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

3 Present for agenda item 9.1

4 Present for agenda item 6.4 and 6.5

5 Present for agenda item 6.4 and 6.5

6 Present for agenda item 6.1

7 Present for agenda items 6.2 and 6.3

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Roland Franz and Hubert Rauscher (JRC).

2. Adoption of agenda

The agenda was adopted with the addition of 'Discussion on the applicability of the Nano Guidances to certain hydrocolloids/macromolecular polysaccharides/gums' under Any Other Business.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁸ and the Decision of the Executive Director on Competing Interest Management⁹, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 35th Working Group meeting held on 11 July 2022, by WEB-conference.

The minutes of the 35th Working Group meeting were agreed by written procedure on 25 July 2022¹⁰.

5. Hearing Experts

Georges Bories (Member of the Working Group (WG) on Toxicology of the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)) was invited to present Item 6.4 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Request for assistance from the FIP Unit on the re-evaluation of silicon dioxide (E 551) as a food additive (EFSA-Q-2018-00526¹¹)

In the context of the implementation of its Nano Guidances^{12,13}, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Food Ingredients and Packaging (FIP) Unit on the re-evaluation of silicon dioxide (E 551) as food additive (EFSA-Q-2018-00526¹⁰) for infants below 16 weeks of age and as a follow-up to the 2018 ANS Panel Opinion on the re-evaluation of silicon dioxide as a food additive¹⁴.

After the delivery of the tasks allocated at the last meeting, the WG discussed a draft version of the advice on nanoscale considerations for the assessment of the study design and study results of relevant toxicological evidence on E 551. The WG agreed to produce a summary table of the key elements of the advice to further support in the assessment of toxicological studies. In this regard, additional tasks were distributed to WG members and a revised draft advice for discussion will be presented at the next WG meeting.

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

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

10 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

11 <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00526>

12 <https://www.efsa.europa.eu/it/efsajournal/pub/6768>

13 <https://www.efsa.europa.eu/en/efsajournal/pub/6769>

14 <https://www.efsa.europa.eu/en/efsajournal/pub/5088>

6.2. Request for assistance from the NIF Unit on Powder of Chitosan (EFSA-Q-2019-00324¹⁵)

In the context of the application of its Guidance on Particle – Technical Requirements¹², the ccWG Nano was requested for support by the EFSA Nutrition and Food Innovation (NIF) Unit on the Novel Food dossier ‘Powder of Chitosan’ (EFSA-Q-2019-00324). The WG was updated with the new information submitted by the applicant. After a short discussion, the WG agreed on the advice to be submitted to the requestor.

6.3. Request for assistance from the NIF Unit on Urolithin A (EFSA-Q-2018-00724¹⁶)

In the context of the application of its Guidance on Particle – Technical Requirements, the ccWG Nano was requested for support by the EFSA NIF Unit on the Novel Food dossier Urolithin A (EFSA-Q-2018-00724). The WG was presented with the response and new information provided by the applicant on particle size. After a discussion, the WG agreed on the advice to be submitted to the requestor.

6.4. Request for assistance from the FEEDCO Unit on Cycostat 66G[®] (Robenidine hydrochloride¹⁷) for rabbits for breeding and for fattening (EFSA-Q-2020-00539)

In the context of the implementation of its Guidance on Particle – Technical Requirements, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the coccidiostat feed additive Cycostat 66G[®] (Robenidine hydrochloride) for rabbits for breeding and for fattening (EFSA-Q-2020-00539). After a discussion on the reply submitted by the applicant and the available information, the WG agreed on a final advice to be submitted to the requesting Unit.

6.5. Request for assistance from the FEEDCO Unit on Elancoban[®] (monensin sodium) for chickens for fattening, chickens reared for laying and turkeys (EFSA-Q-2021-00537)¹⁸

In the context of the implementation of its Guidance on Particle – Technical Requirements, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on the coccidiostat feed additive Elancoban[®] (monensin sodium) for chickens for fattening, chickens reared for laying and turkeys (EFSA-Q-2021-00537). The ccWG Nano continued the discussion and the final advice has been agreed.

7. Proposal for a Scientific Publication on Nano

The WG was updated on the status of the manuscript and agreed on proceeding with its finalisation. A final version of the manuscript will be shared with the WG members before submission to the selected scientific journal.

8. Any Other Business

8.1. Handover of ccWG Nano Chairmanship

The WG was informed that the current Chair of the WG, Jose Tarazona, will leave EFSA by end of September 2022. EFSA is organizing the handover of the ccWG Nano Chairmanship and will keep the WG informed of any update.

15 <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00324>

16 <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00724?search=>

17 <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00539>

18 <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00537>

8.2. Update on the implementation of the Nano guidances in the area of feed additives

The WG was updated that on 16 September 2022 members of the WG on Toxicology and the WG on Animal nutrition of the FEEDAP Panel discussed the implementation and applicability of the Nano Guidances to the risk assessment of feed additives.¹⁹

8.3. Update on NanoNetwork organisation

The WG was informed on the ongoing activities for the organisation of the 12th meeting of the Network on Nanotechnologies in Food and Feed (NanoNetwork), which will be held in the mornings of 24-25 October 2022 by WEB-conference.

8.4. NANOCULTURE Final Event: presentation “EFSA 2021 guidance documents on risk assessment of nanoparticles and nanomaterials in food and feed chain”

The WG was informed on the upcoming NANOCULTURE Final Event²⁰ (22 September 2022), where EFSA will provide a presentation on the Nano Guidances. NANOCULTURE (Risk assessment and mitigation of the presence of engineered NANOMaterials in Atlantic aquaCULTURE), an Interreg Atlantic Area project, will provide knowledge (and tools) on the presence and effects of the most-used nanoparticles (TiO₂ and Ag) in the most common Atlantic Area aquaculture products (turbot, mussels, seaweed); and will assess the human risk of exposure by oral intake of these products.

8.5. Discussion on the applicability of the Nano Guidances to certain hydrocolloids/macromolecular polysaccharides/gums

The WG was briefly presented with the topic and agreed to organise a follow up discussion based on real examples among EFSA sectors as soon they become available.

8.6. Confirmation of next meeting dates and workplan

The WG discussed and agreed the workplan and next meeting dates.

9. Next meetings

The next meetings are scheduled for:

- 10 October 2022, WEB-conference (from 9.00 to 13.00)
- 7 November 2022, WEB-conference (from 9.00 to 13.00)
- 30 November 2022, WEB-conference (from 9.00 to 13.00)

¹⁹ <https://www.efsa.europa.eu/sites/default/files/wgs/feed-additives/wg-toxicology-2018-2021.pdf>

²⁰ <https://nanoculture.ciimar.up.pt/>



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 35TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 11 July 2022
(Agreed on 25 June 2022)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)
Panagiotis Daskaleros (DG SANTE)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: José Tarazona (Chair), Maria Chiara Astuto, Irene Cattaneo.

Feed and Contaminants (FEEDCO) Unit¹: Orsolya Holczknecht.

Food Ingredients and Packaging (FIP) Unit²: Ana Rincon, Agnieszka Mech.

Nutrition and Food Innovation (NIF) Unit: Reinhilde Schoonjans³.

1 Present for agenda item 5.1, 5.2 and 5.3

2 Present for agenda item 5.4 and 5.5

3 Present for agenda item 6

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from Stefan Weigel.

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 Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 34th Working Group meeting held on 13 June 2022, by WEB-conference.

The minutes of the 34th Working Group meeting were agreed by written procedure on 23 June 2022⁶.

5. Scientific topic(s) for discussion

5.1. Request for assistance from the FEEDCO Unit on one example of coccidiostat feed additive (Elancoban®/monensin sodium (EFSA-Q-2021-00537'))

In the context of the implementation of its Guidance on Particle – Technical Requirements⁸, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on one example of feed additive from the category of coccidiostats, Elancoban®/monensin sodium (EFSA-Q-2021-00537'). The ccWG Nano provided the FEEDCO Unit with some recommendations on the information to be requested to the applicant regarding specific information requirements needed to address nano aspects. Further discussion on the advice to be submitted to the FEEDCO Unit is scheduled for the next meeting.

5.2. Request for assistance from the FEEDCO Unit on examples of technological feed additives of mineral origin (i.e. clays)

In the context of the implementation of its Nano Guidances^{8,9}, the ccWG Nano was asked for support from the EFSA FEEDCO Unit on examples of technological feed additives of mineral origin (i.e. clays). The advice on two examples, previously discussed during WG meetings held on 5 April and 16 May 2022, was finalised to be submitted to the FEEDCO Unit.

5.3. Standard letter for nanostructured/nanomaterials feed additives

In the context of the implementation of its Nano Guidances^{8,9}, the ccWG Nano was presented by the FEEDCO Unit with a standard letter targeted to applicants on safety evaluation strategy and

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

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

6 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

7 <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00537>

8 EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

9 EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

corresponding testing strategy for materials that may be present in a nanostructured form and/or may contain a fraction of particles in the nano range.

5.4. Request for assistance from the FIP Unit on the re-evaluation of silicon dioxide (E 551) as a food additive (EFSA-Q-2018-00526¹⁰)

In the context of the implementation of its Nano Guidances^{8,9}, the ccWG Nano was asked for support from the EFSA Food Ingredients and Packaging (FIP) Unit on the re-evaluation of silicon dioxide (E 551) as food additive (EFSA-Q-2018-00526¹⁰) for infants below 16 weeks of age and as a follow-up to the 2018 ANS Panel Opinion on the re-evaluation of silicon dioxide as a food additive¹¹. The WG continued the discussion on technical aspects concerning physicochemical characterisation of the material and suitable methodology of analysis. Further discussion on the elements to be considered to draft the advice on nanoscale considerations for the assessment of the study design and study results of relevant toxicity studies for the assessment of this food additive was held. A revised draft for discussion will be presented at the next WG meeting.

5.5. Request for assistance from the FIP Unit on a list of food additives with specific internal structure

In the context of the implementation of its Nano Guidances^{8,9}, the ccWG Nano was asked for support from the WG on Specification of Food Additives of the EFSA Panel on Food Additives and Flavourings (FAF) on a list of food additives with internal structure (e.g. E 552) similar to E 551. Further discussion on this topic is expected at the next WG meeting.

6. Proposal for a Scientific Publication on Nano

The ccWG Nano updated on the status of the manuscript and agreed on proceeding with its finalisation. The draft text will be further refined before being reviewed from the WG members in its final version.

7. Any Other Business

7.1. Update on the draft Annex on 'Degradation/dissolution rate under acidic conditions', produced to update the Guidance on Particle – Technical requirements⁸

The ccWG Nano was informed that the draft Annex on 'Degradation/dissolution rate under acidic conditions' was endorsed with unanimity at the last Scientific Committee Plenary meeting for an external consultation with the NanoNetwork¹². All comments received on the draft Annex will be discussed at the annual NanoNetwork meeting, which is scheduled for 24-25 October 2022. The intention is to finalise the draft Annex and update the Guidance on Particle – Technical Requirements⁸ by end of 2022.

7.2. Update on the EFSA's call for proposals on the outsourced activity NAMS4NANO

The ccWG Nano was informed on the publication of the call for proposals "GP/EFSA/MESE/2022/01 - NAMS4NANO: Integration of New Approach Methodologies results in chemical risk assessments: Case studies addressing nanoscale considerations"¹³. The main objective of the call is to establish a partnership between EFSA and grant beneficiaries to implement the New Approach Methodology (NAM)-based data integration activities in chemicals risk assessment described in the recently

10 <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00526>

11 <https://www.efsa.europa.eu/en/efsajournal/pub/5088>

12 <https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/scientific-committee#networks>

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

published EFSA Roadmap for NAMs¹⁴. The call asks Member States organisations to submit proposals for case studies covering the nanoscale considerations using NAMs instead of new animal studies.

7.3. Report on TiO₂ as a food additive from Health Canada

The ccWG Nano was informed of the completion of a "state of the science" report on titanium dioxide (TiO₂) as a food additive by the Health Canada's Food Directorate.¹⁵

7.4. Workplan and next meetings

The WG discussed and agreed the workplan and next meeting dates, which are scheduled as a teleconference as follows:

- 16 September 2022 (from 14.00 to 18.00)
- 10 October 2022 (from 9.00 to 13.00)
- 7 November 2022 (from 9.00 to 13.00)
- 30 November 2022 (from 9.00 to 13.00)

¹⁴ <https://www.efsa.europa.eu/it/supporting/pub/en-7341>

¹⁵ <https://www.canada.ca/en/health-canada/services/food-nutrition/reports-publications/titanium-dioxide-food-additive-science-report.html>



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 34th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 13 June 2022
(Agreed on 23 June 2022)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel¹

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)
Panagiotis Daskaleros (DG SANTE)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: José Tarazona (Chair), Maria Chiara Astuto, Irene Cattaneo.

Feed and Contaminants (FEEDCO) Unit²: Orsolya Holczknecht, Maria Vittoria Vettori, Rita Navarrete, Daniel Plaza.

Food Ingredients and Packaging (FIP) Unit: Ana Rincon³, Stavroula Sampani.

Nutrition and Food Innovation (NIF) Unit: Reinhilde Schoonjans⁴.

¹ Present for agenda items 6, 7 and 8.

² Present for agenda item 5.1 and 5.2

³ Present for agenda item 5.3

⁴ Present for agenda item 7

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the introduction of the item "Request from the WG on Specification of Food Additives of the FAF Panel (EFSA Panel on Food Additives and Flavourings) on dissolution rate method (Guidance on Particle-TR)" under Any Other Business.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 33rd Working Group meeting held on 16 May 2021, by WEB-conference.

The minutes of the 33rd Working Group meeting were agreed by written procedure on 1 June 2022⁷.

5. Discussion on cases

5.1. Request for assistance from the FEEDCO Unit on examples of coccidiostat feed additives (Quinox/decoquinat (EFSA-Q-2021-00428⁸) and Nicacox/nicarbazin (EFSA-Q-2021-00259⁹))

In the context of the implementation of its Guidance on Particle – Technical Requirements¹⁰, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on two examples of feed additives from the category of coccidiostats and histomonostats, Quinox/decoquinat (EFSA-Q-2021-00428) and Nicacox/nicarbazin (EFSA-Q-2021-00259). The advice to be submitted to the FEEDCO Unit was discussed and finally agreed by the WG members.

5.2. Request for assistance from the FEEDCO Unit on generic approaches for the implementation of the Nano Guidances on technological feed additives of mineral origin (i.e. clays) and coccidiostat feed additives

In the context of the implementation of its Nano Guidances^{10,14}, the ccWG Nano was asked for advice from the EFSA FEEDCO Unit on a list of application dossiers of technological feed additives of mineral

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

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

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

8 <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00428>

9 <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00259>

10 EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

origin (i.e. clays)¹¹ and on a list of application dossiers of coccidiostat feed additives¹². The ccWG Nano provided the FEEDCO Unit with some recommendations on the information to be requested to applicants regarding specific information requirements needed to address nano aspects.

5.3. Request for assistance from the FIP Unit on the re-evaluation of silicon dioxide (E 551) as a food additive (EFSA-Q-2018-00526)¹³

In the context of the implementation of its Nano Guidances^{10,14}, the ccWG Nano was asked for support from the EFSA Food Ingredients and Packaging (FIP) Unit on the re-evaluation of Silicon Dioxide (E551) as food additive (EFSA-Q-2018-00526) for infants below 16 weeks of age and as a follow-up to the 2018 ANS Panel Opinion on the re-evaluation of silicon dioxide as a food additive¹⁵. The WG discussed some technical aspects concerning the material's data on particle size characterisation submitted by the applicant. Further discussion on the elements to be considered to draft the advice on nanoscale considerations for the assessment of the study design and study results of E551 toxicity studies was held. A first draft for discussion will be presented at the next WG meeting.

6. Draft Annex on 'Degradation/dissolution rate under acidic conditions', produced to update the recently published Guidance on Particle – TR¹⁰

The draft Annex on 'Degradation/dissolution rate under acidic conditions' has been produced to provide further clarifications regarding the application of the Guidance on Particle – Technical Requirements¹⁰ to substances that only meet the dissolution/degradation rate threshold under acidic conditions. After formal endorsement at the April Scientific Committee (SC) plenary meeting, the draft document was subjected to a period of internal consultation with EFSA Panels and Units. During the present meeting, the WG revised the draft Annex based on the feedback received from the internal consultation and agreed on a new version of the document to be presented at the next SC plenary meeting (5-6 July 2022) for endorsement by the SC in order to initiate the consultation with the Nanonetwork.

7. Proposal for a Scientific Publication on Nano

The WG Nano updated on the status of the manuscript and agreed on proceeding with its finalisation. The draft text will be further refined before being reviewed from the WG members in its final version.

11 Technological feed additives of mineral origin (Clays):

- Kaolinitics clays, free of asbestos (E 559) for all animal species (EFSA-Q-2019-00527)
- Sepiolite and diatomaceous earth for all terrestrial species (EFSA-Q-2019-00301)
- Kieselgur (diatomaceous earth, purified) for all animal species (EFSA-Q-2019-00662)
- E 566 Natrolite-phonolite (PHIL 75®) for all animal species (EFSA-Q-2014-00888)
- Natrolith-Phonolith for all animal species (EFSA-Q-2014-00890)
- E 551a silicic acid, precipitated and dried and E 551b colloidal silica for all animal species (EFSA-Q-2014-00887)
- Silicic acid, precipitated and dried (E 551 a) for all animal species (EFSA-Q-2015-00518)
- Synthetic calcium silicate (E552) for all animal species (EFSA-Q-2014-00886)

12 Coccidiostat feed additives:

- Coxidin (monensin sodium; carrier wheat bran) for chickens for fattening and turkeys for fattening and Coxidin (monensin sodium; carrier calcium carbonate) for chickens for fattening, chickens reared for laying and turkeys for fattening (EFSA-Q-2016-00643 and EFSA-Q-2020-00405)
- Clinacox 0.5% (diclazuril) for chickens for fattening and Clinacox 0.5% (diclazuril) for chickens reared for laying (EFSA-Q-2020-00201 and EFSA-Q-2020-00203)
- AVATEC® 150G (lasalocid A sodium) for turkeys for fattening and AVATEC® 150G (lasalocid A sodium) for pheasants, guinea fowl, quails and partridges (EFSA-Q-2019-00745 and EFSA-Q-2020-00597)
- Maxiban G160 (narasin and nicarbazin) for chickens for fattening (EFSA-Q-2019-00739)
- Nicarb® (nicarbazin) for chickens for fattening (EFSA-Q-2019-00768)
- Sacox® (salinomycin sodium) for rabbits for fattening (EFSA-Q-2020-00282)
- Cycostat 66 G (robenidine hydrochloride) for rabbits for breeding and rabbits for fattening (EFSA-Q-2020-00539)
- Coxiril (diclazuril) for chickens for fattening, turkeys for fattening, other - guinea fowl for fattening and breeding (EFSA-Q-2021-00472)
- Stenorol® (halofuginone hydrobromide) for chickens for fattening and turkeys (EFSA-Q-2021-00321)
- Monteban® G100 (narasin) for chickens for fattening (EFSA-Q-2020-00557)

13 <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00526>

14 EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

15 <https://www.efsa.europa.eu/en/efsajournal/pub/5088>

8. Any Other Business

8.1. Request of the WG on Specification of Food Additives of the FAF Panel on dissolution rate method (Guidance on Particulate – TR¹⁰)

Upon a request of the WG on Specification of Food Additives of the EFSA Panel on Food Additives and Flavourings (FAF), advice regarding the exact starting point of the method to be applied for the dissolution rate described in the Guidance on Particulate - TR¹⁰ was asked and discussed. It was reiterated that focusing on the half-life, instead of the value at 30 min, could facilitate the interpretation of the results.

8.2. Workplan and next meetings

The WG discussed and agreed the workplan and next meeting dates, which are scheduled as a teleconference as follows:

- 11 July 2022 (from 9.00 to 13.00)
- 16 September 2022 (from 14.00 to 18.00)
- 10 October 2022 (from 9.00 to 13.00)
- 7 November 2022 (from 9.00 to 13.00)
- 30 November 2022 (from 9.00 to 13.00)



SCIENTIFIC COMMITTEE

MINUTES OF THE 33rd MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 16 May 2022
(Agreed on 1 June 2022)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel¹

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)²
Panagiotis Daskaleros (DG SANTE)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: José Tarazona (Chair), Maria Chiara Astuto, Irene Cattaneo.

Feed and Contaminants (FEEDCO) Unit³: Orsolya Holczknecht, Fabiola Pizzo, Anita Radovnikovic, Rita Navarrete, Daniel Plaza.

Food Ingredients and Packaging (FIP) Unit⁴: Ana Rincon, Agnieszka Mech.

Nutrition and Food Innovation (NIF) Unit: Annamaria Rossi⁵, Paolo Colombo⁶.

¹ Absent for agenda items 5.4, 5.5 and 7

² Present for agenda items 5.3 and 6

³ Present for agenda item 5.1 and 5.2

⁴ Present for agenda item 5.3

⁵ Present for agenda item 5.4

⁶ Present for agenda item 5.5

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 Independence⁷ and the Decision of the Executive Director on Competing Interest Management⁸, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 32nd Working Group meeting held on 5 April 2021, by WEB-conference.

The minutes of the 32nd Working Group meeting were agreed by written procedure on 22 April 2022⁹.

5. Discussion on cases

5.1. Request for assistance from the FEEDCO Unit on examples of technological feed additives of mineral origin (i.e. clays)

In the context of the implementation of its Guidance on Particle – Technical Requirements¹⁰, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on examples of technological feed additives of mineral origin (i.e. clays). Two examples were discussed and further discussion is scheduled for the next meeting on a broader list of application dossiers on this type of feed additives to provide a final advice based on the specific features of each substance. The ccWG Nano and the FEEDCO Unit also agreed to consider the preparation of a Technical Report focused on the implementation of the Nano Guidances to clays as feed additives, in order to cover general nano considerations for future dossiers under assessment.

5.2. Request for assistance from the FEEDCO Unit on examples of coccidiostat feed additives (Quinox/decoquinate (EFSA-Q-2021-00428¹¹) and Nicacox/nicarbazin (EFSA-Q-2021-00259¹²))

In the context of the implementation of its Guidance on Particle – Technical Requirements¹⁰, the ccWG Nano was asked for support from the EFSA FEEDCO Unit on two examples of feed additives from the category of coccidiostats and histomonostats, Quinox/decoquinate (EFSA-Q-2021-00428) and Nicacox/nicarbazin (EFSA-Q-2021-00259). Further discussion in this regard and finalisation of an advice to be submitted to the FEEDCO Unit is scheduled for the next meeting.

5.3. Request for assistance from the FIP Unit on the re-evaluation of silicon dioxide (E 551) as a food additive (EFSA-Q-2018-00526¹³)

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

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

9 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

10 EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

11 <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00428>

12 <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00259>

13 <https://open.efsa.europa.eu/questions/EFSA-Q-2018-00526>

In the context of the implementation of its Nano Guidances^{10,14}, the ccWG Nano was asked for support from the EFSA Food Ingredients and Packaging (FIP) Unit on the re-evaluation of Silicon Dioxide (E551) as food additive (EFSA-Q-2018-00526) for infants below 16 weeks of age and as a follow-up to the 2018 ANS Panel Opinion on the re-evaluation of silicon dioxide as a food additive¹⁵. The ccWG Nano was asked to provide feedback on a list of search terms to perform an open literature search. Also, the WG was requested to produce an advice on nanoscale considerations for the assessment of the study design and study results of E 551 toxicity studies by September 2022. Further discussion on this request is scheduled for the next WG meeting.

5.4. Request for assistance from the NIF Unit on Cannabidiol (CBD) as Novel Food

In the context of the implementation of its Nano Guidances^{10,11}, the ccWG Nano was asked for support from the EFSA Nutrition and Feed Innovation (NIF) Unit on the evaluation of Cannabidiol (CBD) dossiers. Following the discussion, the ccWG Nano agreed on the best way forward to finalise an advice that will be agreed by written procedure and submitted to the WG on Novel Foods.

5.5. Request for assistance from the Working Group on Novel Foods on PPST-L® as Novel Food (EFSA-Q-2019-00549¹⁶)

In the context of the implementation of its Nano Guidances^{10,11}, the ccWG Nano was asked for support by the WG on Novel Foods of the Scientific Panel on Nutrition, Novel Foods and Food Allergens (NDA) on the Novel Food Application of phosphopropylsilanetriol stabilized on lactose (PPST-L®) (EFSA-Q-2019-00549). The ccWG Nano was previously consulted for advice on this case and after discussing the new request, it was decided that an advice will be agreed by written procedure and submitted to the WG on Novel Foods.

6. Proposal for a Scientific Publication on Nano

The WG revised the content of the draft manuscript based on the proposals received from the different members and agreed to proceed with the finalisation by written procedure.

7. Any Other Business

7.1. Workplan and next meetings

The WG discussed and agreed the workplan and next meeting dates, which are scheduled as a teleconference as follows:

- 13 June 2022 (from 9.00 to 13.00)
- 11 July 2022 (from 9.00 to 13.00)
- 16 September 2022 (from 14.00 to 18.00)
- 10 October 2022 (from 9.00 to 13.00)
- 7 November 2022 (from 9.00 to 13.00)
- 30 November 2022 (from 9.00 to 13.00)

14 EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

15 <https://www.efsa.europa.eu/en/efsajournal/pub/5088>

16 <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00549>



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 32nd MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 05 April 2022
(Agreed on 22 April 2022)

Participants

■ Working Group Members:

Jacqueline Castenmiller¹
Qasim Chaudhry
Francesco Cubadda
Roland Franz
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)
Panagiotis Daskaleros (DG SANTE)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: José Tarazona (Chair), Maria Chiara Astuto, Irene Cattaneo

Feed and Contaminants (FEEDCO) Unit²: Orsolya Holczknecht, Fabiola Pizzo, Anita Radovnikovic, Rita Navarrete, Daniel Plaza.

¹ Absent for agenda items 8 and 9

² Present for agenda item 5

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies for absence were received from David Gott.

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 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 31st Working Group meeting held on 03 March 2021, by WEB-conference.

The minutes of the 31st Working Group meeting were agreed by written procedure on 21 March 2022⁵.

5. Discussion on cases

5.1. Request for assistance from the FEEDCO Unit in the context of the implementation of the Guidance on Particulate – Technical Requirements to examples of technological feed additives of mineral origin (i.e. clays)

In the context of the implementation of its Guidance on Particulate – Technical Requirements⁶, the cross-cutting Working Group on Nanotechnologies (hereafter ccWG Nano) was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on examples of technological feed additives of mineral origin (i.e. clays). Two examples were discussed as preparatory work for future assessments and renewal on this group. After discussing the available data, it was agreed to continue the discussion on the advice at the next WG meeting.

5.2. Request for assistance from the FEEDCO Unit in the context of the implementation of the Guidance on Particulate – Technical Requirements to examples of nutritional feed additives (i.e. trace elements)

In the context of the implementation of its Guidance on Particulate – Technical Requirements⁶, the ccWG Nano was asked for support from the EFSA Feed and Contaminants (FEEDCO) Unit on two cases of nutritional feed additives under renewal (i.e. trace elements), Dicopper chloride trihydroxide (EFSA-Q-2021-00547) and Zinc chloride hydroxide monohydrate (EFSA-Q-2021-00548). After discussing the available data, it was decided that a written advice will be agreed by written procedure and submitted to the FEEDCO Unit.

6. Stakeholder workshop on small particles and nanoparticles in food

The Chair congratulated with the WG members for the successful outcome of the EFSA Stakeholder Workshop on small particles and nanoparticles in food⁷, held as two half-day meetings on the 31st of

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

5 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

6 EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

7 <https://www.efsa.europa.eu/it/events/stakeholder-workshop-small-particles-and-nanoparticles-food>

March and 1st of April 2022. As follow-up activity to the event, the WG members will prepare and publish a comprehensive document including questions asked from participants during the Workshop with related replies. The questions will be presented as generalised issues and grouped by topic following the structure of the guidance documents.

7. Scientific topics for discussion

7.1. Annex on “RA considerations in the process for setting the threshold related only to the fraction of small particles”

The WG members discussed the draft proposal for the Annex “Dissolution/degradation rate under acidic conditions” that will provide further clarifications regarding the application of the Guidance on Particle – Technical Requirements⁶ to substances that only meet the dissolution/degradation rate threshold under acidic conditions. The Annex will specify for these cases a dissolution test under similar conditions but at pH 5, aiming to cover the group of infants under 16 weeks of age for which standard dissolution tests prescribed at pH 3 and 7 are not considered the physiologically relevant range. The Annex will also include additional specific recommendations for the interpretation of the results for substances that only reach the degradation/dissolution test under acidic conditions. The draft proposal will be finalised by the WG members through written procedure and presented to the Scientific Committee (SC) for endorsement at the next SC Plenary on 27-28 April 2022. The Annex will then be subjected to a first internal consultation with EFSA Panels and Units and to an external one with the Nanonetwork.

8. Proposal for a Scientific Publication on Nano

The WG revised the content of the draft manuscript based on the proposals received from the different members and agreed to proceed with the finalisation at the next WG meeting.

9. Any Other Business

9.1. Update of EFSA project on integration of NAMs data for nanomaterials (NAMS4NANO)

The WG was updated on the new EFSA project on integration of NAMs data for nanomaterials (NAMS4NANO) to develop proof of concept case studies demonstrating that in the food/feed area, Integrated Approaches to Testing and Assessment (IATAs) based on existing knowledge combined with New Approach Methodologies (NAMs) for addressing mechanistically nano-specific issues, provide better information for safety assessment than new *in vivo* studies. A dedicated workshop to brainstorm with experts in the field on current methods for avoiding or limiting animal testing is scheduled for 12 April 2022. The meeting will be aimed at discussing which methods and tools can be prioritised in the nano food and feed area, and the input received will be used to draft the technical specifications for the project.

9.2. Workplan and next meetings

The WG discussed and agreed the workplan and next meeting dates, which are scheduled as a teleconference as follows:

- 16 May 2022 (from 9.00 to 13.00)
- 13 June 2022 (from 9.00 to 13.00)
- 11 July 2022 (from 9.00 to 13.00)
- 16 September 2022 (from 14.00 to 18.00)
- 10 October 2022 (from 9.00 to 13.00)
- 7 November 2022 (from 9.00 to 13.00)
- 30 November 2022 (from 9.00 to 13.00)



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 31st MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 03 March 2022
(Agreed on 21 March 2022)**

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen¹
Agnes Oomen
Stefan Weigel

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)
Panagiotis Daskaleros (DG SANTE)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: José Tarazona (Chair), Maria Chiara Astuto, Irene Cattaneo

Nutrition and Food Innovation (NIF) Unit: Paolo Colombo², Reinhilde Schoonjans³.

¹ Present until agenda Item 5

² Present for Agenda Item 7.1

³ Present for Agenda Item 8

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 Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 30th Working Group meeting held on 29 November 2021, by WEB-conference.

The minutes of the 29th Working Group meeting were agreed by written procedure on 10 February 2022⁶.

5. Stakeholder workshop on small particles and nanoparticles in food

The WG was informed with additional details on the programme of the event⁷, the external experts involved and some organisational and practical aspects. The cross-cutting WG on Nanotechnologies further discussed on proposals for presentations to be shared during the meeting on examples of implementation of the Nano Guidances covering the most relevant generic issues.

6. Scientific topics for discussion

6.1. Considerations for substances that only dissolve under acidic conditions

The WG members discussed and agreed on the need for providing further clarifications regarding the application of the Guidance on Particle - Technical Requirements⁸ to substances that only meet the dissolution/degradation rate threshold under acidic conditions. One of the elements discussed and initially agreed was the need for conducting, in these cases, a dissolution test under similar conditions but at pH 5, which is considered physiologically more relevant for young infants below the age of 16 weeks; results at this intermediate pH may also be needed, in certain cases, to cover other children groups. Other elements, such as the influence of the presence of food in the gastrointestinal tract could be addressed as recommendations regarding the interpretation of the results. The WG confirmed that the inclusion of a new Annex with recommendations for the interpretation of the results for substances that only reach the degradation/dissolution rate threshold under acidic conditions is the best approach for handling this issue. This proposal will be presented to the Scientific Committee for their endorsement. Tasks allocations were also agreed.

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

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁷ <https://www.efsa.europa.eu/en/events/stakeholder-workshop-small-particles-and-nanoparticles-food>

⁸ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

Moreover, the WG finalised the discussion on possible effects of the food matrix on dissolution of nanocoated materials. The WG concluded that no amendments to the Guidance on Particle - Technical Requirements are needed, since the Guidance already covers nano specific testing considerations.

7. Discussion on cases

7.1. PPST-L (EFSA-Q-2019-00549)⁹

In the context of the application of its Nano Guidances, the cross-cutting WG on Nanotechnologies (hereafter ccWG Nano) was informed and updated by the WG on Novel Foods of the Scientific Panel on Nutrition, Novel Foods and Food Allergens on the Novel Food Application of phosphopropylsilanetriol stabilized on lactose (PPST-L[®]) as a novel food and 'nutrient' source for silicon to be used in food supplements (EFSA-Q-2019-00549). The ccWG Nano acknowledged the outcome and the conclusions that the WG on Novel Foods reached on this already discussed case.

7.2. Risk Assessment considerations in the process for setting the threshold related only to the fraction of small particles

Jan Mast reported to the ccWG Nano some reflections on a specific case in which a material could have less than 10% of the particles (number-based) with at least one external dimension smaller than 250 nm when considering all the particles, but more than 10% if considering the sub-500 nm fraction. The WG acknowledged that this peculiar situation could generally occur when setting a threshold, but no contradictions in the Guidance on Particle - Technical Requirements are present. The WG concluded that as the current approach in the Guidance is conservative, no need for refinement is required.

8. Proposal for a Scientific Publication on Nano

The WG revised the content of the draft manuscript based on the proposals received from the different members. Further elements for improvement were identified and additional tasks were distributed among the WG members.

9. Any Other Business

9.1. Workplan and next meetings

The WG discussed and agreed the workplan and next meeting dates, which are scheduled as a teleconference as follows:

- 5 April 2022 (from 9.00 to 13.00)
- 16 May 2022 (from 9.00 to 13.00)
- 13 June 2022 (from 9.00 to 13.00)
- 11 July 2022 (from 9.00 to 13.00)
- 16 September 2022 (from 14.00 to 18.00)
- 10 October 2022 (from 9.00 to 13.00)
- 7 November 2022 (from 9.00 to 13.00)
- 30 November 2022 (from 9.00 to 13.00)

⁹ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00549>



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 30th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 28 January 2022
(Agreed on 10 February 2022)**

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)
Panagiotis Daskaleros (DG SANTE)

■ EFSA:

Methodology and Scientific Support (MESE) Unit: José Tarazona (Chair), Maria Chiara Astuto, Irene Cattaneo

Nutrition and Food Innovation (NIF) Unit: Reinhard Ackerl¹, Ruth Roldan Torres², Reinhilde Schoonjans³.

¹ Present for Agenda Item 9.1

² Present for Agenda Item 9.2

³ Present for Agenda Item 6

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the addition of Item 10.1 on Nano-precipitated Calcium Carbonate under Any Other Business.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 29th Working Group meeting held on 29 November 2021, by WEB-conference.

The minutes of the 29th Working Group meeting were agreed during the meeting on 29 November 2021⁶.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed.

6. Proposal for a Scientific Publication on Nano

The WG revised the content of the draft manuscript based on the proposals received from the different members. Further elements for improvement were identified and additional tasks were distributed among the WG members.

7. Stakeholder workshop on small particles and nanoparticles in food

The WG was informed about the publication on the EFSA website of the announcement and programme⁷ of the Stakeholder workshop on small particles and nanoparticles in food. The Workshop, originally planned as a hybrid event, was converted to fully online mode due to the current pandemic situation. The cross-cutting WG on Nanotechnologies will be part of the organising committee of the meeting and its experts will be invited to present examples of implementation of the Nano Guidances to actual cases. A provisional task allocation was agreed and proposals for presentations will be shared with the WG members for discussion at the next meeting.

8. Scientific topics for discussion

8.1. Guidance on Particle – Technical Requirements: pH value for infants below 16 weeks of age

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

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁷ <https://www.efsa.europa.eu/en/events/stakeholder-workshop-small-particles-and-nanoparticles-food>

The WG members discussed whether the pH values for the dissolution test indicated in the Guidance on Particle - Technical Requirements⁸ also cover the gastrointestinal conditions of infants below 16 weeks of age. The WG considers that, being this age group characterised by a less acidic pH in the gastrointestinal tract than other age groups, a clarification in the Guidance might be needed to adapt the technical requirements in case of applications intended for this age group. Further discussion on this topic is expected for the next meeting.

8.2. NAMs for nanoparticles risk assessment

The Chair announced that EFSA is considering a proposal for launching a new project on the use of New Approach Methodologies (NAMs) for the development of IATA protocols based on non-animal testing for the risk assessment of nanoparticles in food. If, following the internal prioritisation by EFSA, this activity is launched, the WG members will be invited to participate, also involving the organisations under the Nanonetwork, for contributing with their relevant expertise to the design and development of the project. The ccWG members supported this proposal and confirmed that NAMs are promising tools for reducing animal testing and improving mechanistic understanding in the safety assessment of nanomaterials in the food and feed area.

9. Discussion on cases

9.1. Iron Milk Proteinate (EFSA-Q-2020-00492)⁹

In the context of the application of its Nano Guidances, the cross-cutting WG on Nanotechnologies (hereafter ccWG Nano) was asked for support by the WG on Novel Foods of the Scientific Panel on Nutrition, Novel Foods and Food Allergens on the Novel Food Application Iron Milk Proteinate (EFSA-Q-2020-00492). The ccWG Nano is asked to discuss the new data provided by the applicant about the identity and ADME of the novel food, after a request for additional information in a previous advice dated March 2021. After a discussion, a written advice was agreed and submitted to the WG on Novel Foods.

9.2. Zinc L-carnosine (EFSA-Q-2020-00263)¹⁰

In the context of the application of its Nano Guidances, the ccWG Nano was asked for support by the WG on Novel Foods of the Scientific Panel on Nutrition, Novel Foods and Food Allergens on the Novel Food Application Zinc L-carnosine (EFSA-Q-2020-00263). After discussing the adequacy of the data provided by the applicant, the WG agreed on a written advice to be submitted to the WG on Novel Foods.

10. Any Other Business

10.1. Nano precipitated Calcium Carbonate (EFSA-Q-2019-00232)¹¹

The WG was informed that the Scientific Opinion on Nano precipitated Calcium Carbonate has been adopted by the EFSA Scientific Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) and will be published soon in the EFSA Journal. The WG discussed follow up reflections from this case about the importance of the best conditions for the dissolution test for infant formulae, as discussed under point 8.1, and possible influence of the food matrix. Further discussion on this topic is expected for the next meeting.

10.2. Workplan and next meetings

⁸ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

⁹ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00492>

¹⁰ <https://open.efsa.europa.eu/questions/EFSA-Q-2020-00263>

¹¹ <https://open.efsa.europa.eu/questions/EFSA-Q-2019-00232>

The WG discussed and agreed the workplan and next meeting dates, which are scheduled as a teleconference as follows:

- 3 March 2022 (from 9.00 to 13.00)
- 5 April 2022 (from 9.00 to 13.00)
- 16 May 2022 (from 9.00 to 13.00)
- 13 June 2022 (from 9.00 to 13.00)
- 11 July 2022 (from 9.00 to 13.00)
- 16 September 2022 (from 14.00 to 18.00)
- 10 October 2022 (from 9.00 to 13.00)
- 7 November 2022 (from 9.00 to 13.00)
- 30 November 2022 (from 9.00 to 13.00)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 29th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 29 November 2021
(Agreed on 29 November 2021)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)
Panagiotis Daskaleros (DG SANTE)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto, Irene Cattaneo, Daniela Maurici

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Roland Franz.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 28th Working Group meeting held on 14 October 2021, by WEB-conference.

The minutes of the 28th Working Group meeting were agreed during the meeting on 14 October 2021³.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Completeness Checklist on the Guidance on Particulate Matter - TR and Timelines for the Clock Stop Letters on the Nano Guidances

EFSA updated the WG about internal activities ongoing in the context of the implementation of the Nano Guidances^{4,5}. A Completeness Checklist of information requirements for the Guidance on Particulate Matter-TR⁵ will be produced in collaboration with the EFSA Application Desk (APDESK) Unit and is aimed to create a checklist information requirements that could be used by APDESK to check incoming dossiers before they enter the risk assessment process. This would contribute to the consistent application of the Guidance on Particulate Matter – TR for all the regulated areas, while monitoring the presence of nanotechnology in EFSA's applications. Internal activities are also ongoing in collaborations with other EFSA Units to update the indicative timelines to be requested to applicants in Clock Stop Letters (CSL) for submitting supplementary information in accordance with the Nano Guidances.

7. Stakeholders event

The WG was informed about the preparatory work currently underway for the organisation of the Stakeholders Workshop event foreseen in the first half of 2022.

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

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

³ <http://www.efsa.europa.eu/sites/default/files/wqs/cross-cutting-science/wq-nanotechnologies.pdf>

⁴ EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

⁵ EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. <https://doi.org/10.2903/j.efsa.2021.6769>

8. Proposal for a Scientific Publication

The WG was notified about the proposal for a scientific publication, a review article to explain the scientific aspects as to why and how particles at the nanoscale must be examined in risk assessment to ensure consumers safety. A draft outline of the manuscript was shared and discussed, with initial task distribution.

9. Any Other Business

9.1. Next meetings

The WG agreed on the proposed meeting plan for 2022. The meetings are tentatively scheduled as teleconference for:

- 28 January 2022
- 3 March 2022
- 5 April 2022
- 16 May 2022
- 13 June 2022
- 11 July 2022
- 16 September 2022
- 10 October 2022
- 7 November 2022
- 30 November 2022

9.2. Adoption of the minutes

The minutes of the present meeting were revised and agreed.



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 28th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 14 October 2021
(Agreed on 14 October 2021)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
David Gott
Jan Mast
Alicja Mortensen¹
Agnes Oomen
Stefan Weigel

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto, Irene Cattaneo
NUTRI Unit: Andrea Germini²
COM Unit: Arthur Healy³, Willem Beks³

¹ Only for agenda item 6

² Only for agenda item 7

³ Only for agenda item 11

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Roland Franz and Panagiotis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 27th Working Group meeting held on 17 September 2021, by WEB-conference.

The minutes of the 27th Working Group meeting were agreed during the meeting on 17 September 2021⁶.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Nanonetwork organisation and tasks subdivision

The WG discussed the organisation of the next meeting of the Network of Nanotechnologies in Food and Feed, which will be held on 29 October 2021. A draft presentation was discussed, and additional tasks were distributed among the WG members to finalise the presentation.

7. Updates on a previous request for consultation on Guidance on Nano-RA in the context of the Novel Food application 'Iron Hydroxide Adipate Tartrate' (EFSA-Q2020-00200)

In the context of the application of the SC Guidance on Nano-RA, the ccWG Nano was asked for support by the EFSA Nutrition Unit/Novel Foods WG to assist on the safety evaluation of the Novel Food dossier on 'Iron Hydroxide Adipate Tartrate' (EFSA-Q-2020-00200), the first engineered nanomaterial submitted as a Novel Food. Andrea Germini (Nutrition Unit) updated the WG with the status of this application and the finalisation of the opinion.

8. Updates on advanced materials

The WG was presented by Agnes Oomen with background and latest developments in the field of advanced materials in food. The complexity in the understanding of the term and characterisation of advanced materials was presented. A panoramic of the national strategic approach and the current international activities ongoing to address this specific issue were presented, such as the H2020 project SUNSHINE and current activities by OECD and JRC.

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

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

9. Feedback on Biostimulants/nanofertilizers (SIMBA, Uni Parma) and Training on Metrology

The WG was presented by Francesco Cubadda with the latest developments in the field of biostimulants and nanofertilisers, after participating to the SIMBA (Sustainable Innovation of Microbiome Applications in Food System – H2020) training course organised by the University of Parma.

10. Updates from EFSA

EFSA presented the WG members with the ongoing and future communication activities related to the presentation and diffusion of the published Nano Guidances.

11. PLS initiative from EFSA Journal

The WG was presented by Arthur Healy (EFSA Journal Team) with the latest activities of the EFSA Journal on providing plain language summaries (PLS) on key EFSA outputs. A pilot project was launched together with an external contractor, for a PLS on the nanomaterial guidances. The strategy for this pilot project was discussed.

12. Any Other Business

12.1. Next meetings

The dates for the next meetings have been agreed for:

- Friday, 29 October 2021 (held concomitantly with the 11th Network on Nanotechnologies in Food and Feed (NanoNetwork))
- Monday, 29 November 2021 (time to be decided)

The dates for 2022 will be agreed by written procedure.

12.2. Adoption of the minutes

The minutes of the present meeting were revised and agreed.



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 27th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 17 September 2021
(Agreed on 17 September 2021)**

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ Hearing Expert¹ representative of the FAF Panel:

Laurence Castle²

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)³

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto, Irene Cattaneo
FIP Unit: Ana Rincon³, Giorgia Vianello²
NUTRI Unit: Andrea Germini⁴

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

² Present only for Item 6.1

³ Present only for Item 6.1 and 7

⁴ Present only for Item 6.2

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Roland Franz and Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 26th Working Group meeting held on 9 July 2021, by WEB-conference.

The minutes of the 26th Working Group meeting were agreed during the meeting on 9 July 2021⁷.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Placeholder for cases

6.1. Request on gellable substances

In April 2021, the Panel on Food Additives and Flavourings (FAF Panel) requested clarifications on gellable substances in the context of the applicability of the Guidance on Particle – TR. Following this request, the ccWG Nano decided to integrate the draft Guidance with a case-specific footnote in Section 3.2. In June 2021, further discussions took place during the FAF Panel plenary meeting, in the context of a specific substance (E 466). The ccWG Nano was consulted on this topic and, after a discussion, the advice on the specific substance E 466 has been agreed. Further refinement of the text will take place after the meeting and the advice will be submitted to the FIP Unit.

6.2. Request for assistance on the Guidance on Particle-TR⁸ in the context of the Novel Food application Inositol-Stabilized Arginine Silicate (EFSA-Q-2017-00071)

In the context of the application of the Guidance on Particle-TR, the ccWG Nano was asked for support by the WG on Novel Food on the Novel Food application Inositol-Stabilized Arginine Silicate (EFSA-Q-2017-00071). The ccWG discussed the new information provided by the applicant and elaborated a written advice to be considered by the NDA WG Novel foods.

7. Nanonetwork organisation and tasks subdivision

The WG discussed the organisation of the next meeting of the Network of Nanotechnologies in Food and Feed, which will be held on 29 October 2021. A preparatory presentation was proposed for further

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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

⁸ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6769>

refinement by the WG members. After a discussion, the members agreed on task subdivision and related workplan.

8. Nano Guidances implementation plan and next steps

In the context of the publication of the Guidance on Nano-RA⁹ and the Guidance on Particle-TR¹⁰, the ccWG discussed their implementation plan and future activities.

9. Any Other Business

9.1. Reconfirmation of the SC in September and of all SC WGs: refitting exercise

The ccWG was informed that a confirmation and refitting exercise of all the Scientific Committee (SC) activities and WGs will be held at the next SC Plenary meeting.

9.2. Adoption of the minutes

The minutes of the present meeting were revised and agreed.

10. Next meeting(s)

The dates for the next meetings have been agreed for:

- Thursday, 14 October 2021 (TC start at 9am)
- Friday, 29 October 2021 (held concomitantly with the 11th Network on Nanotechnologies in Food and Feed (Nano Network))
- Monday, 29 November 2021 (time to be decided)

⁹ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6768>

¹⁰ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6769>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 26th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 9 July 2021
(Agreed on 09 July 2021)

Participants

■ Working Group Members:

Jacqueline Castenmiller (Rapporteur)
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ Hearing Expert¹ representative of the FAF Panel:

Laurence Castle

■ European Commission and/or Member States representatives:

Takis Daskaleros (DG SANTE)
Hubert Rauscher (JRC)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto, Irene Cattaneo
FIP Unit: Ana Rincon, Ellen Van Haver, Giorgia Vianello

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 25th Working Group meeting held on 08 June 2021, by WEB-conference.

The minutes of the 25th Working Group meeting were agreed during the meeting on 8 June 2021⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269) and Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)

Both documents, Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health (Guidance on Nano - Risk assessment (RA)) and the Guidance on Particle Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (Guidance on Particle - Technical Requirements (TR)) were presented at the 104th Scientific Committee plenary meeting on 30 June and adopted with unanimity. The cross-cutting Working Group on Nanotechnologies (ccWG Nano) discussed the feedback received during the plenary. The adopted version of both Nano Guidances, together with the Technical Report of the public consultation of the Guidance on Particle - TR, are proceeding into publishing phase.

7. Placeholder for cases

7.1. Gellable substances

In April 2021, the FAF Panel requested clarifications on gellable substances in the context of the applicability of the Guidance on Particle - TR. Following this request, the ccWG Nano decided to integrate the draft Guidance with a case-specific footnote in Section 3.2. In June 2021, further discussions took place during the FAF Panel plenary meeting, in the context of a specific substance (E

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/sites/default/files/competing_interest_management_17.pdf

4 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

466). The ccWG Nano was consulted on this topic. Further discussion on this agenda item and finalisation of a draft advice is scheduled for the next WG meeting.

7.2. Request for consultation on the Nano Guidances in the context of the Food Contact Materials application Chopped Carbon Fibre (EFSA-Q-2021-00006)

In the context of the application of the Nano Guidances, the ccWG Nano was asked for support by the EFSA Food Ingredients and Packaging (FIP) Unit/Food Contact Material WG. The ccWG discussed the information provided and elaborated a written response to be submitted to the Food Contact Material WG.

8. Nanonetwork organisation, trainings and tasks subdivision

The WG discussed the organisation of the next Network of Nanotechnologies in Food and Feed, which is scheduled for 29 October 2021. A preparatory presentation was proposed for further refinement by the WG members. After a discussion, the members agreed on task subdivision and related workplan.

9. Discussion on the Nano Guidances implementation plan

This agenda item had to be postponed to the next WG meeting due to lack of time.

10. Any Other Business

10.1. Recommendations for future regulatory science: request from EC interservice consultation group on the paper "Transition towards climate neutral, digital, circular and toxic-free environment with nanomaterials"

The ccWG Nano was informed by the Chair on the request for input by the European Commission interservice group on the paper "Transition towards climate neutral, digital, circular and toxic-free environment with nanomaterials". Comments on the paper as well as research priorities were discussed, for submission to DG RTD.

10.2. Reconfirmation of the Scientific Committee (SC) in September and of all SC Working Groups (WGs)

This agenda item had to be postponed to the next WG meeting due to lack of time.

10.3. Over 10 years of Nano Guidance work and adoption of both Nano Guidances

The Chair thanked the WG members for all the work done during the past decade, and congratulated on the adoption of both Nano Guidances.

10.4. Adoption of the minutes

The minutes of the present meeting were revised and agreed.

11. Next meeting(s)

The dates for the next meetings have been agreed for:

- Friday 17 September 2021 (from 10 to 17 CET)
- Thursday 14 October 2021 (time to be decided)
- Friday 29 October 2021 (held concomitantly with the 11th Network on Nanotechnologies in Food and Feed (NanoNetwork))
- Monday 29 November 2021 (time to be decided)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 25th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 8 June 2021
(Agreed on 8 June 2021)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ Hearing Experts¹:

Not applicable

■ European Commission and/or Member States representatives:

Takis Daskaleros (DG SANTE) (absent)
Hubert Rauscher (JRC)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto, Irene Cattaneo
FIP Unit: Ana Rincon

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted with additions to any other business.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 24th Working Group meeting held on 23 April 2021, by WEB-conference.

The minutes of the 24th Working Group meeting were agreed by written procedure on 5 May 2021⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269) and Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)

After discussion at the April Scientific Committee plenary meeting, the updated draft Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: Part 1, human and animal health (Guidance on Nano – Risk assessment (RA)) and the draft EFSA Guidance on Particle Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (Guidance on Particle – Technical Requirements (TR)) were distributed to the relevant EFSA Units and Panels for a three-weeks consultation. After gathering all the comments received, the cross-cutting Working Group on Nanotechnologies (ccWG Nano) discussed the feedback received and agreed to amend some parts of the document to improve clarity. A final draft of both Nano Guidances was agreed and will be presented for possible adoption at the next Scientific Committee plenary meeting, which will be held on 30 June-1 July 2021.

7. Placeholder for cases

7.1. Request for consultation on the Nano Guidances in the context of the Novel Food application 'Bacterial cellulose aqueous suspension' (EFSA-Q-2018-00294), updates from the applicant for discussion

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

In the context of the application of the SC Guidance on Nano-RA, the ccWG Nano was asked for support by the EFSA Nutrition Unit/Novel Foods WG to assist on the safety evaluation of the Novel Food dossier on 'Bacterial cellulose aqueous suspension' (EFSA-Q-2018-00294). The ccWG discussed the email received by the applicant and elaborated a written response to be submitted to the Novel Food WG.

8. Any Other Business

8.1. 2021 Nanonetwork organisation

The WG discussed the organisation of the next Network of Nanotechnologies in Food and Feed, which is scheduled on 29 October 2021.

8.2. Survey on the definition of 'nanomaterial'

The WG was informed on an ongoing targeted stakeholder consultation relating to the Review of the EU Recommendation 2011/696/EU on the definition of the term "nanomaterial"⁵.

8.3. Workplan

The WG agreed on tasks allocation and related work plan.

9. Next meeting(s)

The dates for the next meetings have been agreed for:

- Friday 9 July 2021 (held by teleconference from 14 to 17)
- Friday 17 September 2021 (to be decided)
- Thursday 14 October 2021 (to be decided)
- Friday 29 October 2021 (held concomitantly with the 11th Network on Nanotechnologies in Food and Feed (NanoNetwork)) (to be decided)
- Monday 29 November 2021 (to be decided)

⁵ https://ec.europa.eu/environment/chemicals/nanotech/review_en.htm



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 24th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 23 April 2021
(Agreed on 5 May 2021)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ Hearing Experts¹:

Not applicable

■ European Commission and/or Member States representatives:

Takis Daskaleros (DG SANTE)
Hubert Rauscher (JRC)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
FIP Unit: Ana Rincon, Giorgia Vianello (present for Item 7.1)
NUTRI Unit: Andrea Germini (present for Item 7.2), Tilemachos Goumperis (present for Item 7.3)

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 23rd Working Group meeting held on 22 March 2021, by WEB-conference.

The minutes of the 23rd Working Group meeting were agreed by written procedure on 26 March 2021⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269) and Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)

The updated draft Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: Part 1, human and animal health (Guidance on Nano – Risk assessment (RA)) and the draft EFSA Guidance on Particle Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (Guidance on Particle – Technical Requirements (TR)) were submitted for discussion at the last Scientific Committee plenary meeting, which was held on 14-15 April 2021.

The Chair presented the cross-cutting Working Group on Nanotechnologies (ccWG Nano) with the feedback received from the Scientific Committee and discussed the major points.

The ccWG Nano was presented by Jacqueline Castenmiller (Rapporteur) with the results of the preparatory meeting held to improve the figures of the Guidance on Nano-RA. An updated version of the figures was presented and, after a short discussion, few changes and additional text on the caption were agreed.

The ccWG Nano was presented with the elements emerged at the last SOT FDA Colloquium on Nanomaterials. After discussing the major points, the WG agreed to add further clarifications in the Guidance on Nano-RA on the importance of proper dispersion for covering realistic worst-case consumer exposure conditions.

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

After finalisation, the draft documents will be distributed to all relevant EFSA Panels/Units and DG SANTE. The intention is to ensure Panels and Units feedback when presenting this draft Guidance for possible adoption by the Scientific Committee, which will have its next meeting on 30 June-1 July 2021.

7. Placeholder for cases

7.1. Gellable substances

Following a request from the FAF WG on specifications for food additives, the ccWG Nano was presented with a discussion paper on substances that in the specifications are so-called as swellable substances. Analytic details of some examples of these substances to be used as food additives were also presented. The group discussed implications (both before and after ingestion) of this characteristic when applying the provisions of the Guidance on Particle-TR. These substances in solid form are powders and in contact with water the particles become surrounded by aggregating water molecules to form a gel. The formation of a gel confirms that the material is in dispersion, not a true solution, and is concentration dependent. The information available to the WG indicates that this process does not change the size of the constituent particles, particles are surrounded by water and at high concentrations the interaction between swelled particles creates the gel conditions. The ccWG considered that in solid powder forms particles may be present as large agglomerates. When dispersed in water at high concentrations, the gel formation may create difficulties for measuring the particle size distribution, these problems are solved by using more diluted dispersions at which no gel is formed. The ccWG concluded that current provisions in the Guidance, detailing screening and quantitative methods for measuring the particle size, provide the necessary information for covering these substances and that no specific criteria are needed; nevertheless, to facilitate the use of the guidance by applicants, it was agreed to add a new sentence detailing the need of using concentrations lower than those producing gellification as proper conditions for measuring such substances. The ccWG also considered that the described methods are in general appropriate, in case of technological difficulties for using electron microscopy for some materials, the applicants may justify the use of another method for measuring the particle size. In addition, other appraisal routes, such as those describing in Section 4 may be used by the applicants for demonstrating a proper coverage of the fraction of small particles by the existing safety studies.

7.2. Request for consultation on Guidance on Nano-RA in the context of the Novel Food application 'Iron Hydroxide Adipate Tartrate' (EFSA-Q2020-00200), updates from the applicant for information

In the context of the application of the SC Guidance on Nano-RA, the ccWG Nano was asked for support by the EFSA Nutrition Unit/Novel Foods WG to assist on the safety evaluation of the Novel Food dossier on 'Iron Hydroxide Adipate Tartrate' (EFSA-Q-2020-00200), the first engineered nanomaterial submitted as a Novel Food. Andrea Germini (Nutrition Unit) shared for information updates on the new information submitted by the applicant.

7.3. Request for consultation on the Nano Guidances in the context of the Novel Food application 'powder of chitosan' (EFSA-Q-2019-00324), new information provided by the applicant

In the context of the application of the Guidance on Nano – RA and the draft Guidance on Particle-TR, the ccWG Nano was requested for support by the EFSA Nutrition Unit/Novel Foods WG on the Novel Food dossier 'powder of chitosan' (EFSA-Q-2019-00324). Tilemachos Goumperis (Nutrition Unit) and Francesco Cubadda updated the group on the new information submitted by the applicant. The group discussed the specific questions asked by the Novel Food Working Group. The discussion will continue in a dedicated meeting and the advice will be finalised by written procedure.

7.4. Exchange on experiences gained with requests for advice on cases

The WG exchanged experiences from the requests for advice for cases received on the Nano Guidances. Elements that allowed working efficiently were endorsed and best practices can be further developed.

8. Any Other Business

8.1. Workplan

The WG agreed on tasks allocation and related work plan.

9. Next meeting(s)

The dates for the next meetings have been agreed for:

- Tuesday 8 June 2021 (held by teleconference from 10 to 17)
- Friday 9 July 2021 (held by teleconference from 10 to 17)
- Friday 17 September 2021 (to be decided)
- Thursday 14 October 2021 (to be decided)
- Friday 29 October 2021 (held concomitantly with the 11th Network on Nanotechnologies in Food and Feed (NanoNetwork) (to be decided)
- Monday 29 November 2021 (to be decided)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 23rd MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 22 March 2021
(Agreed on 26 March 2021)**

Participants

- Working Group Members:
 - Jacqueline Castenmiller (absent)
 - Qasim Chaudhry
 - Francesco Cubadda
 - Roland Franz (absent)
 - David Gott
 - Jan Mast
 - Alicja Mortensen
 - Agnes Oomen
 - Stefan Weigel
- Hearing Experts¹:
 - Not applicable
- European Commission and/or Member States representatives:
 - Takis Daskaleros (DG SANTE)
 - Hubert Rauscher (JRC) (absent)
- EFSA:
 - SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
 - NUTRI Unit: Ruth Roldan Torres (present for Item 7.1)

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jacqueline Castenmiller, Roland Franz and Hubert Rauscher.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 22nd Working Group meeting held on 11 March 2021, by WEB-conference.

The minutes of the 22nd Working Group meeting were agreed by written procedure on 24 March 2021⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)

The 'Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health' (Guidance on Nano – Risk assessment (RA)), was published in July 2018 and was subjected to further revisions due to advances in science, implementation of the Guidance during a pilot phase, and feedback from relevant stakeholders and EFSA users.

The cross-cutting WG on Nanotechnology (ccWG Nano) finalised the discussion on the pending issues identified at the previous meeting and agreed on a final draft of the document. The draft Guidance is now ready for submission for discussion by the Scientific Committee. The draft will be also distributed to all relevant EFSA Panels/Units and DG SANTE. The intention is to ensure Panels and Units feedback when presenting this draft Guidance for possible adoption by the Scientific Committee, which will have its next meetings on 14-15 April and 30 June-1 July 2021.

7. Placeholder for requests for advice on cases

7.1. Request for consultation on the nano guidances in the context of the Novel Food application Calcidol (EFSA-Q-2018-00514)

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

In the context of the application of the draft Guidance on Particle – TR and the Guidance on Nano – RA, the ccWG Nano was asked for support by the EFSA Nutrition Unit/Novel Foods WG on the novel food dossier Calcidiol (EFSA-Q-2018-00514). Ruth Roldan Torres (NUTRI Unit) and Francesco Cubadda summarised the new information presented by the applicant. The ccWG Nano reviewed the internal assessment of the information provided with respect to the requirements listed in the Guidance on Particle – TR. The notes from the internal review were endorsed and were submitted to the NUTRI colleagues.

8. Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)

The draft EFSA Guidance on Particle Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (Guidance on Particle – Technical Requirements (TR)) was published for public consultation from 9 July to 9 September 2020. After the delivery of the tasks allocated, the group finalised the discussion on the last pending issues and agreed on a final draft of the document. The draft Guidance is now ready for submission for discussion by the Scientific Committee, together with the Technical Report from the public consultation. The draft will be also distributed to all relevant EFSA Panels/Units and DG SANTE. The intention is to ensure Panels and Units feedback when presenting this draft Guidance for possible adoption by the Scientific Committee, which will have its next plenary meetings on 14-15 April and 30 June-1 July 2021.

9. Any Other Business

9.1. Workplan

The WG agreed on tasks allocation and related work plan.

10. Next meeting(s)

The dates for the next meetings have been agreed for:

- Friday 23 April 2021 (held by teleconference from 10 to 17)
- Tuesday 8 June 2021 (held by teleconference from 10 to 17)
- Friday 9 July 2021 (held by teleconference from 10 to 17)
- Friday 17 September 2021 (to be decided)
- Thursday 14 October 2021 (to be decided)
- Friday 29 October 2021 (held concomitantly with the 11th Network on Nanotechnologies in Food and Feed (NanoNetwork)) (to be decided)
- Monday 29 November 2021 (to be decided)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 22nd MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

WEB-conference, 11 March 2021
(Agreed on 24 March 2021)

Participants

- Working Group Members:
Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott (absent)
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Takis Daskaleros (DG SANTE)
Hubert Rauscher (JRC) (present in the morning)
- EFSA:
SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
NUTRI Unit: Emanuela Turla, Reinhard Ackerl

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from David Gott.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 21th Working Group meeting held on 1 March 2021, by WEB-conference.

The minutes of the 21th Working Group meeting were agreed by written procedure on 10 March 2021⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting. The WG members were also informed that, in favour of Microsoft Teams, the Document Management System (DMS) will no longer be used for working on documents.

6. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)

The 'Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health' (Guidance on Nano – Risk assessment (RA)), was published in July 2018 and was subjected to further revisions due to advances in science, implementation of the Guidance during a pilot phase, and feedback from relevant stakeholders and EFSA users.

The cross-cutting WG on Nanotechnology (ccWG Nano) continued the revision of the Guidance on Nano – RA following the feedback received from the two-weeks consultation with the members of the Nano Network, the comments submitted by the EFSA Working Group on Food Contact Materials (FCM) on the applicability of this Guidance to FCM, and clarifications on regulations suggested by DG SANTE. After a discussion on the feedback received, the ccWG agreed to adjust some parts of the text in these areas. Specific tasks have been distributed among the WG members to address the elements identified for possible improvement. The pending issues will be addressed at the next WG meeting on 22 March 2021, after which a final version of the draft Guidance is expected to be ready for submission for discussion and possible endorsement by the Scientific Committee. The draft will be also distributed to all relevant EFSA Panels and DG SANTE. The intention is to ensure Panels feedback when presenting this draft Guidance for possible adoption at the Scientific Committee plenary meeting, which will have its next meeting on 14-15 April 2021.

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

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

4 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

7. Placeholder for requests for advice on cases

7.1. Request for consultation on the nano guidances in the context of the Novel Food application Urolithin A

In the context of the application of the draft Guidance on Particle – TR and the Guidance on Nano – RA, the ccWG Nano was asked for support by the EFSA Nutrition Unit/Novel Foods WG on the novel food dossier on Urolithin A (NF 2018/0538). Emanuela Turla (NUTRI Unit) and Francesco Cubadda summarised the new information presented by the applicant on particle size. The ccWG Nano discussed the adequacy of the information provided with respect to the requirements listed in both Nano Guidances and an advice has been agreed upon. The advice will be submitted to the next Novel Food WG meeting.

7.2. Request for consultation on the nano guidances in the context of the Novel Food/Nutrient Source application Iron Milk Proteinate

In the context of the application of the draft Guidance on Particle – TR and the Guidance on Nano – RA, the ccWG Nano was asked for support by the EFSA Nutrition Unit/Novel Foods WG on the novel food/nutrient source dossier on Iron Milk Proteinate. The group discussed the specific questions asked by the Novel Food Working Group and an advice was agreed upon. The advice will be submitted to the next Novel Food WG meeting.

8. Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)

The draft EFSA Guidance on Particle Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (Guidance on Particle – Technical Requirements (TR)) was published for public consultation from 9 July to 9 September 2020. Further discussion on this agenda item was postponed to the next meeting due to lack of time.

9. Any Other Business

9.1. Workplan

The WG agreed on tasks allocation and related work plan.

10. Next meeting(s)

The dates for the next meetings have been agreed for:

- Monday 22 March 2021 (held by teleconference from 10 to 17)
- Friday 23 April 2021 (held by teleconference from 10 to 17)
- Tuesday 8 June 2021 (held by teleconference from 10 to 17)
- Friday 9 July 2021 (held by teleconference from 10 to 17)
- Friday 17 September 2021 (to be decided)
- Thursday 14 October 2021 (to be decided)
- Friday 29 October 2021 (held concomitantly with the 11th Network on Nanotechnologies in Food and Feed (NanoNetwork)) (to be decided)
- Monday 29 November 2021 (to be decided)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 21st MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 1 March 2021
(Agreed on 10 March 2021)**

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ Hearing Experts¹:

Not applicable

■ European Commission and/or Member States representatives:

Takis Daskaleros (DG SANTE)
Jonathan Briggs (DG SANTE)
Bastiaan Schupp (DG SANTE)
Hubert Rauscher (JRC) (present in the morning)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work :
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 20th Working Group meeting held on 22 January 2021, by WEB-conference.

The minutes of the 20th Working Group meeting were agreed by written procedure on 5 February 2021⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting. The WG members were also informed that, in favour of Microsoft Teams, the Document Management System (DMS) will no longer be used for exchanging meeting documents.

6. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)

The 'Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health' (Guidance on Nano – Risk assessment (RA)), was published in July 2018 and was subjected to further revisions due to advances in science, implementation of the Guidance during a pilot phase, and feedback from relevant stakeholders and EFSA users.

The cross-cutting Working Group on Nanotechnologies (ccWG Nano) continued the revision of the Guidance on Nano – RA following the feedback received from the two-weeks consultation with the members of the NanoNetwork. In addition, the ccWG Nano revised the comments submitted by the EFSA Working Group on Food Contact Materials (FCM) on the applicability of this Guidance to FCM. After discussing the feedback received, the ccWG agreed to integrate some comments and modify some parts of the sections accordingly. The suggested amendments of the figures were FCM-specific and could be incorporated in the Appendix on FCM. Further suggested changes to regulatory references need further clarification with DG SANTE.

After the delivery of the tasks allocated in the previous meeting, the WG members discussed further possible improvements on the different chapters of the document, which will continue at the next WG meeting of 11 March. Further editorial comments will be addressed in a preparatory meeting with the

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

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

4 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

Chair before the next WG meeting, and proposals to further improve the text will be discussed at the next meeting.

7. Placeholder for requests for advice on cases

7.1. Bacterial cellulose

Further to an earlier request for advice on the bacterial cellulose dossier as novel food, the ccWG Nano was updated on this case for information purposes only.

The applicant on the bacterial cellulose (EFSA-Q-2018-00294) has provided new data on ADME. The EFSA Novel Food Working Group (NDA Unit) evaluated the adequacy of the information received in the context of the implementation of the 2018 Guidance on Nanomaterials, and the applicant was requested to provide further clarification in a clock stop letter.

The ccWG was informed about the result of the call GP/EFSA/SCER/2020/03 on the Use of New Approach Methodologies (NAMs) for the hazard assessment of nanofibers and specifically nanocellulose; Lot 1: nanocellulose oral exposure: gastrointestinal digestion, nanofibers uptake and local effects; Lot 2: exploring the use of gut-on-a-chip models. After a selection procedure, Lot 1 has been assigned to a consortium led by Istituto Superiore di Sanità (ISS), with several organisations and partners, including Sciensano. The kick-off meeting for the project has been scheduled and the WG will be kept informed on the activities.

7.2. Request for consultation on the nano guidances in the context of the EC Mandate to the FIP Unit on re-evaluation of E 171 as a food additive (EFSA-Q-2020-00262)

EFSA has received a mandate from the European Commission for an updated scientific opinion on the safety of titanium dioxide (E 171) as a food additive (EFSA-Q-2020-00262). The ccWG Nano was requested for support on this mandate from the FIP Unit.

The ccWG Nano provided case-specific advice on nanoscale considerations for the assessment of the study design and study results of TiO₂ toxicity studies. In this session the WG finalised the draft advice, that will be submitted to the FAF Panel. This second advice follows the first advice requested by the FIP Unit to the ccWG Nano on nano-specific search criteria for inclusion/exclusion of articles retrieved from the systematic literature search.

8. Any Other Business

8.1. Workplan

The WG agreed on tasks allocation and related work plan.

9. Next meeting(s)

The dates for the next meetings have been agreed for:

- Thursday 11 March 2021 (held by teleconference from 10 to 17)
- Monday 22 March 2021 (held by teleconference from 10 to 17)
- Friday 23 April 2021 (held by teleconference from 10 to 17)
- Tuesday 8 June 2021 (held by teleconference from 10 to 17)
- Friday 9 July 2021 (held by teleconference from 10 to 17)

The dates for the second half of the year and for the nano network will be decided on 11 March.



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 20TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**WEB-conference, 22 January 2021
(Agreed on 5 February 2021)**

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott (absent)
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ Hearing Experts¹ participating as representative of the EFSA FAF Panel:
Maged Younes, Maria Jose Frutos and Laurence Castle (Present for Item 7)

■ European Commission and/or Member States representatives:

Takis Daskaleros (DG SANTE)
Hubert Rauscher (JRC) (present in the morning)
Virginia Rodriguez Unamuno (ECHA) (present in the morning)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
FEED Unit: Maria Vittoria Vettori, Jaume Galobart (Present for Item 6)
FIP Unit: Ana Rincon, Camilla Smeraldi (Present for Item 7)
NUTRI Unit: Ruth Roldan Torres (Present for Item 8)

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from David Gott.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 19th Working Group meeting held on 9-10 December 2020, by teleconference.

The minutes of the 19th Working Group meeting were agreed by written procedure on 22 December 2020⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)

The 'Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health' (Guidance on Nano – Risk assessment (RA)), was published in July 2018 and was subjected to further revisions due to advances in science, implementation of the Guidance during a pilot phase, and feedback from relevant stakeholders and EFSA users.

The cross-cutting WG on Nanotechnology (ccWG Nano) continued the revision of the Guidance on Nano – RA following the feedback received from the PPR Panel, the FEED Unit and the ccWG on Genotoxicity on the related chapters. After the delivery of the tasks allocated in the previous meeting, the WG members discussed further possible improvements on the different chapters of the document.

The ccWG Nano was presented by Maria Vittoria Vettori and Jaume Galobart (FEED Unit) with the comments submitted from the FEED Unit on Appendix D.3 dedicated to Feed Additives. The group discussed further improvements and agreed on some additional clarifications.

Further discussions on the Guidance have been postponed to the next WG meeting due to lack of time. The next meeting will focus on the finalisation of the document, which will be shared for consultation with the NanoNetwork, before submission to the Scientific Committee.

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/sites/default/interest_management_17.pdf

4 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

7. Request for consultation on the nano guidances in the context of the EC Mandate to the FIP Unit on re-evaluation of E 171 as a food additive (EFSA-Q-2020-00262)

The FIP Unit (Food Ingredients and Packaging) has received a mandate from the European Commission for an updated scientific opinion on the safety of titanium dioxide (E 171) as a food additive (EFSA-Q-202000262). In the context of the implementation of the Guidance on Nano – RA (and draft Guidance on Particle – TR), the ccWG Nano was requested for support on this mandate from the FIP Unit.

In line with the general provisions of both guidance documents, the ccWG Nano provided case-specific advice on nanoscale considerations for the assessment of the study design and study results of TiO₂ toxicity studies. Such criteria can be incorporated in the appraisal criteria to be established by the FAF and the Genotoxicity WGs tasked with the evaluation of individual studies. In this joint session with representative members of the FAF Panel, Maged Younes (Chair of the FAF Panel), Maria Jose Frutos, and Laurence Castle, the WG finalised the draft advice (developed during the 13th meeting of the ccWG Nano in September 2020) and remaining uncertainties. The advice will be finalised by written procedure or at the next meeting. This second advice follows the first advice requested by the FIP Unit to the ccWG Nano on nano-specific search criteria for inclusion/exclusion of articles retrieved from the systematic literature search.

8. Request for consultation on the nano guidances in the context NDA/NUTRI Novel Food dossier Calcidol (EFSA-Q-2018-00514)

In the context of the application of the Guidance on Nano – RA (and the draft Guidance on Particle – TR), the ccWG Nano was requested for support by the EFSA Nutrition Unit/Novel Foods WG on the Novel Food dossier Calcidol (EFSA-Q-2018-00514). Ruth Roldan Torres (NUTRI Unit) and Francesco Cubadda presented the data on particle characterisation provided by the applicant. The group discussed the adequacy of the data provided for this specific case in view of the possible presence of nanoparticles. The advice will be finalised by written procedure, to be submitted to the next Novel Food WG meeting.

9. Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)

The draft EFSA Guidance on Particle Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (Guidance on Particle – Technical Requirements (TR)) was published for public consultation from 9 July to 9 September 2020. Further discussion on this agenda item was postponed to the next meeting due to lack of time.

10. Any Other Business

10.1. Workplan

The WG agreed on tasks allocation and related work plan.

11. Next meeting(s)

The dates for the next meetings have been agreed for:

- Monday 1 March 2021 (held by teleconference from 10 to 17)
- Thursday 11 March 2021 (held by teleconference from 10 to 17)
- Monday 22 March 2021 (held by teleconference from 10 to 17)
- Friday 23 April 2021 (held by teleconference from 10 to 17)
- Tuesday 8 June 2021 (held by teleconference from 10 to 17)
- Friday 9 July 2021 (held by teleconference from 10 to 17)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 19TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**Teleconference, 9-10 December 2020
(Agreed on 22 December 2020)**

"This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection."

Participants

- Working Group Members:
Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel
- Hearing Experts¹ participating as representative of the EFSA FCM WG:
Laurence Castle (Present for Item 6)
- European Commission and/or Member States representatives:
Takis Daskaleros (DG SANTE) (absent)
Hubert Rauscher (JRC) (present both days in the morning)
Virginia Rodriguez Unamuno (ECHA) (present from 2 to 3 pm on the 9th December)
- EFSA:
SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
NUTRI Unit: Emanuela Turla, (Present for Item 7) Andrea Germini (Present for Item 8)
FIP Unit: Eric Barthélémy (Present for Item 6)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 18th Working Group meeting held on 27 October 2020, by teleconference.

The minutes of the 18th Working Group meeting were agreed by written procedure on 16 November 2020⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)⁵

The draft EFSA Guidance on Particle Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (Guidance on Particle – Technical Requirements (TR)) was published for public consultation from 9 July to 9 September 2020.

The ccWG members continued the revision of the document according to the comment received from the public consultation, the 10th NanoNetwork, the feedback from the EFSA Panels, and actual cases. The WG agreed to amend the document for improving the clarity of the figure explaining the link between the two Nano guidances and the sectoral guidance documents, and to clarify the scope, e.g. by adding a clear reference to nanostructured materials and integrating the text with the scientific rationale for the decision criteria selected. Proposals for further amendments were discussed and new additions will be presented at the next meeting.

The ccWG Nano was informed by Eric Barthélémy (FIP Unit) and Laurence Castle (FCM WG) with the outcome on the discussion on the practical applicability of the EFSA Guidance on Particle – TR to food contact materials (FCM) by the FCM WG. The group was also presented with a proposal for integrating

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

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

4 <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

5 EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

text to clarify the applicability of the draft Guidance to FCM. After a discussion, the group agreed on new text to be integrated to improve the draft Guidance.

7. Novel Food (NF) dossier Urolithin A (EFSA-Q-2018-00724)⁶, follow-up

In the context of the application of the Guidance on Particle – TR and the Guidance on Nano – RA, the ccWG Nano was asked for support by the EFSA Nutrition Unit/Novel Foods WG on the novel food dossier on Urolithin A (NF 2018/0538). Emanuela Turla (NUTRI Unit) and Francesco Cubadda presented the new data provided by the applicant. The group discussed the adequacy of the data provided with respect to the requirements listed in both Nano Guidances. The advice will be finalised by written procedure, to be submitted to the next Novel Food WG meeting.

8. Novel Food (NF) dossier 'Iron Hydroxide Adipate Tartrate' (EFSA-Q-2020-00200)⁷

In the context of the application of the SC Guidance on Nano – RA, the ccWG Nano was asked for support by the EFSA Nutrition Unit/Novel Foods WG to assist on the safety evaluation of the Novel Food (NF) dossier on 'Iron Hydroxide Adipate Tartrate' (EFSA-Q-2020-00200), the first engineered nanomaterial submitted as NF. Andrea Germini (Nutrition Unit) and Francesco Cubadda presented the main structure of the dossier and specific questions for discussion with the ccWG Nano. The WG members were consulted to evaluate the adequacy of the information provided and the tests submitted throughout the different parts of the dossier. The advice will be finalised by written procedure based on the result of the evaluation.

9. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)⁸

The 'Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health' (Guidance on Nano – Risk assessment (RA)), was published in July 2018 and was subjected to further revisions due to advances in science, the implementation of the Guidance during a pilot phase, feedback from stakeholders and EFSA users of the Guidance.

The draft Guidance on Nano – RA was presented at the November Scientific Committee (SC) plenary meeting to receive feedback from the SC members and relevant EFSA Panels. The group addressed the comments received from the NDA Panel and agreed on further actions to clarify the some part of the text and related graphics based on the feedback received. The group proceeded discussing further possible improvements based on the last achievements from the Guidance on Particle – TR. Lastly, the WG members agreed on the task allocation and related work plan for the next meeting. After the finalisation and before submission to the Scientific Committee, the updated version of the Guidance will be shared for consultation with the NanoNetwork.

10. Any Other Business

10.1. Workplan

The WG agreed on tasks allocation and related work plan.

6 EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00724>

7 EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00200>

8 EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

11. Next meeting(s)

The dates for the next meetings have been agreed for:

- Friday 22 January 2021 (held by teleconference from 10 to 17)
- Monday 1 March 2021 (held by teleconference from 10 to 17)
- Thursday 11 March 2021 (held by teleconference from 10 to 17)
- Monday 22 March 2021 (held by teleconference from 10 to 17)
- Friday 23 April 2021 (held by teleconference from 10 to 17)
- Tuesday 8 June 2021 (held by teleconference from 10 to 17)
- Friday 9 July 2021 (held by teleconference from 10 to 17)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 18TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Teleconference, 27 October 2020
(Agreed on 16 November 2020)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry (absent)
Francesco Cubadda
Roland Franz
David Gott (absent)
Jan Mast
Alicja Mortensen (present until 2PM)
Agnes Oomen
Stefan Weigel

■ Hearing Experts¹:

Not applicable

■ European Commission and/or Member States representatives:

Takis Daskaleros (DG SANTE) (absent)
Hubert Rauscher (JRC) (present from 4 to 5PM)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
NUTRI Unit: Andrea Germini (Present for Item 8)
FIP Unit: Eric Barthélémy (Present for Item 7)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Qasim Chaudhry, Takis Daskaleros, David Gott. Alicja Mortensen was present until 2PM and Hubert Rauscher was present from 4 to 5PM.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 17th Working Group meeting held on 21-22 October 2020, by teleconference.

The minutes of the 17th Working Group meeting were agreed by written procedure on 4 November 2020⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Particulate Matter - Technical Requirements (TR) (EFSA-Q-2019-00692)⁵

The draft EFSA Guidance on Particulate Matter Technical Requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles was published for public consultation from 9 July to 9 September 2020. All the comments received will be considered for the finalisation of the Guidance. This work is ongoing and some issues for discussion with the WG have been identified. These issues as well as further amendments will be discussed at the next meeting.

7. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)⁶

The 'Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health', was published in July 2018 and was

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁵ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

⁶ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

subjected to further revisions due to advances in science, the implementation of the Guidance during a pilot phase, feedback from stakeholders and EFSA users of the Guidance. Proposals for revisions and suggestions for refinements were discussed and approved by the cross-cutting Working Group on Nanotechnology.

The ccWG members continued to revise the figures, the sub-structures of some chapters and some scientific details of the Guidance on Nano – RA. Upon suggestions provided by Eric Barthélémy (FIP Unit) on the practical use of the Guidance for FCM, more clarity will be established for such use of nanomaterials.

8. Novel Food (NF) dossier 'Iron Hydroxide Adipate Tartrate' (EFSA-Q-2020-00200)⁷

The EFSA Nutrition Unit/Novel Foods WG presented the Novel Food (NF) dossier for 'Iron Hydroxide Adipate Tartrate' (EFSA-Q-2020-00200), the first nanomaterial submitted as NF. Andrea Germini (Nutrition Unit) and Francesco Cubadda presented the general structure of the dossier to the ccWG Nano. The substance is in a first assessment phase by the NF WG. The ccWG Nano will be consulted for nano-specific issues regarding the adequacy of the tests submitted throughout the different parts of dossier.

9. Any Other Business

9.1. Workplan

The WG agreed on tasks allocation and related workplan. The key elements of both guidance documents will be presented at the next Scientific Committee plenary meeting, which will be held on 11-12 November 2020.

10. Next meeting(s)

The dates for the next meetings have been agreed for:

- 9-10 December (TC switch to reduce the risk of coronavirus infection): from 10 to 17 on both days

⁷ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00200>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 17TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**Teleconference, 21-22 October 2020
(Agreed on 4 November 2020)**

This meeting was back-to-back with the 10th meeting of the
EFSA Network on Nanotechnologies in Food and Feed

Participants

- Working Group Members:
 - Jacqueline Castenmiller (absent in the breakout session on 22AM)
 - Qasim Chaudhry
 - Francesco Cubadda (absent in the breakout session on 22PM)
 - Roland Franz
 - David Gott (absent)
 - Jan Mast (absent in the breakout sessions on 21)
 - Alicja Mortensen (absent in the breakout session on 22PM)
 - Agnes Oomen
 - Stefan Weigel (absent)
- Hearing Experts¹:
 - Not applicable
- European Commission and/or Member States representatives:
 - Takis Daskaleros (DG SANTE) (absent in the breakout sessions)
 - Hubert Rauscher (JRC) (participated in the breakout sessions only on 21PM, 22AM)
- EFSA:
 - SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
 - Nutrition Unit: Reinhard Ackerl (participated only in the breakout session on 21AM)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from David Gott and Stefan Weigel. Takis Daskaleros (DG SANTE) was absent in the breakout sessions. Jacqueline Castenmiller was absent in the breakout session on 22AM, Francesco Cubadda was absent in the breakout session on 22PM, Jan Mast was absent in the breakout session on 21, Alicja Mortensen was absent in the breakout session on 22PM, and Hubert Rauscher (JRC) was absent in the breakout sessions in 21AM, 22PM).

2. Adoption of agenda

The agenda, which was embedded in the agenda of the 10th meeting of the EFSA Network on Nanotechnologies in Food and Feed, was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 16th Working Group meeting held on 9 October 2020, by teleconference.

The minutes of the 16th Working Group meeting were agreed by written procedure on 20 October 2020⁴.

5. Addressing comments received in both guidances (Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)⁵ and Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)⁶

The last updates on the 'Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health' and the draft 'EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles' were presented at the 10th meeting of the EFSA Network on Nanotechnologies in Food and Feed.

During the breakout sessions of the Nanonetwork, the WG members met separately and held their 17th WG meeting to discuss and address the feedback received from the network members on both documents. Network members as well as observers have given feedback on the approach proposed by the two guidance documents and its implementation. Taking into account this feedback, the ccWG discussed how to restructure (parts of) the Guidance on Nano – RA to improve clarity to the reader and revised the last updates in the Glossary. More detailed explanatory texts to clarify the rationales and the approaches proposed by the Guidance on Particle – TR was deemed useful and will be developed. Further updates and improvements on both documents will be discussed in the next meeting.

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁵ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

⁶ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

6. Any Other Business

6.1. Nanonetwork

The 10th meeting of the EFSA Network on Nanotechnologies in Food and Feed was held on 21-22 October 2020, concomitantly with the 17th cross-cutting Working Group on Nanotechnology.

6.2. Workplan

The WG agreed on tasks allocation and related workplan. The aim is to present key elements of both guidance documents at the November Scientific Committee plenary meeting.

7. Next meeting(s)

The dates for the next meetings have been agreed for:

- 27 October (TC): from 10 to 17
- 9-10 December (TC switch to reduce the risk of coronavirus infection): from 10 to 17.



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

MINUTES OF THE 16TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**Teleconference, 9 October 2020
(Agreed on 20 October 2020)**

Participants

- Working Group Members:
Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott (absent)
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel
- Hearing Experts¹:
Not applicable
- European Commission and/or Member States representatives:
Takis Daskaleros (DG SANTE) (present until 11AM)
Hubert Rauscher (JRC) (present in the morning)
- EFSA:
SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from David Gott. Hubert Rauscher was absent in the afternoon and Takis Daskaleros was present until 11AM.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 15th Working Group meeting held on 23-25 September 2020, by teleconference.

The minutes of the 15th Working Group meeting were agreed by written procedure on 7 October 2020⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Particulate Matter - Technical Requirements (TR) (EFSA-Q-2019-00692)⁵

The draft EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles was published for public consultation from 9 July to 9 September 2020. The draft document received approximately 200 comments from 24 contributors. All the comments received were subdivided by section and presented for consideration to the ccWG Nano.

The WG members continued the discussion on the comments received from the public consultation. The members agreed to update and re-organise some Sections of the Guidance. Some of the ameliorations proposed were agreed and some parts of the text were amended to improve the understandability of the document and to facilitate its applicability. All the relevant comments received will be used for the finalisation of the Guidance, and a Technical Report will be published indicating how the comments were considered in the final document.

7. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)⁶

The 'Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health', was published in July 2018 and was subjected to further revisions that are pending for approval of the cross-cutting Working Group on Nanotechnology.

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁵ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

⁶ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

The ccWG members continued the revision of the structure and text of the Guidance on Nano – RA after the new achievements agreed for the Guidance on Particle – TR. A new proposal of the explanatory figure on the relationship between the two guidance documents has been discussed and agreed upon. The WG members continued to discuss new updates in the last sections of the Guidance, including new additions in the Glossary. New amendments were agreed and additional tasks were allocated among the WG members.

8. Any Other Business

8.1. Nanonetwork agenda

The WG was informed on the structure of the agenda for the 10th meeting of the EFSA Network on Nanotechnologies in Food and Feed, which will be held on 21-22 October 2020 by teleconference.

8.2. Workplan

The WG agreed on tasks allocation and related workplan. The aim is to present key elements of both guidance documents at the November Scientific Committee plenary meeting.

9. Next meeting(s)

The dates for the next meetings have been agreed for:

- 21-22 October: Nanonetwork
- 27 October (TC): from 10 to 17
- 9-10 December (TC switch to reduce the risk of coronavirus infection): from 10 to 17.



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 15TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

**Teleconference, 23-25 September 2020
(Agreed on 7 October 2020)**

This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott (absent on 23 and 25)
Jan Mast
Alicja Mortensen (absent)
Agnes Oomen
Stefan Weigel

■ Hearing Experts¹:

Not applicable

■ European Commission and/or Member States representatives:

Takis Daskaleros (DG SANTE) (absent)
Hubert Rauscher (JRC) (absent on 24)
Bruno Teste (ANSES, FR member of the EFSA NanoNetwork) (present for Item 9)
Virginia Unamuno (ECHA)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
Nutrition Unit: Tilemachos Goumperis (present for Item 8)
FIP Unit: Eric Barthelemy (present for Item 6), Ana Rincon (present for Item 6)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alicja Mortensen. Hubert Rauscher was absent on 24 September, and David Gott was absent on 23 and 25 September. Eric Barthelemy (FIP Unit) and Ana Rincon (FIP Unit) participated only for Item 6, Tilemachos Goumperis (Nutrition Unit) for Item 8, and Bruno Teste for Item 9.

2. Adoption of agenda

This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection. The agenda was adopted without further changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 14th Working Group meeting held on 29 June 2020, by teleconference.

The minutes of the 14th Working Group meeting were agreed by written procedure on 10 July 2020⁴.

5. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the meeting.

6. Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)⁵

The draft EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles was published for public consultation from 9 July to 9 September 2020. The draft document received approximately 200 comments from 24 contributors. All the comments received were subdivided by section and presented for consideration to the ccWG Nano. The WG members revised some text in the Guidance according to the contributions received and discussed the new elements and ameliorations that emerged from the consultation. The members agreed to include explanatory text in the Guidance to improve the understandability of the document and to facilitate its applicability. All the relevant comments received will be used for the finalisation of the Guidance and a Technical Report will be published indicating how the comments were considered in the final document.

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁵ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

Moreover, the WG was informed by Eric Barthelemy (FIP Unit) on some considerations on the applicability of the Guidance on Particle - TR to Food Contact Materials (FCM) that can be useful for further improvements. The WG on FCM will provide views and proposals. Finally, Ana Rincon (FIP Unit) described some aspects of the applicability of the Guidance to food additives.

7. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)⁶

The 'Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health', was published in July 2018 and was subjected to further revisions that are pending for approval of the cross-cutting Working Group on Nanotechnology.

The ccWG members revised the structure and text of the Guidance on Nano - RA after the new achievements agreed for the Guidance on Particle - TR. The WG members discussed new possible improvements concerning the harmonisation of the two Nano Guidances, to clarify their applicability in relation to the sectoral guidances, and in relation to the lessons learned from the cases during the pilot phase (e.g. novel food cases or food additives such as E 171 (mandate nr M-2020-0058)).

The WG members delivered the tasks allocated at the previous meeting and proceeded with the revision of the document focusing on the new proposals for updates. The structure of the first chapters was amended to highlight the renewed scope. The members discussed possible ameliorations for the explanatory figure and related text on the relationship between the 'Guidance on Nano-RA', 'Guidance on Particle-TR', and the 'sectoral guidances' within the EFSA legal remit. Table 1 and related techniques have been updated according to the Guidance on Particle - TR. A glossary and reference terminology will be developed for both guidances. Lay-out of figures will have to be checked.

8. Request for consultation on the nano guidances in the context of the Novel Food (NF) dossier 'powder of chitosan' (EFSA-Q-2019-00324)⁷

The EFSA Nutrition unit/Novel Foods WG requested the support of the ccWG Nano for the Novel Food (NF) dossier 'powder of chitosan' (EFSA-Q-2019-00324). Tilemachos Goumperis (Nutrition Unit) and Francesco Cubadda presented the case to the WG. The members discussed the information presented and agreed on the advice that is based on the practical implementation of the EFSA SC Guidance on Nano-RA and the EFSA Guidance on Particle-TR.

9. Presentation by ANSES on their activities on Nanomaterials

Bruno Teste (ANSES) presented the recent activities of ANSES in the field of Nanotechnology and in particular in the context of its recently published work⁸ proposing an approach and methods to decide if a material comprises a fraction of nanoparticles and if that material should follow a nanospecific risk assessment. The WG was provided with an overview of the comments submitted by ANSES during the public consultation of the draft EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles.

⁶ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

⁷ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00324>

⁸ <https://www.anses.fr/en/system/files/ERCA2016SA0226Ra.pdf>

10. Any Other Business

10.1. Update on the procurement on Nano ERA

The WG was informed on the recent advancement on the procurement project. The final deliverable is on track and will provide a knowledge base for future Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (Part 2), on environmental risk assessment. The Chair presented the agreed table of content of the document.

10.2. Nanonetwork agenda

The Chair informed on the structure of the agenda for the 10th meeting of the EFSA Network on Nanotechnologies in Food and Feed, which will be held on 21-22 October 2020 by teleconference.

10.3. Update on the nanofibers case-study

The call for proposals on the use of New Approach Methodologies (NAMs) for the hazard assessment of nanofibers have been launched and all the information are available in the EFSA website⁹.

10.4. Workplan

The WG agreed on tasks allocation and related workplan. The aim is to present key elements of both guidance documents at the November Scientific Committee plenary meeting.

11. Next meeting(s)

The dates for the next meetings have been agreed for:

- 9 October (TC): from 9 to 17
- 27 October (TC): from 9 to 17
- 9-10 December (TC switch to reduce the risk of coronavirus infection): from 9 to 17.

⁹ <https://www.efsa.europa.eu/en/art36grants/article36/gpefsascer202003-use-new-approach-methodologies-nams-hazard>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 14TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Tele-conference, 29 June 2020

(Agreed on 10 July 2020)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen

■ Hearing Experts¹:

Shareen Doak (for Item 7)
Matthew Wright (for Item 7)

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC) (until 11am)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
FIP Unit: Camilla Smeraldi, Ana Maria Rincon (for Item 7)
NUTRI Unit: Emanuela Turla (for Item 8)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Stefan Weigel, and Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 13th Working Group meeting held on 26 June 2020, TELE-conference.

The minutes of the 13th Working Group meeting were agreed by written procedure on 10 July⁴.

5. Hearing Expert (s)

Prof. Shareen Doak was invited in order to address specific questions from the WG on *in vitro* toxicity testing with nanomaterials. In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA invited Prof. Shareen Doak to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e. not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework⁷.

6. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed.

7. Request for consultation on the nano guidances in the context of the EC Mandate to the FIP Unit on TiO₂ mandate

The FIP Unit (Food Ingredients and Packaging) received a new mandate from the EC for an updated scientific opinion as regards the safety of titanium dioxide (E 171) as food additive (EFSA-Q-2020-00262). Based on the principles of the 'Guidance on Nano-RA' (formerly EFSA SC Guidance on nano, 2018) and the Guidance on Particles - TR, the ccWG provided advice on nanoscale criteria to be

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ Decision of the Executive Director on Competing Interest Management, Article 9:

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

considered in the assessment of the relevance and reliability of experimental study design and study results. Such criteria can be incorporated in the appraisal criteria to be established by the FAF and the Genotoxicity WGs. In this second joint session with Matthew Wright, the appointed Chair of the new WG of the EFSA FAF Panel established for the re-evaluation of TiO₂, the WG finalised the discussion on the proposed scoring system, which is based on the evaluation of the level of dispersion (according to the instructions provided by the Guidance on Particle-TR). This second advice should be considered as integrated to the first advice on the other nano-specific criteria to be considered in the assessment of articles retrieved from the systematic literature search.

8. Request for consultation on the nano guidances in the context of the mandate to the NDA/Nutri Unit on Urolithin A (NF 2018/0538)

In relation to the safety assessment of the novel food Urolithin A (NF 2018/0538) by the EFSA NDA Panel (EFSA-Q-2018-00724)⁸, the WG nano is asked to provide consultation on the safety evaluation of this substance in the context of the nano guidances. The WG members discussed the specific nature of the material and the possible associated nano-specific concern, in the light of the instructions provided by the Guidance on Particle - Technical Requirements (TR). The advice will be finalised by written procedure by the WG members, to be submitted to the next NDA working group meeting.

9. Request for consultation on the nano guidances in the context of the mandate to the NDA/Nutri Unit on orthosilicic acid-vanillin complex (OSA-VC)

In relation to the previous advice of the WG nano to the NDA Panel for the novel food application orthosilicic acid-vanillin complex (OSA-VC) (EFSA-Q-2019-00440)⁹, the WG nano is asked to analyse the new documentation provided by the applicant. The WG members discussed the new evidence presented. The advice will be concluded for a final agreement by written procedure by the WG members, to be submitted to the next NDA working group meeting.

10. Any Other Business

10.1. NAMs nanofibers case-study

The WG members were informed on the outcome of the Workshop on the NAMs nanofibers case-study. The tender specification for the public call will be published soon.

10.2. ERA procurement

The WG members were informed on the recent updates of the Part 2 of the Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, on environmental risk assessment.

10.3. Joint WPMN-WNT Expert Group on Toxicokinetics of Nano-particles

The WG members were informed on the parallel activities of the new Joint WPMN-WNT Expert Group on Toxicokinetics of Nano-particles. Documentation on background information on the group activities and interests were shared with the experts.

⁸ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00724>

⁹ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00440>

11. Next meeting(s)

The dates for the next meetings have been agreed for:

- 23-25 September (TC switch to reduce the risk of coronavirus infection): from noon to noon
- 9 October (TC): from 9 to 17
- 27 October (TC): from 9 to 17
- 9-10 December (TC switch to reduce the risk of coronavirus infection): 2 full days



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 13TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Tele-conference, 26 June 2020

(Agreed on 10 July 2020)

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ Hearing Experts¹:

Shareen Doak
Matthew Wright (for Item 9)

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto
FIP Unit: Camilla Smeraldi, Ana Maria Rincon (for Item 9)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 12th Working Group meeting held on 25-27 May 2020, TELE-conference.

The minutes of the 12th Working Group meeting were agreed by written procedure on 11 June 2020⁴.

5. Hearing Expert (s)

Prof. Shareen Doak was invited in order to address specific questions from the WG on *in vitro* toxicity testing with nanomaterials. In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA invited Prof. Shareen Doak to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e. not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework⁷.

6. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the tele-meeting. A manual instructions on the new improvements of the Teams platform has been shared with WG members.

7. Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)⁸

The Guidance on Particle - Technical Requirements (TR) has been endorsed for public consultation at the last Scientific Committee plenary meeting. After a discussion on the comments received from the

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ Decision of the Executive Director on Competing Interest Management, Article 9:

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

⁸ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

Scientific Committee, the members addressed the comments provided by DG SANTE. The proposed ameliorations to the document were agreed and the draft document has been finalised for 8 weeks of public consultations. All the comments submitted through this process will be used for the further refinement of the document.

8. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)⁹

The Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health, was published in July 2018 and is under revision by the WG.

Based on the new achievements from the finalisation of the first draft of the Guidance on Particle-TR, the WG discussed on further refinement of the Guidance on Nano-RA. New ameliorations were discussed and agreed, and additional tasks will be distributed among the WG members based on their specific expertise. Additional discussion on this topic had to be postponed due to lack of time.

9. Request for consultation on the nano guidances in the context of the EC Mandate to the FIP Unit on TiO₂ mandate

The FIP Unit (Food Ingredients and Packaging) received a new mandate from the EC for an updated scientific opinion as regards the safety of titanium dioxide (E 171) as food additive (EFSA-Q-2020-00262¹⁰). Based on the principles of the 'Guidance on Nano-RA' (formerly EFSA SC Guidance on nano, 2018) and the Guidance on Particles - TR, the ccWG provided advice on Nanoscale criteria to be considered in the assessment of the relevance and reliability of experimental study design and study results. Such criteria can be incorporated in the appraisal criteria to be established by the FAF and the Genotoxicity WGs. This was a joint session with Matthew Wright, the appointed Chair of the new WG of the EFSA FAF Panel established for the re-evaluation of TiO₂. The WG proposed a scoring system, based on the evaluation of the level of dispersion (according to the instructions provided by the Guidance on Particle-TR).

10. Any Other Business

10.1. Next meetings and workplan

The Chair presented to the WG members slight amendments on the next meeting dates. Further action points and the related workplan were agreed.

11. Next meeting(s)

The dates for the next meetings have been agreed for:

- 29 June (TC): from 9 to 13
- 23-25 September (TC switch to reduce the risk of coronavirus infection): from noon to noon
- 9 October (TC): from 9 to 17
- 27 October (TC): from 9 to 17
- 9-10 December (TC switch to reduce the risk of coronavirus infection): 2 full days

⁹ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

¹⁰ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00262>



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 12TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Tele-conference, 25-27 May 2020

(Agreed on 11 June 2020)

This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

Participants

■ Working Group Members:

Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz (present on 25 and 26am)
David Gott
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel

■ Hearing Experts¹:

Shareen Doak (present for item 5 and 9 on 26 and 27am)

■ European Commission and/or Member States representatives:

Takis Daskaleros (DG SANTE) (present on 25 and 26)
Hubert Rauscher (JRC) (present on 25 and 26)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto,
Christina Kyrkou, Rositsa Serafimova (present for item 8 on the 26pm and 27am)

FIP Unit: Camilla Smeraldi (present for item 8 on the 26pm and 27am), Ana Maria Rincon, Ndip Galvin Eyong (present on 25 and 26am)

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Shareen Doak for the 25 May, and Roland Franz for the 26pm and 27 May. Takis Daskaleros and Hubert Rauscher were absent on 27 May. Camilla Smeraldi, Rositsa Serafimova, and Christina Kyrkou participated only for item 8.

2. Adoption of agenda

The agenda was adopted without further changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the (11)th Working Group meeting held on 8 May 2020, TELE-conference.

The minutes of the 11th Working Group meeting were agreed by written procedure on 18 May 2020⁴.

5. Hearing Expert (s)

Prof. Shareen Doak was invited to present her views on specific questions that the WG has on *in vitro* toxicity testing with nanomaterials and to check if the chapter on genotoxicity testing of the scientific Guidance on nano risk assessment is still up to date. In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA invited Prof. Shareen Doak to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e. not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework⁷.

6. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed at the beginning of the tele-meeting.

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ Decision of the Executive Director on Competing Interest Management, Article 9:

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

7. Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)⁸

The ccWG revised the different Sections of the draft Technical Guidance Nano following the comments provided by the members. From now on this document will be referred to as 'Guidance on Particle - Technical Requirements (TR)' and it is an EFSA guidance document. The Scientific Guidance Nano from the EFSA Scientific Committee will be referred to as 'Guidance on Nano - Risk Assessment (RA)', to improve clarity. The Guidance on Particle-TR should provide appraisal routes to assess the possible presence of particles in materials whereas the Guidance Nano-RA should guide applicants on the risk assessment of nanomaterials that are under the EFSA remit. A final draft of the document has been agreed, and will be presented to the June EFSA Scientific Committee plenary meeting for endorsement for public consultation.

8. Request for consultation on the nano guidances in the context of the EC Mandate to the FIP Unit on TiO₂ mandate

The FIP Unit (Food Ingredients and Packaging) received a new mandate from the EC for an updated scientific opinion as regards the safety of titanium dioxide (E 171) as food additive (EFSA-Q-2020-00262⁹). Based on the principles of the 'Guidance on Nano-RA' (formerly EFSA SC Guidance on nano, 2018), this ccWG has been invited to give feedback on the search string and general exclusion criteria for the systematic literature search performed by the FIP Unit in cooperation with the AMU Unit. During the meeting, the WG members finalised their advice for the FIP Unit. The document contains nano-specific considerations to be taken into account during the screening, prioritization and further weight of evidence of the information retrieved from the literature search to be analysed by the future FAF WG.

9. Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)¹⁰

The Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health, was published in July 2018 and was subjected to further revisions that are pending for approval of the group. The WG members discussed the new proposal of having an explanatory figure on the relationship between the 'Guidance on Nano-RA', the 'Guidance on Particle-TR' and the 'sectoral guidances' within the EFSA legal remit according to the use of the nanomaterial. Moreover, nano-specific considerations in the Section on *in vitro* genotoxicity were revised according to the recent state of the art. This version of the document is now ready to be distributed to the WG members and comments are elicited in July-August. Further comments and feedback on the revised text will be discussed at the next WG meetings.

10. Any Other Business

10.1. Update on the submission of the nano article

The WG has a nano article in preparation and before submission, the article could reflect the new elements from the EFSA Guidance on Particle-TR.

10.2. Update on the Nano ERA Guidance

⁸ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

⁹ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00262>

¹⁰ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

The Chair informed on the advancement of the preparatory work done for Part 2 of the Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, on environmental risk assessment.

10.3. Update on the NAM case study on nanofibers/nanocellulose

The WG was informed about the EFSA NAM (new approach methodology) case study on nanofibres/nanocellulose.

10.4. Placeholder for cases

There were no further cases to be addressed.

10.5. Workplan

The WG agreed on next action points and related workplan.

11. Next meeting(s)

The dates for the next meetings have been agreed for:

- 26 June (TC): from 9 to 13
- 29 June (TC): from 9 to 13
- 23-25 September (TC switch to reduce the risk of coronavirus infection): from noon to noon
- 9 October (TC): from 9 to 17
- 27 October (TC): from 9 to 17
- 9-11 December (TC switch to reduce the risk of coronavirus infection): from noon to noon



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 11TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Tele-conference, 8 May 2020

(Agreed on 18 May 2020)

Participants

- Working Group Members:
Jacqueline Castenmiller
Qasim Chaudhry
Francesco Cubadda
Roland Franz
Jan Mast
Alicja Mortensen
Agnes Oomen
Stefan Weigel
- Hearing Experts¹:
Shareen Doak (for item 5 and 9)
- European Commission and/or Member States representatives:
Takis Daskaleros (DG SANTE)
Hubert Rauscher (JRC)
- EFSA:
SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto, Christina Kyrkou, Rositsa Serafimova
FIP Unit: Camilla Smeraldi, Ana Maria Rincon, Ndip Galvin Eyong

1. Welcome and apologies for absence

The Chair welcomed the participants. The Chair introduced the new Hearing Expert Shareen Doak for presenting specific topics of *in vitro* assays and answering specific questions.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

2. Adoption of agenda

The agenda was adopted without further changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the (10)th Working Group meeting held on 16-17 March 2020, TELE-conference.

The minutes of the 10th Working Group meeting were agreed by written procedure on 30 March 2020⁴.

5. Hearing Expert (s)

Prof. Shareen Doak was invited to present her views on *in vitro* toxicity. In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA invited Prof. Shareen Doak to submit an Annual Declaration of Interest. Her participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e. not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework⁷.

6. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed.

7. Request for consultation on the nano guidances in the context of the EC Mandate to the FIP Unit on TiO₂ mandate)

The FIP Unit (Food Ingredients and Packaging) received a new mandate from the EC for an updated scientific opinion as regards the safety of titanium dioxide (E 171) as food additive (EFSA-Q-2020-00262⁸). Based on the principles of the nano Guidance, the ccWG nano has been invited to give feedback on the search string and general exclusion criteria for the systematic literature search performed by the FIP Unit in cooperation with the AMU Unit. During the meeting, the members provided further advice on questions from the FIP unit regarding the relevance of the retrieved studies, that have been classified according to the tested material. The ccWG also gave input to the parameters that are planned to be extracted during the full text screening. Nano-specific considerations, to be

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

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

⁴ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ Decision of the Executive Director on Competing Interest Management, Article 9:

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

⁸ EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00262>

taken into account during prioritization and further weight of evidence by the future FAF WG were discussed.

8. Technical Guidance (EFSA-Q-2019-00692)

The ccWG addressed the feedback from the Scientific Committee after the first reading on 23 April. The WG proceeded revising the Technical Guidance, specifically focusing on the link between this document and the Scientific Guidance on nanotechnologies. Furthermore, the members reflected on the different nano-ranges that may influence toxicity and how to integrate that in the final assessment of the safety of a given product; e.g. how to solve this with the mixture toxicity suggested by the EFSA Guidance on mixtures. A new clean document will be distributed for comments to be addressed at the next meeting, and prior to public consultation. It is proposed that the above consultation on TiO₂ will be used as a case study to verify the implementation of this document prior to its publication, which might be slightly postponed. In agreement with the comments received, and upon confirmation by the EC, the TG will be applicable after a transitional period (to be defined).

9. Scientific Guidance (EFSA-Q-2020-00269)

Hearing expert Prof Shareen Doak prepared a presentation for *in vitro* toxicity. Further discussions on the Scientific Guidance had to be postponed due to lack of time. The Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health, was published in July 2018 and was subjected to further revisions that are pending for approval of the group. Bilateral preparatory meetings with the Chair⁹ were continued for such proposed revisions.

10. Any Other Business

There were no further cases to be addressed. The WG agreed on next action points and workplan.

11. Next meeting(s)

The dates for the next meetings have been agreed for:

- 25-27 May (TC): from noon to noon
- 26 June (TC): from 9 to 13
- 29 June (TC): from 9 to 13
- 23-25 September, Parma (tbc): from noon to noon
- 9 October (TC): from 9 to 17
- 27 October (TC): from 9 to 17
- 9-11 December, Parma (tbc): from noon to noon

⁹ Further bilateral preparatory meetings with the chair were held on 26 March 2020 (10.00 – 12.00 h), 2 April 2020 (14.00 – 16.00 h), 15 April 2020 (14.00 – 16.00 h), and 28 April 2020 (10.00 – 12.00 h) with Jacqueline Castenmiller



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 10TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Held on 16-17 March 2020, Teleconference

(Agreed on 30 March 2020)

This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

Participants

■ Working Group Members:

Qasim Chaudhry
Alicja Mortensen
Stefan Weigel
Francesco Cubadda
Roland Franz
Agnes Oomen
Jacqueline Castenmiller
Jan Mast

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)
Takis Daskaleros (DG SANTE) (present only on the 17th morning)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona and Maria Chiara Astuto

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without further changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed.

5. TG delivery of tasks allocated in the previous meeting

The members of the WG presented the tasks allocated in the previous meeting for Sections 2, 3 and 4 of the Technical Guidance (TG). The Sections were revised after the update with the individual contributions provided by the members. Finally, the entire text of the document has been improved accordingly to the comments submitted by the WG members, including images and tables.

6. Further discussion and workplan

Further steps will be the finalization of the draft version of the Technical Guidance for the Scientific Committee consultation. After receiving the latest inputs and a revision for consistency, the draft Technical Guidance will be sent to the WG for the next round of comments. Simultaneously, a draft will also be passed on to the EFSA Scientific Committee for a first reading in context of the April plenary meeting.

7. Updates on the SG

The Scientific Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health has been published in July 2018 and has been in a Pilot phase. This Scientific Guidance (SG) is reopened for revision and work is ongoing on the version stored in Teams.

The ccWG nano revised the text updating the Scientific Guidance (SG) accordingly to the modifications proposed for Sections 8 and 9. New figures for Section 3 were revisited and commented. Since 2020 and given the workload of the ccWG Nano with the Technical Guidance, bilateral preparatory meetings with the Chair³ were organised. In each of the bilateral meetings, updates in the SG guidance were discussed by the Chair and Jaqueline Castenmiller. The preparations and developments made prior to each bilateral meeting, were evaluated for acceptance or modification. The best proposals were formulated and proposed to all ccWG nano members, so that important decisions for updating the SG can be taken with the full ccWG nano in an efficient manner.

The working group approved the continuation of this way of organising the preparatory work and for making decisions together.

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

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

³ Bilateral meetings were held on 16 January 2020 (14.30 – 16.30 h), 29 January 2020 (14.30 – 16.30 h), 7 February 2020 (10.00 – 12.00 h), 28 February 2020 (10.00 – 12.00 h), 12 March 2020 (14.00 – 16.00 h), and 18 March 2020 (9.30 – 12.00 h) with Jaqueline Castenmiller

8. Placeholder for cases and Any Other Business

There were no cases to be discussed. The WG members agreed on the 2020 meeting dates and related work plan.

9. Next meeting(s)

The dates for the next meetings have been agreed for:

- 8 May (TC): from 9 to 17
- 25-27 May (TC): from noon to noon
- 26 June (TC): from 9 to 13
- 29 June (TC): from 9 to 13
- 23-25 September, Parma: from noon to noon
- 9 October (TC): from 9 to 17
- 27 October (TC): from 9 to 17
- 9-11 December, Parma: from noon to noon



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 9TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Held on 10-12 February 2020, Parma

(Agreed on 4 March 2020)

Participants

■ Working Group Members:

Qasim Chaudhry
Alicja Mortensen
Stefan Weigel (from TC)
Francesco Cubadda
Roland Franz
Agnes Oomen
Jacqueline Castenmiller
Jan Mast

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC) (absent)
Takis Daskaleros (DG SANTE) (present on the 11th afternoon)
Rodriguez Unamuno Virginia (ECHA)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona and Maria Chiara Astuto
FIP Unit: Ana Maria Rincon, Camilla Smeraldi

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hubert Rauscher (JRC).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

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(s) of Interest made at the beginning of the meeting, please refer to the Annex.

4. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed. The individual contributions of the ccWG members have been merged in a unique document to facilitate the revision and finalization of the Technical Guidance. The documents under development have been renamed 'EFSA Guidance on technical requirements' and 'EFSA Scientific Guidance'.

5. TG delivery of tasks allocated in the previous meeting

The members of the WG presented the tasks allocated in the previous meeting for the Section 2, 3 and 4 of the Technical Guidance (TG). The content of the Sections has been revised accordingly to the comments submitted by the WG members, including amendments in terminology. The proposal of methodologies to be used has been modified based on the WG members expertise to improve the technical practicality.

6. Further discussion and workplan

Further steps will be the finalization of the Section 2-3 of the TG and the further development of the Section 4, in accordance with the conceptual variation accomplished during the meeting.

7. Updates on the SG

The WG revised the text updating the Scientific Guidance (SG) accordingly to the modifications proposed for Sections 1-3. The scope of the Guidance has been revised in line with the latest developments under REACH and the clarifications received with the new mandate on the Technical Guidance. The next step will be the adjustment of the text in conformity with the revised scope and the continuation with the revision of the other sections of the document. Possible updates on the Section 6 (i.e. on toxicokinetic evaluations) will be presented at the next meeting.

8. Placeholder for cases and Any Other Business

The WG supported the FIP unit with specific expert advice for the application dossiers on polydextrose and calcium carbonate. The EFSA colleagues from the Food Ingredients and Packaging Unit (FIP) asked the WG about a searching strategy for existing studies that are available in the public domain, that are relevant under the EFSA Nano Guidance and that could be relevant for assessing food grade TiO₂ (E171). The WG agreed on the meeting date for the Nano Network which will be held on 21-23 October in Belgium (from/to midday). The WG members continued to exchange important publications through

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

a folder on the EFSA Document Management System (DMS). Lastly, the WG members agreed on action points regarding the draft article on the Nano Guidance, which is in preparation to be published in peer review journal.

9. Next meeting(s)

The dates for the next meetings have been confirmed for:

- 16-17 March (Parma)
- 8 May (TC)
- 25-27 May (Rome)
- 29 June (TC)

Annex

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

NO CONFLICT: With regard to this meeting, Dr Agnes Oomen, declared the following interest: being co-author on a paper in press that reviews studies performed with TiO₂. 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



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 8TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Held on 17 January 2020, Teleconference

(Agreed on 31 January 2020)

Participants

■ Working Group Members:

Qasim Chaudhry
Alicja Mortensen
Stefan Weigel
Francesco Cubadda
Roland Franz
Agnes Oomen
Jacqueline Castenmiller
Jan Mast

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC) (present from 9 to 13)
Takis Daskaleros (DG SANTE) (absent)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona and Maria Chiara Astuto

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Feedback on digital cooperation in Teams 365

The members of the WG provided feedback on the digital cooperation in Teams and technical issues were addressed.

5. TG delivery of tasks allocated in the previous meeting

The members of the WG presented the tasks allocated in the previous meeting for the Section 2, 3 and 4 of the Technical Guidance (TG).

6. Further discussion and workplan

Further steps will be the finalization of the Section 2-3 of the TG, the preparation of the editorial proposal of this first part and the further development of the Section 4.

7. Updates on the SG

The WG discussed the proposal for updating the Scientific Guidance in Chapters 1, 2, and 3. Updating Chapter 4 has also initiated. Some scoping issues will be discussed on the next meeting and cross checked in the current regulatory context.

8. Placeholder for cases and Any Other Business

The WG examined a FMC case study about calcium carbonate.

9. Next meeting(s)

The dates for the next meetings have been confirmed for:

- 10-12 February (Parma)
- 16-17 March (Parma)
- 8 May (TC)
- 25-27 May (Rome)
- 29 June (TC)

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



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 7TH MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Held on 11-13 December, Parma

(Agreed on 17 January 2020)

Participants

■ Working Group Members:

Qasim Chaudhry (not present on 11 Dec)

Alicja Mortensen

Stefan Weigel (absent)

Francesco Cubadda

Roland Franz

Agnes Oomen

Jacqueline Castenmiller

Jan Mast

■ Hearing Experts¹:

None

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC) (absent)

Takis Daskaleros (DG SANTE) (participating by phone on 11 Dec)

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona and Maria Chiara Astuto

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Stefan Weigel and Hubert Rauscher.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Feedback on digital cooperation in Teams 365 and other technical issues

The WG discussed the experience and agreed on the practicalities regarding the new EFSA collaboration environment on Teams.

5. TG delivery of tasks allocated in the previous meeting

The members of the WG presented the tasks allocated in the previous meeting, focusing on the first and second points of the Terms of Reference for the EFSA Technical Guidance (TG).

6. Further discussion and workplan

The workplan was updated in line with the progress achieved at the meeting and the timelines for the planned discussions at the Scientific Committee plenary meetings.

7. Updates on the SG

The WG agreed on the procedure for handling the proposals for updating the EFSA Scientific Committee Scientific Guidance (SG).

8. Any Other Business

Additional need for expertise was identified in order to cover the *in vitro* toxicology of nanomaterials and new assessment methodologies (NAM). The chair will follow up the suggested expansion of the cc-WG nano accordingly.

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

Several members updated the WG on participations at related scientific meetings, including the 1st Thematic Conference on Advanced Materials and the annual meetings of the EU Horizon 2020 research projects GRACIOUS and PATROLS.

The WG was updated on the progress of the ongoing procurement, covering the preparatory work for the second part of the guidance addressing the environmental risk assessment.

9. Next meeting(s)

Tentatively, dates for the next meetings were proposed for 2020:

- 17 January (TC)
- 10-12 February (Parma)
- 16-17 March (Parma)
- 8 May (TC)
- 25-27 May (Rome)
- 29 June (TC)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 6th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

TELE-conference, 18 November 2019

(Agreed on 2 December 2019)

Participants

■ Working Group Members:

Qasim Chaudhry
Alicja Mortensen
Stefan Weigel
Francesco Cubadda
Roland Franz
Agnes Oomen
Jacqueline Castenmiller
Jan Mast

■ European Commission and/or Member States representatives:

Hubert Rauscher (JRC)

■ Hearing Experts¹:

None

■ EFSA:

SCER Unit: Reinhilde Schoonjans (Chair), José Tarazona, Maria Chiara Astuto

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros (DG SANTE).

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



2. Adoption of agenda

The agenda was adopted with minor additions in any other business and with deletion of the placeholder for cases.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declaration of Interest, as well as the Oral Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex I and II of the minutes of the 2nd WG meeting presented (available below in this document). No additional Oral declarations were made at the beginning of this meeting.

4. Feedback on digital cooperation in Teams 365

After starting to use the Microsoft Teams platform, cc-WG members discussed the practical implications related to its use.

5. Delivery of tasks allocated in the previous meeting

The cc-WG members revised the tasks allocated for the development of the Technical Guidance (TG) and discussed on the points that also require an update of the Scientific Guidance (SG). Such Updates will be predominantly based on experiences with actual cases and on harmonization with newly published guidance (e.g. SCCS GD). In particular, physicochemical properties (e.g. solubility, solution rate) should be evaluated as initial screening for the presence of potentially biopersistent small particles or nanoparticles. The options that were suggested to allow for accepting old toxicological studies are based on the degree of correspondence between technical specification of the marketed material and the tested material. The cc-WG members expressed the general interest to explore for integration the topics of BMD, NMDR and mixtures.

6. Any Other Business

Dates for the 2020 meeting were proposed and reported below. The cc-WG members received a brief updated on the new Fertilisers Regulation, the new eREACHnano tool and the new SCCS guidance document on the safety assessment of nanomaterials in cosmetics. In particular, the latter may be considered for updating the EFSA SG. The cc-WG members congratulated on the acceptance of the Article related to the nano risk assessment strategy presented in the EFSA SG.

7. Next meeting(s)

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



The next meeting has been confirmed for 11(pm) – 13(am) December.

The dates for the next meetings in 2020 were proposed:

17 January (TC)

10-12 February (meeting in Parma)

23-25 March (meeting in Parma)

8 May (TC)

25-27 May (meeting in Parma)

29 June (TC)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 5th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

Parma, 21-23 October 2019

(Agreed on 30 October 2019)

Participants

- Working Group Members:
 - Qasim Chaudhry
 - Alicja Mortensen
 - Stefan Weigel (TC)
 - Francesco Cubadda
 - Roland Franz
 - Agnes Oomen
 - Jacqueline Castenmiller
 - Jan Mast (not present on 22 oct pm)
- European Commission and/or Member States representatives:
 - Hubert Rauscher (JRC) (not present on 23 Oct)
 - Takis Daskaleros (DG SANTE) (22 am only)
- Hearing Experts¹:
 - None
- EFSA:
 - SCER Unit: Reinhilde Schoonjans (Chair) and José Tarazona
 - NDA Unit: Céline Dumas, Annamaria Rossi, Wolfgang Gelbmann, Andrea Germini

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declaration of Interest, as well as the Oral Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex I and II of the minutes of the 2nd WG meeting presented (available below in this document). No additional Oral declarations were made at the beginning of this meeting.

4. EC Mandate for technical guidance

The mandate of the European Commission was received and the cross-cutting Working Group (cc-WG) discussed the terms of reference (ToRs) in detail. The interpretation of the terms of Reference was cross checked with the EC representative and a first workplan was established. An initial outline for such technical guidance was endorsed and used for collecting the elements that address the ToR.

5. Revision of the scientific guidance

The cc-WG has been preparing clarifying updates in the scientific guidance⁴ (under revision) to address the feedback from users of the guidance (e.g. the feedback from the Stakeholders Workshop on nanomaterials and nanotechnology organised by EFSA on April 1-2, 2019 in Parma). Now that the distinction between technical and scientific guidance has been clarified in line with the received ToR, the WG proposed to revise the scientific guidance after the technical guidance is drafted. It is expected that the scientific guidance can largely remain as it is.

6. Regulated products.

EFSA is evaluating several cases for which nanospecific aspects need to be clarified. The ccWG nano has delivered technical expert input for 3 such cases under evaluation by the NDA Panel: bacterial cellulose aqueous suspension (HydroFibreTM), Orthosilicic acid-vanillin complex (OSA-VC) and Ferric sodium EDTA (Ferrazone XF).

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

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

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5327>



7. Any Other Business

For the meeting dates in 2020, a doodle for availability will be sent out.

The cc-WG members started using the Microsoft platform Teams to jointly work on the technical guidance as well as on the update of the scientific guidance.

8. Next meeting(s)

The dates for the next meetings were confirmed for 2019:

18 November (TC)

11 (pm)-13(am) December



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 4th MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

TELE-conference, 10 September 2019

(Agreed on 27 September 2019)

Participants

- Working Group Members:
 - Qasim Chaudhry
 - Alicja Mortensen
 - Stefan Weigel
 - Francesco Cubadda
 - Roland Franz
 - Agnes Oomen
 - Jacqueline Castenmiller
- European Commission and/or Member States representatives:
 - Hubert Rauscher (JRC)
- Hearing Experts¹:
 - None
- EFSA:
 - SCER Unit: Reinhilde Schoonjans (Chair) and Jose Tarazona

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Takis Daskaleros (DG SANTE).

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declaration of Interest, as well as the Oral Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex I and II of the minutes of the 2nd WG meeting presented (available below in this document). No additional Oral declarations were made at the beginning of this meeting.

4. EC Mandate for technical guidance

The European Commission informed prior to the meeting that the draft mandate has gone through revision and will be sent to EFSA in the coming weeks. The cross-cutting Working Group (cc-WG) was informed about the preliminary projected timelines and discussed, in connection to the revision of the scientific guidance, the best way forward for the technical guidance content.

5. Revision of the scientific guidance

The cc-WG continued with the assessment of the feedback from users of the guidance (e.g. the feedback from the Stakeholders Workshop on nanomaterials and nanotechnology organised by EFSA on April 1-2, 2019 in Parma). All the members have identified areas of updates in the different sections of the EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, Part 1, human and animal health⁴. The cc-WG redistributed some of the tasks for the next meeting, according to their expertise, and discussed further how to make the distinction between technical and scientific guidance.

6. Nano Article – version 10 Final revisions & Publication

The cc-WG members were informed about the final version of the draft of the article, that is ready to be sent for publication to the agreed journal for inclusion in a special edition by mid-September.

7. APCRA International Initiative – case study on nanofibres nanocellulose

Further to the input given by the cc-WG on the bacterial nanocellulose, EFSA has taken the initiative to propose a follow up activity on the *in vitro* assessment of digestibility and gastrointestinal absorption of nanofibers. The proposal will be discussed with the collaborating scientists from APCRA (Accelerating the Pace of Chemical Risk Assessment); an International Governmental Collaborative Initiative. The cc-WG was invited to submit comments to the project outline.

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

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

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5327>



8. Any Other Business

EFSA briefly updated the cc-WG members on the status of the ongoing procurement with RIVM covering the environmental risk assessment.

The cc-WG members discussed practical implications regarding the use of EFSA DMS system or the Microsoft platform Teams.

9. Next meeting(s)

The dates for the next meetings were confirmed for 2019:

21(pm)-23(am) October

18 November (TC)

11 (pm)-13(am) December



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 3rd MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

TELE-conference, 24 June 2019

(Agreed on 02 July 2019)

Participants

- Working Group Members:
 - Qasim Chaudhry
 - Alicja Mortensen
 - Stefan Weigel
 - Francesco Cubadda
 - Roland Franz
 - David Gott
 - Agnes Oomen
 - Jacqueline Castenmiller
- European Commission and/or Member States representatives:
 - Hubert Rauscher (JRC)
 - Takis Daskaleros (DG SANTE)
- Hearing Experts¹:
 - None
- EFSA:
 - SCER Unit: Reinhilde Schoonjans and Jose Tarazona
 - FIP Unit: Ana Rincon
 - NUTRI Unit: Cecile Dumas

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received for the full meeting, but some participants were only able to attend parts of the tele-conference.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declaration of Interest, as well as the Oral Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex I and II of the minutes of the 2nd WG meeting presented (available below in this document). No additional Oral declarations were made at the beginning of this meeting.

4. EC Mandate for technical guidance

The European Commission presented a revised draft mandate; the cc-WG made suggestions to clarify some elements presented in the background information and conducted a preliminary discussion on the best way for addressing the proposed terms of reference.

5. New request for assistance from the NDA Panel/NUTRI Unit on bacterial nanocellulose

The cc-WG received a request for assistance from the Nutrition (NUTRI) Unit on the evaluation of specific studies in the dossier of the above material that characterise the structure of the material and possible dimensions within the nano-scale. The evaluation by the cc-WG on the information provided by the applicant will be reported to the Novel Foods WG.

6. Revision of the scientific guidance

The cross-cutting Working Group (cc-WG) continued with the assessment of the feedback received during the Stakeholders Workshop on nanomaterials and nanotechnology organised by EFSA on April 1-2, 2019 in Parma, in order to identify possible updates in the different sections of the EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, Part 1, human and animal health⁴. The cc-WG members established a preliminary distribution of tasks. A plan for conducting the update will be discussed at the next meetings.

7. Nano Article – version 9 Final revisions & Publication

The cc-WG members discussed the comments received on the updated version. The final draft of the article will then be sent for publication to the agreed journal for inclusion in a special edition.

8. Any Other Business

EFSA briefly updated the cc-WG members on the status of the ongoing procurement with RIVM covering the environmental risk assessment.

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



The cc-WG members agreed on practicalities regarding the use of EFSA DMS system.

9. Next meeting(s)

Tentative days for the next meetings were discussed.



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 2nd MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

TELE-conference, 29-30 April 2019

(Agreed on 20 June 2019)

Participants

- Working Group Members:
 - Qasim Chaudhry
 - Alicja Mortensen
 - Stefan Weigel
 - Francesco Cubadda
 - Roland Franz
 - David Gott
- European Commission and/or Member States representatives:
 - Hubert Rauscher (JRC)
- Hearing Experts¹:
 - None
- EFSA:
 - SCER Unit: Reinhilde Schoonjans and Berrak Eryasa
 - FCM Unit: Eric Barthélémy

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Agnes Oomen, WG Member.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declaration of Interest, as well as the Oral Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex I and II respectively.

4. Scientific topic(s) for discussion

4.1. EFSA request to follow up from the Nano Stakeholders workshop

The cross-cutting Working Group (cc-WG) evaluated the Stakeholders Workshop on nanomaterials and nanotechnology organised by EFSA on April 1-2, 2019 in Parma, Italy. The agenda and the presentations were published on the EFSA website:

<https://www.efsa.europa.eu/en/events/event/190401>.

The cc-WG members grouped the feedback received during the workshop according to the main sections of the EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, Part 1, human and animal health⁴. The cc-WG members appreciated that the presentations made by the users of the guidance and their suggestions were directly linked to the respective guidance sections that will now be reconsidered for revision. Dedicated meetings will be organised to make such amendments.

4.2. Draft Request from the European Commission for technical guidance

The European Commission drafted a request for a new technical EFSA guidance on the scientific requirements for regulated food and feed products to establish the presence of particles in the nanoscale. This initial draft was discussed and the cc-WG made suggestions to clarify both the background information as well as the terms of reference.

4.1. Request from the CEF Panel on Titanium Dioxide surface treated with fluoride-modified Alumina

The cc-WG received a request for assistance from the Food ingredients and packaging (FIP) Unit on the evaluation of specific studies in the dossier of the above material, that characterise the fraction of small particles including within the nano-scale. The evaluation by the cc-WG on the robustness of the evidence and the conclusions from the applicant will be reported to the FCM WG.

4.1. Request from the NUTRI Panel on Inositol Stabilised Arginine Silicate

The request for assistance from the NDA Unit on the above substance were discussed at the meeting in November 2018 in Rome (<https://www.efsa.europa.eu/sites/default/files/event/181115-1-m.pdf>), resulting in a first response from the ccWG to the NDA Unit. The applicant meanwhile submitted additional information and the cc-WG was asked to confirm whether this was corresponding the EFSA guidance for risk assessment. A follow-up report with the views of the cc-WG will be provided to the NDA Unit.

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



5. Any Other Business

The cc-WG members agreed on the final internal revision deadline for the article based on the EFSA guidance (by mid-June 2019). The final draft of the article will then be sent for publication to the agreed journal for inclusion in a special edition.

6. Next meeting(s)

To be confirmed.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Dr R. Franz the following interest has been declared: in the context of his employment at Fraunhofer Institute for Process Engineering and Packaging (IVV), he has responsibilities as head of department "Product Safety and Analytics". Research and contract work in the field of chemical safety of food contact materials is conducted by his institute, not only for public, but also for private enterprises. This includes e.g. also analytical measurements for industry, in particular in the field of technical innovations for food contact materials (occasionally the test reports are used by the companies in preparation of a dossier to be submitted for evaluation by EFSA), which constitutes a conflict of interest (CoI) with the mandate of the EFSA ccWG Nano.

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 ccWG Nano, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. Pursuant to Article 21(6) of the above-mentioned Decision, Dr Franz's involvement is authorised as "member" in the scientific group for which the waiver is granted, but he is not allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

Annex II

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

With regard to this meeting, Dr R. Franz declared the following interest: his laboratory has done some experimental work in support of the application Titanium dioxide treated with fluoride modified alumina, which is subject to a request for assistance from this working group. In accordance with EFSA's Policy on Independence⁷ and the Decision of the Executive Director on Competing Interest Management⁸, 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) but it has been waived pursuant to the Decision of the Executive Director on Competing Interest Management. This means that the expert should not suffer from the exclusion from the meeting, but he may not be the chairmanship, vice-chairman or rapporteur of the WG.

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

MINUTES OF THE 1st MEETING OF THE CROSS-CUTTING WORKING GROUP ON NANOTECHNOLOGIES

TELE-conference, 7 March 2019

(Agreed on 25 March 2019)

Participants

- Working Group Members:
 - Qasim Chaudhry
 - Alicja Mortensen
 - Stefan Weigel
 - Francesco Cubadda
 - Roland Franz
- European Commission and/or Member States representatives:
 - Hubert Rauscher (JRC)
- EFSA:
 - SCER Unit: Reinhilde Schoonjans and Berrak Eryasa
 - FCM Unit: Eric Barthelemy
 - FIP Unit: Ana Rincon

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from David Gott, WG Member.

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 Independence and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the



issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion

The cross-cutting WG met to discuss the draft presentations for the Stakeholders Workshop on nanomaterials and nanotechnology organised on April 1-2, 2019 in Parma, Italy. The cc-WG members were supported by the EFSA staff from the FIP unit and FCM unit to exchange views on the questions raised that are related to their expertise.

Due consideration was given to all draft presentations submitted to the workshop by the cc-WG members and EFSA staff joining to this meeting.

The cc-WG members appreciated that the presentations are directly linking the issues to be raised with the EFSA's Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain, Part 1, human and animal health¹. Furthermore, the questions and suggestions expected to be raised by the speakers are presented on the slides.

The workshop is planned to have four sessions, each dedicated to a selection of chapters in the guidance. The Chairs of the relevant sessions will address the questions from the audience during the general discussion time slot at the end of each session. All participants agreed that the legal definitions of nanomaterials (such as the Recommendations², currently under review) is not within the scope of EFSA nor of this workshop.

The final versions of the presentations in the PDF format and the agenda of the WS will be published as the outcomes of this Stakeholders WS.

5. Any Other Business

None

6. Next meeting(s)

To be confirmed.

¹ <https://www.efsa.europa.eu/en/efsajournal/pub/5327>

² Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial. OJ L 275, 20.10.2011, p. 38–40, under revision.