



## SCIENTIFIC COMMITTEE AND EMERGING RISK UNIT

### MINUTES OF THE 19<sup>TH</sup> 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 Experts<sup>1</sup> 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 9<sup>th</sup> 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)

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

## **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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## **4. Agreement of the minutes of the 18<sup>th</sup> Working Group meeting held on 27 October 2020, by teleconference.**

The minutes of the 18<sup>th</sup> Working Group meeting were agreed by written procedure on 16 November 2020<sup>4</sup>.

## **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)<sup>5</sup>**

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 10<sup>th</sup> 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

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

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

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)<sup>6</sup>, 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)<sup>7</sup>**

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)<sup>8</sup>**

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.

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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 18<sup>TH</sup> 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 Experts<sup>1</sup>:

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)

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

## **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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## **4. Agreement of the minutes of the 17<sup>th</sup> Working Group meeting held on 21-22 October 2020, by teleconference.**

The minutes of the 17<sup>th</sup> Working Group meeting were agreed by written procedure on 4 November 2020<sup>4</sup>.

## **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)<sup>5</sup>**

The draft EFSA Guidance on Particle 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)<sup>6</sup>**

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

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

<sup>5</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

<sup>6</sup> 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)<sup>7</sup>**

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

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<sup>7</sup> <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 17<sup>TH</sup> 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 10<sup>th</sup> 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 Experts<sup>1</sup>:

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)

<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>



## 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 16<sup>th</sup> Working Group meeting held on 9 October 2020, by teleconference.

The minutes of the 16<sup>th</sup> Working Group meeting were agreed by written procedure on 20 October 2020<sup>4</sup>.

## 5. Addressing comments received in both guidances (Guidance on Particle - Technical Requirements (TR) (EFSA-Q-2019-00692)<sup>5</sup> and Guidance on Nano - Risk Assessment (RA) (EFSA-Q-2020-00269)<sup>6</sup>

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 10<sup>th</sup> 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.

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

<sup>5</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

<sup>6</sup> 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 17<sup>th</sup> 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 16<sup>TH</sup> 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 Experts<sup>1</sup>:

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.

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

## 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 15<sup>th</sup> Working Group meeting held on 23-25 September 2020, by teleconference.

The minutes of the 15<sup>th</sup> Working Group meeting were agreed by written procedure on 7 October 2020<sup>4</sup>.

## 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)<sup>5</sup>

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)<sup>6</sup>

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.

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

<sup>5</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

<sup>6</sup> 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 15<sup>TH</sup> 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 Experts<sup>1</sup>:

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)

<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

## 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 14<sup>th</sup> Working Group meeting held on 29 June 2020, by teleconference.

The minutes of the 14<sup>th</sup> Working Group meeting were agreed by written procedure on 10 July 2020<sup>4</sup>.

## 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)<sup>5</sup>

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.

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

<sup>5</sup> 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)<sup>6</sup>**

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)<sup>7</sup>**

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 work<sup>8</sup> 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.

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<sup>6</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

<sup>7</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00324>

<sup>8</sup> <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 website<sup>9</sup>.

### 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.

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<sup>9</sup> <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 14<sup>TH</sup> 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 Experts<sup>1</sup>:  
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)

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

## 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 13<sup>th</sup> 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 July<sup>4</sup>.

## 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 framework<sup>7</sup>.

## 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 TiO<sub>2</sub> 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

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>7</sup> 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](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 TiO<sub>2</sub>, 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)<sup>8</sup>, 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)<sup>9</sup>, 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.

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<sup>8</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2018-00724>

<sup>9</sup> 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 13<sup>TH</sup> 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 Experts<sup>1</sup>:  
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)

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

## 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 4. Agreement of the minutes of the 12<sup>th</sup> 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 2020<sup>4</sup>.

## 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 framework<sup>7</sup>.

## 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)<sup>8</sup>

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

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>7</sup> 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](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>8</sup> 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)<sup>9</sup>**

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 TiO<sub>2</sub> 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<sup>10</sup>). 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 TiO<sub>2</sub>. 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

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<sup>9</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00269>

<sup>10</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00262>





# SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## MINUTES OF THE 12<sup>TH</sup> 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 Experts<sup>1</sup>:

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)

<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

## 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 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 2020<sup>4</sup>.

## 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 framework<sup>7</sup>.

## 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.

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>7</sup> 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](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)<sup>8</sup>

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 TiO<sub>2</sub> 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<sup>9</sup>). 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)<sup>10</sup>

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

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<sup>8</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692>

<sup>9</sup> EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-00262>

<sup>10</sup> 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 11<sup>TH</sup> 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 Experts<sup>1</sup>:

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.

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

## 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## 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 2020<sup>4</sup>.

## 5. Hearing Expert (s)

Prof. Shareen Doak was invited to present her views on *in vitro* toxicity. In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 framework<sup>7</sup>.

## 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 TiO<sub>2</sub> 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<sup>8</sup>). 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

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

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

<sup>4</sup> <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf>

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>7</sup> 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](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>8</sup> 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 TiO<sub>2</sub> 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 Chair<sup>9</sup> 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

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<sup>9</sup> 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 10<sup>TH</sup> 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 17<sup>th</sup> 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### 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 Chair<sup>3</sup> 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.

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>3</sup> 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 9<sup>TH</sup> 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 11<sup>th</sup> 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration(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 TiO<sub>2</sub> (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

<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

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 TiO<sub>2</sub>. In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

### MINUTES OF THE 8<sup>TH</sup> 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 Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### **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)

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<sup>1</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

## SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

### MINUTES OF THE 7<sup>TH</sup> 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 Experts<sup>1</sup>:
  - 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

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



## **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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## **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.

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

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

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 6<sup>th</sup> 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 Experts<sup>1</sup>:

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).

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



## 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. 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 2<sup>nd</sup> 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)

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

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



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 5<sup>th</sup> 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 Experts<sup>1</sup>:

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.

<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



## 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. 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 2<sup>nd</sup> 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 guidance<sup>4</sup> (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).

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

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

<sup>4</sup> <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 4<sup>th</sup> 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 Experts<sup>1</sup>:
  - 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.

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. 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 2<sup>nd</sup> 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 health<sup>4</sup>. 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.

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

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

<sup>4</sup> <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 3<sup>rd</sup> 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 Experts<sup>1</sup>:
  - 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.

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



## 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. 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 2<sup>nd</sup> 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 health<sup>4</sup>. 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.

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

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



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 2<sup>nd</sup> 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 Experts<sup>1</sup>:
  - 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.

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work:  
<http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.



### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. 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 health<sup>4</sup>. 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.

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

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





## **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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>8</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

### MINUTES OF THE 1<sup>st</sup> 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 health<sup>1</sup>. 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 Recommendations<sup>2</sup>, 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.

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<sup>1</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/5327>

<sup>2</sup> 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.