

Scientific Committee

Minutes of the 12th meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 16-18 April 2018, Parma (Italy)

(Agreed on 31 May 2018)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), David Gott, Qasim Chaudhry (Vice-Chair), Francesco Cubadda, Agnes Oomen, Stefan Weigel

- **Hearing Experts¹:** none

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

Hubert Rauscher (JRC) participated per teleconference

- **EFSA:**

SCER Unit: Reinhilde Schoonjans and Berrak Eryasa

- **Others:**

DTS Unit: Guido Zunino, Jacopo Alabiso

COMMS Unit: Saba Giovannacci

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 11th Working Group meeting held on 20-22 March 2018, Parma.

The minutes of the 11th Working Group meeting held on 20-22 March 2018 were agreed.⁴

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

The working group further considered the comments received during the public consultation. All comments were evaluated and the text of the draft guidance was refined where necessary and helpful to enhance clarity. No major shifts or changes were necessary. Some chapters have been shortened to delete non-nanospecific information. Recurrent comments on a number of key issues were answered with a general response. These general responses will be mentioned in the body text of the technical report on the public consultation. The technical report will be published together with the endorsed guidance. Possible endorsement by the Scientific Committee is scheduled for 28-29 May.

6. Any Other Business

6.1. Document management system

The working group is still taking part in the try-out of a new digital cooperation platform to work on the guidance. New bibliographic references are classified in a "new folder" after each meeting on the conventional DMS system

6.2. Standing Working group and Pilot phase

At the Scientific Committee meeting of 11-12 April, it was approved that the endorsed guidance will enter a pilot phase in EFSA with the support of a Standing Working Group on nanotechnologies. This guidance will be applied by all relevant EFSA Panels, EFSA Units, the NanoNetwork members and stakeholders dealing with nanomaterials in food- and feed-

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

related applications. All members of the current working group have expressed availability for such support during the upcoming pilot year. At the end of 2019, the experiences will be evaluated and the guidance will be made final.

7. Next meeting(s)

The following dates were discussed:

- First standing working group meeting: to be decided
- Nanonetwork meeting: 15-16 November 2018
- Stakeholders meeting: after 23 January

Scientific Committee

Minutes of the 11th meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 20-22 March 2018, Parma (Italy)

(Agreed on 16 April 2018)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), David Gott, Francesco Cubadda, Agnes Oomen, Stefan Weigel.

Qasim Chaudhry (Vice-Chair), participated via telemeeting on the third day)

- **Hearing Experts¹:** none

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

Hubert Rauscher (JRC)

- **EFSA:**

SCER Unit: Reinhilde Schoonjans and Berrak Eryasa

- **Others:**

DTS Unit: Guido Zunino, Jacopo Alabiso, Ernesto Guisado Ferrer

COMMS Unit: Saba Giovannacci

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Qasim Chaudhry for the 2 first days.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <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 and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process.

For further details on the outcome of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

4. Agreement of the minutes of the 10th Working Group meeting held on 28-29 November 2017, Parma.

The minutes of the 10th Working Group meeting held on 28-29 November 2017 were agreed.²

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

The working group addressed all the comments received during the public consultation. All comments were evaluated individually and the text of the guidance was refined where necessary. The draft document will be further revisited during the next working group meeting in April. Afterwards, it will be prepared for possible endorsement of the Scientific Committee on 28-29 May.

6. Any Other Business

6.1. Document management system

The working group has a new digital cooperation platform to work on the guidance. New bibliographic references are classified in a "new folder" after each meeting.

² <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

7. Next meeting(s)

The following dates were blocked for the processing of the comments of the public consultation:

- 16-18 April 2018 (2 full days, lunch to lunch)

Annex:

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

With regard to this meeting Dr. David Gott declared the following interest: "As part of my FSA employment, I am the Scientific Secretary to the UK's Committee on Toxicity (COT). Comments have been submitted by the COT following discussion at their February meeting. This has been the established FSA approach to seek independent scrutiny when FSA officials have been involved in their personal capacity as experts in EFSA work. I presented the opinion and answered questions from the Committee. However, the drafting and submission of their comments were delegated to another member of the Secretariat.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director Declarations of Interest⁴, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest. This results in the exclusion of the expert from any discussion, voting or other processing of the COT comments by the concerned scientific group.

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014>

Network & Working Group on Nanotechnologies in Food and Feed

Minutes of the 7th Network meeting and 10th Working Group meeting

**Held on 28th November – 29th November 2017, Parma
(Agreed on 20 March 2018)**

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	Name
Austria	APOLOGIES
Belgium	Jan Mast
Bulgaria	APOLOGIES
Croatia	Darko Mikec
Cyprus	APOLOGIES
Czech Republic	Vladimir Ostry
Denmark	Katrin Loschner
Estonia	Angela Ivask
Finland	Pertti Koivisto
France	Bruno Teste
Germany	Alfonso Lampen
Greece	Aristotelis Xenakis
Hungary	Andrea Zentai
Ireland	Karl McDonald
Italy	Francesco Cubadda
Lithuania	APOLOGIES
Luxembourg	Micheline Rosch
Netherlands	Jacqueline Castenmiller
Norway	Ragna Bogen Hetland
Poland	APOLOGIES
Portugal	APOLOGIES
Romania	Gina Popovici
Slovak Republic	Peter Simon
Slovenia	APOLOGIES
Spain	José Manuel Barat
Sweden	Lena Hellmer
United Kingdom	David Gott

- **Nano working group:**

Alicja Mortensen (NANO WG Chair), Qasim Chaudhry (NANO WG vice Chair), Agnes Oomen (NANO WG member)

- **European Commission:**

Takis Daskaleros (DG SANCO), Hubert Rauscher (DG JRC)

- **EFSA:**

SCER Unit: Reinhilde Schoonjans (Scientific Officer and meeting Chair), Melpo Karamitrou (Trainee)

FIP Unit: Federica Lodi and Ana Maria Rincon (teleconference)

NDA Unit: Reinhard Ackerl (teleconference)

1. Welcome and apologies for absence

The Chair, Reinhilde Schoonjans, welcomed the participants.

Apologies were received from Daniela Hofstaedter (Austria), Angel Angelov (Bulgaria), Popi Kanari (Cyprus), Vaclovas Jurgelevicius (Lithuania), Wojciech Wąsowicz (Poland), Viviana Golja (Slovenia), Helena Carmo (Portugal)

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes

a. The minutes of the 6th meeting of the Network on Nanotechnologies in Food and Feed held on 30 June and 1 July 2016, Madrid.

The minutes were agreed by written procedure on 30 September 2016 and published on the EFSA website¹.

b. The minutes of the 9th meeting of the Working Group on Nanotechnology in agri/food/feed

The minutes were agreed without changes and published on the EFSA website².

¹ <https://www.efsa.europa.eu/en/events/event/160630>

² <https://www.efsa.europa.eu/sites/default/files/wqs/cross-cutting-science/wgNanotechnologies.pdf>

4. Declarations of interest and confidentiality statements

Network members duly addressed declarations of interest and confidentiality statement according to the EFSA policy.

Declarations of Interest of Working Groups members: In accordance with EFSA's Policy on Independence and Scientific Decision Making Processes and the Decision of the Executive Director on Declarations of Interest, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

5. Topic for discussion: Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health.

The Chair, Reinhilde Schoonjans, introduced the goals of this meeting:

(1) Comments received from the Member States on the draft update of the guidance, are to be addressed immediately in the text. Comments which need further consideration will be addressed at the next working group meeting in March 2018. The major topics that needed clarification in each section are presented below.

(2) Outstanding tasks for the working group were addressed while going through each section of the guidance.

The Chair, Reinhilde Schoonjans (EFSA), welcomed the active contributions received by all participants beforehand. During a tour the table, all participants expressed their general views on this guidance.

General comments and principles

In response to the general comments received from Member States, the following principles were clarified as underlying this draft guidance:

- This draft guidance appears as a summarising guidance to be followed by applicants as well as a (lengthy) scientific opinion explaining rationales. This is because this draft document can only give generic guidance and cannot anticipate every possible case with its specific requirements for risk assessment. Because of the latter, it was deemed beneficial that the draft guidance describes also to a large extent, the issues with materials that are known and that are relevant for safety.
- Nano specific data must come from the applicants, even if there is still some uncertainty on the legal framework for some materials. The guidance should stimulate safety testing.

- Where testing approaches and protocols are not yet established, this draft guidance cannot be more specific for risk assessment. Whilst highlighting the issues that require attention, it is expected that a degree of expert judgement will be applied to address them in risk assessment.

■ Chapter 1: Introduction

1.2. Terms of Reference as provided by EFSA

It was asked how the draft guidance deals with risk assessment of nanomaterials in food supplements. Since food supplements contain nutrients, they will be assessed under the nutrient source legislation. In addition, a food supplement may be a novel food. In this section a few examples are presented for the products that are covered by the guidance. There is no need for an exhaustive list of examples.

1.2.2. Definition of nanomaterial

It was questioned whether the definition of nanomaterial is always followed in the guidance or to be determined on a case by case basis. Several situations have been outlined in the guidance to address this, based on current experiences with materials under assessment that do not fall clearly in the definition of nanomaterial as per the EU recommendation. In these situations, the general food law and the principles of this guidance apply.

For example, *“potential risks arising from specific properties related to the nanoscale have to be assessed focusing on such properties and potentially related hazards, which may be independent of the proportion of particles constituting the material with a size below 100 nm”*. There is no scientific basis for establishing a threshold for such a proportion; moreover, there is a limit of detection of analytical techniques/uncertainties.

Regarding the *“particles above 100 nm which retain properties that are characteristic of the nanoscale”*, a maximum size for a nanoparticle in that sense can also not be established. Such an upper limit is not specified in the guidance due to weak evidence. The upper sizes are associated with the capability for uptake by certain mechanisms by the gut (i.e. likely 250nm).

It was clarified that this guidance will be valid from its date of publication. EFSA guidance is not legally binding, but will be implemented by EFSA panels. Nano food or food supplement producers can already start following the guidance.

1.3. Scope of the guidance and when to apply

A concern was expressed that the minimum information that needs to be provided by the applicant is not clearly enough delineated from the extensive list of properties mentioned in the guidance. The concern is that

it will be very difficult for the applicants to investigate all these properties. The decision was taken not to make any changes and wait for the results from public consultation. Moreover, whilst the list of parameters to be provided is comprehensive, it is acknowledged that the entire set does not apply to each material. There is freedom for the applicants to not provide all the parameters upon justification.

■ **Chapter 2: Data and methodologies**

No major comments on this chapter.

■ **Chapter 3: Risk assessment of nanomaterials: general outline**

No major comments on this chapter.

■ **Chapter 4: Physicochemical characterisation of nanomaterial**

4.1. Framework for distinguishing nanomaterials and non-nanomaterials

Changes were made in the text to enhance clarity as per suggestions by Member States. Figure 2 on the “*overview of NanoDefine global decision flow scheme material evaluation according to the EC nanomaterial definition*” will be substituted by a later version (after being published) with more explanation given upon such publication.

4.2. Material characterisation

As requested by a Member State, a footnote was added to explain the difference between a coating and a shell. For the purpose of this guidance, a material is considered as a ‘coating’ where it is bound or adhered to the surface of a nanomaterial in the form a continuous outside layer, or a ‘shell’ where it is in the form of a nanosized covering/casing in which a (nano)material may be contained.

Table 1: Comments from MSs were discussed, clarifications were given and changes were made in the Table. It was suggested by many of the MS representatives and decided by the WG members to divide this Table in three different sections: Table 1A-Information on the overall material, Table 1B-Information on the chemical components, Table 1C-extrinsic properties.

To have a clear image of the uncertainty of a value measured, applicants should provide details for particle size measurement units and they should also specify if the value is measured directly in the unit provided or converted from another unit.

The question was raised if homo/hetero agglomeration/aggregation should be discussed in the guidance. At present the working group experts consider this too difficult to be measured. It is acknowledged,

however, that lessons can be learned from the field of ecotoxicology, but no guidance can be given because tools are not available and the field is still in development.

■ Chapter 5: Exposure Assessment

Parts of the text were found confusing and will be considered for rephrasing. Figures 1 and 3 will be checked for alignment.

■ Chapter 6: Hazard identification and hazard characterisation

6.3: Toxicokinetics (ADME)

It was noted that this topic is still under scientific development e.g. with respect to optimal sizes for uptake. The main issue is the relative density of nanomaterials and their possible sedimentation. A suggestion was made to check ISSD models, but to go into public consultation with the text as it stands.

6.4: In vitro dissolutions tests

What happens if aggregation occurs? The working group considers that aggregation is not expected to be formed in physiological conditions as it needs high energy conditions and occurs typically during production.

6.5: Genotoxicity testing

It was suggested to consider from this section onwards the possible need to test the safety of the coating (if applicable), especially in the cases when the stability studies indicate that under physiological conditions the coating is released from the nanomaterial. The group considers this aspect extremely challenging and EU research is ongoing.

6.6: In vitro toxicity testing

It was asked how one can decide which in vitro assay to use. Examples that can be relevant are mentioned in this draft guidance, but the working group so far cannot give more guidance for tests nor endpoints.

6.7: In vivo repeated-dose 90-day oral toxicity study

It was noted by the Netherlands that this guidance suggests a risk assessment that relies heavily on animal studies. Not only a 90-day oral study is requested /advised, but for kinetic studies extensions are requested. In addition, it is noted that additional studies might be needed depending on the outcomes of the 90-day studies. Briefly, integrated or intelligent testing strategies are mentioned (section 6.10.1). This is not in line with the most recent scientific insights and societal demands to reduce animal testing (nor is it in line with the Dutch ambitions to replace animal testing for regulatory toxicology in a few years' time). EFSA is recommended to define a strategy and roadmap to replace the need for animal testing in its guidance in a few years' time. Likely this can be

achieved by improving the current in vitro models and in combination with in silico modelling (IVIVE: in vitro in vivo extrapolations).

In response to this note, it was mentioned that the tiered approach, including in vitro tests and read across, can indeed minimize the in vivo animal testing. Also, it can be better clarified in the text that the working group is in favour of reducing animal testing. This information will be elaborated in a new section on how to use this guidance.

6.8: Tiered approach to toxicity testing

It was clarified that also for conventional materials such a tiered approach is followed. The triggers needed for such a tiered approach are explained in this nano-specific guidance, but the approach is the same as for conventional materials.

■ **Chapter 7: Risk characterisation**

No major comments received from the MSs.

■ **Chapter 8: Uncertainty analysis**

No major comments received from the MSs.

■ **Chapter 9: Conclusions and Recommendations**

No major comments received from the MSs.

■ **Appendix A: NanoDefine Decision flow scheme**

The figure will be replaced by a more recent one (once published).

■ **Appendix B: Demonstration fact sheet**

Changes will be made to avoid repetitions.

6. Date for next meeting

The 2018 Nano Network meeting will be scheduled depending on the outcome of the public consultation.

7. Conclusions

The Chair thanked the participants for all the extensive and valuable comments received on the draft guidance and for the constructive cooperation during the meeting.

8. Closure of the meeting

Scientific Committee

Minutes of the 9th meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 9-10 October 2017, Parma (Italy)

(Agreed on 29 Nov 2017)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), Qasim Chaudhry (Vice-Chair), David Gott, Francesco Cubadda, Agnes Oomen, Stefan Weigel.

- **Hearing Experts¹:**

Barbara Drasler

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

None

- **EFSA:**

SCER Unit: Reinhilde Schoonjans

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<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 and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 8th Working Group meeting held on 03 July 2017, Parma.

The minutes of the 8th Working Group meeting held on 03 July 2017 were agreed.⁴

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

At the meeting of 9-10 October, the working group addressed all the comments received during the Scientific Committee meeting held on 13 September as well as additional written comments from Hub Noteborn, Thorhallur Halldorsson and Roland Solecki. The drafts were distributed to all EFSA Units and specific needs were addressed by the FIP Unit (ANS + FCM), FEED, and PPR, with the help of Eric Barthelemy, Ana Maria Rincon, Federica Lodi, Dimitra Kardasi. Comments from JRC-ISPRA (Hubert Rauscher and Stefania Gottardo) as well as from the European Commission (Panagiotis Daskaleros and Andreia Alvarez Porto) were also welcomed and addressed in the text.

The text was refined as necessary. The draft document will be prepared for possible endorsement of the Scientific Committee for public consultation on 15 November.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

6. Any Other Business

6.1. Document management system

The working group has an information exchange platform to work on the update of the guidance. New bibliographic references are classified in a “new folder” after each meeting.

7. Next meeting(s)

The following dates were blocked for processing the comments of the public consultation:

- 20-22 March 2018 (2 full days, lunch to lunch)
- 16-18 April 2018 (2 full days, lunch to lunch)

Scientific Committee

Minutes of the 8th meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 3 July 2017, Parma (Italy)

(Agreed on 9 October 2017)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), Qasim Chaudhry (Vice-Chair), David Gott, Francesco Cubadda, Agnes Oomen, Stefan Weigel.

- **Hearing Experts¹:**

Barbara Drasler

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

None

- **EFSA:**

SCER Unit: Reinhilde Schoonjans

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 7th Working Group meeting held on 14-15 June 2017, Parma.

The minutes of the 7th Working Group meeting held on 14-15 June 2017 were agreed.⁴

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

During the teleconference, the working group progressed with all the sections of chapter 6 and addressed the latest comments on genotoxicity, neurotoxicity, and immunotoxicity/allergenicity. In particular the stand alone *in vitro* testing sections were discussed in detail and agreed. The group has also read through the entire document and prepared for the construction of abstract, summary and conclusions/recommendations. Further tasks were agreed to be finished over the summer period. The draft document will be prepared for submission to the Scientific Committee on 4 September.

6. Any Other Business

6.1. Document management system

The working group has an information exchange platform to work on the update of the guidance. New bibliographic references are classified in a "new folder" after each meeting.

7. Next meeting(s)

- 9 October (9.00-18.00 h) and 10 October (8.30–16.30 h)

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

Scientific Committee

Minutes of the 7th meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 14-15 June 2017, Parma (Italy)

(Agreed on 27 June 2017)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), Qasim Chaudhry (Vice-Chair), David Gott, Francesco Cubadda, Agnes Oomen, Stefan Weigel.

- **Hearing Experts¹:**

Barbara Drasler

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

JRC: Hubert Rauscher

- **EFSA:**

SCER Unit: Reinhilde Schoonjans and Melpo Karamitrou

PPAS Unit: Dimitra Kardassi (15/6 14:00-15:00), Marcella De Maglie (15/6 14:00-15:00)

FEED Unit: Manuela Tiramani (14/6 15:30-16:00)

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <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 and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 6th Working Group meeting held on 29-30 March 2017, Parma.

The minutes of the 6th Working Group meeting held on 29-30 March 2017 were agreed.⁴

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

The working group had two preparatory telephone conferences on 5 May and 11 May, in advance of this 14-15 June meeting. During these telephone conferences, progress was made on chapters 4-6 and on Appendix E on feed additives and nanopesticides.

At the meeting, the further distribution of tasks for the remaining chapters 7-9 was agreed as well as consistency in terminology (e.g. nanomaterial, small particles and non-nanomaterial). The other chapters were refined with input received from the members and more tasks for finalisation were attributed.

The working group thanked the EFSA colleagues from the FEED and PRAS Units for their contribution and discussions at the meeting. The new subchapters in the appendices on feed additives is considered final and for the pesticides chapter more time was scheduled through bilateral meetings.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

Under chapter 8 for uncertainty, a new chapter on uncertainty analysis of the “quick dissolution rate” was developed. A small drafting group will convene on 27 June prior to the telephone conference scheduled on 3 July.

6. Any Other Business

6.1. Document management system

The working group has an information exchange platform to work on the update of the guidance. New bibliographic references are classified in a “new folder” after each meeting.

6.2. Relevant meetings - projects

Reinhilde Schoonjans shared feedback from her visit to ECHA and the new hearing expert, Barbara Drasler, described the outcomes of the ProSafe project as well as her contribution to the project.

6.3. Expertise

Andrea Zijno participated in the teleconference of 5 May as a new expert but has since resigned from the group due to work commitments.

7. Next meeting(s)

- 3 July (09.30-17.00h): via teleconference
- 9 October (9.00-18.00 h) and 10 October (8.30–16.30 h)

Scientific Committee

Minutes of the 6th meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 29-30 March 2017, Parma (Italy)

(Agreed on 14 June 2017)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), Qasim Chaudhry (Vice-Chair), David Gott, Francesco Cubadda, Agnes Oomen, Stefan Weigel.

- **Hearing Experts¹:**

Roland Franz

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

None

- **EFSA:**

SCER Unit: Reinhilde Schoonjans and Melpo Karamitrou

Pesticides Unit: Dimitra Kardassi (30/3 14:00-15:30), Marcella De Maglie (30/3 14:00-15:30)

FIP Unit: Alexandros Lioupis (29/3 14:00-16:00)

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alicja Mortensen for the morning session of the 29th and by Qasim Chaudhry for the first meeting day.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

2. Adoption of agenda

The agenda was adopted after adding some more scientific contributions to be discussed: in vitro digestion, wrap-up of FCM issues and the incorporation of FEED expertise.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 5th Working Group meeting held on 19-20 January 2017, Parma.

The minutes of the 5th Working Group meeting were agreed after minor editorial changes.⁴

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

The working group had two preparatory telephone conferences on 17 February and 7 March, in advance of this 29-30 March meeting. Progress was made in chapters 1-3 during these preparatory meetings, meaning that most of the outstanding comments were resolved and updated sections were delivered. Chapters 1-3 are now close to final drafts with few outstanding tasks. Figure 1 will be amended according to the suggestions of the participants. Chapter 3 on physico-chemical characterization was reviewed by the working group and a new diagram will be inserted as a decision flow scheme. Additions for FCM were also reviewed and accepted.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

Chapter 4, on exposure assessment, was reviewed and amended according to the suggestions of the participants.

The structure for chapter 5, on hazard identification and characterisation, was further discussed and agreed. The different subsections were then further commented and/or elaborated: progress was made for the subsections on read across, in vitro digestion, ADME, endocrine endpoints and genotoxicity. Tasks were allocated for the subsections on general toxicity, developmental toxicity, neurotoxicity, immunotoxicity/allergenicity and effects on the gut microbiome.

All specific issues for FCM were inserted into the guidance body text and considered as final draft stage.

Specific issues for pesticides and feed additives were discussed with EFSA staff from the respective Units. For pesticides, the draft text was approved for further elaboration.

6. Any Other Business

6.1. Document management system

The working group has an information exchange platform to work on the update of the guidance. New bibliographic references are classified in a “new folder” after each meeting.

6.2. Relevant meetings

The working group shared plans for attending future scientific conferences and Reinhilde Schoonjans shared feedback from a teleconference with the European Commission.

6.3. Expertise

It will be investigated if extra feed (expertise from EFSA staff) and in vitro toxicity expertise (external expert) will be needed.

7. Next meeting(s)

- 24 April (09.00-18.00h): via teleconference (drafting group)
- 5 May (09.30-17.00h): via teleconference
- 11 May (09.30-17.00h): via teleconference
- 14 June (9.00-18.00 h) and 15 June (8.30–16.30 h)
- 3 July (09.30-17.00h): via teleconference
- 9 October (9.00-18.00 h) and 10 October (8.30–16.30 h)

Scientific Committee

Minutes of the 5th meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 19-20 January 2017, Parma (Italy)

(Agreed on 29 March 2017)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), David Gott, Francesco Cubadda, Agnes Oomen, Stefan Weigel and Jonathan Powell.

- **Hearing Experts¹:**

Roland Franz

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

None

- **EFSA:**

SCER Unit: Reinhilde Schoonjans

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Qasim Chaudhry.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<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 and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 4th Working Group meeting held on 15 December 2016, Parma.

The minutes of the 4th Working Group meeting held on 15 December 2016 were agreed without changes.⁴

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

The working group processed all the comments and contributions on chapters 1-3 in detail. Final tasks were identified to advance these chapters by the March meeting, which will be preceded by two preparatory telephone conferences on 17 February and 7 March.

For chapter 1, an agreement was reached on the aim and the scope of this guidance.

For chapter 2, a revision of the general scheme was proposed to reflect the decisions that users of this guidance have to make.

For chapter 3, the updated table with physico-chemical parameters that can be relevant to characterise nano-sized particles was discussed in detail. It will be clarified that not all parameters may be applicable in all cases.

It was decided to merge chapters 4 and 6 on exposure and update the figure in line with the general scheme of chapter 2.

Tasks for chapter 5 were discussed and allocated.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

6. Any Other Business

6.1. Document management system

The working group has an information exchange platform to work on the update of the guidance. New bibliographic references are classified in a “new folder” after each meeting.

7. Next meeting(s)

- 17 February (13.30-17.00h): via teleconference
- 7 March (13.30-17.00h): via teleconference
- 29 March (09.00-18.00h) and 30 March (09.00-16.30h)
- 24 April (09.00-18.00h): via teleconference (drafting group)
- 5 May (09.30-17.00h): via teleconference
- 11 May (09.30-17.00h): via teleconference
- 14 June (9.00-18.00 h) and 15 June (8.30–16.30 h)
- 3 July (09.30-17.00h): via teleconference
- 9 October (9.00-18.00 h) and 10 October (8.30–16.30 h)

Scientific Committee

Minutes of the 4th meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 15 December 2016, Parma (Italy)

(Agreed on 19 January 2017)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), David Gott, Francesco Cubadda, Agnes Oomen, Stefan Weigel (via teleconference), Jonathan Powell and Qasim Chaudhry.

- **Hearing Experts¹:**

Roland Franz

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

None

- **EFSA:**

SCER Unit: Reinhilde Schoonjans

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted after an initial discussion on the scope of nanotechnologies and nanoscience, including nanomaterials.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts:
<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 and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 3rd Working Group meeting held on 27-28 October 2016, Parma.

The minutes of the 3rd Working Group meeting held on 27-28 October 2016 were agreed without changes.⁴

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

Qasim Chaudhry gave a presentation on the developments in QSAR and new in silico methods for nanomaterials. Many models have been published but they have been developed largely on the basis of chemical descriptors that are not nano-specific, and the models have also not yet been tested on any adequate number of nanomaterials to establish that their predictions are reliable. Nano-specific descriptors have not yet been developed, and may not be available in the near future. Members gave input e.g. on how important the size is, and the complexity of the relation between physicochemical properties and biological/toxicological effects (subtle changes in the former may affect the latter).

Chapter 1.1 was further amended to reflect the scope of the document that covers nanotechnologies and nanoscience, including nanomaterials.

Chapter 3 on physicochemical characterisation was reviewed and amended according to the suggestions of the participants. Now that the draft outline is agreed, the next revision will include more details.

For Chapter 5, the group first looked at the outline of the tiered approach as developed for food additives and applied for novel foods. Then, the

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

proposal developed for this guidance with nano-specific requirements was presented and commented. Particularly for Tier 0 and 1, progress was made and a text will be developed to describe the biological information required, the reasons why and the decisions that may follow from evaluating the biological information.

6. Any Other Business

6.1. Document management system

The working group has an information exchange platform to work on the update of the guidance. New bibliographic references are classified in a “new folder” after each meeting.

6.2. Relevant meetings

The working group shared feedback from diverse meetings attended by the participants and kept a list updated with future relevant scientific meetings.

7. Next meeting(s)

- Thursday 19 January (13.30) – Friday 20 January (8.30–16.30 h)
- Wednesday 29 March (13.30) – Thursday 30 March (8.30–16.30 h)
- Thursday 8 June (13.30) – Friday 9 June (8.30–16.30 h)

Scientific Committee

Minutes of the 3rd meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 27-28 October 2016, Parma (Italy)

(Agreed on 15 December 2016)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), David Gott (via teleconference), Francesco Cubadda, Agnes Oomen, Stefan Weigel, Jonathan Powell and Qasim Chaudhry.

- **Hearing Experts¹:**

Roland Franz

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

None

- **EFSA:**

SCER Unit: Reinhilde Schoonjans

FIP: Camilla Smeraldi

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 2nd Working Group meeting held on 29-30 September 2016, Parma.

The minutes of the 2nd Working Group meeting held on 29-30 September 2016 were agreed without changes.⁴

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

A presentation was given on gut absorption. The known pathways of particle uptake, the targeting of intestinal cells by ingested particles and their potential for systemic absorption was presented by Jonathan Powell. He also discussed how particle size dictates the pathway(s) of uptake. This in depth knowledge is useful to further focus the level of detail for the guidance on bioavailability and sites of potential cell targeting and/or accumulation.

A new table 1 with a classification for the p-chem characterisations was presented, aligning with other research projects or ongoing guidance development in this area.

A tiered approach for toxicological testing was discussed as applied for food additives and for novel foods. Possible "entry" and "exit" points for testing were discussed according to the type of material.

The contributions received for the first chapters on characterisation, ADME and *in vitro* studies were incorporated and reviewed.

6. Any Other Business

6.1. Expertise

No extra animal health expertise was considered needed, as the ADME aspects are most important and covered by this group.

6.2. Task for supporting

The working group was informed that the launch for reopening the call to collect info on carrier nanomaterials was launched on 18 October 2016 and deadline for submission is 28 November 2016 [afterwards extended until 23 December]. Final delivery date for the report is end 2017.

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁴ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

6.3. Document management system

The working group has an information exchange platform to work on the update of the guidance. New bibliographic references are classified in a “new folder” after each meeting.

6.4. Relevant meetings

The working group shared feedback from diverse meetings attended by the participants and kept a list updated with future relevant scientific meetings.

7. Next meeting(s)

- Thursday 19 (13.30) – Friday 20 January 2017 (8.30–16.30)
- Wednesday 29 (13.30) - Thursday 30 March 2017 (8.30–16.30)
- Wednesday 8 (13.30) – Thursday 9 June 2017 (8.30–16.30)

Scientific Committee

Minutes of the 2nd meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 29-30 September 2016, Parma (Italy)

(Agreed on 27 October 2016)

Participants

- **Working Group Members:**

Alicja Mortensen (Chair), David Gott, Francesco Cubadda, Agnes Oomen, Stefan Weigel, Jonathan Powell

- **Hearing Experts:**

Roland Franz

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

None

- **EFSA:**

SCER Unit: Reinhilde Schoonjans

FIP: Camilla Smeraldi

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Qasim Chaudhry.

2. Adoption of agenda

The agenda was adopted with the change of adding the adoption of the previous WG minutes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Agreement of the minutes of the 1st Working Group meeting held on 23 June 2016, Parma.

The minutes of the 1st Working Group meeting held on 23 June 2016 were agreed without changes.³

5. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

It was proposed to include in the guidance overviews of data requirements and methods for testing where those are available, as was done in 2011 for physico-chemical characteristics (current Table 1). The working group agreed to make the guidance as practical as possible, and will also explore the introduction of a tiered approach. Two options could be considered: (1) data requirement tables in between the current descriptive text or (2) one comprehensive table + descriptive text in annexes. These options will be further considered.

The experts went to the document and reviewed the contributions. New tasks were identified in the first chapters on characterisation, ADME and *in vitro* studies. A tiered approach was discussed as well as a flexible conceptual framework where "entry" and "exit" points for testing may vary according to the nature of the material.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

³ <http://www.efsa.europa.eu/en/cross-cutting-issues/working-groups>

6. Any Other Business

6.1. Expertise

It will be investigated if extra animal health expertise will be needed.

6.2. Task for supporting

The working group helped finalising the specific objectives for an outsourcing contract, in support of the work of the working group.

6.3. Document managing system

The working group has a dedicated folder on the document exchange platform in order to work in sequence on the updated guidance. New bibliographic references will be classified in a “new folder” after each meeting.

7. Next meeting(s)

- Thursday 15 December 2016 (8.30am – 16.30pm)
- Thursday 19 (13.30pm) – Friday 20 January 2017 (8.30am – 16.30pm)
- Wednesday 29 (13.30pm) - Thursday 30 March 2017 (8.30am – 16.30pm)
- Thursday 8 (13.30pm) – Friday 9 June 2017 (8.30am – 16.30pm)

Scientific Committee

Minutes of the 1st meeting of the Working Group on Nanotechnology in agri/food/feed

Held on 23 June 2016, Parma (Italy)

(Agreed on 29 September 2016)

Participants

- **Working Group Members:**

Alicja Mortensen, Qasim Chaudhry, David Gott, Francesco Cubadda, Stefan Weigel

- **Hearing Experts:**

Agnes Oomen, Roland Franz

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

None

- **EFSA:**

SCER Unit: Reinhilde Schoonjans

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the participants who introduced themselves during a tour de table.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Guidance on the human and animal risk assessment of the application of nanoscience and nanotechnologies in agri/food/feed ([EFSA-Q-2016-00281](#))

After a presentation of the mandate and the approved terms of reference, the working group started to identify and discuss the topics that require updating in the current guidance document. Also new elements in the state of the art that require changes in the guidance were discussed. A preliminary task division was agreed for the first few chapters.

5. Any Other Business

5.1. Expertise

The expertise required for the work, as well as third party involvement, was discussed and additional experts will be invited to the working group.

5.2. Task for supporting

The working group helped prioritising the tasks that should be outsourced in support of the work of the working group.

5.3. Document management system

The working group has a special IT platform to exchange information and to work in sequence on the updated guidance. New bibliographic references will be classified in a "new folder" after each meeting.

6. Next meeting(s)

- September Thursday 29 (9:00am) – Friday 30 (13:00pm)
- October Thursday 27 (13.30pm) – Friday 28 (13.00pm)

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

- December Thursday 15 (8.30am – 16.30pm)