



## Network on Nanotechnologies in Food and Feed Minutes of the 11<sup>th</sup> meeting

**WEB-conference, 29/10/2021**

**(Agreed on 24 November 2021)**

### Participants

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

Country	Name
Austria	Veronika Plichta
Belgium	Jan Mast, Eveline Verleysen (alternate)
Bulgaria	<i>Apologies</i>
Cyprus	Elena Anastasi, Demetris Kafouris (alternate)
Croatia	Ivana Vinković Vrček
Czech Republic	<i>Apologies</i>
Denmark	Katrin Loeschner
Estonia	Kaja Kasemets
Finland	Pertti Koivisto
France	Bruno Teste
Germany	Holger Sieg
Greece	Aristotelis Xenakis, Nikolaos Katerelos (alternate)
Hungary	Zsafia Keresztes (alternate)
Ireland	Patrick O'Mahony
Italy	Francesco Cubadda
Lithuania	Vaclovas Jurgelevicius
Luxembourg	Micheline Rosch
Netherlands	Jacqueline Castenmiller, Agnes Oomen (alternate)
Norway	Gro Haarklou Mathisen
Poland	<i>Apologies</i>
Portugal	Maria de Lourdes Bastos
Romania	<i>Apologies</i>
Slovakia	Peter Simon, Jana Tulinska (alternate)
Slovenia	Viviana Golja
Spain	José Manuel Barat Baviera, Maria del Carmen González Azón (alternate)
Sweden	<i>Apologies</i>

- **Members of cross cutting Working Group on Nanotechnologies**

Jacqueline Castenmiller (also Network member The Netherlands), Mohammed Qasim Chaudry, Francesco Cubadda (also Network member Italy), Jan Mast (also Network member Belgium), Alicja Mortensen, Agnes Oomen (also Network alternate The Netherlands), and Stefan Weigel.

- **Observers**

European Commission:

Ana Cruz (EMA), Panagiotis Daskaleros (DG SANCO), Andrej Kobe (DG ENV), Juan Riego Sintes (JRC), Hubert Rauscher (JRC) (only in the afternoon), Abdelgader Sumrein (ECHA), Jenny Holmqvist (ECHA), Amaia Rodriguez Ruiz (ECHA).

Other:

Anil Patri (US FDA)

- **External speakers**

Angela Kämpfer (PATROLS, IUF – Leibniz Research Institute for Environmental Medicine), Vicki Stone (GRACIOUS Project Coordinator, Heriot-Watt University).

- **EFSA:**

SCER Unit: Reinhilde Schoonjans (meeting Chair), José Tarazona, Maria Chiara Astuto, Irene Cattaneo, Ana Lambergar

TS Unit: Alessandra Anghelli

FIP Unit: Ana Maria Rincon, Camilla Smeraldi

PREV Unit: Renata Leuschner

FEED Unit: Maria Vittoria Vettori, Jordi Tarres Call

## **1. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from: Bulgaria, Czech Republic, Poland, Romania, Sweden, Franz Roland and Gott David (ccWG Nano members).

## **2. Update of Memberships**

The Chair welcomed the new members of the Network Daniela Hofstaedter (Austria, alternate), Ivana Vinković Vrček (Croatia, member), Annika Leis (Estonia, alternate), Zsafia Keresztes (Hungary, alternate), Kettil Svensson (Sweden, alternate), Nikolaos Katerelos (Greece, alternate). A reminder on the current procedures for the appointment and replacement of network members was also provided, according to Article 6 of the new Management Board Decision concerning the establishment and

operation of European Networks of scientific organisations operating in the fields within the Authority's mission<sup>1</sup>.

### **3. Adoption of the agenda**

The agenda was adopted without changes.

### **4. Minutes of the previous meeting and AF forum reports**

#### **a. Agreement of the minutes of the 10th meeting of the Network on Nanotechnologies in Food and Feed held on 21-22/10/2020 by teleconference**

The minutes were agreed by written procedure on 12<sup>th</sup> November 2020 and published on the EFSA website<sup>2</sup>.

#### **b. Advisory Forum (AF) forum reports**

The Annual report of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed for 2020 is available for future reference in the EFSA Journal website<sup>3</sup>, where it was published on 4 March 2021.

### **5. Declaration of Interest (DOI) and Confidentiality**

In line with Article 12 of the EFSA Management Board Decision<sup>4</sup> the Nano Network members, alternates and observers were requested to submit their Declaration of Interest (DOI), confidentiality agreement, and commitment, via the EU Survey tool.

### **6. New Management Board decision and New Terms of Reference (ToR) of the Nanonetwork**

The Chair, Reinhilde Schoonjans, updated the Network members with the recent Management Board Decision concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission and new Terms of Reference of the Network on Nanotechnologies in Food and Feed<sup>5</sup>. The main objectives of the Nano Network are to facilitate harmonisation of methodologies by sharing guidance, best practices and experience and promote information exchange between EFSA and Member States. Furthermore, the Network ensures international coordination, mutual cooperation, surveillance on national applications, and flags priority research needs. EFSA may entrust certain tasks to the network, such as collection of data and identification of emerging risks, as well as organisation of

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<sup>1</sup> <https://www.efsa.europa.eu/sites/default/files/assets/panelnetworksrop.pdf>

<sup>2</sup> <https://www.efsa.europa.eu/it/events/event/10th-meeting-efsa-scientific-network-risk-assessment-nanotechnologies>

<sup>3</sup> EFSA (European Food Safety Authority), 2021. Annual report of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed for 2020. EFSA supporting publication 2021: 18(3):EN-6502. 12 pp. doi:10.2903/sp.efsa.2021.EN-6502

<sup>4</sup> <https://www.efsa.europa.eu/sites/default/files/assets/panelnetworksrop.pdf>

<sup>5</sup> <https://www.efsa.europa.eu/sites/default/files/Nanonetwork.pdf>

national conferences/trainings/workshops on the EFSA relevant guidance documents with interested and relevant stakeholders. These Terms of Reference for the Nano Network meeting have been approved by the EFSA Advisory Forum. The Nano Network and its expected outputs are herewith confirmed until 2024.

## **7. Implementation of the Nano Guidances**

The Nano Network members were introduced by the Chair with the background and scope of the newly published Guidance on Particle - Technical Requirements (TR)<sup>6</sup> and the updated Guidance on Nano - Risk Assessment (RA)<sup>7</sup>. Both Nano Guidances underwent at draft stage multiple consultations that EFSA held with its sector-specific Panels and Units, the Nano Network members and observers, and relevant stakeholders, considering also international developments in the field.

The 'Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles' (Guidance on Particle - TR) has been designed to assess the possible presence of nanoparticles in conventional materials under the EFSA remit. The Guidance sets out information requirements and provides appraisal routes to determine whether the material under assessment requires application of the Guidance on Nano - RA (i.e. if there is a need for a nanospecific risk assessment).

The 'Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health' (Guidance on Nano - RA) was firstly published in 2018 and has been recently published in an updated version. The update of this Guidance was driven by new scientific knowledge, harmonisation with the new achievements gained with the Guidance on Particle - TR and feedback from stakeholders who used the Guidance. The updated version also provides graphical representation of a stepwise approach to be followed if the material needs nanospecific risk assessment.

The Nano Guidances are complementary to each other and should be considered by applicants and risk assessors to be integrated in the specific sectorial risk assessment frameworks, which depend on the end-use of the product and remain the mainframe of the safety evaluation.

After this introduction, the Nano Network was presented by some members of the cross-cutting working group (WG) of Nanotechnologies with examples of implementation of the Guidances. The presentation covered requests received by the WG from other EFSA Panels and Units on risk assessment dossiers in the field of food additives, food contact materials, and novel foods. The cases of implementation also aided the finalisation of the newly published Nano Guidance documents and the improvement of their practical usability. An open discussion on experience gained and lesson learned was held.

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

<sup>7</sup> EFSA Scientific Committee, 2021. Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

## 8. TiO<sub>2</sub> Opinion

The Nano Network was presented by Ana Rincon (EFSA Food Ingredients and Packaging (FIP) Unit) and Jose Tarazona (EFSA Scientific Committee and Emerging risks (SCER) Unit) with the newly published Scientific Opinion on the safety assessment of titanium dioxide (E171) as a food additive<sup>8</sup>, which was recently re-evaluated by the EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings) upon request from the European Commission. The assessment involved a dedicated FAF Panel Working Group (WG) on E171, which was supported by the EFSA Scientific Committee cross cutting (cc) WGs on Nanotechnologies and Genotoxicity. The Network was introduced with the background, data and methodologies used for the assessment. Near 12000 publications were screened during an internal literature review that resulted in 500 final selected publication, including *in vivo* and *in vitro* experimental studies. Relevance, reliability, and specific considerations for testing nanomaterials were considered during the appraisal of the *in vivo* toxicological studies. Furthermore, reliability and relevance of the results was also considered during the appraisal of genotoxicity studies. Only publications with sufficient level of relevance of the results were considered for the risk assessment. The Network was presented with the elements considered by the ccWG on Nanotechnologies as a basis for the advice to the FAF Panel WG on E171 on the nano-specific considerations for study design and relevance of results. After being presented with the outcome of the Opinion, a short discussion was held on future consequences and implications.

## 9. Feedback from Member States on new developments

### a. RIVM (The Netherlands) work on SAS

The Nano Network was presented by Agnes Oomen (The Netherlands and member of the ccWG Nanotechnologies) with experiences from the risk assessment of oral exposure to synthetic amorphous silica (SAS) nanoparticles<sup>9</sup>. After being introduced with background information and an overview of experimental data available for the assessment, the Network was presented with the conclusions of the work and the remaining uncertainties. Recommendations on the need for further information and research on the topic were discussed.

## 10. Intestinal *in vitro* models of PATROLS

The Network was presented by Angela Kämpfer (IUF – Leibniz Research Institute for Environmental Medicine) with an overview of advanced intestinal *in vitro* models developed and applied in PATROLS. PATROLS is a European Project that, thanks to its Consortium of organisations, focuses on the development and implementation of physiologically anchored tools for realistic nanomaterial hazard assessment. The main objective is to establish and standardise a battery

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<sup>8</sup> EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), 2021. Scientific Opinion on the safety assessment of titanium dioxide (E171) as a food additive. EFSA Journal 2021;19(5):6585, 130 pp. <https://doi.org/10.2903/j.efsa.2021.6585>

<sup>9</sup> Brand W, van Kesteren P, Peters R, Oomen AG, 2021. Issues currently complicating the risk assessment of synthetic amorphous silica (SAS) nanoparticles after oral exposure. Nanotoxicology, 15(7), 905–933. <https://doi.org/10.1080/17435390.2021.1931724>

of innovative, next generation hazard assessment tools to better predict adverse effects caused by long-term, low dose engineered nanomaterials exposure in human and environmental systems to support regulatory risk decision making. The models developed were presented<sup>10,11</sup> and a short discussion followed on their practical application and future implementation in the regulatory context.

### **11. The GRACIOUS Framework: Using grouping and read-across to support risk assessment of nanomaterials**

The Network was presented by Vicki Stone (GRACIOUS Project Coordinator, Heriot-Watt University) with the activities of the GRACIOUS Project<sup>12</sup>, recently finished. GRACIOUS is a Horizon 2020 project aimed at generating a highly innovative science-based framework to enable practical application of grouping, leading to read-across and classification of nanomaterials and nanoforms. The GRACIOUS Framework and Integrated Approaches to Testing and Assessment (IATA) for grouping and read-across of nanomaterials and an example of its application to the oral exposure to SiO<sub>2</sub> nanoform was presented<sup>13</sup>. A discussion followed on the possible implementation of this approach to regulatory risk assessment.

### **12. Feedback from MS on ongoing activities or issues of concern from the MS**

#### **a. Nano-biostimulant and nano-fertilisers: an emerging topic**

The Network was presented by Francesco Cubadda (Italy and member of the ccWG Nanotechnologies) with the new developments in the field of nano-biostimulant and nano-fertilisers, and their risk assessment implications according to the provisions described by the Guidance on Nano – RA. Exponential applications of nano-fertilisers and nano-biostimulants are expected and nanospecific risk need to be evaluated to protect consumers' safety. The Network members were asked to provide feedback on the status of this emerging issue at national level.

### **13. Science informed risk governance of nanotechnology - perspective of the H2020 RiskGONE project**

The Network was presented by Ivana Vinković Vrček (Croatia) with the recent activities of the RiskGONE project on Science informed risk governance of nanotechnology. RiskGONE is an H2020 project aimed at promoting risk governance framework and firm science-based interdisciplinary risk

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<sup>10</sup> Ude et al., 2019. Using 3D gastrointestinal tract in vitro models with microfold cells and mucus secreting ability to assess the hazard of copper oxide nanomaterials. *Journal of nanobiotechnology*, 17(1), 70.  
<https://doi.org/10.1186/s12951-019-0503-1>

<sup>11</sup> Kämpfer, et al., 2021. Model Complexity as Determining Factor for In Vitro Nanosafety Studies: Effects of Silver and Titanium Dioxide Nanomaterials in Intestinal Models. *Small* 2021, 17, 2004223.  
<https://doi.org/10.1002/smll.202004223>

<sup>12</sup> <https://www.h2020gracious.eu/>

<sup>13</sup> Stone et al., 2020. A framework for grouping and read-across of nanomaterials- supporting innovation and risk assessment, *Nano Today*, Volume 35, 2020, 100941, ISSN 1748-0132,  
<https://doi.org/10.1016/j.nantod.2020.100941>

management procedures for nanotechnology, based on a clear understanding of risks, risk management practices, and the perception of risk to all stakeholders. Ongoing activities and workplan of this project were presented, including the establishment of a Nanotechnology Risk Governance Council and the promotion of the Safety by Design concept for nano-enabled materials.

#### **14. Feedback from MS on joint research highly needed**

##### **a. High-content/high-throughput testing platform for assessing neurodevelopmental adverse effects of complex chemical mixtures with nanoplastics**

The Network was presented by Ivana Vinković Vrček (Croatia) with an ongoing research activity on the development of high-content (HCA) and high-throughput (HTP) testing platform for assessing neurodevelopmental adverse effects of complex chemical mixtures containing micro and nanoplastics. Possible future applications of this framework for risk assessment of nano-enabled materials were also presented.

#### **15. AoB and Conclusions**

##### **a. MS Expertise**

The Network members were asked to provide feedback on available expertise on nanomaterials risk assessment and interest for future collaboration with EFSA. Furthermore, the group was asked to inform on laboratories interested in trainings organised by the JRC on the screening and identification of nanoparticles in food.

##### **b. Upcoming trainings from EFSA – registration deadline 1 November**

An online training on EFSA Nano Guidances and nanomaterials risk assessment organised by EFSA c/o Fraunhofer Institute is open for registration until 1 November 2021<sup>14</sup>. The Network members were encouraged to disseminate the information.

##### **c. National conferences/trainings/workshops on the EFSA relevant guidances**

As representative of the Belgian reference laboratory for nanotechnologies in food, Jan Mast will give a short presentation during the “Communication Group Meeting” of the federal agency for food security (FAFS) on November 25, 2021. This meeting is accessible for Belgian appointed (first-line) analytical laboratories working on food analysis for the FAFS and for involved governmental representatives. The presentation will cover “New EFSA Guidance regarding applications of nanotechnologies in food and feed and their impact on specification, risk analysis and control of food additives”. The presentation will focus strongly on implementation of the new EFSA Nano Guidances.

#### **16. Placeholder for cases (ccWG Nano members only)**

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<sup>14</sup> <https://www.item.fraunhofer.de/en/events/efsa-training-courses/training-course-2o.html>

There were no new cases for discussion.

### **17. Closure of the meeting**

The Chair thanked the members of the Nano Network for their continued contribution and scientific support to the work of EFSA.