Workshop on risk assessment of nanomaterials and materials containing small/nanoparticles in the food and feed chain| 11-12 June - Brussels, Belgium

Programme

Day 1 | Wednesday, 11 June 2025

09:00-09:30	**Registration**	
SESSION 1 | EXISTING GUIDANCE, FRAMEWORKS AND RELEVANT ACTIVITIES ON NANOTECHNOLOGIES AND NANOPARTICLES RISK ASSESSMENT Chair: Qasim Chaudry (Chair of the EFSA's Working Group on Particle Risk Assessment) and Hubert Rauscher (European Commission - Joint Research Centre)		
09:30-09:40	**Welcome and introduction to the event**	**Claudia Roncancio Peña** (Head of Methodology & Scientific Support Unit – European Food Safety Authority (EFSA) **& Chair**
09:40-10:05	**Overview on the implementation of EFSA 2021 Nano Guidance documents, workplan for the guidance update and key scientific aspects to address**	**Qasim Chaudry** (Chair EFSA Working Group on Particle Risk Assessment) **& Maria Chiara Astuto** (EFSA)
10:05-11:00	**Relevant guidance documents, frameworks and ongoing activities at other EU agencies and international bodies**	**Hubert Rauscher** (Joint Research Centre (JRC) **Emily Hams** (European Medicines Agency (EMA) Expert Group, Health Products Regulatory Authority - Ireland)
11:00-11:30	**Coffee/Tea break**	
11:30-12:50	**Relevant guidance documents, frameworks and ongoing activities at other EU agencies and international bodies (continuation)**	**Virginia Rodriguez Unamuno** (European Chemicals Agency (ECHA) online **Mar Gonzalez** (Organization for Economic Co-operation and Development (OECD) **Anil Patri** (Food and Drug Administration – United States (US FDA) online
12:50-13:00	**Concluding remarks for Session 1: Key points of concordance and divergence between EU agencies/international bodies approach**	**Chair**
13:00-14:30	**Lunch break**	
SESSION 2 | TECHNICAL ASPECTS OF NANOMATERIALS AND SMALL/NANO PARTICLE RISK ASSESSMENT Chair: Qasim Chaudry (Chair of the EFSA's Working Group on Particle Risk Assessment) and Hubert Rauscher (European Commission - Joint Research Centre)		
14:30-14:40	**Introduction to Session 2 "Plenary discussion on fundamental aspects of nanomaterials and small/nano particle risk assessment"**	**Chair**

14:40-15:30	**Thematic discussion A -** How to identify materials requiring small/nano particle related risk assessment	**Jan Mast** (EFSA Working Group on Particle Risk Assessment, Sciensano - Belgium), **Hubert Rauscher** (JRC), **Frederic Klein** (EMA Expert Group, Federal Agency for Medicines and Health Products - Belgium) **Stakeholders:** **Marie Rouault** (Nutraveris) **Federico Benetti** (ECAMRICERT SRL) **All participants**
15:30-16:30	**Thematic discussion B -** Sample preparation methods for characterisation and toxicological testing: high degree of dispersion of small/nano particles or dispersion in line with a realistic exposure scenario?	**Francesco Cubadda** (EFSA Working Group on Particle Risk Assessment, National Health Institute - Italy), **Ivana Vinković Vrček** (EFSA Working Group on Particle Risk Assessment, Institute for Medical Research and Occupational Health - Croatia) **Stakeholders:** **Claus-Peter Drexel and Jürgen Nolde** (Evonik Operations GmbH and Grace GmbH representing the Association of Synthetic Amorphous Silica Producers (ASASP) **All participants**
16:30-17:00	**Coffee/Tea break**	
17:00-18:00	**Thematic discussion C -** How to consider internal exposure to small/nano particles in toxicological evaluations	**Agnes Oomen** (EFSA Working Group on Particle Risk Assessment, National Institute for Public Health and the Environment - The Netherlands), **Francesco Cubadda** (EFSA Working Group on Particle Risk Assessment, National Health Institute - Italy) **Stakeholder:** **Jonathan Powell** (University of Cambridge) **All participants**
18:00-18:30	**Questions and other input received from the audience and online registrants**	**Chair, All participants**
18:30-20:00	**Networking cocktail**	

Day 2 | Thursday, 12 June 2025

SESSION 2 | TECHNICAL ASPECTS OF NANOMATERIALS AND SMALL/NANO PARTICLE RISK ASSESSMENT Chair: Qasim Chaudry (Chair of the EFSA's Working Group on Particle Risk Assessment) and Hubert Rauscher (European Commission - Joint Research Centre)		
09:00-09:05	**Introduction to Session 2 "Plenary discussion on fundamental aspects of nanomaterials and small/nano particle risk assessment" (continuation)**	**Chair**
09:05-09:55	**Thematic discussion D -** Minimum criteria for the acceptance of data from existing/historic studies	**Wim De Jong** (EFSA Working Group on Particle Risk Assessment), **Ivana Vinković Vrček** (EFSA Working Group on Particle Risk Assessment, Institute for Medical Research and Occupational Health - Croatia) **Stakeholders:** **David Esdaile** (Charles River Laboratories) **William Blanco-Bose and Julie Faitg** (Amazentis SA) **All participants**
09:55-10:45	**Thematic discussion E -** Qualification and practical integration of New Approach Methodologies (NAMs) in the small/nano particle risk assessment strategy	**Susanne Bremer-Hoffmann** (JRC), **Olimpia Vincentini** (EFSA Working Group on Particle Risk Assessment, National Health Institute - Italy) **Speaker:** **Andrea Haase** (NAMs4NANO Lot 1 Project Coordinator, Federal Institute for Risk Assessment - Germany) **All participants**
10:45-11:15	**Coffee/Tea break**	
11:15-11:45	**Thematic discussion F -** Conditions for the acceptance of read-across for small/nano particle risk assessment	**Agnes Oomen** (EFSA Working Group on Particle Risk Assessment, National Institute for Public Health and the Environment - The Netherlands), **Qasim Chaudry** (Chair EFSA Working Group on Particle Risk Assessment) **All participants**
11:45-12:15	**Thematic discussion G -** Considerations for special cases (e.g. gellable nanomaterials, plate-like nano-structures, organic small/nanoparticles, hybrid/composite materials, characterisation in complex matrices)	**Jan Mast** (EFSA Working Group on Particle Risk Assessment, Sciensano - Belgium), **Francesco Cellesi** (EFSA Working Group on Particle Risk Assessment, Polytechnic University of Milan - Italy) **All participants**

12:15-12:35	**Questions and other input received from the audience and online registrants**	**Chair/Moderators**
12:35-13:00	**Wrap up & concluding remarks**	**Chair & EFSA**
13:00	**End of the meeting**	

Background information for thematic plenary discussions:

A) How to identify materials requiring small/nano particle related risk assessment

Background:

Definitions of nanomaterials are available from both regulatory (e.g. from food regulations[1]) and consensus bodies (e.g. ISO/CEN). However, from a risk assessment point of view, materials not covered by any of the above-mentioned definitions may also require particle-specific risk assessment. This can be triggered for example by measurable physicochemical criteria indicating the presence of small/nano particles, and by low solubility and/or slow dissolution rate (e.g., capability to persist as solid particles after ingestion by consumers). In particular, materials consisting of "small" particles may pose similar risks as noted for nanomaterials, and may contain a fraction of particles with a size at the nanoscale. EFSA's 2021 Nano Guidance documents propose a threshold for particles with an external dimension of up to 250 nm ('small particles') as evidence indicates that absorption/translocation mechanisms for particles in the human intestine extend up to approximately such a size threshold. Notably, risk assessment of a particulate material differs from a conventional (soluble) chemical in that it needs to take into account certain additional considerations for the potential risk of small/nano particles.

Key points for discussion:

1. Description of a clear threshold and appropriate counting rules for establishing the proportion of 'relevant small particles' to establish whether a particulate material would require small/nano particle-related risk assessment.
2. Description of clear criteria for solubility and dissolution rate in consideration of the actual use level(s).

B) Sample preparation methods for characterisation and toxicological testing: high degree of dispersion of small/nano particles, or dispersion in line with a realistic exposure scenario?

Background**:**

Due to their higher surface/volume ratio as compared to larger particles, small and nano particles have a high tendency to stick together to form larger sized agglomerates, but these can deagglomerate again depending on different physical, chemical and biological conditions. Equally, they can re-agglomerate depending on particle concentration and media conditions. Small/nano particle agglomeration/deagglomeration/re-agglomeration can therefore be a dynamic process. However, as a general principle, concerns over consumer safety increase with

[1] Definition of engineered nanomaterial of the Novel Food Regulation (EU) No 2015/2283 or definition of nanomaterial in Recommendation 2022/C 229/01 for materials in nanoform used in Food Contact Materials (FCM) manufacturing or active substances in Plant Protection Products (PPPs), consisting of or containing nanoforms.

a decrease in particle size. This is because, due to greater surface area, smaller particles (constituent, aggregates and agglomerates) can be more reactive, and because of their size are more likely to cross biological membrane barriers than larger sized particles. For these reasons, it is important for risk assessment to focus on data from toxicological tests with particulate materials that have been performed after small/nano particles have been dispersed as much as possible in view of realistic exposure situations to represent the case of maximum potential small/nanoparticle exposure and possible attribution of toxicological effects. Classical dispersion protocols apply probe sonication to break apart agglomerates into isolated constituent particles or aggregates and they achieve stable dispersion by adapting the dispersion medium conditions such as pH, ionic strength, and protein concentration. However, sonication energy needs to be adapted for each specific material to avoid artifacts and a generalised dispersion protocol covering all possible small/nano particulate materials and matrices is currently not available, and may not be even achievable. Furthermore, sonication-based protocols may not be possible in some specific cases (e.g. nanostructured materials that can be structurally altered/disrupted by the treatment). In this regard, it is also important that any available information on realistic exposure scenario(s) is considered in the dispersion method used as well as in the overall risk assessment process. The challenge therefore is to find a balance that avoids harsh dispersions that may artificially generate small/nano particles but still allows the assessment of any small/nano particles that may result from the deagglomeration of a particulate material in food/feed product, or after its consumption.

Key points for discussion:

1. What minimum degree of sample preparation could be considered adequate for small/nano particle-related risk assessment? How to consider actual use level and realistic exposure scenarios while ensuring adequate dispersion for characterisation and toxicity testing of small/nano particles?
2. How to weigh the impact of particle dispersion/agglomeration on the relevance of toxicity studies evaluating small/nano particulate materials?
3. How to consider uncertainties regarding the possible impact of small/nano particle agglomeration/deagglomeration/re-agglomeration or transformation during toxicity testing in risk assessment?
4. Can threshold(s) for adequate dispersion of small/nano particles be set in consideration of different types of materials? How can inconsistencies and/or lack of reproducibility of results due to different degrees of agglomeration be prevented?
5. Can provisions be made on how to consider the agglomeration states of small/nano particle under real-life exposure scenarios in the risk assessment?

C) How to consider internal exposure to small/nano particles in toxicological evaluations

Background:

For small and nano particles, the external dose may not be representative of internal exposure. This is mainly because the level of agglomeration increases with concentration and thus dose, and increased agglomeration will reduce the fraction of particles absorbed. Doses used in regulatory toxicological testing are much higher than actual human exposure and therefore may result in a remarkably increased agglomeration, thus may reduce the effective exposure to these particles. In addition, the degree of agglomeration may be affected by the mode of administration, i.e. the method used for dispersing particles, and the matrix of administration. Insight to the degree of agglomeration in the exposure media at each tested dose may help to

interpret the results of hazard/kinetic studies and prevent the need for additional experimental studies. On the other hand, characterisation of the internal exposure at each tested dose (*via* determination of tissue levels, ideally discriminating the particulate fraction deposited) offers an insight into the fraction absorbed and allows to assess to what extent the study may inform risk assessment of small/nano particles. It should be noted that determination of particles in tissues and organs, especially when present at very low levels, might be difficult and/or not possible. A step-wise approach may be applied to identify/characterise both the chemical and particle aspects of a test material.

Key points for discussion:

1. What is the best methodological route to determining the degree of agglomeration and internal exposure to small/nano particle in toxicological investigations?
2. How can information on internal exposure be used in risk assessment?

D) Minimum criteria for acceptance of data from existing/historic studies

Background**:**

Before undertaking any new testing, it should be considered whether existing/historic safety studies, not originally designed to address potential risks from the presence of nanomaterials and small/nano particles, may still be useful for particle-related assessment. However, demonstration that existing/historic safety studies cover the possible adverse effects linked to the fraction of small/nano particles is necessary. Two conditions are essential: (a) the available information should demonstrate that the test material (at the time of existing/historic study) had included the fraction of small/nano particles as in the current material under evaluation that have been characterised following the 2021 EFSA Nano Guidance documents and (b) the study selection and study design, including appropriate sample preparation and/or testing under realistic exposure scenario(s). Furthermore, information on the systemic presence of small/nano particles can be useful for interpreting the study for risk assessment.

Key points for discussion:

1. What information about study design and execution (e.g., level of dispersion/degree of agglomeration) is necessary?
2. Can a general scoring system for appraising nano-specific aspects of study internal validity be developed?
3. Can additional provisions be included on how to integrate toxicological studies for conventional risk assessment in the Weight of Evidence (WoE)?
4. Is it possible to set some minimum criteria for establishing similarity between a historically produced and tested small/nano particulate material, and the same/similar material produced/ tested at present?

E) Qualification and practical integration of New Approach Methodologies (NAMs) in the small/nano particle risk assessment strategy

Background**:**

New Approach Methodologies (NAMs) include *in silico*, *in chemico*, *in vitro* methods. While implementing 3Rs principles (Refinement, Reduction, Replacement), NAMs offer potential for providing a means for gathering new data to enable safety assessments. This is particularly relevant in the field of nanomaterials and small/nano particle-related assessment considering the general unavailability of OECD Test Guidelines (TGs) for traditional animal methods adapted

to address nanoscale hazards. A limited number of NAMs in the form of alternatives to animal testing has been validated and included in OECD TGs. However, in absence and/or in addition to 'validated' methods, scientifically 'valid' methods providing sufficient information for regulatory use may be used in the hazard assessment. In particular, the 2021 EFSA Nano Guidance documents propose several NAM-based options and highlight the relevance of Integrated Approaches to Testing and Assessment (IATA) and Weight of Evidence (WoE) approach for particle-related assessment.

To further promote the implementation of NAMs for nanoparticles risk assessment, EFSA launched an exploratory project named NAMs4NANO. The project was awarded to several EU Member States and extra EU organisations, and includes a partnership with European Commission Joint Research Centre (JRC). Lot 1 of the project is aimed to review of NAM-based tools for nano-specific risk assessment and develop a Qualification System for NAMs in EFSA[2] using the experience from EMA & US FDA, where the system is in place. The Qualification System aims to support faster regulatory implementation of NAMs and to guide NAM development for a specific context-of-use. It is based on an expert judgement following specific criteria on which information needs to be provided, and can improve regulatory readiness of NAMs for development of OECD TG and validation.

Key points for discussion:

1. What are the obstacles and incentives for the use of NAMs for particle-related assessment.
2. How to integrate results from non-guideline NAMs which can be considered "qualified" to be used for small/nano particle safety assessment.

F) Conditions for the acceptance of read-across for small/nano particle risk assessment

Background**:** a given small/nano particulate material can be developed in several variant forms in terms of e.g. different particle sizes, crystalline forms, particle shapes and/or surface characteristics. Rather than performing new (e.g. animal-based toxicity) studies, there is an option to fill data gaps otherwise. With adequate justification, a read-across may be possible to allow the use of data from one or more nanomaterials to another nanomaterial of the same chemical composition to fill a data gap (e.g., physicochemical, toxicokinetic and hazard profiles). As for historic studies also for read across the level of similarity needs careful attention.

Key points for discussion:

1. Under what conditions can read-across be accepted for use for different variants of a given (nano)material, and where may case-by-case assessment be required instead?
2. Is it possible to conclude on a certain (minimum) level of similarity between the various variants of small/nano particulate materials?
3. What are the obstacles and incentives to use read-across for data-gap filling in a regulatory dossier concerning small/nano particles?

[2] Haase A, Barroso J, Bogni A, Bremer-Hoffmann S, Fessard V, Gutleb AC, Mast J, McVey E, Mertens B, Oomen AG, Ritz V, Serchi T, Siewert K, Stanco D, Usmani SM, Verleysen E, Vincentini O, van der Zande M, Cubadda F, 2024. Proposal for a fit for purpose qualification system for New Approach Methodologies (NAMs) in the food and feed sector. EFSA supporting publication 2024: 21(9):EN-9008. 96 pp. https://doi.org/10.2903/sp.efsa.2024.EN-9008

G) Considerations for special cases (e.g. gellable nanomaterials, plate-like nano-structures, organic small/nanoparticles, hybrid/composite materials, characterisation in complex matrices)

Background**:** specific categories of particulate substances presenting certain physicochemical properties (e.g. gellable nanomaterials, plate-like nanostructures, organic small/nanoparticles and nanofibrils, hybrid/composite materials) may pose special technical challenges for physicochemical characterisation (e.g. including in complex matrices), dispersion, sample preparation, and toxicological testing.

Key issues for discussion:

Can specific provisions be identified to provide guidance to overcome technical challenges for certain specific types of materials? For example:

1. How to disperse and determine quantitative particle size distribution of a plate-like (nano) structures and/or small/nanofibrils without altering their original structure? Which dimensions need to be measured?
2. Due to the tendency to incorporate water, some hydrocolloidal materials may exhibit gel-like properties. To what extent do gellable substances need nano-specific considerations? Can cases be identified where the gel network may break after ingestion to release small/nano components?
3. What other considerations might be relevant for special cases?

Biographies

Claudia Roncancio Peña | Head of Methodology & Scientific Support Unit – European Food Safety Authority (EFSA)

Currently, Mrs. Roncancio Peña is Head of the Methodology and Scientific Support Services at the European Food Safety Authority (EFSA) based in Parma (Italy). Previously, she led the EFSA's Units on Feed Additives and Food Ingredients and Packaging. Before joining EFSA in 2004, Roncancio Peña was working at the European Commission - DG Environment and at the University of Liege (Belgium). She has long standing experience in Risk Assessment in different areas in food and feed and has acquired strong expertise in regulatory science. She finds that working in multidisciplinary environments enriches our knowledge and supports co-creation of projects. She has been actively supporting EU initiatives, in particular the One-Substance-One-Assessment.

Qasim Chaudry | Chairperson of EFSA Working Group on Particle Risk Assessment)

Qasim Chaudry is a visiting Professor at the University of Chester. His academic background is in chemistry and biochemical toxicology, with expertise in leading research into health and environmental safety of food and non-food consumer products.
His scientific career spans over 35 years, including 25 years at the UK's Food and Environment Research Agency (Fera).
As an independent scientific Expert, he provides advice to the European Commission's Scientific Committee on Consumer Safety (SCCS) for risk assessment of chemicals and nanomaterials in cosmetics; and various working groups of the European Food Safety Authority (EFSA).

Maria Chiara Astuto | Toxicologist, Methodology & Scientific Support Unit – European Food Safety Authority (EFSA)

Involved in the coordination of EFSA's Scientific Committee cross-cutting Working Group on Particle Risk Assessment (former ccWG Nanotechnologies) and EFSA's Network with EU Member States on Nanotechnologies in Food and Feed, Maria Chiara Astuto is also contributing to several ongoing activities aimed at promoting the use of New Approach Methodologies in regulatory risk assessments, such as the EFSA NAMs4NANO Project. After a Bachelor's and a Master's Degree in Toxicology at the University of Milan, she contributed to several scientific activities of EFSA's Scientific Committee in the area of chemical risk assessment since 2019.

Emily Hams | European Medicines Agency (EMA) Expert Group, Health Products Regulatory Authority – Ireland

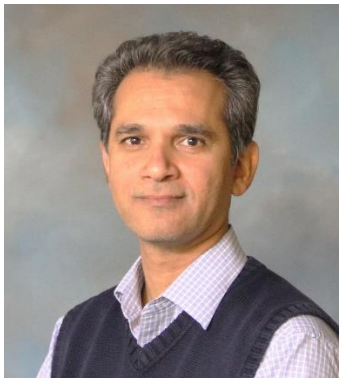
Dr Emily Hams is currently a pharmaceutical assessor for veterinary immunological and biological products as well as novel veterinary medicinal products at the Irish Health Products Regulatory Authority and has held this position for 5 years.

Currently she is also a member of the Novel Therapies and Technologies Working Party within the European Medicines Agency, which provides recommendations to the Committee for Veterinary Medicinal Products on topics relating to novel veterinary therapies and technologies. This committee is currently writing guidance on the safety of nanoparticles in the context of the establishment of MRL and veterinary marketing authorisations and Dr Hams is one of the co-ordinators involved in the preparation of the guideline.

Previously Dr Hams was a principal investigator in Trinity College Dublin, where her research interests focused on immunometabolism, immunoparasitology and immune tolerance and has published extensively in these areas, including one paper on the use of nanoparticles to target sepsis.

Dr Hams has a BSc in Biochemistry and Medical Biochemistry and a PhD in Immunology, both from Cardiff University in the UK.

Anil Patri | Food and Drug Administration – United States (US FDA)



Dr. Anil Patri began working in the nanotechnology field with the synthesis of dendritic nanomaterial and their application in targeted drug delivery and imaging for cancer before broadening his portfolio to various kinds of nanomaterial and applications. He joined FDA's National Center for Toxicological Research (NCTR) in 2014 and serves as the Director of Nanocore and appointed chair of the Nanotechnology Task Force in the FDA Office of the Commissioner/Office of the Chief Scientist. He serves on the Nanoscale Science, Engineering, and Technology subcommittee and the Nanotechnology Environmental and Health Implications working group for inter-agency coordination on behalf of the FDA. Dr. Patri also serves as co-chair of the US-EU Communities of Research on Characterization. He is a member of the American Society for Testing and Materials (ASTM) International E56, ISO TC 229, and the Organisation for Economic Co-operation and Development's Working Party on Manufactured Nanomaterials and facilitates standards development relevant to FDA.

Prior to joining FDA, Dr. Patri served as the Deputy Director of the National Cancer Institute's Nanotechnology Characterization Laboratory. In a decade-long tenure, he oversaw translation and pre-clinical assessment of promising cancer nanomedicines with proof-of-principle efficacy for cancer with a multidisciplinary research team, resulting in many products in clinical trials. Dr. Patri was a guest researcher at the National Institute of Standards and Technology (NIST) and co-led the development of the first "Nanosized Gold Reference Material Standards" with NIST collaborators. He served at the University of Michigan, Center for Biologic Nanotechnology and he earned a Ph.D. degree in chemistry from the University of South Florida.

Jan Mast | EFSA Working Group on Particle Risk Assessment, Sciensano – Belgium

Jan Mast is an agricultural engineer with a PhD in Applied Biological Sciences. He is the head of the service "Trace elements and nanomaterials" of Sciensano. He specializes in the physicochemical characterization of nanoparticles focusing on applications in the food chain and in consumer products. As an expert in workgroups of the European Commission, EFSA, CEN and of the Belgian government, he develops guidance and standards on measuring and defining nanomaterials in a regulatory context and for risk assessment. He manages a variety of research projects and publishes high quality research papers and reports. He is part of the Belgian reference laboratory for nanotechnologies and of the European reference laboratory for food improvement agents.

Marie Rouault | Nutraveris

Marie Rouault is a consultant in scientific affairs specialized in the management of novel food applications within the context of EFSA submission. With a strong background in the EU novel food regulatory framework and experience in the preparation of technical dossiers, she supports applicants throughout the novel food process, including in the evaluation of nanoparticles under the current guidance.

Marie works at Nutraveris, part of FoodChain ID, a consultancy company specialized in the regulatory and scientific affairs for food ingredients and nutraceuticals in the EU and international markets. Nutraveris assists clients in building robust scientific dossiers and navigating regulatory procedures for novel foods and food additives.

Federico Benetti | ECAMRICERT SRL

Federico Benetti received his BSc in Biological Sciences and PhD in Molecular Physiology and Structural Biology from the University of Padua. He then joined the Prion Biology Laboratory at the Scuola Internazionale Superiore di Studi Avanzati (SISSA, Trieste), where he studied the role of micronutrients in the modulation of central nervous system physiology and pathology and the folding/misfolding and stability of proteins. Since 2011, he has focused his research on the sustainable development of nanotechnology at the ECSIN European Centre for the Sustainable Impact of Nanotechnology (part of the Mérieux NutriSciences Group), where he is currently Laboratory Manager. Federico Benetti is actively involved in several working groups on nanomaterials and microplastics. He is the author of more than 60s scientific publications on medical and biological topics, nanomaterials and microplastics. He has participated as a speaker, chairman and organizer in numerous congresses, workshops and courses, and is always involved in contributing to national and European projects on the topic of microplastics and nanomaterials.
ECSIN Laboratory is a research center dedicated to the support of sustainable development of nanotechnologies. In particular, the main areas of expertise of ECSIN Lab are the physico-chemical characterization of nanomaterials and micro- and nano-plastics and *in vitro* testing by using validated and accredited methods. In fact, the ECSIN laboratory is ISO17025 and Good Laboratory Practices accredited.

Francesco Cubadda | EFSA Working Group on Particle Risk Assessment, National Health Institute – Italy

Francesco Cubadda holds an Msc in Chemistry (cum laude) and a PhD in Toxicology. Senior Scientist at the Istituto Superiore di Sanità, the Italian National Institute of Health, he leads a group with a long track record in the areas of physicochemical characterisation, toxicology and risk assessment of nanomaterials. Current interest lies in the use of NAMs in nano-risk assessment, with the coordination of international projects such as NANOCELLUP and NAMs4NANO (Lot 3). He also serves as Head of the Italian delegation to the OECD's Working Party on Manufactured Nanomaterials and Head of the National Reference Laboratory on Nanomaterials in Food. He has a long standing expertise in food safety risk assessment, in both the chemical and the nutritional domain, and served in several working groups of the European Food Safety Authority. He is a current member of the EFSA Cross cutting Working Group on Particle Risk Assessment and national scientific expert in the EFSA Network for Risk Assessment of Nanotechnologies in food and feed.

Ivana Vinković Vrček | EFSA Working Group on Particle Risk Assessment, Institute for Medical Research and Occupational Health - Croatia

Claus-Peter Drexel | Director Regulatory Affairs, Silica, Evonik Operations GmbH

Area of expertise: Chemistry and application of silica, silicates and metal oxides, Physico-chemical characterisation of nanomaterials and regulatory affairs.

Evonik Operations GmbH, Director Regulatory Affairs, Silica since July 2019.

Evonik is on the world's leading speciality chemicals companies. Amongst many other products we manufacture synthetic amorphous silica since more than 80 years for a versatile portfolio of application.

Jürgen Nolde | Director Global Product Stewardship, Grace GmbH representing the Association of Synthetic Amorphous Silica Producers (ASASP)

Phd in process engineering

Director Global Product Stewardship, Grace Europe Holding GmbH

Since 1995 Dr Nolde has held various positions working for Grace and responsible for different Product Stewardship tasks since 1999.

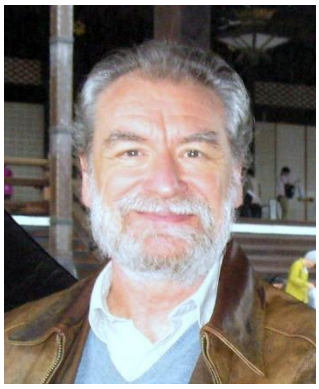
Grace is a leading producer of silica gel, precipitated and colloidal silica and different catalyst systems for the non-food area. Silica gel and precipitated silica are used as food additive e 551 and both forms are nano structured.

- Vice chair of Cefic Sector Group ASASP (association of Synthetic Amorphous Silica Producers) and chair of the Cosmetic Working Group
- Chair of the Cefic Sector Group European Zeolite Producer Association (EUZEPA)
- Chair of the VCI Working Group Particle

Wim De Jong | EFSA Working Group on Particle Risk Assessment

Wim H. De Jong, graduated as veterinarian at Utrecht University, the Netherlands in 1978 and was registered specialist in Experimental Pathobiology, and Toxicological Pathology. He worked as senior scientist at the National Institute for Public Health and the Environment (RIVM), Bilthoven, the Netherlands from which he retired in 2019. He obtained his PhD in May 1985 with the PhD thesis ”Immunotherapy of cancer with Bacillus Calmette-Guérin”. His research career started with experimental oncology studying immunostimulation as immunotherapy for cancer, and using liposomes to diminish toxicity of doxorubicin and cis-platin while keeping antitumor activity. He switched research to in vivo and in vitro assays for safety evaluation of biomaterials/medical devices and nanomaterials. His expertise includes safety evaluation and risk assessment of xenobiotics, biomaterials/medical devices and nanomaterials, and development of alternative testing methods for toxicological endpoints. He has publsihed over 180 papers in peer reviewed journals and several book chapters. He participated in several European projects on nanotoxicology and nanomaterial risk assessment. Dr De Jong has been a member of various national and international advisory working groups and committees e.g. ISO/TC 194, CEN/TC 206, EFSA, SCENIHR, SCHEER, and SCCS. He was chairman of ISO/TC 194, WG 8 on irritation and sensitization, and participated in many other working groups of ISO/TC 194 Biological and Clinical Evaluation of Medical Devices. He was member of ISO/TC 229 Nanotechnologies in Working Group 3 on Health, Safety and Environmental Aspects of Nanotechnologies. Currently he is a member of the Scientific Committee for Health, Environmental and Emerging Risks (SCHEER) of the European Commission, and member of the Scientific Committee on Consumer Safety (SCCS) Working Group on Nanomaterials in Cosmetic Products, that evaluates the safety and use of nanomaterial cosmetic ingredients. He was member of the first EFSA working group drafting a guidenace for nanomaterial risk assessment, and recently became a member of the working group drafting the revision of the latest EFSA guidance on safety evaluation of nanomaterials in food/feed. He is member of the editorial board and reviewer for several scientific journals including journals on particle toxicology such as Particle and Fiber Toxicology (PFT), and Nanotoxicology.

David Esdaile | Charles River Laboratories



David Esdaile has been a toxicologist for over 45 years, working in the UK, France and currently in Hungary, where he is 'Director of Science and Regulatory Affairs for Charles River. The Veszprem site of CRL specialises in food related and nano toxicology, as well as *in vitro* tox, rodent tox (by all routes including inhalation), reprotox, genotox, medical device tox, biopesticide tox and environmental tox. In the last 24 months, 23 nano commercial projects were performed, most of which were with food-related nanos, the other nano projects were chemical, agro, cosmetic and medical devices.

The commercial services provided for nano materials has included ECHA nano characterisation and Annex VII studies (including OECD 318), EFSA nano investigations for solubility/digestibility and particle size enumeration and distribution, genotox, daphnia/algae tox, inhalation tox and *in vitro* tox. Current research projects with nano materials includes *in vitro* dermal and intestinal absorption, bioaccumulation in an earthworm model and cellular localisation of nanoparticles.

William Blanco-Bose, Ph.D. | Amazentis SA

William is Vice President, Global Mitopure Development and Regulatory Affairs at Amazentis. He earned his PhD at Stanford University in Molecular Pharmacology. His role has allowed him to gain extensive experience in pre-clinical toxicology and particle size characterization. Over the last several years, he has regularly interacted with EFSA, while seeking novel food approval for Amazentis' flagship food ingredient, Urolithin A (Mitopure). Through the application process, he has gained broad knowledge on the current regulatory review process for ingredients with a fraction of small particles.

Julie Faitg, Ph.D. | Amazentis SA

Dr. Julie Faitg is a mitochondrial biologist with a PhD from the Wellcome Trust Centre for Mitochondrial Research. Her work focuses on mitochondrial dynamics and metabolism across muscle, brain, and skin. At Amazentis, she leads applied research and regulatory strategy for Mitopure (Urolithin A), a postbiotic targeting mitochondrial health. Over the past 3.5 years, she has led scientific development and regulatory dossier preparation —including EFSA submissions —gaining in-depth expertise in toxicology and regulatory aspects of novel ingredients, including nanoparticle assessment—now a key consideration in EU safety evaluations.

Amazentis, SA

Amazentis is an innovative life science company dedicated to employing breakthrough research and clinical science to bring advanced therapeutic nutrition products to life.

Amazentis, employs rigorous science to pioneer the discovery and clinical development of the next generation of naturally derived food ingredients, such as Mitopure (Urolithin A), sold through its brand Timeline. Our focus is the development of innovative products designed to meet the health needs of an aging population.

Susanne Bremer-Hoffmann | Joint Research Centre (JRC)

Susanne Bremer-Hoffmann, Dr. rer nat, holds a PhD degree in Biology obtained from the Charite University Hospital Berlin in Germany for her work on the development of immunotherapies against leukemia. After post-doctoral research at the Federal Institute for Risk Assessment in Germany, Susanne moved to the Joint Research Centre (JRC) of the European Commission and became a team member of the European Centre for the Validation of Alternative Methods (ECVAM) in 1995. She was involved in formal validation studies of toxicological in vitro tests detecting embryotoxicity and endocrine disruption as well as their international acceptance as OECD TG. Susanne collaborated in several EU Framework projects and is currently involved in the EFSA funded project NAMS4NANO. She contributed to more than 100 peer-reviewed scientific paper.

Olimpia Vincentini | EFSA Working Group on Particle Risk Assessment, National Health Institute - Italy

Olimpia Vincentini is senior research scientist in the field of human nutrition and Health at the Department of Food Safety, Nutrition and Veterinary Public Health at the Italian National Institute of Health, Roma, Italy. She is a biologist with a PhD in Experimental and clinical Pathology. Her Scientific activity is focused on toxicological studies on in vitro advanced models (NAMs), with emphasis on food and nanomaterials sector. In the area of toxicology, major studies have addressed development of advanced in vitro intestinal models aimed at modelling the intestinal fate for the uptake, transport and toxicity of nanoparticles and food contaminants and the effects fermented food on the intestine.

She is also interested in the pathogenesis of celiac disease by assessment of dietary exposure and analyzing antigens contained in the diet and the inflammatory mediators . She is also working on the Implementation of national pediatric screening programs for autoimmune diseases as celiac disease and type 1 diabetes. She is Expert for:

-EFSA- WG Particle Risk assessment

-Committee for scientific evaluation for preclinical studies for Phase 1 clinical Trials

-WPMN for the OECD Guidance on Sample Preparation and Dosimetry for Manufactured Nanomaterials

-OECD Guidance Document for integrated in vitro testing of the intestinal fate of ingested nanomaterials

She is actually involved in the EFSA NAMS4NANO project.

Andrea Haase | NAMs4NANO Lot 1 Project Coordinator, Federal Institute for Risk Assessment - Germany

Francesco Cellesi | EFSA Working Group on Particle Risk Assessment, Polytechnic University of Milan – Italy

Francesco Cellesi is an Associate Professor at the Politecnico di Milano, in the Department of Chemistry, Materials, and Chemical Engineering "Giulio Natta". He earned his Master's degree in Chemical Engineering from the University of Pisa in 1999. He completed his Ph.D. at the Institute for Biomedical Engineering of ETH Zurich in 2003, and in 2006 he was appointed Lecturer at the School of Pharmacy, University of Manchester (UK). In 2013, he joined the CEN Foundation – European Center for Nanomedicine and the IRCCS Ca' Granda Foundation – Ospedale Maggiore Policlinico as a Group Leader in Milan. His research interests focus on nanomedicine, polymer synthesis, applied physical chemistry, and biomaterials.