



International Fresenius Conference

Nanomaterials

Regulation, Characterisation and Risk Assessment of Substances in Nanoform

27 and 28 November 2018
in Mainz/Germany

Highlights

Regulatory Developments

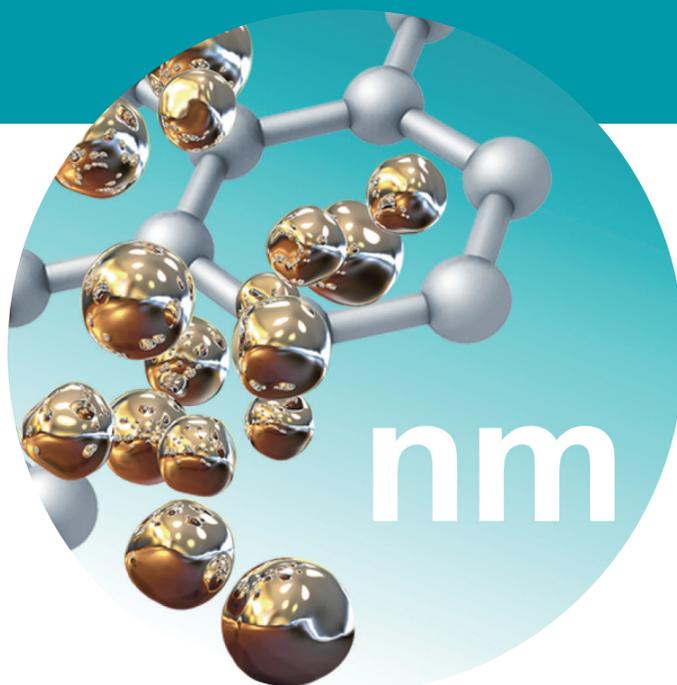
- Update from the EU Commission: Regulatory changes for substances in nanoforms
- ECHA strategy on substances in nanoforms
- Update on the OECD Test Guidelines for nanomaterials safety testing

Nano-Forms and Human Health

- Grouping concept for Nanomaterials
- The EFSA guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain – potential risks for human health
- Overarching characteristics of nanoforms that could have impact on health
- Updates in search for unifying nanoscale features that impact living organisms

Nano-Forms in the Environment

- New developments in modelling the flows of nanomaterials to the environment
- Environmental impact of TiO₂ nanoparticles used as UV filters in sunscreen cosmetics
- Nanomaterials and nano-plastics in aquatic environments



The Experts

Björn Braun Evonik Resource Efficiency | **Francesco Cubadda** Italian National Institute of Health (ISS)/EFSA Working Group on nanoscience and nanotechnology in food/feed | **Kenneth A. Dawson** Centre for BioNano Interactions, University College Dublin | **Laurence Deydier Stephan** European Chemicals Agency (ECHA) | **Tamara Galloway** University of Exeter | **Mar Gonzalez** Organisation for Economic Co-operation and Development (OECD) | **Andrej Kobe** European Commission | **Jerome Labille** European Centre for Research and Teaching in Environmental Geoscience (Cerege) | **Iseult Lynch** University of Birmingham/Facility for Environmental Nanomaterials Analysis and Characterisation (FENAC) | **Bernd Nowack** Swiss Federal Laboratories for Materials Science and Technology (EMPA) | **Karsten Schlich** Fraunhofer Institute for Molecular Biology and Applied Ecology | **Katharina Schwarz** Fraunhofer Institute for Toxicology and Experimental Medicine | **Blanca Serrano** The European Chemical Industry Council (CEFIC) | **Christine Spirlet** International Zinc Association | **Michael Stintz** Technical University Dresden | **Lang Tran** British Institute of Occupational Medicine (IOM) | **Karin Wiench** BASF

The Programme

Get-Together on Monday, 26 November 2018

Will you arrive on Monday?
Come into the hotel bar at 8 p.m. and meet other participants and experts in a relaxed atmosphere.



Tuesday, 27 November 2018

8.30 Registration and coffee

9.00 Welcome address by the organisers and introduction by the Chair

Karin Wiench, BASF, Germany

Regulatory Developments

9.10 EU-Update: Regulatory changes for substances in nanoforms

Andrej Kobe, European Commission, DG ENV, Belgium

9.35 ECHA strategy on substances in nanoforms

- Further updates to ECHA's guidance documents on nanomaterials
- Requirements for an effective implementation of REACH for substances with nanoforms
- Implementation experiences under REACH and BPR

Laurence Deydier Stephan, European Chemicals Agency (ECHA), Finland

10.00 OECD test guidelines for nanomaterials safety testing: Update on the work underway

- OECD focus on test guidelines for nanomaterials
- New and updated test guidelines recently published
- Upcoming test guidelines and planned work at OECD

Mar Gonzalez, Organisation for Economic Co-operation and Development (OECD), France

10.25 Panel Discussion

10.55 Coffee break

Characterisation of Substances in Nanoform

11.25 The nanoform definition and characterisation requirements as set in REACH: Challenges in implementation

- Amended REACH Annexes for nanoforms
- Implementation

Blanca Serrano, The European Chemical Industry Council (Cefic), Belgium

11.50 Nanospecific annexes in REACH: Practical experiences in creating sets of nanoforms and updating dossiers

Björn Braun, Evonik Resource Efficiency, Germany

12.15 Overarching characteristics of nanoforms that could have impact on health: Updates in search for unifying nanoscale features that impact living organisms

Kenneth A. Dawson, Centre for BioNano Interactions (CBNI), University College Dublin, Ireland

12.40 Panel discussion

13.10 Lunch

Nanoforms and Human Health

14.30 Grouping concept for nanomaterials human health

- DF4nano grouping developed by ECETOC
- ECHA's appendix for nanomaterials applicable to the guidance on QSARs and grouping of chemicals

Karin Wiench

14.55 The EFSA guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain – potential risks for human health

Francesco Cubadda, National Institute of Health (ISS), Italy / EFSA Working Group on nanoscience and nanotechnology in food/feed

15.20 Biokinetics and dose-response of internalised nanomaterials: Atherosclerosis as a case study

Lang Tran, Institute of Occupational Medicine (IOM), United Kingdom

15.45 Panel discussion

16.15 Coffee break

16.45 Estimation of inhalation exposure to nano-forms by particle release measurement and propagation modelling

- The gap between release and inhalation exposure is limiting the current risk assessment
- The need to evaluate the design of safe nanomaterials or release-free processes in terms of particle release at first
- Propagation modelling as a way to interpret release data in terms of exposure data

Michael Stintz, Technical University Dresden, Germany

17.10 Nano-forms in cosmetic spray and powder products: Inhalation potential and dosimetry

Katharina Schwarz, Fraunhofer Institute for Toxicology and Experimental Medicine, Germany

17.35 Panel discussion

18.10 End of first day

19.10 Departure time for the evening event



You are most welcome to attend our evening event. At the end of the first conference day, Akademie Fresenius invites you to a leisurely evening, which will take us to Ingelheim for a visit at the brewery „Der Goldene Engel“ (“The Golden Angel”). Don't miss out on this opportunity and join us to continue the day's discussions in a relaxed and leisurely atmosphere.

Wednesday, 28 November 2018

9.00 Welcome address by the Chair

Iseult Lynch, University of Birmingham/Facility for Environmental Nanomaterials Analysis and Characterisation (FENAC), United Kingdom

Nano-Forms in the Environment

9.10 New developments in modelling the flows of nanomaterials to the environment: Material flow modelling vs. environmental fate modelling

- Where are we with respect to quantifying flows to the environment?
- Considering the form of the released materials

Bernd Nowack, Swiss Federal Laboratories for Materials Science and Technology (EMPA), Switzerland

9.35 Nanomaterials/Nano-plastics in aquatic environments

- How are micro- and nano-plastics transformed in natural waters?
- Does this influence their bioaccumulation and biological effects?
- Can we use this information in risk assessment?

Tamara Galloway, University of Exeter, United Kingdom

10.00 Environmental impact of TiO₂ nanoparticles used as UV filters in sunscreen cosmetics

- Nano-forms release, hazard and exposure throughout the product lifecycle
- Effects of the nanoparticle surface functionalisation
- Risk minimisation toward a sunscreen safe by design

Jerome Labille, European Centre for Research and Teaching in Environmental Geoscience (Cerege), France

10.25 Panel discussion

10.55 Coffee break

11.25 Current work at the ACEnano project on nanomaterials characterisation for risk assessment and regulatory decision-making

Iseult Lynch

11.50 Sulfidation of AgNM (nanosilver) – influence on terrestrial long term effects in lab and outdoor experiments

- Outdoor lysimeter experiments
- Long-term tests
- Soil microorganisms

Karsten Schlich, Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Germany

12.15 Zinc oxide as a nanomaterial

- Environmental fate and behaviour
- Ecotoxicity profile

Christine Spirlet, International Zinc Association (IZA), Belgium

12.40 Panel discussion

13.10 Lunch and end of the conference



Information available online at:
www.akademie-fresenius.com/2588

The Experts

Björn Braun holds a PhD in Chemical Engineering and is responsible for Chemicals Management at Evonik Resource Efficiency. He currently heads the Cefic sector group "Association of synthetic amorphous silica producers (ASASP)" and the consortium for the REACH registration of silica.

Francesco Cubadda is Research Scientist and Team Leader at the ISS, the Italian National Institute of Health. He has been an expert in EFSA working groups since 2008 and is a national scientific expert in the EFSA NanoNetwork.



Kenneth A. Dawson is a Professor and Director of the Centre for BioNano Interactions (CBNI) at University College Dublin. He is also Chair of Physical Chemistry and Chairman of the National BioNanoscience Action. His professional roles include representing Ireland on various international bodies, including the OECD and ISO working groups on standards for nanotechnology.



Laurence Deydier Stephan is working as Scientific Officer in ecotoxicology for the European Chemicals Agency. She has held positions in scientific regulation for the last 14 years and has a background training in aquatic ecotoxicology, biogeochemical modelling and chemistry. For the last 5 years she has focused and developed her knowledge on nanomaterials.



Tamara Galloway is Professor of Ecotoxicology at the University of Exeter and also holds an Honorary Chair at University of Exeter Medical School. Her research focus is on the health effects of some of the most pressing priority and emerging pollutants: including complex organics, plastics additives, micro- and nanoparticles.



Mar Gonzalez is an Administrator at the Organisation for Economic Co-operation and Development (OECD), in the Environment, Health and Safety Division. Her work has mainly focused on promoting international harmonisation in the regulation of chemicals, in particular nanotechnology.



Andrej Kobe is a Policy Officer at European Commission's Directorate General Environment where he has long been involved in the ongoing activities on improving the regulation for substances in nanoform. He previously held a position with the Environment Agency of the Republic of Slovenia where he was in charge of setting up the national reference laboratory for the ambient air quality monitoring.

Jerome Labille (PhD) coordinated the ERA-NET SIINN research Program Nanoheter (2013-2016), which focused on the role of heteroaggregation with natural particulate



matter in the environmental fate of engineered nanoparticles. Since 2007, he has coordinated different research consortia devoted to study the environmental impact of TiO₂ nanoparticles.

Iseult Lynch joined the University of Birmingham in 2013 becoming Professor of Environmental Nanosciences in 2016. She is an Associate Editor for Environmental



Science: Nano, and Deputy director for the Facility for Environmental Nanomaterials Analysis and Characterisation (FENAC) at the University of Birmingham. Her research focuses on the environmental interactions of nanoparticles and nanostructured surfaces with biological entities from macromolecules to organisms.

Bernd Nowack holds a PhD in environmental sciences and is currently leading the „Environmental Risk Assessment and Management“ group at EMPA, the Swiss Federal



Laboratories for Materials Science and Technology. He is also an adjunct professor at ETH Zurich. His current research deals with the environmental risks of engineered nanomaterials, nanobiomaterials and microplastics.

Karsten Schlich has been investigating the effects of nanomaterials in the aquatic and terrestrial environment at Fraunhofer IME since 2008. Since 2013, he has been responsible for the algae and macrophyte testing of chemicals under REACH and is also continuing his work on questions concerning the effect and the fate of nanomaterials in the terrestrial environment.



Katharina Schwarz is currently the Department Head of Aerosol Technology at Fraunhofer Institute for Toxicology and Experimental Medicine. She conducts R&D



projects in the field of physical-biological particle-lung-interactions with a major focus on exposure science including exposure characterisation and systemic uptake of airborne substances via inhalation.

Blanca Serrano is currently Director at the European Council of the Chemical Industry (Cefic) dealing with product stewardship issues related to nanomaterials, microplastics and the Classification, Labelling and Packaging Regulation (CLP). She joined Cefic in 2015 and has extensive experience in chemical regulatory affairs from her previous role as Product Stewardship Coordinator in FEIQUE, the Spanish Chemical Industry Association.

Christine Spirlet holds a PhD in Marine Biology. She has been working at the International Zinc Association since 2007 and currently holds the position of Manager Regulatory Affairs. She is mostly involved in regulatory work and provides scientific follow-up on guidances, technical notes and various issues.



Michael Stintz is Associate Professor for Mechanical Process Engineering at the Institute of Process Engineering and Environmental Technology of TU Dresden, where he leads the Particle Characterisation Laboratory.



Lang Tran is Principal Computational Toxicologist in Research Division at the British Institute of Occupational Medicine (IOM) and an Expert Consultant on the SAFEnano Initiative. He is one of the editors of the Journal Nanotoxicology and Particle and Fiber Toxicology and has coordinated several EU projects. He is an Honorary Professor at Heriot Watt University (UK).

Karin Wiench has been working at BASF since 1993. She is Director in the Product Safety Unit for Regulatory Toxicology Chemicals, responsible for toxicological and ecotoxicological hazard and risk assessments. Since 2004 she has also been engaged in the field of nanotoxicology in international research projects.



About

Who do you meet?

Groups that should take part:

Professionals working in the fields of

- Toxicology and ecotoxicology
- Research and development
- Registration, regulatory affairs
- Chemical risk assessment
- Legal and general counselling

Sectors taking part:

- Chemical/biocide/agrochemical/
pharmaceutical/cosmetic
industries
- Research institutes
- Regulatory authorities
- Environmental and health risk
consultants
- Testing laboratories and contract
research organisations (CROs)
- NGOs

Trade Exhibition

Our conference provides you with the opportunity of presenting your company in a trade display. Present your products and services and reach out to your specific target groups. We would be happy to provide you with information on all the various options available – from displaying product information to an exhibition stand – with no further obligation on your part.

Use the attached fax reply sheet to request our information material. Or simply call us. We would be more than pleased to assist you personally.

Semsiğül Yalcin

phone: +49 231 75896-94
syalcin@akademie-fresenius.de

The Organiser

For over 20 years, Akademie Fresenius has been your partner for practice-orientated training on all the latest topics surrounding the safety and quality of food, consumer goods and chemical products along the whole production chain. Our portfolio not only includes international conferences but also offers national trade meetings, intensive practical seminars and training in small work groups.

Our events are designed to promote an active exchange amongst our participants and offer the perfect platform for bringing the industry, the scientific sector, the authorities and the consulting field together. Excellent service, all-inclusive. Our wide-ranging advanced training opportunities contribute to giving our customers the competitive edge in all quality assurance, risk assessment, legal, production and technical questions.

Akademie Fresenius is a joint venture between Cognos, one of the largest private and independent education groups in Germany, and SGS Institut Fresenius, one of the leading German providers of chemical laboratory analysis.

You can find details on upcoming and new events at

www.akademie-fresenius.com

Do you have any questions?



Programme and conceptual design

Anja Staudenmaier
phone: +49 231 75896-54
astaudenmaier@akademie-fresenius.de



Organisation and participant management

Analisa Mills
phone: +49 231 75896-77
amills@akademie-fresenius.de

Registration

By web www.akademie-fresenius.com/2588
By email registration@akademie-fresenius.com
By fax +49 231 75896-53

Hotline +49 231 75896-50
Die Akademie Fresenius GmbH
Alter Hellweg 46, 44379 Dortmund



Participation

- I would like to take part in the International Fresenius Conference „**Nanomaterials – Regulation, Characterisation and Risk Assessment of Substances in Nanoform**“, **27 and 28 November 2018 in Mainz/Germany**.
Fee: € 1,795.00 plus VAT.
- I am a **representative of an authority or a public university** and therefore eligible for a reduced fee of € 795.00 plus VAT (please provide evidence).
The reduced fee cannot be combined with other rebates.
- I would like to take part in the **evening event on 27 November 2018** (included in the above price).

Event Documentation

- Unfortunately, I am unable to attend. Please send me the complete documentation for € 295.00 plus VAT.

Trade Exhibition

- Please send me information on available options for trade exhibition and presenting product information.

Your Account Number (if available)

Title / First name / Name

Position

Department

Phone / Fax

Email

Company (complete company name including legal form)

Street / Number or P.O. Box / Building

ZIP-code / City / Country

Your order number / Cost unit (if required)

Your VAT ID No. (for registrations from EU countries except Germany)

Date

Signature

Billing Address (only if different from the above address)

Terms of Participation and Purchase

The registration fee includes the event participation, event documentation, lunch, coffee breaks, beverages as well as the evening event. You will receive written confirmation of your registration. Upon receiving our invoice, please transfer the amount due without further deductions before the event begins.

The price of the conference documentation includes a hard copy of the documentation as well as an access code to the secure Akademie Fresenius download area. Both the documents and the secure access code will be dispatched around two weeks after the event and as soon as advance payment has been received.

Group Reductions

For joint bookings received from one company we grant a 15% discount from the third participant onwards.

Terms of Cancellation

Written cancellations or transfers will be accepted free of charge up to four weeks prior to the start of the event. After this date and up to a week prior to the start of the event we will reimburse 50% of the registration fee. We cannot, unfortunately, provide refunds for later cancellations. Please note that you can name a substitute free of charge at any time.

General Terms and Conditions

By registering, you agree to our General Terms and Conditions as well as to our Privacy Policy. You can find our GTC on the internet (www.akademie-fresenius.com/general-terms) or receive them on request.

Personal Data

The Akademie Fresenius will keep your personal data for the purpose of organising this event. We will under no circumstances use your data for commercial trade purposes. In signing this form you consent to our occasionally contacting you by mail, email, fax or phone (please strike through if unwanted) in order to provide you with further information from our company. You can, of course, withdraw your consent whenever you wish. Occasionally we go around taking photos and videos at our event. These are then published anonymously on our website. Further information can be found at: www.akademie-fresenius.com/dataprotection.

Picture Credit

© Kateryna Kon/shutterstock.com, © Evannovostro/shutterstock.com, © Stadt Ingelheim

Venue

Atrium Hotel Mainz
Flugplatzstr. 44, 55126 Mainz
phone: +49 6131 491-0
info@atrium-mainz.de, www.atrium-mainz.de/en

We have reserved a limited number of rooms for our participants at reduced rates at the hotel. These rooms can be booked up to four weeks prior to the start of the event. Please book early and directly through the hotel quoting "Fresenius" as reference.