

NanoFATE Regulatory Input Short Report - January 2014

With the rapidly growing use of nanomaterials, how to bridge the gap between current research knowledge and regulatory needs?

NanoFATE is one of the European Commission FP7 projects addressing the relatively under-researched area of safety and hazard of engineered nanoparticles (ENPs) in aquatic and soil ecosystems. NanoFATE work is geared in particular to showing how safety testing and hazard assessment as well as existing regulation (REACH, TSCA) can be made “fit for nano” with minimum changes.

- This Short Report surveys the diverse forms of input provided by NanoFATE to the regulatory debate on assuring the safety of engineered nanomaterials.

Please access our [Advice Notes](#) for detailed insights, and our [Newsletters](#) for quick review of the overall results of [work packages](#) (which can then direct your interest in our [public report summaries](#) and [ISI papers](#)). Consult our [SETAC 2013 Posters](#).

- **NanoFATE Bespoke Workshop to ECHA**

Presentation to scientific staff of issues related to the environmental assessment of nanomaterials (first quarter 2014).

NanoFATE's soil and aquatic fate and effects studies will be presented directly to the interested parties at ECHA.

An example is NanoFATE model predictions of Europe wide water loadings of ZnO and Ag NPs from consumer products. The team of A. C. Johnson (NERC CEH) has produced Predicted Environmental Concentration estimates for 1.2 million kilometres of EU rivers, overlaying these with watercourse chemistry to give a sedimentation element to use for removal from the water phase - the flipside being the spatial sediment loading profiles across the EU. Consult:

- [NanoFATE Deliverable 6.6 Maps of the Regional Risk Assessment of Selected ENPs; Including Representation of PECs and Exceedances of Threshold Effect Values for a Range of Endpoints \(PNECs for Taxa or Sub-groups, Biomarker Endpoints\) Under Different Usage Scenarios.](#)

- **NanoFATE input to the OECD Working Party on Manufactured Nanomaterials (WPMN)**

In 2013 NanoFATE researchers input to the OECD [Working Party on Manufactured Nanomaterials \(WPMN\)](#). They attended expert meetings or provided information on demand from national delegates. The input is described below (most to least recent).

1) Testing and Assessment Workshop (Paris, December 2013)

NanoFATE's D. Spurgeon (NERC-CEH) attended this OECD WPMN expert workshop through the facilitation of UK Defra.

D. Spurgeon's short [Travel Report](#) identifies the key topics that were under consideration. These included:

- proposals for the revision of existing OECD test guidelines;
- technical consideration of specific guideline on characterisation and bioaccumulation;
- gaps in current protocols where new methods may be needed (e.g. soil leaching, transformations)
- and the development of better processes for data sharing.

As the OECD Sponsorship Program for the Regulatory Testing of Nanomaterials is now complete, there was considerable attention paid to current efforts to compile the results of this large program of research prior to their ultimate free release to the wider research community. Clearly there remains much to discuss including in many areas where NanoFATE science can play a key role, in particular:

- generating a specific guideline on [characterisation](#) and [bioaccumulation](#);
- providing new methods to address [soil leaching and particle transformations](#).

2) Survey on concepts of grouping, equivalence and read-across based on physical-chemical properties of nanomaterials for their human health and ecosystem hazard assessment in regulatory regimes - OECD WPMN Steering Group 5/6 "Risk Assessment and Regulatory Programmes" (Paris, Dec. 2013).

NanoFATE's C. Svendsen (NERC), C.A.M. van Gestel (VUA) and S. Loureiro (UAV) input to this survey in response to a request by the national coordinators for the United Kingdom, Netherlands and Portugal, respectively.

NanoFATE indeed tests in depth the applicability of grouping, equivalence and read-across methods to hazard assessment for ENPs. Our work programme uses pairs of commercial Ag and ZnO NPs, testing and comparing their environmental behaviour in natural media and the resulting effects seen on a range of exposed species. For specific studies these key commercial particles have been augmented with a range of specifically designed particles with ranging sizes and coatings.

The NanoFATE response to the WPMN survey gave insight into the major challenges for the development of grouping, equivalence and read-across methods, based on NanoFATE experience with methods of measurement and sample preparation for physical-chemical properties, and dealing with a variety of surface modifications.



- In terms of Phys-Chem properties for the particles the NanoFATE variations have mainly been of size and surface coating for the Ag and ZnO NPs (for example, aquatic algae were tested with a range of 8 different Ag NPs forming a matrix of coatings and sizes).
- In terms of Phys-Chem properties of the exposure media NanoFATE has covered a range of standard ecotox test media as well as the widest possible ranges of natural variation that the organisms would allow or that were realistic in media chemistry (e.g pH and Organic matter content). For example the same particles have been tested in up to seven different soils.
- In terms of endpoints NanoFATE covers a range within several species from marine, freshwater and terrestrial systems. The analysis of comparability and spread in the observed results and sensitivities is undertaken following the principle of Species Sensitivity Distributions. NanoFATE results clearly indicate that the ranking of species sensitivities to the ionic form of a metal does not infer the ranking of the same species sensitivity to the nano forms, nor do sensitivities to one nano particle appear to read-across very well to another NP of the same core metal.

3) Expert meeting, Ecotoxicology of nanomaterials (Berlin, February 2013)

Geert Cornelis (UGOT) attended this OECD WPMN meeting and gave an oral presentation on measurement methods for nanomaterials in soils based on his work within NanoFATE and MARINA projects.

This talk was to meant to spark discussions around protocols for measurement and particularly nanomaterial dose assessment in soils. In sessions on fate in freshwaters and soils, NanoFATE experience made an impact, particularly around the issue of using multiple rather than one reference soil for fate studies (our project introduced a similar concept for freshwaters). Cornelis will participate for NanoFATE once again in the 2014 OECD WPMN meeting in Vienna to be focused on protocols for nanomaterial dissolution and dispersion preparation.

4) Expert Meeting, Ecotoxicology & environmental fate (Paris, January 2013)

NanoFATE's C.A.M. van Gestel provided input to the Dutch (RIVM) delegates to OECD WPMN on several aspects related to the testing of nanoparticles in soils.

The input concerned NanoFATE experiences with the methods of spiking nanoparticles into soils, interpreting results from toxicity tests with metal-based nanoparticles taking into account short-term and long-term dissolution behaviour of the particles, etc. Consult:

- [Waalewijn-Kool, P.L., Diez Ortiz, M. & van Gestel, C.A.M. \(2012\). Effect of different spiking procedures on the distribution and toxicity of ZnO nanoparticles in soil. *Ecotoxicology*, 21, 1797-1804.](#)
- [Waalewijn-Kool, P.L., Diez Ortiz, M., van Straalen, N.M. & van Gestel, C.A.M. \(2013\). Sorption, dissolution and pH determine the long-term equilibration and toxicity of coated and uncoated ZnO nanoparticles in soil. *Environmental Pollution*, 178, 59-64.](#)

Resulting directly or indirectly from the meeting were draft documents on new guidance or new test guidelines for assessing the effects on biotic systems and the environmental fate

of nanomaterials. At the request of the Dutch national OECD coordinator (RIVM), NanoFATE's van Gestel commented on these drafts.

● EU 2nd Regulatory Review of Nanomaterials

Workshop (Brussels, 30 January 2013)

An EU workshop was organised in Brussels following the [Communication on the EU 2nd Regulatory Review of Nanomaterials](#) in October 2012. While NanoFATE did not input directly to the Review, N. Schneider (SYMLOG) attended the discussion workshop and provided a [Travel Report](#) which handily summarises the proceedings.

The workshop aim was to present and discuss the main Review findings with representatives from the European Parliament, Member States and stakeholders. The major questions addressed were:

- Is the new definition of nanomaterials accurate enough?
- Should nanomaterials be considered in the same way as any other (chemical) substance?
- What framework/tools should be used to identify, register and assess nanomaterials?
- Will Europe succeed in being an open place for innovation by tackling the risks appropriately, with a simplified regulatory framework that creates no unnecessary burdens on industry, meeting the EU safety standards while allowing growth and job creation in the context of an economic crisis?

A large audience attended the workshop gathering multi-national companies (e.g. Apple, Coca-cola, Henkel, 3M, EADS, etc.) as well as industry federations and associations, NGOs and consumer associations, representatives of Member States ministries, national Protection Agencies etc. Discussion was quite animated. Much debate remains on the approaches to assuring nanomaterials safety and on the conclusions of this 2nd EU Review on Nanomaterials. Consensus among the actors/stakeholders appeared rare. N. Schneider's [NanoFATE Travel Report](#) (11pp) summarises the positions expressed during the workshop and provides excerpts from speeches and presentations.

Our [website](#) includes many resources to learn more about NanoFATE approaches and findings. Consult the [2013 SETAC Glasgow posters](#). Download a short document describing NanoFATE's context, concept and example of [2012 results](#). Our [Library offerings](#) including [Advice Notes](#), [Newsletters](#), and [Events](#) downloadables will be of interest as well.

● Joint Open Environmental Fate and Ecotoxicology Meeting

NanoSafety Cluster Open Meeting (London, Sept. 2011)

In conjunction with the 6th International ENI Meeting, NanoFATE, ENNSATOX and NanoRetox convened a meeting with other projects and stakeholders at London's Science Museum to discuss the environmental context of our research, our specific methodological needs and way forward.

The open meeting provided an introduction to FP7 NanoSafety Cluster Projects with an Environmental Context. In attendance were Cluster project members, government and regulatory authorities and industry representatives from nine European countries and the USA. The following themes were presented:

- Environmental Load and Fate Assessments. *Current knowledge and issues faced in estimating nanoparticle sources and predicting realistic environmental concentrations.*
- Ecotoxicology and Characterisation in experimental work - Techniques review. *Experiences so far in terms of preparing, maintaining and characterising realistic nanoparticle exposures in environmental media. Is there a minimum set of characterisation needs?*
- Characterisation of NP in Environmental matrices and tissues. *Characterisation techniques applicable for nanoparticles in environmental matrices and tissues.*
- End users/stakeholders session - needs & wishes. *What do industry and regulators require from the research community?*

Regulatory issues were discussed at the meeting with the following observations and questions:

- Progress has been made in effects assessment, but is less well advanced in exposure assessment.
- Is there an issue regarding human health and environment? Predicted environmental ENP concentrations are compared to both previous environmental loadings seen and Predicted no-effect concentrations (e.g. the case of silver used over the years and recent work on cerium dioxide).
- Science outputs mismatch with regulatory needs to legislate: improved communication is required both ways.
- Will standard tests (OECD) be appropriate? What are the minimum modifications needed to make them nano applicable? To what extent are standard tests the best research tool?
- Where is risk assessment in the regulatory process? Should exposure be examined and regulated first?
- In order to assess risk we need to know how much nano is used in what product types, how much is released and where it ends up. Improved support and openness from industry are needed to provide data.

Details may be had in the [meeting report](#), co-authored with ENNSATOX project personnel.