Gov4Nano

meeting the needs of nanotechnology

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement 814401

Status of current work on OECD TGs/GDs in Gov4Nano

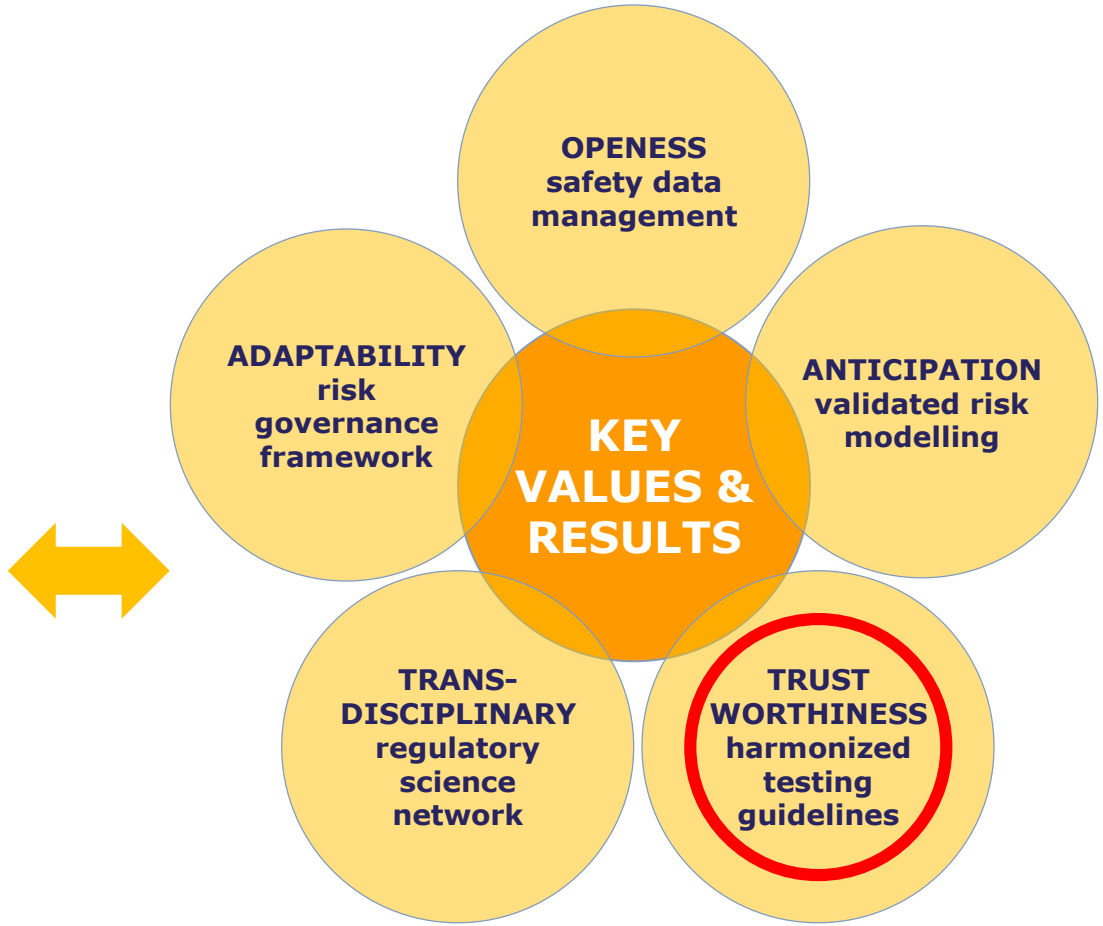
Eric Bleeker

NanoHarmony/NANOMET Project Workshop
29 November 2022

Gov4Nano – Key results

Systematic and value-based approach for efficient and effective Risk Governance:

Common risk governance portal and platform: knowledge & information sharing



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Ongoing OECD activities

Section 1 Physical Chemical Properties	Section 2 Effects on Biotic Systems	Section 3 Env. Fate and Behaviour	Section 4 Health Effects
TG on determination of the (volume) specific surface area of manufactured nanomaterials **WNT 1.3** TG published 2022	Adaptation of OECD TGs 201, 202 and 203 for the determination of the ecotoxicity of MNs **(FR/ES) WPMN**	TG on dissolution rate of nanomaterials in aquatic environment **(DE) WNT 3.10**	GD on the adaptation of *in vitro* mammalian cell based genotoxicity TGs for testing of manufactured nanomaterials **(EU)**
TG on particle size distribution of nanomaterials **(DE) WNT 1.4** TG published 2022		GD on assessing the accumulation of nanomaterials **(DE) WNT 3.12**	Applicability of the key event based TG 442D for skin sensitisation of nanomaterials **(CH) WNT 4.133**
GD on determination of solubility and dissolution rate of nanomaterials relevant for synthetic biology **(DK/DE) WNT 1.5**		GD on environmental transformation of nanomaterials **(AT) WNT 3.13**	TG on toxicokinetics to accommodate testing of nanoparticles **(NL/UK) WNT 4.146**
GD on identification and quantification of chemistries relevant for nano- and microscale materials **(DK/DE) WNT 1.6**		Scoping review for a tiered approach for reliable bioaccumulation assessment of MNs in environ. organisms minimising use of higher tier vertebrate tests **(UK) WPMN**	Integrated *in vitro* approach for intestinal fate or orally ingested nanomaterials **(IT) WNT 4.158**
TG on determination of surface hydrophobicity of manufactured nanomaterials **(EU) WNT 1.7**		Assessment of the durability of NMs and their surface ligands in env. surroundings (biodurable/ biodegradable) **(SA/Korea) WPMN**	GD on the determination of concentrations of nanoparticles in biological samples for (eco)toxicity studies **(UK) WNT**
TG on determination of the dustiness of manufactured nanomaterials **(DK/FR) WNT 1.8**			

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OECD TGs/GDs in Gov4Nano

Providing a scientific basis for OECD TGs/GDs

- **Test No. 124: Determination of the Volume Specific Surface Area of Manufactured Nanomaterials** – Published in July 2022: doi.org/10.1787/abb72f8f-en

- Determination of **solubility and dissolution rate** of nanomaterials in water and relevant synthetic biologically media
- Identification and quantification of the **surface chemistry** and coatings on nano- and microscale materials
- New TG on determination of the **dustiness** of manufactured nanomaterials
- GD and TG on **aquatic (environmental) transformation** of nanomaterials
- GD on assessing the **apparent accumulation potential** for nanomaterials with TG 305
- Applicability of the TG 442D **in vitro skin sensitisation** for nanomaterials

- Guidance on **release tests** for manufactured nanomaterials

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GD on environmental abiotic transformation of nanomaterials

Background

- Environmental abiotic transformation of NM is one of the major pathways of NM transformation (transformation – dissolution – agglomeration) in the environment
- Essential to determine the transport, distribution and assess the exposure of organisms in the environment to aged/transformed NMs
- One possible pathway of NMs degradation

Objectives

- Framing the concept of NM transformation pathways in aquatic environments
- Determining of the important and relevant parameters to consider in the investigation of NMs transformation in risk assessment studies
- Development/identification of suitable experimental approaches, media composition and analytical techniques for the testing of NMs transformations
- Making the outcomes available in the form of an OECD guidance document

Expected Outcomes

- Scientific and methodological basis for the OECD guidance document in WNT project 3.16
- Starting point for developing the related TG

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GD on environmental abiotic transformation of nanomaterials

Current and upcoming scientific work

- The selected method to investigate transformation is to fix NMs on TEM grids and analyse them with TEM-EDX before and after exposure in synthetic media
- The method has been tested against realistic exposure in sediment pore waters and analysis with synchrotron-based X-ray techniques
- Differences in transformation reactions can be observed between realistic, near-natural and synthetic media, but under similar exposure both methods show similar results.

- The results are currently fed into Deliverable 2.21 which will be finished in November.
- Within a new project funded by the German BMU a Technical Guideline ist developed (2022 – 2024) and the work on the GD and TG hs been harmonized and synchronized. The related OECD SPSF has been adapted.

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GD on environmental abiotic transformation of nanomaterials

2020	• Definition of transformation pathways and related media composition(s) for experiments	✓
2021	• Experimental strategy and analytical methodology	✓
2021/2022	• Comparing synthetic media with real world exposure (redox gradient in sediment pore waters) analysed in TEM-EDX and XAS (as reference)	✓
2022	• Description of methodology and results from comparison of techniques → deliverable 2.21	←
2022/2024	• Moving onwards to a suite of TG and related GD for environmental transformation	

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GD on assessing the apparent accumulation potential for nanomaterials

Background

- Difficulties in applying TG305 to MNs due to, in general, their limited solubility and their limited stability in water
- For most of the cases the preferred route of exposure for MNs would be the dietary exposure instead of the water exposure but a BMF will be derived instead of a BCF
- Problems to determine MNs in tissues

Objectives

- To further develop the bioaccumulation testing for MNs to provide further guidance on the application of OECD Test Guideline 305 focusing mainly on dietary exposure.

Expected Outcomes

- New Guidance Document on assessing the apparent accumulation potential for nanomaterials

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GD on assessing the apparent accumulation potential for nanomaterials

Current and upcoming scientific work

Finalised scientific work

- Report on all the available information on bioaccumulation studies in fish and on analytical techniques to determine MNs in solid matrices
- Report on the experimental data on spiked fish feed with NM
- Report on the analytical techniques to determine nanomaterials and its transformation products in fish tissues
- Report on the results of the bioaccumulation assays performed and BCFs and BMFs derived (dietary and aqueous exposures of CuO spherical, CuO nanorods, COOH-coated CdTe QDs, PEG-coated CdTe QDs)

Current and upcoming

- Analytical capabilities to determine difficult to determine MNs in fish and tissues such as CNTs.
- Interlaboratory comparison study on fish feed spiking
- Draft of Guidance document

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GD on assessing the apparent accumulation potential for nanomaterials

April 2018	• Focus on developing GD for NMs in TG305	✓
2021/2022	• Generation of new data and information	✓
2022/2023	• Drafting GD on applying TG305 to NMs	←
2023/2024	• Draft GD will be circulated for commenting by the WNT	

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Applicability of the key event based TG 442D for in vitro skin sensitisation testing of nanomaterials

Background

- Investigate the applicability of the ARE-Nrf2 luciferase method (TG 442D) for nanomaterials with an experimental focus on the KeratinoSens® assay.
- To evaluate whether it is fit for purpose, or whether some adaptations are needed, e.g. in the TG itself, in the SOP or in some additional guidance.

Initial objectives

- Recommendations for adaptation of TG 442D
- Recommendations for validation of future adaptations

Initial expected Outcomes

- Background Document

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Applicability of the key event based TG 442D for in vitro skin sensitisation testing of nanomaterials

Summer 2021	• Report on experimental outcome	✓
Mid 2021	• Recommendation for adaptation of TG 442D	✓
Summer 2022	• First commenting round at OECD WNT	←
2022/2023	• Second commenting round at OECD WNT • Final OECD Study Report	

Final Document anticipated in Summer 2023

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Guidance on release tests for manufactured nanomaterials

Background

- Release of manufactured nanomaterials is the first step towards exposure
- Workers, consumers and the environment are considered
- Release tests can contribute to (regulatory) frameworks e.g. exposure assessment, life cycle assessment, safe(r)-and-sustainable-by-design
- Release tests provide qualitative and quantitative information about the amount and the state of released nanomaterials during a specific process
- However: lack of detailed guidance on standardised release tests suitable for nanomaterials

Objectives

- Provide guidance on available (standardised and not yet standardised) release tests applicable for manufactured nanomaterials
- Conceptually link release tests to release scenarios, release processes and release mechanisms
- Outlook to possible applications of data obtained by release tests, such as exposure or life cycle assessments and safe(r)-and-sustainable-by-design approaches

Expected Outcomes

- An OECD WPMN Guidance on Release Tests for Manufactured Nanomaterials
- Including a decision framework to help producers, processors and users of manufactured nanomaterials with the choice of appropriate release tests.

baua:

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Guidance on release tests for manufactured nanomaterials

Current and upcoming scientific work

- Overview on release tests, which was compiled in the project Gov4Nano in Deliverable 2.2 was expanded.
- Applicability of the reviewed release tests for manufactured nanomaterials and nanomaterial-containing products will be discussed in detail among the participating experts.
- A draft decision framework that facilitates a justified choice to use a specific test method for a respective release process was developed and will further be developed.
- A detailed guidance will be written.
- Additional partners and contributions are very welcomed.

baua:

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Guidance on release tests for manufactured nanomaterials

Summer 2021	• Presentation of the project proposal at OECD WPMN	✓
Winter 2021	• Presentation of the project proposal at OECD WPMN Steering Group Exposure Measurement and Mitigation (SG-EM) • Commenting round of the project proposal at OECD WPMN SG-EM	✓
March 2022	• Kick-off meeting	✓
June 2022	• Presentation and discussion at OECD WPMN	✓
2022/2023	• Regular meetings of the project team • Development of the guidance	←
Spring 2023	• First draft of the guidance ready for project internal commenting round	
Spring 2024	• Final draft of the guidance ready for commenting round at OECD WPMN	
June 2024	• Presentation of final guidance draft to WPMN	

baua:

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OECD TGs/GDs in Gov4Nano

Summarising timelines

- GD and TG on **aquatic (environmental) transformation** of nanomaterials
  - 2024
- GD on assessing the **apparent accumulation potential** for nanomaterials with TG 305
  - 2024
- Applicability of the TG 442D **in vitro skin sensitisation** for nanomaterials
  - 2023
- Guidance on **release tests** for manufactured nanomaterials
  - 2024

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Future-proof Approaches for Risk Governance

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Lessons Learned from Nanomaterials

31st January 2023 ONLINE SESSION

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as a follow-up of the joint NMBP-13 projects conference on 24th and 25th of January 2023 at OECD addressing future challenges in risk governance of nano- & advanced materials, including safe- and sustainable by design (SSbD) and harmonisation and standardisation.

www.gov4nano.eu/event/nmbp-13-future-proof-approaches-for-risk-governance-lessons-learned-from-nanomaterials

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