NIA
Nanotechnology
Industries Association

Meeting Global Regulations for Nanomaterials

Overcoming Perceived Environmental and Toxicological Concerns around Nanotechnology

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Housekeeping

- Questions can be asked using the in-aisle microphone or via **slido.com** using code **AMU2022** and selecting **Theater 2**
- Mobiles on silent and vibrate mode off, flash photography and taking photos of slides is prohibited
- Presentations that the organisers have authorisation to share, will be made available to view/ download, via the event websites, post event
- Questions can be directed to a specific panel member, or the Chair will direct them as seems appropriate
- Your questions help make the session lively and interactive!

Comparing US/EU Regulations

Registration, Evaluation, Authorisation and Restriction of Chemicals *vs* Toxic Substance Control Act

Both are Implemented to protect consumer health and safety by restricting the use of substances known to harm human health or damage the environment

However

Compliance with one does not automatically mean compliance with the other

Comparing US/EU Regulations

Since 2007

REACH, CLP, PIC, POP, BPR regulations
in the EU, Norway, Iceland and Liechtenstein.

No Data No Market

Over 100,000 notifications

Since 1970

Clean Air Act, Clean Water Act
United States of America

Over 86,000 chemicals of which
over 41,000 are active

Comparing US/EU Regulations

	REACH	TSCA
	• Excluding those cover by other regulations or research • All substances in the market on their own or in mixtures over 1 MT/year • No more stringent EU member state regulations • Obligation in communicating information (SVHC, SDS)	• Excluding those cover by other regulations • Implementation of Confidential Business Information (CBI) • Includes manufacturing and processes • Existing and new chemicals • Risk based assessment • Not all information in TSCA inventories is open
Chemical Substance	*"Chemical elements and its compounds in a natural state or obtained by any manufacturing process including any additive necessary to preserve its stability and any impurity derived from the process used but excluding any solvent used...without affecting the stability of the substance of its composition"*	*"any organic or inorganic substance of a particular molecular identity, including any combination Of these substances occurring in whole or in part As a result of a chemical reaction or occurring In nature"*

Challenges for Industry

- Interpreting and complying with multiple regulatory frameworks
- Changing regulatory environment
- Cost of testing materials
- Availability of testing methods for nanomaterials and advanced materials
- Identifying contract research organisations able to perform tests
- Meeting customer and consumer demands
- Anticipating future risks

The OECD Test Guidelines (TG) Programme

Organisation of Economic Co-operation and Development (OECD)

- Intergovernmental organisation
- 38 Member Countries representatives and European Commission
- Industry representation
  (Business & Industry Advisory Committee, BIAC)
- Animal welfare organisations
  (International Council on Animal Protection in OECD Programmes, ICAPO)
- Green NGOs
- Other partners (i.e. China, Malaysia, Thailand, South Africa)
- International Organisations (i.e. WHO, UNITAR, UNEP, ISO)

OECD – Mutual Acceptance of Data

"Tested once, accepted everywhere"

Chemicals / Nanomaterials

Test Guidelines

A single quality standard should be applied for testing of all chemical substances

Good Laboratory Practice

A single quality standard for test facilities throughout OECD

Mutual Acceptance of Data

Legally binding on OECD Member countries and other MAD Adherents*

*Argentina, Brazil, India, Malaysia, Singapore, South Africa and Thailand

OECD projects for nanosafety

Some of the existing OECD TG available are applicable for nanomaterials, but in many instances, there is a need to adapt or create new test guidelines (TGs)

- Missing TGs/missing endpoints
- Not (clearly) applicable for nanomaterials
- Difficult to perform/understand
- New equipment needed

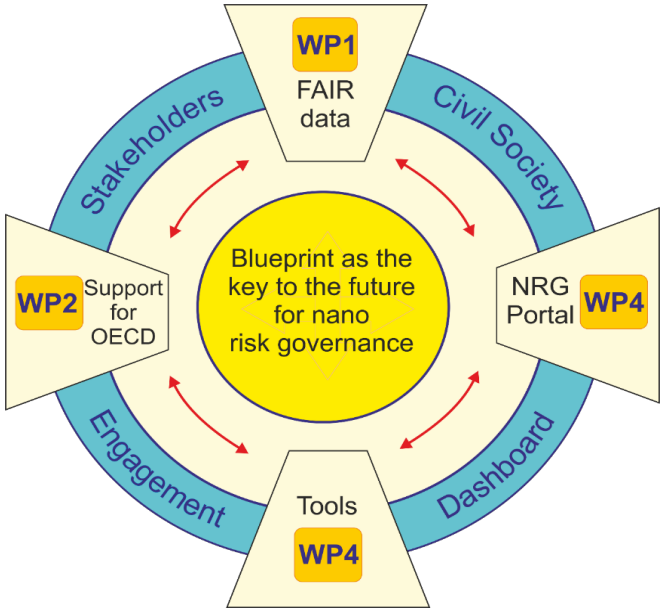
➔ Important: exchange between all international stakeholders (science, industry, regulation, CROs, SMEs,…)

Ongoing TG developments for NMs

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 nanom **GP 1.3** Completed 2022	Recommendations for guidance on adaptations needed when using OECD TG 201, determination of the Ecotoxicity of MNs **(FR/ES) WPMN**	TG on dissolution rate of nanomaterials in aquatic environment **(DE) TGP 3.10**	Study Report and preliminary guidance on the Ada in Vitro Ma Based Genotoxicity TGs fo ting of MNs **(EU) TGP 4.95** Completed 2022
TG on particle size and size distribut nufactured nanomaterials **(DE) TGP 1.4**		GD on assessing the apparent accumulation potential for nanomateria **3.12**	Applicability of the key event based TG 442D for *in vitro* skin sensitisation testing of na CH) **TGP 4.133**
GD on determination d dissolution rate of nanomaterials in wate synthetic biological media **(DK/DE) TG**		GD on environmental abiotic transformation of nanomaterials **(AT) TGP 3.**	TG on toxicokinetics to accommodate testing of nanoparticles **(NL/UK) TGP 4.146**
GD on identification a ion of the surface chemistry and coatin d microscale materials **(DK/DE) TGP 1.6**		Scoping review for a tiered approach for reliable bioaccu assess of MNs in environ. o use of higher tier vertebrate tests **(UK) WPMN**	Integrated *in vitro* approach for intestinal fate of orally ingested nanomaterials **(IT) WPM**
TG on determination of manufactured nanomaterials **(DK**			
TG on determination of surface hydrophobicity of manufactured nanomaterials **(EU) TGP 1.7**			
GD on the determi ions of nanoparticles in biological sampl udies **(UK) TGP 1.10**			

Governing the Risks of Nanotechnology Now and in the Future: Gov4Nano Project

Gov4Nano
meeting the needs of nanotechnology



1. Improve the FAIRness of the nano-Environmental Health Safety (EHS) data infrastructure
2. Develop harmonized guidance for characterization and testing of nanomaterials
3. To understand how risk perception on nanotechnologies is formed in (a) civil society and (b) (re-) insurance industry
4. To develop a NanoSafety Governance Portal with tools, data, and guidance
5. To develop conditions for an organisational form for Nano Risk Governance
6. To progress stakeholder involvement in the organisational form for Nano Risk Governance
7. Develop mechanisms and tools to monitor the progress on implementation of risk governance for nanotechnology

About the NIA

Regulatory pathways to market

Understanding nanomaterials within sector regulations

Confidence in nanomaterials

The right information and cooperation with your value chain for strong product development to market

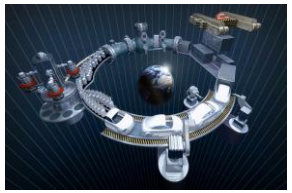
Find the right people, sectors and places

Only common factor is size, it's a big nano world

Know your place in the chain

Product stewardship to end of life, recycling and disposal

Strong positioning with your clients



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Take part in open activities

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- Follow us on LinkedIn (/company/nanotechnology-industries-association)...
- …and Twitter (@nanotechia)

Become a member (nanotechia.org/membership) and drive activities

- Set industry priorities
- Be part of policy and regulatory consultations
- Get showcased and network for your business development

- Visit us on stand 1041

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