

Regulatory Research Roadmap NanoSafety Cluster

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Regulator Research Roadmap Team

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Regulatory Research Roadmap Purpose

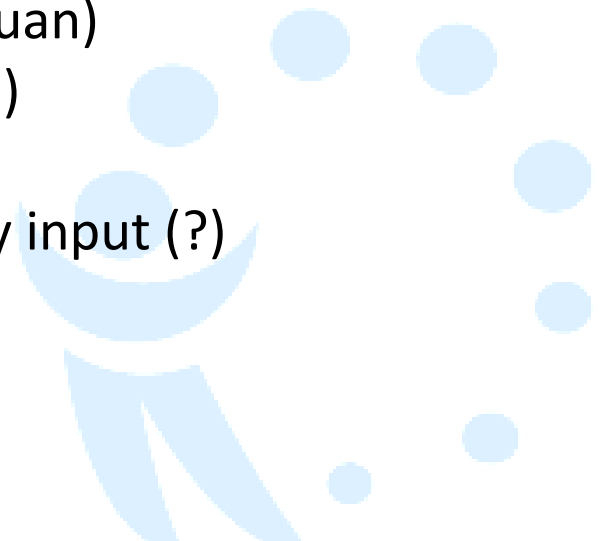
- To identify and structure the research required to deliver effective regulation of nanomaterial safety
- Including
 - Consumer
 - Occupational
 - Sector specific issues
- Excluding
 - Nanomedicine

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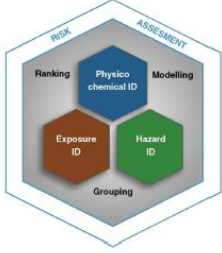
Stage 1 – Identifying activities relevant to the RRR

- ITS-NANO hexagon diagrams to illustrate research prioritisation (Vicki)
- NANoREG gap analysis (Susan)
- US research and regulatory development (Phil Sayes EPA)
- MARINA tiered approach for RA (Agnes)
- Nanonext.nl (Adrienne)
 - Dutch nanotechnology development programme
 - Risk Analysis and Technology Assessment (RATA)
- NANoREG questions relevant for regulators (Juan)
- Safety-by-Design – SUN and NanoGuide (Vicki)
- REACH (Juan, Wim)
- EU occupational and safety at work regulatory input (?)
- Educational framework (?)



Research Prioritisation to deliver an Intelligent Testing Strategy for Engineered Nanomaterials

RESEARCH PRIORITISATION TO DELIVER AN INTELLIGENT TESTING STRATEGY FOR THE HUMAN AND ENVIRONMENTAL SAFETY OF NANOMATERIALS

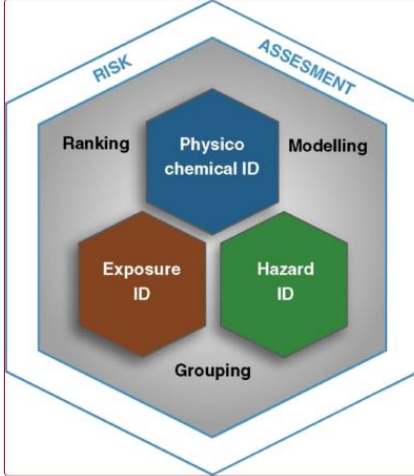


The diagram shows a central hexagon divided into five colored sections: a blue top section labeled 'Physico-chemical ID', a brown bottom-left section labeled 'Exposure ID', a green bottom-right section labeled 'Hazard ID', a grey bottom section labeled 'Grouping', and a grey top-left section labeled 'Ranking'. The top-left and top-right corners of the hexagon are labeled 'RISK' and 'ASSESSMENT' respectively.

ITS NANO

<http://www.nano.hw.ac.uk/research-projects/itsnano.html>


pft PARTICLE AND FIBRE TOXICOLOGY



The diagram is identical to the one in the first slide, showing a hexagon with sections for Physico-chemical ID, Exposure ID, Hazard ID, Grouping, and Ranking, under the labels RISK and ASSESSMENT.

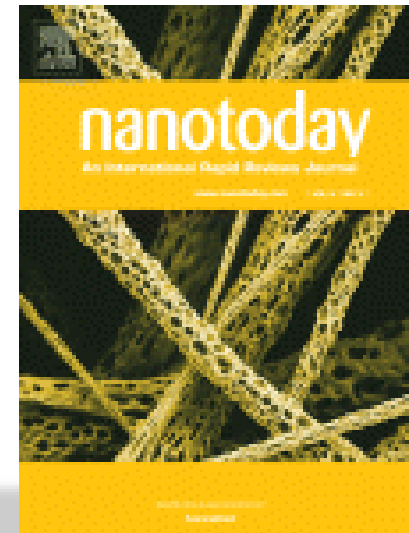
ITS-NANO - Prioritising nanosafety research to develop a stakeholder driven intelligent testing strategy

Stone *et al*

 BioMed Central

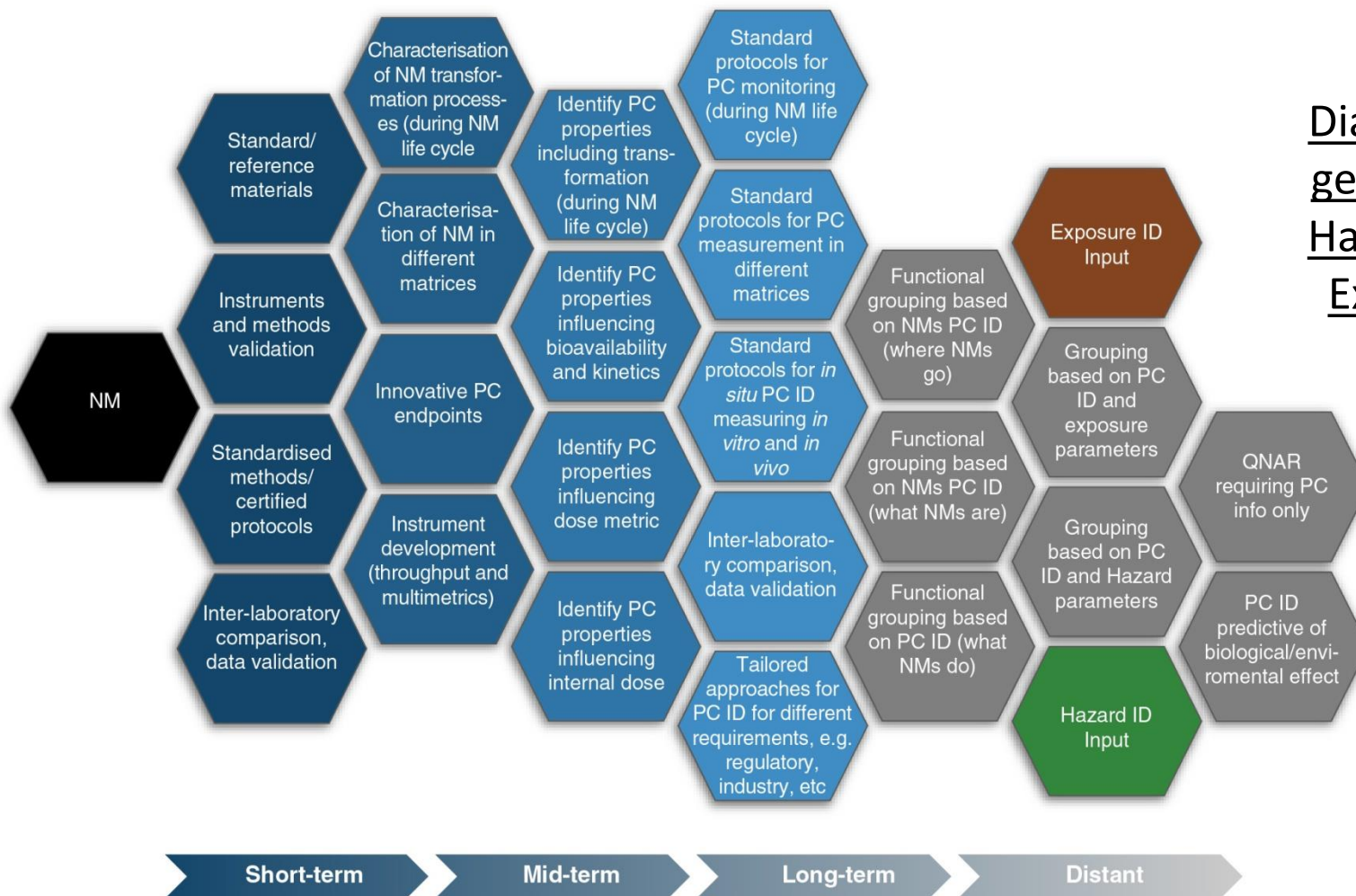
Stone et al. Particle and Fibre Toxicology 2014, 11:9
<http://www.particleandfibretoxicology.com/content/11/1/9>

Stone et al., Particle and Fibre Toxicology 2014, **11:9**



ITS NANO

Physicochemical Priorities



Diagrams also generated for Hazard ID and Exposure ID

ITS-NANO hexagon approach

Regulatory research priorities

Core priorities

Product to market research priorities

Current position

Future



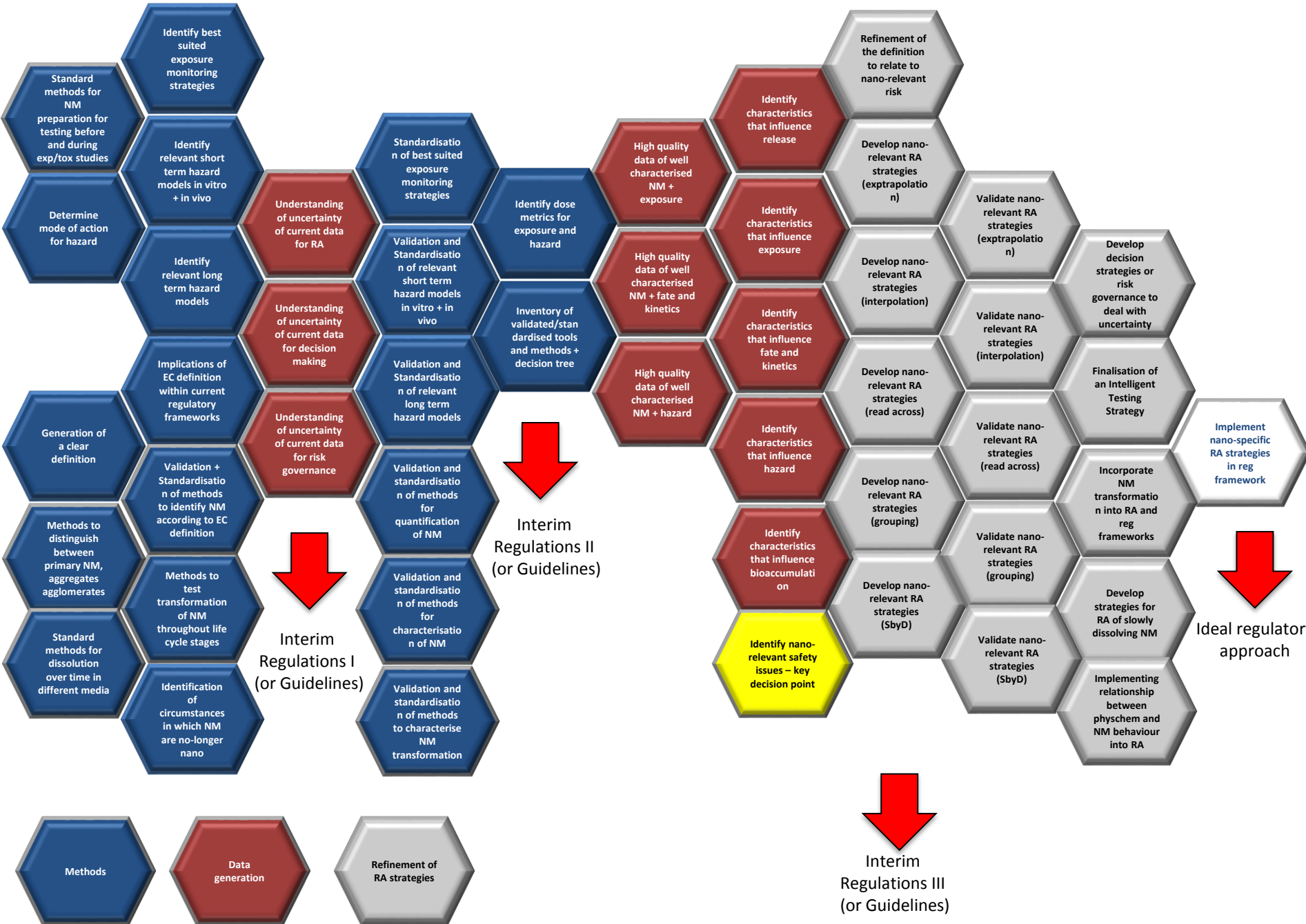
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The Plan

- Convert NANoREG Regulation Research Gap analysis into a hexagon diagram.
- Colour code the hexagons by identifying which research priorities are relevant or common to both road maps.
- Interrogate the diagram using the Regulatory Questions from NANoREG and edit as appropriate.
- Interrogate the diagram in relation to current EU regulations (in particular REACH) and edit as appropriate.
- Compare and contrast the hexagon diagram generated with US activities and edit as appropriate.
- Generate one paragraph of text to outline each hexagon/priority and link to the relevant references, reports and projects.
- Put together the final text that introduces the roadmap, provides the roadmap diagram, the short description for each hexagon/priority with references, and the final conclusions.

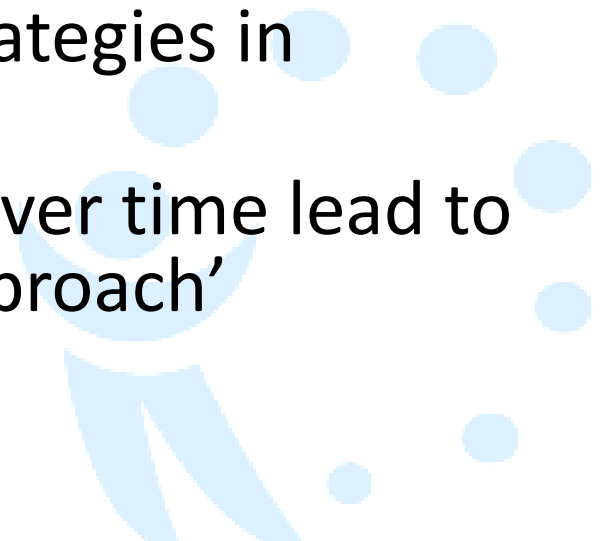
Short term

Long term

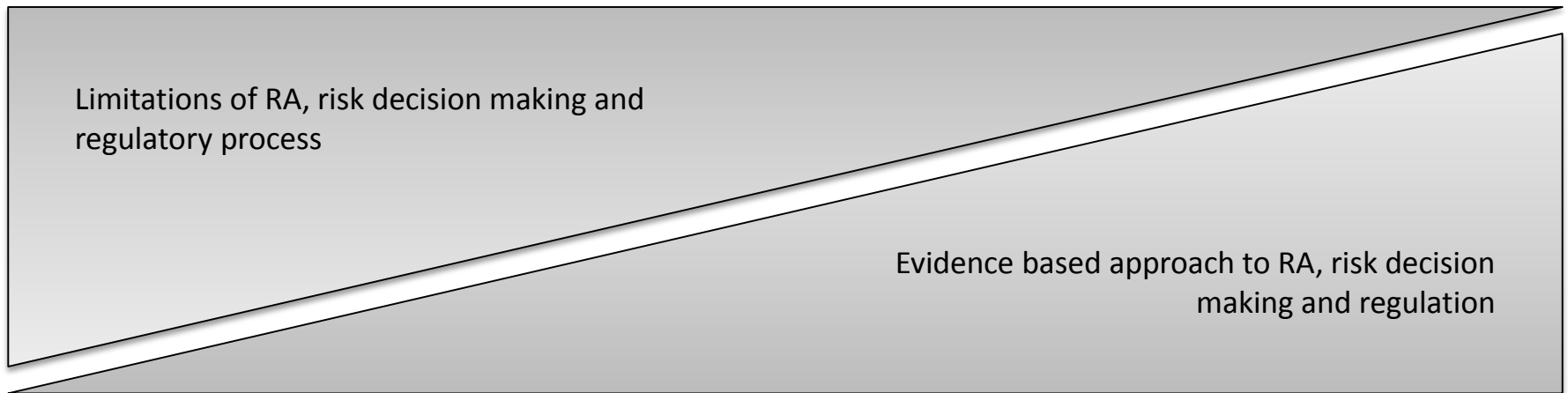


RRR diagram so far

- 51 (or 50) Research priority hexagons identified
- 21 methods
- 11 data generation
- 17 (perhaps 16) Refinement of RA strategies
- 1 Identify nano-relevant safety issues – key decision point
- 1 implement nano-specific RA strategies in regulatory frameworks
- 3 interim regulations generated over time lead to a final fourth 'ideal regulatory approach'



We can't wait 15 years before identifying and acting upon nano-relevant regulation needs.....

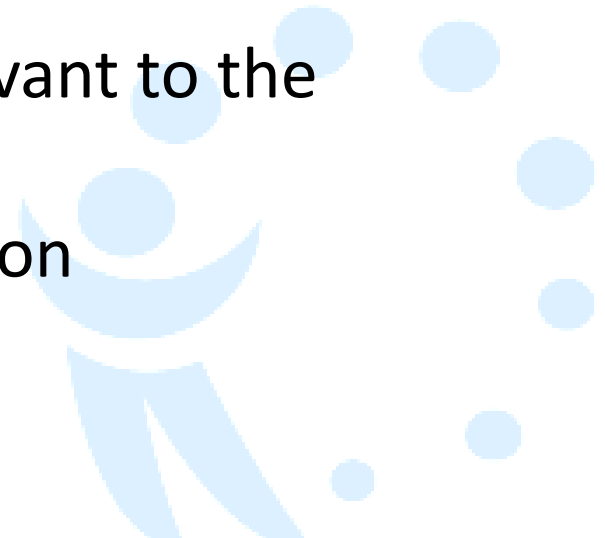


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Regulatory approaches could increase in sophistication with time as the knowledge base increases - 'something is better than nothing'

Text requirements

- Potential authors have been identified for all missing research priorities
- Each section needs to
 - Clarify why it is a research priority
 - Clarify what research is already encompassed within the priority
 - Generate recommendations relevant to the priority
 - Provide links to further information



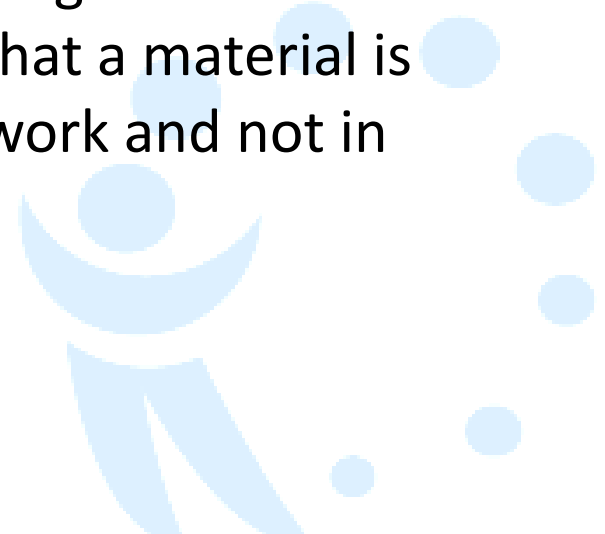
Example

Generation of a clear definition – Why?

A clear definition of nanomaterial should

- be scientifically driven (i.e. evidence based),
- exhibit a well-defined scope
- be possible to implement
- be as uniform as possible across different legal frameworks and global locations, in order to prevent that a material is regarded as a nanomaterial in one framework and not in another.

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Example

Generation of a clear definition – What?

The European Commission (EC) published a recommendation in 2011 on the definition of nanomaterial (2011/696/EU):

http://ec.europa.eu/research/industrial_technologies/pdf/policy/commission-recommendation-on-the-definition-of-nanomater-18102011_en.pdf

Most probably the most distinguishing aspect of the EC nanomaterial definition is the use of particle size distributions based on the numbers of particles, and not on the mass or volume of the particles, as the main classification feature.

Lately (August 2014) Joint Research Centre Institute for Reference Materials and Measurements published the second review report namely, Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 2: Assessment of collected information concerning the experience with the definition:

http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/32544/1/jrc_nm-def_report2_eur26744.pdf

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Example

Generation of a clear definition – Recommendation

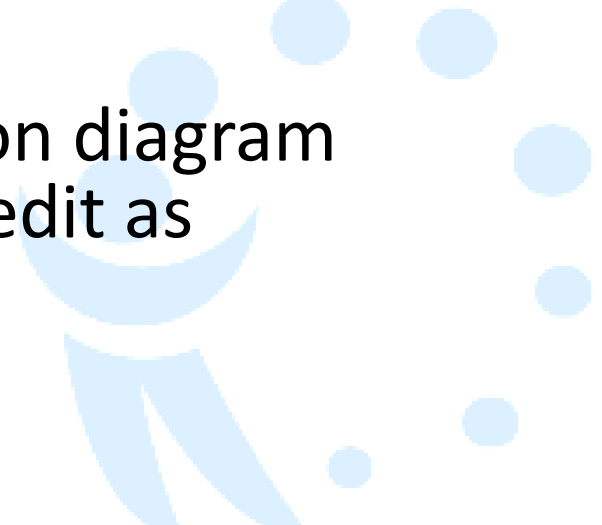
An attempt by different regulators to align their definitions (e.g. via an OECD workshop) would be helpful.

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Next steps

- Finish first draft of report for circulation to cluster members
- Interrogate the diagram using the Regulatory Questions from NANoREG and edit as appropriate.
- Interrogate the diagram in relation to current EU regulations (in particular REACH) and edit as appropriate.
- Compare and contrast the hexagon diagram generated with US activities and edit as appropriate.



Nanocluster input

- First draft will be circulated for comment – those with substantial suggestions will be invited to become part of the team

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