

Merging of the Roadmaps

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NanoSafety Cluster meeting,
Grenoble, November 9, 2016

Overall goals of the merging of the roadmaps

- To carry out the necessary updating of the documents
- To align the documents with each other to prepare one stand-alone document the elements of which support each other
- To provide a meaningful path: 1) from the lab and discovery; 2) through supporting regulations; 3) to economically beneficial innovations and marketable products; 4) by supporting the safety and responsible use of ENM and nanotechnologies at all stages of the process

Strategic Research Agenda (SRA), Research Roadmap

- Strategic Research Agenda (so called blue book) “Nanosafety in Europe 2015 – 2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations” was prepared by the NSC during 2011 – 2013 and modified and finalized by the Coordination Group
- The document was handed to the EU Commission during EURONANOFORUM ‘2013 in Dublin, and has been used to shape contents of the HORIZON’2020 nanosafety call texts

Purpose of the SRA

- Provide understanding of the current situation and present the research landscape when preparing the SRA
- Analyze the prerequisites of successful nanosafety research
- Identify the knowledge gaps and knowledge needs
- Propose priorities for future nanosafety research

CONTENTS OF THE SRA

Preface

Executive summary

Strategic Research Agenda compact

1. Introduction and background

2. The nanosafety research landscape

3. Prerequisites for nanosafety research

4. Common nanosafety research themes

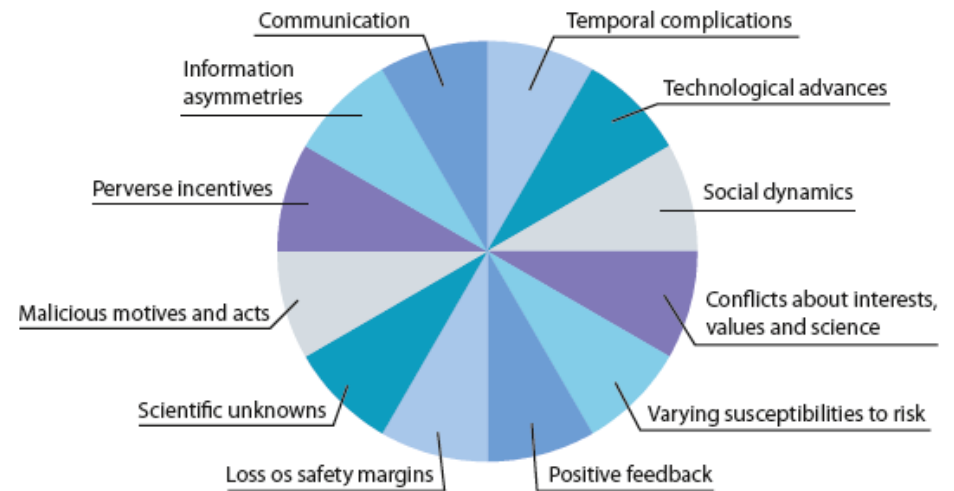
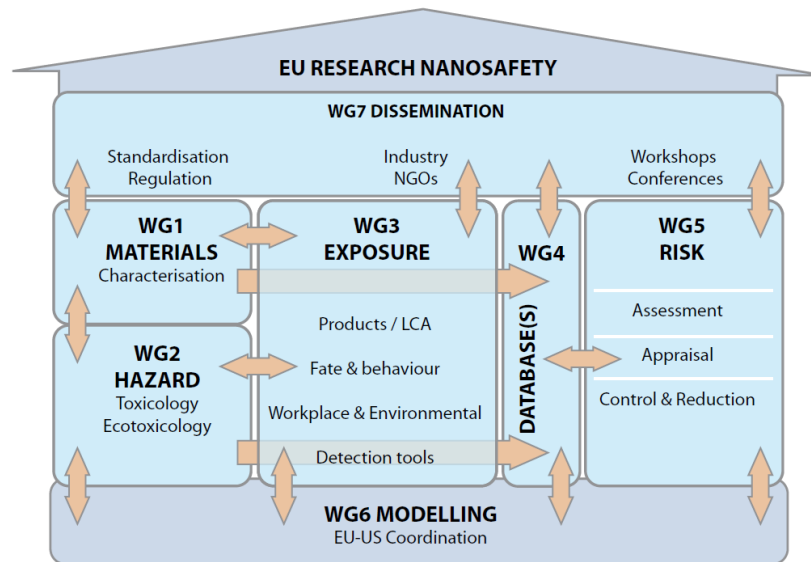
- 4.1. Nanomaterial identification and classification
- 4.2. Exposure, transformation and the life cycle
- 4.3. Hazard mechanisms, biokinetics, and vulnerable populations
- 4.4. Risk prediction and management tools

5. Research priorities and roadmap

6. Implementation of the roadmap

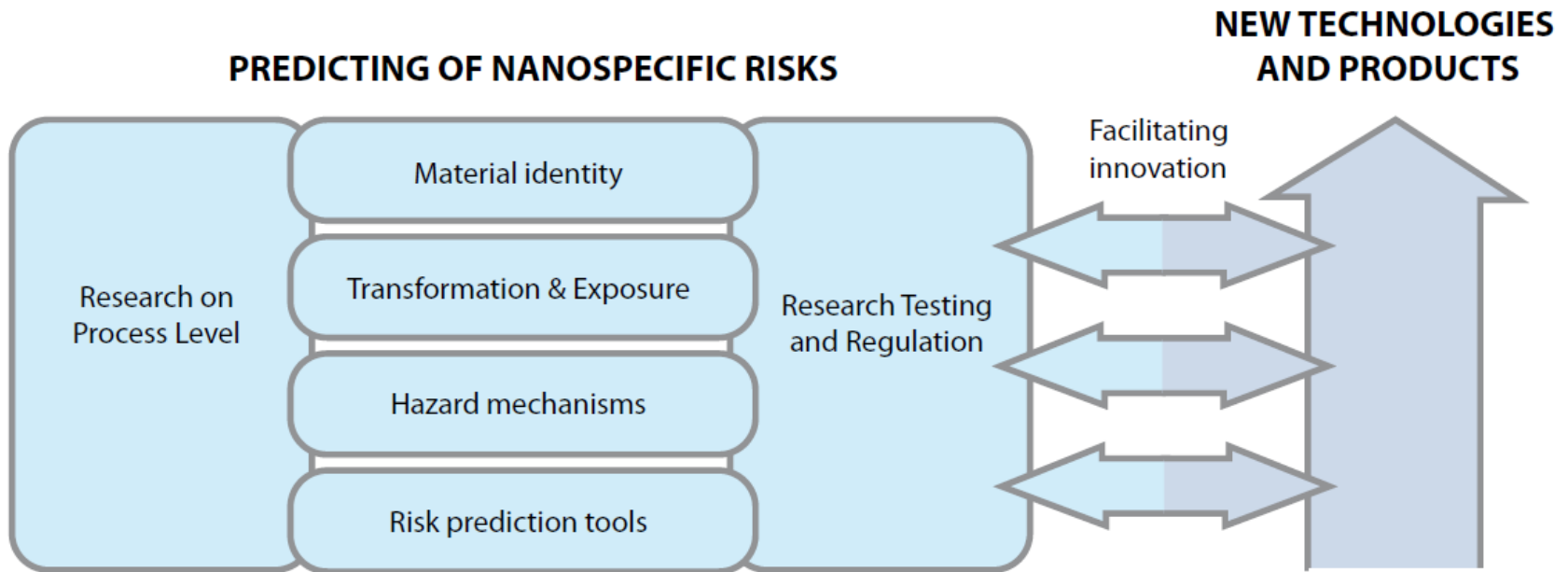
Annex : Editorial group and contributors of the document

Introduction & the nanosafety research landscape



Introduction and background

Nanosafety for Innovation and Sustainability



All subaims shall feed to the overall aims of predicting and controlling possible nanospecific risks.

Common nanosafety research themes

1. Nanomaterial identification and classification
2. Exposure, transformation and the life cycle
3. Hazard mechanisms, biokinetics, and vulnerable populations
4. Risk prediction and management tools

The goal would be to reassess the nanoscience-based safety and innovation needs, the landscape & **research priorities** to boost innovations, and align the SRA with RRR & CTTM

Regulatory Research Roadmap

Vicki Stone & WG (following slides from
Vicki Stone)

Regulatory Research Roadmap Purpose

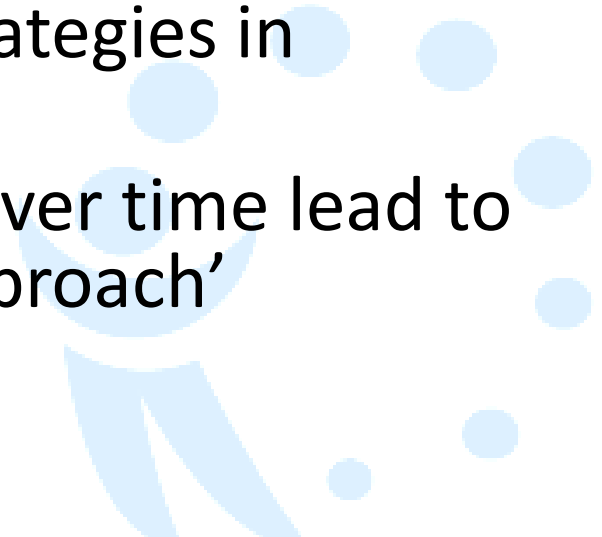
- To identify and structure the research required to deliver effective regulation of nanomaterial safety
- Including
 - Consumer
 - Occupational
 - Sector specific issues
- Excluding
 - Nanomedicine

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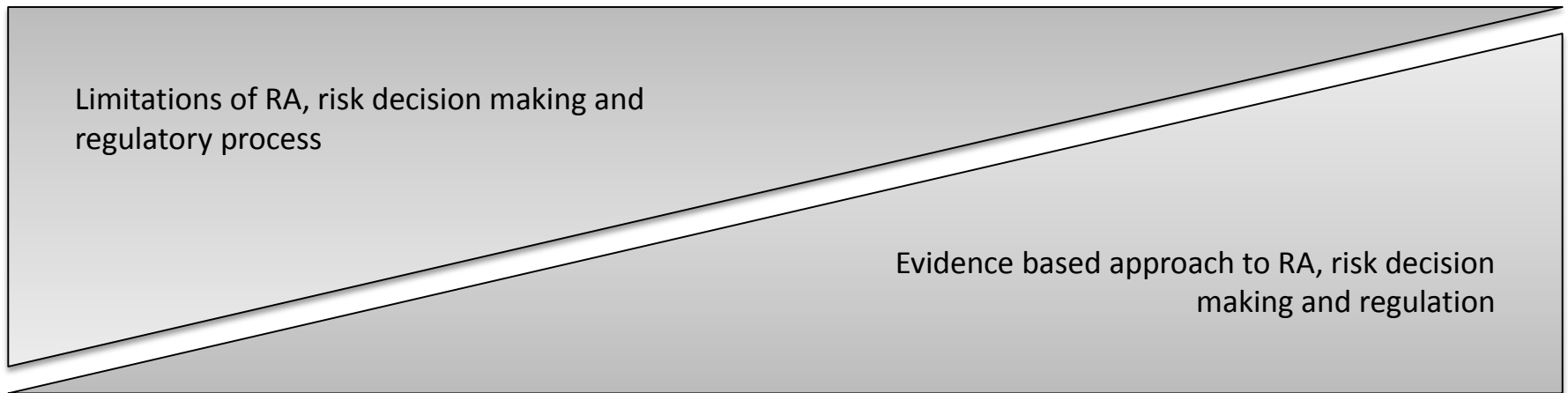


RRR diagram so far

- 50 Research priority hexagons identified
- 21 methods
- 11 data generation
- 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'

RRR text so far (37 pages)

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The colour coding groups hexagons (research priorities) in order to simplify understanding

1.1

Generation of a clear definition

A clear definition of nanomaterial should be scientifically or exhibit a well-defined scope and it should be possible to find The definition should be as uniform as possible across different global locations, in order to prevent that a material is regulated in one framework and not in another.

The European Commission (EC) published a recommendation on the definition of nanomaterial (2011/695/EU): http://ec.europa.eu/research/industrial_technologies/pdf/policy_recommendation-on-the-definition-of-nanomaterial-18102011_en.pdf

The European Parliament and the Council, European Parliament 2013 on a new agenda for European Consumer Policy (IP) <http://www.europarl.europa.eu/ides/getDoc.do?pubRef=-//EP//IP13-0239+0-00+0-00/L4/01/EN/IMJ/eng/upt+EN>

Most probably the most distinguishing aspect of the EC recommendation is the use of particle size distributions based on the number of particles, as the main classification criterion.

More recently (March 2014) Joint Research Centre Institute for Health and Consumer Protection published a review of the EC definition recommendation of the EC Recommendation for a definition of the term 'nanomaterial' (publications.jrc.ec.europa.eu/epos/isy/bist/sem/111111/Term.pdf)

Latest (August 2014) Joint Research Centre Institute for Health and Consumer Protection published the second review report (namely, EC Recommendation for a definition of the term 'nanomaterial' (publications.jrc.ec.europa.eu/epos/isy/bist/sem/111111/def_report2_en20144.pdf)

Based on the feedback received regarding the current definition report of the series, and its assessment, presented in this document, we are now working on a set of indications on how the definition could be improved in terms of clarity, effectiveness and applicability. These recommendations will be included in the next version of the definition report.

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Subsidiarity/sensitivity according to species, age, status or genetic variation).

ITS-NANO
Phil Sayre
Ulila Vogel
Viola Stone

Standard methods for NM preparation for testing exposure/toxicology studies

There is a need for more clarity regarding the best methods for human and environmental hazard testing. This is true for tests and environmental exposure models. Such tests are cut and monitor, making it difficult to interpret the results. The need to improve understanding of dispersion characteristics and environmentally relevant media. This will enable better but at the same time there is a need to link to the knowledge states of dispersion in the environment, in relation to the fate of the particles.

The above text suggests that development of a single method however, is unlikely due to the variations in NM physical matrices and exposure scenarios/routes. In the future, a mix of dispersion options will be required to guide researchers/hazard assessors in the most appropriate protocols. Protocols may not necessarily be mono-dispersed suspensions. In many situations, they may be realistic situations with aggregated or agglomerated particles.

Which projects have or are currently developing protocols for the preparation of nanomaterials for testing exposure/toxicology studies?

ITS-NANO
Phil Sayre
Ulila Vogel

Identify best suited exposure monitoring strategies

Exposure monitoring can be done for a variety of risk assessment, epidemiology, compliance testing and testing measures (e.g., local exhaust ventilation systems, enclosures). The nature of the monitoring strategy will heavily depend on the assessment. For example, testing the effectiveness of compliance with standards (e.g. OELs) or quantitative assessment on the use of personal monitoring approaches. Exposure monitoring for NMs is complicated as:

- 1) There is a lack of standard approaches and metrics (area, or other) that can be used for risk assessment/information.
- 2) The majority of direct reading instruments for measurement are not specific to engineered nanomaterials.

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Arbeitsplatz-Bewertung-von-Schutzmaßnahmen-Index-3.xls

Van Broekhuizen, et al. (2012) Exposure Limits for Nanoparticles: Report of an International Workshop on Nano. Reference Values. Ann. Occup. Hyg., Vol. 50, No. 5, pp. 515-524. Available at: <http://emph.oxfordjournals.org/content/50/5/515.full.pdf.html>

Combine with 5.15

Autocomb

4.6

Validate nano-specific RA strategies (80y0)

What is required to validate?

Combine with 5.18?

4.7

Develop decision strategies or risk governance to deal with uncertainty

4.8

Finalisation of an Intelligent Testing Strategy

Viola Stone

4.9

Incorporate NM transformation into RA and regulatory frameworks

4.10

Develop strategies for RA of slowly dissolving NM

4.11

Implement relationships between physicochemical and NM behaviour into RA

4.12

Implement nano-specific RA strategies into regulatory frameworks

Markup Area

Goals & to be done

- Align identified research priorities with the regulatory needs, to assure large enough overlap
- A few days of edits to be incorporated
- Summary
- Conclusions
- Goal – finish by Christmas

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Closer to the Market (CTTM) Roadmap

NanoSafety Cluster Meeting; 9th of November 2016, Grenoble

ANDREAS FALK

**BIONANONET FORSCHUNGSGESELLSCHAFT MBH (BNN), AUSTRIA
(SLIDES FROM ANDREAS FALK)**

Scope

- Identify best practice and unfulfilled gaps in terms of where and how the scientific/research community, via H2020 and member state funding initiatives, can support the commercialization
- main directions/goals:
 - Setting minimum requirements for nanosafety-related **jobs, skills and/or tools**
- CTTM is a plan that matches short-term to long-term goals with specific solutions to help meet those goals (see chapter 2.5 and 2.6)
- CTTM has three major uses:
 - it helps reach a consensus about a set of needs and the technologies required to satisfy those needs;
 - it provides a mechanism to help forecast technology developments; and
 - it provides a framework to help plan and coordinate technology developments

Bottlenecks

- Bottleneck – Solutions – Layer(s) concerned

<p>Lack of nanosafety management systems</p> <p>Lack of integration of nanosafety issues into industry processes.</p>	<ul style="list-style-type: none"> • (sector specific) nanosafety management systems, proportional to the respective situation • Standardisation, training and certification • Translate and encapsulate the results of research in a battery of practical methods, strategies and tools for the management of nano-risks • Harmonized standards 	<p>1. Scientific knowledge</p> <p>3. CTM</p>
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- Chapter 2.5

Actions proposed

- Current challenges – Activities – Timeline

<p>Lack of nanosafety management systems Lack of integration of nanosafety issues into industry processes.</p>	<ul style="list-style-type: none"> • Reporting/Networking <ul style="list-style-type: none"> ▪ Development, testing, validation and dissemination of holistic, consistent and cost effective RMM • Certification of methods <ul style="list-style-type: none"> ▪ Transferability of RMM methods need to be demonstrated in a second stage, typically be performing round robin exercises 	<p>Short term</p>
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- short term → 2018-2020; long term → 2020 and beyond
- Chapter 2.6

Expected outcome

- Guidance to market actors (e.g. industry, public authorities)
- Best practice
- Standards, technical approvals
- Environmental protection
- Operational certification systems
- Epidemiological studies

Impact

- improvement of efficacy of toxicology studies of nanomaterials and certification of methods
- provide industrial stakeholders and the general public with appropriate knowledge on the risks of nanoparticles and NMs for human health and the environment
- overcome the existing lack of knowledge transfer in the economic and societal point of view
- earlier building of “Business Plan(s)” and integrate in the “Business Plan” the nanosafety dimension of any product supports the better and the faster movement towards the market
- permit industry to “internalise” in their plans the safety issues

> integrate of CTTM in “strategic research and innovation agenda” of



Goals and summary

- Update and align the roadmaps with each other
- Re-analyze the research landscape with the current achievements and identify updated research goals plus prerequisites to achieve them
- Identify, structure, and prioritize the research necessary for ENM RA & subsequent regulations
- Identify safety actions required for safe ENM innovations and safe commercialization
- Create a logical path from discovery through regulations supporting safe innovations reaching the market place

THANK YOU!