HORIZON 2020

Leadership in Enabling and Industrial Technologies (*LEIT*)

Key Enabling Technologies for European Growth

Nanosafety Research policy in the EU
Risk governance

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Research and Innovation

2016-2017 topics

- *Analytical techniques and tools in support of nanomaterial risk assessment*

ACEnano and npScope started on 1st Jan. 2017

- *Promoting safe innovation through consolidation and networking of nanosafety centres*

EC4SafeNano started on 1st Nov. 2016

- *Advanced and realistic models and assays for nanomaterial hazard assessment*
- *Framework and strategies for nanomaterial characterisation, classification, grouping and read-across for risk analysis*

H2020: NMPB Work Programme 2018-20

Nanotechnologies, Advanced Materials, Biotechnology and Advanced manufacturing and processing

- ***GOVERNANCE, SCIENCE-BASED RISK ASSESSMENT AND REGULATORY ASPECTS***
- ***Risk Governance of nanotechnology***
- ***Nanoinformatics: from materials models to predictive (eco)toxicology***
- ***Safe by design, from science to regulation: metrics and main sectors***
- ***Safe by design, from science to regulation: behaviour of multi-component nanomaterials***

International cooperation is strengthened

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EU-US cooperation on nanosafety

Framework: Science and Technology Cooperation Agreement

Communities of Research, CoRs: http://us-eu.org

1. **Risk Management and Control**
2. **Risk Assessment**
3. **Human Toxicity** (including bio-uptake and bioaccumulation, human-tox testing, and systems biology approaches)
4. **EcoToxicity** (including bio-uptake and bioaccumulation, eco-tox testing, and systems biology approaches)
5. **Exposure Throughout the Lifecycle** (Including nanomaterial release, transport, transformation studies, through to bioavailability estimates)
6. **Databases and Computational Modeling for NanoEHS**
7. **Characterization COR** (including material characterization, associated system characterization, protocol development, and linkages with domain expertise CORs)

Exploring the possibility of parallel calls

WHERE NOW? WHAT NEXT?
Some actions of strategic importance should continue

Community building, research policy and roadmaps, cross-projects cooperation

Close cooperation with the Member States programmes

Strengthening and extending international cooperation

Integrate scientific research with regulatory research and with implementation

Close cooperation with regulatory authorities and agencies

EU strong contribution in the international scene: ISO-CEN, OECD-WPMN

What next?

Passing to safety technology implementation through:

1, The application of safety management in other projects, first the PILOTS cluster

2, Engaging the Civil Society is a challenge

3, Communication

4, Supporting the activity of market palyers and learning from them

5, Opening new roads to safe Innovation: Safe By Design

6, Learning lessons and fill-in gaps

In other words: RISK GOVERNANCE

Governance?

Action Plan for Nanotechnologies: *Creativity, responsibility, synergy and coherence of efforts are needed more than ever and an effective governance approach is indispensable.*

The 2010 report on the public consultation for the follow-up action plan breaks down "governance" in the following lines:

Consultation of stakeholders

Public dialogue, communication, transparency

Addressing issues of risk (for workers, consumers, and the environment) and benefit

Addressing ethical issues

Addressing issues of privacy and fundamental rights

Setting of research priorities

Addressing especially Nano-bio-cogno-applications (e.g. enhancement) by additional targeted regulation

Implementation of regulation

This is fine but not really governance!

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What is then Governance?

Governance is focused on converting knowledge (including limited knowledge) into choice (including the choice not to choose) and converting choice into action (including the choice of not to act) towards a goal.

Governance is therefore primarily consisting in defining a <u>goal</u>, or a consistent (or at least not-self-contradicting) <u>set of goals</u>.

Then to be able to implement policies towards the goal and take action on <u>Information, Communication, Planning and Feedback, and Progress Monitoring</u>.

Innovation Governance or Risk Governance

Let's start with the low hanging fruit; <u>Risk</u>

A coherent community exists: the nanosafety cluster

On industrial materials but also cosmetics and food

Risk assessment and safety-by-design

Scientific and regulatory research level

Good links with the PILOTS cluster

Projects pay good attention to safety.

Good international cooperation

Several running projects address governance issues. They can provide financial support to experts at start.

Some input can be provided from completed projects.

Governance: Information

Principle: *Agents must collect their own information, convey the existing information to all other agents, and inform about their current work and on what may be expected next.*

Several projects and organisations address this issue well but common action is weak.

Common ontology (done and progressing)

Common SOPs, Standard Operating Procedures

Databases (work progressing)

Nano-observatory (to be established and maintained at ECHA)

Publication of a projects compendium annually

Problems in terms of data quality, data collection storage and curation are well known.

Governance: Communication

Principle: Agents must give this information out in content and shape necessary for comprehension at different levels e.g. Authority, Stakeholders, Civil Society, Public.

Open access publications compulsory
Open data access in pilot phase

Still lots to do

Governance: Planning and Feedback

Principle: The Governance structure seeks to parallel the addressed paradigm to similar well studied paradigms of the past, and to anticipate or speculate on the future.

Policy and roadmaps exist and progress
Learning from other risks of the past is still weak
No collective look at research policy making
Little anticipation/speculation about the future
Long time periods for delivery of reliable research results
Policy making at global level is weak
Gaps between scientific and regulatory levels

Governance: Progress monitoring

Principle: It means continuous follow-up, critical review of field operations and conditions, goal review, re-schedule and revision of planning.

New field and multidimensional

Competences and skills need improvement

Team work needed

Little feedback from the technology application field

This is the most difficult operational phase of governance but is the most important for success.

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NMBP-13-2018: Risk Governance of nanotechnology (RIA)

<u>Specific challenge</u>: Significant progress has been achieved in relation to research regarding the safety of nanomaterials and considerable efforts have been put in place to transfer this knowledge into regulation. Still, more needs to be done to cover not only the research but also the innovation phase. To fill this gap transdisciplinary risk governance is required. It should be based on a clear understanding of risk by all stakeholders and of societal risk perception. It should propose and apply clear criteria for risk evaluation and acceptance and for transfer of acceptable risk. It should develop reinforced decision making tools including such aspects and facilitate risk communication to relevant stakeholders, including industry, regulators, the insurance sector and the general public.

The implementation of risk governance should take societal concerns and ethical considerations into account and will increase the societal trust in nanotechnology to contribute to the sustainability of the sector. Risk governance will need to encompass the entire material life-cycle from scientific research and product development through use to the end of life and should address the different stages of product innovation. For this to be effective, development of skills through education and training will be required.

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Scope:

Consistent information management taking into account the existing EU and MS information platforms (e.g. nanosafety cluster, nano-observatory, DaNa, nano-smile) for risk assessment, for both hazard and exposure and for both human health and the environment, and risk mitigation including regulatory aspects of safe-by-design. In particular, the areas of increasing reliability and trust in nanosafety risk assessment methods, improved understanding of risk perception and risk acceptance, effective risk communication and transfer of acceptable risk to insurance need specific attention.

Responsible communication with stakeholders and the civil society based on quality information. This should be aimed at developing reliable decision making, risk monitoring and feed-back procedures based on improved understanding of risk perception and behaviour at stakeholder levels.

Plans for future scientific and regulatory research paying due attention to social, ethical and environmental aspects. These should be based on past experiences, include appropriate pre-market assessment of potential impact in different stages of product innovation, post use monitoring, and organised consultation of stakeholders and public dialogue.

Mechanisms to monitor progress in several industrial sectors and revise plans.

Activities are expected to focus on Technology Readiness Levels 5 to 6.

The Commission considers that proposals requesting a contribution from the EU between EUR X and Y million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Type of Action: Research and Innovation Action

To discuss ...

The essential elements of a risk governance framework (Stone et al.)

How to address complex risks in the presence of high uncertainty?

Three emements: Advanced tools, an integrated model, regulatory requirements.

Tools feed into a DSS

The decisions are guided by legal/regulatory frameworks

Real life situations

Rational, transparent, inclusive

Open society addressing emerging technology

Beyond compliance

No piece meal solutions

Expected impacts:

Establish and launch a transparent, self-sustained and science-based risk governance body.

Govern possible risks from nanotechnologies in order to implement their social, environmental and economic benefits.

Sustainable solutions at a level that will allow both consistent integration of scientific results and regulatory application of scientifically sound concepts.

Ensure consistency of science based risk management approaches in all EU Member States.

Ensure synergy with similar actions internationally.

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Thank you for your attention!

Find out more:

www.ec.europa.eu/research/horizon2020