Policy Conference: A Future-proof approach to Nanomaterials

WHICH RESEARCH STRATEGY?

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Research and Innovation

What does "Strategy" mean?

- **A strategy implements a policy.**

Vision, purpose (Long term vision ! Move away from today's obstacles !)

- **It must be** global **and** comprehensive**.**

  Goals (not self-contradicting)

  State of the Art (Progress and risks)

  Roadmap(s)

  Evaluation (milestones)

  Review (when, criteria)

  Resources

  Mechanisms of implementation

  Accountability

Regulating Nanomaterials in the EU

Principles

- Framework for proper functioning of the internal market and a high level of protection of health and the environment
- Science based, workable nanomaterial definition
- State of the art risk assessment approaches
- Consistent application across pieces of legislations
- Ensuring proper enforcement
- Transparency

Overview of selected EU regulations with relevance for nanomaterials.

Regulatory framework	Definition 696/2011	Approval procedure	Safety assessment	Labelling	Guidance
REACH (chemicals) regulation 1907/2006					
CLP (classification, labelling and packaging) regulation 1272/2008					×
Biocidal products regulation 528/2012	×	×	×	×	
Cosmetic products regulation 1223/2009	×	×	×	×	×
Novel food regulation 2015/2283	×	×	×	×*	×
Food additives regulation 1333/2008			×	×*	×
Plastic food contact materials regulation 10/2011		×	×		
Active and intelligent food contact materials regulation 450/2009		×	×		
Provision of food information to consumers regulation 1169/2011	×			×	
Medical devices regulations 2017/745 and 2017/746	×	×	×	×	

*Labelling of novel foods and food additives containing nanomaterials is required under the Regulation on the Provision of Food Information to Consumers 1169/2011.

A research policy basics

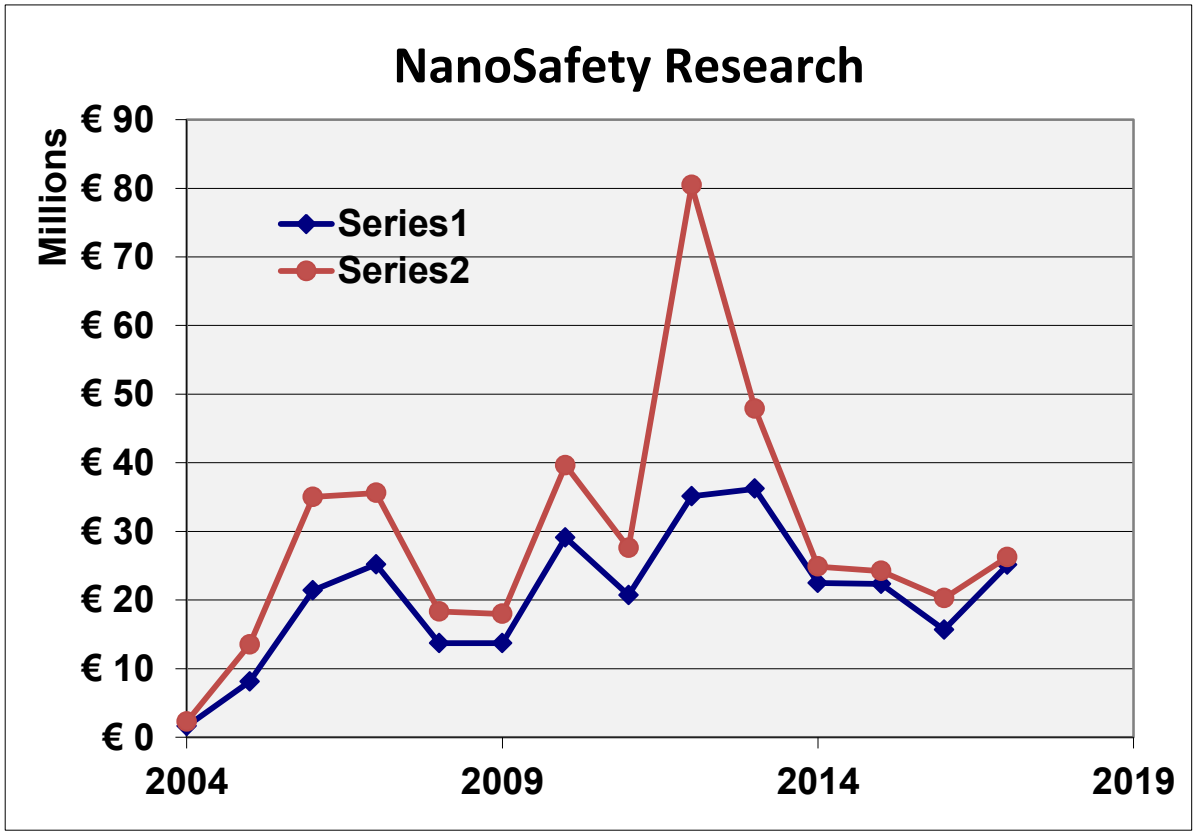
Policy: New technologies driven innovation can only succeed if all possible or perceived as possible risks are convincingly managed.

Policy actions should be shaped along the lines of:

- **Completeness: All technical areas to be addressed: Hazard – Exposure – Risk Assessment – Risk Appraisal - Safe-by-Design**
- **Consistency: All safety management layers to be addressed: Science and technology– regulatory research – market implementation**
- **Efficiency: Synergy with Member States and International cooperation**
- **Continuity: A challenge**

A strategy (and roadmap) should respect these.

Nanosafety research in FPs and H2020 Investment



NB: These figures do not include safety research in application-oriented projects nor nanomedicine

European Commission

Expected developments in the field of nanotechnology / nanomaterials research in the next 5 - 20 years

- What is RTD's view on a future outlook of safe nanomaterials / safe use of nanomaterials?
- How can Member States contribute on a national or international level; i.e. in what way can MS support the Commission to come to an efficient and effective regulation of nanomaterials.
- Which are the first –three?- urgent steps to be taken according to RTD? In this respect, there might be certain expectations on the outcome of this Policy Conference?

Science and Technology

We have to get the science right in the first place and provide technology and skills (including for rules implementation).

- Mostly done by academia in hypothesis driven research.
- Largely supported by EU and mostly by NMBP programme.
- Well progressed in Risk Assessment (hazard and exposure), less in Safe-by-Design, even less in Risk Governance.
- Data on this level are not adequate for regulatory purposes.
- International cooperation is fruitful.
- New concepts (low TRLs) must be continuously supported, HTS, ITS, AOPs, -omics, ...

Regulatory (translation) level

Translation of research findings to regulatory tools

- Large gaps exist between scientific and regulatory levels.
- International collaboration is a must.
- Difficult to apply for particular areas (eg perception of risk).
- Legitimisation is needed at global level (OECD).
- Outcomes in the shape of OELs, or environmental limitations may range depending on applications.
- Consistency with science is continuous concern.
- Data curation and ontology need continuous effort.

Too expensive to be supported by EU-FP resources alone.

Regulation and its implementation

Most risks (few exceptions) are regulated at EU level.

- Regulation alone is no solution.
- How does nanosafety link to safe chemicals innovation?

There are efforts to streamline rules globally.

- Rules are made centrally but applied locally.
- MS should support local risk centres and the EU the networking.
- Certification for known risks? And skills?
- Multiple sectors and even more regulatory frameworks (high complexity, high potential for unexpected interactions)
- Overall definition of nanomaterials but also specific provisions

Future outlook

The EU has a world class research programme on safety of nanomaterials which ought to continue.

It should be extended to next generations of NM.

EU and MS should act together.

International cooperation to continue.

EU and MS working together

- *ERANET SIINN was a first try*
- *NanoReg/Prosafe was a success case*
- *NanoReg2 less so*
- *EC4SafeNano another good example*
- *Next comes the "Malta" project*

Lessons learned:

Things work best when the EU action is close to MS near-term interests and schedules.

The next steps

- Major actions to start soon for Risk Governance and Nano-Informatics; projects starting in 2019
- Grouping of NM, new methods for NM testing, materials characterisation, modelling; projects running
- Safe by Design conceptual phase is ongoing. The two next years' topics will address application, (40-50 M€); projects starting in 2020 and 2021

Hence, work until 2023-2024 is already defined

All of these need MS support for the regulatory bit

The "Malta" project

- The work should start in 2018 with existing ressources

- An extra 2M€ have been allocated to the Risk Governance topic

- An topic is proposed for the next 2019 call; to be published end 2018

- Another 2020 topic is being considered for other "guidelines" needs

Expected developments in the field of nanotechnology / nanomaterials research in the next 5 - 20 years

- What is RTD's view on a future outlook of safe nanomaterials / safe use of nanomaterials?

- Future rather positive for the first generation NM and perhaps for the second (active NM)

- Work should continue to reduce costs and times

- Strategy to be redefined for FP9

- Close the gap between science and regulatory science

Expected developments in the field of nanotechnology / nanomaterials research in the next 5 - 20 years

How can Member States contribute on a national or international level; i.e. in what way can MS support the Commission to come to an efficient and effective regulation of nanomaterials.

- *Not much different than for other risks eg Seveso, Fire, ATEX, …*
- *Help to get the science right and use MS resources to close the gap with regulatory science.*
- *Organise their own expertise centres and support the EU in networking those*
- *Support international cooperation*
- *Support standardisation bodies*
- *Take the next steps in regulation*

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Consolidate the progress made with NanoReg – support the "Malta" project (with own resources)

Establish Risk Governance

Advance Safe by Design

Look at the broader picture: Safe Chemicals Innovation

Thank you for your attention!

Find out more:

www.ec.europa.eu/research/horizon2020