HORIZON 2020

Leadership in Enabling and Industrial Technologies (*LEIT*)

Key Enabling Technologies for European Growth

Nanosafety Research policy in the EU

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Research and Innovation

Horizon 2020: Key elements

- A single programme with **3** pillars:
  - ***Excellent Science***
  - ***Industrial Leadership***
  - ***Societal Challenges***

- Less prescriptive topics – strong emphasis on expected impact
- More emphasis on innovation and involvement of industry e.g. industrial deployment of key enabling technologies, Public-Private Partnerships
- Strategic approach, two-year work programmes
- Focus areas bring together different technologies
- Simplification – in access and in participation rules

Policy Context

Four of President Juncker's priorities

- Jobs, growth and investment
- Digital single market
- Energy Union
- Europe a stronger global actor

Commissioner Moedas' priorities

- Open innovation,
- Open science
- Open to the world

http://bookshop.europa.eu/en/open-innovation-open-science-open-to-the-world-pbKI0416263/

Policy context NMBP

- **Sustainable jobs and growth:**
  Boost jobs, growth and investment
  Deeper and fairer internal market with a strengthened industrial base
- **Re-industrialisation of EU**
  towards a strong industrial base
- **Digital Single Market**
  Factories of the Future, '4th industrial revolution'
- **EU Energy Union:**
  Energy-efficient Buildings, Materials for Energy, etc.
- **Circular economy:** boosting growth and renewing industrial capacities in a world of finite resources
  ➲ focus area in 2016-2017 on 'Industry 2020 in the Circular Economy'

EU nanosafety research starts

Nanotechnologies innovation can only succeed if possible, or perceived as possible, risks are convincingly managed.

2004: First efforts in nanosafety with 12 projects under FP6

Including the large project NANOSAFE2 – April 2015

First international conference NANOSAFE2008 in Grenoble

EU nanosafety research policy basics

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

The EU must aim for leadership in the safety management of nanotechnologies.

2007-2013: Continuation with 48 projects under FP7

2009: EU nanosafety research policy actions shaped along the lines of:

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

2014: Efforts continue under H2020 with 9 projects until now.

2016 – 10+ years: Good progress in all fields

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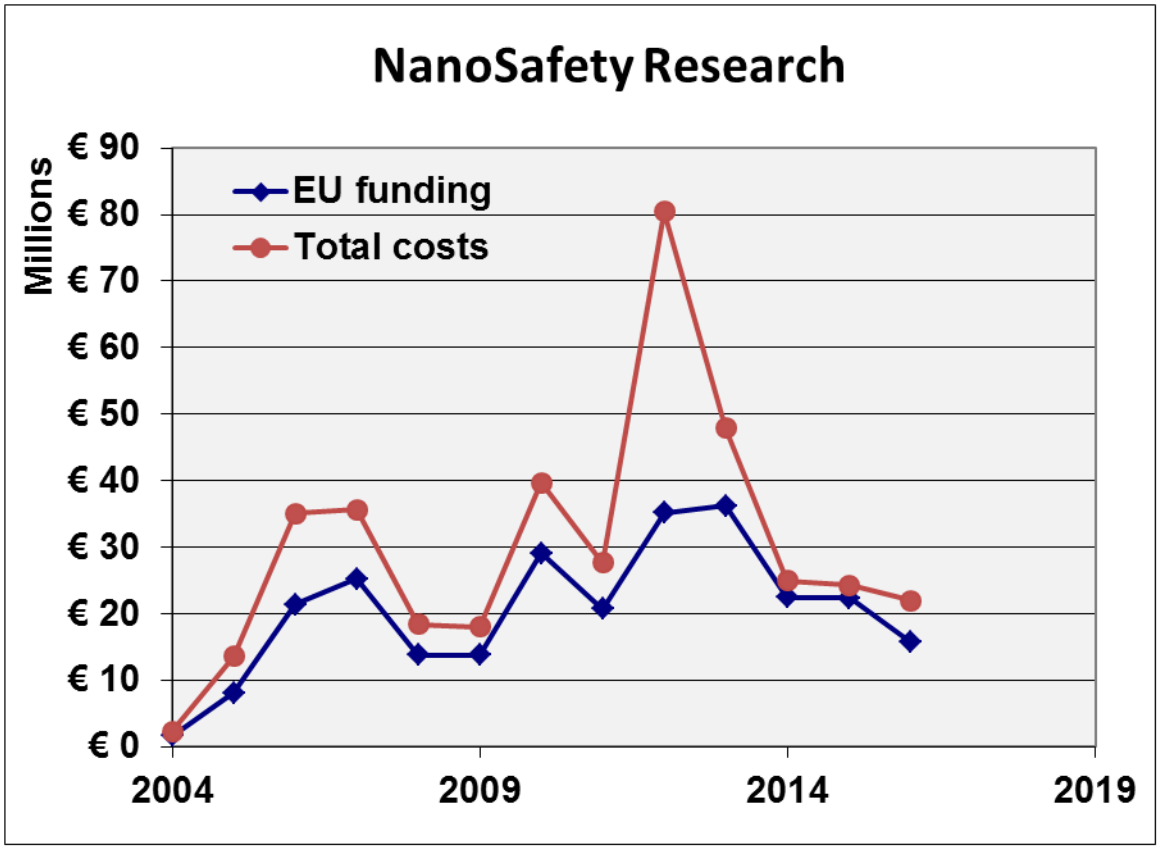
Nanosafety research in FPs and H2020 Investment and Compendium

- First nanosafety projects in FP5 (1998-2002)
- Regular budget increase, now levelled off at ~30M€
- FP7: 48 funded nanosafety projects, representing a total EU investment of 177 M€ (corresponding to total projects costs of 262M€).
- H2020: 9 projects; 60,5M€ EU funding
- ~5% NMP budget, ~10% Nano@NMP
- In addition to FP, Member States annual funding efforts about 70 M€

  → European (EU + EU MS) nanosafety funding about 100 M€ annually.



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

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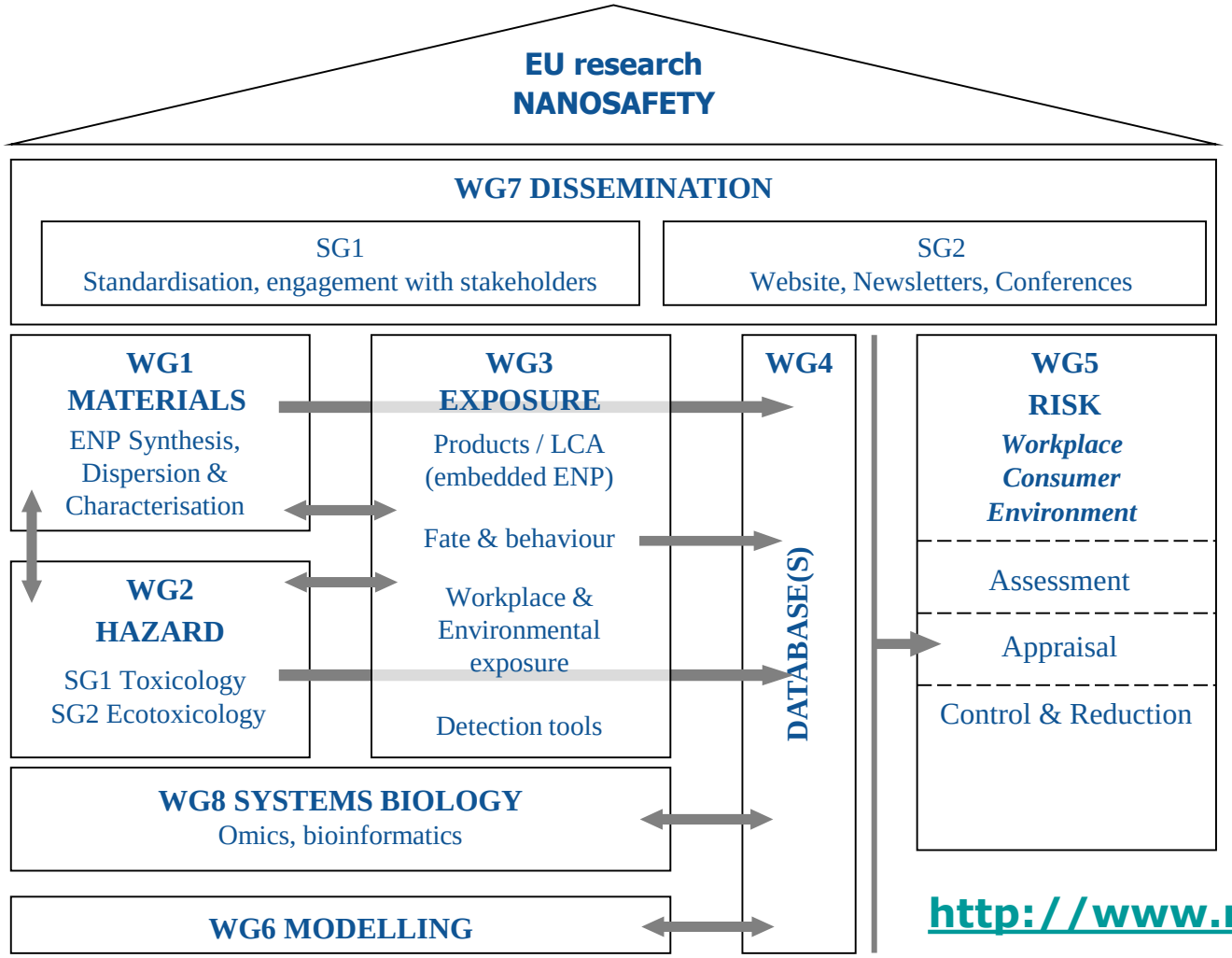

- Finding synergies & complementarities
- To avoid duplicating work and improve efficiency
- To provide a forum for discussion, problem solving and planning R&D activities in Europe (strategic research agenda
- To provide industrial stakeholders and the general public with appropriate knowledge

http://www.nanosafetycluster.eu

H2020: NMPB Work Programme 2014-15

Nanotechnologies, Advanced Materials, Biotechnology and Advanced manufacturing and processing

- Safety of nanotechnology-based applications and support to the development of regulation:

NMP 26-2014: Joint EU & MS activity on the next phase of research in support of regulation "NanoReg II"

NMP 27-2014: Coordination of EU and international efforts in the safety of nanotechnology

NMP 28-2014: Assessment of environmental fate of nanomaterials

NMP 29-2015: Increasing the capacity to perform nano-safety assessment

NMP 30-2015: Next generation tools for risk governance of nanomaterials

- NMP 26-28: NANOREG II; PROSAFE; NANOFASE
- NMP-29-30: SMARTNANOTOX, HISENTS, CALIBRATE start in 2016

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2016-2017 topics

- Analytical techniques and tools in support of nanomaterial risk assessment

ACEnano and npScope in preparation

- 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

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Regulatory research on risk assessment NANOREG – PROSAFE

*A **joint action** supported by public funding from EU FP7 (20%), Member States and FP7-associated states and industry (80%).*
*Brings together EU MS and industry contribution to the **OECD-WPMN**.*
*A credible reply to the **EP resolution of 2009** for a special fund.*

CSA PROSAFE started on 1-2-2015 for 2 years:
- Complements NANOREG and supports the EU-USA CoRs
- Launch of one joint call with few MS and USA funding

Completion in early 2017
Results will be released at project end.

White paper with contributions from several EU projects will be presented and discussed in a conference at OECD Paris, on 29/11-1/12/2016 and published in March 2017.

Regulatory research roadmap
OECD-WPMN is reference platform

Quantifying Risk(s): *NanoReg I and PROSAFE; main focus of WPMN so far*

-Materials characterisation

-Hazard(s) quantification, combined hazards

-Exposure monitoring and metrics

Risk assessment

-Criteria for risk evaluation/acceptance are needed.

-Costs-Benefits Analysis

-Risk communication

Relatively weak middle area in regulatory terms

Safe by Design: *NanoReg II*

(not yet included in OECD-WPMN work programme but expected)

How to bring (high or unknown) risk back to acceptable level ?

(without shutting down production and use)

Securing efficiency

-Best practice guides

-International cooperation

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Safe – by – Design: What does it mean?

SbD is not new.

- Safety is integral part of the innovation process.
- It is routine in several sectors and for several risks.
- Design values may vary and be subject to change.
- Risk levels too.

SbD means that:

- Materials are designed for both performance and safety.
- Jobs are always and everywhere done in a prescribed manner.
- Skills are developed and available along the whole chain.
- Operations remain sustainable in technical and economic terms.
- Control and feedback mechanisms are in place and reliable.
- Learning from failures is made easy.
- Acceptable risk can be insured against affordable primes.

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Ensuring continuity and consistency: Building up the market level

Basis: Competence centres are established in several countries.
Member States support the centres, EU the networking

The coordination action EC4SafeNano
started on 1st November 2016

Draft Roapmap published at www.nanosafetycluster.eu

Building-up collaboration between the Pilots projects cluster and the nanosafety cluster for safety management

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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

European Commission

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

Continue cooperation with USA-NNCO and agencies

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: 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!

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 goal, or a consistent (or at least not-self-contradicting) set of goals.

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

Innovation Governance or Risk Governance

Let's start with the low hanging fruit; Risk

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.

Interested? Welcome!

Agenda for NanoSafety Cluster Meeting, Grenoble, 9 November

Time: *Wednesday 9 November; 14.00-18.20*

Venue: *Maison MINATEC, Meeting Room Titane 2*
Address: Parvis Louis Néel, 38054 Grenoble Cedex 9.

16.30-18.20	**Session 2: Launch of the EC risk governance action** Chairs: Dr Georgios Katalagarianakis and Dr Jean-François Damlencourt

Thank you for your attention!

Find out more:

www.ec.europa.eu/research/horizon2020

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