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

European Commission

Horizon 2020 is different

- A strong challenge-based approach, allowing applicants to have considerable freedom to come up with innovative solutions
- Simplified list of possible types of action (e.g. research and innovation -100%; innovation actions - 70%,…)
- Less prescription, strong emphasis on expected impact
- Broader topics
- Cross-cutting issues mainstreamed (e.g. social sciences, gender, international…)

Three Pillars of Horizon 2020

Excellent science

- ***European Research Council***
- ***Future and EmergingTechnologies***
- ***Marie Curie actions***
- ***Research infrastructures***

Indicative Budget:
24 598 M€*

Industrial leadership

- ***Leadership in enabling and industrial technologies***
- ***Access to risk finance***
- ***Innovation in SMEs***

Indicative Budget:
17 938 M€*

Societal challenges

- ***Health, demographic change and wellbeing***
- ***Food security, sustainable agriculture, marine and maritime research & the bioeconomy***
- ***Secure, clean and efficient energy***
- ***Smart, green and integrated transport***
- ***Climate action, resource efficiency and raw materials***
- ***Inclusive societies***
- ***Secure societies***

Indicative Budget:
31 748 M€*

* 2014-20, in constant 2011 prices

Research and Innovation

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

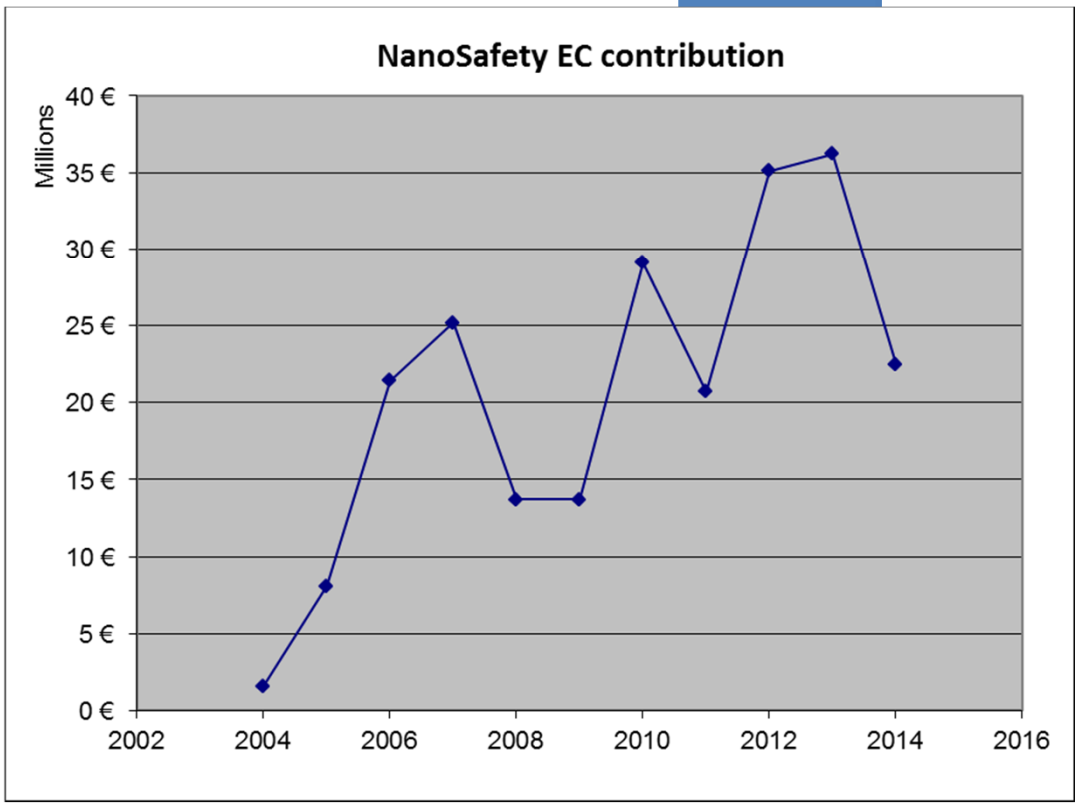
NMP 29-2015: Increasing the capacity to perform nano-safety assessment

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

Nanosafety research in FPs 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€).
- ~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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Emerging Technologies raise new Ethical, Legal and Societal Implications (ELSI) and EHS questions

Suitability of the current regulatory framework?
(REACH/CLP, product-specific legislation)

YES but specific requirements for nanomaterials:

- **Definition of Nanomaterials 2011/696/EU**
- **Revision of REACH annexes for NMs**
- **Specific NMs requirements in Cosmetics, Food Safety, Biocides**

"Real Life" implementation

Exploratory research: hazards, exposures, risk assessment

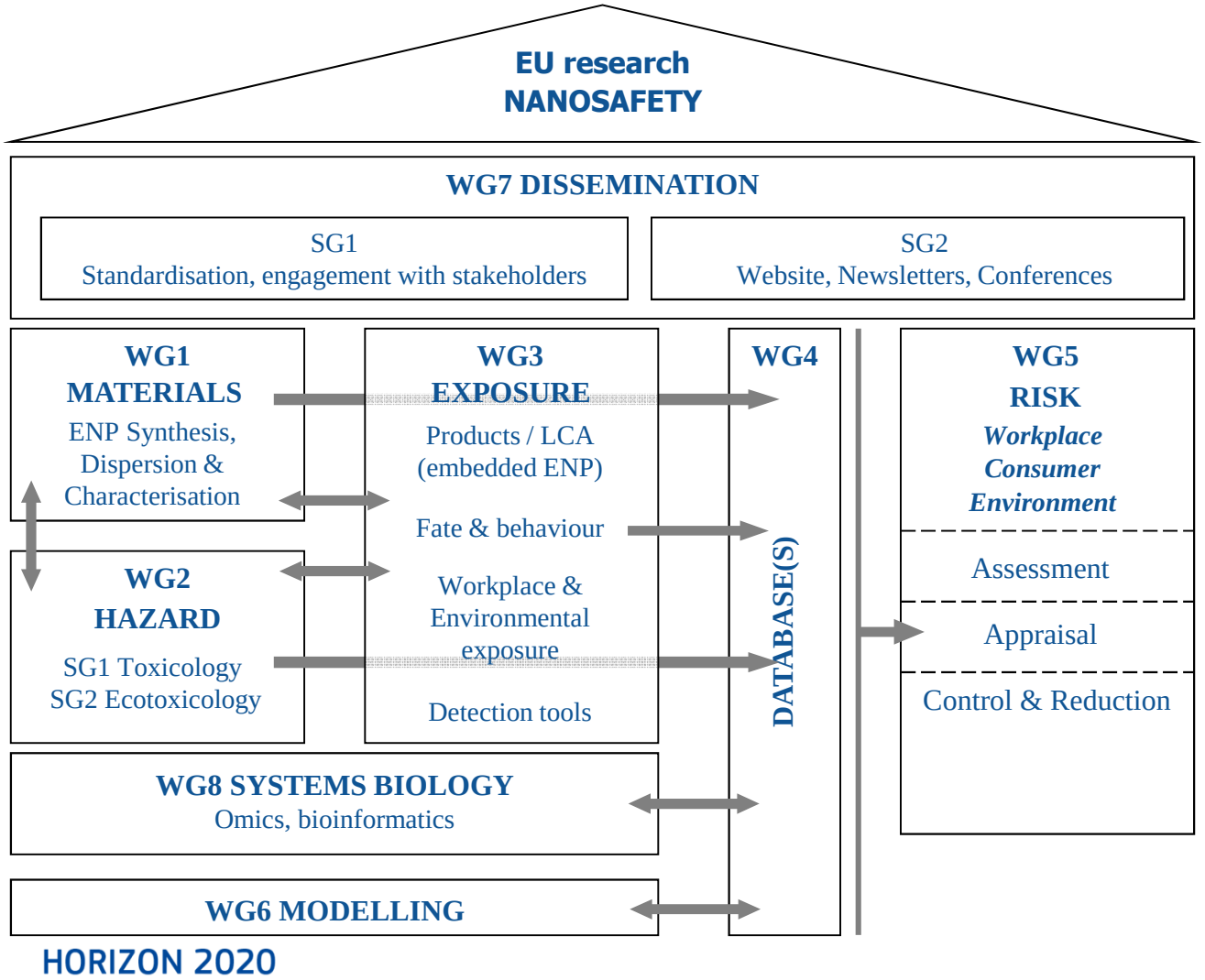
Regulatory Research: Validation, Adaptation or Development of test methods

Market Support Research

FP6 FP7 H2020

Projects clustering:

NanoSafety Cluster



- 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

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Nanosafety RTD roadmap

Positive environment for research is crucial

Impact of chemicals and occupational safety regulations

Infrastructure for nanosafety research is highly important

Innovation, value chain and nanosafety research

Communication and dissemination to ensure impact

International cooperation; nanosafety is a global issue

Research needs

Nanomaterial identification and classification

Exposure transformation and the Life Cycle

Hazard mechanisms, biokinetics, and vulnerable people

Risk prediction and risk management tools

http://www.nanosafetycluster.eu/news/83/66/Nanosafety-in-Europe-2015---2025.html

Nanosafety
Regulatory research roadmap (in progress)

Quantifying Risk(s)

-Materials characterisation data are insufficient to underpin Risk Assessment.

-Hazards quantification are not standardised, combined hazards are unclear.

-Exposure monitoring and metrics reliability is low.

-In-situ characterisation technologies are needed.

-Life-Cycle Analysis data are inadequate.

Safe by Design

-Criteria for Risk evaluation/acceptance are needed.

-Costs-Benefits Analysis is just starting and for very few applications.

-Risk communication is not really up to challenges.

Securing efficiency

-Few best practice guides have been published.

-International cooperation

NanoReg I and NanoReg II (in preparation) are reference.

Regulatory research; NANOREG - PROSAFE

A joint action supported by public funding from EU, Member States and FP7-associated states and industry. Total project size €50M.

Contribution of resources from:
- Brazil and South Korea of 2M€ each
- Czech Republic of 0,5M€
- Interest from Greece and Malta

First 18-month review completed successfully

CSA PROSAFE starts on 1-2-2015:
- Complements NANOREG
- Supports the EU-USA CoRs
- Launch of one joint call with MS funding

Safe by Design in regulatory terms to be addressed by NANOREG II (in preparation phase).

Third SIINN Call: Participation of Funding Agencies from 8 Countries

- **Belgium**
  - Fonds de la Recherche Scientifique (FNRS)
- **Germany**
  - Federal Ministry for Education and Research (BMBF)
  - Project Management Jülich (PtJ)
- **Austria**
  - Ministry for Transport, Innovation and Technology (BMVIT)
  - Austrian Research Promotion Agency (FFG)
- **Portugal**
  - Foundation for Science and Technology (FCT)
- **Region Nord – Pas de Calais (France)**
  - Regional Council of Nord – Pas de Calais
- **Romania**
  - Executive Agency for Higher Education, Research, Development and Innovation Funding (UEFISCDI)
- **Spain**
  - Ministry of Economy and Competitiveness (MINECO)
- **USA**
  - National Science Foundation (U.S. NSF)
  - Consumer Protection Safety Commission (U.S. CPSC)
  - National Institute of Environmental Health Sciences (U.S. NIEHS)

EU-US cooperation on nanosafety

Framework: Science and Technology Cooperation Agreement

Communities of Research, CoRs:

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)

Open to global participation *http://us-eu.org*

Research/ Innovation

Roadmap and future action: Building up the market level

Basis: Competence centres are established in several countries.

-Networking
-Certification
-Benchmarking
-Regulation
implementation technology and mechanism

Technical scope:
Risk monitoring
Risk control
Risk prevention
Risk mitigation

Skills development
Risk perception and communication
Safety management services
Standardisation

The to do list:

- **MS support the centres, EU the networking**
- **The nanosafety cluster needs support for their activities (eg the young researchers' forum)**
- **The joint calls with MS funding (SIINN, PROSAFE) should continue**

2016-2017 topics

- Analytical techniques and tools in support of nanomaterial risk assessment

- Promoting safe innovation through consolidation and networking of nanosafety centres

- Advanced and realistic models and assays for nanomaterial hazard assessment

- Framework and strategies for nanomaterial characterisation, classification, grouping and read-across for risk analysis

Commission Communication on the second regulatory review - Overview

- Definition
- Types and uses of nanomaterials, including safety aspects (main conclusions from Staff Working Paper)
- REACH and CLP
- Other relevant health, safety and environmental legislation
- Information needs

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0572&from=EN

Staff Working Paper on Nanomaterial Types and Uses, including Safety Aspects – Overview

- Definition (in more detail than Communication and comparison to ISO definition)
- Markets, uses and benefits
- Health and safety aspects
- Risk assessment
- Information and databases

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF

Transatlantic Economic Council

Oversees the implementation of the **FRAMEWORK FOR ADVANCING TRANSATLANTIC ECONOMIC INTEGRATION BETWEEN THE EUROPEAN UNION AND THE UNITED STATES OF AMERICA, 2007**

http://ec.europa.eu/enterprise/policies/international/files/tec_framework_en.pdf

To promote transatlantic economic integration in IPR, investment, secure trade, financial markets and innovation

Innovation and Technology: Health, RFID, e-health record systems, eco-efficient bio-based products, genomics, nanotechnology

Actions:

exchange of experts and discussion of best practice,

exchange of views on policy options,

common research actions,

exchange of best practices to promote innovation,

Standardisation

Innovation drivers and economic performance

Communication

Communication; example projects

nanosmile SAFETY OF NANOMATERIALS

nanodiode

New in nanosafety projects

- **Open access publications compulsory**
- **Open data access in pilot phase**

International conferences on nanosafety

- **NANOSAFE**
- **SENN**
- **NANOREG?**

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Thank you for your attention!

Find out more:

www.ec.europa.eu/research/horizon2020

Research/ Innovation