



# Laboratoire national de métrologie et d'essais





# **International Workshop on Challenges to Increased Use of Documentary Nanotechnology Standards**

## **Overview of the European Commission use of nanotechnology issues**

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representing EC*

# The European Strategy & The Action plan

- Towards a European Strategy for nanotechnology
  - ✓ On 12 May 2004, the European Commission adopted the Communication "Towards a **European Strategy** for Nanotechnology" COM(2004) 338. It seeks to bring the discussion on nanosciences and nanotechnologies to an institutional level and proposes an integrated and responsible approach for Europe.
  
- Nanosciences & nanotechnologies: An Action Plan for Europe 2005-2009
  - ✓ On 7 June 2005, the European Commission adopted the Communication "Nanosciences and nanotechnologies: an **Action Plan** for Europe 2005-2009" (COM(2005) 243).

# The European Strategy & The Action plan

- Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009.
  - ✓ **First Implementation Report 2005-2007**
  - ✓ On 6 September 2007, the European Commission adopted the Communication "Nanosciences and Nanotechnologies: an action plan for Europe 2005-2009."
  - ✓ **Second Implementation Report 2007-2009**
  - ✓ On 29 October 2009, the European Commission adopted the Communication "Nanosciences and Nanotechnologies: an action plan for Europe 2005-2009."

## Policy

- The EU has decided to take an “integrated, safe and responsible approach” to the development of nanotechnologies. This includes:
  - ✓ Reviewing and adapting EU laws
  - ✓ monitoring safety issues
  - ✓ engaging in dialogue with national authorities, stakeholders and citizens.

## Risk assessment

- The European Commission's work on risk assessment for nanotechnologies serves to:
  - ✓ review risk-assessment methodologies and develop risk assessment approaches
  - ✓ set priorities for related EU research funding
  - ✓ support the EU regulatory framework and related policy initiatives
  - ✓ feed knowledge into the work of European and international bodies such as CEN, the OECD, ISO, etc.
  - ✓ inform and stimulate the dialogue between the Commission and stakeholders, citizens and international authorities.

## Risk assessment and dialogue at EU-level

### ■ EU Risk Assessment system

- ✓ In addition to the three non-food Scientific Committees managed by DG SANCO (SCCS, SCHER, SCENIHR), the EU Risk Assessment system includes, inter alia, the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), The European Chemicals Agency (ECHA), the European Centre for Disease Control and Prevention (ECDC), the European Environment Agency (EEA) and the Scientific Committee on Occupational Exposure Limits (SCOEL), managed by DG Employment.

### ■ EU co-operation on Risk Assessment

- ✓ In 2005, DG SANCO launched regular meetings of Chairs and Secretariats of the Scientific Committees and Panel of Community bodies involved in risk assessment as a standing forum for facilitating the sharing of best practices between risk assessors.

### ■ Risk assessment days

- ✓ To engage into a dialogue with the European Parliament and relevant stakeholders, the Directorate General for Health and Consumers regularly holds information sessions for members and staff of the European Parliament, and dialogue sessions with stakeholders.

## International risk assessment dialogue

- Scientific risk assessment plays an increasing role internationally for global risk governance and as a tool to support sustainable trade practices. Divergence often arises on risk policies and measures, sometimes due to different risk assessment approaches. Therefore, international co-operation in this area is of utmost importance. To that end, DG SANCO has taken action to organise risk assessment dialogues involving scientists at global level in order to establish a sustained transatlantic dialogue on risk assessment.

## What has been done so far in terms of legislation (Key actions)

- **Communication on Regulatory Aspects 2008**
- **REACH CASG Nano 2008**
- **REACH Guidance**
- **Recommendation on the definition of a nanomaterial**
- **Several pieces of legislation with specific provisions for nanomaterials and more to come**

## European Parliament

- **Resolution on regulatory aspects of nanomaterials 2009**
  - ✓ Use of nanomaterials should respond to real need of citizens
  - ✓ No data no market principle to apply to nanomaterials
  - ✓ Disagrees with Commission that « current legislation covers risks of nanomaterials »
  - ✓ Due to lack of appropriate data and risk assessment methods nano risks cannot be addressed
  - ✓ Lack of information about the safety of nanomaterials already on market
- **Commission Response to the Parliament, July 2009 – follow-up promised in 2011**
- **Specific nano requirements have been introduced in Cosmetics, Food, waste etc.**

## What is currently being considered?

- **Commission key deliverables in 2011:**
  - ✓ **Bringing RiPoN into operation**
  - ✓ **2nd regulatory review of nanomaterials**
  - ✓ **Report on nanomaterial types and uses on the market and safety**
  - ✓ **Definition of a nanomaterial**

## 2nd Regulatory Review of nanomaterials

- REACH, waste, water, air, worker safety etc
- EP ask Evaluation of need to review REACH
  - ✓ Simplified registration for nano <1 tonne/year
  - ✓ All nanomaterials new substances?
  - ✓ Chemical safety report and exposure assessment for registered nanomaterials
  - ✓ Notification requirements
- Other relevant aspects

## “Nanomaterials in REACH registration dossiers and adequacy of available information”

- **COM will review nano-relevant dossiers for content on health and safety information specific to nanomaterials**
  - ✓ **1. Identify all relevant dossiers**
  - ✓ **2. Pick a representative set (46 found in 1st search, 25 are being reviewed)**
  - ✓ **3. Review submitted information and compare with information requirements currently advised for nanomaterials (beyond REACH Annex requirements and guidance)**
  - ✓ **4. Identify possible (legal) gaps**
  - ✓ **5. Identify effective means to rectify gaps and assess consequences**

## Definition of a nanomaterial

- To determine when a material should be considered as a nanomaterial for legislative and policy purposes in the EU
- Definition based on available scientific knowledge, particularly:
  - ✓ JRC report
  - ✓ SCENIHR opinion
- **Draft Proposal agreed between services in October 2010 subject to public consultation** (received input from 195 stakeholders)
- **Final text adopted on 18 October**

## Definition of a nanomaterial

- "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.
- In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.
- By derogation from point 2 (1 on this slide), fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

## Key messages

- **Competitiveness and Innovation fundamental for the EU**
- **Uncertainty impacts consumer behaviour (i.e. less demand) and investment decisions (i.e. less supply)**
- **Key to increase certainty are:**
  - ✓ Safety
  - ✓ Sustainability
  - ✓ Facts (+ Precautionary principle)
- **Legislative reviews ongoing to enable a conclusion on the above**

## 7th Framework programme 2007 - 2013

- **Theme 4 : Nanosciences, nanotechnologies, materials & new production technologies (NMP)**
  - ✓ The core objective of the 'Nanosciences, Nanotechnologies, Materials and new Production Technologies (NMP)' theme is to improve the competitiveness of European industry and generate the knowledge needed to transform it from a resource-intensive to a knowledge-intensive industry.

## European Innovation Partnership

### ■ Key issues

- ✓ Major societal challenges require joint responses across policies and across EU
- ✓ Numerous sub-critical, uncoordinated initiatives:
  - Between EU/Members states/Regions
  - R&D/ Market-side actions (public procurement, standards, regulation)

### ■ European Innovation partnerships are:

- ✓ Frameworks bringing together main actors and actions
  - At EU and national levels
  - From research to market
  - Around common objectives and targets



## FP6 - NMP NanoSafety PROJECTS

- **ON SAFETY OF NANOPARTICLES:**
  - **CELLNANOTOX:** Cellular Interaction and Toxicology with Engineered Nanoparticles
  - **DIPNA:** Development of an Integrated Platform for Nanoparticle Analysis to verify their possible toxicity and eco-toxicity
  - **NANOINTERACT:** Development of a platform and toolkit for understanding interactions between nanoparticles and the living world
  - **NANOSH:** Inflammatory and genotoxic effects of engineered nanomaterials
  - **NANOCAP:** Nanotechnology Capacity Building NGOs (FP6-SOCIETY)
  - **IMPART:** Improving the understanding of the impact of nanoparticles on human health and the environment
  - **PARTICLE-RISK:** Risk Assessment of Exposure to Particles (FP6-NEST)
  - **NANOTOX:** Investigative support for the elucidation of the toxicological impact of nanoparticles on human health and the environment
- **SAFETY OF PROCESSES**
  - **NANOSAFE2:** Safe production and use of nanomaterials
  - **SAPHIR:** Controlled Production Of High Tech Multifunctional Products And Their Recycling
- **STANDARDISATION AND METROLOGY:**
  - **NANO-STRAND:** Standardization related to Research and Development for Nanotechnologies
  - **NANOTRANSPORT:** The Behaviour of Aerosols Released to Ambient Air from Nanoparticle Manufacturing - A Pre-normative Study

*By courtesy of George Katalagarianakis – EC DG Research & Innovation*

# EC Research Framework Programme (FP 6 & 7)

EUROPEAN COMMISSION / Research & Innovation / 7th Framework Programme  
**Impact on Health and the Environment**  
**FP7-NMP, 1st year, 2007,**  
**Projects launched in 2008-2009**

NMP-2007-1.3-1 <b>Large RTD Projects</b>	Specific, easy-to-use portable devices <b>NANODEVICE</b> : Novel Concepts, Methods, and the Measurement and Analysis of Airborne
NMP-2007-1.3-2 <b>Small RTD projects</b>	Risk assessment of engineered nanoparticles <b>NANOMMUNE</b> : Comprehensive assessment <b>NANORETOX</b> : The Reactivity and Toxicity <b>NEURONANO</b> : Do nanoparticles induce neuronal species and protein aggregation and
NMP-2007-1.3-3 <b>Coordination</b>	Scientific review on the data and studies of engineered nanoparticles <b>ENRHES</b> : Engineered Nanoparticles: Review
NMP-2007-1.3-4 <b>Coordination</b>	Creation of a critical and commented nanoparticles <b>NHECD</b>
NMP-2007-1.3-5 <b>Coordination</b>	Coordination in studying the environmental nanotechnology based materials and products <b>NANOIMPACTNET</b> : The European Network
HEALTH-2007-1.3-4 <b>Small RTD projects</b>	Alternative testing strategies for the medical diagnostics <b>NANOTEST</b> : Development of methodology profile of nanoparticles used in medical diagnosis

EUROPEAN COMMISSION / Research & Innovation / 7th Framework Programme

**Impact on Health and the Environment**  
**FP7-NMP: Topics addressed in 2008**  
**Projects launched in 2009**

NMP-2008-1.3-1 <b>Large RTD Projects</b>	Validation, adaptation and/or development of engineered nano-particles No proposals selected
NMP-2008-1.3-2 <b>Small RTD projects</b>	Impact of engineered nanoparticles <b>ENNSATOX</b> : Engineered Nanoparticle and Toxicology <b>ENPRA</b> : Risk Assessment Of Engineered Nanoparticles <b>HINAMOX</b> : Health Impact of Engineered Nanoparticles <b>INLIVETOX</b> : Intestinal, Liver and Environmental Evaluation of a novel tool for high-throughput <b>NEPHH</b> : Nanomaterials Related Environmental Hazards Throughout Their Life Cycle

EUROPEAN COMMISSION / Research & Innovation / 7th Framework Programme

**Impact on Health and the Environment**  
**FP7-NMP: Topics addressed in 2009**  
**Projects launched in 2010**

NMP-2009-1.3-1 ENV-2009-3.1.3.2 <b>Small RTD projects</b>	Activities towards the development of appropriate solutions for the use of recycled and/or final treatment (Joint call with Theme 6: 'Environment') <b>NANOPOLYTOX</b> : Toxicological impact and recycling of polymer nanocomposites <b>NANOHOUSE</b> : Life Cycle of Nanoparticles <b>NanoFATE</b> : Nanoparticle Fate Assessment <b>NanoSustain</b> : Development of sustainable based on hazard characterization and management
NMP-2009-1.3-2 <b>Coordination</b>	Exposure scenarios to nanoparticles <b>NANEX</b> : Development of Exposure Scenarios
KBSE-2009-2-4-1 <b>Small RTD projects</b>	Analytical tools for characterisation of nanoparticles <b>NanoLyse</b> : Nanoparticles in food: analytical tools

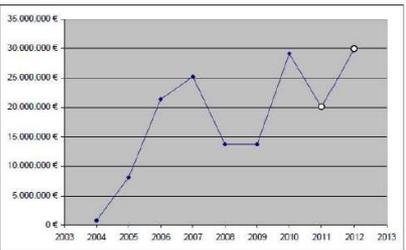
EUROPEAN COMMISSION / Research & Innovation / 7th Framework Programme

**Impact on Health and the Environment**  
**FP7-NMP: Topics addressed in 2010**  
**Projects to be launched in 2011**

NMP-2010-1.3-1 <b>Large RTD projects</b>	Reference methods for managing the risk of engineered nanoparticles <b>MARINA</b> : Managing Risks of Nanoparticles <b>NANOVALID</b> : Development of reference methods for hazard identification, risk assessment and LCA of engineered nanomaterials
NMP-2010-1.3-2 <b>Small RTD projects</b> Coordinated call with USA	Modelling toxicity behaviour of engineered nanoparticles <b>ModNanoTox</b> : Modelling nanoparticle toxicity: principles, methods, novel approaches <b>NanoTransKinetics</b> : Modelling the basis and kinetics of nanoparticle cellular interaction and transport
NMP-2010-4-0-7 <b>Coordination</b>	ERA-NET on nanotechnologies, including nanotoxicology <b>SIINN</b> : Safe Implementation of Innovative Nanoscience and Nanotechnology
INFRA-2010-1.1.31 <b>Infrastructures</b>	Research Infrastructures for processing, analysis and characterisation (physico-chemical properties, health and environmental impact) of engineered nanomaterials, nanoparticles and nanostructures <b>QNano</b> : A pan-European infrastructure for quality in nanomaterials safety testing

## EU RTD investment in nanosafety research

- FP 6:**
- About 30 M (12 projects completed)
- FP 7:**
- FP7, 2007: € 25 M
  - FP7, 2008: € 14 M
  - FP7, 2009: € 14 M
  - FP7, 2010: € 29 M
  - FP7, 2011: € 20 M (estimated)
- FP 7 Total: € 102 M EU funding**



By courtesy of George Katalagarianakis – EC DG Research & Innovation



13-14 December, 2011

Nanotechnology standards use workshop

Disclaimer: Note that this presentation is not legally binding and does not represent any commitment on behalf of the European Commission

*Thank you for your kind attention...*