# European Perspectives on EHS

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# The European Policy in Nanotechnology: integrated, safe and responsible

## The **European Strategy** for nanotechnology, the **Action Plan** and the **first implementation report**

**COM(2004) 338 of 12.5.2004**

**COM(2005) 243 of 7.6.2005**

**COM(2007) 505 of 6.9.2007**

## Policy for ensuring appropriate control of the potential risks of nanotechnologies

- ***Commitment to understanding the potential risks and to managing them with a proportionate regulatory framework***
- ***Existing legislation in diverse areas such as environmental protection, health and safety, and the safety of food, medicines, medical devices cosmetics and consumer products offers protection***
- ***By legislation, manufacturer has to carry out risk assessment to determine whether new new products are safe and can be placed on the market***
- ***Government has the responsibility to ensure adequate methods for identifying hazards and risk evaluations are available***
- ***Risks are managed according to the current state of knowledge, with a precautionary approach taken if there is reason to believe that there might be harm even if the extent of that harm has not been established***

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SEVENTH FRAMEWORK PROGRAMME

**FP5 Projects on safety of nanoparticles**

~2.5M€

**FP6 Projects on safety of nanoparticles**

~25 M€

**FP7 Projects on safety of nanoparticles**

SEVENTH FRAMEWORK PROGRAMME

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# FP5 projects on Safety aspects of Engineered Nanomaterials

**NANO-PATHOLOGY**
**NANODERM**
**NANOSAFE**

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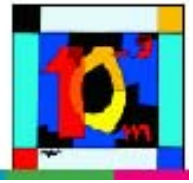
# RUNNING FP6 PROJECTS

- **ON SAFETY OF NANOPARTICLES:**
  - CELLNANOTOX
  - IMPART
  - NANOSH
  - NANOSAFE2
  - NANOCAP
  - DIPNA
  - NANOINTERACT
  - PARTICLE-RISK
  - SAPHIR
- **STANDARDISATION AND METROLOGY:**
  - NANO-STRAND
  - NANOTRANSPORT



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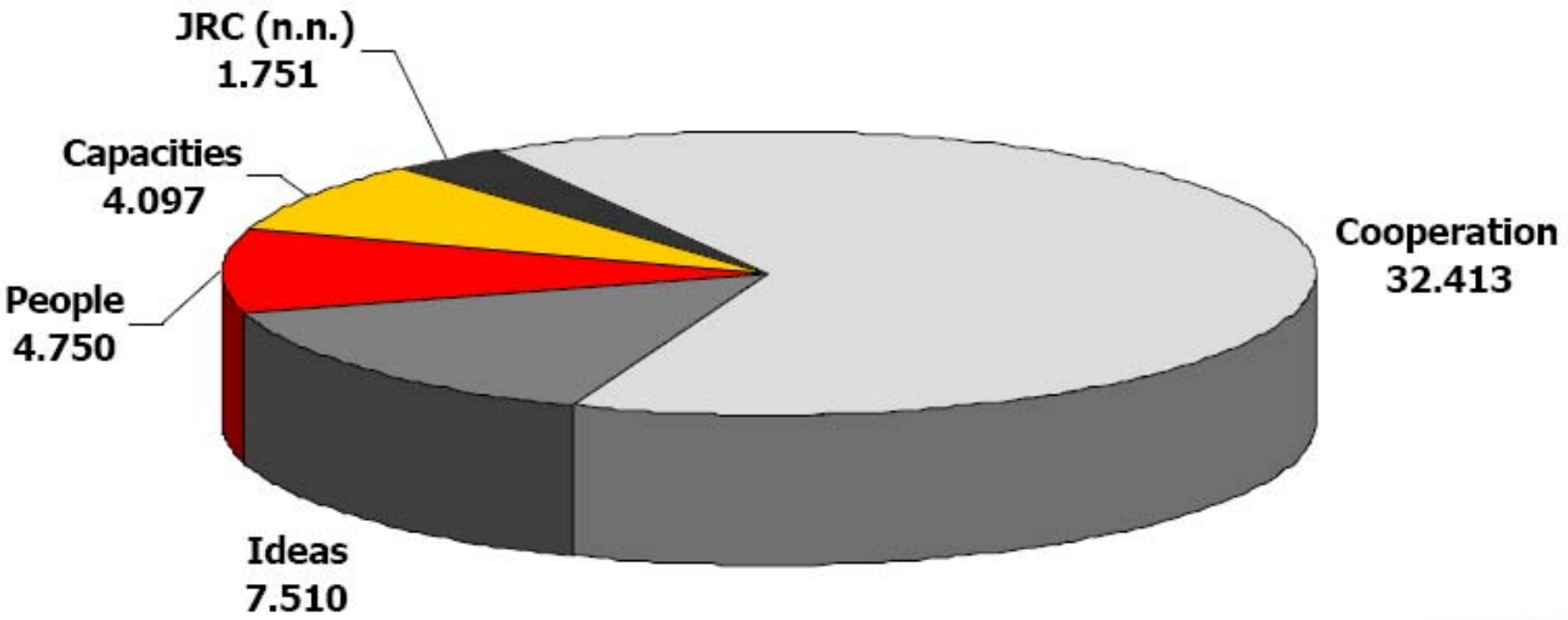
# FP7 budget
## (in billion €, total 50.521)



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# The Cooperation specific programme – 9 themes and budget

| I. Cooperation | Budget (€ million, current prices) |
|---|---|
| 1. Health | 6100 |
| 2. Biotechnology, food and agriculture | 1935 |
| 3. Information and communication technologies | 9050 |
| 4. Nanotechnologies, materials and production | 3475 |
| 5. Energy | 2350 |
| 6. Environment (incl. climate change) | 1890 |
| 7. Transport (incl. aeronautics) | 4160 |
| 8. Socio-economic sciences and the humanities | 623 |
| 9. Security | 1430 |
| 10. Space | 1400 |
| Total | 32 413 |

**R&D activities related to safety can be found under different priorities**

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COOPERATION

# Impact on Health and the Environment calls in WP 2007

| | |
|---|---|
| **NMP-2007-1.3-1**<br>Large CP | **Specific, easy-to-use portable devices for measurement and analysis** |
| **NMP-2007-1.3-2**<br>CP | **Risk assessment of engineered nanoparticles on health and the environment** |
| **NMP-2007-1.3-3**<br>CSA | **Scientific review on the data and studies on the potential impact on health, safety and the environment of engineered nanoparticles** |
| **NMP-2007-1.3-4**<br>CSA | **Creation of a critical and commented database on the health, safety and environmental impact of nanoparticles** |
| **NMP-2007-1.3-5**<br>CSA | **Coordination in studying the environmental, safety and health impact of engineered nanoparticles and nanotechnology based materials and products** |
| **HEALTH-2007-1.3-4**<br>CP | **Alternative testing strategies for the assessment of the toxicological profile of nanoparticles used in medical diagnostics** |

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# Impact on Health and the Environment calls in WP 2008

## Activity 4.1: Nano S&T

### 4.1.3: Health, Safety and Environmental Impacts

- **NMP-2008-1.3-1 Validation, adaptation and/or development of risk assessment methodology for engineered nanoparticles**
- **NMP-2008-1.3-2 Impact of engineered nanoparticles on health and the environment**

# EU Funded Projects

*Cellnanotox*:Cellular interaction and toxicology with engineered nanoparticles – correlation between physicochemical characteristics of NP and their toxic potential on human organs

*Dipna* : Development of an integrated platform for nanotoxicity analysis to verify their possible toxicity and eco-toxicity

*Saphir* : Safe, integrated and controlled production of high tech multifunctional materials and their recycling

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# NanoTEST

## Development of methodology for alternative testing strategies for the assessment of the toxicological profile of nanoparticles used in medical diagnostics

Coordinator **Maria Dusinska, NILU**

Starting date: April 1st, 2008
Length: 42 months

Total budget: 3,934,279 Euro
EC contribution: 2,994,383 Euro

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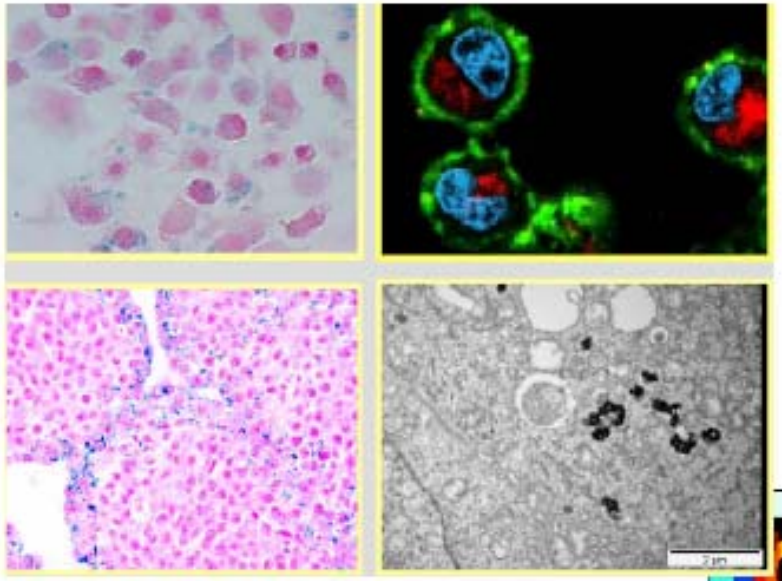
# NanoTEST

SEVENTH FRAMEWORK PROGRAMME

The overall aim is to develop alternative testing strategies and high-throughput toxicity-testing protocols using *in vitro* and *in silico* methods essential for the risk assessment of NP used in medical diagnostics.



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NANO IMPACT NET
SEVENTH FRAMEWORK PROGRAMME

# NanoImpactNet -
# The European Network on the Health and Environmental Impact of Nanomaterials

Coordinator Michael Riediker, Institute for Work and Health, Lausanne

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SEVENTH FRAMEWORK PROGRAMME

# EU nanotechnology R&D in the field of health and environmental impact of nanoparticles

information of 106 projects, 14 of them are from the FPs which give around 32 million € in grants. The others 92 projects are from the EU Members States which spend around 47 million € in grants. This makes a total of some 79 million €.

Available at

ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf

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# Information on Nanotechnology in EC

- **Commission Nanotechnologies homepage**

  http://cordis.europa.eu/nanotechnology/
  http://ec.europa.eu/nanotechnology/index_en.html

- **Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009**:

  http://cordis.europa.eu/nanotechnology/actionplan.htm

- **First Implementation Report 2005-2007:**

  ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/com_2007_0505_f_en.pdf

**Additional information on nanotechnology:**


# Key Priorities

- A fundamental requirement to be able to measure and characterise nanomaterials in a range of media (air, soil, water and in testing nanoparticles for toxicity). This includes having appropriate methods and instrumentation, the ability to differentiate manufactured materials from naturally occurring nanoparticles in the environment and the ability to measure nanomaterials in biological systems.
- A critical need to understand which physico/chemical properties of nanomaterials are important for toxicity/ecotoxicity such as particle size and size distribution, surface area, surface properties, aspect ratio, surface charge etc.

# Key Priorities ( Cont)

- A means of prioritising nanomaterials for EHS studies and identifying a set of 'reference' or representative materials for testing. This requires separate consideration for occupational exposure and exposure from consumer products and via the environment.
- A need to know whether methods used in hazard assessment of chemicals, specifically OECD test guidelines (or their equivalents), are fit for purpose for use with nanomaterials.
- A testing plan for 'reference' or representative materials to establish potential hazards to human health and the environment for a range of nanoparticles through an agreed set of toxicity methods.
- The requirement for a review of current risk assessment approaches and associated methodologies for chemicals with regard to their potential suitability for dealing with nanomaterials.

# Priorities for the development of Measurement Methods

- ***Quantification of dose in toxicological studies***
- ***Quantification and characterisation of engineered nanoparticles against a background of particles of similar size but less aggressive chemistry***
- ***Characterisation of Surface Area and Surface Chemistry***
- ***Compact, rapid, and inexpensive measurement methods that can form the basis for future workplace risk assessment***
- ***Documentary standards describing the above methods, and appropriate reference materials to validate them***

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## Priorities for characterisation of reference/test materials

- Aerodynamic equivalent diameter
- Absolute length
- Specific surface area
- Number of particles per unit mass
- Concentration of bulk and/or surface contaminants
- Polymorphic composition

A further ten characteristics of lower priorities;

Appropriateness and availability of characterisation methods - an issue