FEDERCHIMICA
CONFINDUSTRIA

# The activities of Federchimica on the governance of nanotechnology

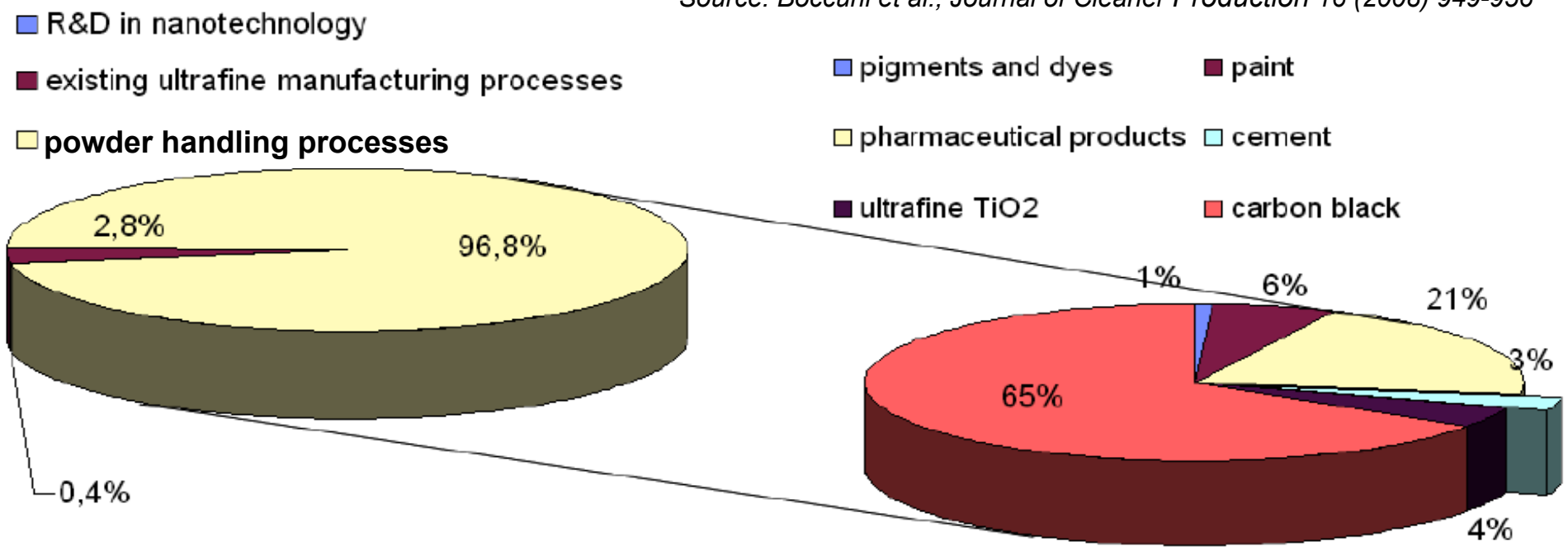
Dania Della Giovanna
Federchimica

Milan, December 2 2010

# Employment in Italy related to "Manufactured Nanomaterials"

**Total: approx 350.000 workers in Italia – 97% "bulk" nanostructured materials**

*Source: Boccuni et al., Journal of Cleaner Production 16 (2008) 949-956*



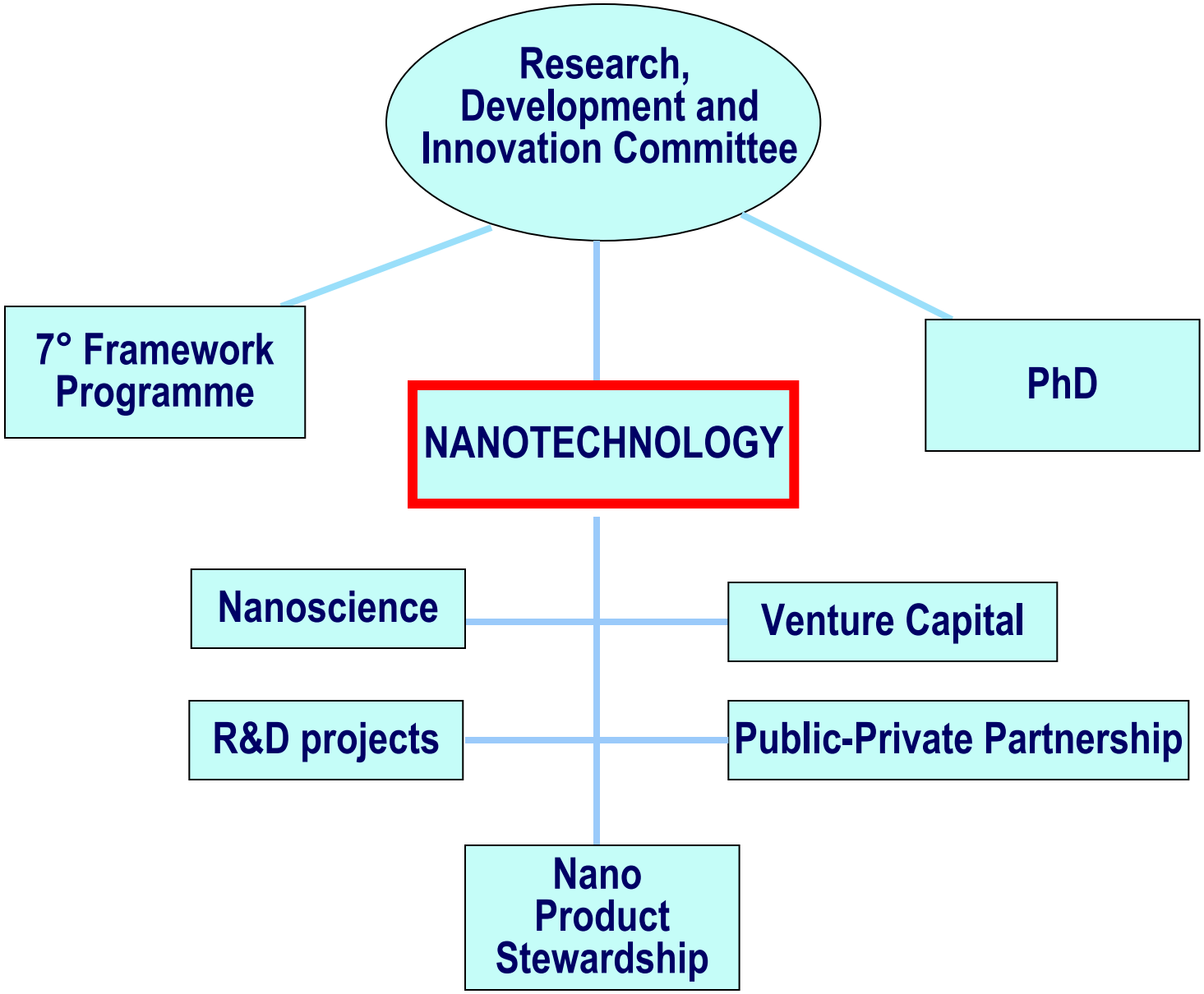

≅ 3 % "Nano-Objects"

- Focus R&D, high potential
- Hazard to be evaluated on a case-by-case base

≅ 97% "Bulk" Nanostructured Materials

- Hazard manageable as for the other chemicals

# Activities of FEDERCHIMICA



# Are nanomaterials already on the market safe?

• Yes

• to identify any associated Hazard, ALL NANOMATERIALS, on a CASE-BY-CASE base, must be examined, AS FOR ANY OTHER CHEMICAL.

• Some High Volume Chemicals (>> 1000 tons/yr) are indeed "Nanostructured Materials":
these are well known and can be tested and monitored in standard way.

• Industry conducts safety research and applies safety measures (risk assessment and risk management) at each step of the production process.

• In addition to implementing chemicals legislation, the chemical industry implements its voluntary initiative Responsible Care©.

## Does existing regulation provide the same level of health and safety protection in relation to nanomaterials, as for "ordinary" chemicals?

• Yes, although to fully address some Nanomaterials more work is needed on implementation tools (e.g. test methods)

• Nanomaterials must follow the same obligation as other chemicals and if, according to the criteria in the CLP regulation, a hazard is identified, this will have to be communicated via a label.
Not all nanomaterials are classified as hazardous.

• Industry must comply with the new EU chemicals legislation REACH.
Under this regime, most nanomaterials will be tested, labelled and registered yet by end 2010.

• Nanomaterials main difference vs "ordinary" Chemicals is that some additional specific chemical-physical data are needed for characterization of Nanomaterials

# Task Force Nano Product Stewardship

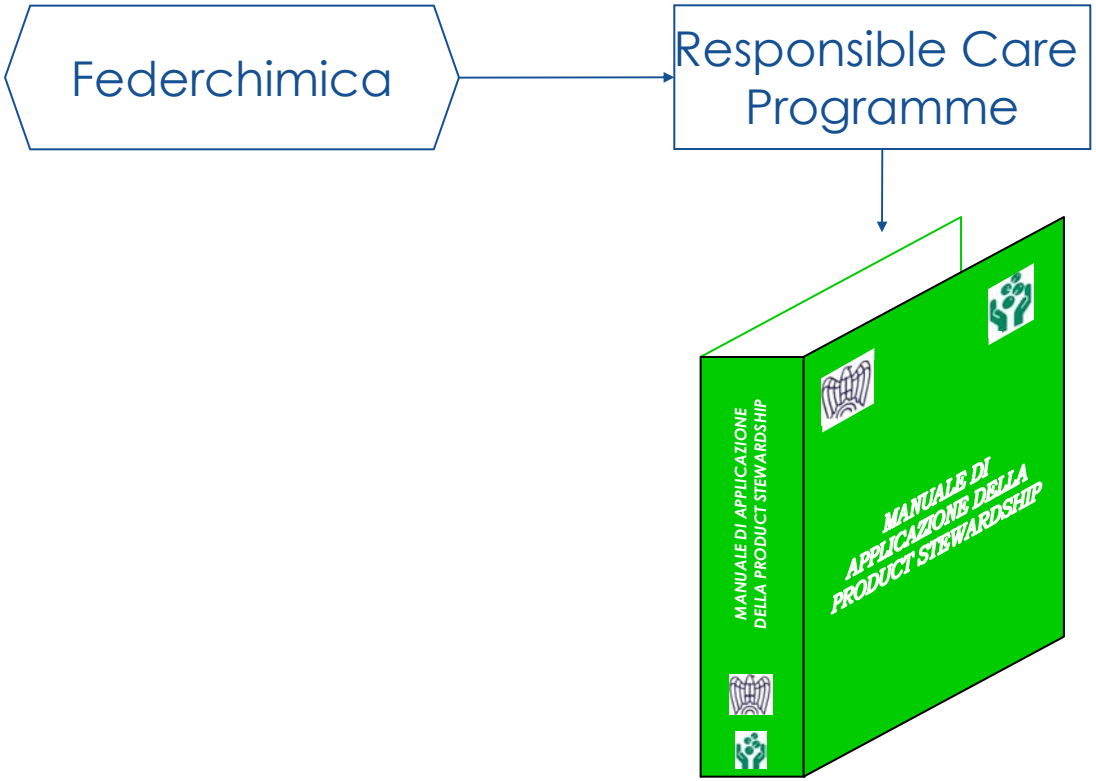
# Activities and objectives

- National level – involvement of:
  - Industrial Associations;
  - Ministry of Economic Development;
  - Ministry of Research;
  - Ministry of Environment;
  - Ministry of Health

- Manual Product Stewardship:
  - Definition guide lines for the responsible management of nanotechnology, from the production to the disposal;
  - Analysis of safety for workers / workplaces;
  - Analysis safety of consumers;
  - Risks/Benefits of nanomaterials.

# Action plan – Manual for the responsible management of nanomaterials

- Evaluation of existing documents:
  - VCI "Responsible Production and Use of Nanomaterials"
  - Cefic "Cefic activities on Nanomaterials"
  - CE "Code of Conduct"
  - CIA "Issue Statement"



# “Nanomaterial” definition

# Nanomaterial definition

*Problem*: lack of a nanomaterial definition useful for a legislative context

Cefic works with National Associations and with Companies in order to agree on a common definition (Colorobbia Italia in Cefic NanoManagement Team)

Participation in the EC consultation for a nanomaterial definition

# Commission Definition

At least one of three indipendent criteria

- 1% number of nano- objects
- Internal structure at the nanoscale (?!?)
- VSSA ≥ 60m² / cm³

# Nanomaterial definition

*Problem*: lack of a nanomaterial definition useful for a legislative context

Cefic works with National Associations and with Companies in order to agree on a common definition (Colorobbia Italia in Cefic NanoManagement Team)

Participation in the EC consultation for a nanomaterial definition

- **Solid, particulate substances**
- **Intentionally manufactured at the nano-scale**
- **Consisting of nano-objects with at least one dimension between 1 and 100nm on the basis of ISO**
- **And their aggregates and agglomerates**
- **With a cut-off of either**

**– 10 wt.-% or more of nano-objects as defined by ISO**

**or**

**– 50 wt % or more of aggregates / agglomerates consisting of nano-objects.**

# Collaboration with Sector Associations

# Work in progress on legislative dossiers

- 1223/2009 Regulation "Cosmetic products"

- Directive 2002/95/CE Revision "Restriction of certain hazardous substances in electrical and electronic equipment"

- Revision of Regulation 258/97/CE "Novel Food"

- Revision of Directive 2002/72 "Plastics Implementation Measures"

- REACH Regulation

# Task Force Nanoscience

# Toxicology and ecotoxicology of nanostructured TiO2

Involved partners:

-Colorobbia

-Centro Reach

-Bracco

-ARPA Bologna

-Federchimica

## Normative needs

- It doesn't exist a specific regulation for nanostructured substances
- Safety and human and environmental protection - linked to production, manipulation, use and disposal of nanomaterials – are ensured by existing legislation
- Voluntary measures have been adopted in some EU and non-EU countries
- REACH Regulation requires that the dispositions are applied to all the substances, irrespective of size, shape and use

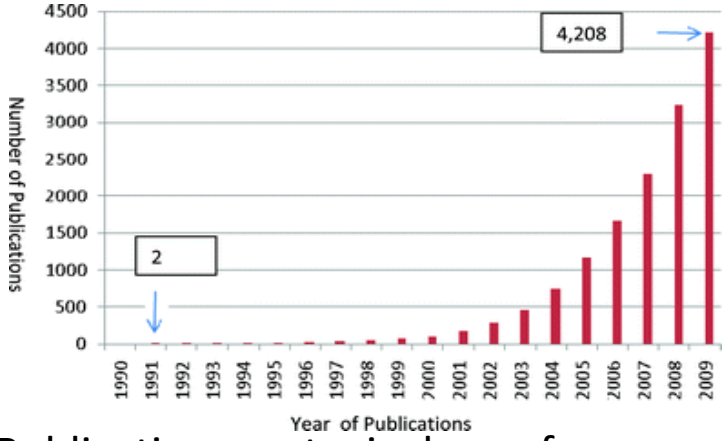
# Scientific needs

- Despite the increase of studies on nanostructured substances, there is no agreement on the hazardousness, risks/benefits ratio, quality and quantity of tests to be conducted (for toxicology and ecotoxicology)
  - E.g. Need for examining not only the nano form, but also the bulk form (> 100 nm) and aggregates
  - In ecotoxicity not use only the analysis applied for regulatory purposes
- The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (2009) declares:
  - "Experts are of the unanimous opinion that the adverse effects of nano-particles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics."

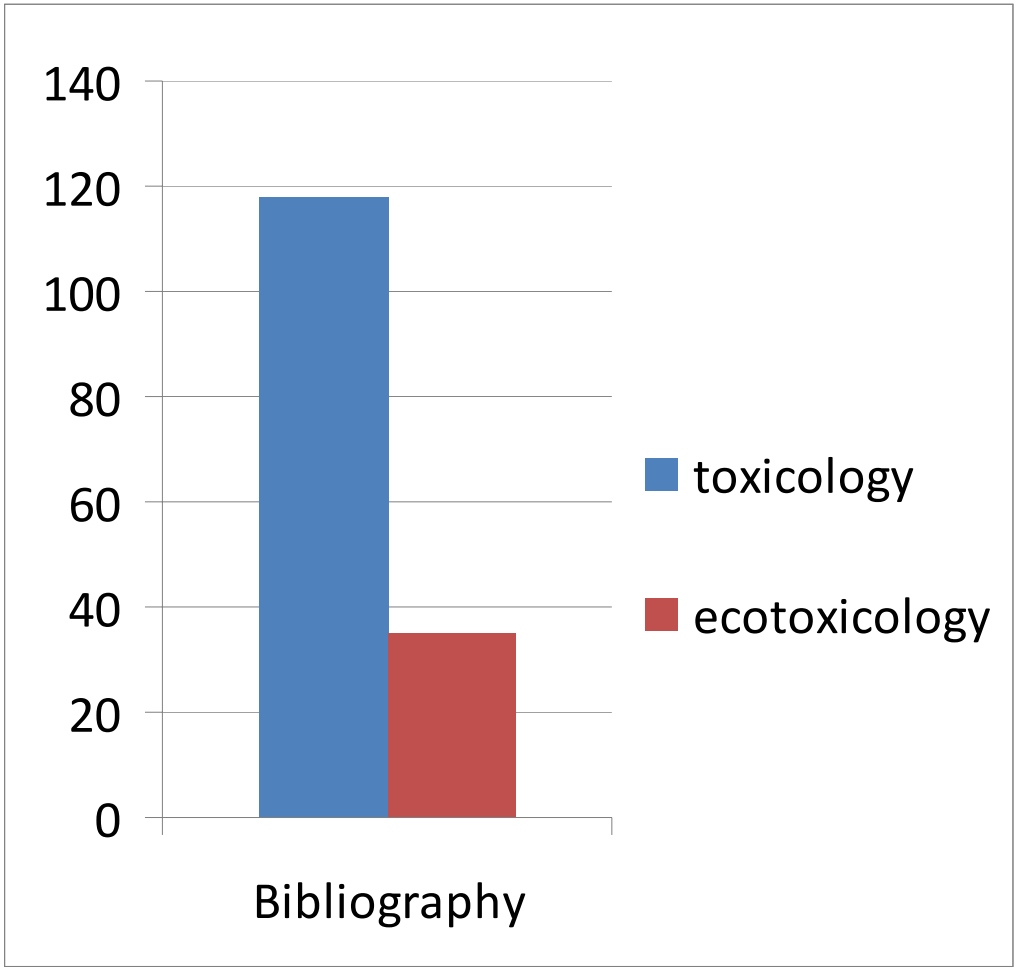
# Objectives

- Examine the literature on toxicology and ecotoxicology of nanostructured $TiO_2$
- Assess the quantity of information which is considered useful and necessary to satisfy the requirements for the registration of a substance under REACH

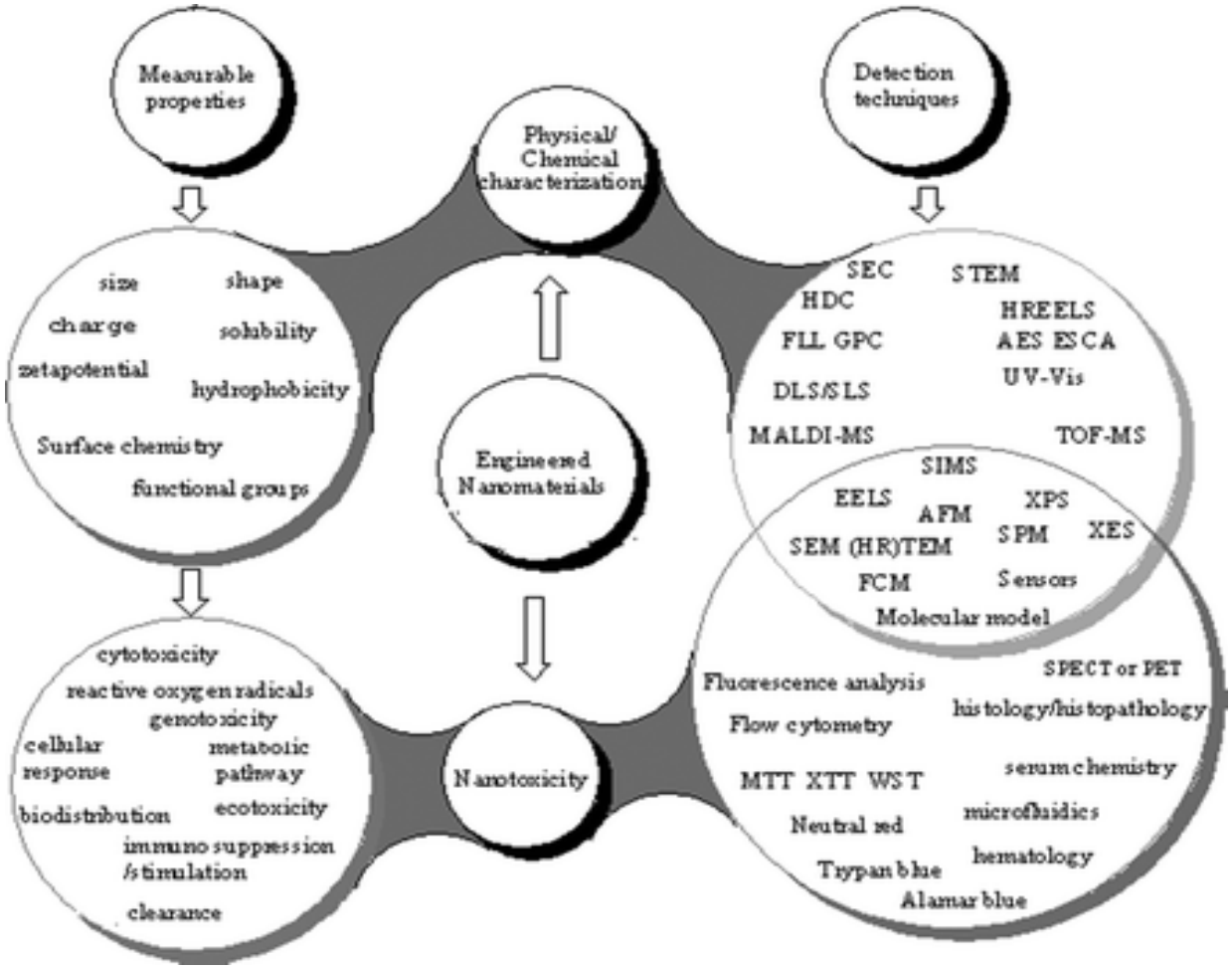
# Available Information




Publications on toxicology of nanomaterials on indexed reviews (J. Environ. Monit., 2009, 11, 1782–1800)



# Instruments and approaches for the study of nanomaterials




J. Environ. Monit., 2009, 11, 1782–1800

# Focus on ecotoxicology

More gaps in information

More complex approach

- Several species
- Several matrixes
- Difficulties in applying principles and techniques normally used for substances not in nano form
  - Different dispersion and bioavailability
  - Possibility of an adaptive response due to the long exposure to nanomaterials already present in the environment

# Conclusions

- The definition of toxicological and ecotoxicological properties of nanomaterials is very complex
- Several data – resulting from specific studies, through validate methodologies - have been published in the last years
- Some of these data are already suitable for the filling in the REACH dossier; other endpoints still need more studies
- Nevertheless nanomaterials require to adapt tests and protocols to obtain more specific characterisations and to identify new texicological properties
- …..overall it is needed a better integration of different professional profiles (physicians, nanomaterials engineers, chemists, toxicologists) in order to reach a shared and coherent definition of risks / benefits of nanomaterials