Research in Support of Consumer Protection Legislation

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http://www.jrc.ec.europa.eu

Research-Based Policy Support

JRC - Robust Science for Policy Making

As a Directorate-General of the European Commission, the JRC provides customer-driven scientific and technical support to Community policy making

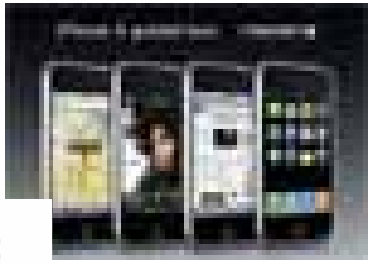
Supporting citizen's security, health and environmental protection, safety of food and chemicals, alternative energies, nuclear safety, econometrics, prospective technologies…

Consumer Products

Industrial Sectors

- *Automotive*
- *Chemical Industry*
- *Construction*
- *Cosmetics*
- *Electronics*
- *Energy*
- *Environment*
- *Food*
- *Nanomedicine*
- *Photonics*
- *Textiles*
- *……*






EU Regulation – Nanotechnology Relevance

Horizontal Legislation	Product Legislation
1. Chemicals Legislation (REACH)	• General Safety of Consumer Products
Control – Major-accidents, Seveso II Directive – Water – Waste	• Cosmetic Products • Aerosol Dispensers • Medicinal Products • Cars • Food Legislation

Safety aspects regarding nanotechnologies are in principle covered.

Need for modification?

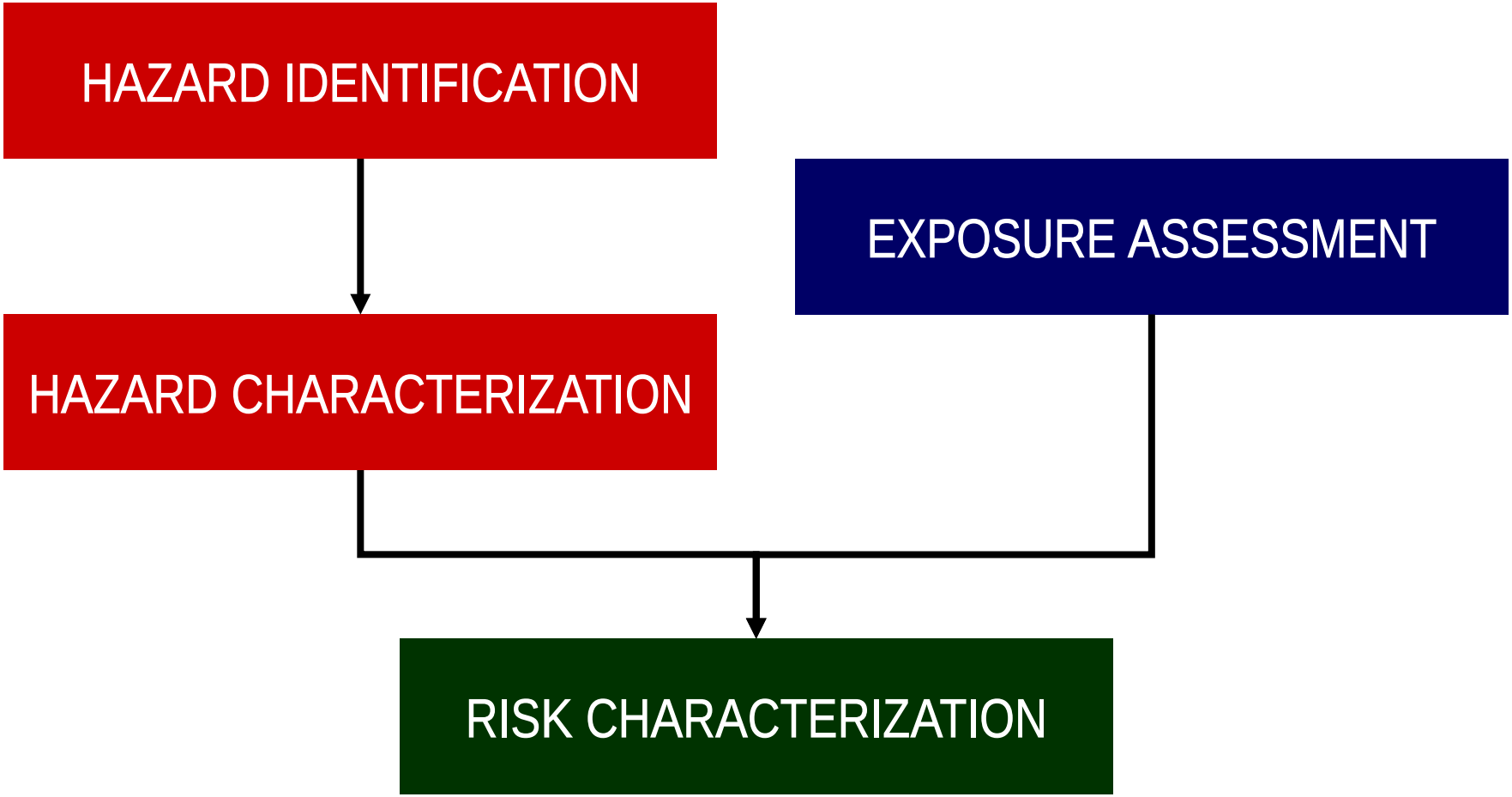
Position of the European Parliament

RESEARCH NEEDS

- *Safety/Risk Assessment*
- *Detection, Quantification and Characterization of Nanomaterials in Complex Matrices*

  – Environment/Health/Safety (EHS) data
  – Labelling of products containing nanomaterials
  – Inventory on types and use of nanomaterials one the EU market

Safety/Risk Assessment



Exposure

Potential

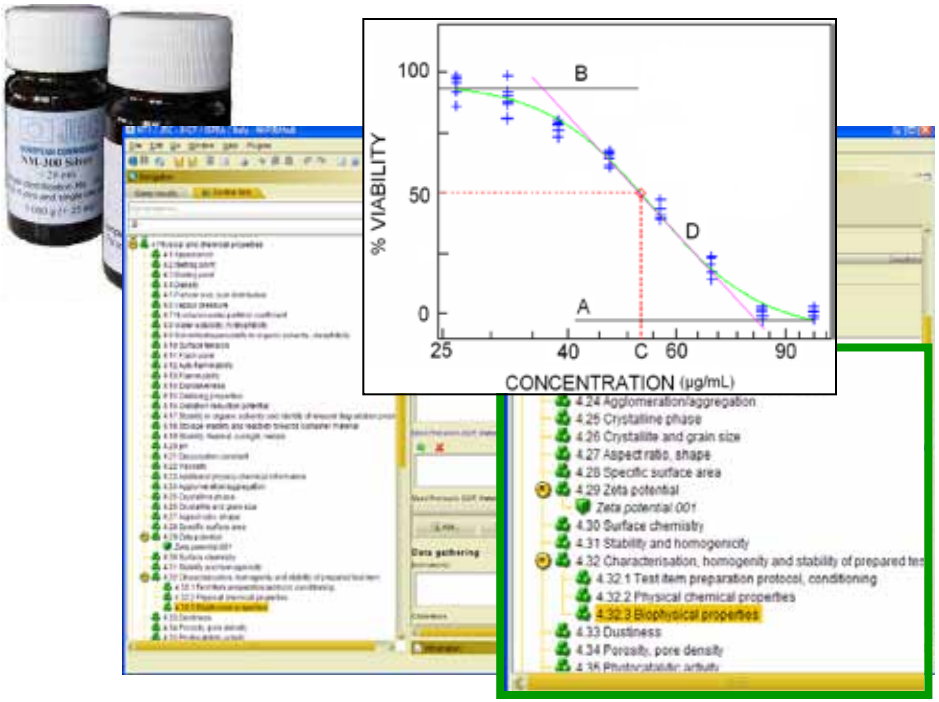
- Liquid, powder or solid?
- Content/concentration?
- Frequency and duration of use?
- Application, e.g.
  - Spraying; e.g. sunscreen
  - Dermal applications, e.g. cosmetics
  - Articles/solid products, exposure due to wear and tear,
  - Accidents?
- Release
- ……

Estimation

- Measurement
  - Metric (mass-, surface-, number-, or?)
  - Size distribution
  - Costs vs. quality of information
  - Background & artefact(s)
  - ….
- Modelling
  - Mainly based on mass-metric
  - not validated for NMs
  - do underlying algorithms take account of nano-specific properties?

Hazard Assessment

- *Assessment Methodology*
  - Definition of Nanomaterial
  - Information requirements
  - Test methods and test strategies
  - Guidelines for safety and risk assessment
- *Tools*
  - Reference nanomaterials
  - Standards and harmonized methods
  - Protocols for testing
  - Databases
- *Data*
  - Relevant for regulation
  - Harmonized data templates
  - Data storage and availability



Test Methods and Test Strategies

NANOMATERIALS

- Size and shape
- Dispersion state
- Physical and chemical properties
- Surface and Porosity
- Surface Chemistry

In vivo

Biol. Response, Pathogenesis

In vitro

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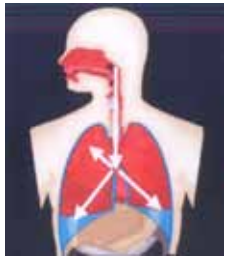
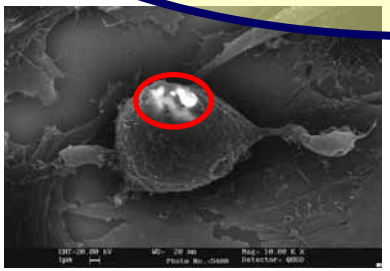
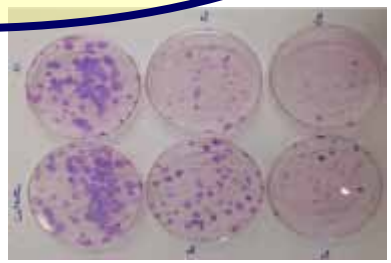
Tissue and Cell Response



vivo





Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

There are no provisions in REACH referring specially to nanomaterials, but

REACH addresses chemical **substances**, in whatever size, shape or physical state.*

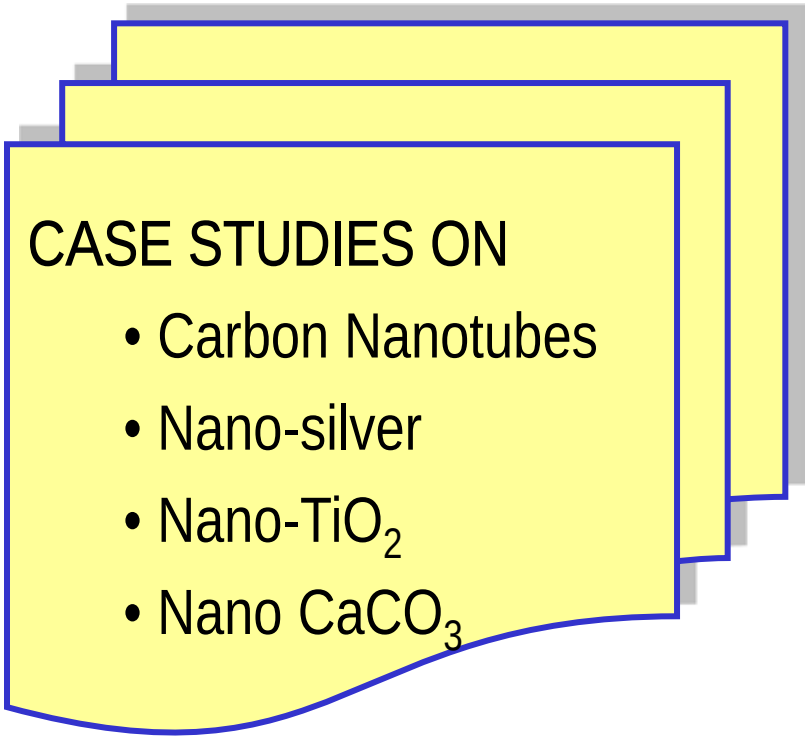
Ø Substances at the nanoscale are covered by REACH and its provisions apply.

ECHA European Chemicals Agency

* Nanomaterials in REACH (CA/59/2008 rev.1)

REACH Implementation Projects on Nano

- Substance Identification of nanomaterials
  - Identification parameters – how to produce information?
- Information Requirements
  - What is needed? (physicochemical properties, toxicity, environmental fate, ecotoxicity)
  - How to generate?
- Chemical Safety Assessment
  - Dose response characterization
  - Exposure scenarios and estimation
  - Metrics



Detection, Quantification and Characterization of Nanomaterials in Complex Matrices

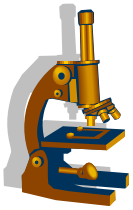
Labelling obligation for ingredients present in the form of nanomaterials,

in the list of ingredients the names of such substances shall be followed by the word 'nano' in brackets:

Titanium Dioxide (nano)

- Ø No hazard labelling
- Ø only for information
- Ø will allow consumers to make a choice

Nanomaterials in Complex Matrices



Detect

- Imaging (SEM, TEM, AFM, …)

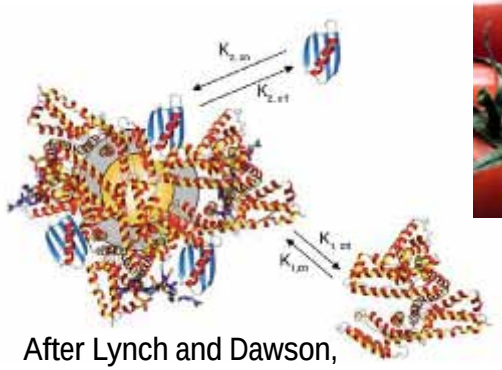
Quantify

- Extraction from matrix
- Separation/fractionation (filtration, centrifugation, chromatography, Field Flow Fractionation,…)
- Elemental analysis (e.g. ICP-MS)

Characterize

- Size
- State of dispersion
- Physico-chemical properties
- Surface properties

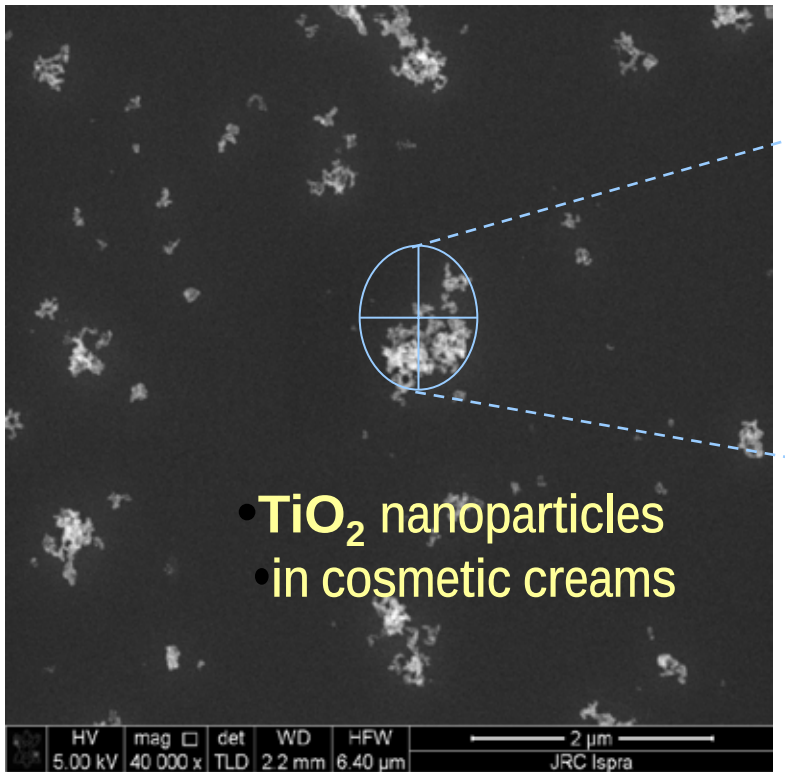
Matrix dependent

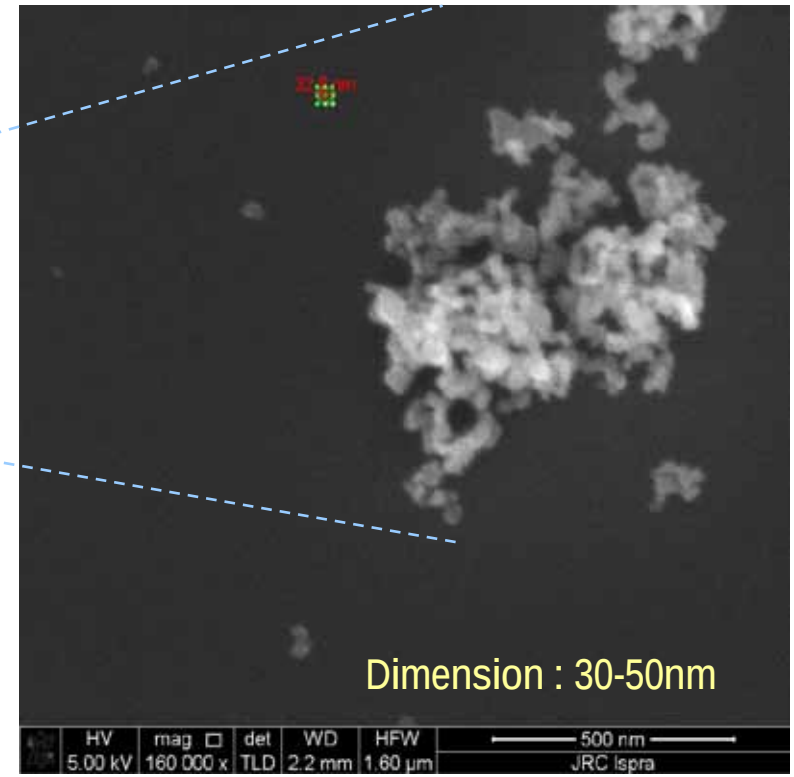


After Lynch and Dawson, Nanotoday 2008, (3) 1-2ß

Nanoparticles in Matrices

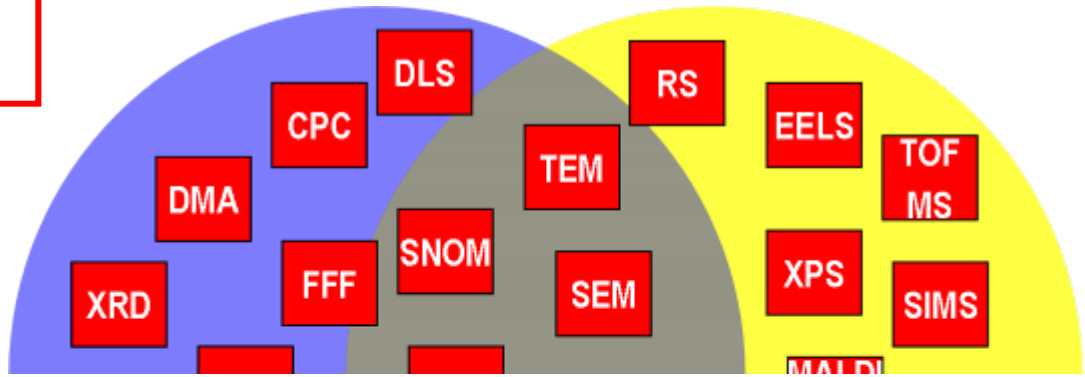
- Sunscreen has been deposited on silicon wafer through Spin-coating
- Samples treated with plasma (Ar:O_2 6 mins) to eliminate organic compounds





Characterization and Detection Techniques

A number of tools –
no best techniques



- All techniques have advantages and drawbacks
- A combination of techniques is needed
- Combination of separation/analysis is particularly promising
- Difficult to make robust analysis without Electron Microscopy
- Most non-imaging methods assume particles with known shape (spherical)

IF TRUE PARTICLE SIZE IS CRITICAL TO YOUR RESEARCH/PRODUCT
DO NOT UNDERESTIMATE THE DIFFICULTIES OF SIZE MEASUREMENT

Standardization Activities

CEN TC 352 Nanotechnology

ISO TC 229 Nanotechnology

ISO VAMAS cen

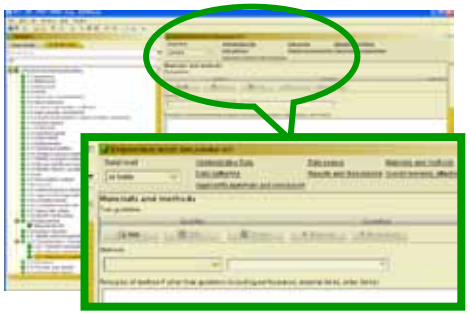
OECD Working Party on Manufactured Nanomaterials

- Safety Testing of a Representative Set of Manufactured Nanomaterials
- Manufactured Nanomaterials and Testguidelines
- The Role of Alternative Methods in Nanotoxicology

OECD

Reference Nanomaterials

IT Platforms and Databases



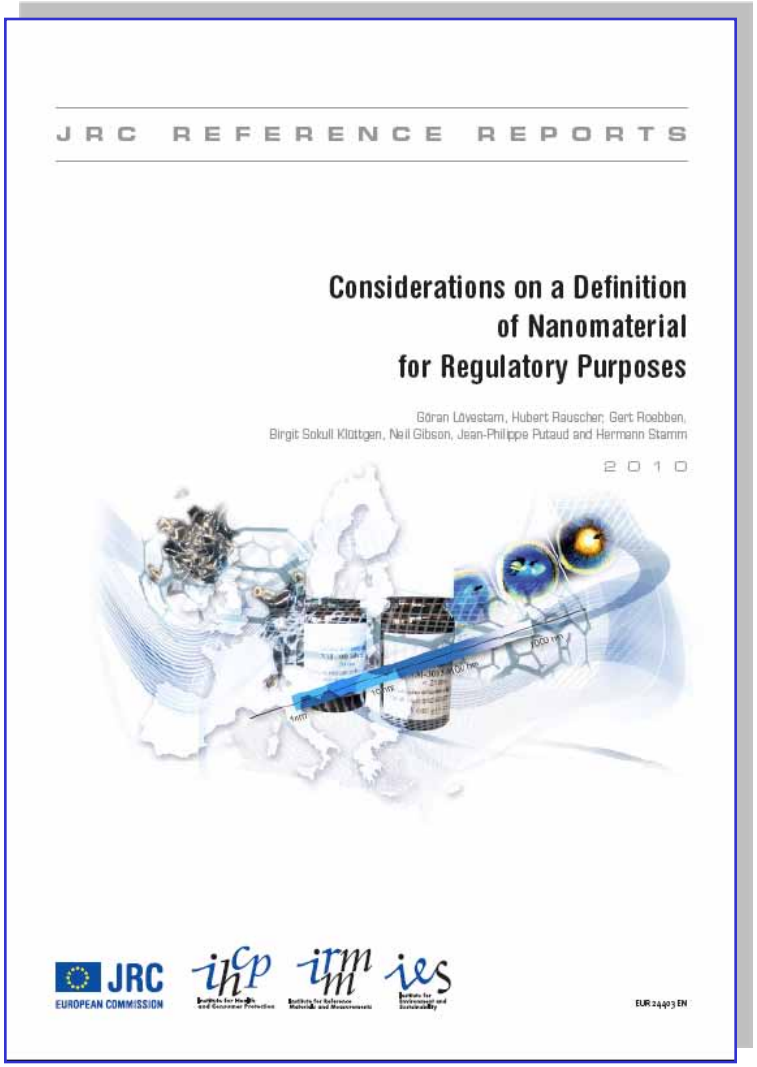
Definition of Nanomaterial for Regulatory Purposes

Requirements

- A single definition broadly applicable in EU legislation and policies
- Legally clear and unambiguous, i.e. enforceable

Questions concerning the key elements of a definition

- What is the nanoscale and which size range should it encompass?
- Should other properties which are the consequence of the material being at the nanoscale be included?



OUTLOOK

- Nanomaterials to be assessed following the provisions of current legislation
- Implementation for nanomaterials difficult:
  - Knowledge gaps
  - Current methodology incomplete
- Need for appropriate test methods and new data
- Harmonized test methods and standards required
- Next generation nanomaterials in consumer products
- International cooperation necessary

Nanobiosciences

Thank you for your attention