

NANOTECHNOLOGY AND HEALTH: CHALLENGES FOR RESEARCH IN SUPPORT OF EUROPEAN UNION POLICIES



Hermann Stamm

*Institute for Health and Consumer Protection
Joint Research Centre, Ispra*



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

'Nano' Everywhere - Benefits and Promises

- Scratch resistant painting
- New drug delivery systems
- Intelligent clothing
- Fabrics to resist stains
- Thermochromic glass
- Light bicycle frames
- Fuel cells
- Electronic devices



**What is the issue?
Why is support needed?
What are the needs?**

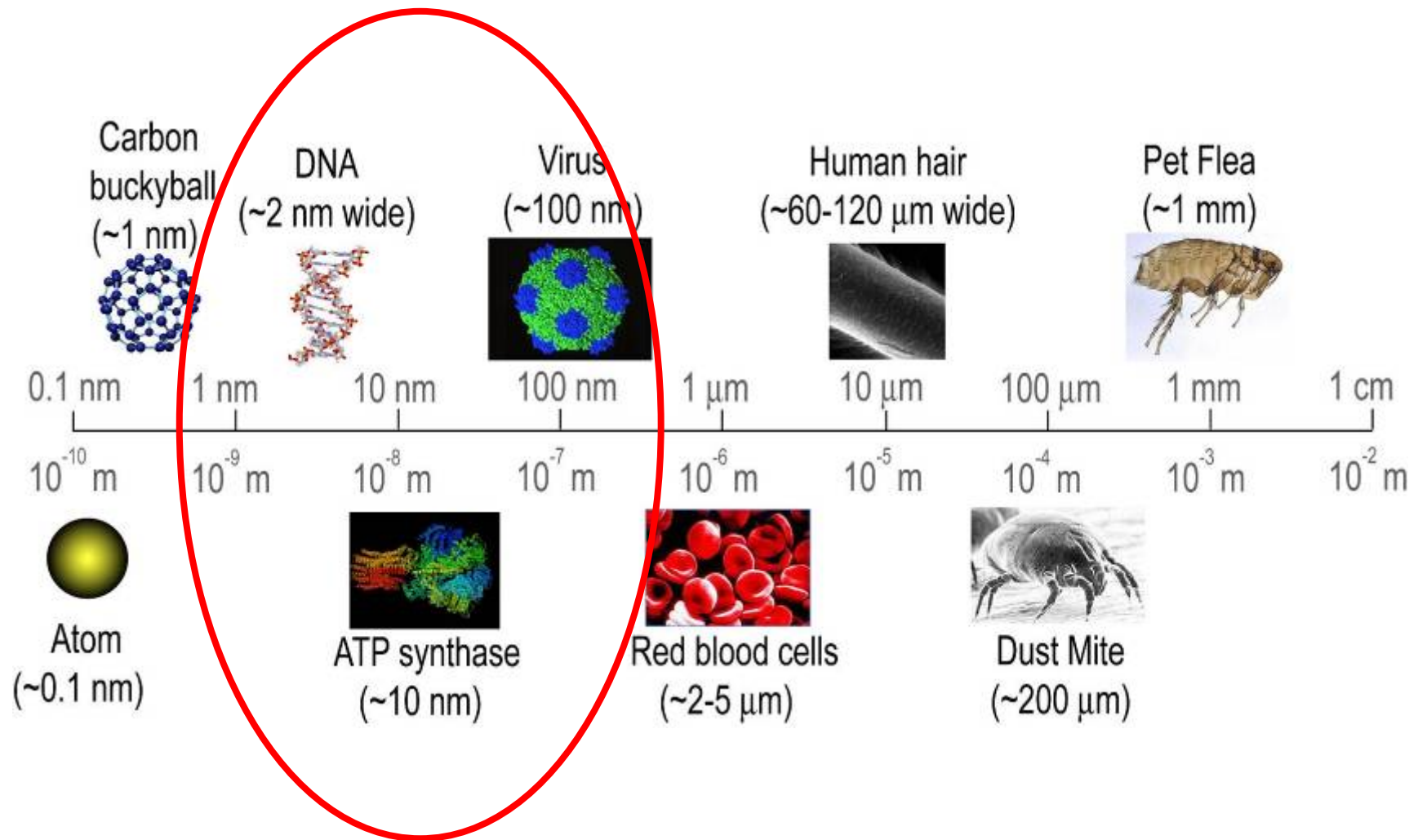
The role of the Joint Research Centre

What is 'nano'



$1 \text{ nm} =$
 $0,000000001 \text{ m} =$
 10^{-9} m

NANOSCALE



What is NANOTECHNOLOGY

- Typical size scale: ca. 1 nm – about 100 nm
- Create and exploit *size-dependent* properties and *new functions* of matter at the nanoscale
- Manufacture new devices by *manipulating* material at the nanoscale

Under discussion!!

Not accidental!!

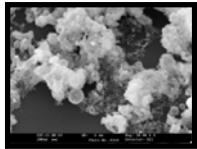
Benefits

- Improved Health
- Smarter Electronics
- Advanced agriculture
- Cleaner sources of energy
- Environmental remediation
- Enhanced security
-

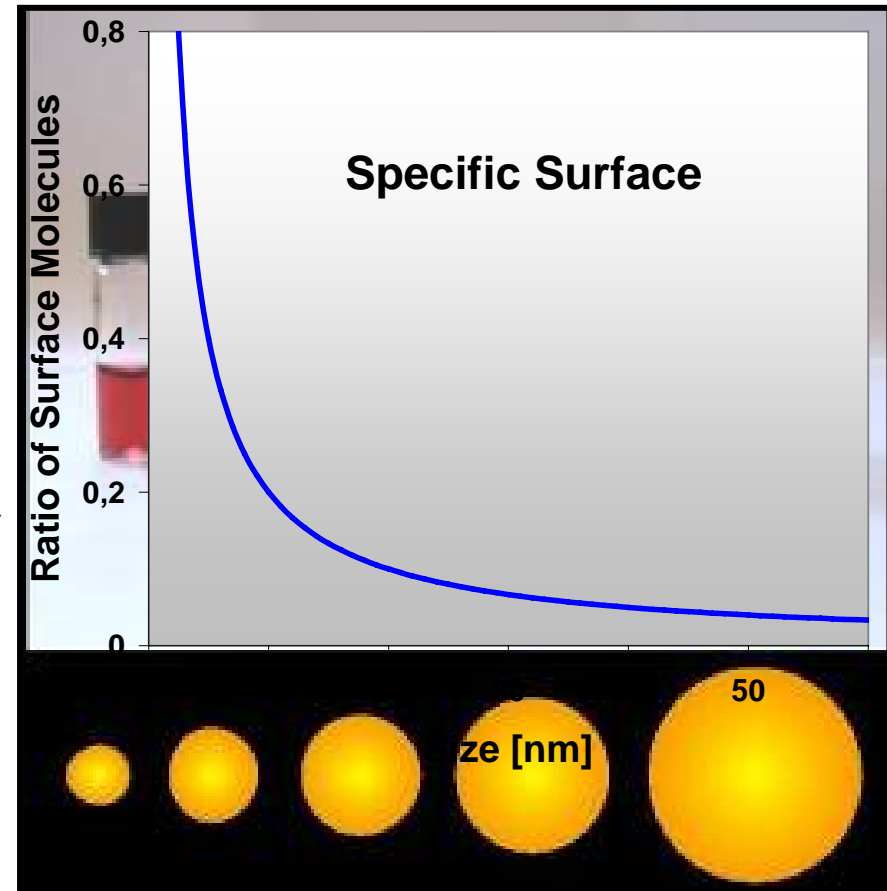
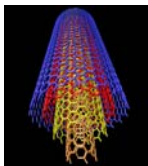
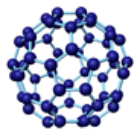
Risks

- Nanoparticles may translocate to organs and cause toxic effects
- Environmental impact of nanoparticles unknown
-
- Threats to privacy – covert surveillance
- Exacerbation of social inequality
-

Manufactured Nanoparticles – what is the difference?



- Quantum effects lead to special mechanical, electronic, optical and magnetic properties
- Chemical reactivity very different compared to bulk material
- Large specific surface
- New chemical forms: fullerenes, nanotubes



NT Consumer Products on the Market



TiO₂ Automotive Sunscreen



Samsung® Washing Machine



DNA Skin Optimizer



Antibacterial Kitchenware
Nano Care Technology, Ltd.



Lexon Nano-Silver Sock



Ultima® Photo Paper
Eastman Kodak® Company

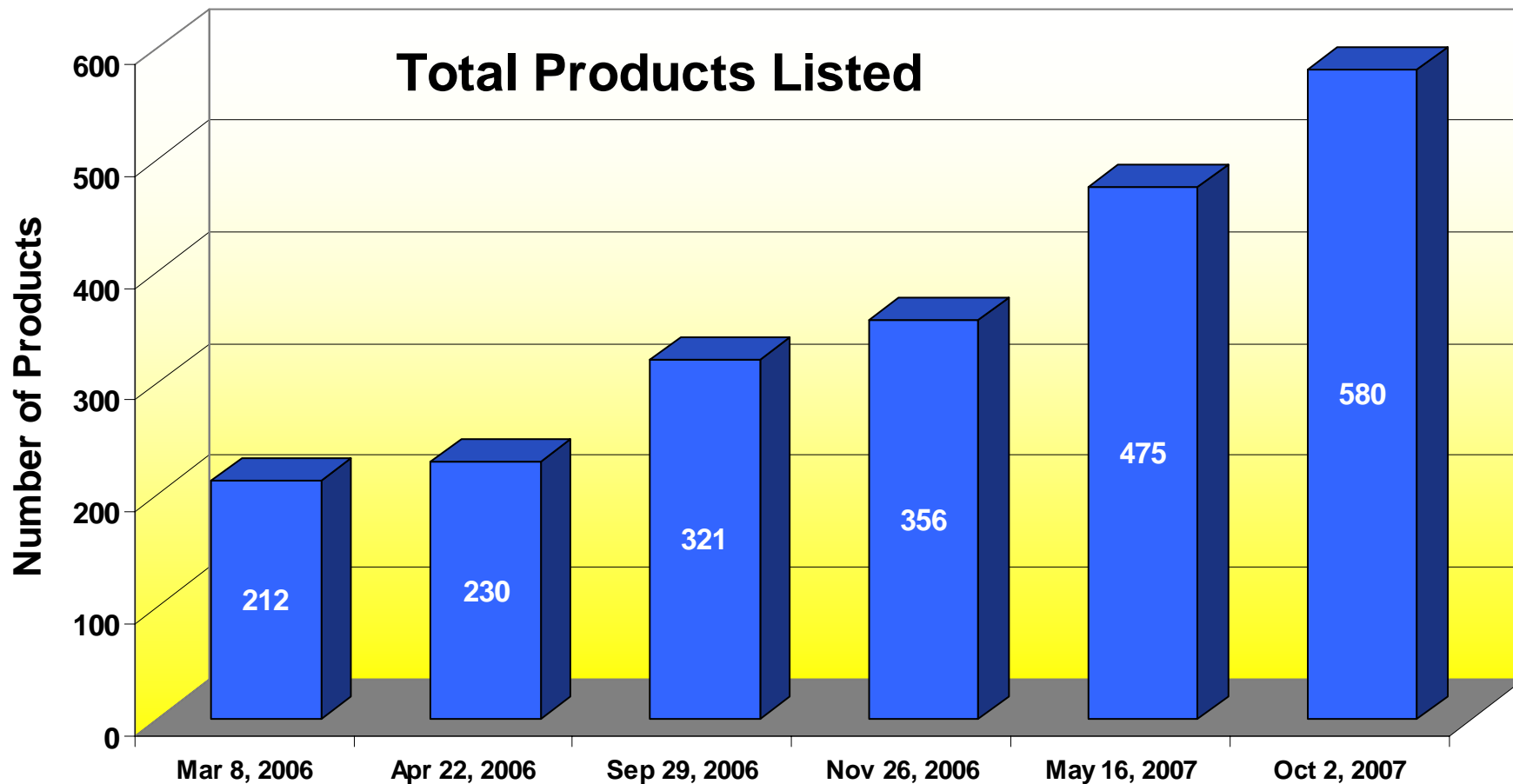


Babolat® NS™
Tour Tennis Racket



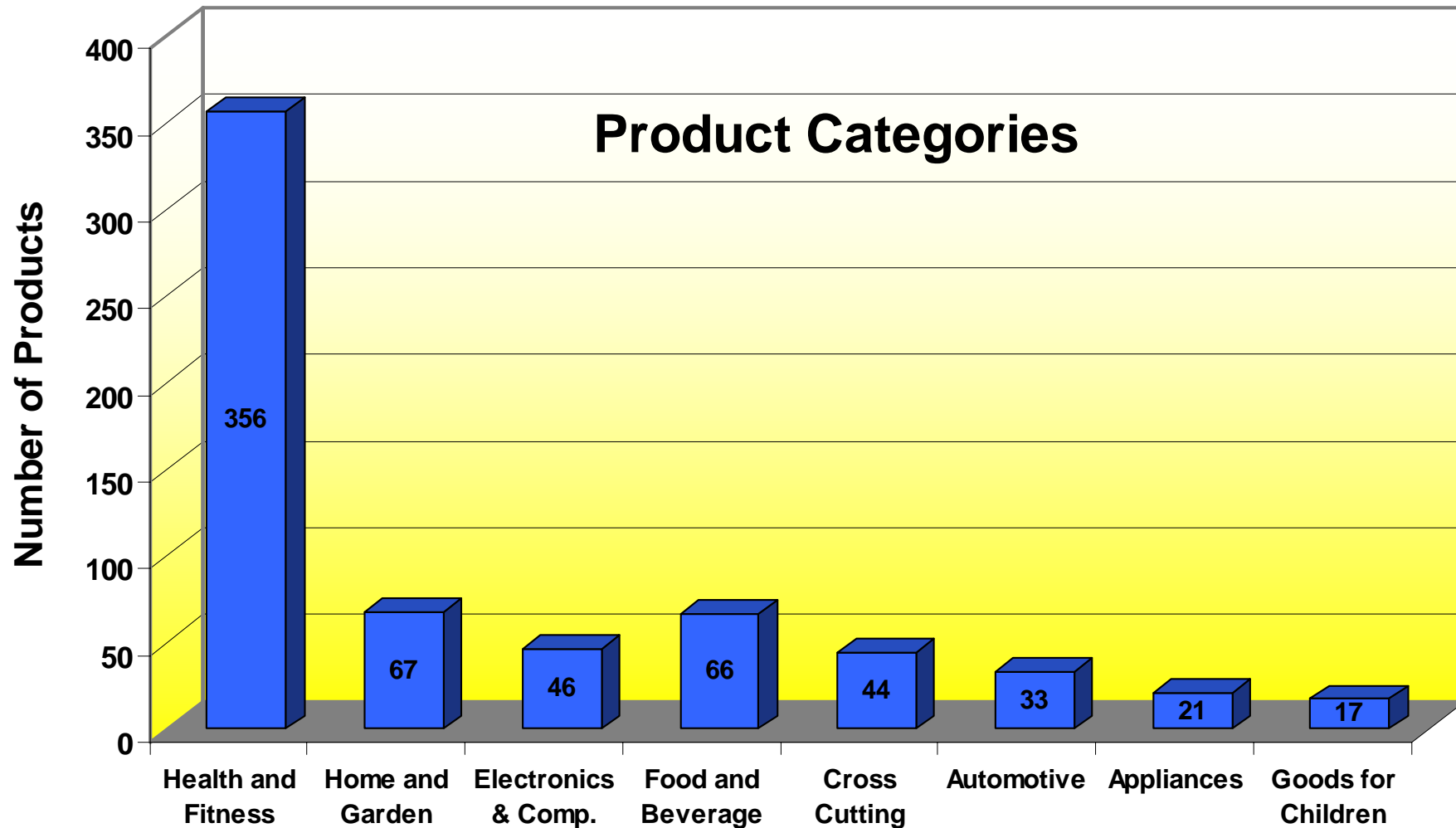
Donny the Dog Plush Toy

NT Consumer Products on the Market



Source: Woodrow Wilson Databank <http://www.nanotechproject.org/>

NT Consumer Products on the Market



Source: Woodrow Wilson Databank <http://www.nanotechproject.org/>

RISK: Toxicity of Nanomaterials

- Studies with ultrafine particles from *combustion processes* exhibit different biokinetics and effects
- Epidemiological studies demonstrate the *relation* between *air pollution* and *cardiovascular diseases*
- Experiences with *fibre toxicology* (asbestos, silicates...)



CHALLENGES FOR POLICY

Nanotechnology – Challenges for Policy

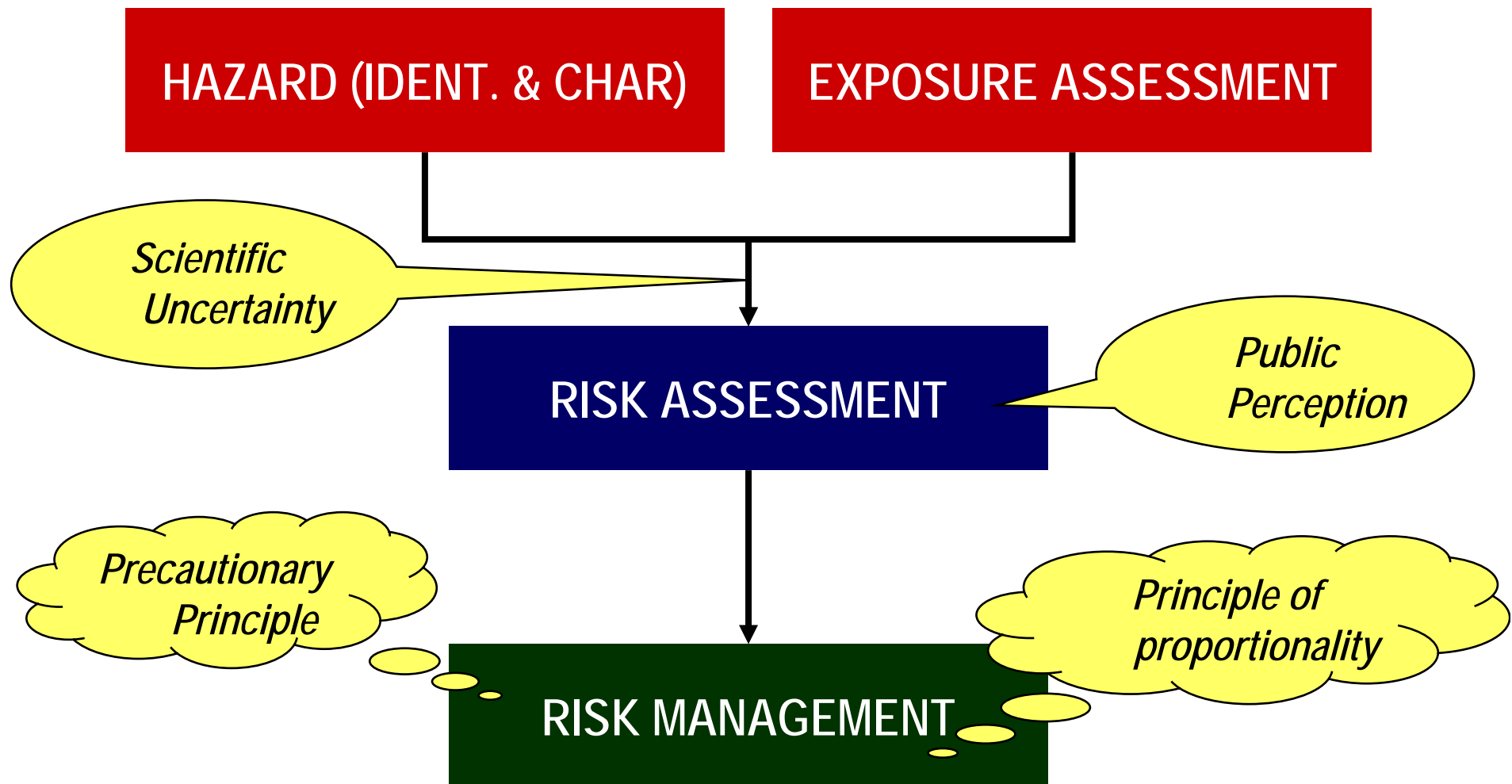
- High *expectations* on contribution to economic growth, jobs, social welfare and sustainable development
- Nanotechnology *pervades* many different traditional scientific disciplines and technological fields
- *Implications* of the use of nanotechnology are very *diverse* and depend on application areas
- ~~'nanotechnology market'~~ ➔ 'nanotechnology value chain'

Nanotechnology – Challenges for Policy

- *Uncertainties* about health and environmental impacts
- Different societal *perceptions* and *ethical concerns*
 - exaltation ↔ moratorium
 - real risks ↔ perceptual risks
- Little *trust* in industrial risk managers and public regulators



How does legislation deal with risks?



Key Elements of the EU Regulatory Framework

Horizontal Legislation	Product Legislation
<p>1. Legislation covering all type of industrial activities:</p> <ul style="list-style-type: none">-Environment Protection-Workers protection <p>2. Legislation covering chemical substances (REACH regulation)</p> <ul style="list-style-type: none">-General legislation concerning industrial chemical substances	<ul style="list-style-type: none">• General Product Safety• Automotive industry• Electronic industry• Construction• Medicinal products• Medical devices• Cosmetics• Textile• Food and drinks• Household• Sport articles• Materials

Key Elements of the EU Regulatory Framework

- Great *variety of areas*: production control, worker protection, product legislation, environmental protection
- Risk-based, *technology-neutral* approach
- Simultaneous application of *legislation in different areas*
- *Intervention mechanisms* in case of safety issues

Health safety and environmental protection aspects associated with nanotechnologies are in principle covered.

Need for modification?

RESEARCH FOR POLICY SUPPORT

The JRC as a research based policy support organization

Risks of Manufactured Nanomaterials

RISK ASSESSMENT

- Hazard identification
- Hazard characterization
- Exposure assessment

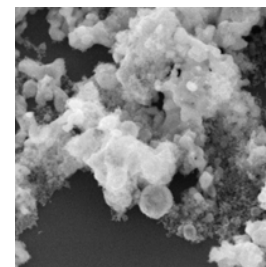
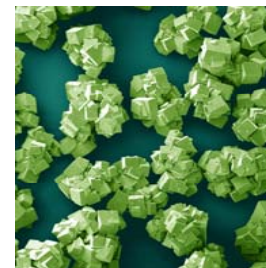
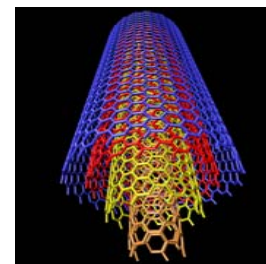
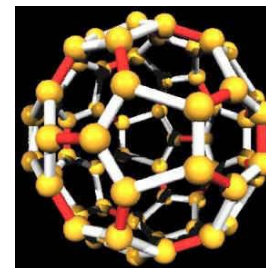
3 fundamental questions

1. How to characterize nanoparticles?
2. What determines their toxicity?
3. Exposure?

Integrated Testing Strategy

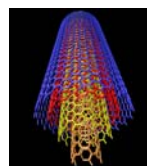
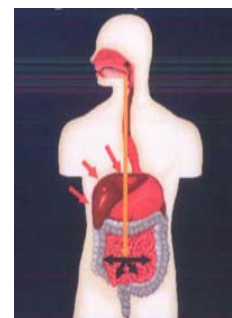
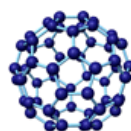
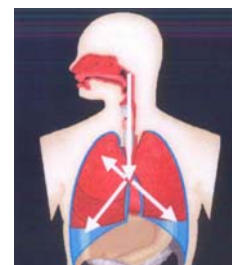
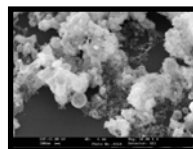
- Physico-chemical characterization
- *In silico* studies
- *In vitro* test systems
- *In vivo* studies

JRC



Understanding the biological response

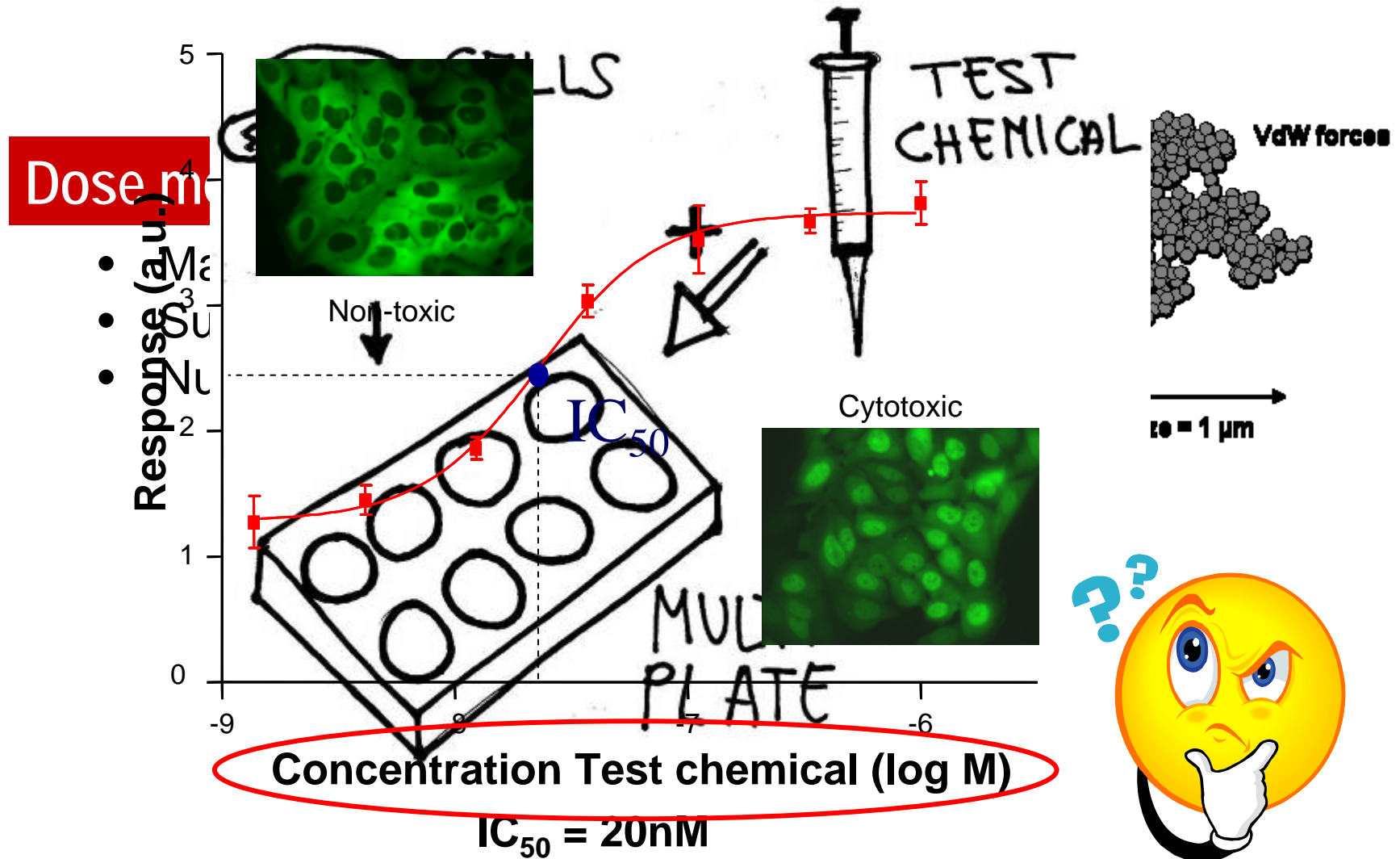
- **Size and Shape**
 - Size distribution
 - Shape
- **State of Dispersion**
 - Agglomeration/Aggregation
- **Physical and Chemical Properties**
 - Crystalline phase and crystallite size
 - Water solubility
 - Electro-optical properties
- **Surface Area and Porosity**
- **Surface Chemistry**
 - Surface composition
 - Catalytic properties
 - Surface charge
 - Reactivity
 - Adsorption/desorption of molecules



EFFECT

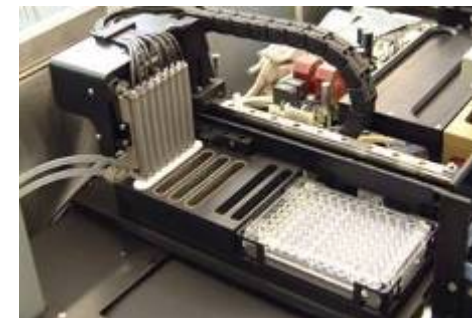
- Translocation from portal of entry to target organs
- Protein binding properties
- Cellular uptake
- Accumulation and retention

Dose-Effect Relationship In vitro Tests

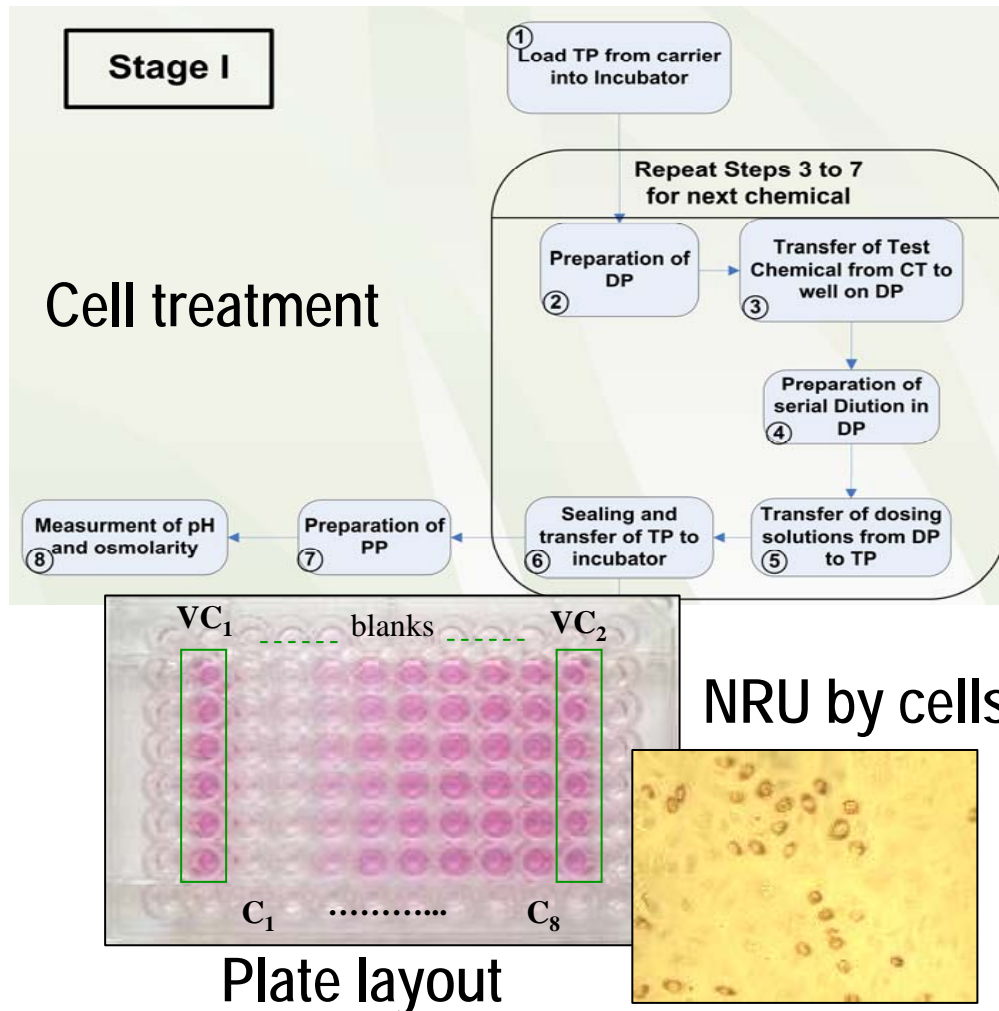


In vitro Testing Technologies and Assay Automation

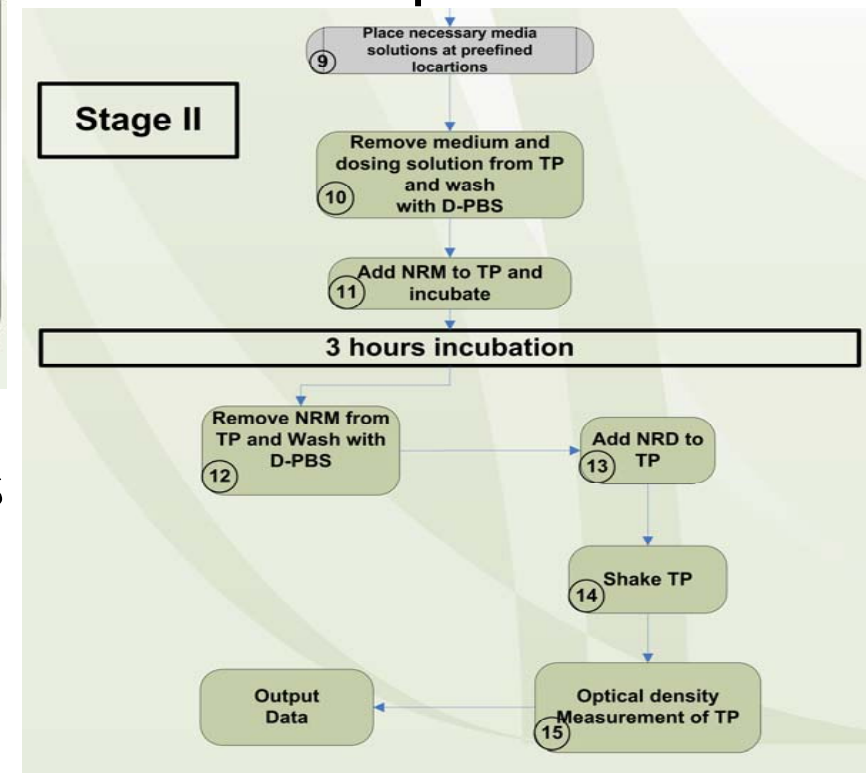
- Automation is necessary for assay standardization and production of *high quality data*
- *High-throughput protocols* for screening
- Use the test platform for the rigorous and *systematic assessment* of novel in vitro tests.
- Important role for test method *validation*



Process Automation of in vitro tests

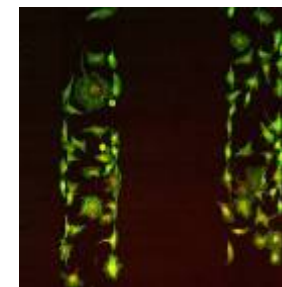
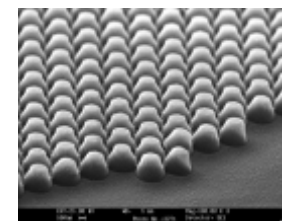
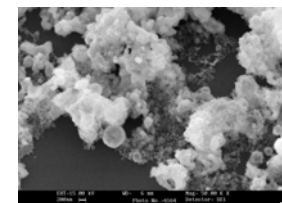
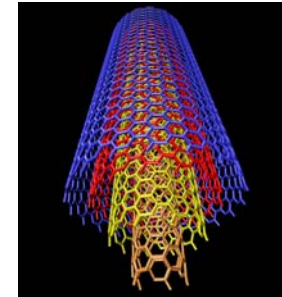


⇒ 48h ⇒ Endpoint measurement

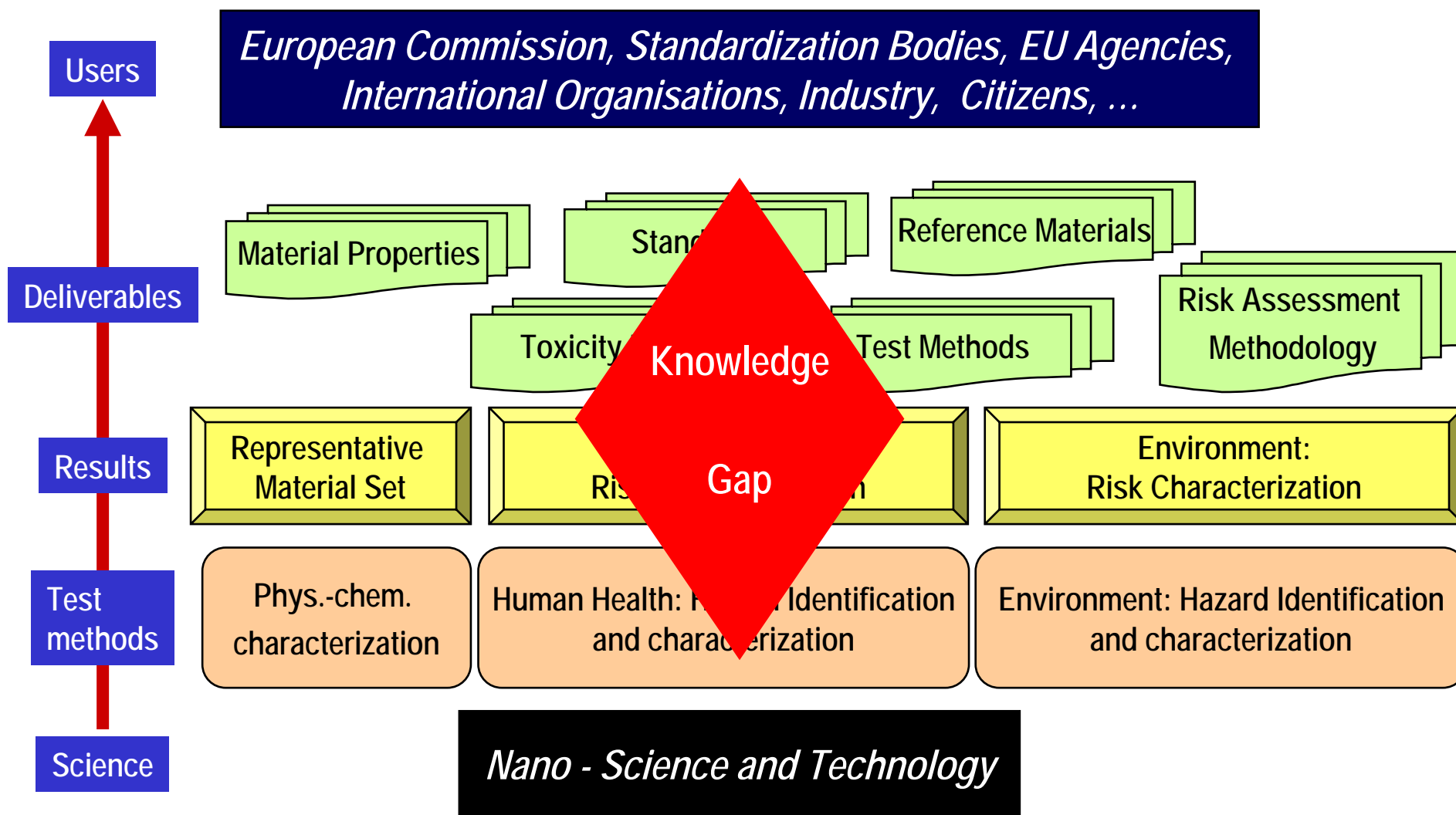


JRC Nanobiotechnology Research

- **Surface Science – Bio/non-bio interfaces**
 - Central to the understanding of the biological response of nanostructured materials
- **Nanotoxicology**
 - physico-chemical characteristics of nanoparticles
 - development of reference materials
 - In vitro test methods, biosensor development
 - In silico studies, database development
- **Assay Automation**
- **Molecular and cell imaging**
- **Risk assessment and information management tools**



Science for Policy Support



JRC Nanotechnology Policy Support



European Commission Directorates General

- Enterprise and Industry
- Environment
- SANCO
- Employment, Social Affairs and Equal Opportunities



CHALLENGES FOR RESEARCH IN SUPPORT OF EUROPEAN UNION POLICIES

The JRC as a research based policy support organization

Is the regulatory framework appropriate?

Close the knowledge gap – produce data

Develop integrated risk assessment methodologies

Perform underpinning research for health, safety and the
environment

Joint Research Centre (JRC)

Robust science for policy making

Thank you for your attention

Web: www.jrc.ec.europa.eu

Contact: jrc-info@ec.europa.eu