

Nanotechnology: European Regulatory Issues

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*The views expressed in this presentation are personal and may not necessarily reflect those of the European Commission

INTRODUCTION

EUROPEAN REGULATORY APPROACH

EXAMPLE: REACH

RESEARCH FOR POLICY SUPPORT

NT Consumer Products on the Market



TiO₂ Automotive Sunscreen



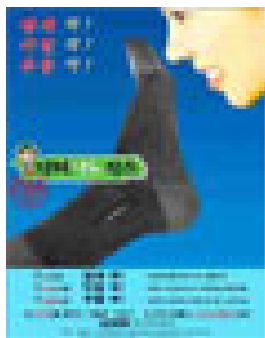
Samsung® Washing Machine



DNA Skin Optimizer



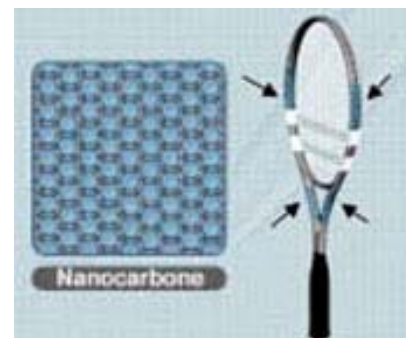
Antibacterial Kitchenware
Nano Care Technology, Ltd.



Lexon Nano-Silver Sock



Ultima® Photo Paper
Eastman Kodak® Company

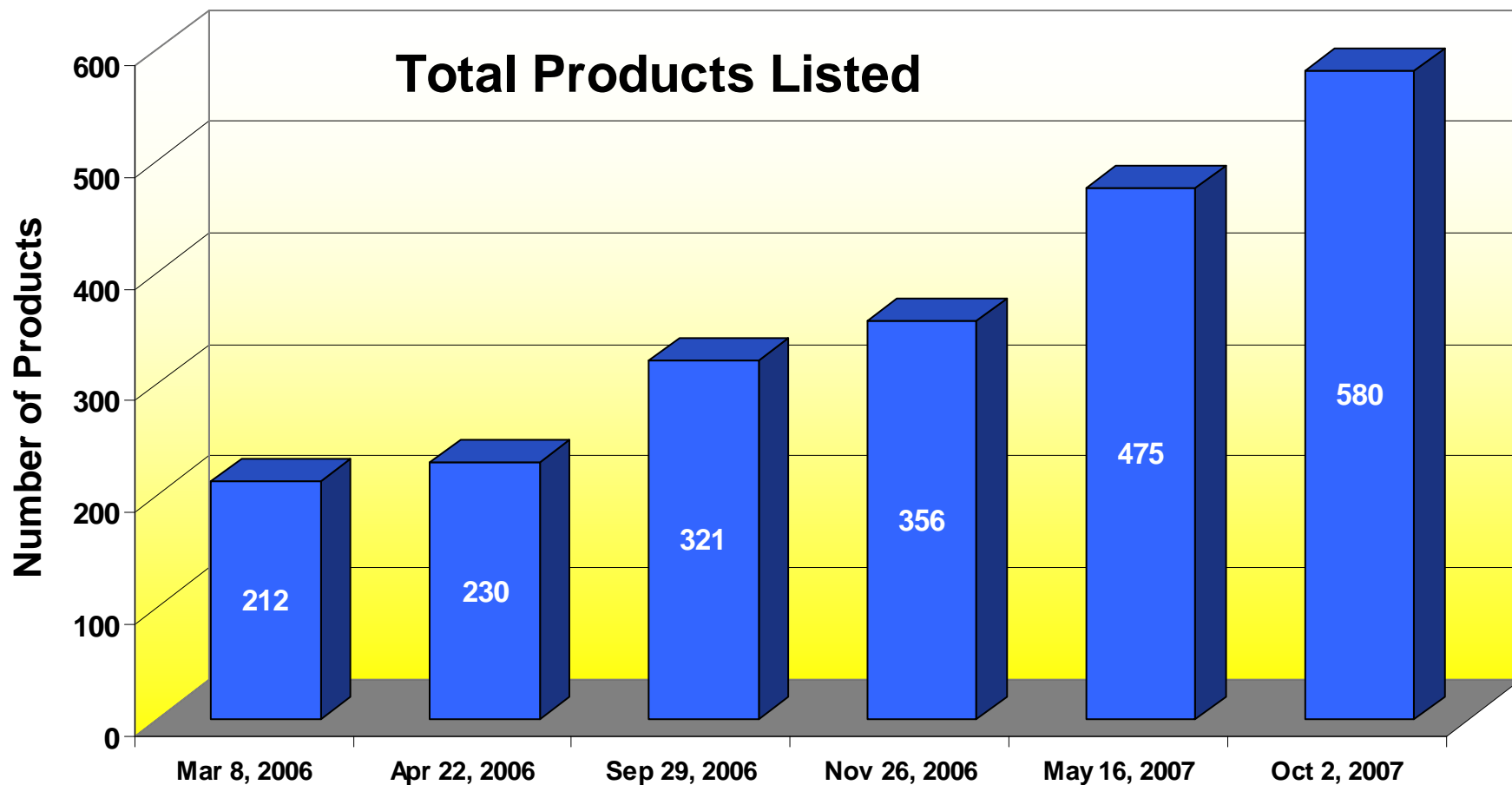


Babolat® NS™
Tour Tennis Racket



Donny the Dog Plush Toy

NT Consumer Products on the Market



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

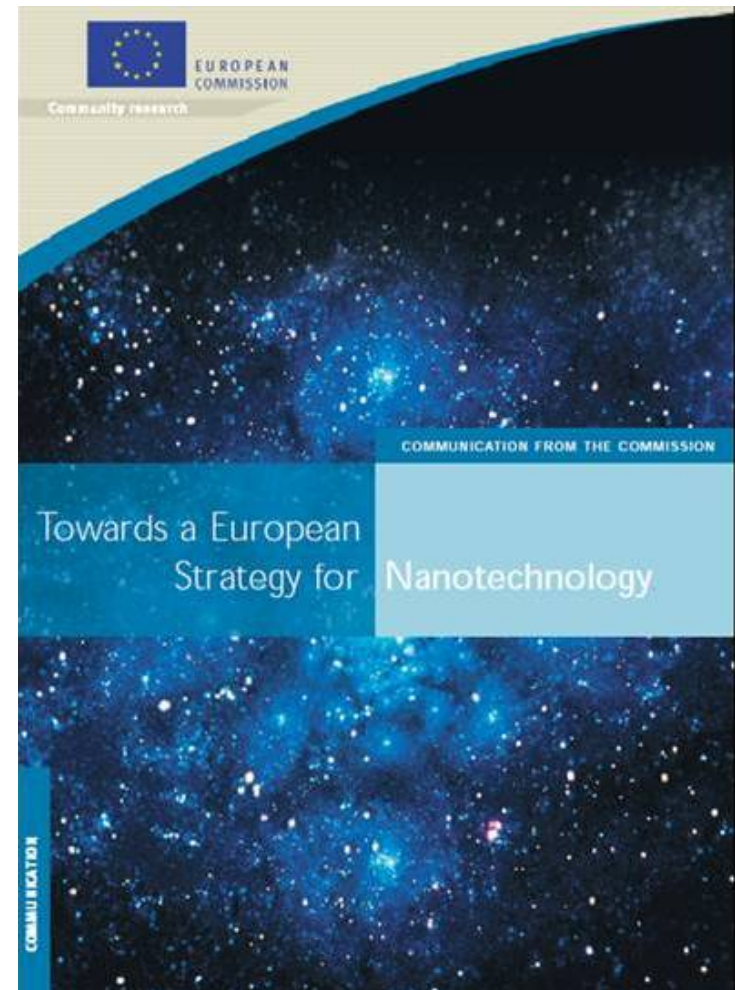
- *Uncertainties* about health and environmental impacts
- Different societal *perceptions* and *ethical concerns*
 - exaltation ↔ moratorium
 - real risks ↔ perceptual risks
- Little *trust* in industrial risk managers and public regulators



Towards a European Strategy for Nanotechnology

Safe, integrated and responsible strategy

Addressing **potential risks of products** obtained by the means of nanotechnology and possibly affecting **consumers' and public health, occupational health and safety and the environment** at the earliest possible stage



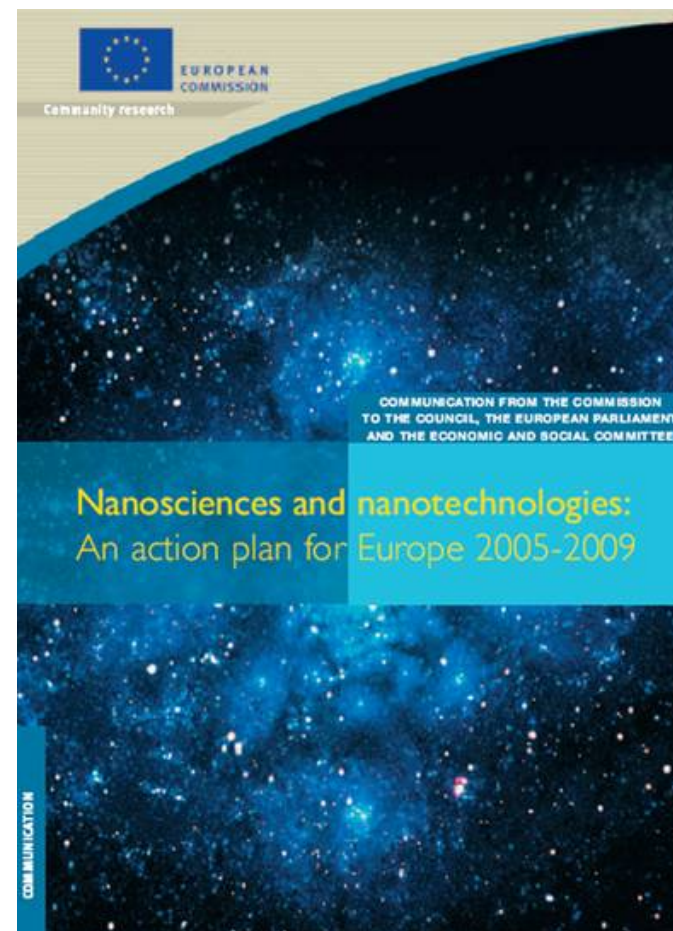
An action plan for Europe 2005 - 2009

EU Action Plan - Chapter 6 - Environment and Health Safety

The Commission will ...

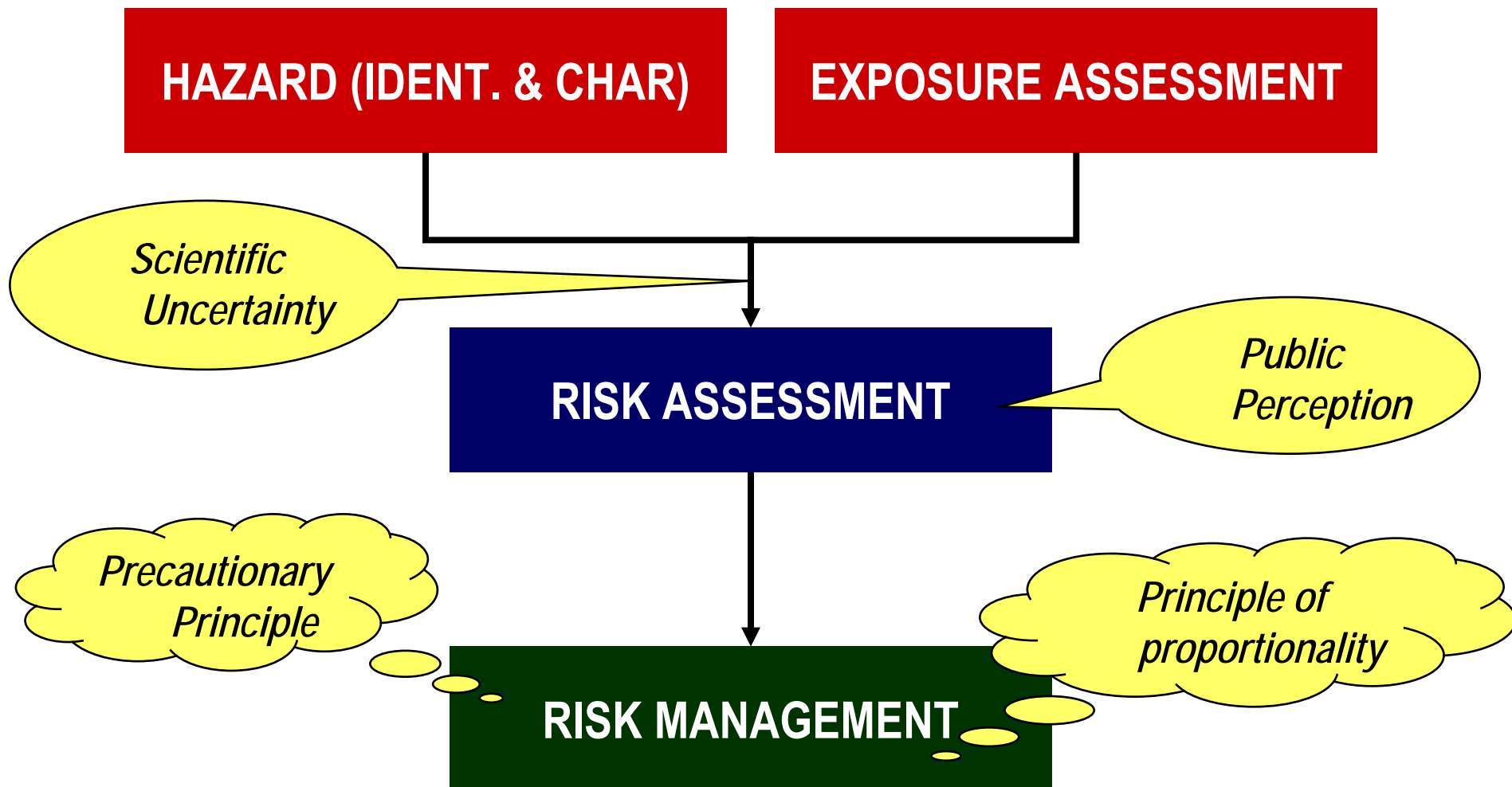
examine and, where appropriate, propose adaptations of EU regulations in relevant sectors ...
paying particular, but not exclusive, attention to

- (i) toxicity thresholds,
- (ii) measurement and emission thresholds,
- (iii) labelling requirements,
- (iv) risk assessment and exposure thresholds
- (v) production and import thresholds, below which a substance may be exempt from regulation, are typically based upon mass quantities.



EUROPEAN REGULATORY APPROACH

How does legislation deal with risks?



EU Regulation relevant for EHS aspects of NT

Horizontal Legislation	Product Legislation
<p>1. Chemicals Legislation (REACH)</p> <p>2. Worker Protection</p> <p>3. Environmental Legislation</p> <ul style="list-style-type: none">– Integrated Pollution Prevention and Control– Major-accidents, Seveso II Directive– Water– Waste	<ul style="list-style-type: none">• General Safety of Consumer Products• Plant Protection Products• Biocides• New Approach Legislation• Cosmetic Products• Aerosol Dispensers• Medicinal Products• Cars• Food Legislation

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?

Chemicals Legislation: REACH

Regulation on the **R**egistration, **E**valuation, **A**uthorisation and Restrictions of **CH**emicals

- **Overarching legislation** applying to the manufacture, import, placing on market and use of substances on their own, in preparations or in articles
- **Responsibility** for the safe use of chemicals allocated to manufacturers, importers and downstream users
- **Nanomaterials** not explicitly covered, however, the 'substance' definition in REACH comprises nanomaterials
- Provisions underpinned by the **Precautionary Principle**

REACH

KEY ELEMENTS

- One **single** and coherent system (for **new and existing** chemicals)
- Core elements:
 - **Agency** to manage system
 - **Registration** of substances ≥ 1 **tonne/yr** (staggered deadlines)
 - **Evaluation** of some substances by Member States
 - **Authorisation** only for substances of **very high concern**
 - **Restrictions** - the safety net
- Focus on priorities:
 - **high volumes** (as a proxy for potential risk)
 - **greatest concern** (substances & uses with highest risk)
 - Carcinogenic, Mutagenic, Reproductive Toxic (**CMR**)
 - Persistent, Bioaccumulative, Toxic (**PBT**)
- Shift of responsibilities
 - from public authorities **towards industry**

REACH and Nanomaterials

- REACH requirements apply to nanomaterials. REACH **does not contain specific provisions** for nanomaterials
- On the basis of **knowledge development**:
 - **Guidance for implementation**, e.g. on safety assessment, may need to incorporate specific elements related to nanomaterials
 - **Review** REACH at a later stage as appropriate with regard to adequacy to address and manage the safety of nanomaterials (incl. information requirements, assessments and management by industries)

EU Regulation relevant for EHS aspects of NT

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IMPLEMENTATION OF LEGISLATION

TO DISTINGUISH

- Regulatory framework
- Implementation, in particular through the adoption of documents that support implementation, such as implementing legislation, guidance, standards, testing methods, etc.

EC SCIENTIFIC COMMITTEES

Three independent non-food Scientific Committees provide the Commission with the sound scientific advice it needs when preparing policy and proposals relating to *consumer safety, public health and the environment*. The Committees also draw the Commission's attention to the new or *emerging problems* which may pose an actual or potential threat.

- Scientific Committee on Consumer Products (SCCP)
- Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR)
- Scientific Committee on Health and Environmental Risks (SCHER)

In addition, the Commission relies upon the work of the

- European Chemicals Agency (ECHA)
- European Food Safety Authority (EFSA),
- European Medicines Evaluation Agency (EMA),
- European Centre for Disease Prevention and Control (ECDC)

SCIENTIFIC COMMITTEES: OPINIONS

SCENIHR

The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies

The Appropriateness of the Risk Assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterials

The scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies

SCCP

Safety of nanomaterials in cosmetic products

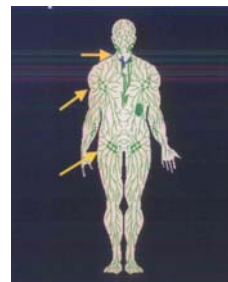
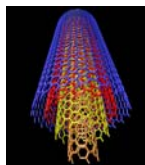
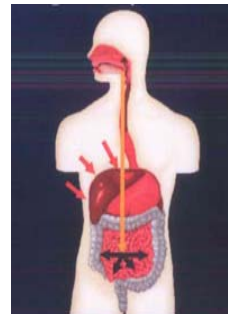
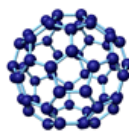
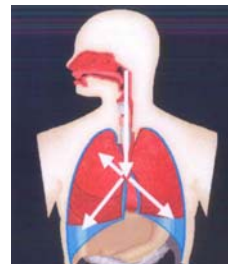
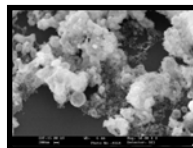
RESEARCH FOR POLICY SUPPORT



The JRC as a research based policy support organization

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

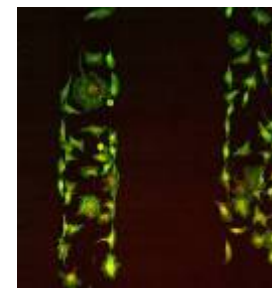
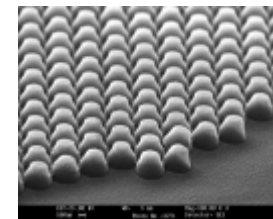


EFFECT

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

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**



JRC Nanotechnology Policy Support



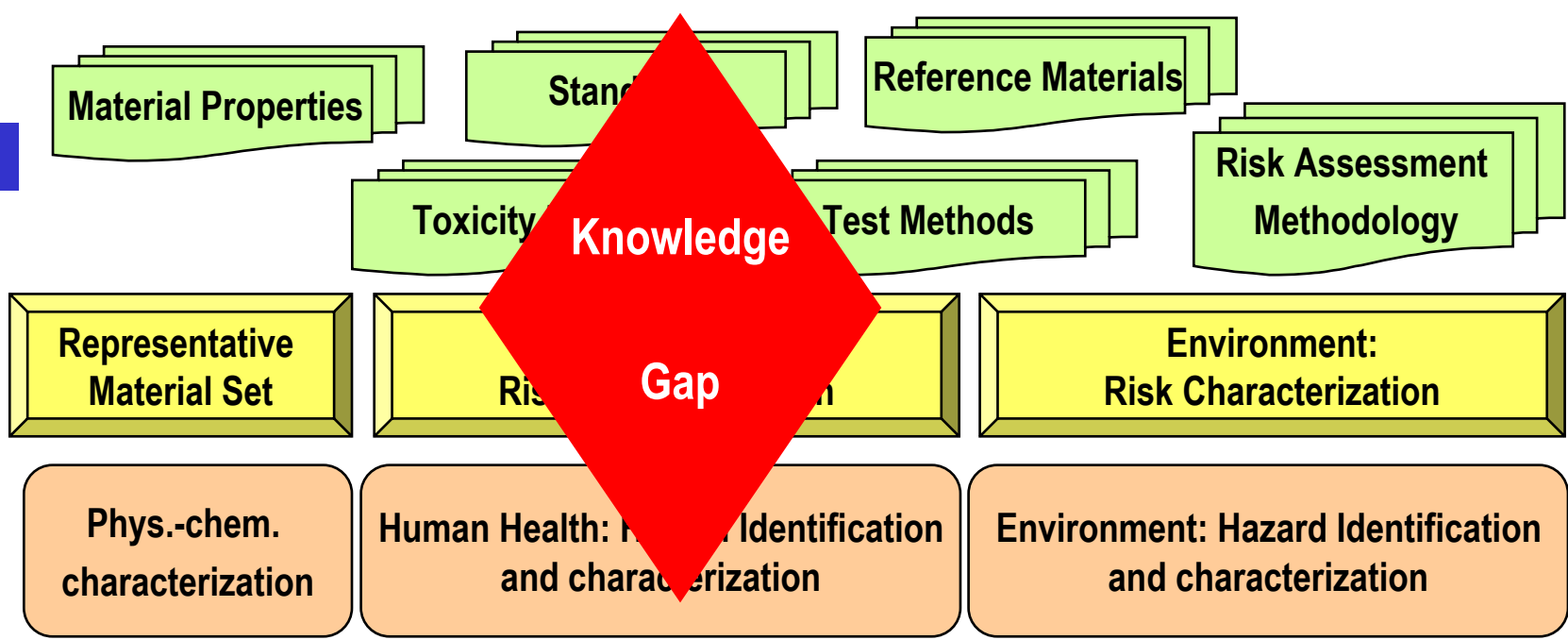
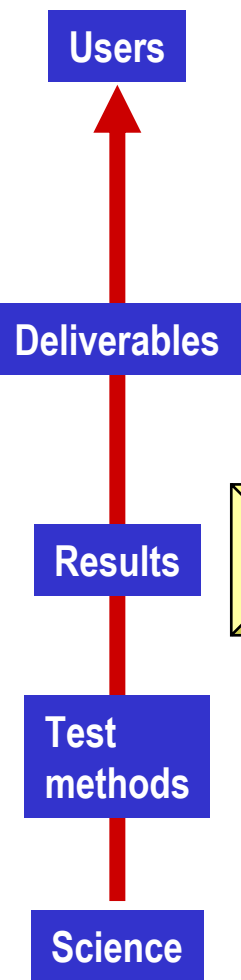
European Commission Directorates General

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



Science for Policy Support

European Commission, Standardization Bodies, EU Agencies, International Organisations, Industry, Citizens, ...



Joint Research Centre (JRC)

Robust science for policy making

Thank you for your attention

Web: www.jrc.ec.europa.eu

<http://ecb.jrc.it/REACH/>

Contact: jrc-info@ec.europa.eu