Directorate-General for Enterprise and Industry

Safety for Success Dialogue
25 - 26 October 2007

The EU Perspective on
Policy and Regulatory Aspects

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Nanotechnology in Europe,

a "*Safe, Integrated and Responsible" Approach*

Commission Communications:

- Towards a European Strategy for Nanotechnology (May 2004)
- Nanotechnology Action Plan for Europe 2005-2009 (June 2005)
- Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. First Implementation Report 2005-2007 (September 2007)

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"Action Plan for Europe 2005 – 2009" announces a Regulatory Review

Commission will "examine and, where appropriate, propose adaptations of EU regulations in relevant sectors…. "

This regulatory review is currently being carried out. At this stage, an EU Commission position is not available. Only views of Commission services are presented, that do not commit the Institution.

The challenge…….

- **New technology, fast developing R&D and technological applications**
- **High expectations on contribution to economic growth, jobs, social welfare and sustainable development**
- **Uncertainties about health and environmental impacts. Ethical concerns about some applications**
- **Different perceptions, from exaltation to requests for a moratorium**

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Regulator's challenge

How to protect public health, safety, environment… whilst allowing technological progress to take place,
bearing in mind competitiveness of industry and creation of jobs ?

A clear distinction must be made between

Regulatory framework

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

Implementation and Enforcement

Key elements EU regulatory framework

a **great variety of areas**: production control, worker protection, product legislation, environmental protection

a **risk-based, technology-neutral approach**, covering also risks in relation to nanomaterials

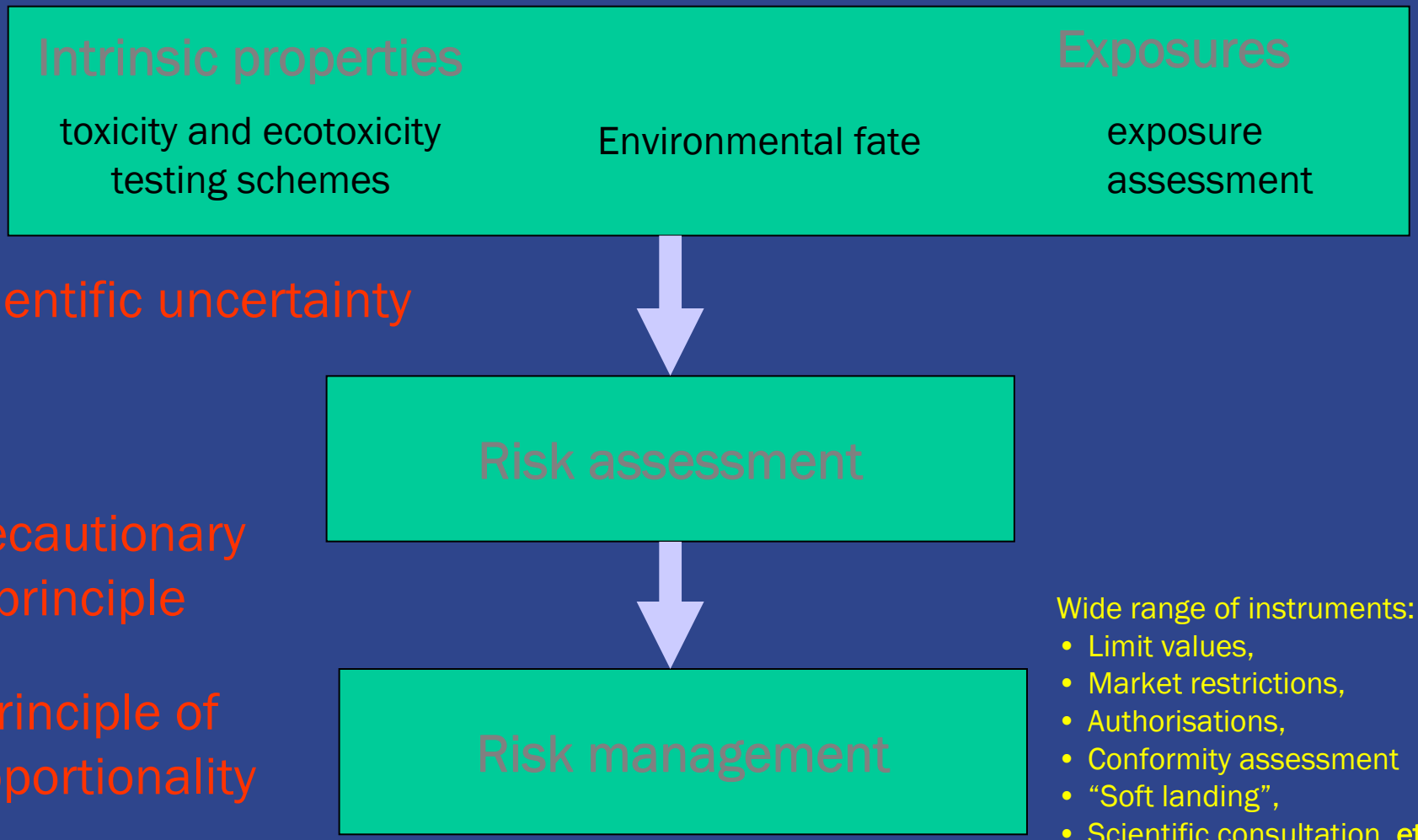
simultaneous application of legislation in different areas

intervention mechanisms (regulation or market intervention) in case of safety issues

Health, safety and environmental protection aspects associated with nanomaterials and nanotechnologies are in principle covered, to different degrees, by current EU regulatory framework

Where the need arises, regulatory change will be proposed

How does legislation deal with risks ?



An example of regulatory review: The Directive on Cosmetic Products and Novel Technologies

New elements under examination

- clear and detailed requirements for the cosmetics **safety assessment**
- administrative cooperation and coordination between **Member States** in the assessment of products and their supporting information, including rules for product withdrawal
- an obligation for industry to **actively report serious undesirable effects** as part of an **early detection mechanism for risks for human health**
- one **single notification portal**

Implementation and Documents supporting implementation

Different in forms, different in nature

Implementing legislation, BAT, technical or legal guidance, test methods, definitions, scientific opinions, European and international standards, etc.

Adopted in different ways

"Comitology", sector-specific Working Groups/Competent Authorities meetings, international organizations, EU Agencies, the EU Scientific Committees, standards organizations….

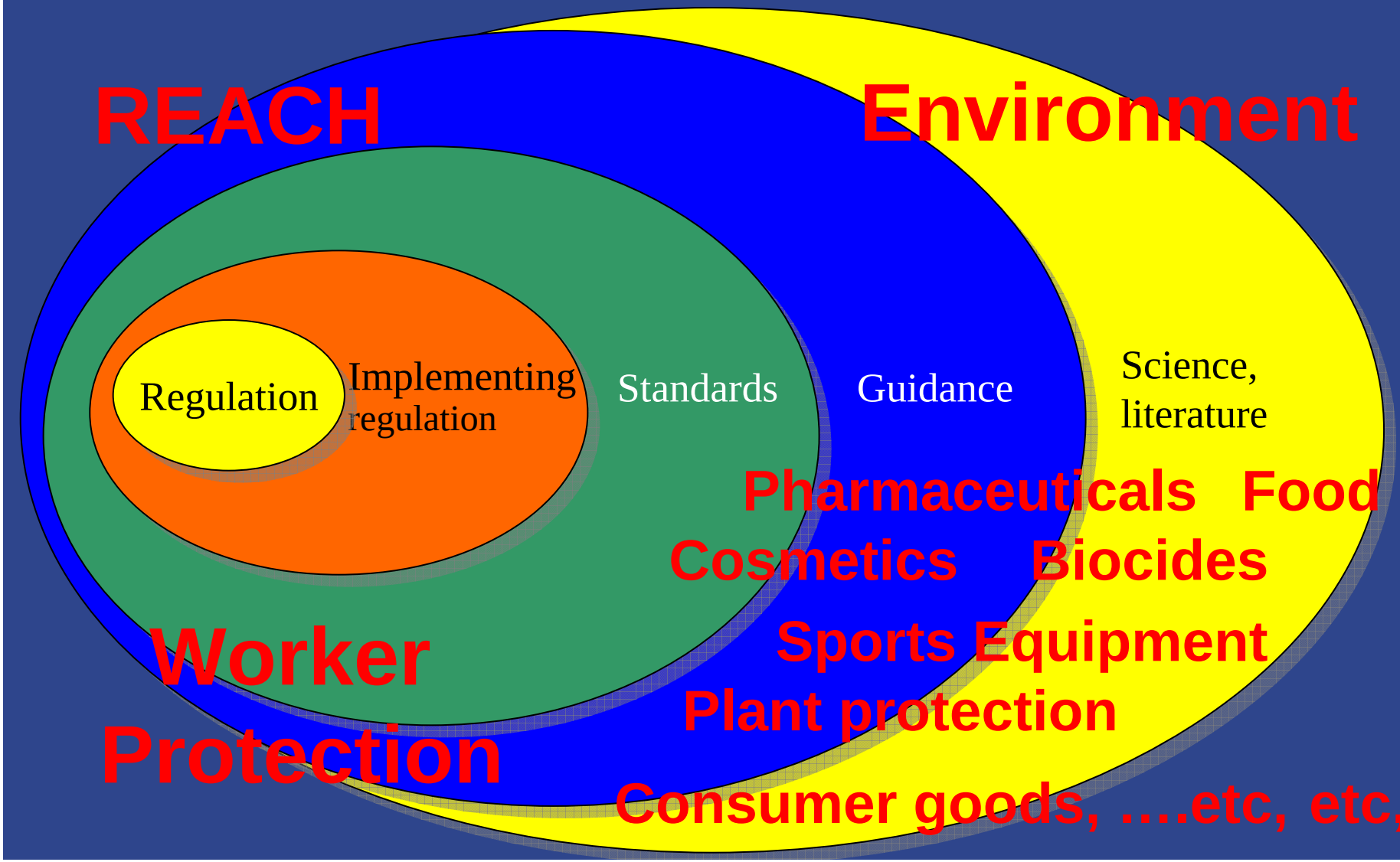
Most EU action in relation to nano technologies and materials is likely to occur at the level of "supporting documents", within the existing legal framework

Documents supporting implementation

Whatever their form and nature, they

- Specify **legal requirements**
- Facilitate **demonstration of compliance** with legal requirements
- Create more **certainty** on implementation
- Take on board **new evidence or results of R&D**

Supporting documents are *de facto* an essential and indispensable tool for implementation, be it for authorities, industry, employers, research institutes, etc……


REACH
Environment
Regulation
Implementing regulation
Standards
Guidance
Science, literature
Pharmaceuticals
Food
Cosmetics
Biocides
Worker Protection
Sports Equipment
Plant protection
Consumer goods, ….etc, etc,

Examples of regulatory tools for implementation available or already being examined

- Reclassification of medical devices presenting risks associated with nanomaterials
- REACH: restrictions on the marketing and use of dangerous substances and preparations
- REACH: subjecting substances to authorisation
- Plant Protection Products: authorisation of active substances
- Food packaging: authorisation of substances for specific groups of materials and articles
- Waste: qualification of waste as hazardous waste
- Biocides: datasets for biocidal products
- etc. etc

Ongoing task for Commission and national competent authorities to monitor implementation and to set, whenever required, new implementing rules

Examples of Standards Standardizing documents

European standards bodies and the international bodies to work on

- Nomenclature, terminology, characterisation
- Test methods
- Exposure Assessment Tools

ESOs to cooperate with international standards bodies and standardizing bodies

Commission has given a “programming” mandate, and we expect an answer from the ESOs first half 2008.

Examples of Guidance

Chemicals legislation

Technical Guidance Document on Risk Assessment for new notified substances for existing substances biocidal products, used in the framework of the

elaboration of the REACH Implementation Projects (RIPs)

Scientific Committee for Consumer Products

Notes of guidance for the testing of cosmetic ingredients and their safety

evaluation

Examples of Scientific Opinions

SCENHIR

- 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

SCCP

Safety of nanomaterials in cosmetic products

Implementation and Enforcement A main challenge….

- Fast developing R&D and scientific results; fast evolving market for products and nanotechnology ("**moving target**")
- Assessment on a **case-by-case** basis
- Necessary "**supporting documents**" not being available
- Based on **sound science** and **best knowledge and data available**
- Taking into consideration the **precautionary principle**
- Scarcity of resources, requiring **intensified cooperation** between authorities
- A main responsibility of **all** parties involved

Overall Assessment

- Current legislation does **not contain specific provisions** on nanomaterials.
- Substances in the nano-scale fall under the scope of legislation and their health and environment properties must be assessed following the **relevant provisions of current legislation.**
- **Implementation in many areas is difficult**, as current methodologies for identifying hazards and evaluating risks of substances may not necessarily fully allow specific properties of substances in the nano-scale to be taken into account.
- Relevant provisions of legislation, but more likely methods for hazard and risk assessment, as well as any relevant guidance and tools developed to **support implementation**, have to be **reviewed and amended as appropriate**, as soon as scientifically valid new methods for assessing substances in the nano-scale become available**.**

Action currently taking place

EU Scientific Committees on Risk Assessment, Cosmetics…..

Standardization mandate to ESO

EU Joint Research Center
Measurement, reference materials, testing

Regulatory priorities identified for EU Framework Programs
Increased funding FP 7

Action currently taking place

European Ethics Group nano-medicine

ECB, EMEA, EFSA,…

Regulatory dialogue with major trading partners, e.g. US/FDA

OECD

EU Commission sectoral working groups

Factors for a successful approach

- **Coordination**
- **Where possible, at the international level**
- **At horizontal and sectoral level**
- **Dialogue with major trading partners**
- **Transparency**
- **Involving various actors and bodies, and the general public at large**
- **Making available financial resources for R&D**

Review of regulation and its implementation
is an ongoing process

Commission WGs will take on board assessments of regulation that have been carried out by Member States and interested parties

A new overall assessment may be necessary within a given period of time

Thank you !

(and we are interested in your views !)

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