IRGC Annual Event 2011 Roundtable 2

EU Regulatory Context for Innovative Technologies

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3 November 2011 Lausanne, Switzerland

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2. Regulatory options for the governance of innovative technologies
   - The Risk Assessment Paradigm
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3. Industry's due diligence – how to mitigate risk
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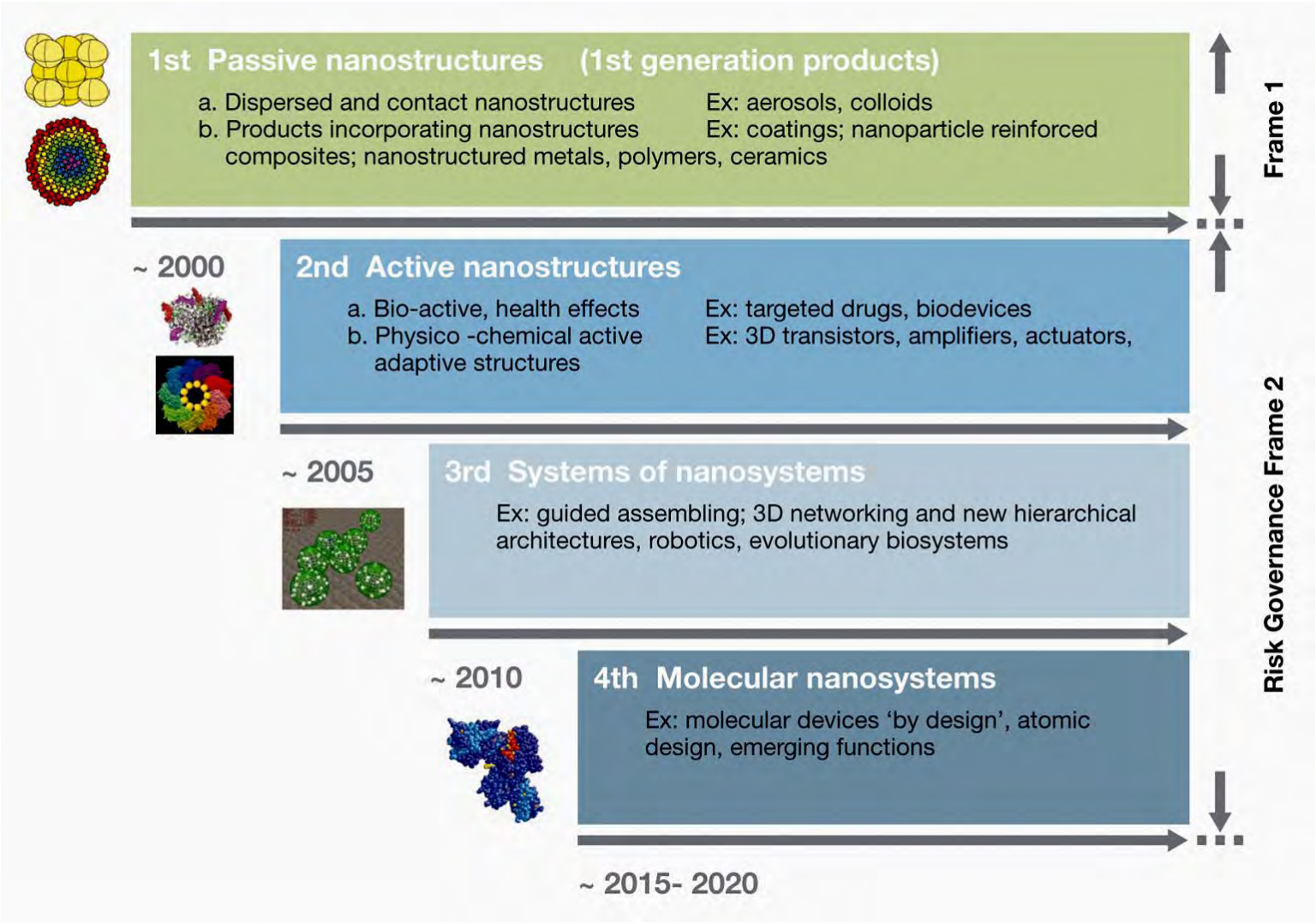
CHALLENGES

- Knowledge is fast evolving – but knowledge gaps may create uncertainty
- Lack of regulatory experience (extrapolating from past scenarios)
- Difficulty to anticipate and recognize risk with a potential long-tail event
- Lack of harmonized approach - potential for proliferation of different rules
- Perception matters - lack of trust between stakeholders
- Understanding the need for communication

FOUR GENERATIONS OF NANOTECHNOLOGY

(Courtesy: International Risk Governance Council, 2009)



RISK ASSESSMENT PARADIGM

Intrinsic properties: interaction health and environment

HAZARD

X

If widespread applications: increased potential for

EXPOSURE

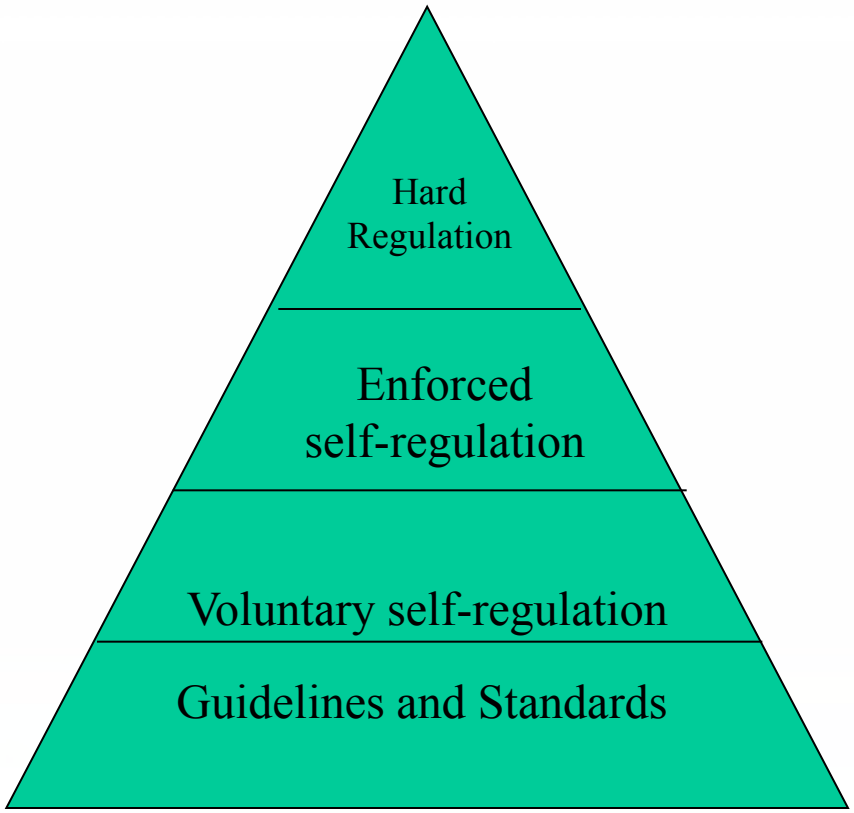
Pressure for regulatory oversight:

- Total moratorium until the technology is proven safe?
- Existing regulatory framework is sufficient to control
- It is industry's ultimate responsibility to only place safe products on the market

THE REGULATORY PYRAMID

- Observatory Nano Project:

  http://www.observatorynano.eu/project/filesystem/files/DevelopmentsInNanotechnologiesRegulationandStandards_2011.pdf:



THE REGULATORY PYRAMID (cont.)

- On top: hard regulation, enforced by regulatory authorities
- Under it: enforced self-regulation (such as mandatory reporting schemes, data call-ins)
- Below: voluntary self-regulation (codes of conduct, industry risk management systems)
- Base level: guidelines and standards (ISO, OECD and national bodies)

"HARD" REGULATION

- **Horizontal Legislation:**
  - ✓ General Product Safety and Product Liability Legislation
  - ✓ Workers' Protection Legislation
  - ✓ Environmental Legislation
  - ✓ Chemicals Legislation (REACH and CLP)

- **Vertical (Application Specific) Legislation:**
  - ✓ Food / Novel Food / Food-contact
  - ✓ Cosmetics
  - ✓ Biocides
  - ✓ RoHS
  - ✓ Medical Devices
  - ✓ etc.

HARD REGULATION: EXISTING LEGAL FRAMEWORK

- **Horizontal Legislation: PRODUCT LIABILITY DIRECTIVE (85/374/EEC)**
  - ✓ (Article 1) *The producer shall be liable for damage caused by a defect in his product*
  - ✓ (Article 4) *The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage*
  - ✓ (Article 6) *A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:*
    - *(a) the presentation of the product;*
    - *(b) the use to which it could reasonably be expected that the product would be put;*
    - *(c) the time when the product was put into circulation.*
  - ✓ (Article 7) *The producer shall **not be liable** as a result of this Directive if he proves:*
    - *(e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered;*

"SOFT" REGULATION EXAMPLE: NANO RISK FRAMEWORK

- DuPont in partnership with Environmental Defence (Environmental NGO)
- A comprehensive tool:
  - ✓ to organize, document and communicate what the user knows about the material;
  - ✓ to acknowledge where the information is incomplete;
  - ✓ to explain how information gaps were addressed; and
  - ✓ to show the rationale behind the risk management decisions and actions.

INDUSTRY'S DUE DILIGENCE

- Risk assessment is left to the business operator
- Safety should be demonstrated on a case-by-case basis:
  - ✓ sufficient hazard information
  - ✓ lack of exposure
- Requires proper product stewardship through the entire life-cycle of the product

THE ASBESTOS STORY

- 1900 First evidence: risk became apparent; first reported deaths cases
- 1900 – 1930 Scientific publications
- 1931 First regulation; UK
- 1950-60 Asbestosis is recognized as occupational disease; first lawsuits filed for compensation
- 1975 First asbestos ban; Sweden
- 1985-2005 Stop using asbestos; rising litigation (estimated total cost of mass tort $ 200-260bn)

STATE OF THE ART KNOWLEDGE DEFENCE

- One of the most controversial points in the asbestos lawsuits relates to the defendant (typically the industry)'s knowledge of the potential for hazards associated with asbestos exposure (see Product Liability Directive; *infra*)
- The defendant's liability is linked to the state-of-the art knowledge of the risk at the time of the exposure to asbestos

GOVERNANCE OPTIONS

- Proper governance should include all viable regulatory options; voluntary measures and mandatory requirements; and should be based on an international consensus. Isolated efforts may result in trade disputes
- Early, non-mature mandatory rules may be counter-productive, resulting in regulatory discrepancies
- The interest of responsible industry is to place safe products on the market, which drives towards minimized risk; governance should integrate voluntary industry standards
- The interest of responsible industry is effective and knowledge-based regulatory oversight, which drives towards cooperation to produce and share reliable data with authorities ensuring "good" regulation and consumer trust

THANK YOU

http://www.steptoe.com/nanoresourcecenter

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