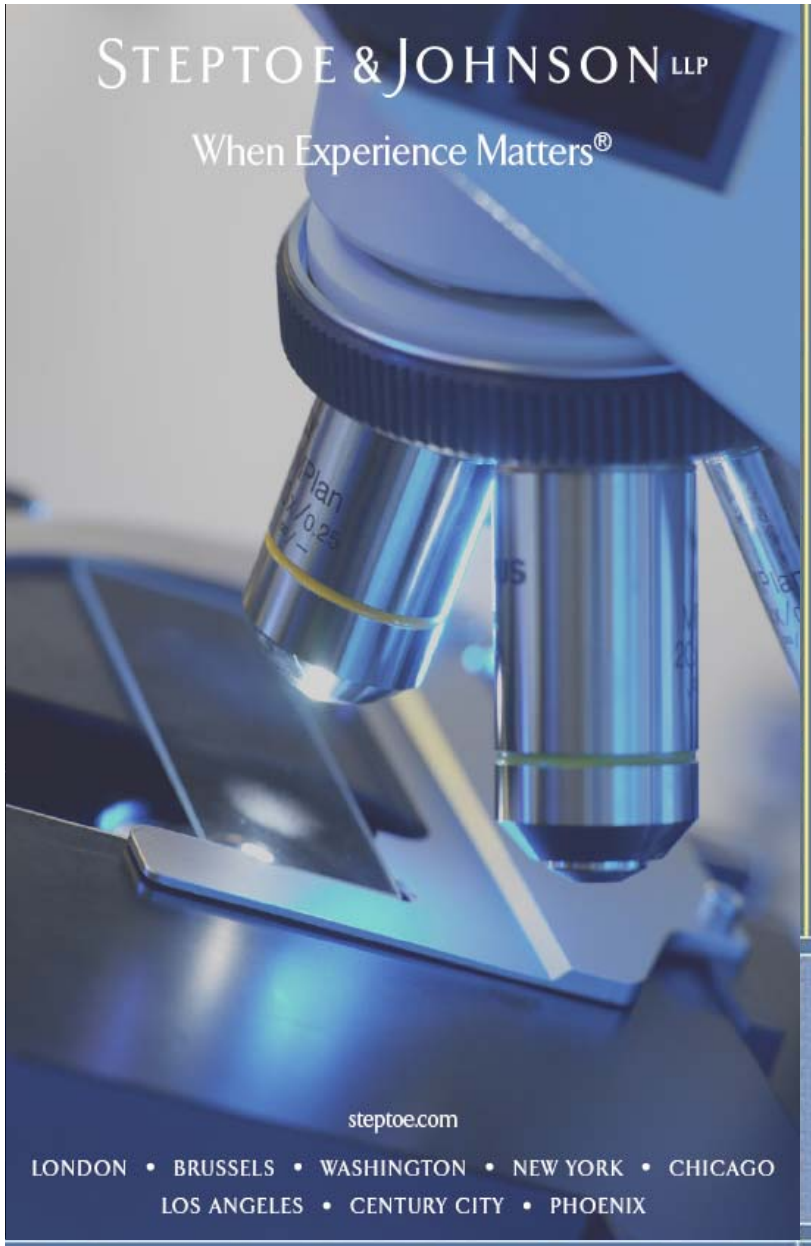

ETP Conference 2010

Open Innovation in Nanotechnologies

Governance of Nanotechnologies

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STEPTOE & JOHNSON LLP

OUTLINE

1. The Role of Regulation in General
2. Regulatory Pressure for Nanotechnologies
3. The EU Response
4. Conclusions: Expectations for Concerted Actions

REGULATION: DEFINITION

Definition: (Wikipedia)

- **Regulation** refers to "controlling human or societal behavior by rules or restrictions"[1]. Regulation can take many forms: legal restrictions promulgated by a government authority, self-regulation, social regulation (e.g. norms), co-regulation and market regulation.
- Regulations, like any other form of coercive action, have costs for some and benefits for others. Efficient regulations may only exist where the total benefits to some exceed the total costs to others.

[1] Bert-Jaap Koops et al. Starting Points for ICT Regulations, Deconstructing Prevalent Policy One-liners, Cambridge University Press, Cambridge: 2006, p. 81

REGULATION: GENERAL

Important aims of Regulation are to:

- Achieve maximum societal benefits
- Control and mitigate any adverse effects

Regulation as a tool can:

- Reduce uncertainty
- Clarify operational standards
- Secure consumer trust

► **BUT ….**

REGULATION:A PREREQUISITE

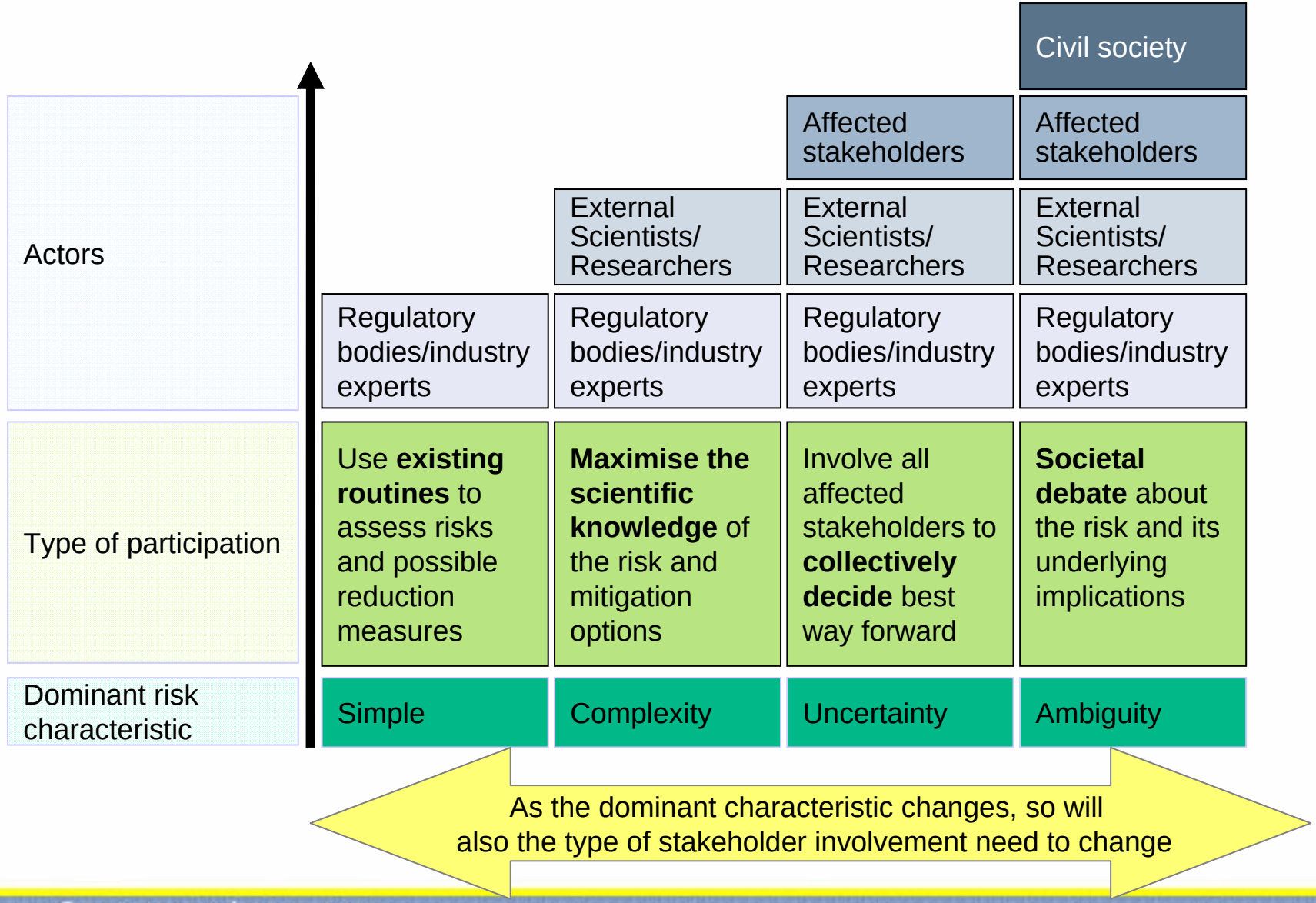
…to create relevant rules evidence is needed on:

- intended effects
- actual impact
- enforcement
- foresight

- Knowledge on these areas is key to create "good" regulation, as opposed to "bad" regulation

STAKEHOLDER INVOLVEMENT

(Courtesy: International Risk Governance Council, 2009)



NANOTECHNOLOGY REGULATION

The pressure for regulatory oversight is mounting:

- some call for a total moratorium until the technology is proven safe
- others consider that the existing regulatory framework is sufficient to control use
- while industry innovates, fulfilling its ultimate responsibility to only place safe products on the market

SOME SPECIFIC REGULATORY AREAS FOR NANOTECHNOLOGIES

- **Worker's safety** issues at product development and commercial manufacturing stages
- **Health and environmental issues** directly relating to manufactured nanoparticles
- Health and environmental issues related to manufactured nanoparticles in different products in downstream use. Their biological and environmental fate during the entire life cycle, their persistence and transformation in waste management

►**Are addressed today on the basis of existing regulation and adequate due diligence**

EU REGULATION: NOW

- **European Commission:**

  Horizontal Legislation: (applicable, but pre-nano)

  General Product Safety and Product Liability Legislation

  Chemicals Legislation (REACH and CLP)

  Vertical (Application Specific) Legislation: (nano-specific)

  Food / Novel Food / Food-contact / Cosmetics / Medical Devices etc.

- **European Parliament:** Resolution of 24 April 2009 requesting the Commission to review all relevant legislation within two years to ensure safety

- **Member States:** National initiatives either on voluntary (Germany, UK) or mandatory (France) basis

EU REGULATION: FUTURE

- **New information may be needed to cover:**
  - ✓ nano-specific characteristics of the substance; such as particle size, form, flexibility, surface treatment, charge, concentration (mass, number and surface area related) etc.
  - ✓ interaction with the environment; dissolution, agglomeration, dis-agglomeration and coalescence behaviour, stability, surface reactivity (adsorption of other substances), solubility, biodegradability and other potential characteristics or interaction, if relevant
  - ✓ storage conditions prior use and disposal conditions post use potentially effecting these characteristics
- **Not yet known whether:**
  - ✓ new endpoints (such as *in vitro* oxidative stress) or
  - ✓ new target organs (such as *in vivo* genotox studies for the respiratory tract) or
  - ✓ new mechanisms (such as translocation) might need to be considered
- ► **Consensus on these issues is needed before "good" regulation can be established. Otherwise ….**

HOW TO AVOID "BAD" REGULATION?

NANOTECHNOLOGIES REGULATION: CONCLUSIONS

- Early, non-mature mandatory rules may be counter-productive, resulting in regulatory discrepancies or in worst cases dead-lock
- 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 market disruptions and trade disputes
- Effective oversight requires a wealth of reliable data; a common interest to contribute to the knowledge-pool ensuring "good" regulation should drive cooperation
- The interest of responsible industry to place safe products on the market drives towards minimized risk; governance should integrate self-policed voluntary industry standards
- All responsible stakeholders should work together on all possible levels to achieve these objectives