Regulating nanotechnologies: overview and prospects

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The regulatory contract

- ...what is known about hazards
- ...social attitudes to risks and uncertainties

Emerging technologies and uncertainty

- Hans Jonas
  - Technology and the power of present people over the lives of future people
- David Collingridge's "control dilemma"
  - An informational problem, plus:
    - A power problem
- How to write the "regulatory contract" in these circumstances?
  - Based on precaution, transparency and corrigibility

Nanotechnology's contested futures

Drexlerian advanced mechanosynthesis
(Mihail Roco's Four Generation schema)

Uncertainties in the present

- Royal Society and Royal Academy of Engineering report
  Nanoscience and nanotechnologies: opportunities and uncertainties (2004)
- Questions of equivalence
  - Physico-chemical characteristics
  - Possibility of complex interactions with environment throughout material/product life-cycle
- Problems of diversity and complexity
  - Huge numbers of nanomaterials
  - Bound and free forms
  - Easy to vary physico-chemical characteristics of materials by altering production parameters
  - Lifecycle exposure issues

Regulatory options

- Nanospecific legislation
  - Yes: nanotechnology applications fully captured by existing regulations
  - No: blanket precautionary approach
  - Case by case adaptive approach recommended by RCEP 2008

Adaptive regulation: issues facing regulators

- Diversity of products → focus on chemicals
- Key challenges
  1. Characterisation of physico-chemical properties
  2. Regulatory gaps (e.g. thresholds)
  3. Towards a lifecycle basis for risk assessment

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- Characterisation of physico-chemical properties
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An example: REACh

- Purpose: central register for all chemicals in commercial use in EU
- Life-cycle based assessment
- Devolve responsibility to producers/dowstream users
- What data is required and when depends on
  1. Volume of substance
  2. Intrinsic harmfulness (e.g. SHVCs)

- Permit, control, or ban
- No data, no market

Problems
- 1. Coverage (definitions and thresholds)
- 2. Equivalence and testing

Other EU regulations: “nanoproducts”

- Biocidal products directive (98/8/EC)
  - Ongoing discussions
  - Nano-relevant amendments may be made on basis of “the latest scientific information”
- Novel foods directive (EC/258/97)
  - May introduce labelling requirements
- Cosmetics regulation (EC/1223/2009)
  - Coming into force from next year
  - By 11 January 2014: publicly accessible catalogue of nanomaterials in cosmetic products
  - Labelling provisions: “nano” for engineered nanoingredients

Beyond “hard law”

- “Soft regulation”
- Corporate social responsibility
- Insurance and reinsurance
- Public technology assessment
- Standardisation

Beyond “hard law”

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