Regulating nanotechnologies: overview and prospects

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The regulatory contract

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

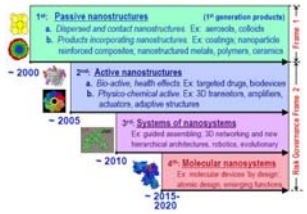
Emerging technologies and uncertainty

- 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**

Nanotechology's contested futures

Drexlerian advanced mechanosynthesis
(image from Nanorex, http://www.nanoengineer-1.com)

Mihail Roco's Four Generation schema[1]

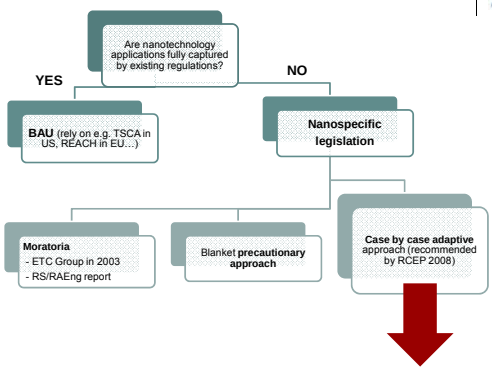


1. Roco, M. C. and Bainbridge, W. S. 2005. Societal implications of nanoscience and nanotechnology: Maximizing human benefit. *Journal of Nanoparticle Research* 7(1), pp. 1-13.

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



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)[1]
  3. Towards a **lifecycle** basis for risk assessment

1. Frater, L. et al. 2006. *An overview of the framework of current regulation affecting the development and marketing of nanomaterials.* Cardiff: BRASS.

An example: REACh

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

1. Permit, control, or ban
2. **No data, no market**

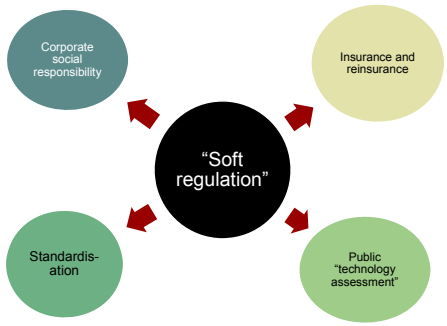
Problems
1. Coverage (definitions and thresholds)[1]
2. Equivalence and testing[1,2]

1. Lee, R. G. and Vaughan, S. 2010. REACHing down: nanomaterials and chemical safety in the European union. *Law, Innovation and Technology* 2(2), pp. 193-217.
2. Franco, A. et al. 2007. Limits and prospects of the "incremental approach" and the European legislation on the management of risks related to nanomaterials. *Regulatory Toxicology and Pharmacology* 48(2), pp. 171-183.

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"



www.brass.cf.ac.uk/Nanotechnologies.html