Research Project: Sustainable Technologies and Responsible Innovation: Nanotechnology Regulation

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Background: Nanotechnology is an industry that is rapidly developing and whose risks are not yet well understood (See A13). Law and regulation often struggle to keep pace with such new and emerging technologies, and legislative solutions can be slow to develop even when new technologies entail potential risks to human health and the environment. The regulation of potential risks associated with 'new technologies' raises important questions about the setting of safety standards in situations of scientific uncertainty, and regulatory solutions for nanotechnologies has been an important focus for BRASS research work.

Aims & objectives:

- To understand the socio-legal implications of nanotechnologies, particularly in terms of the ability of existing regulatory frameworks to handle the potential risks posed by materials adjudged to be 'safe' at conventional scale, but which may behave differently at a nanoscale.
- To assess the role of CSR as a voluntary and self-regulatory approach by industry itself to tackle the potential risks related to nanotechnologies. The main objective was to evaluate what motivates or inhibits industry to adopt responsible practices by applying a societal approach to risk assessment and management based on CSR principles.
- To explore the likely future scenarios for nanotech development in the UK and their implications for regulation, CSR and stakeholder relationships, and research needs within the industry.

About the research: BRASS research tackles many of the issues raised in relation to the regulation of the development, manufacture, use and disposal of nanomaterials including encompassing legislative frameworks, regulatory theory, regulation of risk, sociology of risk and uncertainty, and the role of the precautionary principle. In 2006, BRASS was appointed by the Office of Science & Innovation (OSI) to provide an analysis of the potential gaps in the regulation of the development, manufacture, supply, use and end of life of free-engineered nanoparticles. The project considered current and future foreseeable applications of nanomaterials and mapped these applications against existing regulatory frameworks that might govern their lifecycle. The assessed regulations serve a number of purposes including: controls on marketing; health and safety; consumer and environmental protection; and waste regulation. Sixty separate pieces of regulation were subjected to careful scrutiny of their capacity to fulfil basic risk governance functions. This research was later followed by an expert multi-stakeholder (academia, business, consultants, NGOs, policy) Delphi exercise looking at four scenarios, which outline how various relevant factors (science base, commercial environment, regulatory developments, social acceptance) may combine to shape the next ten years of innovation in nanotechnologies in the UK. Other research considered the potential for integration between European chemicals regulation and nano-materials.

Results and outputs: The work on nanotechnology regulation identified the situation that shortfalls in consistent definitions, metrics and toxicology make it difficult to generate traditional legislative approaches to the regulation of novel materials such as nanomaterials. The work suggests the need for inclusive, soft law mechanisms (such as codes or protocols) for the regulation of technology pending the adaptation of more formal regulation becoming possible.

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Impacts achieved/potential for impact: BRASS research has informed policy makers both in the UK and internationally, industry bodies and research funding organisations about how to improve the legal regulation of technological advances in nanotechnology. The 2006 report for Defra was later acknowledged in the Government's nanotech strategy, and the OSI/DTI report found gaps in the coverage of the current regulatory framework. The findings from the reports were also presented to the *Nanotechnology Stakeholder Forum* (main liaison body between government and industry led by BIS), the *Nanotechnology Issues Dialogue Group* (Inter-departmental government group), and to the Government Legal Service. The Royal Commission on Environmental Pollution also devoted a session to considering BRASS work on nanotech regulation for OSI/DTI, at which Prof Lee and Dr Stokes gave evidence, before drawing up their own report on regulation of novel materials.

BRASS was also featured in a special issue of *Modern Government* on Nanotech, and a policy brief on nanotech in food was presented to the House of Lords Select Committee on Science & Technology. BRASS also Co-organised a Nanotechnology and CSR event in May 2009 and contributed to a Responsible Nanoforum/Food & Drink Federation "Nano & Food" stakeholder roundtable in February 2010. BRASS also developed the 'Nano & Me' public information website for 'Matter' supported by the Dept. for Business Innovation and Skills.

BRASS Nanotech methodologies have also been adopted by other research studies and reports including the "*Review of health safety aspects of nanotechnologies in food production*" (RIKILT & RIVM, Holland) and "*International Approaches to the Regulatory Governance of Nanotechnology*" (Canada).The work also led to the development of a British Standards Institution Publicly Available Specification (PAS 137) offering practical guidance to UK companies (including SMEs) on the implementation of legislation and standards relevant to the importation, manufacture, processing, distribution and sale of nanomaterials and nanotechnology-based products.