Institution: Cardiff University

Unit of Assessment: UoA20

Title of case study: Regulating nanotechnology: shaping government strategy and industry standards

1. Summary of the impact

Nanotechnology is one of the world's fastest developing industrial sectors; as well as the economic significance of nanomaterials, they have potentially serious implications for health and the environment. Impact from research on governance and legal regulation of nanotechnology by a Cardiff Law School research team operating within the ESRC-Centre for Business Relationships, Accountability, Sustainability and Society (BRASS) has: shaped UK government nanotech strategy; decisively influenced industry and industrial standards; and reached across other States and international organisations. Research by the team has: demonstrated that existing regulation dealt poorly with nanotechnologies and the health/environmental risks they might pose; identified regulatory gaps; recommended the introduction of nano-specific guidance/standards; evaluated the need for a nanotech moratorium; and analysed social responsibility and performance of nanotechnology companies. This research has now been codified in the first British Standards Institution (BSI) Publicly Available Specification (PAS) on nanotechnology.

2. Underpinning research

In 2006, a research team based at Cardiff Law School was commissioned by the Office of Science and Innovation (OSI) within the (then) Department for Trade and Industry (DTI) to report on the regulation of applications of nanotechnology[3.1, 3.2]. The team (Frater (Research Manager, 2007-), Lee (Professor, 1995–2013), Oriola (Graduate Teaching Assistant, 2006–2009) and Stokes (Lecturer, 2008–2013; Senior Lecturer 2013-)) worked in the context of the interdisciplinary ESRC-funded Centre for Business Relationships, Accountability, Sustainability and Society (BRASS 2001-2013). (Cardiff Law School played a central role in BRASS: Lee was Co-Director for the duration of its existence; Frater was Senior Research Manager; Stokes, initially a BRASS-associated PhD student and later a BRASS Research Affiliate; and Oriola, a BRASS-associated PhD student.)

BRASS' research impact mission included the sustainable and responsible use of new technologies. The Centre sought to realise this in relation to emerging nanotechnologies through the development of the Law School/BRASS research team. The invitation from the OSI/DTI to report on regulation affecting the development and marketing of nanomaterials (the DTI report) was a product of the team's efforts to build close relationships with government departments. Analysing 1) 60-plus pieces of legislation and 2) interview data with nanotechnology experts and policy-makers, the 2006 DTI report[3.1] addressed the coverage and adequacy of existing legal regulations for nanotechnology. The report's key conclusions were:

- Existing regulations were not specific enough to control applications of nanotechnology over their lifecycle;
- Gaps in the regulations occurred because of ill-suited regulatory provisions and a lack of information about the health / environmental effects of applications of nanotechnology;
- While new regulatory structures were needed in the long-term, in the interim the existing regulatory framework could be supplemented (with new guidance, standards), amended and extended to apply to nanotechnology.

In 2009 the team, augmented by Vaughan[3.3] (Associate Lecturer, 2008–2010; Lecturer, 2010–2012) and three BRASS social scientists including Groves (Research Associate 2008-), undertook research for Defra[3.4,3.5], including quantitative content analysis of Corporate Social Responsibility (CSR) reporting by UK nanotechnology companies, and in-depth interviews on industry attitudes to nanotechnology stakeholder issues. This research found little or no CSR reporting among smaller companies, little evidence of a 'continuous improvement' model of CSR in companies of any size, a general preference for 'do no harm' over 'adding positive social value' approaches, and support among industry stakeholders for soft (rather than legislative) forms of regulation, such as further

guidance documents and standards dealing specific with nanotechnology. The Cardiff research suggested that the CSR agenda might assist in promoting responsible innovation through voluntary and self-regulation in nanotechnology research and development.

From the mid-2000s pressure groups such as Friends of the Earth began to call for a moratorium on nanotechnology development. Team research published in 2009 analysed the costs and benefits of different regulatory strategies and consequently questioned the viability of a moratorium approach [3.6].

3. References to the research

(1) **Frater L, Stokes E, Lee R, and Oriola T**: **'**An Overview of the Framework of Current Regulation affecting the Development and Marketing of Nanomaterials' Office of Science and Innovation (OSI)/Department of Trade and Industry (DTI) (URN 06/2220) - December 2006, pp 191) http://www.dti.gov.uk/files/file36167.pdf (Available as a pdf from the HEI, on request)

(2) The DTI report is summarised in **BRASS** written evidence to House of Lords at 294 of http://www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/22ii.pdf (Available as a pdf from the HEI, on request)

(3) **Lee R** and **Vaughan S**: 'REACHing Down: Nanomaterials and Chemical Safety in the EU', Journal of Law, Innovation and Technology, 2 (2) (2010) 193-217 http://dx.doi.org/10.5235/175799610794046168 (Available from the HEI, on request)

(4) **Groves C**, **Frater L**, **Lee RG**, Jenkins H, Yakovleva, N: 'An examination of the nature and application among the nanotechnologies industries of corporate social responsibility in the context of safeguarding the environment and human health' (June 2009) Defra http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=16262; (Available as a pdf from the HEI, on request)

(5) **Groves, C**, **Frater L**, **Lee R** and **Stokes E**, 'Is There Room at the Bottom for CSR? Corporate Social Responsibility and Nanotechnology in the UK', (2011) Journal of Business Ethics, doi: 10.1007/s10551-010-0731-7 http://link.springer.com/article/10.1007%2Fs10551-010-0731-7 (Available from the HEI, on request)

(6) **Stokes, E**: (2009), 'Regulating nanotechnologies: sizing up the options', Legal Studies, 29:281–304 http://dx.doi.org/10.1111/j.1748-121X.2009.00121.x (Available from the HEI, on request)

4. Details of the impact

The Cardiff research has impacted on nanotechnology regulation in a number of ways:

- It has helped shape new Government strategy on nano regulation by identifying regulatory gaps for UK policy-makers;
- Team members drafted a British Standards Institution Publicly Available Specification (BSI PAS137) – a key measure to address the regulatory gaps identified by their research;
- Government cited it in its rejection of a moratorium on the new technology in the UK;
- It is shaping the research agenda of, and future planning for, UK industry and scientists as well as contributing to wider public debate;
- It is influencing international debates including at the Organisation for Economic Co-operation and Development (OECD) and EU levels as well as in Canada and Germany.

Awareness of regulatory gaps and new Government strategy

In the pre-REF period the DTI report had alerted many organisations to the gaps in the coverage of the existing regulatory framework. In the REF period, the Royal Commission on Environmental Pollution devoted a special meeting to consideration of the DTI Report in its work on Novel Materials (2008). The Commission's report (later reviewed by Lee and Stokes) cited the "regulatory gap" analysis developed at Cardiff[5.1] and repeated the call for adapting and extending the existing regulatory framework "as a matter of urgency". The House of Lords' Science and Technology Committee's study on Nanotechnologies and Food (January 2010) quoted the team's written evidence based on the DTI report: "Even if the current regulatory regime is capable of addressing the current applications of nanotechnologies and nanomaterials in the food sector, some witnesses questioned whether this would remain the case as the science and applications of nanotechnologies and nanomaterials developed. The BRASS team, for example, anticipated that

'gaps in current legislation will only grow to be more pronounced…current regulation will, in our opinion, need to be amended to account for more sophisticated nano-based products and processes.'"[5.2.] Two months later the Government published its Nanotechnologies Strategy[5.3] and stated: "The [Cardiff] research concluded that while many areas had strong regulatory cover, some gaps existed. Departments and Agencies within Government are working to ensure that regulations and policies in all sectors are applied appropriately to nanomaterials and that the issues identified by BRASS are addressed." The strategy sets out actions in four areas where nanotechnology is most likely to affect the environment or health: food, cosmetics, healthcare and the workplace.

A new Publicly Available Specification from the British Standards Institution

Team research – notably the regulatory gaps identified in the DTI report and concerns about CSR in nanotech companies analysed in the Defra report had impact on the Department of Business, Innovation and Skills (BIS) and the BSI. The research influenced the BIS decision to commission a BSI PAS (137 on Nanomaterials and Nanotechnology), which the team was contracted to write (reflecting its strong profile with industry and good reputation in government). As well as drawing on several years of research undertaken by the team (including the DTI and Defra reports), the drafting of the Specification (commissioned in 2009) involved close engagement with a Steering Group composed of key representatives of industry and government[5.5]. The team's work on the PAS constituted an important element of central government's developing strategy for the regulation of nanotechnology. The Specification aims to overcome problems identified by the team, such as the lack of nanotechnology-specific regulatory measures and the potential health and environmental consequences of nanomaterials. PAS 137 has been designed as the reference point for the whole of British industry, signposting regulation and standards relevant to researching, manufacturing, marketing, managing and distributing nanomaterials at all stages of industrial development. Lee, Stokes, Vaughan and Groves made up the group funded to create PAS 137 which was written between 2009 and 2013 (and published in October 2013)[5.5].

Rejection of a nanotechnology moratorium

Non-governmental organisations (e.g. Friends of the Earth, Action Group on Erosion, Technology and Concentration) called for a moratorium on nanotechnology development and use until the risks could be more accurately assessed. Research by the Cardiff team, including Stokes' 2009 paper[3.4], concluded a moratorium would incur high administrative and compliance costs and would have an inhibitive effect on innovation. This research underpinned a briefing to policy-makers helping to shape a 2009 UK Government statement on nanotechnology: "The Government agrees with…the Economic and Social Research Centre for Business Relationships, Accountability, Sustainability and Society that a moratorium on the marketing of nanotechnologies would not be an appropriate response."[5.4]

Impact on industry and the wider public

As a direct result of the DTI report, Lee became an invited member of Defra's Social and Economic Dimensions of Nanotechnologies Task Force, its overarching body – the Nanotechnology Research Coordination Group (which met until the end of 2009) and the Research Councils United Kingdom Nanoscience Strategic Advisory Team. These groups set research objectives on behalf of government departments, regulatory agencies and research councils, helping to shape the research agendas and horizon-scanning activities of industry practitioners, scientists and research councils responsible for the research and development of novel technologies[5.7].

Research has also contributed to the development of public information resources. Stokes compiled pages about the regulation system for the Nano & Me (www.nanoandme.org) website funded by the Department for Business Innovation and Skills (BIS), described by Professor Andrew Maynard (science and technology blogger at 2020science.org), as 'quite possibly the best one-stop-shop for down to earth information on nanotech around' and by the Nanotechnology Stakeholder Forum as "a good platform from which to engage stakeholders including the public, consumers and industry". Lee and Stokes wrote a section on regulation for the UK Environmental Law Association's website "Law and Your Environment" (for advice agencies and citizens) which gets 30,000 monthly visits.

International impact

The Organisation for Economic Co-operation and Development (OECD) recommended the DTI report to its Working Party on Manufactured Nanomaterials (WPMN - particularly Steering Group 5 on regulatory measures). WPMN held six meetings (meeting numbers 3 to 8) between 2008 and 2011. In so doing OECD identified the DTI report's relevance beyond the UK: "The [DTI] report finds that in the interim, the existing framework can be adapted generally by ensuring that where appropriate the regulation extends to nanomaterials. In this context the work of international standard setting bodies is crucial in resolving issues of definition and taxonomy, allowing effective standard setting in relation to nanoparticles and opening up the prospects of a uniform global response to the marketing and circulation of nanomaterials."[5.8]

In 2009 the team submitted written evidence on regulation and engagement to the EU Consultation on a Strategic Nanotechnology Action Plan. In the same year, in Canada, the Regulatory Governance Initiative noted that "an interesting aspect of the Cardiff report was their approach of examining a lifecycle approach to the regulation of nanomaterials"[5.9]. The German Federal Institute for Occupational Health and Safety cited the DTI report as contributing to the "statutory background" to its research strategy[5.10] (which identified urgent priorities implemented between 2008 and 2010).

5. Sources to corroborate the impact

1. Royal Commission on Environmental Pollution, 27th Report, *Novel Materials in the Environment: The Case of Nanomaterials* Cm 7468, November 2008, http://www.official-documents.gov.uk/document/cm74/7468/7468.pdf 4.43 and 4.52 call for adaptation of the regulatory regime. Appendix J cites Cardiff analysis of legislation.
2. House of Lords' Select Committee *Nanotechnologies and Food* (First report, 2009-2010, January 2010 Volume I Report, Volume II Written Evidence) cites the team submission based on the DTI report at p.53. http://www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/22i.pdf
3. http://www.bis.gov.uk/assets/goscience/docs/u/10-825-uk-nanotechnologies-strategy.pdf paragraph 53 (page 27 of 55) of this 2010 Department of Business, Innovation and Skills publication confirms that Departments and Agencies within Government are working to ensure that the regulatory gaps identified by the team's DTI report are addressed.
4. http://webarchive.nationalarchives.gov.uk/+/http://www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf confirms Cardiff's influence on Government moratorium rejection.
5. The Foreword of PAS 137: 2013 acknowledges Lee, supported by Stokes and Vaughan, as technical author of the document, confirms the Law School/BRASS team's involvement in the development of the specification and identifies organisations involved in the Steering Group. Copy available from the HEI as a pdf, on request.
6. Defra Chemicals and Emerging Technologies Advisor will confirm the research's influence on the Nanotechnology Stakeholders' Forum.
7. http://www.rcuk.ac.uk/research/xrcprogrammes/prevprogs/nano/further/Pages/Strategicadvisory.aspx confirms Lee's membership of the RCUK Nanotechnology Strategic Advisory Team.
8. http://www.oecd.org/fr/env/ess/nanosecurite/anoverviewoftheframeworkofcurrentregulationaffectingthedevelopmentandmarketingofnanomaterials.htm confirms the OECD's application of the research outside the UK.
9. Pelley J and Saner M, *International Approaches to the Regulatory Governance of Nanotechnology*. Regulatory Governance Initiative, Carleton University, Canada http://www.regulatorygovernance.ca/publication/regulation-paper-nanotechnology-regulation-paper/wppa_open/ confirms Cardiff's influence on the lifecycle approach to nanomaterial regulation.
10. BAuA, http://www.baua.de/cae/servlet/contentblob/717962/publicationFile/48347/research-strategy.pdf confirms the research as background to German research strategy at p 11 and dates for implementation of urgent research at pp47-52.

(All documents and web pages saved as pdfs and available on request from the HEI)