The Private Dimension in the Regulation of Nanotechnologies: Developments in the Industrial Chemicals Sector

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ABSTRACT

This Article examines the rise of self-regulation for nanotechnologies with particular attention to the initiatives within the industrial chemical sector. These initiatives may be viewed as a window into the evolution of nanotechnologies more broadly. The commercialization of nanotechnology-based products has taken place against a backdrop of regulators and risk assessors attempting to evaluate the adequacy of conventional risk assessment paradigms. These assessments aim to predict the potential risks of engineered nanoparticles (ENPs), including bio-persistent ENPs, which have increasingly found their way into a range of consumer products including, for example, personal care products. Such products have emerged despite concerns over the lack of risk assessment data. Notwithstanding current gaps in knowledge, one leading scientific commentator has stated that "there has been enough [research into risks] to reasonably conclude that there are some applications that will present problems."[1] In addition, our focus on this sector is due not only to the industry's earlier success with the Responsible Care program, but also to the transatlantic regulatory divergence that has recently occurred

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1. ANDREW D. MAYNARD, NANOTECHNOLOGY: A RESEARCH STRATEGY FOR ADDRESSING RISK 8 (2006).

with the implementation of the REACH Regulation in the European Union.[2]

The industrial chemicals sector therefore presents an interesting case study in how different countries and regulatory cultures choose to approach similar problems of adequately regulating under existing regimes, and more challengingly, future nanotechnology-based products and processes. This is a crucial issue because the limited number of government and independent regulatory reviews that have been undertaken in the United Kingdom, the European Union, the United States and Australia suggest that, while for the most part these products and applications will fall under existing instruments, some gaps or weaknesses do exist. Recognition of current limitations in science and law has acted as a catalyst for industry to develop their own responses to ensure the responsible development of nanotechnologies. These proactive initiatives have included the development and implementation of risk governance and risk management frameworks, in addition to both individual and collective codes of conduct. Importantly, they do not seek to replace current regulatory requirements, but rather supplement them where the organisations perceive regulatory gaps. However, the vital question remains: can citizens and governments rely on the private sector to adequately regulate their own behaviour as they seek to maximise returns from their investments?

Drawing on these issues, this Article argues that credibility, transparency, independent oversight, and sanctions are pivotal components to any effective self-regulatory scheme and that they should be core elements of regulatory solutions and instruments being developed and utilised by the private sector.

2. For an analysis of the REACH regime, *see generally* Daniel A. Farber, *Five Regulatory Lessons from REACH* (UC Berkeley Pub. Law & Legal Theory Research Paper Series, Paper No. 1301306, 2008), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id= 1301306. *See also* EUROPEAN COMMISSION, ENV'T DIRECTORATE GEN., REACH IN BRIEF (2007) http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf; Anna Gergely, *Regulation of Nanotechnology - within REACH?*, NANO NOW, Feb. 2007, at 44.

I. INTRODUCTION

Most aspects of contemporary life are affected by regulation to a greater or lesser degree. Regulation influences how people and societies eat, drink, travel, work, play and interrelate generally. This is true for less developed as well as advanced economies. The strategic importance of regulation in daily life is increasing rapidly in all countries around the world as the effects of globalisation and dynamic technological development grow in their extent and intensity, and national economies and societies become more interconnected and interdependent.

Regulation has a ubiquitous effect on and in societies around the globe, and it is into this "Brave New Regulatory World" that nanotechnologies are entering. It is quite possible that the impacts of nanotechnologies may also have ubiquitous effects as this century develops. The technology promises to have a significant impact across all industry sectors, with some commentators suggesting that advancements are "likely to be at least as great as that of the Industrial Revolution."[3] While the nanotechnology "label" has emerged relatively recently, this heterogeneous family of technologies has already engendered a high degree of enthusiasm from both the public and private sectors alike, along with attendant lofty expectations.

The strategic importance of nanotechnologies in the short-to-medium term has prompted government and industry alike to invest heavily in research and development (R&D) programs. A recent article by Andrew Maynard and David Rejeski of the Project on Emerging Nanotechnologies provides an insight into the current level of nanotech-funding around the world, with the authors noting that global public and private spending on R&D-related activities was in the vicinity of $18 billion U.S. dollars per year.[4] This can be compared to the levels of global funding in 2004, which Lux Research estimated to be in the ball-park of $10

3. Fredrick A. Fiedler & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593, 595 (1994).
4. Andrew Maynard & David Rejeski, *Too Small to Overlook*, 460 NATURE 174 (2009).

billion U.S. dollars per year, with the greatest proportion of this funding being provided by the public sector at that time.[5] While both figures are somewhat speculative, the rapid increase in investment in R&D activates—some $8 billion U.S. dollars over five years—is suggestive of the increasing perceived importance of the technology to both the private and public sectors.

Against this backdrop, it has been suggested that since 2005 private sector investment has equaled and subsequently surpassed that of the public sector. As this Article discusses, private sector actors have also have been prominent in the development of regulatory initiatives relating to nanotechnologies.

Based on global R&D activities, it is not surprising that the number of nanotechnology-based products has been purported to have increased dramatically over the last three or four years.[6] With engineered nanoparticles (ENPs) having already been incorporated into product categories ranging from cosmetics to therapeutic goods, paints, construction materials and food contact materials, the number of people already involved in the manufacture or transportation of ENPs, as well as those actively utilising these products is likely to be significant at this time. Industry experts have hypothesised that this trend will accelerate over the coming decade as the technologies mature, developers see new commercialisation opportunities, and consumer demand increases for new or improved products across industry sectors.[7] Predicted human and environmental benefits associated with many of the anticipated products are broad and include, for example, a so-called paradigm shift for the health care sector through nano-medicines.[8]

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5. *Nanotechnology: Where Does the U.S. Stand?: Hearing Before the Subcomm. on Research of the H. Comm. on Sci.*, 109th Cong. 5 (2005).

6. *See, e.g.*, The Project on Emerging Nanotechnologies Consumer Products Page, http://www.nanotechproject.org/inventories/consumer/ (last visited Aug. 4, 2010).

7. *See, e.g.*, Mihail C. Roco & William S. Bainbridge, *Societal Implications of Nanoscience and Nanotechnology: Maximizing Human Benefit*, 7 J. NANOPARTICLE RESEARCH 1 (2005); LUX RESEARCH, THE NANOTECH REPORT 2004: INVESTMENT OVERVIEW AND MARKET RESEARCH FOR NANOTECHNOLOGY (3d ed. 2004); CIENTIFICA, HALF WAY TO THE TRILLION DOLLAR MARKET? A CRITICAL REVIEW OF THE DIFFUSION OF NANOTECHNOLOGIES (2007); CIENTIFICA, THE NANOTECHNOLOGY OPPORTUNITY REPORT (3d ed. 2008).

8. EUR. SCIENCE FOUND., NANOMEDICINE (2005). *See also* Mauro Ferrari, *Cancer Nanotechnology: Opportunities and Challenges*, 5 NATURE REVIEWS CANCER 161 (2005); S.K. Sahoo, S. Parveen & J.J. Panda, *The Present and Future of Nanotechnology in Human Health Care*, 3 NANOMEDICINE: NANOTECHNOLOGY, BIOLOGY & MED. 20 (2007); Moein S. Moghimi, Christy A. Hunter & Clifford J. Murray,

Notwithstanding these benefits, there is increasing concern among members of the scientific community that the very properties that make ENPs attractive from a product and investment point of view may have the potential to give rise to unintended health and safety consequences.[9] For example, studies have shown that under specific experimentation parameters, certain types of carbon nanotubes display toxic and pathogenic behaviour.[10] Importantly however, the authors of these studies have, along with other commentators, noted a number of caveats in relation to these findings.[11] The Royal Commission on Envi-

Nanomedicine: Current Status and Future Prospects, 19 J. OF THE FEDERATION OF AM. SOCIETIES FOR EXPERIMENTAL BIOLOGY 311 (2005).

9. *See, e.g.*, THE ROYAL SOC'Y AND ROYAL ACAD. OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004), *available at* http://www.nanotec.org.uk/finalReport.htm; Maria C. Powell & Marty S. Kanarek, *Nanomaterial Health Effects - Part 1: Background and Current Knowledge*, 105 WIS. MED J. 16 (2006); Maria C. Powell & Marty S. Kanarek, *Nanomaterial Health Effects - Part 2: Uncertainties and Recommendations for the Future*, 105 WIS. MED J. 18 (2006); Andrew D. Maynard et al., *Safe Handling of Nanotechnology*, 444 Nature 267 (2006); Andrew D. Maynard, *Nanotechnology: The Next Big Thing, or Much Ado About Nothing?*, 51 ANN. OF OCC. HYG. 1 (2007); ROYAL COMMISSION ON ENVTL. POLLUTION, NOVEL MATERIALS IN THE ENVIRONMENT: THE CASE OF NANOTECHNOLOGY (2008); SCIENTIFIC COMM. ON CONSUMER PRODUCTS, OPINION ON SAFETY OF NANOMATERIALS IN COSMETIC PRODUCTS (2007); EUR. FOOD & SAFETY AUTH., SCIENTIFIC OPINION: THE POTENTIAL RISKS ARISING FROM NANOSCIENCE AND NANOTECHNOLOGIES ON FOOD AND FEED SAFETY - SCIENTIFIC OPINION OF THE SCIENTIFIC COMMITTEE (QUESTION NO. EFSA-Q-2007-124A) (2009); Karinne Ludlow, *One Size Fits All? Australian Regulation of Nanoparticle Exposure in the Workplace*, 15 J.L. & MED. 136 (2007) (arguing that occupational exposure is "likely to be the most serious and immediate environmental, health and safety concern raised by nanomaterials").

10. *See, e.g.*, Robert F. Service, *Nanotubes: The Next Asbestos?*, 281 SCI. 941 (1998); Craig A. Poland et al., *Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos like Pathogenicity in a Pilot Study*, 3 NATURE NANOTECHNOLOGY 423 (2008); FRIENDS OF THE EARTH AUSTRALIA & FRIENDS OF THE EARTH U.S., NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS (2006); Ken Donaldson et al., *Carbon Nanotubes: A Review of Their Properties in Relation to Pulmonary Toxicology and Workplace Safety*, 92 TOXICOLOGY SCIENCES 5 (2006); Gunter Oberdörster, Vicki Stone & Ken Donaldson, *Toxicology of Nanoparticles: A Historical Perspective*, 1 NANOTOXICOLOGY 2 (2007); Ludlow, *supra id.*; SWISS RE, NANOTECHNOLOGY: SMALL MATTER, MANY UNKNOWNS (2004); Atsuya Takagi et al., *Induction of Mesothelioma in p53+/- Mouse by Intraperitoneal Application of Multi-wall Carbon Nanotubes*, 33 J. OF TOXICOLOGICAL SCIENCES 105 (2008).

11. *See, e.g.*, Agnes B. Kane & Robert H. Hurt, *The Asbestos Analogy Revisited*, 3 NATURE NANOTECHNOLOGY 378 (2008) (Kane and Hurt who have noted that the studies are very specific, and as such, the findings cannot be extrapolated so as to be applied to all types of CNTs); John C. Monica, Jr. & John C. Monica, *A Nano-Mesothelioma False Alarm*, 5 NANOTECHNOLOGY L. & BUS. 319 (2008) (Monica and Monica have also stated that such studies are not necessarily representative of real world human exposure scenarios).

ronmental Pollution acknowledged, for example, that there are plausible concerns relating to the potential toxicity of some ENPs under certain conditions and consequently have called for directed research programs to address these uncertainties.[12]

Even where adverse results have been demonstrated and reported, the authors of such studies have commented on the need for "further research"[13] and cautioned against the generalisation or extrapolation of researching findings from one specific type of ENP to other nanoscale particles.[14] Such statements have done little to placate the growing anxiety being voiced by some stakeholders including Friends of the Earth Australia[15] and the International Center for Technology Assessment[16] over the potential risks posed by certain aspects of nanotechnologies. A number of recent high profile reports and peer-reviewed articles within the scientific literature have not significantly lessened these concerns.[17]

For the most part, however, it has been suggested that when ENPs are fixed or embedded into solid matrices or materials, the particles are unlikely to present a toxicological hazard to either humans or the environment because in this state they are unable to interact with biological systems and cause harm.[18] The majority of consumer products will incorporate fixed ENPs, and consequently pose little concern at this time. By contrast, free ENPs (i.e., those not within a matrix) have greater mobility and may interact with biological systems and processes and impact on human and environmental safety. Exposure to free ENPs appears most likely during the manufacturing and production of

12. ROYAL COMMISSION ON ENVTL. POLLUTION, *supra* note 9, at 32-52.

13. Eva Oberdörster, *Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 ENVTL. HEALTH PERSPECTIVES 1058, 1058-1062 (2004); POLAND, *supra* note 10, at 423.

14. Nancy A. Monteiro-Riviere & Alfred O. Inman, *Challenges for Assessing Carbon Nanomaterial Toxicity to the Skin*, 44 CARBON 1070 (2006); Kane & Hurt, *supra* note 11, at 379.

15. FRIENDS OF THE EARTH AUSTRALIA, MOUNTING EVIDENCE THAT CARBON NANOTUBES MAY BE THE NEW ASBESTOS (2008); FRIENDS OF THE EARTH, *supra* note 10; RYE SENJEN & IAN ILLUMINATO, NANO & BIOCIDAL SILVER (2009).

16. INT'L CENT. FOR TECH. ASSESSMENT, CITIZEN PETITION TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION (2006); INT'L CENT. FOR TECH. ASSESSMENT, GROUPS DEMAND EPA STOP SALE OF 200+ POTENTIALLY DANGEROUS NANO-SILVER PRODUCTS (2008).

17. *See, e.g.*, Oberdörster, *supra* note 13; Carlos Medina et al., *Review: Nanoparticles: Pharmacological and Toxicological Significance*, 150 BRIT. J. PHARMACOLOGY 552 (2007).

18. ROYAL SOC'Y, *supra* note 9, at 47.

ENPs when in the dry form, during the handing and transportation phase (prior to the ENPs being fixed), and in certain types of consumer products, such as cosmetics.[19] It would appear that there is the potential for exposure to also occur upon the break down or recycling of products containing what were initially fixed ENPs.[20]

The scaling up of global manufacturing of ENPs combined with questions over hazard and exposure has, unsurprisingly, resulted in a number of commentators questioning the ability of governments to adequately govern the technology.[21] Such concerns are not unique to nanotechnologies *per se*, with the Royal Commission on Environmental Pollution having eloquently reminded us that "the policy challenge posed by novel materials is a specific instance of the more general dilemma of how to govern the emergence of new technologies which, by definition, cannot be fully characterised with respect to their potential benefits and drawbacks".[22] While there appears to be a growing consensus among stakeholders that some sort of amendments are required to the current governance regimes, questions remain as to the form that these changes should take, and the speed at which they should be implemented. There is, however, much that can be learned from the emergence of governance structures for earlier technologies, products, or applications, especially those either in their formative stages or which have evolved rapidly and as such, have been difficult to regulate through traditional command and control approaches.

This Article focuses in particular on how private sector actors have, to date, been influential in the political economy context of regulating nanotechnologies. Section II discusses some of the models of regulation that have had widespread influence under conditions of late-modern capitalism and which conceptual lenses we feel can be useful not only in helping to deconstruct debates about how nanotechnologies have been regulated to date

19. NSW LEGIS. COUNCIL STANDING COMM. ON STATE DEV., NANOTECHNOLOGY IN NSW 39 (2008).

20. ROYAL COMMISSION ON ENVTL. POLLUTION, *supra* note 9, at 30.

21. *See, e.g.*, ETC GROUP, NANOTECH PRODUCT RECALL UNDERSCORES NEED FOR NANOTECH MORATORIUM (2006); CONSUMER COALITION, PRINCIPLES FOR THE OVERSIGHT OF NANOTECHNOLOGIES AND NANOMATERIALS (2007), *available at* http://nanoaction.org/nanoaction/doc/nano-02-18-08.pdf; NSW, *supra* note 19; COMM. ON THE ENV'T, PUB. HEALTH & FOOD SAFETY, EURO. PARLIAMENT, DRAFT REPORT ON REGULATORY ASPECTS OF NANOMATERIALS (2008/2208(INI)) (2009).

22. ROYAL COMMISSION ON ENVTL. POLLUTION, *supra* note 9, at 7.

but also how they might be expected to be regulated into the future. Section III examines specific regulation initiatives and how contemporary regulatory infrastructure for nanotechnologies has evolved. Section IV focuses specifically on the industrial chemicals sector as a case study in the emergence of nanotechnology-specific regulation, and in particular, the roles played by private sector actors in these processes. Section V concludes the paper by 'crystal-gazing' and offers some projections, based on earlier analysis as to how one might expect regulation for nanotechnology-based products and process to develop.

II.
REGULATORY MODELS AND NANOTECHNOLOGIES

Regulation, as suggested by Black, "attempt[s] to alter the behaviour of others with the intention of producing a broadly identified outcome or outcomes."[23] There are a substantial number of regulatory models which sit squarely within this broad definition of regulation, some of which can operate in some contexts in a fairly discrete fashion, while at other times or in other contexts, meld with other regulatory models to varying degrees.

Deconstructing which regulatory models are likely to be influential in regards to nanotechnologies—and to what extent across jurisdictions and within the international sphere—is an inexact science. To date, production and applications incorporating nanotechnologies have largely been regulated under traditional 'command and control' frameworks established by state-based instruments. These include, for example, Acts, Regulations, Directives and Government Guidelines. This long-established approach to regulation has considerable legitimacy with the public because of their compulsory nature and the appearance of strong accountability. Ludlow, Bowman and Kirk have suggested that, "[c]lear and consistent state-based regulation can provide many advantages compared with no regulation. For example, industry might prefer this form of regulation because it provides a level playing field and protection against short-cutting competitors."[24]

That being said, over the last few decades there has been a movement away from reliance on highly prescriptive forms of

23. Julia Black, *Critical Reflections on Regulation*, 27 AUSTRALIAN J. LEGAL PHIL. 1, 19 (2002).

24. Karinne Ludlow, Diana M. Bowman & Dwayne D. Kirk, *Hitting the Mark or Falling Short with Nanotechnology Regulation?*, 27 TRENDS IN BIOTECH. 615, 615 (2009).

regulation generally, with governments preferring instead to rely on models of self-regulation and co-regulation. This shift would appear to be in part due to the growing awareness of the limitations or weaknesses of traditional state-based regulatory approaches.[25] Perceived limitations of command and control regulation include an inherent lack of flexibility, significant costs associated with implementation and oversight, the stifling of innovation, and being slow to respond to the various challenges placed before it.[26] The movement away from command and control regulation would also, in the words of Gunningham and Rees, appear to be a response to "the broader problem of regulatory overload."[27]

Levi-Faur and Comaneshter have noted that command and control regulation is traditionally utilised by the state when the designers of the system "know and define the problems and the solutions in advance, and design the rules to mandate those responses."[28] Information deficiencies surrounding the development trajectory and the risks posed by nanotechnologies would therefore appear to challenge the designers of any such legal framework as they face the pressing current need to craft a suitable solution. This limitation would appear to be widely recognised by governments and regulatory bodies and is arguably a significant reason as to why many cities/governmental actors have largely resisted the temptation to enact new legislative arrangements for areas of particular concern.

Against this backdrop, there are a number of regulatory models that have become increasingly prominent. These include self-regulation and co-regulation. The Australian Office of Regulatory Review in its 1998 *Guide to Regulation* noted that "[s]elf-

25. Darren Sinclair, *Self-Regulation Versus Command and Control? Beyond False Dichotomies*, 19 DENV. L. & POL'Y. 529 (1997); Marius Aalders & Ton Wilthagen, *Moving Beyond Command-and-Control: Reflexivity in the Regulation of Occupational Safety and Health and the Environment*, 19 DENV. L. & POL'Y. 415 (1997).

26. Cass R. Sunstein, *Paradoxes of the Regulatory State*, 57 U. CHI. L. REV. 407 (1990); Alan Moran, *Tools of Environmental Policy: Market Instruments Versus Command-and-Control, in* MARKETS, THE STATE AND THE ENVIRONMENT: TOWARDS INTEGRATION (1995); Sinclair, *supra id.* .; PETER UTTING, RETHINKING BUSINESS REGULATION: FROM SELF-REGULATION TO SOCIAL CONTROL (2005).

27. Neil Gunningham & Joseph Rees, *Industry Self-Regulation: An Institutional Perspective*, 19 DENV. L. & POL'Y 363, 363 (1997).

28. David Levi-Faur & Hanna Comaneshter, *The Risks of Regulation and the Regulation of Risks: The Governance of Nanotechnology, in* NEW GLOBAL REGULATORY FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 149, 155 (Graeme Hodge, Diana Bowman & Karinne Ludlow eds., 2007).

regulation is generally characterised by industry formulating rules and codes of conduct, with industry solely responsible for enforcement. . ."[29] Strong supporters of self-regulation see it as flexible, informed, responsive, targeted and likely to promote regulatory compliance.

Self-regulation is not, however, homogenous in nature. Black has articulated seven different types of self-regulation:[30]

1. Mandated—a collective group is required or designated by the government to formulate and enforce norms within a broad framework set by government
2. Sanctioned—the collective group formulates rules which are then approved by the government
3. Coerced—the collective group formulates and imposes regulation, but only in response to the threat of statutory regulation ("regulation in the shadow of the law")
4. Voluntary—no government involvement, direct or indirect, in promoting or mandating self-regulation
5. Stakeholder—involvement with other groups in the regulatory process such as NGOs or consumer groups
6. Verified—where third parties such as auditors are responsible for monitoring compliance, and
7. Accredited—when rules and compliance are accredited by another non-governmental body such as a standards council or other technical committee.

As with state-based regulation, models of self-regulation have been viewed as suffering from a range of perceived limitations. Detractors of self-regulation have, for example, labeled it as tending to be self-interested, self-serving and lacking in sanctions. It has also been suggested that self-regulation lacks the accountability and legitimacy of government regulation.[31] Gunningham and Rees have also noted that in relation to self-regulation "the effectiveness (or ineffectiveness) of self-regulation [can] var[y] enormously among industries. . ."[32]

29. AUSTRALIAN OFFICE OF REGULATION REVIEW, A GUIDE TO REGULATION E8 (2d ed. 1998).

30. Julia Black, *Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a 'Post-Regulatory World'*, 54 CURRENT LEGAL PROBS. 103 (2001).

31. *See, e.g.*, John Braithwaite, *Responsive Regulation for Australia*, *in* BUSINESS REGULATION AND AUSTRALIA'S FUTURE 81 (Peter Grabosky & John Braithwaite eds., 1993) (discussing the perceived limitations of self-regulation); Kernaghan Webb & Andrew Morrison, *The Legal Aspects of Voluntary Codes*, *in* EXPLORING VOLUNTARY CODES IN THE MARKETPLACE SYMPOSIUM (David Cohen & Kernaghan Webb eds., 1996).

32. Gunningham & Rees, *supra* note 27, at 370.

Sitting at the interface of models of state-based regulation and self-regulation is co-regulation. This model of regulation usually refers to the situation where industry develops and administers its own arrangements, but governments provide legislative backing to enable the arrangements to be enforced. These can then be employed to underpin the codes or standards. Interdependencies and interactions between government and social actors are ongoing in regulatory praxis, and can be local, regional or international. Thus, regulation is "co-produced."[33] Co-regulation is perhaps the fastest growing model at the present time under conditions of late-modern capitalism and globalisation, as it has the potential to be shaped most easily to meet both state and private actor interests. This inherent flexibility of co-regulation may well result in it emerging as the most prevalent regulatory model with respect to nanotechnologies. However, the more interesting issues are not simply some putative ranking of regulatory model influence, but rather the processes by which co-regulation and other regulatory models gain influence, and the primary drivers in different jurisdictions and in different industries. Consideration of such issues, it would appear, sit at the very core of the current debates regarding the regulation of, for example, consumer products containing nanomaterials, industrial nanomaterials and worker exposure to ENPs.

Regulation in an era of late-modern capitalism inevitably involves interdependence between sophisticated and powerful private sector actors. This dynamic is played out against a backdrop of state participation that varies between different jurisdictions at any time and within any individual jurisdiction at different times. The most dominant regulatory influence under capitalism has been that of large private corporations that pursue private sector success but which share public characteristics with state agencies and the communities with which they operate. As this Article demonstrates, the short history of regulating nanotechnologies to date shows similar influences at work. We should not be too surprised by this because, as Baldwin and Cave note, in general, "the commodity of regulation would go to those who valued it most and producers would thus tend to be better served by regu-

33. CLAUS OFFE, CONTRADICTIONS OF THE WELFARE STATE, STUDIES IN CONTEMPORARY GERMAN SOCIAL THOUGHT 310 (John Keane ed., 1984).

lation than the (more diffused, less organized) masses of consumers."[34]

Given the myriad of parties interested in how different facets of nanotechnologies should be regulated and the different capacities that they possess to shape regulation, we contend that a legitimacy orientation possesses significant interpretative potential for understanding the emerging regulatory praxis for nanotechnologies. Legitimacy affects the character of power relations and can help explain systems of power, not only how power works as an ongoing process, but also how it originates. In Beetham's view, there are two types of legitimacy: one is a story of developmental stages; and the other is how self-confirming processes are at work within more settled sets of power relations to reproduce and consolidate their legitimacy.[35] This power of routinisation and its capacity for self-affirmation should not be under-estimated. However, this cycle is never perfect or complete, and is open to contextual influences, whether those influences reside in arenas as diverse as the domestic political sphere or the international regulatory context. Nanotechnologies and their associated regulatory issues will of course, by virtue of their inherent character, feature both in domestic and multilateral contexts. Legitimacy is integral to any system of regulation or body of knowledge and it can reside in positions of authority or in institutions. However, it is a complex concept involving not only beliefs, but also legality, judicial determination, the potential for differential interpretation, and consent, both active and passive. As we consider how legitimacy and consent have affected the regulation of nanotechnologies, it is important to remember that they can be highly affected by cultural and political specifics. Therefore, notions of legitimacy and consent can be subject to various and sometimes competing interpretations. Perceptions of legitimacy can be fluid in certain contexts, and on certain issues, so it is helpful to think of it as a continuum of belief and evaluation.[36]

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34. Robert Baldwin & Martin Cave, Understanding Regulation: Theory, Strategy, and Practice 22 (1999).

35. David Beetham, The Legitimation of Power 98-99 (1991).

36. Mark C. Suchman, *Managing Legitimacy: Strategic and Institutional Approaches*, 20 Acad. of Mgmt. Rev. 571, 571 (1995).

III.
THE EVOLUTION OF REGULATION FOR NANOTECHNOLOGIES

As nanotechnologies have matured and products and processing incorporating nanoscale materials have become increasingly tangible, it would appear that so too have the concerns about them. Whereas the focus of many of the earlier debates was on the regulation of nanotechnologies generally, recent contributions have been more specific and have begun to differentiate discrete areas and ENP families which may present the most significant challenges to health and safety, and, consequently, the regulatory regimes. As noted in Section I, the area of greatest concern at this stage is the manufacturing, handling and transportation of free ENPs.[37] The use of free ENPs within a range of consumer products, including food and food contact materials,[38]

37. *See* CEMENT CONCRETE & AGGREGATES AUSTRALIA, SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE: INQUIRY INTO WORKPLACE EXPOSURE TO TOXIC DUST 1 (2005), http://www.aph.gov.au/Senate/committee/clac_ctte/completed_inquiries/2004-07/toxic_dust/submissions/sub28.pdf; R.J. Aitken et al., *Manufacture and Use of Nanomaterials: Current Status in the UK and Global Trends*, 56 OCCUPATIONAL MED. 300 (2006); CEMENT CONCRETE & AGGREGATES AUSTRALIA, SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE, WORKPLACE EXPOSURE TO TOXIC DUST 1 (2005), http://www.aph.gov.au/senate/committee/clac_ctte/completed_inquiries/2004-07/toxic_dust/report/report.pdf; HEALTH AND SAFETY EXECUTIVE, REVIEW OF THE ADEQUACY OF CURRENT REGULATORY REGIMES TO SECURE EFFECTIVE REGULATION OF NANOPARTICLES CREATED BY NANOTECHNOLOGY: THE REGULATIONS COVERED BY HSE (2006), http://www.hse.gov.uk/horizons/nanotech/regulatoryreview.pdf; Ludlow, *supra* note 9; NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH NANOTECHNOLOGY RESEARCH CTR., PROGRESS TOWARDS SAFE NANOTECHNOLOGY IN THE WORKPLACE (2007), *available at* http://www.cdc.gov/niosh/docs/2007-123/pdfs/2007-123.pdf; NEW SOUTH WALES PARLIAMENT LEGISLATIVE COUNCIL STANDING COMM. ON STATE DEV., NANOTECHNOLOGY IN NEW SOUTH WALES (2008), *available at* http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/35d2e3e37498a908ca2574f1000301bb/$FILE/Final%20Report%20Oct.pdf.

38. *See* ETC GROUP, DOWN ON THE FARM: THE IMPACT OF NANO-SCALE TECHNOLOGIES ON FOOD AND AGRICULTURE (2004), *available at* http://www.etcgroup.org/upload/publication/80/01/etc_dotfarm2004.pdf; MICHAEL R. TAYLOR, REGULATING THE PRODUCTS OF NANOTECHNOLOGY: DOES FDA HAVE THE TOOLS IT NEEDS? (2006), *available at* http://nanotechproject.org/file_download/files/PEN5_FDA.pdf; GEORGIA MILLER & RYE SENJEN, OUT OF THE LABORATORY AND ON TO OUR PLATES: NANOTECHNOLOGY IN FOOD & AGRICULTURE (2008), *available at* http://www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf; Scientific Comm., Eur. Food & Safety Auth., Scientific Opinion, *The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety*, 958 EFSA J. 1 (2009), *available at* http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en,0.pdf?ssbinary=true; Parliament.uk, Call for Evidence: Nanotechnologies and Food, http://www.parliament.uk/parliamentary_committees/lords_s_t_select/cfenanotechfood.cfm (last visited Sept. 18, 2009);

the use of insoluble, biopersistent ENPs within topically applied personal care products (including cosmetics) and sunscreens,[39] and the subsequent impact of such ENPs on the environment have similarly been identified as potential areas of concern by a number of stakeholders,[40] including those within the European Parliament.[41]

The scientific uncertainties associated with ENPs and challenges thereof in safeguarding human and environmental safety have resulted in some commentators calling upon governments to implement regulatory change. These calls have varied from more modest requests at one end calling upon government to tweak existing regulatory instruments, to the more extreme calls for moratoriums on, for example, "the further commercial release of personal care products that contain engineered nano-

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Anna Gergely, Diana Bowman & Qasim Chaudhry, *Small Ingredients in a Big Picture: Regulatory Perspectives on Nanotechnologies in Foods and Food Contact Materials*, *in* NANOTECHNOLOGIES IN FOOD (Qasim Chaudhry, Lawrence Castle & Richard Watkins eds., 2010).

39. *See* GEORGIA MILLER, FRIENDS OF THE EARTH AUSTRALIA, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS (2006), *available at* http://www.foeeurope.org/activities/nanotechnology/nanocosmetics.pdf; Nic Fleming, *Women Buying Creams Made of Tiny Particles 'Used as Guinea Pigs,'* THE DAILY TELEGRAPH (London), May 5, 2006, at 6; TAYLOR, *supra* note 38; Diana M. Bowman & Geert van Calster, *Flawless or Fallible? A Review of the Applicability of the European Union's Cosmetics Directive in Relation to Nano-Cosmetics*, 2 STUD. IN ETHICS, L., & TECH. 1 (2008); ANTJE GROBE, ORTWIN RENN & ALEXANDER JAEGER, INTERNATIONAL RISK GOVERNANCE COUNCIL, RISK GOVERNANCE OF NANOTECHNOLOGY APPLICATIONS IN FOOD AND COSMETICS (2008), *available at* http://www.irgc.org/IMG/pdf/IRGC_Report_FINAL_For_Web.pdf; Tom Faunce et al., *Sunscreen Safety: The Precautionary Principle, the Australian Therapeutic Goods Administration and Nanoparticles in Sunscreens*, 2 NANOETHICS 231 (2008).

40. *See* Richard Owen & Michael Depledge, *Nanotechnology and the Environment: Risks and Rewards,* 50 MARINE POLLUTION BULL. 609 (2005); QASIM CHAUDHRY ET AL., FINAL REPORT: A SCOPING STUDY TO IDENTIFY GAPS IN ENVIRONMENTAL REGULATION FOR THE PRODUCTS AND APPLICATIONS OF NANOTECHNOLOGIES (Mar. 17, 2006) *available at* http://www.defra.gov.uk/science/project_data/DocumentLibrary/CB01075/CB01075_3373_FRP.doc; AUSTRALIAN COUNCIL OF TRADE UNIONS, FACT SHEET: NANOTECHNOLOGY – WHY UNIONS ARE CONCERNED (2009), *available at* http://www.actu.asn.au/Images/Dynamic/attachments/6494/actu_factsheet_ohs_-nanotech_090409.pdf; ROYAL COMMISSION, *supra* note 9.

41. *See* Press Release, European Parliament, MEPs Approve New Rules on Safer Cosmetics (Mar. 24, 2009), *available at* http://www.europarl.europa.eu/news/expert/infopress_page/066-52333-082-03-13-911-20090323IPR52331-23-03-2009-2009-true/default_en.htm; CARL SCHLYTER, COMM. ON THE ENV'T, PUB. HEALTH & FOOD SAFETY, EUR. PARLIAMENT, DRAFT REPORT ON REGULATORY ASPECTS OF NANOMATERIALS (2009), *available at* http://www.europarl.europa.eu/meetdocs/2004_2009/documents/pr/763/763225/763225en.pdf.

materials"[42] and "the use of synthetic nanoparticles in the lab and in any new commercial products."[43] In these instances, moratoriums have been demanded until the potential scientific risks of ENPs in these contexts are understood well enough so as to allow governments to implement the appropriate safeguards.

There have of course been numerous initiatives and projects initiated across different jurisdictions and involving a diverse range of stakeholders—as highlighted by Table 1—as part of a conscious effort to address the scientific and technical research needs. Certain activities have been perceived to be more legitimate than others. The urgent need for fundamental data on ENPs would appear to have been a key driver behind the mandatory data call-in implemented by the California Department of Toxic Substances Control in relation to carbon nanotubes in January 2009,[44] and the mandatory reporting requirement being discussed by the Canadian and French Governments.[45] Table 1 provides an overview of how some jurisdictions have attempted to respond to increasing societal and political pressure to do *something* in regard to policy and regulatory challenges posed by nanotechnologies, while edging closer to enacting harder approaches to ENPs.

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42. MILLER, *supra* note 39, at 3.

43. ETC GROUP, NO SMALL MATTER II: THE CASE FOR A GLOBAL MORATORIUM: SIZE MATTERS! 10 (2003), *available at* http://www.etcgroup.org/upload/ publication/165/01/occ.paper_nanosafety.pdf.

44. Letter from Jeffrey Wong, Chief Scientist, California Department of Toxic Substances Control to California carbon nanotube manufacturers or importers (Jan. 22, 2009), *available at* http://www. dtsc.ca.gov/TechnologyDevelopment/Nano technology/upload/Formal_AB289_Call_In_Letter_CNTs.pdf. Carbon nanotubes are not the only nanomaterial of interest to the California Department of Toxic Substances Control, with the Department having added several other nanomaterials, including silver, zerovalent iron and cerium oxide, to their list. *See* California Department of Toxic Substances Control, Nanotechnology, http://www.dtsc.ca.gov/ TechnologyDevelopment/Nanotechnology/ (last visited Mar. 18, 2010).

45. Project on Emerging Nanotechnologies, World's First Mandatory National Nanotech Requirement Pending, (Jan. 28, 2009), http://www.nanotechproject.org/ news/archive/7061/; Mayer Brown, EU Competition - Brussels Client Alert: France Might Take the Lead on Nanotechnology Regulation (March 5, 2009), http:// www.mayerbrown.com/publications/article.asp?id=6317&nid=6.

TABLE 1: EXAMPLES OF GOVERNMENT NANO-INITIATIVES[46]

Year	*Initiative*	*Nature*	*Primary Drivers of Initiative*
2004	Initiation of the NanoMark certification system	Development of national nanotechnology certification system	Taiwan government
2005	International Organizations for Standardization (ISO) technical committee, ISO/TC 229 *Nanotechnologies* hosts its first meeting.	Development of voluntary standards	27 countries, including the U.K., Japan and the U.S.
	OECD Chemical Committee hosted the first OECD Workshop on the Safety of Manufactured Nanomaterials.	Multilateral meeting	OECD countries
2006	Australia's National Industrial Chemical Notification and Assessment Scheme launched its voluntary call for data on nanomaterials	Voluntary reporting scheme	Australian government
	Department of Environment Foods and Rural Affairs (DEFRA) launched the U.K. Voluntary Reporting Scheme for engineered nanoscale materials.	Voluntary reporting scheme	U.K. government
	City of Berkeley, California, amended the Hazardous Materials and Waste Management sections of the Berkeley Municipal Code to regulate 'manufactured nanoparticles'.	Amendment to City Code	U.S. local council
2007	The OECD's Committee for Science and Technology Policy established a Working Party on Nanotechnology	Multilateral meeting	OECD countries
2008	EPA formally launched its two-year 'Nanoscale Materials Stewardship Program'	Voluntary call for information	U.S. government
	European Commission launched its voluntary 'Code of Conduct for Responsible Nanoscience and Nanotechnologies Research'	Voluntary code of conduct	European Commission
	Australia's National Industrial Chemical Notification and Assessment Scheme launched its second voluntary call for data on nanomaterials	Voluntary reporting scheme	Australian government
	Federal Register notice by the EPA to inform manufacturers that carbon nanotubes are to be registered	Federal Register notice	U.S. government
	Commission Regulation amended Annexe IV of the REACH Regulation, which removed nanoscale carbon and graphite from the list of substances from the list of substances exempt from registration	Amendment to Regulation	European Commission

46. Adapted from George Gilligan & Diana M. Bowman, *'Netting Nano': Regulatory Challenges of the Internet and Nanotechnologies*, 22 INT'L REV. L., COMPUTERS & TECH. 231, 235-36 (2008).

Year	Initiative	Nature	Primary Drivers of Initiative
2009	California Department of Toxic Substances Control announced their mandatory data 'call-in' for carbon nanotubes	Mandatory data call-in	Californian government
	French Government proposed legislation to create a mandatory reporting scheme for nanoparticles	Proposed mandatory reporting scheme	French government
	European Parliament voted in favour of a report relating to the recast of the Novel Foods Directive; the proposed Novel Foods Regulation put forward by the Parliament specifically included nanomaterials within its scope and provided a definition of nanomaterials for the purpose of the Regulation	Vote on a Proposed Regulation by the European Parliament	European Parliament
	Australia's National Industrial Chemical Notification and Assessment Scheme published a public discussion paper outline a range of potential steps for specifically regulating nanoscale industrial chemicals	Discussion paper	Australian Government
	Adoption of the final text of the Cosmetic Regulation by the European Parliament and Council. The Regulation specifically incorporated mandatory provisions–including labeling requirements–relating to the regulation of cosmetic products containing nanomaterials.	Adoption of the final text of a EU Regulation	European Parliament and Council

Governments within a number of jurisdictions—such as Australia, the EU, the United Kingdom and the United States—have begun to examine how current regulatory processes apply to nanotechnologies, including the effectiveness of these processes when faced with the scientific uncertainties associated with ENPs.[47] These reviews have not been uniform in nature, with the terms of reference, scope and subject matter examined differing significantly. To a large degree, these reviews have been undertaken through the lens of traditional "black letter law", and the regulatory instruments that underpin the implementation of

47. *See, e.g.*, CHAUDHRY ET AL., *supra* note 40; KARINNE LUDLOW ET AL., A REVIEW OF POSSIBLE IMPACTS OF NANOTECHNOLOGY ON AUSTRALIA'S REGULATORY FRAMEWORK (2007), *available at* http://www.industry.gov.au/Industry/Nanotechnology/Documents/MonashReport2008.pdf; FOOD STANDARDS AGENCY, A REVIEW OF POTENTIAL IMPLICATIONS OF NANOTECHNOLOGIES FOR REGULATIONS AND RISK ASSESSMENT IN RELATION TO FOOD (2008), *available at* http://www.food.gov.uk/multimedia/pdfs/nanoregreviewreport.pdf; FOOD SAFETY AUTH. OF IRELAND., THE RELEVANCE FOR FOOD SAFETY OF APPLICATIONS OF NANOTECHNOLOGY IN THE FOOD AND FEED INDUSTRIES (2008); HEALTH AND SAFETY EXECUTIVE, *supra* note 37; U.S. EPA, NANOTECHNOLOGY WHITE PAPER (2007), *available at* http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf; Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Regulatory Aspects of Nanomaterials*, COM (2008) 366 final (June 17, 2008); Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Regulatory Aspects of Nanomaterials: Summary of Legislation in Relation to Health, Safety and Environment Aspects of Nanomaterials, Regulatory Research Needs and Related Measures*, COM (2008) 2036 (June 17, 2008).

these legislative mechanisms. Chaudhry et al. (2006) were charged with the task of, for example, considering "the appropriateness of existing regulatory frameworks for environmental regulation."[48] In contrast, Ludlow et al. (2008) were required to take a broader approach in their review, having been requested to, among other things, "assess Australia's existing regulatory frameworks to determine if, and under what conditions, nanotechnology-based materials, products and applications, and their manufacture, use and handling, are covered by the existing regulatory frameworks. . ."[49] A similarly broad remit was adopted by the European Commission, who under the auspices of their own internal review were asked to determine whether and under what circumstances ENPs are covered by existing European Union regulatory instruments and identify research needs to support the regulatory frameworks.[50]

Despite their obvious variation, a number of recurring themes radiate from each of the regulatory reviews. For instance, each of the jurisdictions examined had comprehensive "command and control" regulatory matrices, each of which had been built up and refined over a number of decades in response to evolving scientific knowledge and risk management practices. These were supported by a range of softer and more flexible instruments, including guidelines, many of which were designed to assist in the implementation of the more formal legislative mechanisms.

Key principles or approaches underpinning these regimes in relation to some product categories included, for example, premarket authorisation procedures, post-market enforcement and surveillance requirements, and general duty obligations on manufacturers and suppliers to ensure the safety of their product. The regulatory instruments comprising the higher levels of the frameworks were found to apply equally to conventional products and products incorporating ENPs; they did not differentiate between the two. This indicates that such products utilising nanotechnology fall within the scope of current regimes.

Yet, even while the authors of these reports showed that the existing regulatory frameworks and legislative instruments 'cap-

48. CHAUDHRY ET AL., *supra* note 40, at 10.

49. DEP'T OF INDUSTRY TOURISM & RESEARCH, REQUEST FOR TENDER: REVIEW OF POSSIBLE IMPACTS OF NANOTECHNOLOGY ON AUSTRALIA'S REGULATORY FRAMEWORKS 5 (2006).

50. *Regulatory Aspects of Nanomaterials, supra* note 47; *Summary of Legislation in Relation to Health, Safety, and Environment Aspects of Nanomaterials, Regulatory Research Needs and Related Measures, supra* note 47.

tured' nanotechnologies, a number of shortcomings in relation to the adequacy of the implementation of the regimes were noted. Several of the reviews have, for example, illustrated how the regimes do not in their current form contain the necessary 'triggers' to differentiate between ENPs and their bulk chemical counterparts. This was found to be important, for instance, in relation to risk assessment requirements and the adequacy thereof for products subject to pre-market safety assessments. Taken together, these reviews highlighted the fact that the current concerns over the adequacy of existing regulatory framework are being driven by concerns over the implementation of the regulatory instruments and the scientific uncertainties such as the adequacy of conventional risk assessment paradigms for evaluating the toxicity of nanomaterials. Research aimed at supporting the latter, including the validation of risk assessment protocols, will have to be addressed before a greater understanding can be achieved in relation to effectiveness of current regulatory regimes.

Questions over the adequacy of existing legislative instruments and regulatory models to effectively regulate nanotechnologies are not new, having been discussed and debated within different forums for some time now.[51] It is important to recognise that many of the issues raised within these deliberations have not been new *per se*, nor necessarily confined to the challenges posed specifically by nanotechnologies. Moreover, while debate over the addition of nano-specific provisions to key European legislative instruments intensified as the dates approached for the European Parliament and Council to vote on the recast of these instruments, including *Council Directive 76/768/EEC relating to*

51. *See, e.g.*, Fiedler & Reynolds, *supra* note 3; Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 HARV. J.L. & TECH. 179 (2003); ROYAL SOC'Y, *supra* note 9; ALISON WARDAK, NANOTECHNOLOGY & REGULATION: A CASE STUDY USING THE TOXIC SUBSTANCE CONTROL ACT (TSCA) (2003), *available at* http://www.nanotechcongress.com/Nanotech-Regulation.pdf; Francisco Castro, *Legal and Regulatory Concerns Facing Nanotechnology*, 4 CHI.-KENT J. INTELL. PROP. 140 (2004); Michael Bennett, *Does Existing Law Fail to Address Nanotechnoscience?*, IEEE TECH. & SOC'Y MAG. 27 (2004); ENVTL. LAW INST., SECURING THE PROMISE OF NANOTECHNOLOGY: IS U.S. ENVIRONMENTAL LAW UP TO THE JOB? 1 (2005), *available at* http://www.elistore.org/Data/products/d15_10.pdf; ETC GROUP, THE BIG DOWN: ATOMTECH - TECHNOLOGIES CONVERGING AT THE NANO-SCALE (2003), *available at* http://www.etcgroup.org/upload/publication/171/01/thebigdown.pdf; ETC GROUP, *supra* note 38; Robert D. Pinson, *Is Nanotechnology Prohibited By the Biological and Chemical Weapons Conventions?*, 22 BERKELEY J. INT'L L. 279 (2004); Symposium, Gary E. Marchant & Douglas J. Sylvester, *Transnational Models for Regulation of Nanotechnology*, 34 J.L. MED. & ETHICS 714 (2006).

cosmetic products (Cosmetics Directive) and *Regulation (EC) 258/97 concerning Novel Foods and Novel Food Ingredients* (the Novel Foods Directive),[52] it is important to remember that these instruments have been scheduled for a range of other reasons. The recast of the Cosmetics Directive was, for example, initiated in order to "remove legal uncertainties and inconsistencies," and curtail the "divergences in national transposition which do not contribute to product safety,"[53] but not on the basis of the need for the instruments to specifically address the challenges presented by cosmetic products incorporating nanomaterials.

That being said, it is important to note that the European Parliament and Council officially adopted the final text of the Cosmetic Regulation in November 2009, and in doing so, became the first national or supranational government body to establish new, mandatory and specific requirements in relation to nanomaterials. For the purposes of the Regulation, Article 2 of the Regulation defines nanomaterials as "insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm." From 2011 onwards, cosmetic products placed on the European market which incorporate nanomaterials will be subject to a number of mandatory requirements including labeling provisions.[54] This decision by the European Parliament and Council to adopt text which specifically regulates certain types of nanomaterials within cosmetic products is a fundamental departure from the European Commission's stance on regulating nanotechnologies, as the Commission had previously stated "that risks can be dealt with under the current legislative framework."[55]

Such action by the European Parliament and Council has been simultaneously applauded and criticised by a number of actors

52. It is important to note that at the time of writing this article, the European Council had not approved the revised text adopted by the European Parliament in March 2009. As such, it is unknown at this time as to whether the Council will accept the proposed provisions in the form that they were approved by the Parliament.

53. Commission of the European Committees, *Proposal for a Regulation of the European Parliament and of the Council on Cosmetic Products*, 49 COM 2 (Feb. 5, 2008).

54. *See* Commission Regulation 3623/09, Cosmetic Products, *available at* http://register.consilium.europa.eu/pdf/en/09/st03/st03623.en09.pdf (last visited Mar. 18. 2010).

55. *Regulatory Aspects of Nanomaterials*, *supra* note 47, at 3.

for occurring too slowly and for not going far enough.[56] It is important to remember that such responses will not be unique to the nanotechnology context having previously been observed in relation to the debates surrounding climate change. Much like the field of climate change regulation, nanotechnology is a field in which potential negative implications are difficult to prove and any so-called "premature intervention" on the part of government has the potential to impinge on the rational pursuit of profit motivations for both state and private sector actors.

Moreover, despite demands for prescriptive legal obligations by government at this time, the European Union's adoption of nano-specific requirements as part of the new Cosmetics Regulation is likely to be of concern to some commentators. These commentators include policymakers, scientists and members of industry who believe that such action is premature given the current lack of scientific knowledge regarding the potential effects of nanomaterials. As eloquently summarised by Gill in relation to the mooted data-collection initiative of the Canadian Government, scientists are concerned "that there are too many gaps in the basic knowledge of nanoparticles' properties to support the development of informed regulation."[57]

Recognition of the current scientific limitations and the subsequent implications for the law would appear to have acted as a catalyst for industry participants to develop their own regulatory responses to ensure the responsible development of nanotechnologies. While Black has sought to remind us that "self-regulation is neither a new phenomenon, nor one which is likely to disappear[,]"the increasing use of the practice across different sectors has not been without controversy.[58] It is the rise and role of self-regulation for organisations investing in the development and commercialisation of nanotechnologies to which this Article now turns. As noted earlier, within this context, particular attention will be paid to the activities of companies within the industrial chemical sector.

With national and supranational governments having generally favoured and implemented softer approaches to addressing the

56. *See, e.g.*, EuroActive.com, *Germany Opposed 'Nano' Label for Cosmetics*, Nov. 24, 2009, http://www.euractiv.com/en/enterprise-jobs/germany-opposed-nano-label-cosmetics/article-187583.

57. Victoria Gill, *Nano-regulation Creeps Closer*, Feb. 25, 2009, http://www.rsc.org/chemistryworld/News/2009/February/25020901.asp.

58. Julia Black, *Constitutionalising Self-Regulation*, 59 MOD. L. REV. 24, 25 (1996).

policy and regulatory challenges posed by nanotechnologies, it would appear that a window of opportunity has existed for industry to place themselves at the forefront of regulatory developments for the technology. It is arguably this window of opportunity, combined with a range of other factors and motivations, that has resulted in a range of proactive nanotechnology-specific initiatives being developed and implemented over the last five years. These have included both individual and collective codes of conduct by companies such as BASF and risk governance and management frameworks which have been developed and implemented by DuPont in partnership with Environmental Defense. These and others are discussed in more detail below. The initiatives, just like the chemical industry's Responsible Care program, have not sought to supplant existing regulatory requirements. Rather, they supplement them. Key participants in their development have included some of the world's largest chemical companies, a number of smaller companies and various non-governmental actors.

The adoption of models of self-regulation by organisations actively involved in nanotechnologies has been steadily increasing over the past few years as illustrated by Table 2 below. As highlighted by Section II, this movement is part of a larger trend occurring across jurisdictions and industry sectors towards the increasing employment and utilisation of forms of civil regulation more generally.[59]

59. *See, e.g.*, Rob Baggott, *Regulatory Reform in Britain: The Changing Face of Self-Regulation*, 67 PUB. ADMIN. 435 (1989); Neil Gunningham, *Environment, Self-Regulation, and the Chemical Industry: Assessing Responsible Care*, 17 DENV. L. & POL'Y 57, 57-58 (1995); Jennifer Nash & John Ehrenfeld, *Codes Of Environmental Management Practice: Assessing Their Potential as a Tool for Change*, 22 ANN. REV. OF ENERGY & THE ENV'T 487, 488 (1997); Rory Sullivan, *Code Integration: Alignment or Conflict?*, 59 J. BUS. ETHICS 9, 10 (2005).

TABLE 2: EXAMPLES OF NON-GOVERNMENT NANO-SPECIFIC REGULATORY INITIATIVES[60]

Year	Initiative	Nature	Primary Drivers of Initiative
2000	Foresight Nanotech Institute releases the Foresight Guidelines on Molecular Nanotechnology; voluntary guidelines for the responsible development of nanotechnology.	Industry code of conduct	U.S. NGO
2003	Luna Innovations initiated the development of NanoSAFE, a nanotechnology risk governance framework.	Voluntary code of conduct	U.S. industry
2004	*Code of Conduct for Nanotechnology* published by BASF	Industry Code of Conduct	German industry
2006	Foresight Nanotech Institute releases Version 6 of its revised Foresight Guidelines on Molecular Nanotechnology.	Industry Code of Conduct	U.S. NGO
	NGO Coalition files legal petition with the U.S. Food and Drug Administration requesting that the regulatory body issues nano-specific regulations for sunscreens containing nanoparticles	Legal petition	NGO community
	International Risk Governance Council (IRGC) releases their White Paper on nanotechnology risk governance.	Outline for international risk governance framework	Multilateral NGO
2007	Coalition of Non-Governmental Organizations published their 'Principles for the Oversight of Nanotechnologies and Nanomaterials'	Voluntary code of conduct	NGO community
	Environmental Defence and DuPont publish their 'Nano Risk Framework'	Voluntary risk governance framework	NGO and U.S. industry
	Launch of the CENARIOS risk management framework	Risk governance framework	NGO and Swiss consulting company
2008	Swiss Retailer's Association publish their own 'Code of Conduct for Nanotechnologies'	Voluntary code of conduct	Swiss industry
	German Chemical Industry Association (Verband der Chemischen Industrie/VCI) announce their decision to incorporate nano-specific provisions into their national Responsible Care program	Voluntary code of conduct	German chemical industry association
	The Soil Association announces its ban on the use of nanoparticles	Voluntary ban	NGO community
	NGO Coalition files legal petition with the U.S. Environmental Protection Agency demanding that the sale of pesticides containing nanoscale silver be banned	Legal petition	NGO community
	Launch of the Responsible Nano Code and the Benchmarking Framework	Voluntary code of conduct	Coalition of organizations

As highlighted by the above Table, voluntary, non-government initiated mechanisms designed to improve the governance of nanotechnologies are beginning to emerge across jurisdictions. These forms of private regulation, which have been driven by both industry and civil society actors, have been designed to control behaviour through informal means as a way of promoting best practices and, in turn, the responsible and sustainable devel-

60. Gilligan & Bowman, *supra* note 46.

opment of nanotechnologies.[61] These vehicles have been designed to complement formal regulatory obligations and do not seek to "roll back the state" or replace the regulatory frameworks in which they operate. While the rise of civil regulation for nanotechnologies has only just begun, Bowman and Hodge have suggested that these innovative forms of self-regulation represent a first cut of a new governance regime for an emerging and rapidly developing technology which is characterised by significant uncertainty.[62] In their view, such soft approaches provide the necessary flexibility to enable the framework to develop and evolve in line with the evolving scientific data, something that conventional command and control approaches may struggle to do.[63]

Industry's foray into the realm of nanotechnology governance under the umbrella of civil regulation has not been without controversy. A number of commentators have criticised this approach. One such example of this occurred upon the release of Environmental Defense-DuPont's draft 'Nano Risk Framework' in February 2007. Its publication was met with fierce criticism from the so-called "Civil Society-Labor Coalition" (CSLC). In an open letter, the CSLC clearly stated their views on the use of civil regulation in relation to nanotechnologies arguing that "the DuPont-ED proposal is, at best, a public relations campaign that detracts from urgent worldwide oversight priorities for nanotechnology; at worst, the initiative could result in a highly reckless policy and a precedent of abdicating policy decisions to industry by those entrusted with protecting our people, communities, and land."[64]

The civil society organisations who have authored the *Principles for Nanotechnologies and Nanomaterials Oversight* have also argued that "voluntary initiatives are wholly inadequate to oversee nanotechnologies. Voluntary programs lack incentives for 'bad actors' or those with risky products to participate, thus leav-

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61. ROYAL SOC'Y ET AL., RESPONSIBLE NANOTECHNOLOGIES CODE: CONSULTATION DRAFT - 17 SEPTEMBER 2007 (2007).

62. Diana M. Bowman & Graeme A. Hodge, *Counting on Codes: An Examination of Transnational Codes as a Regulatory Governance Mechanism for Nanotechnologies*, 3 REG. & GOV. 145, 159 (2009).

63. *Id.*, at 159-60.

64. CIVIL SOC'Y-LABOR COAL., AN OPEN LETTER TO THE INTERNATIONAL NANOTECHNOLOGY COMMUNITY AT LARGE - CIVIL SOCIETY-LABOR COALITION REJECTS FUNDAMENTALLY FLAWED DUPONT-ED PROPOSED FRAMEWORK, URGES ALL PARTIES TO REJECT THE PUBLIC RELATIONS CAMPAIGN (2007), *available at* http://www.etcgroup.org/upload/publication/610/01/coalition_letter_april07.pdf.

ing out the entities most in need of regulation."[65] In their view, only mandatory state-based regulation will be adequate for managing the potential risks posed by nanotechnology products and processes.[66]

Bearing this contention in mind, the following section examines the rise of self-regulation within the industrial chemical sector for nanotechnologies. This Article's focus on the chemical sector is due not only to the industry's role at the start of the value chain for nanotechnologies, but also due to the industry's twenty-five year experience with the Responsible Care program and the transatlantic regulatory divergence that has recently occurred with the implementation of the *Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation* in the European Union. On the one hand, regulation will need to protect against the unforeseen health and environmental dangers that may be posed by nanomaterials. On the other hand, regulators and industry will face the task of protecting the technology from excessive or irrational public backlash regarding those potential dangers.

IV.
The Industrial Chemicals Sector—A Case Study in the Regulation of Nanotechnologies

In this section, the Article turns its attention to observing how private sector organisations have employed different regulatory models to proactively manage potential risks associated with nanotechnologies. While there are now a number of examples of how organisations have responded to the scientific uncertainties posted by nanotechnologies, this Article intends to focus on mechanisms that have emerged regarding the chemical industry. Our focus on activities within this specific sector is based on the following rationales:

1. Occupational exposure to nanomaterials during the manufacturing processes has been identified as an area of particular concern for human health and safety;[67]

65. Consumer Coal., *supra* note 21, at 3.

66. *Id.*

67. *See, e.g.*, NSW, *supra* note 19, at 45 (who have stated that "[a]ddressing health and safety issues relating to the potential toxicity of nanomaterials in the workplace is the area that requires the most immediate attention – given that workers can be subject to continual exposure.").

2. Regulatory gaps have already been identified by some commentators in relation to the current models employed to regulate industrial nanomaterials in the workplace and their entry into markets;[68]
3. The chemical industry has a long and arguably successful history of utilising voluntary initiatives, as illustrated by Responsible Care;[69] and
4. Companies wishing to gain access to the European market in relation to chemical substances will have to abide by the higher regulatory requirements set down by the *Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation*, which may in turn "diffuse across jurisdictional borders in order to establish a new global de facto standard for chemical regulation."[70]

For the purposes of this Article, four different approaches to self-regulation have been selected. As highlighted by Table 3 below, these initiatives include codes of conduct and risk management vehicles, single party initiatives and partnership arrangements between sectors. We do not suggest that these initiatives are representative of all of the approaches that have been implemented to date. Rather, we merely present a selection of those measures that have been most visible in the public domain.

68. Ludlow, *supra* note 9; AHSON WARDAK, NANOTECHNOLOGY & REGULATION: A CASE STUDY USING THE TOXIC SUBSTANCE CONTROL ACT (TSCA) (2003); CHAUDHRY, *supra* note 40; J. CLARENCE DAVIES, MANAGING THE EFFECTS OF NANOTECHNOLOGY (2006), *available at* http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf; Gary E. Marchant, Douglas J. Sylvester & Kenneth W. Abbott, *Nanotechnology Regulation: The United States Approach, in* NEW GLOBAL REGULATORY FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 189, 189-211 (Graeme A. Hodge, Diana M. Bowman, Karinne Ludlow & Edward Elgar eds. 2007); Ludlow, *supra* note 9.

69. Nash & Ehrenfeld, *supra* note 59.

70. Diana M. Bowman & Geert van Calster, *Does REACH Go Too Far?* 1 NATURE NANOTECHNOLOGY 525, 526 (2007).

TABLE 3: KEY CHARACTERISTICS OF THE SELECTED SELF-REGULATION INITIATIVES[71]

		NanoSAFE[72]	*BASF's Code Of Conduct*[73]	*Environmental Defence-DuPont Nano Risk Framework*[74]	*Responsible NanoCode*[75]
Implementation Year		2003	2004	2007	2008
Sector(s) Involved in Creation / Implementation of Initiative	Government	✓	-	-	-
	Industry	✓	✓	✓	✓
	NGOs	-	-	✓	✓
	Academia	✓	-	-	✓
Formal Public Consultation Processes in Developing the Code	[unknown]	[unknown]	✓	✓	
Nature	Principle based	-	-	-	-
	Principle based, with further guidance material	✓	✓	✓	✓
	Prescriptive	-	-	-	-
Scope	Individual Company	-	✓	-	-
	Multiple Organisations	✓	-	✓	✓
	Sector specific	-	N/A	-	-
	Multi-sector	-	-	✓	✓
	Human and environmental health and safety risks	✓	✓	✓	✓
	Broader societal risks	-	-		✓

71. Adapted from Bowman & Hodge, *supra* note 62, at 150.

72. Candance Stuart, *Making Labor Safety a Priority and a Profit*, SMALL TIMES, Nov./ Dec. 2005, at 32; Matt Hull, *An Innovative Framework for Comprehensive Management of Nanotechnology EHS Risks: Luna Innovations' "Nanosafe" Program* (paper presented to the Regulations for Nanotechnology in Consumer Products Conference, Washington DC, Feb. 8-9 2007).

73. BASF, CODE OF CONDUCT FOR NANOTECHNOLOGY (2004).

74. Letter of Understanding from Environmental Defense to DuPont, *Framework for Responsible Nanotechnology Standards* (Aug. 30, 2005); Environmental Defense and DuPont, *Nano Risk Framework* (2007).

75. ROYAL SOC'Y ET AL., RESPONSIBLE NANOTECHNOLOGIES CODE: CONSULTATION DRAFT - 17 SEPTEMBER 2007 (VERSION 5, 2007); ROYAL SOC'Y ET AL., DRAFT WORK PLAN FOR THE RESPONSIBLE NANOCODE DEVELOPMENT (2008).

Life Cycle Stages Covered	Research	✓	✓	✓	-
	Manufacturing / commercialisation	✓	✓	✓	✓
	Disposal	✓	✓	✓	✓
	End-of-life monitoring requirements	-	-	-	-
Precautionary Principle	Expressly included in text	-	-	-	-
Ongoing Consultation / Engagement Activities		[unknown]	✓	✓	✓

The development of the NanoSAFE Framework by Luna Innovation, a small United States-based company, in partnership with government and academia demonstrates how small-to-medium enterprises may also take a proactive approach to managing potential environmental and health risks posed by nanotechnologies. Initiated by the company in 2003 and financed in part by the public sector, the dynamic framework takes a precautionary approach to managing health and safety.[76] While the exact process by which the five point management program was fashioned remains somewhat unclear, it has been suggested that one of the underlying reasons for its development would appear to be the need for organisations, including small businesses, to prepare themselves for the inevitable state-based nano-specific standards.[77] As with DuPont, it would appear that voluntary self-regulation which goes beyond state-based requirements are perceived by Luna Innovation as being good for their business, despite the initial costs associated with their implementation.[78] The dynamic framework is based on a five-point strategy: managing facilities and product safety; conducting voluntary toxicology studies; employee health surveillance; environmental management; and developing workplace safety technologies.[79] As with the other initiatives outlined here, the NanoSAFE Framework is not prescriptive in nature and has been designed to be dynamic in nature in order for it to evolve alongside the scientific state of the technologies.[80]

76. Stuart, *supra* note 72; Hull, *supra* note 72.

77. Josh Cable, *A Best Practices Approach to Minimizing EHS Risk in Nanotechnology Manufacturing*, OCCUPATIONAL HAZARDS, Oct. 6, 2005, *available at* http://www.occupationalhazards.com/Issue/Article/37825/A_Best_Practices_Approach_to_Minimizing_EHS_Risk_in_Nanotechnology_Manufacturing.aspx.

78. *Id.*

79. Stuart, *supra* note 72; Hull, *supra* note 72.

80. Matthew Hull, *Nanotechnology Risk Management and Small Business: A Case Study on the NanoSafe Framework*, *in* NANOTECHNOLOGY RISK MANAGEMENT: PERSPECTIVES AND PROGRESS (2010).

As the world's largest chemical company with operations on five continents and a workforce of approximately 96,000 individuals, the BASF Group boasts business networks across virtually all industries including chemicals, plastics, performance products, and agricultural products.[81] It is therefore not surprising that the multinational has invested in nanotechnologies over a period of time. The company estimates that it spent €180 million on R&D activities between 2006 and 2008.[82] With BASF continuing to heavily invest in the technology, recognition of the need to ensure the safety of their workers and the desire to promote the legitimacy of the technology would appear to have been driving factors behind the multinational developing their own code of conduct ("Code") for nanotechnologies. The Code commits the company and its employees to the safe manufacturing and production of nanotechnologies.[83] However, the exact nature by which the non-binding initiative was developed, including the actual procedure, parties involved, in-house and external consultation processes, is unknown.

The Code, which is publically available on the company's website, is spelled out through four overarching principles, each of which is supported by mission statements.[84] Pursuant to principle two, the company has committed itself to ensuring that "economic considerations do not take priority over safety and health issues and environmental protection."[85] Through this voluntary initiative, the company also pledged to engage in open and constructive dialogue with consumers with regard to their na-

81. BASF, ANNUAL PRESS CONFERENCE REPORT (2009).

82. BASF, IN DIALOGUE: NANOTECHNOLOGY AT BASF (2006).

83. BASF, *supra* note 73.

84. *Id.* at 1-3 (The four overarching principles are as follows: 1. We, the employees of BASF, develop and use the potential of nanotechnology in order to manufacture products with enhanced performance or new properties using targeted production and the use of new, nanoscale materials. . . 2. To the extent that new technologies are converted into concrete processes and products, the expertise required to weigh up the opportunities against the potential risks related to the use of new technologies in the form of innovative products and processes increases. The same is true for nanotechnology. We take these risks seriously and, in parallel with technological progress, work continuously to identify potential environmental and health risks. . . 3. We have long had nanotechnology-based products in our portfolio and we plan to utilize nanotechnology's potential in the future too, in order to offer our customers products and systems that help them to be successful. . . 4. In our Values and Principles, we have committed ourselves to pursuing a dialogue with society based on openness and trust. We regard it as our duty to provide information about both the opportunities and the potential risks of nanotechnology.)

85. *Id.* at 3.

notechnology-based products, and to develop appropriate controls and standards in order to manage any potential risks to human and environmental safety.[86] In order for this to be achieved, the company stated that it would "only market products if their safety and environmental impact can be guaranteed on the basis of all available scientific information and technology."[87]

Having described itself as the "world's most dynamic science company," DuPont's business operations extend across almost all industries, including agriculture, materials, electronics and industrial chemicals.[88] As with BASF, DuPont (the world's fourth largest chemical company) has recognised the potential for nanotechnologies to add value to each of these traditional sectors.[89] And while the exact nature and economic value of DuPont's investment in nanotech-related R&D remains unspecified, as noted above, their partnership with Environmental Defence to develop the Nano Risk Framework has occurred within the public domain. The project was initiated and funded by the two parties for the purpose of developing a governance "framework for the responsible development, production, use and disposal of nanoscale materials that identifies, manages and reduces risks across all lifecycle phases."[90] Since DuPont intended the Framework not just to be used internally but for a range of organisations across different sectors, the risk management tool was developed through extensive consultation with a wide range of experts and stakeholders.

While the six-step Framework has been designed to be "comprehensive, practical, and flexible,"[91] it—as with the other initiatives presented here—is not overly prescriptive, offering instead principles and practical guidance as to what organisations should do in order to assist in "identifying, managing, and reducing potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product's lifecycle."[92] While

86. *Id.*

87. *Id.*

88. DUPONT, SUSTAINABLE GROWTH THROUGH SCIENCE - 2005 ANNUAL REVIEW 1 (2006).

89. DUPONT, POSITION STATEMENT - DUPONT NANOSCALE SCIENCE & ENGINEERING (2006), *available at* http://www2.dupont.com/Media_Center/en_US/position_statements/nanotechnology.html.

90. Environmental Defense, *supra* note 74 at 5.

91. Environmental Defense & DuPont, *supra* note 74, at 7.

92. *Id.* at 12.

the initiative has been criticised by some commentators, other parties, such as the Nanotechnology Industries Association, have congratulated Environmental Defence and DuPont on the framework, stating that the framework "represent[ed] a timely and well-structured initiative to secure the advancement of nanotechnology in a responsible way."[93] Support also came from the Australian Nano Business Forum and Nanotechnology Victoria who stated that the proposed framework is "an excellent start at the complex task of organizing a uniform approach to the handling of engineered nanomaterials . . . and represents a major step forward."[94]

The final initiative to be outlined here is the recently developed and implemented Responsible NanoCode. A joint initiative of the Royal Society, Insight Investment, the Nanotechnology Industries Association, and more recently, the Nanotechnology Knowledge Transfer Network (the so-called Founding Partners), the voluntary initiative came to fruition after an extensive development and open consultation process with stakeholders across multiple jurisdictions, including the EU, the United States and Australia. As with the other code-based initiatives outlined here, the NanoCode is a principle-based instrument; these non-prescriptive principles are then reinforced through what has been termed "indicators of good practice."[95]

The multi-stakeholder code is designed to encourage organisations across different sectors and jurisdictions to improve their current practices and approaches to risk management, occupational health and safety, transparency and consultation. The NanoCode does not seek to usurp any regulatory regime, but rather aims to supplement such regimes as they are evaluated and revised where necessary. The NanoCode also aims to encourage organisations to consider the broader social aspects of their activities and to engage with a range of stakeholders in the development and application of products. Importantly, the Founding Partners have led by example by being inclusive in the development and revision of NanoCode. Working Group members have included representations from the Founding Partners, as well as

93. NANOTECHNOLOGY INDUSTRIES ASSOCIATION, FEEDBACK FROM NIA (Mar. 30, 2007).

94. AUSTRALIAN NANO BUSINESS FORUM AND NANOTECHNOLOGY VICTORIA, RESPONSE TO DU PONT - ENVIRONMENTAL DEFENCE NANO RISK FRAMEWORK 1-3 (2007).

95. ROYAL SOC'Y ET AL., *supra* note 85.

representatives from BASF, Unilever, Johnson & Johnson, Oxonica, Which?, Practical Action and several leading universities.

As the above discussion highlights, there is no "template" or "best practice" regulatory model: a variety of different models have evolved to date. This is hardly surprising given the emerging nature of the technology, the diversity of products and processes associated with the technology, the range of actors and interests involved in their development, and the significant shortcomings of the current scientific. And, despite their differences, they do appear to share a common theme: the responsible development of nanotechnologies. To this end, regardless of the approach adopted, they all seek to alter behaviour. The extent to which this will be achieved is dependent on a number of different factors, not least their legitimacy.[96] Potential cost, effectiveness and practicality will similarly be important factors.

Of particular interest for this Article are the driving forces and motivations underpinning these self-regulation initiatives, which are likely to be multifaceted and largely ambiguous to the outside world. However, their very existence, it can be argued, may suggest that parties do not believe that the existing frameworks are adequate to the challenges that nanotechnologies present and something more is required. What this *is*, however, is a subject of debate, and will likely remain so for some time yet. But by going beyond regulatory compliance, these organisations are committing themselves to a higher standard of care as a means to avoid or minimise potential harm to their workers, the environment, or the public more generally. It is also possible that the organisations which have committed themselves to the voluntary initiatives have done so for the broader purpose of seeking the public's support and trust in both the technology and their ability to develop products and processes in a safe and responsible manner.[97] Bowman and Hodge have also suggested the possibility that organisations may be embracing voluntary mechanisms for the purpose of delaying or negating formal state-intervention if they perceive that such government intervention would be inappropriate, costly, and likely to stifle innovation.[98]

96. Julia Black, *Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes*, 2 REG. & GOV. 137, 144 (2008).

97. *See, e.g.*, Prakash Sethi & Olga Emelianova, *A Failed Strategy of Using Voluntary Codes of Conduct by the Global Mining Industry*, 6 CORPORATE GOVERNANCE: THE INTERNATIONAL JOURNAL OF EFFECTIVE BOARD PERFORMANCE 226 (2006); Nash & Ehrenfeld, *supra* note 59.

98. Bowman & Hodge, *supra* note 62.

However, they believe this is unlikely to be a major motivating force for the majority of organisations when considering self-regulation.

Putting these potential motivations to one side, it would appear that these voluntary mechanisms will complement the extensive web of regulatory instruments already in operation. This is in part due to the incorporation of precautionary measures such as the "As Low As Reasonably Achievable" (ALARA) principle. The ALARA approach has been designed as a way to minimise worker exposure to potential risks within the workplace. It is therefore not surprising that, in the absence of scientifically sound risk assessment data on ENPs, voluntary initiatives such as the Nano Risk Framework have advocated the use of the principle in the workplace.[99] These mechanisms also provide industry and other organisations with the ability to utilise innovative processes that allow for the incorporation of new data and information as part of their risk management framework. Voluntary programs such as the Environmental Defense–DuPont Nano Risk Framework incorporate extensive data-gathering processes which can then feed back in to the risk management framework in order to develop and refine the risk management approach.[100] Such data gathering processes may then flow into broader information gathering efforts such as those implemented by agencies like the U.S. Environmental Protection Agency.

In order to examine whether regulatory models are sufficient to protect the consumer, the company, and the development and standing of the technology, it is important to consider not only the characteristics of their development, but also operational features of the regulatory models. The natural starting point for such an analysis in relation to the regulation of nanotechnologies is the developments, trends, successes and limitations within in-

99. Environmental Defense and DuPont, *supra* note 74, at 69 (this approach is also known as the 'As Low As Reasonably Practicable' (ALARP) approach and has been endorsed as part of the best practice approach to dealing with ENPs in the workplace by a number of experts). *See, e.g.*, NANOSAFE AUSTRALIA, CURRENT OHS BEST PRACTICES FOR THE AUSTRALIAN NANOTECHNOLOGY INDUSTRY 12 (2007); BRITISH STANDARDS INSTITUTE, NANOTECHNOLOGIES - PART 2: GUIDE FOR SAFE HANDLING AND DISPOSAL OF MANUFACTURED NANOMATERIALS 13, 20 (PD 6699-2:2007) (2007); NSW, *supra* note 19.

100. Environmental Defense and DuPont, *supra* note 74. *See also* INTERSSENGEMEINCHAFT DETAILHANDEL SCHWEIZ, CODE OF CONDUCT: NANOTECHNOLOGIES (Feb. 5, 2008); ROYAL SOC'Y ET AL., DRAFT WORK PLAN, *supra* note 75.

dustries that have previously embraced self-regulatory schemes. The chemical industry's Responsible Care initiative is one such example.

As explained by Nash and Ehrenfeld, while the origins of Responsible Care may be traced back to the late 1970's, the development and implementation of the initiative by the Canadian Chemical Producers Association (CCPA) can be largely credited to the Bhopal chemical accident of December 3, 1984 and the subsequent fallout for the industry.[101] The public relations disaster was underpinned by perceptions of the industry's indifference to human and environmental health and safety concerns, questions over transparency, and lack of scrutiny. In 1985, these concerns acted as a catalyst for the CCPA to implement a principle-based voluntary umbrella program designed to promote ongoing improvements in organisations' human and environmental health and safety performance, rebuild public trust and promote transparency within the industry.[102] According to Nash and Ehrenfeld, the adoption of the principle-based initiative in modified form shortly thereafter by national chemical associations rapidly "transformed Responsible Care from a small voluntary activity to a major worldwide initiative."[103] It is today considered to be the "chemical industry's premier performance initiative" with, as of 2008, some 53 national chemical associations having signed on to the voluntary scheme.[104] It is therefore not surprising that the initiative has been described by one leading academic as "the most significant and far-reaching self-regulatory scheme ever adopted in Australia, or arguably, elsewhere."[105]

The key components of this now global regulatory device can be summarised simply as a voluntary code of conduct which requires companies in participating national associations to commit to a number of fundamental principles and associated milestones in order to "drive continuous improvement in performance."[106] These objectives are achieved not by Responsible Care setting down one-size-fits-all codes of practice for member associations, but rather by requiring each national chemical association to progressively develop their own guiding principles and codes of

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101. Nash & Ehrenfeld, *supra* note 59, at 498.

102. *See, e.g.*, Gunningham, *supra* note 59, at 61-62; INT'L COUNCIL OF CHEM. ASSOCIATIONS, RESPONSIBLE CARE STATUS REPORT 2008 4-5 (2008).

103. Nash & Ehrenfeld, *supra* note 59, at 498.

104. INT'L COUNCIL OF CHEM. ASSOCIATIONS, *supra* note 102, at 6.

105. Gunningham, *supra* note 59, at 61.

106. INT'L COUNCIL OF CHEM. ASSOCIATIONS, *supra* note 102, at 4.

practice designed to promote this continuous improvement within their jurisdiction. As such the voluntary instruments developed at the national level, and the number thereof, vary considerably between jurisdictions and reflect the member associations' views on what constitutes the most pressing human and environmental safety issues to be addressed by the industry within their jurisdiction, the degree of implementation of the program in the member associations, and institutional capacity.

The dynamic nature of Responsible Care has resulted in the progressive development of "independent performance indicators, third-party oversight and direct community involvement" in a number of jurisdictions.[107] As part of the program's commitment to transparency and community engagement, "each chemical company that implements Responsible Care is expected to collect and report data for a core set of environmental, health and safety performance measures. Each national association is expected to collect, collate and report this data from its members to each country."[108] In this sense, participating organisations are required to go beyond the legal requirements set down in the jurisdictions in which they operate in order to ensure compliance with the initiative and avoid their membership in the trade association being revoked.[109]

Despite the "beyond compliance" requirements set down by Responsible Care for participating organisations, the chemical industry's initiative has not escaped criticism. As noted by Gunningham, Responsible Care can be viewed as nothing more than an attempt to placate the public and win back much needed credibility.[110] The initiative has been criticized over the years by some commentators as lacking both "teeth and claws" by virtue of the lack of universal industry acceptance, weak monitoring requirements, the absence of explicit sanctions and the lack of an effective regulatory authority overseeing the initiative.[111] These perceived shortcomings would appear to go to the very heart of

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107. Gunningham, *supra* note 59, at 70.

108. INT'L COUNCIL OF CHEM. ASSOCIATIONS, *supra* note 102, at 5.

109. Aseem Prakash, *Responsible Care: An Assessment*, 39 BUS. SOC'Y. 183, 184 (2000); Nash & Ehrenfeld, *supra* note 59, at 500.

110. Gunningham, *supra* note 59.

111. *See* Andre A. King & Michael J. Lenox, *Industry Self-Regulation Without Sanctions: The Chemical Industry's Responsible Care Program*, 43 ACAD. OF MGMT. J. 698, 712-714 (2000); Prakash, *supra* note 109, at 197; Joseph Rees, *Development of Communitarian Regulation in the Chemical Industry*, 19 DENV. L. & POL'Y 477, 519 (1997).

questioning the program's legitimacy and effectiveness.[112] Is it, therefore, not surprising that a number of scholars have sought to evaluate the effectiveness of Responsible Care. These scholars have suggested a number of mechanisms that could be incorporated into the regime in order to address the deficiencies and "nourish" the scheme. Gunningham has, for example, suggested that the scheme could overcome a number of its weaknesses by "superimposing a degree of government and third-party oversight and intervention. . .", therefore shifting from an environment of self-regulation to co-regulation.[113] This would not only promote legitimacy and trust, but also enable a range of tailored instruments to be employed to encourage performance and compliance.

Evaluations of the effectiveness of models of self-regulation within the chemical industry and other sectors such as the nuclear industry[114] have highlighted the need for transparency, effective monitoring, enforcement mechanisms and sanctions, as well as independent or third party oversight functions.[115] The degree to which the four initiatives presented in this Article embrace such mechanisms is highlighted in Table 4 below.

112. *See* Gunningham, *supra* note 59, at 93.

113. *Id.* at 94.

114. *See* JOSEPH REES, HOSTAGES OF EACH OTHER: THE TRANSFORMATION OF NUCLEAR SAFETY SINCE THREE MILE ISLAND (1994); Rees, *supra* note 111.

115. *See* Neil Gunningham, *Codes of Practice: The Australian Experience*, *in* VOLUNTARY CODES: PRIVATE GOVERNANCE, THE PUBLIC INTEREST AND INNOVATION 317 (Kernaghan Webb ed., 2004); Ian Bartle & Peter Vass, *Self Regulation within the Regulatory State: Towards a New Regulatory Paradigm?* 85 PUB. ADMIN. 885 (2007); RHYS JENKINS, CORPORATE CODES OF CONDUCT: SELF REGULATION IN A GLOBAL ECONOMY (2001), *available at* http://www.unrisd.org/UNRISD/website/document.nsf/240da49ca467a53f80256b4f005ef245/e3b3e78bab9a886f80256b5e00344278/$FILE/jenkins.pdf.

TABLE 4: KEY MECHANISMS OF THE SELECTED SELF-REGULATION INITIATIVES[116]

		Nano-SAFE	*BASF*	*ED-DuPont Nano Risk Framework*	*Responsible NanoCode*
Monitoring	Information disclosure requirements	-	-	-	✓
	Voluntary requirement to self-report / document activities and findings	✓	-	✓	✓
	Mandatory auditing by independent third party	-	-	-	-
	Mandatory third party reporting requirements	-	-	-	-
Sanctions	Does not include any form of sanctions	✓	✓	✓	✓
	Sanctions incorporated into the code for non-compliance	-	-	-	-
	Other means by which enforcement may occur	-	-	-	-
Content and Revision	Voluntary initiative contains clear and relevant objectives	✓	✓	✓	✓
	Requirements of the initiative are clear	✓	✓	✓	✓
	Requirements relevant to the area of concern	✓	✓	✓	✓
	Requirements go beyond those required by the law	✓	✓	✓	✓
	Initiative contains prescriptive quantitative standards	-	-	-	-
	Initiative can be amended to reflect current start of the (scientific) art	✓	✓	✓	✓
Other Mechanisms	Onus on party to share knowledge with other parties	[unknown]	✓	[endorses such an approach]	-
	Ongoing commitment to consultation and engagement	✓	✓	✓	✓

As highlighted by Table 4, each of the initiatives incorporates a range of oversight, or monitoring, mechanisms. While BASF's in-house code of conduct, for example, commits the company to what could be interpreted to be a higher degree of transparency and accountability in relation to its R&D activities for nanotechnologies, it does not provide an explicit framework for how this is operationalised within the company or its subsidiary

116. Adapted from Bowman & Hodge, *supra* note 62.

companies. In the case of the Responsible NanoCode, a "comply or explain" monitoring approach is taken where "organisations adopting the Code are asked to report each year on what steps they have taken to implement the Code, and if they haven't implemented particular aspects, to clearly explain why."[117] Interestingly, at the time of their implementation, mandatory reporting requirements, provisions for independent monitoring or oversight, and/or external auditing of organisations so as to ensure compliance with the initiatives had not been incorporated into the text of any of the four initiatives examined here.

Following consideration of the monitoring requirements of the self-regulatory models and drawing upon the experiences of other industries and self-regulatory initiatives, the voluntary reporting and monitoring functions have significant limitations. As noted by Sethi and Emelianova in their review of voluntary codes within the global mining industry, an essential pre-condition of any effective industry-based code is "independent external monitoring and compliance verification" and a "willingness to make the findings of the independent external audit available to the public without prior censorship."[118] Other leading commentators have made similar statements.[119] For instance, Jenkins was clear that "provisions for the implementation of a particular code, and for effective monitoring, are crucial if it is to have any real impact."[120] Moreover, "the reluctance of many firms to include independent monitoring as an integral part of their code gives rise to some suspicion that they may be used as a public relations exercise rather than a genuine attempt at improving conditions and performance."[121]

Drawing upon the experience of Responsible Care in its formative years, it would appear that the absence of any such formal monitoring and reporting requirements within each of the initiatives outlined in this Article has the potential to undermine their legitimacy in the eyes of the public. Disclosure, or the requirement to be called to account in relation to performance and associated activities, would appear to clearly matter when considering the legitimacy of the schemes in the eyes of the public.[122]

117. ROYAL SOC'Y ET AL., CONSULTATION DRAFT, *supra* note 75, at 4.

118. Sethi & Emelianova, *supra* note 97, at 230-231.

119. *See, e.g.*, Gunningham & Rees, *supra* note 27, at 405-06; JENKINS, *supra* note 115, at iv.

120. JENKINS, *supra* note 115, at iv.

121. *Id.* at 27.

122. Black, *supra* note 96, at 157.

Having said this, it is important to note that the absence of formal monitoring and reporting is not a precondition to the so-called failure of self-regulation. In their review of the chemical industry's Responsible Care initiative, Nash and Ehrenfeld noted "that this high-profile example of industry self-regulation did not prescribe absolute or quantitative environmental standards."[123] Responsible Care relied instead on broad statements of intent with the consequence that "the language of the codes is deliberately broad, requiring firms to decide for themselves precisely how they will implement each requirement."[124]

In fairness, conclusions at this time as to the likely effectiveness of these four regulatory approaches in achieving the objectives and ensuring the future commercial success of the technology are without doubt extremely premature. Such conclusions, if drawn, would fail to take into account the current scientific state of art and the highly dynamic environment thereof. The lack of comprehensive and scientifically sound data on, for example, toxicity, eco-toxicity and potential exposure pathways, has meant that industry's commitment to the responsible development of nanotechnologies can only occur through reliance on aspirational statements rather than prescriptive, stringent, and, therefore, more measurable standards.

With the current inability of leading experts in the area to provide minimum, scientifically validated standards and exposure levels for their dealings with many ENPs, it would appear that industrial organisations have little choice but to rely on best practice guidelines or principles such as the "As Low As Reasonably Practicable" standard. Such principles have been relied upon by industry for prolonged periods of time in relation to different challenges. This being the case, it can be argued that they have the expertise and knowledge to successfully implement such principles in relation to nanotechnologies without excessively inhibiting the development or commercialisation of the technology or associated products. However, the inability to articulate explicit standards does have a consequence. Specifically, the absence of such standards limits the ability of these organisations to monitor and report on meaningful, quantifiable measures associated with the adoption of each of the regulatory approaches.

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123. Nash & Ehrenfeld, *supra* note 59, at 500.

124. *Id.*

The obvious consequence of the lack of specific, quantifiable standards within the instruments is the lack of sanctions that can then be enforced by either the organisation itself or a third party when "violations" occur.[125] As noted by Sinclair, compliance in self-regulatory regimes is essentially dependent on the ongoing commitment, motivation, and goodwill of the individual organisations.[126] Of relevance, Gunningham and Rees suggest that "from a punitive perspective, what is important is the capacity of industry self-regulation to back its norms with the threat of sanction."[127] The current absence of any formal sanctions may therefore logically be viewed by some commentators as rendering these initiatives meaningless because organisations have no real incentive to comply. Sceptics of the regulatory models may also try to make the claim that the inability to hold signatories accountable for non-compliance undermines the longer-term credibility of these instruments. These arguments must be acknowledged.

Balancing these, though, is the modern day importance of corporate reputation and the threat of a high profile accusation of not fulfilling such public commitments, which may in and of itself be a strong behavioural incentive to drive compliance—albeit a decidedly imperfect one.[128] This is particularly the case if the organisation is well known and the threat of criticism through the media exists. While the absence of punishment or other coercive forces is clearly a practical limitation of any such initiative, it may not carry quite as much weight as is often assumed in public debate.

Regardless of industry's ability to effectively regulate nanotechnologies through varying forms of self-regulation, broader questions of credibility and legitimacy are unlikely to fade away

125. *See* JENKINS, *supra* note 115, at 26; Kernaghan Webb, *Understanding the Voluntary Code Phenomenon*, *in* VOLUNTARY CODES: PRIVATE GOVERNANCE, THE PUBLIC INTEREST, AND INNOVATION 3 (Kernaghan Webb ed. 2004); King & Lenox, *supra* note 111.

126. *See* Sinclair, *supra* note 25, at 534.

127. Gunningham & Rees, *supra* note 27, at 386.

128. *See* Doreen J. McBarnet, *Corporate Social Responsibility Beyond Law, Through Law, for Law: the New Corporate Accountability*, *in* THE NEW CORPORATE ACCOUNTABILITY: CORPORATE SOCIAL RESPONSIBILITY AND THE LAW 9, 30 (Doreen J. McBarnet, Aurora Voiculescu & Tom Campbell eds., 2007); Doreen McBarnet, Enforcing Ethics: New Strategies for Tackling Creative Compliance 25 (draft prepared for presentation at the ESRC/GOVNET Workshop, ANU, March 14-15, 2007), *available at* http://cbe.anu.edu.au/capitalmarkets/papers/MCBARNET-CAPITAL-MARKETS.pdf.

until independent and mandatory reporting mechanisms and enforceable sanctions for non-compliance are incorporated into self-regulation models.[129] An undoubted strength of voluntary initiatives is their inherent flexibility and capacity to evolve rapidly.[130] It would seem that the four initiatives presented in this Article have the inherent flexibility and therefore the potential to evolve alongside the increasing body of scientific data and progressively incorporate more specific policies and practices, including monitoring and compliance activities. The ability of all the programs to be reflexive within an evolving environment is clear. Gunningham and Rees have observed that a voluntary code is "an evolving framework in many cases, [and] is usually drafted in very general terms at the outset because the trust, cooperation, and technical consensus necessary for a more detailed agreement is lacking; but as cooperation and consensus grows, it is quite usual for more detailed norms to follow."[131] Such maturation of self-regulatory initiatives is not without precedent in other areas.[132] It is therefore probable that, for the examples presented here, strengthening these self-regulatory mechanisms through the inclusion of independent and transparent oversight mechanisms is very likely to improve their accountability and legitimacy.[133]

Whether or not the organizations who have publically committed themselves to self-regulation are willing to commit to something more than "statement[s] of good intentions" (as Sethi and Emeilanova have put it)[134] remains a significant question and one which is unlikely to be answered for some time yet. Even once the science allows for such provisions to be expressly incorporated into the instruments, corporate attitudes are likely to be dependent on the perceived importance of several factors. Obvious motivations for doing so may include the perceived need to find a compromise with government so as to avert direct regulatory intervention by the state, to influence the nature of future legislation, to limit the extent of increasing public distrust which

129. King & Lenox, *supra* note 111.

130. *See* Webb, *supra* note 125, at 15-17; Aalders & Wilthagen, *supra* note 25, at 415-18; Sinclair, *supra* note 25, at 539.

131. Gunningham & Rees, *supra* note 27, at 376.

132. Matthew Potoski & Aseem Prakash, *The Regulation Dilemma: Cooperation and Conflict in Environmental Governance*, 64 PUB. ADMIN. 152, 154 (2004).

133. Sethi & Emelianova, *supra* note 97, at 226-238; Bartle & Vass, *supra* note 115.

134. Sethi & Emelianova, *supra* note 97, at 229.

threatens the longer-term viability of the technology, and the degree to which their reputation might be enhanced by being a signatory.[135] Industry pressure and mutual benefit may also be important drivers behind establishing a cooperative self-regulatory environment, especially in light of the involvement of high-profile transnational companies such as BASF and DuPont in the development of these self-regulatory initiatives. Such companies are indeed "heavily reliant on their corporate image for their commercial success."[136] Therefore, the ongoing pressure for credibility and the need to continually improve corporate performance may result in these organisations not only committing themselves to stricter monitoring and enforcement provisions but also encouraging other companies to sign up to such initiatives despite the costs of doing so.

A further characteristic of the voluntary initiatives is the ongoing commitment to consultation with stakeholders and seeking broader involvement in the nanotechnologies debate. Whether or not the inclusion of these consultation mechanisms is sufficient to provide the requisite credibility to ensure the support of the public and other stakeholders in the longer term remains to be seen. This is particularly the case in the absence of monitoring and enforcement mechanisms. History would suggest that gaining and maintaining public trust requires more substance than simply defining objectives and principles based solely on independent and consultative input during the developmental phase.

Putting these issues to one side, it is interesting to note that the chemical companies that have promoted the development and implementation of nanotechnology-specific schemes have done so primarily on an *ad hoc* basis and not through the framework of their national chemical associations. We would suggest that this is a shortcoming of the trends outlined in this Article, but one that could be easily rectified moving forward. As evidenced by the discussion presented above on Responsible Care, the chemical industry has a long history of employing what has been described as "one of the most sophisticated and advanced self-regulatory schemes yet developed."[137] Over the past twenty years, it has been rolled out to over fifty jurisdictions. Over that

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135. *See* Baggott, *supra* note 59, at 436; Potoski & Prakash, *supra* note 132, at 156; Webb & Morrison, *supra* note 19; King & Lenox, *supra* note 111, at 707.

136. Gunningham, *supra* note 59, at 63.

137. *Id.* at 93.

period, it has clearly shown the capacity to evolve in order to meet new challenges and address deficiencies within its structure. It is therefore somewhat perplexing to us as to why, with the exception of the German National Chemical Association, companies within this sector have opted to develop independent self-regulatory arrangements for addressing the challenges posed by nanotechnologies rather than leverage off an existing self-regulatory regime. By drawing upon the overarching goal of Responsible Care—"to drive continuous improvement in performance" in relation to health and safety[138]—we would argue that one approach to protecting safety would be to begin to incorporate nanotechnology-specific provisions into the plethora of existing Responsible Care tools while retaining the flexibility to incorporate new nanotechnology-specific codes as the science itself evolves. National chemical associations could therefore capitalise on the existing infrastructure, goodwill and peer-group pressure associated with the participating companies, as well as the credibility that Responsible Care has amassed overtime with the public as well as government authorities. While such an approach would not by itself overcome the many challenges associated with ensuring the responsible development of nanotechnologies, including the need to establish nanotechnology-specific standards within the instruments and to communicate compliance with these standards to the public, it would go some way in promoting a coherent approach to the responsible development of the technology.

V.
CONCLUSION

In the light of the preceding discussion, in particular the case study on the industrial chemicals sector, how might the regulation of nanotechnologies be expected to develop in the future? Moreover, is the influence of self-regulation by industry likely to be significant? The latter question is pretty easy to answer based on experience to date, and logically that answer is yes. The first question is significantly more uncertain and murky, but some reasonable projections might be made.

First, the growing importance of nanotechnologies—not just in the chemicals sector, but in industry and services more generally—is likely to fuel the emergence of an increasing number of new

138. INT'L COUNCIL OF CHEM. ASSOCIATIONS, *supra* note 102, at 4.

rules and a nano-specific regulatory infrastructure. As such, it appears only a matter of time before Marchant and Sylvester's prediction that nanotechnologies "will be subject to a host of regulations" is proven to be correct.[139] For example, the Australian Congress of Trade Unions has made calls for a mandatory labeling requirement for products containing nanomaterials; a national registry of all organisations importing, supplying or manufacturing products containing nanomaterials; and the development of specific nanotechnology handling standards for all industries.[140]

Second, the economic and political importance of industry groups and their capacity to interact with supranational and international actors such as the European Commission, ISO and the OECD will ensure that regulatory initiatives emanating from industry are influential in moulding the governance of nanotechnologies in both national and multi-lateral environments. The likelihood that nanotechnologies will transverse traditional sectors, in conjunction with its relatively low cost of market entry, will ensure that the regulatory agenda is fashioned by a multiplicity of actors. Governments, industry and civil society actors are likely to continue their participation in transnational policy discourse on governance related issues. It might be argued that such multi-pronged input arguably will result in greater legitimacy being ascribed to the policy formation process. However, it remains to be seen whether the ubiquitous capacities of nanotechnologies will prompt permanent parliamentary standing committees or an oversight regulatory agency that straddles several sectors.

Third, uncertainty about the impact of nanotechnologies on human and environmental health and safety may emerge as a brake on the proliferation of such technologies. This is particularly likely to occur if there is some sort of major public or ecological disaster and products incorporating nanomaterials or nanotechnology-based process can be fingered as a significant culprit. History shows that, across all sectors and jurisdictions, nothing begets new regulatory initiatives and agencies like crises, disasters or scandals. Scenarios of this nature may provide some civic actors with opportunities to influence the regulation of nanotechnologies in ways that they have been unable to do to date.

139. Marchant & Sylvester, *supra* note 51, at 714.

140. Dan Harrison, *Unions Call for Action to Oversee Nanotechnology*, AGE, Apr. 14, 2009, at 3.

Fourth, the influence of Adam Smith's "Invisible Hand" will be omnipresent as prevailing political and market realities interact with existing regulatory infrastructures and the priorities of diverse interest groups. This may especially be the case under contemporary recessionary conditions when capital becomes increasingly scarce and profitable investment opportunities less widespread. Applications incorporating nanomaterials which offer superior properties may be perceived in some quarters as especially promising and there may be, as a result, increased reluctance amongst some lawmakers to inhibit such activity.

Fifth, some regulatory strategies seem to hold promise in not only their capacity to promote entrepreneurial drive and innovation in nanotechnology-related contexts but also to promote the contribution of multiple actors to regulatory processes. Thus, these strategies gain traction from a legitimacy perspective whilst simultaneously integrating reasonable standards of public health priorities into regulatory protocols. As such, the private sector may seek to design and implement varying self-regulatory models in order to address the challenges presented by nanotechnologies and are arguably best placed to create such regulatory frameworks at this time. However, for reasons of legitimacy and industry's own best interests, it appears likely that a broader regulatory matrix co-produced by the private sector, governments and civic actors (including consumer and other special interest groups) will emerge in the coming years. The regulatory capacities of these groups will vary across time and relative rate of development, but as seen in the earlier discussion some evaluation of their effects are possible.

As a final comment, the *Holy Grail* of regulatory praxis does not change much whether for new technologies like those in the nano-sphere, or old technologies like water-powered energy or chemicals production. The challenge remains aligning strategic regulatory objectives (both public and private) with the pragmatic rough and tumble of market realities and tempering all of these with the legitimate priorities of public safety and industry development.