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A SMALL MATTER OF REGULATION: AN INTERNATIONAL REVIEW OF NANOTECHNOLOGY REGULATION

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Rapid technological advances and commercialisation within the emerging field of nanotechnology will challenge traditional regulatory regimes. Yet while the promising nanotechnology phenomenon has attracted extensive scientific and commercial interest, there has been only limited debate on the associated regulatory and legal aspects. This paper examines the current domestic and international regulatory frameworks into which nanotechnology is now being thrust. Using the context of the world's leading public sector investors, the United States and Japan, as well as Australia and the United Kingdom, the effectiveness of these regulatory frameworks is investigated. The paper argues that current national frameworks relevant for nanotechnology contain visible gaps. Furthermore, these regulatory fissures are magnified at the international level. As an example, the paper examines the role of the World Trade Organisation's Trade-Related Intellectual Property Rights Agreement and its applicability as one important regulatory mechanism in the commercialisation of nanotechnology. This paper concludes that if we can now learn from past regulatory successes and failures, nanotechnology offers a unique opportunity to re-evaluate the efficacy of current regulatory regimes, thereby circumventing some of the primary regulatory difficulties experienced with earlier technological advances.

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I. INTRODUCTION

Nanotechnology – a form of molecular engineering – promises significant social benefits, including enhancements in medical diagnosis and health treatments, more efficient energy sources, and lighter, faster and cheaper materials and electronic products.[1] Moreover, with Lux Research suggesting that "nanotechnology applications will affect nearly every type of manufactured good over the next ten years," this emerging technology promises economic and strategic significance for public and private sector investors alike.[2]

The rapid advance and commercialisation of this heterogenous family of technologies, however, presents a myriad of complex policy considerations which promise to test existing national and international frameworks. While Forrest[3] and Fielder and Reynolds[4] were among the first to speculate on the legal and regulatory challenges that would accompany the commercialisation of nanotechnology, there has been limited debate on this matter until recently.

This paper firstly defines nanotechnology. It then goes on to examine the range of frontiers relevant in nanotechnology regulation and proposes a conceptual framework covering six arenas of hard and soft law. Third, it considers four domestic regulatory jurisdictions into which nanotechnology is now being thrust – Australia, Japan, the United Kingdom (U.K.) and the United States (U.S.) – discussing briefly the effectiveness of these regulatory arrangements. Noting a distinct lack of nano-specific regulation, the paper then considers how each jurisdiction has chosen to regulate earlier technological advances, specifically genetically modified organisms (GMOs), when faced with social and political pressures for regulatory control. Finally, the article examines the role of international institutions and instruments in regulating nanotechnology, and the current policy initiatives within this sphere, in order to identify current regulatory fissures at the international level.

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[1] *See* Jeffery M. Perkel, *Nanotech Dreams*, 16 The Scientist 34 (2002); Mihail C. Roco, *Nanotechnology: Convergence with Modern Biology and Medicine*, 14 Current Opinion in Biotechnology 337 (2003); Royal Society and Royal Academy of Engineering, Nanoscience and Nanotechnologies: Opportunities and Uncertainties (July 29, 2004), *available at* http://www.nanotec.org.uk/finalReport.htm [hereinafter RS-RAE]; Stephen Wood, Richard Jones & Alison Geldart, *The Social and Economic Challenges of Nanotechnology*, Economic and Social Research Council, July 28, 2003, http://www.esrc.ac.uk/ESRCInfoCentre/Images/Nanotechnology_tcm6-5506.pdf.

[2] *Nanotechnology: Where Does the U.S. Stand*?: *Hearing Before the Subcomm. on Research of the H. Comm. on Sci.*, 109th Cong. 1 (2005) [hereinafter *Hearing*] (statement of Matthew M. Nordan, Vice President of Research, Lux Research Inc.).

[3] David Forrest, *Regulating Nanotechnology Development*, Foresight Nanotech Institute, Mar. 23, 1989, http://www.foresight.org/nano/Forrest1989.html.

[4] Fredrick Fiedler & Glen Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. Cal. Interdisc. L.J. 593 (1994).

II. DEFINING NANOTECHNOLOGY

The term "nanotechnology" encompasses an emerging family of heterogenous technologies including "nanosciences" and "nanotechnologies" enabling the manipulation of matter at the atomic level.[5] Nanotechnology is defined by its scale – the nanometer (nm) or one billionth (10^{-9}) of a meter. Conceptually, nanotechnology refers to the ability to control the composition of molecules and atoms, within the range of 100nm down to 1.0nm,[6] potentially enabling scientists to create specific molecular structures and devices.[7]

The commercial production of nano-scale applications has already begun, and hundreds of products incorporating nanotechnology are commercially available.[8] Products currently incorporating nanotechnology include simple passive nano-scale particles, compounds and composites for use in foods, pesticides, sunscreens, cosmetics, stain resistant clothing, automotive paints and coatings, sporting goods and digital cameras.[9] These are already available to purchase through pharmacies, sports stores and retail shops, as well as via the Internet. While nanotechnology is arguably an extension of traditional techniques within the fields of engineering, biology, chemistry and physics, its novelty lies in the purposeful and precise manipulation and control of atoms and molecules in order to exploit the unique properties of materials that emerge at the nanoscale.[10] At this scale, the classic laws of physics are no longer applicable, resulting

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[5] Eric Drexler, Chris Peterson & Gayle Pergamit, *Unbounding the Future: The Nanotechnology Revolution*, Foresight Nanotech Institute, 1991, http://www.foresight.org/UTF/Unbound_LBW/index.html.

[6] Wood, Jones & Geldart, *supra* note 1, at 1.

[7] Forrest, *supra* note 3.

[8] Environmental Law Institute (ELI), *Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job?*, Oct., 2005, http://www.elistore.org/Data/products/d15_10.pdf [hereinafter ELI].

[9] Robert Pinson, *Is Nanotechnology Prohibited By the Biological and Chemical Weapons Conventions?*, 22 Berkeley J. Int'l L. 279 (2004); ETC Group, *The Big Down: Atomtech - Technologies Converging at the Nano-scale*, 2003, http://www.etcgroup.org/upload/publication/171/01/thebigdown.pdf [hereinafter ETC Group, *The Big Down: Atomtech*]; ETC Group, *Down on the Farm*, Nov., 2004, http://www.etcgroup.org/upload/publication/80/01/etc_dotfarm2004.pdf; ELI, *supra* note 8. For details of commercially available nanotechnology-based consumer products, *see, e.g.*, Project on Emerging Nanotechnology, Woodrow Wilson International Center for Scholars, A Nanotechnology Consumer Product Inventory, http://www.nanotechproject.org/44 (last visited Jan. 26, 2007).

[10] John M. Balbus et al., *Getting Nanotechnology Right the First Time,* Issues in Sci. and Tech., Summer 2005, at 65.

in novel properties and functions.[11] Specifically, materials at the nanoscale, relative to the same materials at a larger size, have significantly different chemical reactivity, electrical conductivity, strength, mobility, solubility, magnetic and optical properties.[12] The Action Group on Erosion, Technology and Concentration (ETC Group) suggests that "by tailoring the structure of materials at the nano-scale, it is possible to engineer novel materials that have entirely new properties never before identified in nature."[13] Carbon nanotube (CNT) materials, already used in Chevrolet cars in the United States, display some of these new properties. CNTs are reportedly "100 times stronger than steel and six times lighter."[14] Another example is ZinClear, nanofine zinc oxide molecules used in creating sunscreen that is transparent, but with a broad spectrum of UV protection.[15]

Putting the amazing properties of these products aside, however, the unpredictability and novelty of manufactured nanoparticles has also seen commentators, such as Balbus et al., suggest that:

> these novel properties may pose new risks to workers, consumers, the public, and the environment. The few data now available give cause for concern: Some nanomaterials appear to have the potential to damage skin, brain, and lung tissue, to be mobile or persistent in the environment, or to kill micro-organisms (potentially including ones that constitute the base of the food web).[16]

Yet, as noted by the Environmental Law Institute (ELI), "even as nanotech products find their way to store shelves, little is known about the risk associated with their manufacture, use, and disposal."[17]

Longer term ideals for nanotechnology are elaborate, challenging and speculative, and could logically be regarded at this stage as in the realm of science fiction. Drexler argues that a later phase of nanotechnology development, which he coined "molecular manufacturing," will be underpinned by the creation of computer-directed nano-scale

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[11] RS-RAE, *supra* note 1.

[12] *Id*. at 7-24; Swiss Reinsurance Company, *Nanotechnology: Small Matter, Many Unknowns*, 2004, http://www.swissre.com (follow "Top Topics view" hyperlink under "Research and Publications" tab; then follow "Nanotechnology" hyperlink; then follow "Nanotechnology: Small Matter, Many Unknowns" hyperlink).

[13] ETC Group, *The Big Down: Atomtech*, *supra* note 9, at 14.

[14] *Id*. at 22.

[15] Advanced Nanotechnology Limited, ZinClear - The Nanofine Zinc Oxide for Cosmetic Clarity and Broad Spectrum UV Protection, http://www.advancednanotechnology.com/zinclear.php (last visited Jan. 26, 2007).

[16] Balbus et al., *supra* note 10, at 65.

[17] ELI, *supra* note 8, at 3.

robots capable of precise manipulation of atoms to form complex atomic devices and machines.[18] Such "nano-bots" may in the future travel through the blood stream seeking and killing off cancer cells, or may assist with the regeneration of healthy cells. At the opposite extreme, it may also be possible to use nano-bots for military purposes to detect motion in a field and transmit signals many miles away, or achieve "programmable" genocide. Drexler's vision is that such robots, known as "assemblers," will have the ability to self-replicate, or clone themselves, and have the subsequent ability to work in unison to build macro-scale devices en masse. While commentators such as Whiteside[19] and Smalley[20] have dismissed these ideas as futuristic hype, nanotechnology nevertheless captures one exciting conceptual possibility, and the idea of "fabrication from a molecular level of virtually any material or structure"[21] continues to have dramatic appeal.[22]

[18] Eric Drexler, *Engines of Creation: The Coming Era of Nanotechnology* 1 (Anchor Books 1986); Eric Drexler, *Machine-Phase Nanotechnology*, Sci. Am., Sept. 2001, at 74.

[19] George M. Whiteside, *The "Right" Size in Nanobiotechnology*, 21 Nature Biotechnology 1161 (2003).

[20] Richard Smalley, *Of Chemistry, Love and Nanobots*, Sci. Am., Sept. 2001, at 76.

[21] Wood, Jones & Geldart, *supra* note 1, at 1.

[22] The doomsday scenario contemplating the accidental release of uncontrollable self-replicating nanobots in the environment which consume everything in their path and cover the whole world in "grey goo" is one such vision of global destruction. While some environmental risks undoubtedly do exist, commentators such as Chris Phoenix of the Center for Responsible Nanotechnology argue that "there's really no risk of molecular manufacturing developing something that could accidentally become grey goo. It simply won't happen in a laboratory. It would be like expecting your laser printer to jump off the desk and go out and forage for toner." *Background Briefing: Nanotechnology – Nature's Toy Box* (ABC radio broadcast Nov. 14, 2004).

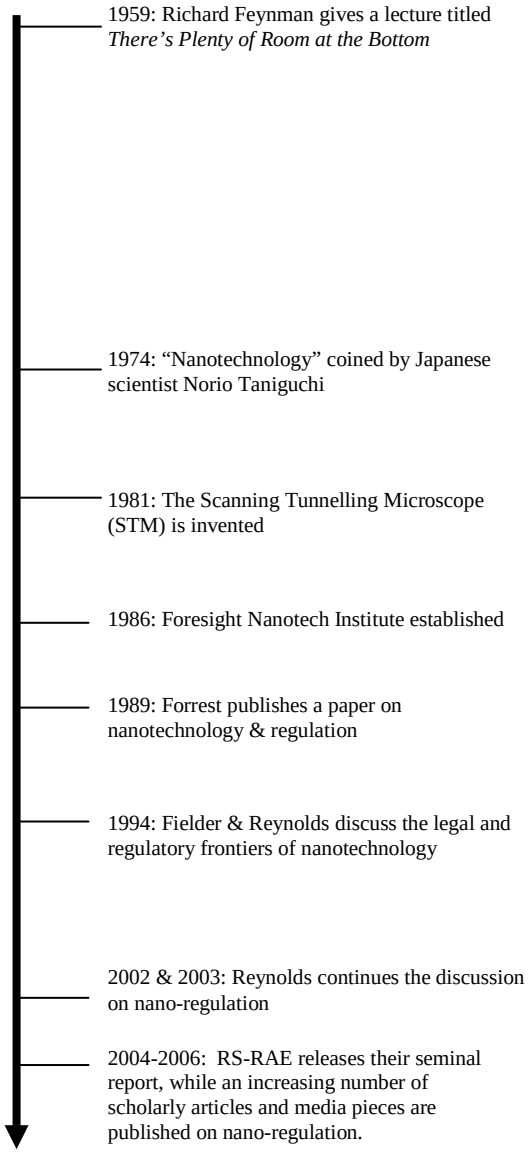

Figure 1 – A Timeline of the Nano-Regulation Debate

III. REGULATORY FRONTIERS

While the primary focus for nanotechnology continues to be on the coordination and funding of R&D initiatives in conjunction with the commercialisation of nano-products, there is increasing attention being paid to the wider impacts of nanotechnology. This has included questions of whether and how to regulate nanotechnology. Arguably the release of the Royal Society and Royal Academy of Engineering's (RS-RAE) seminal report on nanotechnology has acted as a catalyst for the "nano-regulation" debate.[23] However, it is important to recognise that the question in itself is not new, having been canvassed by Forrest some fifteen years earlier (as depicted in Figure 1).[24] Despite the futuristic nature of nanotechnology in the late 1980s, Forrest contended that "[t]he development of nanotechnology . . . will seriously challenge the ability of our regulatory system to respond quickly and to maintain the critical balance between dangers and benefits."[25] This argument led Forrest to conclude that for the safe development of nanotechnology, governments would be required to explore a range of flexible nano-specific regulatory frameworks in which varying degrees of regulatory control exercised would be dependent on each phase of development.

Fiedler and Reynolds similarly provided an early and significant contribution to the examination of legal and regulatory frontiers for nanotechnology in an article which they considered "more of a wakeup call than a road map, [in that] it raises far more questions that it answers."[26] The authors note that nanotechnology may well evolve in a number of distinct phases, each progressing with its own legal, regulatory, societal and political issues. In considering the different phases and potential applications of nanotechnology, Fiedler and Reynolds discussed the blurring of conventional regulatory boundaries and the challenges that this will pose for regulators and current legislation.[27] Even at this early stage of deliberations, they suggested the need for a nano-specific regulatory model, noting that:

> appropriate controls, in the form of regulations and legislation, must be tailored to fit the risk/benefit ratio . . . . One way to positively control nanotechnology is to contemplate the likely directions new technologies will take and to prepare flexible legislation providing for appropriate regulatory schemes even before the products arrive in the marketplace.[28]

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[23] RS-RAE, *supra* note 1, at 69-78.

[24] Forrest, *supra* note 3.

[25] *Id*. at 1.

[26] Fiedler & Reynolds, *supra* note 4, at 595.

[27] *Id*. at 605-18.

[28] *Id*. at 629.

Reynolds has continued to engage in the debate over nano-regulation, articulating the advantages and disadvantages of several theoretical models for regulating nanotechnology.[29] While Reynolds suggests that the "discussions over nanotechnology should begin sooner rather than later, because as the debate grows more intense and as the science approaches feasibility, it becomes more difficult to think carefully about the issues involved," concluding that an effective framework for regulating nanotechnology would require self-regulation and co-regulation.[30]

More recently, scholars such as Hodge and Bowman,[31] Wejnert,[32] Pinson,[33] Marchant and Sylvester,[34] Davies,[35] and Bowman and Hodge,[36] have begun to consider whether and how governments should regulate nanotechnology. Many others have also joined this chorus.[37] In 2004, Hodge and Bowman argued that nanotechnology "is

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[29] Glenn Harlan Reynolds, *Forward to the Future: Nanotechnology and Regulatory Policy*, Pacific Research Institute, 2002, http://www.pacificresearch.org/pub/sab/techno/forward_to_nanotech.pdf; Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 Harv. J.L. & Tech. 180 (2003).

[30] Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, *supra* note 29, at 181.

[31] Graeme A. Hodge & Diana M. Bowman, *Governing Nanotechnology: Setting the Regulatory Agenda*, 10 J. Contemp. Issues Bus. & Gov't 18 (2004).

[32] Jason Wejnert, *Regulatory Mechanisms for Molecular Nanotechnology*, 44 Jurimetrics J. 323 (2004).

[33] Robert D. Pinson, *Is Nanotechnology Prohibited By the Biological and Chemical Weapons Conventions?*, 22 Berkeley J. Int'l L. 279 (2004).

[34] Gary E. Marchant & Doug J. Sylvester, *Transnational Models for Regulation of Nanotechnology*, 34 J.L. Med. & Ethics 714 (2006).

[35] J. Clarence Davies, *Managing the Effects of Nanotechnology*, Woodrow Wilson International Center for Scholars, Jan. 11, 2006, http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf.

[36] Diana M. Bowman & Graeme A. Hodge, *Nanotechnology: Mapping the Wild Regulatory Frontier*, 38 Futures 1060 (2006).

[37] For increasing media discussion on nano-regulations, *see* Rick Weiss, *Nanotechnology Regulation Needed, Critics Say*, Wash. Post, Dec. 5, 2005, at A08; Rick Weiss, *Stricter Nanotechnology Laws Are Urged*, Wash. Post, Jan. 11, 2006, at A02; Kevin Bullis, *Can EPA Regulate Nano?*, Technology Review - An MIT Enterprise, Dec. 20, 2005, http://www.technologyreview.com/read_article.aspx?id=16068&ch=nanotech; Kevin Bullis, *New Nano Law?*, Technology Review - An MIT Enterprise, Jan. 17, 2006, http://www.technologyreview.com/read_article.aspx?id=16152&ch=nanotech. For a more general discussion on the interface between nanotechnology and the law, *see, e.g.*, Sonia E. Miller, *A Matter of Torts: Why Nanotechnology Must Develop Processes of Risk Analysis*, 232 N.Y. L.J. 5 (2004); Sonia E. Miller, *Regulating Nanotechnology: The FDA and the EPA Are*

sufficiently unlike other technologies [so as] to warrant separate consideration" in respect to regulatory frameworks.[38] In doing so, they noted that governments around the world had so far remained passive to the issue of nano-specific regulations as well as broader public policy considerations. Hodge and Bowman articulated, within the Australian context, five broad research questions, which they suggest must be addressed by governments, regulators and academics in order for the benefits of nanotechnology to be realised. The questions posed for nations were:

1. To what extent ought this new technology be treated differently to existing scientific and commercial advances in related arenas?
2. In the context of global research in regulating nanotechnology advances, how well do current [national] regulatory regimes deal with this form of technology?
3. What are the high priority regulatory, ethical and legal issues for our attention in terms of protecting the advances of the business sector on the one hand, and the concerns of communities on the other?
4. What are the relevant lessons in terms of successes and failures in the regulation of other recent advancing technologies?
5. What forms of regulatory, ethical and legal arrangements might be most effective now in meeting . . . priority needs [for the nation]?[39]

In undertaking this international review of nanotechnology regulation, this paper draws upon several of these questions.

Likely Federal Watchdogs, 233 N.Y. L.J. 5 (2005); Allianz & Organization for Economic Co-operation and Development (OECD), *Small Sizes That Matter: Opportunities and Risks of Nanotechnologies*, June 3, 2005, http://www.oecd.org/dataoecd/4/38/35081968.pdf; Munich Re Group, *Nanotechnology: What is in Store for Us?*, 2002, http://www.nanovic.com.au/downloads/whats_in_store.pdf; Swiss Reinsurance Company, *supra* note 12. *See also* Balbus et al., *supra* note 10, at 65; Michael Bennett, *Does Existing Law Fail to Address Nanotechnoscience?*, IEEE Tech. & Soc'y Mag., Winter 2004, at 27; Francisco Castro, *Legal and Regulatory Concerns Facing Nanotechnology*, 4 J. Chi.-Kent Intell. Prop. 160 (2004); Donald Elliott, *Regulate Nano Now*, Envtl. F., July/Aug. 2005, at 43; John Miller, *Beyond Biotechnology: FDA Regulation of Nanomedicine*, 4 Colum. Sci. & Tech. L. Rev. 5 (2003); Graeme A. Hodge et al., Governing the Invisible: The New Regulatory Frontiers of Nanotechnology (Oct. 26-29, 2005) (paper presented at Integrated Governance: Linking up Government, Business & Civil Society, Monash University Prato Centre, Italy), http://www.nanovic.com.au/downloads/governing_invisible.pdf; Mireille Oud, *4th Nanoforum Report: Benefits, Risks, Ethical, Legal and Social Aspects of Nanotechnology - Part 7: The Need for and Rise of New Legislation and Regulation Caused by the Emergence of Nanotechnology*, Nanoforum.org: European Nanotechnology Gateway, Oct. 2005, http://www.nanoforum.org/dateien/temp/ELSIPart%207.pdf?25092006193756; Ahson Wardak, *Nanotechnology & Regulation: A Case Study using the Toxic Substance Control Act (TSCA)* (Woodrow Wilson Int'l Center for Scholars, Discussion Paper No. 2003-6), *available at* http://www.nanotechcongress.com/Nanotech-Regulation.pdf.

[38] Hodge & Bowman, *supra* note 31, at 18.

[39] *Id*. at 29.

Wejnert's examination of the need for a regulatory framework for molecular nanotechnology (MNT) provides a comprehensive critique of how existing regulatory mechanisms – including international treaties and conventions, U.S. domestic regulatory institutions and legislation, self-regulation, standards and controls – may cope with the risks promised by MNT.[40] Articulating both the advantages and disadvantages of each mechanism in conjunction with the issues of outright prohibition and the precautionary principle, Wejnert concludes "that the best approach will be a cooperative government-industry initiative in which there can be open dialogue and input from many different technological and administrative bodies with some expertise in managing technology."[41]

Focusing on the potential military applications promised by nanotechnology, Pinson examines the applicability of existing international warfare conventions – including the Biological Weapons Convention and Chemical Weapons Convention – for regulating this potentially perilous area.[42] Asserting that while "most uses are harmless and need not be regulated," Pinson nevertheless suggests that due to the unique characteristics of this emerging technology – namely invisibility, micro-locomotion and self-replication – a number of nano-applications should be regulated by a moderate new regulatory regime.[43]

Marchant and Sylvester see things differently. They have "complete confidence in one aspect of nanotechnology's future – [that] it will be subject to a host of regulations," and examine whether the locus of regulatory control is best suited to the international or national arena.[44] Hypothesising that "much of nanotechnology's coming regulations will inevitably fall into transnational frameworks," Marchant and Sylvester go on to examine a range of existing international instruments – including environmental agreements, arms control treaties, frameworks, conventions and customary international law – and institutions, as well as their likely effectiveness for regulating nanotechnology. Issues of scope, flexibility, compliance, enforcement, political will and cost are highlighted as potential barriers for the adoption of a nano-specific international regulatory framework.[45] Marchant and Sylvester's analysis concludes that while an international regulatory framework for nanotechnology is unlikely to evolve in the short to medium term, the shaping of regulatory frameworks for earlier technologies provides insight into how a model may be constructed.

Providing a methodical review of how existing U.S. institutions and instruments will regulate nanotechnology, Davies argues that due to the unique characteristics of nanotechnology, the current domestic regulatory framework will not be adequate for

[40] Wejnert, *supra* note 32.

[41] *Id*. at 350.

[42] Pinson, *supra* note 9.

[43] *Id*. at 305.

[44] Marchant & Sylvester, *supra* note 34 (manuscript at 1).

[45] *Id*. (manuscript at 9).

protecting human and environmental safety.[46] By accentuating existing regulatory challenges, Davies concludes that while greater coordination between agencies and/or the tacking on of nano-specific amendments to current legislation may decrease the size of regulatory gaps, new nano-specific legislation may offer a better alternative. [47] Unsurprisingly, this suggestion has received considerable criticism from regulatory agencies, government officials and industry representatives.[48]

In examining the current regulatory framework for nanotechnology in Australia, Bowman and Hodge suggest that the convergence of scientific domains with nanotechnology is resulting in a blurring of traditional decentralised regulatory boundaries.[49] They suggest that as the number and range of nano-products that enter the market increases, the complex nature and interaction of regulatory agencies, codes and practices will require greater transparency between agencies and government. Arguably a failure to clarify issues of regulatory scope for nanotechnology may result in the magnification of existing regulatory fissures.

So, how might we bridge the gaps between the pragmatic "moderate new regulatory regime" suggested by Pinson[50] and the "new nano-specific legislation" recommended by Davies[51] on the one hand, and the conceptual recognition on the other hand that regulatory frameworks for nanotechnology will inevitably be transnational but that they are also unlikely to evolve in the short to medium term?[52] What conceptual frameworks are available here? One suggested step forward is recommended by Bowman and Hodge,[53] as illustrated in Figure 2.

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[46] Davies, *supra* note 35, at 18-23.

[47] *Id*. at 3.

[48] Rick Weiss, *Stricter Nanotechnology Laws are Urged*, Wash. Post, Jan. 11, 2006, at A02; Associated Press, *Regulating Nano*, Tech. Rev., Jan. 11, 2006, http://www.technologyreview.com/read_article.aspx?id=16138&ch=,nanotech&sc=&pg=1.

[49] Bowman & Hodge, *supra* note 36.

[50] Pinson, *supra* note 9, at 308.

[51] Davies, *supra* note 35, at 18-23.

[52] Marchant & Sylvester, *supra* note 34.

[53] Bowman & Hodge, *supra* note 36, at 1069.

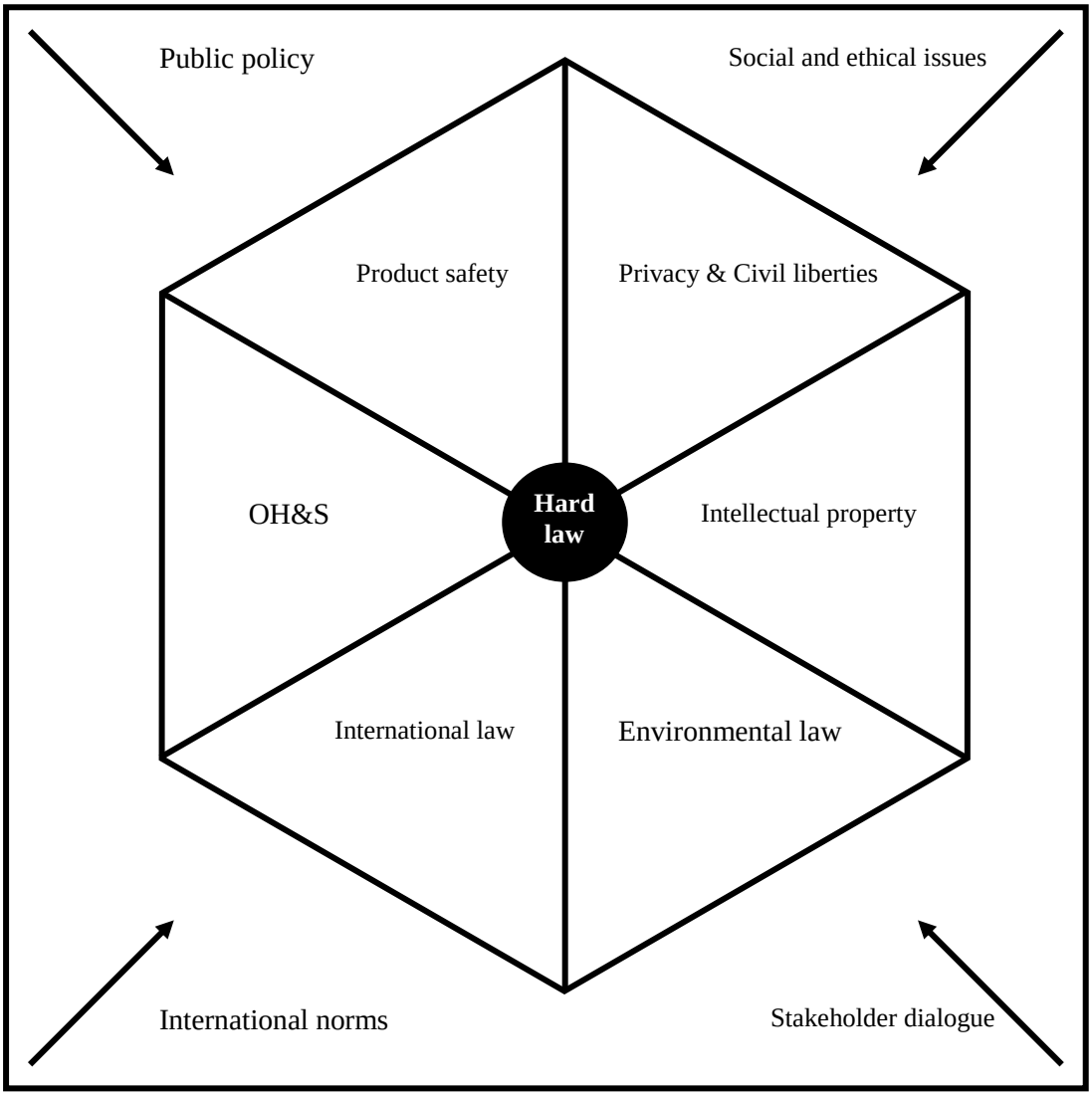

Figure 2 – A Conceptual Model for the Regulatory Frontiers of Nanotechnology

Bowman and Hodge suggest six regulatory frontiers: product safety, privacy and civil liberties, occupational health and safety (OH&S), intellectual property (IP), international law and environmental law. For each specific frontier, they adopt the "enforcement pyramid" notion, proposed by Ayres and Braithwaite, in which a range of regulatory mechanisms are viewed as possible, from the traditional arena of hard law at the top, through licensing, codes of practice, guidelines and other "soft law" roles further

down towards the base of the pyramid.[54] Bowman and Hodge suggest that "regulatory responses will be made within the broader context of public policy concerns and international norms in which stakeholder dialogue occurs."[55] They conclude that governments must now take a proactive role in addressing each of these frontiers in order to avoid the "regulatory failures" associated with earlier technologies, including, for example, asbestos.

Bearing these notes of caution in mind, we now turn our attention to evaluating a number of these regulatory frontiers for nanotechnology within the context of several domestic regulatory frameworks. This section of the paper also considers the potential lessons that may be learnt from the regulatory approach implemented by each jurisdiction to regulate earlier advances of modern biotechnology.

IV. WHO IS REGULATING WHAT? AN EVALUATION OF THE NANOTECHNOLOGY REGULATORY FRONTIERS WITHIN FOUR NATIONAL REGULATORY REGIMES

While the commercialisation of nanotechnology has only just begun, market entry to date has been relatively unconstrained due a distinct absence of nano-specific regulatory frameworks. Bowman and Hodge, for instance, note that "while governments have invested heavily in R&D programs they have been noticeably unenthusiastic about implementing new [nano-specific] regulatory frameworks for risk minimisation."[56] This is not to say, however, that nanotechnology is not regulated per se, with Marchant and Sylvester quick to point out that many nano-products fall within pre-existing regulatory frameworks or oversight.[57] Table 1 below maps three of the six regulatory frontiers for nanotechnology as articulated by Bowman and Hodge – specifically, OH&S, product safety and environmental law – within the currently decentralised national regulatory frameworks in Australia, Japan, the United Kingdom and the United States.[58]

[54] Ian Ayers & John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press 1992).

[55] Bowman & Hodge, *supra* note 36, at 1068.

[56] *Id*. at 1065.

[57] Marchant & Sylvester, *supra* note 34 (manuscript at 1).

[58] Bowman & Hodge, *supra* note 36.

Table 1 - *Mapping the Regulatory Frontiers for Nanotechnology within Four National Regulatory Frameworks*[59]

	Australia		*Japan*		*United Kingdom*		*United States*	
	Regulatory Body	*Key Legislation / Code of Practice*	*Regulatory Body*	*Key Legislation / Code of Practice*	*Regulatory Body*	*Key Legislation / Code of Practice*	*Regulatory Body*	*Key Legislation / Code of Practice*
Nano-specific regulator?	No		No		No		No	
Nano-specific legislation?	No		No		No		No	
Occupational Health and Safety (OH&S)	Australian Safety and Compensation Council.	National Model Regulation for the Control of Workplace Hazardous Substances.	Ministry of Health, Labour and Welfare.	Industrial Safety and Health Law, Law No. 57 of 1972.	Health and Safety Executive.	Health and Safety at Work Act,1974, c. 37; Control of Substances Hazardous to Health Regulations, 2002, S.I. 2002/2677; Workplace (Health, Safety and Welfare) Regulations, 1992, S.I. 1992/3004.	Department of Labor.	Occupational Safety and Health Act, 29 U.S.C. § 651 (1970).
Industrial Chemicals	National Industrial Chemicals Notification and Assessment Scheme.	Industrial Chemicals (Notification and Assessment) Act 1989.	Ministry of Economy, Trade and Industry; Ministry of Health, Labour and Welfare; Ministry of the Environment.	Chemical Substances Control Law, Law No. 117 of 1973.	Chemical Industries Division, Health and Safety Executive; Department of Food and Rural Affairs.	Notification of New Substances Regulations, 1993, S.I. 1993/3050; to be superseded by Registration, Evaluation, Authorisation and Restriction of Chemicals, COM (2003) 644.	Environmental Protection Agency.	Toxic Substances Control Act, 15 U.S.C. § 2601 (1976).

[59] For Australia: *see id.*; Lee Ann Jackson, *Protectionist Harmonization of Food Safety Policies in the Asia-Pacific Region* (U. Adelaide Centre Int'l Econ. Stud., Discussion Paper No. 0301, 2003), *available at* http://www.adelaide.edu.au/cies/papers/0301.pdf. For Japan: *see* Pharmaceutical and Medical Devices Agency (Japan), *Profile of Services*, 2005, http://www.pmda.go.jp/pdf/20050513pamphlet-e.pdf; Ministry of Economy, Trade and Industry (Japan), Policy Information – Chemical Substances Control Law, http://www.meti.go.jp/english/information/data/cKashinLaw.html (last visited Jan. 26, 2007). For the United States: *see* Davies, *supra* note 35; U.S. Department of Agriculture (USDA), U.S. Regulatory Agencies Unified Biotechnology Website - Role of U.S. Agencies, http://usbiotechreg.nbii.gov/roles.asp (last visited Jan. 26, 2007) [hereinafter USDA]. For the United Kingdom: *see* RS-RAE, *supra* note 1; U.K. Health and Safety Executive, Health and Safety Regulation: A Short Guide (2003), http://www.hse.gov.uk/pubns/hsc13.pdf; U.K. Pesticides Safety Directorate Department for Environment, Food and Rural Affairs, *Annual Reports and Accounts 2004/05: Pesticides Safety Directorate*, 2005, http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/PSD_Annual_Report_2004-05_low_resol(1).pdf; Richard Moore, *Nanotechnology and Novel Medical Technology Products: Overcoming Regulatory and Other Challenges* (Nov. 29-30, 2004) (paper presented at the Associazione Italiana per la Ricerca Industriale (AIRI) Conference on Nanotechnology and Smart Materials for Medical Applications, Rome), http://www.nanotec.it/nanomedicine/presentazioni/moore.pdf.

Table 1 - *Mapping the Regulatory Frontiers for Nanotechnology within Four National Regulatory Frameworks* (cont'd)

	Australia		*Japan*		*United Kingdom*		*United States*	
Therapeutic Goods & Medical Products	Therapeutic Goods Administration.	Therapeutic Goods Act 1989.	Pharmaceutical and Medical Device Agency.	Pharmaceutical Affairs Law, Law No. 145 of 1960.	Medicines and Healthcare Products Regulatory Agency, Department of Health; European Agency for the Evaluation of Medicinal Products.	Medicines Act, 1968, ch. 67; Council Directive 93/42/EEC, Medical Devices 1993 O.J. (L 169) 1 (EU); Council Directive 2001/83/EC. Medicinal Products, 2001 O.J. (L 311) 67 (EC); Medical Devices Regulation, 2002, S.I. 2002/618; The Medical Devices (Amendment) Regulations, 2003, S.I. 2003/1697.	Food and Drug Administration.	Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (1938).
Cosmetics	National Industrial Chemicals Notification and Assessment Scheme.	Industrial Chemicals (Notification and Assessment) Act 1989.	Pharmaceutical and Medical Device Agency.	Pharmaceutical Affairs Law, Law No. 145 of 1960.	Department of Health; Department of Trade and Industry.	Council Directive 76/768/EEC Cosmetic Directive, 1976 O.J. (L 262) 169 (EU); Cosmetic Products (Safety) Regulations, 2003, S.I. 2003/835.	Food and Drug Administration.	Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (1938).
Food	Food Standards Australia and New Zealand.	Food Standards Code.	Department of Food Safety; Ministry of Health, Labour & Welfare.	Food Sanitation Law, Law No. 233 of 1947; The Food Safety Basic Law, Law No. 48 of 2003.	Food Standards Agency.	Food Safety Act, 1990, c.16; Food Standards Act, 1999, c.28; Commission Regulation 882/2004, Feed and Food Controls, 2004 O.J. (L 191) 1 (EU).	Food and Drug Administration.	Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (1938).

Table 1 - *Mapping the Regulatory Frontiers for Nanotechnology within Four National Regulatory Frameworks* (cont'd)

	Australia		*Japan*		*United Kingdom*		*United States*	
Pesticides & Veterinary Medicines / Agricultural Chemicals	Australian Pesticides and Veterinary Medicines Authority.	Agricultural and Veterinary Chemicals Administration Act 1992; Agricultural and Veterinary Chemicals (Code) Act 1994.	Ministry of Agriculture, Forestry and Fisheries.	Agricultural Chemicals Regulation Law, Law No. 82 of 1948; Fertilizer Control Law, Law No. 127 of 1950.	Pesticides Safety Directorate(agricultural pesticides); Health and Safety Executive (non-agricultural pesticides).	Food and Environment Protection Act, 1985, c.48; Control of Pesticides Regulations, 1986, S.I. 1986/1510; Council Directive 91/414/EEC, Plant Protection Products, 1991 O.J. (L 230) 1 (EU); Plant Protection Products Regulations, 2005, S.I. 2005/1435.	Food and Drug Administration.	Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136 (1996); Toxic Substances Control Act, 15 U.S.C. § 2601 (1976).
Environment	Department of the Environment and Heritage.	Environment Protection and Biodiversity Conservation Act 1999.	Ministry of the Environment.	Air Pollution Control Law, Law No.97 of 1968; Waste Disposal and Public Cleansing Law, Law No. 137 of 1970; Water Pollution Control Law, Law No. 138 of 1970; The Basic Environment Law, Law No. 91 of 1993.	Environment Agency.	Food and Environment Protection Act, 1985, c.48; Environmental Protection Act, 1990, c.43.	Environmental Protection Agency.	Clean Water Act, 33 U.S.C. § 1251 (1977); Resource Conservation and Recovery Act, 42 U.S.C. § 6901 (1976); Clean Air Act, 42 U.S.C. § 7401 (1970).

As clearly illustrated in Table 1, government regulation of these three frontiers of nanotechnology is based on pre-existing legislation and codes, divided among a number of national agencies. As yet, none of the four countries have enacted nano-specific regulations despite the RS-RAE having noted the existence of a gap within the United Kingdom's regulatory framework for chemicals due to the failure of regulations to evaluate size-dependent risks of "existing" chemicals.[60] As with the United Kingdom, the chemical regulatory frameworks for Australia, Japan and the United States are primarily focused on "new chemicals."[61] And crucially, existing chemicals produced at the nanoscale are not considered to be "new" for purposes of the regulatory framework despite the unpredictability and novelty of manufactured nanoparticles.[62] The failure of each country to address this gap is of increasing concern because, while the commercialisation of products containing manufactured nano-particles continues to escalate, our understanding of technological impacts such as human and environmental toxicology proceeds more slowly. As a consequence of this, our ability to sensibly develop processes to govern the technology remains modest.

While Australia and Japan appear to have only begun grappling with questions regarding regulation and societal concerns,[63] the U.K. government appears to have taken

[60] RS-RAE, *supra* note 1, at 6.

[61] *See, e.g.*, Davies, *supra* note 35, at 10; Australian Government National Industrial Chemicals Notification and Assessment Scheme (NICNAS), About NICNAS, http://www.nicnas.gov.au/About_NICNAS.asp (last visited Jan. 26, 2007); NICNAS, Chemicals in Australia, http://www.nicnas.gov.au/Chemicals_In_Australia.asp (last visited Jan. 26, 2007); Ministry of Economy, Trade and Industry (Japan), Overview of the Chemical Substances Control Law, http://www.meti.go.jp/english/information/data/chemical_substances03.html (last visited Jan. 26, 2007). This is not to say, however, that these systems do not allow for the regulatory agencies to review existing chemicals, but rather that their primary focus is on "new" chemicals, currently not including nanoparticles.

[62] In their report, the Royal Society and Royal Academy of Engineers note that at the nanoscale, quantum effects and a relatively higher surface-area-to-mass ratio than in larger materials can lead to novel properties and functions in materials. RS-RAE, *supra* note 1, at 2. Specifically, relative to the same material of a larger size, materials at the nanoscale will have significantly different chemical reactivity, electrical conductivity, strength, mobility, solubility, magnetic, and optical properties. *Id*.

[63] *See, e.g.*, Prime Minister's Science Engineering and Innovation Council (Australia), *Nanotechnology: Enabling Technologies for Australian Innovative Industries*, Mar. 11, 2005, at 4-7, http://www.dest.gov.au/NR/rdonlyres/1E1B501A-727A-4153-85EF-134B2DAF0925/4112/nanotechnology_pmseic110305.pdf; Press Release, Australian Government Minister of Industry, Tourism, and Resources, Report into the Technology of the Small – Nanotech (Sept. 12, 2006), http://minister.industry.gov.au/index.cfm?event=object.showContent&objectID=9F438BD9-B559-B871-73AFDD21B1A3207D; National Nanotechnology Strategy Taskforce (Australia), *Options for a National Nanotechnology Strategy*, June, 2006, at 3, http://www.industry.gov.au/assets/documents/itrinternet/taskforcereportweb2picture20060904103551.pdf; The Royal Society (U.K.) & Science Council of Japan, *Report of Workshop on Potential Health, Environmental and Societal Impacts of Nanotechnologies*, July 11-12, 2005, at 1,

a leading role in generating discussion on nano-regulation. For instance, in 2003, the U.K. Better Regulation Taskforce identified nanotechnology as an area of potential regulatory concern.[64] The findings of the report provided the impetus for the U.K. government to commission the RS-RAE to conduct a joint inquiry into nanotechnology. The result of this inquiry was that "the evidence suggests [that] present regulatory frameworks at [the European Union] and U.K. level are sufficiently broad and flexible to handle nanotechnologies at their current stage of development. However, some regulations will need to be modified on a precautionary basis."[65] A prime example here might be that of food standards. To avoid the emergence of new regulatory fissures, the report recommended that that "all relevant regulatory bodies consider whether existing regulations are appropriate to protect humans and the environmental hazards outlined in the report and publish their review and details of how they will address any regulatory gaps."[66] In its response to the RS-RAE, the U.K. government supported the recommendation that all relevant existing regulatory bodies should assess their regimes for current regulatory gaps and future regulatory gaps,[67] and noted that regulatory agencies including the Food Standards Agency (FSA) were currently in the process of undertaking "horizon scanning programmes" to identify potential regulatory gaps.[68]

Similarly, the U.K. government has supported the RS-RAE's recommendation that nanoparticles be considered as new chemicals under the existing U.K. and proposed European Union (E.U.) regulatory regime (covering Registration, Evaluation and Authorisation of Chemicals (REACH)). Moreover, in their response, the U.K. government noted that it "considers it likely that sector-specific regulations, in addition to REACH, may be required, and this will be a key question addressed in the regulatory review."[69] While these reviews[70] and horizon scanning exercises were still incomplete at

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http://www.royalsoc.ac.uk/displaypagedoc.asp?id=17357; Masafumi Ata et al., *Research Project on Facilitation of Public Acceptance of Nanotechnology: Summary and Policy Recommendations*, National Institute of Advanced Industrial Science and Technology (Japan) et al., Mar. 31, 2006, at 2, http://unit.aist.go.jp/techinfo/ci/www/honkaku/project/nanotech_society/summary_e.pdf.

[64] Better Regulation Task Force (U.K.), *Scientific Research: Innovation with Controls*, Jan., 2003, at 32-33, http://www.brc.gov.uk/downloads/pdf/scientificresearch.pdf.

[65] RS-RAE, *supra* note 1, at 6.

[66] *Id*. at 8.

[67] U.K. Government, *Response to the Royal Society and Royal Academy of Engineering Report: 'Nanoscience and Nanotechnologies: Opportunities and Uncertainties*,' Feb., 2005, at 13, http://www.dti.gov.uk/files/file14873.pdf.

[68] Advisory Committee on Novel Foods and Processes (U.K.), *Nanoparticles in Foods* (Committee Paper for Discussion No. ACNFP/70/4, 2005), at 2, *available at* http://www.food.gov.uk/multimedia/pdfs/acnfp_70_4.pdf.

[69] U.K. Government, *supra* note 67, at 7. Arguably a key step by the U.K. government in defining manufactured nanoparticles as "new" chemicals has been the introduction in September 2006 of a "Voluntary Reporting Scheme for Engineered Nanoscale Materials," which is being

the time of writing, it appears likely that the United Kingdom will be one of the first countries to adopt nano-specific regulations.

Within the United States, Miller notes that "U.S. regulators maintain that the unique size and properties of nanoscale materials do not warrant new regulation,"[71] with the Food and Drug Administration (FDA) for instance stating that "the existing battery of pharmacotoxicity tests is *probably adequate* for most nanotechnology products that [they] will regulate."[72] In contrast, Davies has argued that this framework (as illustrated by Table 1), is inadequate for regulating nano-products, with "all of these laws either suffer[ing] from major shortcomings of legal authority, or from a lack of resources, or both." [73] In his comprehensive review, Davies identified a number of weaknesses within what is considered to be the primary regulatory instrument, the Toxic Substances Control Act (TSCA) – including low volume exemptions and its implicit assumption that a lack of scientific knowledge equates to a lack of risk; weaknesses of other existing legislation are similarly articulated, including for example, the Food, Drug and Cosmetic Act (FDCA).

While it appears that the United States is intent on treating nano-based products as the substantial equivalent of conventional products, the government is not, however, unaware of the increasing concern over nanoparticles. The Environmental Protection Agency (EPA) for instance is currently considering the implementation of a voluntary nanotechnology stewardship program in order to get a better understanding of existing chemicals being manufactured at the nanoscale, which fail to trigger the notification of the TSCA.[74] While such a voluntary approach is interesting, it is unlikely that the

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administered by the Department for Environment, Food and Rural Affairs. For information regarding the scheme, *see, e.g.*, Department of Environment Food and Rural Affairs (Defra), *UK Voluntary Reporting Scheme for Engineered Nanoscale Materials*, Sept., 2006, http://www.defra.gov.uk/ENVIRONMENT/nanotech/policy/pdf/vrs-nanoscale.pdf.

[70] *See, e.g.*, Qasim Chaudhry et al., *Final Report: A Scoping Study to Identify Gaps in Environmental Regulation for the Products and Applications of Nanotechnologies*, Defra Science and Research, Mar. 17, 2006, http://www.defra.gov.uk/science/project_data/DocumentLibrary/CB01075/CB01075_3373_FRP.doc.

[71] Miller, *A Matter of Torts: Why Nanotechnology Must Develop Processes of Risk Analysis*, *supra* note 37, at 5.

[72] U.S. Food and Drug Administration (FDA), FDA Regulation of Nanotechnology Products, http://www.fda.gov/nanotechnology/regulation.html (last visited Jan. 26, 2007) (emphasis added).

[73] Davies, *supra* note 35, at 3.

[74] U.S. Environmental Protection Agency (EPA), *Considerations Relevant to the Toxic Substance Control Act (TSCA) Application to Nanoscale Materials*, Docket No.: OPPT-2004-0122 (2005); Press Release, EPA, EPA Invites Public Participation in Development of Nanotechnology Stewardship Program (Oct. 18, 2006), http://www.epa.gov/ (follow "EPA Newsroom" hyperlink; then follow "News Releases" hyperlink; then follow "2006" hyperlink; then follow "10/18/2006 - EPA Invites Public Participation in Development of Nanotechnology Stewardship Program" hyperlink). In addition to these activities, in 2006 the FDA formed its

program by itself will prevent increasingly large regulatory gaps from occurring within the United States in the near future.

Looking at these four jurisdictions as a whole, it also appears unlikely in the short to medium term that these four countries will enact a battery of nano-specific regulations. Having said this, of course, things could change in an instant. As Harper and Dunn suggest, "[w]hile regulatory bodies from Europe and Japan are currently waiting for some conclusive results before acting [on legislation], a single industrial accident involving nanoparticles could precipitate a knee-jerk reaction."[75] Also, we have already noted that Marchant and Sylvester believe nano-specific regulations are inevitable.[76] With commentators such as Mehta suggesting that the regulation of agri-biotechnology end products may provide a number of lessons for nanotechnology,[77] we now turn to the current regulatory frameworks for genetically modified organisms (GMOs) within Australia, Japan, the United Kingdom/European Union and the United States, to gain insight into the regulatory models that may be employed with nanotechnology.[78]

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own internal Nanotechnology Task Force to consider the interface between its current regulatory framework and FDA-related nano-products. S*ee, e.g.*, Press Release, FDA, FDA News - FDA Forms Internal Nanotechnology Task Force (Aug. 9, 2006), http://www.fda.gov/bbs/topics/NEWS/2006/NEW01426.html.

[75] Tim Harper & Andrew Dunn, *Nanotechnologies: Risks & Rewards*, Cientifica Ltd., 2004, at 8, http://www.innovationsgesellschaft.ch/images/publikationen/Cientifica_RisksandRewards_WP.pdf.

[76] Marchant & Sylvester, *supra* note 34 (manuscript at 14).

[77] Michael Mehta, Regulating Biotechnology and Nanotechnology in Canada: A Post-Normal Science Approach for Inclusion of the Fourth Helix (Apr. 19, 2002) (paper presented at the International Workshop on Science, Technology and Society: Lessons and Challenges, Singapore) *available at* http://www.nanoandsociety.com/ourlibrary/documents/mehta-nus-paper2002.pdf.

[78] The issue of transatlantic policy divergence over the regulation of genetically modified organisms (GMOs) has received significant scholarly attention, which is not intended to be replicated in this paper. For a comprehensive review of this policy divergence, *see, e.g.*, *Biotechnology: The Making of a Global Controversy* (Martin W. Bauer & George Gaskell eds., Cambridge University Press 2002); Diahanna Lynch & David Vogel, *The Regulation of GMOs in Europe and the United States: A Case Study of Contemporary European Regulatory Policies* (Apr. 5, 2001), http://www.cfr.org/publication/8688/regulation_of_gmos_in_europe_and_the_united_states.html; Lee Ann Patterson & Tim Josling, Regulating Biotechnology: Comparing EU and US Approaches (July 4, 2001) (paper presented at the Western Economic Association International 76th Annual Conference, San Francisco), *available at* http://www.ucis.pitt.edu/euce/pub/policypapers/2002-TransatlanticBiotech.pdf; Thomas Bernauer, *Agricultural Biotechnology: Why Do Regulations in the European Union, the United States, and Japan Differ?* (Swiss Fed. Inst. of Tech. Zurich Center for Int'l Stud., Working Paper 5-2002), *available at* http://www.ib.ethz.ch/docs/working_papers/wp_2002_05.pdf [hereinafter Bernauer, *Agricultural Biotechnology*];Thomas Bernauer & Erika Meins, *Technological Revolution Meets Policy and the Market: Explaining Cross-National Differences in Agricultural*

The key features of each of the current national regulatory frameworks for GMOs are highlighted in Table 2. Importantly, the divergence in regulatory approaches, as evident in Table 2, is not new. According to Bernauer, "at the outset of the regulatory process in the mid-1980s, authorities in the [European Union], the United States, and Japan were divided over whether to restrict or promote biotechnology in agriculture, and over whether to regulate genetically modified organisms (GMOs) predominantly in terms of products or production processes."[79]

Biotechnology Regulation, 42 Eur. J. Pol'y Res. 643 (2003) [hereinafter Bernauer & Meins, *Technological Revolution Meets Policy and the Market*]; Assem Prakash & Kelly Kollman, *Biopolitics in the EU and US: A Race to the Bottom or Convergence to the Top?*, 47 Int'l Stud. Q. 617 (2003) [hereinafter Prakash & Kollman, *Biopolitics*].

[79] Bernauer, *Agricultural Biotechnology*, *supra* note 78, at 7.

Table 2 - *Current Regulatory Frameworks for GMO Regulation* [80]

	Regulatory Regime for GM products	*Predominant Regulatory Approach*	*Key Regulatory Bodies*	*Key Legislation*	*Labelling policy*
E.U.	GM specific	Process-based	Environmental Directorate General; Standing Committee on the Food Chain and Animal Health; European Food Safety Authority.	Council Directive 90/219, GMOs in laboratories, 1990 O.J. (L 1127) 1 (EU)); Commission Regulation 258/97, Novel Food Regulations, 1997 O.J. (L 43) 1 (EC); Council Directive 2001/18, Deliberate Release Directive, 2001 O.J. (L 106) 1 (EC); Commission Regulation 1829/2003, Food and Feed Regulation Recommendation, 2003 O.J. (L268) 1 (EC); Commission Regulation 1830/2003, Traceability and Labelling Directive , 2003 O.J. (L 268) 24 (EC); Commission Regulation 2004/787, Sampling and Testing, 2004 O.J. (L 348) 18 (EC).	Mandatory
Australia	GM specific; Gene Technology Regulator	Process-based	Office of the Gene Technology Regulator, in coordination with: Therapeutic Goods Administration; Food Standards Australian and New Zealand.	Gene Technology Act 2000.	Mandatory
Japan	Decentralised; regulated under existing regulatory agencies	Process-based	Ministry for Health, Labour and Welfare; Ministry for Agriculture, Forestry and Fisheries.	Food Sanitation Law, Law No. 233 of 1947; Law Concerning Standardization and Proper Quality Labelling of Agricultural Forestry Products, Law No. 175 of 1950.	Mandatory
U.S.	Decentralised; regulated under existing regulatory	Product-based	U.S. Department of Agriculture; Food and Drug Administration;	Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 (1938);	Voluntary

[80] Ron Bailey, *Functional Foods in Japan: FOSHU ("Foods for Specified Health Uses") and Foods with Nutrient Function Claims*, *in* Regulation of Functional Foods and Nutraceuticals: A Global Perspective (Clare M. Hasler ed., Blackwell Publishing 2005); Bernauer & Meins, *Technological Revolution Meets Policy and the Market*, *supra* note 78; Zhiqi Chen & Alison McDermott, *International Comparisons of Biotechnology Policies*, 21 J. Consumer Pol'y 527 (1998); Akihiro Hino, *Safety Assessment and Public Concerns for Genetically Modified Food Products: The Japanese Experience*, 30 Toxicology Pathology 126 (2002); Shelia Jasanoff, *Product, Process, or Programme: Three Cultures and the Regulation of Biotechnology*, *in* Resistance to New Technology (Martin W. Bauer ed., 1995); Karinne Ludlow, *Cultivating Chaos: State Responses to Releases of Genetically Modified Organisms*, 9 Deakin L. Rev. 1 (2004) [hereinafter Ludlow, *Cultivating Chaos*]; Karinne Ludlow, *Regulation on Agricultural and Genetically Modified Organisms in Australia*, 2 Int'l J. Biotechnology L. 123 (2005) [hereinafter Ludlow, *Regulation on Agricultural GMO in Australia*]; Peter W.B. Phillips, *International Trade in Genetically-Modified Agri-Food Products*, *in* Agricultural Globalization, Trade and the Environment (Charles Moss et al. eds., 2002); Prakash & Kollman, *Biopolitics*, *supra* note 78; Jackson, Protectionist Harmonization of Food Safety Policies in the Asia-Pacific Region, *supra* note 59; Donald J. MacKenzie, The Canadian Biotechnology Advisory Committee, International Comparison of Regulatory Frameworks for Food Products of Biotechnology (2000), http://www.agbios.com/docroot/articles/2000350-A.pdf; Defra, European Union and International Issues - Traceability and Labelling of GMOs, including Food & Feed, http://www.defra.gov.uk/environment/gm/internat/old/tracelabel.htm (last visited Jan. 26, 2007); USDA, *supra* note 59.

As shown in Table 2, the European Union and its member states, including the United Kingdom, have adopted a process-based regulatory regime for GMOs.[81] Implicit within this approach is the belief that the process of genetic modification is in itself a potential hazard which presents unique risks that must be regulated. This belief has been further underpinned by the adoption and strict interpretation of the precautionary principle.[82] The framing of GMOs within this context has resulted in the adoption of a number of specific GMO regulations by the European Union, including foods and feed (EC 1830/2003) as well as traceability and labelling (EC 1829/2003), which are legally binding on all E.U. member states, including the United Kingdom.[83] As summarised by Bernauer, the stringent regulatory framework adopted by the European Union has led to "very stringent regulations on the approval of GM-crops and GM-foods, and to increasingly stringent and harmonized labeling [sic] requirements."[84]

Australia's approach to regulating GMOs is through a national regulatory scheme introduced in 2001, supplemented by state regulations.[85] Under this framework, the Gene Technology Regulator (GTR) regulates GMOs as a process rather than as a product, thereby establishing what they believe to be "some of the toughest regulation in the world concerning biotechnology."[86] The GTR is not, however, the sole federal regulator of GMOs. Existing federal agencies, including the Therapeutic Goods Administration (TGA) and Food Standards Australia and New Zealand (FSANZ) continue to regulate GM products[87] that have fallen within their legislative scope prior to the introduction of the 2001 scheme.[88] In concept, regulatory gaps within this framework are minimised through a legislative requirement that these prior-existing regulatory agencies seek and

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[81] Nicholas Guehlstorf & Lars K. Hallstrom, *The Role of Culture in Risk Regulation: A Comparative Case Study of Genetically Modified Corn in the United States of America and European Union*, 8 Envtl. Sci. & Pol'y 327, 333 (2005).

[82] Bernauer & Meins, *Technological Revolution Meets Policy and the Market*, *supra* note 78, at 651.

[83] Chen & McDermott, *supra* note 80, at 537; Defra, *supra* note 80; David Morgan and Gavin Goh, *Genetically Modified Food Labelling and the WTO Agreements*, 13 Rev. Eur. Community Int'l Env't L. 306, 307 (2004).

[84] Bernauer, *Agricultural Biotechnology*, *supra* note 78, at 10.

[85] Ludlow, *Cultivating Chaos*, *supra* note 80; Ludlow, *Regulation on Agricultural GMO in Australia*, *supra* note 80.

[86] Biotechnology Australia, Regulation, http://www.biotechnology.gov.au (follow "About biotechnology" hyperlink; then follow "Regulation" hyperlink) (last visited Jan. 26, 2007).

[87] GM products may include, for example, human therapeutics, foods and veterinary chemicals.

[88] Ludlow, *Regulation on Agricultural GMO in Australia*, *supra* note 80; Zada Lipman, *Gene Technology Regulation and the Precautionary Principle: How Australia Measures Up*, 8 J. Int'l Wildlife L. & Pol'y 63 (2005).

take into account advice from the GTR, and notify the GTR of their decisions so that they can be included in the GMO Record.[89]

In contrast to Australia's approach, the Japanese government has opted to address GMOs through existing regulatory agencies and revised regulation for risk assessment and labelling.[90] The Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health, Labour and Welfare (MHLW) are the principal regulatory bodies for GMOs within Japan. However, no individual ministry has the power to coordinate the different ministerial activities, resulting in inevitable regulatory overlap.[91] Although the Japanese ministerial risk assessment guidelines are based on Organisation for Economic Co-operation and Development (OECD) guidelines of "'familiarity' and 'substantial equivalence,'"[92] Bailey suggests that "in general, the Japanese regulations regarding 'GMO' foods and food ingredients are much closer to the more restrictive E.U. regulations than is the more open U.S. Food and Drug Administration (FDA) approach."[93] Bernauer, on the other hand, suggests that the Japanese regulatory approach represents the middle ground between the E.U. and the U.S. approaches,[94] as illustrated by Figure 3.

Figure 3 – The GMO Regulatory Continuum

[89] Office of the Gene Technology Regulator (OGTR), Australian Government Dept. of Health and Ageing, About the OGTR, http://www.ogtr.gov.au/about/index.htm (last visited Jan. 26, 2007).

[90] Jackson, *supra* note 59; Bernauer, *Agricultural Biotechnology*, *supra* note 78.

[91] Chen & McDermott, *supra* note 80; Bernauer, *Agricultural Biotechnology*, *supra* note 78.

[92] Mariko Nishizawa & Ortwin Renn, *Responding Public Demand for Assurance of Genetically Modified Crops: Case from Japan*, 9 J. Risk Res. 41 (2006).

[93] Bailey, *supra* note 80.

[94] Bernauer, *Agricultural Biotechnology*, *supra* note 78.

The regulatory approach adopted by the United States is based on existing legislation. Guehlstorf and Hallstrom note that "the [U.S.] regulatory regime of GM acceptance has never passed a single law specifically addressing food biotechnology." [95] With the trigger for regulatory oversight being the "novelty" of a product's characteristics,[96] the framework is underpinned by the notion that techniques of biotechnology are not in and of themselves risky, and that biotechnology regulation should not revolve around processes, but rather around the products of biotechnology – the same way products of other techniques are regulated in the United States.[97]

Despite the coordinated regulatory approach that has been implemented in the United States,[98] David Winickoff et al. note that in 1998, "[u]nder U.S. law, StarkLink [a form of maize hybrid] was at once a crop, a food, and a pesticide, requiring risk assessments by three separate agencies: the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA)."[99] While instances of overlapping regulatory activity have since been minimised through revised risk assessment procedures, this example highlights how technological advances have the capacity to blur and confuse traditional regulatory boundaries.

So, what have we learned here? This review of the national and supranational regulatory frameworks for GMOs indicates that earlier technological advancements, including biotechnology, have forced governments to re-evaluate regulatory frameworks in order to grapple with new issues.[100] Despite the uncertainties associated with GMOs, some governments have implemented a range of regulatory models to safeguard against risks and scientific uncertainties. It appears that when nano-specific regulations or frameworks are implemented at the national and supranational level, a central question to be asked is: should nanotechnology risks be assessed on the basis of each nano-product, or on the basis of the process itself? This question is similarly applicable to the international regulatory space, and it is to this inquiry that we now turn our attention.

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[95] Guehlstorf & Hallstrom, *supra* note 81, at 330.

[96] Grant Isaac & Peter Phillips, *Market Access and Market Acceptance for Agricultural Biotechnology Products* (June 17-19, 1999) (paper presented at the Int'l Consortium on Agric. Biotechnology Res. (ICABR) Conference on the Shape of the Coming, Agricultural Biotechnology Transformation: Strategic Investment and Policy Approaches from an Economic Perspective, Italy), *available at* http://agecon.lib.umn.edu/cgi-bin/pdf_view.pl?paperid=2199&ftype=.pdf.

[97] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302-01 (proposed June 26, 1986).

[98] While the lead regulatory body in the United States is the USDA, a coordinated framework does exist. *See id*.

[99] David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 Yale J. Int'l L. 81, 102 (2005).

[100] Peter W.B. Phillips & William A. Kerr, *Frustrating Competition Through Regulatory Uncertainty: International Trade in the Products of Biotechnology*, 25(1) World Competition 81 (2002).

V. INTERNATIONAL AND SUPRANATIONAL REGULATION OF NANOTECHNOLOGY

The potential scope of nanotechnology across many jurisdictions, and multiple sectors, will ensure that a number of international institutions and instruments will be relevant to the regulation of nanotechnology. While the technology does not currently come under any one institution's umbrella or is specifically the subject of any single international instrument, many nano-products will fall within pre-existing international regulatory frameworks as they do with national regulatory models. Building on the argument of Marchant and Sylvester that much of the nano-regulation will occur in the international sphere,[101] this section of the paper explores key international institutions that are likely to be at the forefront of governing nanotechnology – the OECD and the World Trade Organisation (WTO). As well, the potential role and influence of the European Union and transnational non-governmental organisations (NGOs) will also be considered. With an increasing number of international actors turning their attention to the issue of nano-regulation, this review provides a timely opportunity to consider how health and safety concerns may be balanced against broader economic goals, and how harmonization of international guidelines may avert the global trade barriers that have occurred with biotechnology.[102]

A. *International Standards*

It is important to recognise that for a regulatory framework to evolve at the international or national level some degree of "technical standardisation" must first occur. Without consensus on definitions, common nomenclature and standards for classification and testing of nanotechnology and nanomaterials, it is extremely difficult to define or classify the objects or processes to be regulated. In recognition of the need for a common language for nanotechnology, the International Standards Organisation (ISO), a voluntary standards development body, established the ISO/TC 229 Nanotechnologies technical committee in 2005.[103] The aim of the technical committee, which comprises three working groups convened by Canada, Japan and the United States, is to develop "[i]nternational [s]tandards for nanotechnologies."[104] The ISO believes that "by giving

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[101] Marchant & Sylvester, *supra* note 34 (manuscript at 9).

[102] *See, e.g.*, Panel Report, *European Communities - Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, WT/DS292, WT/DS293 (Sept. 29, 2006) [hereinafter Panel Report, *European Communities*].

[103] Press Release, International Organization for Standardization (ISO), ISO Launches Work on Nanotechnology Standards (Nov. 16, 2005), http://www.iso.org/iso/en/commcentre/pressreleases/archives/2005/Ref980.html.

[104] *Id.* The three working groups that will be launched under ISO/TC 229 are: WG 1, Terminology and nomenclature, which will be convened by Canada; WG 2, Measurement and characterization, to be convened by Japan; and WG 3, Health, safety and environment, to be convened by the United States.

nanotechnologists a common language and processes, standardisation will facilitate safer and faster product development and will enable interoperable end-products."[105] It is likely that the work of several national and international standards development bodies, including the British Standards Institute (BSI), American Nationals Standards Institute (ANSI), ASTM International and the Taiwan Accreditation Foundation (TAF), each of which has already initiated voluntary standards development for nanotechnology, will assist the ISO in establishing "norms" for nanotechnology and thus start to meet the standardisation challenges posed by nanotechnology.[106] This work on standards represents an important first stage in both national and international regulatory development processes.

B. *International Institutions - The Organisation for Economic Cooperation and Development (OECD)*

Intergovernmental dialogue on the challenges and risks posed by manufactured nanoparticles has, to date, primarily occurred within the confines of the OECD. This transnational forum comprises thirty countries that "work together to address the economic, social and governance challenges of globalisation."[107] Australia, Japan, the United Kingdom and the United States are all OECD member countries, and this forum provides an opportunity for each of these players to exert their influence on international nanotechnology research and regulatory programs. The history of OECD initiatives has been generally to disseminate information freely to non-OECD countries,[108] and their focus on harmonization is likely to see the OECD emerge as a key player in the development of any international regulatory framework for nanotechnology.[109]

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[105] Press Release, ISO, New ISO Committee Will Develop Standards for Nanotechnologies (Nov. 10, 2005), http://www.iso.org/iso/en/commcentre/pressreleases/archives/2005/Ref978.html. The inaugural meeting of ISO/TC 229 was hosted on Nov. 9-11, 2005, by the ISO member for the United Kingdom, the British Standards Institute (BSI), and was attended by twenty-four delegates, including representatives from Australia, China, France, Germany, Israel, Japan, Korea and the United States, in conjunction with eight "observer" delegates. The focus of the meeting was primarily to refine the scope and focus of the committee.

[106] Diana M. Bowman & George Gilligan, *Emerging Trends in the International Regulatory Framework for Nanotechnology*, *in* New Global Frontiers in Regulation: The Age of Nanotechnology (Graeme A. Hodge et al. eds., forthcoming 2007).

[107] OECD, *OECD - What is it?*, http://www.oecd.org (follow "About OECD" hyperlink; then follow "Overview of the OECD" hyperlink) (last visited Jan. 26, 2007).

[108] Swedish Chemicals Agency (KEMI), *Risk Reduction of Chemicals: A Government Commission Report*, KEMI Report No. 1/91 (1991).

[109] Sylvia Karlsson, *Institutionalized Knowledge Challenges in Pesticide Governance: The End of Knowledge and Beginning of Values in Governing Globalized Environmental Issues*, 4 Int'l Envtl. Agreements: Pol., L. & Econ. 195, 204 (2004).

The locus of activity regarding nanotechnology within the OECD has been driven by the network of multidisciplinary experts within the Chemicals Committee who hosted the first OECD Workshop on the Safety of Manufactured Nanomaterials in December of 2005.[110] The workshop provided "one of the first opportunities for governments to discuss [the] topic at the international level, together with other stakeholders."[111] A key initiative to come out of the Workshop was the establishment of the Working Party on Manufactured Nanomaterials (WPMN), whose role will be to "promote international co-operation in health and environmental safety related aspects of manufactured nanomaterials (MN), in order to assist in the safe development of manufactured nanomaterials, while avoiding non-tariff barriers to trade."[112]

The first meeting of the WPNM in October 2006 resulted in the development of a Draft Program of Work 2006-2008. In prioritising the OECD's role in addressing policy, risks and challenges posed by nanotechnology, the program has been designed to focus on three key work areas, specifically: 1) "Identification, Characterisation, Definitions, Terminology and Standards;" 2) "Testing Methods and Risk Assessment;" and 3) "Information Sharing, Co-operation and Dissemination."[113]

Importantly, the subsequent development of guidelines and principles by the Working Group, or more generally the Chemical Committee, will not be binding on member countries. They would nonetheless represent *prima facie* a member country's commitment to implement the guidelines or recommendations within their national regulatory framework. Arguably, the non-binding, soft law "norms" established by the OECD, including an internationally agreed instrument, may become a foundation for any emerging consensus on global regulatory frameworks.

C. *International Institutions - The World Trade Organisation (WTO)*

Established on January 1, 1995, as a replacement body to the Contracting Parties of the General Agreement on Tariffs and Trade (GATT), the World Trade Organisation is the key international institution concerned with the liberalisation of trade rules (as

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[110] OECD, Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication 11, Env/Jm/Mono (Apr. 28, 2006) [hereinafter OECD, Building Co-operation, Co-ordination and Communication]; OECD, *OECD – What is it?*, *supra* note 107.

[111] OECD, Building Co-operation, Co-ordination and Communication, *supra* note 110, at 11.

[112] OECD, General Presentation: Nano Activities (Dec. 19, 2006), http://www.oecd.org/env/nanosafety (follow "Publications & Documents" hyperlink; then follow "Staff Papers/Presentations" hyperlink; then follow "General Presentation: Nano activities" hyperlink).

[113] *Id.*

provided for under the World Trade Organisation Agreement (WTOA)).[114] As such, the WTO will have an interest in the governance of all nanotechnology products in so far as domestic regulatory frameworks impact their trade. However, as noted by Buckingham and Phillips, "[t]he WTO does not hold itself out to be a venue for international regulatory co-ordination for products of biotechnology."[115] This statement is equally true for products of nanotechnology. Nevertheless, as with the OECD, a primary concern for the WTO in relation to nanotechnology is likely to be over any trade restrictions arising from divergent national regulatory frameworks.

D. *The Sanitary and Phytosanitary Measures (SPS) Agreement*

As with biotechnology, any safety concerns raised by WTO members in relation to nano-products will fall within the scope of the Sanitary and Phytosanitary Measures (SPS) Agreement. As stated in *Article 1 – General Provisions*, the SPS Agreement "applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade." [116] Under the SPS Agreement, any SPS measure implemented by a WTO member which conforms to recognised standards, guidelines and recommendations, for example those produced in relation to foods by the Codex Alimentarius Commission (Codex), will be *prima facie* consistent with that nation's obligations under the SPS Agreement.[117]

However, with the current lack of international nanotechnology specific standards, governments will be required either to base any national measures on analogous international standards,[118] or demonstrate, using scientific risk assessments, that a higher level of protection is necessary to protect human and environmental safety.[119] The establishment of a higher level of protection must be scientifically

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[114] WTO, The WTO in Brief, http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr01_e.htm (last visited Jan. 26, 2007).

[115] Donald Buckingham & Peter W.B. Phillips, *Hot Potato, Hot Potato: Regulating Products of Biotechnology by the International Community*, 35 J. World Trade 1, 9 (2001).

[116] Agreement on the Application of Sanitary and Phytosanitary Measures, pmbl., Apr. 15, 1994, 1867 U.N.T.S. 493 [hereinafter SPS Agreement].

[117] *Id.*

[118] Donald Buckingham & Peter W.B. Phillips, *Issues and Options for the Multilateral Regulation of GM Foods*, 2 Estey Centre J. Int'l L. & Trade Pol'y 178 (2001).

[119] Article 5.1 of the SPS Agreement, which states: "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations." SPS Agreement, *supra* note 116, art. 5.1.

justifiable if it is to survive examination by other member states.[120] Given the limited number of published toxicological and epidemiological studies on manufactured nanoparticles and their often contradictory findings, it appears likely that members may resort to relying on Article 5.7 of the SPS Agreement when formulating national SPS measures.[121] Article 5.7 of the SPS Agreement enables a member state to employ provisional SPS measures under strict conditions, as established by the Appellate Body in *Japan – Measures Affecting Agriculture Products* (*Japan – Agricultural Products*).[122] However, the recent WTO report dealing with the SPS Agreement, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (*EC – Biotech Products*),[123] suggests that it will be extremely difficult for a member to have a right to recourse under the SPS Agreement's Article 5.7 when formulating their national SPS frameworks.[124] Moreover, should a member wish to incorporate a precautionary approach in relation to, for example, nano-foods within their national SPS framework, such measures will need to be consistent with the existing scientific evidence for risk assessments in order for the member to act consistently with its obligations under the SPS Agreement.

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[120] Ruth MacKenzie, The International Regulation of Modern Biotechnology: Globalisation and the International Governance of Modern Biotechnology 15 (2003), http://www.gapresearch.org/governance/RMregulationfinal.pdf.

[121] Article 5.7 of the SPS Agreement states: "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time." SPS Agreement, *supra* note 116, art. 5.7.

[122] Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R (Feb. 22, 1999) [hereinafter *Japan – Agricultural Products*]. In this dispute, the Appellate Body dealt with a complaint by the United States "relating to the requirement imposed by Japan to test and confirm the efficacy of the quarantine treatment for each variety of certain agricultural products." *Japan – Agricultural Products* ¶ 1. In its decision, the Appellate Body stated that the SPS Agreement's Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. *Japan – Agricultural Products* ¶ 80. An overly broad and flexible interpretation of that obligation would render Article 5.7 meaningless. *Id*. The Appellate Body subsequently articulated four requirements that must be met in order for a Member to adopt and maintain a provisional SPS measure: it must be (1) imposed in respect of a situation where relevant scientific information is insufficient; and (2) adopted on the basis of available pertinent information. After adopting provisional measures, the Member must: (3) seek to obtain the additional information necessary for a more objective assessment of risk; and (4) review the measure accordingly within a reasonable period of time. *Japan – Agricultural Products* ¶ 89.

[123] Panel Report, *European Communities*, *supra* note 102.

[124] *Id*.

E. *The Agreement on Technical Barriers to Trade (TBT)*

Any "technical regulations and standards, including packaging, marking and labelling requirements" of nano-products passed by WTO members will fall within the scope of the Technical Barriers to Trade (TBT) Agreement.[125] The TBT Agreement recognises, however, that "no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health."[126] As with the SPS Agreement, the establishment by a member state of a higher level of protection for nanotechnology end products would need to be based on scientific risk assessment data. For example, if a country implemented a national labelling policy for nano-foods or nano-cosmetics for reasons other than safety, the WTO Dispute Body, if the case was brought before it, would probably judge such an action to be a barrier to trade. In light of the expected Panel decision in *EC – Biotech Products*, it appears unlikely that the WTO will provide its members with additional latitude under the TBT Agreement for nanotechnology products. There is a significant potential tension here with sovereign democratic public policymaking.

F. *The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*

The WTO's Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement)[127] will provide the international framework for intellectual property protection of nanotechnology inventions, particularly patent protection. By its very nature, nanotechnology falls within the patentable subject matter covered by Article 27(1) of the TRIPS Agreement, thereby providing a *prima facie* protection regime. Accordingly, if a nanotechnology patent application satisfies the criteria of novelty, inventive step (or non-obviousness within the United States), utility and public disclosure,[128] members of the WTO are prohibited from excluding it from patent protection under their domestic legal framework.[129] Importantly, however, not all nanotechnology applications may be protected, as Article 27(1) provides patent protection only for *inventions* and not mere discoveries. While the TRIPS Agreement fails to provide a definition of "invention," Article 27(1) discriminates between the

[125] Agreement on Technical Barriers to Trade, pmbl., Apr. 12, 1979, 31 U.S.T. 405, 1186 U.N.T.S. 276.

[126] *Id.*

[127] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, 29, Apr. 15, 1994, 33 I.L.M. 1125, 1869 U.N.T.S. 299 [hereinafter TRIPS].

[128] *Id.*

[129] Where nanotechnology inventions fulfil the requirements of Articles 27 & 29 of TRIPS, patent protection must be provided by all WTO members for a minimum period of twenty years from the filing date, according to TRIPS art. 33, thereby providing the patentee with a bundle of exclusive rights. *Id.*

rapidly blurring distinctions of "inventions" and "discoveries." This distinction has been maintained with current nano-products including CNTs. Since these compounds are naturally occurring, Article 27(1) technically prohibits the patenting of the compounds themselves. Article 27(1) does, however, enable that a requisite inventive step be deemed as the process of creation, rather than the creation itself.

Bastani and Fernandez note that the development of cutting edge technologies including nanotechnology has resulted in a blurring of the interface that previously existed between discoveries and inventions.[130] This had also previously been the case for biotechnology, which saw technological changes broadening the scope of international patent law. This distinction between discoveries and inventions remains pivotal because of its role in defining the scope of patentable subject matter. The ETC Group contends that "breathtakingly broad nanotech patents are being granted that span multiple industry sectors and include sweeping claims on entire classes of the Periodic Table."[131] With the advancement of nanotechnology, the ETC Group suggests that the ability to patent basic nanoscale materials "could mean monopolizing the basic elements that make life possible,"[132] a concern similarly highlighted by Wood, Jones and Geldart.[133] The convergence of nanotechnology with biotechnology (nanobiotechnology – enabling the manipulation of living organisms with atomic precision) within the short to medium term will further complicate the debate over what is patentable in legal terms as well as what is desirable in terms of social policy.

G. *Safeguards at the Supranational Level*

At the supranational level, the European Union and its member states have turned their attention to the issue of nanotechnology and the need for safeguards against potential risks posed by nanotechnology. While the European Union is yet to enact any regulations specifically addressing the production and use of nanotechnology, the European Commission is funding a range of research projects examining epidemiological studies looking at nanoparticle toxicity and risk.[134] In conjunction with these activities, "the European Commission [has sought] international debate on nanotechnology-related

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[130] Behfar Bastani & Dennis Fernandez, *Intellectual Property Rights in Nanotechnology*, 420-21 Thin Solid Films 472, 473 (2002).

[131] ETC Group, *Nanotech's "Second Nature" Patents: Implications for the Global South*, 87 & 88 Communiqués 1, 5 (Mar./Apr. & May/June 2005) (Special Report).

[132] *Id*. at 11.

[133] Wood, Jones & Geldart, *supra* note 1, at 33.

[134] These projects include for example, NanoDerm, NanoSafe and NanoSafe 2, NanoPathology, NanoTox, Impart and NanoCare. *See* European Commission, Nanotechnology: Proceedings of the Workshop: Research Needs on Nanoparticles 29-42 (Renzo Tomellini & Cederic de Villepin eds., Jan. 25-26, 2005), http://cordis.europa.eu/nanotechnology/src/pe_workshop_reports.htm.

issues such as public health, safety, environment, consumer protection, risk assessment, metrology, [and] norms."[135] Moreover, the European Union has recently articulated the need for governments and industry to develop an international "code of good conduct" for the responsible development of nanotechnology.[136] While it appears unlikely that the European Union will be able to negotiate an enforceable "code of good conduct" in the short to medium term, societal pressures, primarily from within the European Union itself, may result in the development of a set of guiding principles for the responsible development of nanotechnology. As with the development of international environmental regulation, this form of soft law initially could be broad in its scope, with the potential to evolve as the technology develops. Similar to the OECD process, Bowman and Gilligan note that a "code of good conduct" developed primarily by the European Union could establish norms for the international conduct and regulatory behaviour for nanotechnology, while offering an alternative to the extension of formal international and national regulatory frameworks.[137]

H. *Non-Government Organisations (NGOs)*

There is an increasing prominence of transnational NGOs within the nano-regulation discourse. While Environmental Defense has, for example, displayed leadership through its partnership with industry and government,[138] arguably the most significant NGO to date in politicising the nanotechnology debate has been the ETC Group. In an effort to safeguard human and environmental health and safety, the ETC Group has called for a moratorium on the use and release of manufactured nanoparticles until a "transparent global process" for evaluating nanotechnology's various implications has been established, in conjunction with advocating the development of a legally binding, international convention for the evaluation of emerging technologies.[139] This perspective has been supported by commentators such as Davies, who saw the potential risks posed as disproportionate to the benefits promised by the technology.[140] Numerous

[135] Catherine Halliwell, An Overview of Nanotechnology Initiatives in the EU 21 (July 11-12, 2005) (paper presented at U.K./Japan Workshop on Health, Environmental and Societal Issues of Nanotechnologies, London), http://www.royalsoc.ac.uk/downloaddoc.asp?id=2386.

[136] *Towards a European Strategy for Nanotechnology*, at 23, COM (2004) 338 final (May 12, 2004).

[137] Bowman & Gilligan, *supra* note 106.

[138] *See* Fred Krupp & Chad Holliday, *Let's Get Nanotech Right*, Wall St. J., June 14, 2005, at B2.

[139] ETC Group, *The Big Down: Atomtech*, *supra* note 9, at 27-72; ETC Group, *No Small Matter!: Nanotech Particles Penetrate Living Cells and Accumulate in Animal Organs*, 76 Communiqué 1, 8 (May/June 2002).

[140] Davies, *supra* note 35, at 22-23.

other NGOs are also likely to be influential in shaping the debate around the nanotechnology regulation agenda as well as any consequential regulatory frameworks that evolve. To date, NGOs such as Greenpeace and Friends of the Earth have all expressed concerns over the potential risks posed by manufactured nanoparticles,[141] but there is much work yet to be done in this area. The mapping of potential transnational NGOs likely to be influential in future debates, along with the presence of both multinational pharmaceutical companies and other transnational institutions, would provide a useful analytical tool for observing the evolving policy coalitions. It would also be central to the inevitable debate which will occur over the social, democratic and jurisdictional legitimacy of any evolving regulatory regime for nanotechnology.

I. *Fissures in International Regulatory Space?*

While this paper has noted several current frameworks that will be employed in regulating nanotechnology within the international sphere, it is apparent that a number of institutions, instruments and actors will be involved in regulating nanotechnology. It is also clear that much regulation will also occur in an ad hoc, decentralised manner. As well, it is likely that in the short to medium term regulatory oversight will occur by default – if we learn from the case of biotechnology.[142] In other words, the evolving regulatory regime will in large part simply be the result of nano-products falling within the existing scope of these existing institutions and instruments.

A central question here is the degree to which any gaps or "regulatory fissures" might exist in national and international regimes. On this matter, there is again much work to be done including the mapping of existing regulations within the nation state, reviewing their interpretation and assessing the adequacy of any softer guidelines, codes and practices presently in existence. To illustrate this point, take the case of the rapid commercialisation of pure carbon molecules, most notably CNTs. Simply put, CNTs are naturally-occurring hollow tubes of rolled carbon sheets (graphene sheets), which have potential applications across the fields of nano-electronics, fuel cells, biosensors and drug

[141] *See, e.g.*, Friends of the Earth, Submission from Friends of the Earth Australia to the Senate Community Affairs Committee, Inquiry into Workplace Exposure to Toxic Dust (2005), http://www.aph.gov.au/senate/committee/clac_ctte/toxic_dust/submissions/sub10.pdf; Friends of the Earth, Nanomaterials, Sunscreens and Cosmetics: Small Ingredients, Big Risks (2006), http://nano.foe.org.au/node/100 (follow "Nanomaterials, sunscreens and cosmetics: Small ingredients, big risks" hyperlink; then follow "download" hyperlink); Greenpeace Envtl. Trust, *Future Technologies, Today's Choices: Nanotechnology, Artificial Intelligence and Robotics; A Technical, Political and Institutional Map of Emerging Technologies* (Alexander Huw Arnall ed., 2006), http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5886.pdf.

[142] Buckingham & Phillips, *supra* note 118; Donald Buckingham et al., The International Coordination of Regulatory Approaches to Products of Biotechnology (June 30, 1999) (submitted to Agriculture and Agri-food Canada), http://www.usask.ca/politic/phillips/pdfs/AAFCfinal_report_3_Buck.pdf.

delivery mechanisms.[143] As CNTs consist only of carbon molecules,[144] under existing national regulatory frameworks such as those found in the United States or Australia, they are not automatically defined as "new" chemicals.[145] This is because the chemical composition of the CNT is equivalent to that of macro or micro carbon particles, and existing regulations do not take into account the novel properties exhibited by CNTs, including their potential toxicity. Moreover, given the potential applications of CNTs across fields such as industrial chemicals, therapeutic goods and devices, and veterinary chemicals, it appears likely that CNTs will fall within the regulatory scope of multiple national agencies, thereby increasing the likelihood of products falling into a regulatory fissure. The patchwork approach within the international sphere presents additional obstacles, magnified by a lack of comprehensive standards, oversight, specialised bodies, risk assessment frameworks and universally accepted regulatory frameworks. Likewise, within the international sphere, issues of implementation, enforcement and politics become problematic.

Without a doubt, the rapid growth forecasted for nanotechnology will result in an increasingly diverse and complex application of nanotechnology across numerous sectors and jurisdictions.[146] Powered by its likely economic importance, the regulatory fissures observed with CNTs at the national level, including issues of occupational health and safety, product safety and human and environmental health and safety, appear destined to be magnified within the international sphere in the absence of a rigorous and collective approach to addressing the potential risks posed.

VI. CONCLUSIONS

This paper investigated the current domestic and international regulatory frameworks into which nanotechnology is now being thrust. It observed that the regulation of nanotechnology manufacturing processes and products presents a myriad of complex policy and regulatory challenges for public and private sector actors. Conceptually, we conclude that regulatory discussion, debate and development will grow on six frontiers – product safety, privacy and civil liberties, occupational health and

[143] ETC Group, *The Big Down: Atomtech*, *supra* note 9, at 21-22; RS-RAE, *supra* note 1, at 8-12.

[144] S. Iijima, *Helical Microtubes of Graphitic Carbon*, 354 Nature 56 (1991).

[145] For discussion on nanomaterials and existing regulatory frameworks, *see, e.g.*, Diana M. Bowman & Graeme A. Hodge, *Nanotechnology Products in Australia: Chemicals, Cosmetics and Regulatory Character*, *in* New Global Frontiers in Regulation: The Age of Nanotechnology (Graeme A. Hodge et al. eds., forthcoming 2007); Davies, *supra* note 35, at 10-12; RS-RAE, *supra* note 1, at 69-78; Wardak, *supra* note 37.

[146] *Hearing*, *supra* note 2; National Science Foundation, *Report from the Workshop on Societal Implications of Nanoscience and Nanotechnology: Societal Implications of Nanoscience and Nanotechnology* 1 (Mihail C. Roco & William S. Bainbridge eds., 2001), http://www.wtec.org/loyola/nano/NSET.Societal.Implications/.

safety, intellectual property, international law and environmental law. And within each of these areas, mechanisms ranging from soft law to hard law will have a role to play in the future. Looking briefly at the regulatory terrain into which nanotechnologies will be thrust for three of these frontiers across four jurisdictions, we observe that existing regulatory frameworks will form the immediate basis for regulating nanotechnologies.

Looking further afield, we also observe that there have been no nanotechnology-specific regulatory responses thus far. As a result, a range of serious regulatory fissures are now emerging. In countries such as the United Kingdom, Australia, Japan and the United States, regulation of nanotechnologies continues to rely primarily on the trigger of "new chemicals" being identified. Critically though, existing chemicals now being produced at the nanoscale are not considered to be "new" for purposes of these regulatory frameworks, despite the unpredictability and novelty of manufactured nanoparticles. The failure to address this gap is of increasing concern. Both escalating commercialisation of products containing manufactured nano-particles as well as our embryonic understanding of technological impacts, such as human and environmental toxicology, suggest that the emerging regulatory debate on nanotechnology has now become urgent. While national responses to the question of new arrangements for regulating nanotechnologies have generally been slow, two further points can be made at present. It is likely that we will face a choice of regulatory path if we learn from the various regulatory responses to GMOs, where a continuum has been observed from the product-based response of the United States through to the process-based response of the European Union. As well, it appears that of the four jurisdictions reviewed in this paper, the United Kingdom is presently the most advanced in leading the development and implementation of a nano-specific regulatory regime. We can also conclude that it will be a careful and targeted approach in the short to medium term rather than anything more comprehensive or grandiose. Notwithstanding this, it is recognised that this could, of course, change in an instant given a single industrial accident involving nano-particles and the knee-jerk regulatory reaction that would probably follow.

Within the international context, a patchwork of existing institutions and instruments will play a role in regulating future nanotechnologies. Likewise, it is evident from this review that traditional nano-products are likely to fall within the pre-existing international regulatory frameworks. Importantly, the next step forward in this arena appears to be the work of the international standards-setting bodies – for both national and international regulation. Additionally, the OECD's effort to establish guidelines (i.e., forms of "soft law") is likely to become a foundation for any emerging consensus on global frameworks and codes of conduct. Importantly, though, the potential scope of nanotechnology will result in this framework being incomplete and inconsistent in effectively regulating the technology. It is therefore likely that the regulatory fissures that are beginning to appear at the national level are destined to be magnified at the international level. The consequence of this is that nanotechnology is likely to fall between the regulatory cracks of ad hoc, incomplete and decentralised regulatory regimes. It is also likely that transnational NGOs will play an increasingly important and visible role in future policy and regulatory debates, and their involvement will challenge the social, democratic and jurisdictional legitimacy of the coming nano-age.

Regulation of Nanotechnology Materials; discussion of the steps various goverments are taking to regulate products containing nanomaterials.Â Regulation of Nanotechnology Materials and Products. The lead in your pencil is a larger scale or bulk version of carbon that has different properties than carbon nanotubes and buckballs, even though all three share the same chemical composition. Because these bulk versions of materials are not considered hazardous, many regulatatory agencies did not initially put in place different regulations on the use nanosized versions of the same substances.Â "ensure that nanoscale materials receive appropriate regulatory review.