Nanotechnology Regulation: Potential and Progress for International Coordination

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Abstract

Nanotechnology is likely the most transformative technology in the history of industrial production, and is being actively pursued by all industrial economies. Nanotechnology also presents challenging regulatory issues for the protection of health, safety and the environment, which all nations are currently grappling with. Given the problems and inefficiencies from discordant national regulations of previous technologies such as genetically modified organisms, international coordination of nanotechnology regulation may be a worthy goal. This article surveys the policies and regulatory responses to nanotechnology in three of the leading jurisdictions of the world in promoting this technology - the United States, European Union and the Republic of Korea. The overall finding from this analysis is that the policies and regulatory responses to nanotechnology to date by the mentioned jurisdictions and others are relatively consistent. The article next assesses the potential benefits of international coordination of nanotechnology oversight and then describes a number of existing multilateral and bilateral mechanisms that are in place for fostering such international coordination. The article concludes with some observations and suggestions for the future of international coordination of nanotechnology governance and oversight.

Key Words: Nanotechnology; Legislation; Regulation; Comparative regulation; International harmonization

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I. Introduction

Nanotechnology is likely the most transformative technology in the history of industrial production, and is being actively pursued by all industrial economies.[1] This emerging technology holds unprecedented potential for beneficial applications in medicine, energy, environmental technologies, materials, consumer goods, electronic goods, foods, cosmetics and many other product types. At the same time, nanotechnology holds unprecedented potential for the international coordination of regulatory approaches to a new emerging technology. The relatively recent and rapid development of nanotechnology makes both of these statements about its potential true. All industrialized nations are simultaneously trying to promote the beneficial development of nanotechnology while also trying to address the regulatory challenges that this new and prevalent technology presents. This concordance in national policies and priorities creates a window of opportunity to develop a new model of international technology coordination that may set a precedent for future emerging technologies.

As one leading U.S. official on nanotechnology (Mihail Roco) recently stated at the 9th Annual Korea-U.S. Nano Forum in Seoul: "International collaboration in nanoscale science and engineering is essential at this moment because the field is growing rapidly with different focuses and multidisciplinary breakthroughs in different countries, and the synergism of such contributions determines faster and more efficient development."[2] It is the thesis of this article that this international collaboration in nanotechnology should not only exist for the development of the technology itself, but also for the regulatory oversight of nanotechnology. While such a model of international coordination would have many benefits, it also must confront several difficult obstacles.

This article addresses the potential benefits and challenges of international coordination of nanotechnology oversight. Part II provides a brief overview of nanotechnology and the unique regulatory challenges and the opportunities it creates. In Part III, the regulatory status and activities of nanotechnology

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1. At least 60 nations have established national nanotechnology programs.

2. Quoted in Oh Kyu-wook, *Collaboration Key on Nanotech: Expert*, The Korea Herald, June 7, 2012, *available at* http://nwww.koreaherald.com/view.php?ud=20120607001128&cpv=0 (last visited Dec. 21, 2012).

are reviewed for three leading jurisdictions in the world promoting the technology – the United States, the European Union and the Republic of Korea (ROK).[3] Part IV then proposes a new model of international coordination of technology governance, and discusses the opportunities and challenges in achieving this model for nanotechnology.

II. Background on Nanotechnology

A. The Nanotechnology Revolution

Nanotechnology is the utilization of the unique properties that many materials demonstrate at the nanoscale, which is usually considered to be in the range of 1 to 100 nanometers. One nanometer is one-billionth of a meter, or approximately 1/100,000 the thickness of a typical piece of paper.[4] At this nanoscale range, the proportionally higher surface area of materials, combined with quantum effects due to the contained space of the atoms, causes materials to display unique properties, generally in the direction of being more active and reactive.[5] For example, while gold, as we know it, is a solid metal, relatively inert and gold in color, at the nanoscale, this same material is a red semi-liquid that is much more reactive and conducts electricity.

Companies are exploiting the unique properties of nanomaterials for thousands of different applications, ranging from stronger to lighter materials for products such as tennis rackets and car parts, to more precisely targeted medicines and better UV radiation absorbing sunscreens. Well over 1000 nanotechnology consumer products are already on the market,[6] with count-

3. While these countries are among the very top proactive countries promoting nanotechnology, other active countries include China, Japan, Russia, India, Australia and Canada. *See, e.g.*, Xuan Liu, *Trends for Nanotechnology Development in China, Russia, and India*, 11 J. Nanopart. Res. 1845 (2009): Saori Ishizu *et al*., *Toward the Responsible Innovation with Nanotechnology in Japan: Our Scope*, 10 J. Nanopart. Res. 229 (2008).

4. U.S. National Nanotechnology Initiative, Size of the Nanoscale, *available at* http://www.nano.gov/nanotech-101/what/nano-size (last visited Dec. 22, 2012).

5. The UK Royal Society & the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* 5 (2004), http://www.nanotec.org.uk/finalReport.htm (last visited Dec. 12, 2012).

6. Project on Emerging Nanotechnologies, http://www.nanotechproject.org/inventories/consumer/analysis_draft (last visited Feb. 17, 2013).

less more industrial and process-based uses of nanomaterials. More complex and sophisticated nano systems are rapidly being developed, resulting in fast developing technology that is ever changing and evolving, creating a moving target for both researchers and regulators.

National governments are currently spending a combined total of approximately $10 billion per year on nanotechnology research and development, with private companies spending an equivalent amount.[7] Around the world, nanotechnology has expanded steadily and rapidly over the past decade, with a global annual rate of an increase (in the period from 2000 to 2008) of 35 percent per year in overall R&D funding, 35 percent for venture capital investments, 25 percent for number of jobs, 35 percent for the number of patent applications and 25 percent for the number of commercially available products.[8] No previous technology has grown so quickly, or has become so central to the product portfolio and the future of virtually every industry in modern economies.

B. Nanotechnology Risks and Regulation

Unfortunately, the very same properties, such as the small size and greater reactivity that make nanomaterials so promising for an incredible array of beneficial applications, also makes nanomaterials potentially capable of causing harm to human health and the environment.[9] For example, the small size of nanomaterials may allow them to cross important biological barriers, such as the placenta and the blood-brain barrier, potentially presenting novel risks.[10] There are enormous uncertainties about the risks of nanomaterials, which seem to be determined by factors other than the chemical structure used to estimate many traditional chemical risks, such as particle sizes, sur-

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7. Cientificia Ltd., Global Funding of Nanotechnologies & Its Impact 2 (2011), http://cientifica.com/wp-content/uploads/downloads/2011/07/Global-Nanotechnology-Funding-Report-2011.pdf (last visited Dec. 6, 2012).

8. Mihail C. Roco *et al.*, *Nanotechnology Research Directions for Societal Needs in 2020: Retrospective and Outlook*, at xxxviii (2010).

9. John E. Sargent Jr., Cong. Research Serv., RL34614, *Nanotechnology and Environmental, Health, and Safety: Issues for Consideration* 4 (Jan. 20, 2011).

10. Harald F. Krug & Peter Wick, *Nanotoxicology: An Interdisciplinary Challenge*, 50 Angewandte Chemie Int'l Ed. 1260, 1269–70 (2011); Peter Wick *et al.*, *Barrier Capacity of Human Placenta for Nanosized Materials*, 118 Envtl. Health Perspect. 432 (2009).

face areas and surface properties.[11] Some initial studies on nanomaterial hazards, primarily in animal studies, have been reported[12] with somewhat mixed results, as some studies indicate potential hazards while other studies suggest that the tested materials are relatively non-toxic.[13] In the meantime, there are no consensus test methods, even specifications or definitions of nanotechnology to ensure consistency in the toxicity testing.

The only two conclusions that seem to be clearly supported at this time are: (i) nanomaterials in general present more risk uncertainties than do non-nano substances;[14] and (ii) the risks of nanomaterials are not uniform but rather, are likely to vary across different categories, types and applications of nanomaterials.[15] The U.K. Royal Commission on Environmental Protection summarized this situation of unresolved uncertainty as follows:

> It is a matter of concern that we were repeatedly told by competent organizations and individuals that there is currently insufficient information to form a definitive judgment about the safety of many types of nanomaterials. In some cases, the methods and data needed to understand the toxicology and exposure routes of nanomaterials are insufficiently standardized or even absent. There appears to be no clear consensus among scientists about how to address this deficit.[16]

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11. Andrew D. Maynard, *Nanotechnology: The Next Big Thing, or Much Ado About Nothing?*, 51 Annals Occupational Hygiene 1, 6-7 (2007).

12. *E.g.*, Craig A. Poland *et al*., *Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-Like Pathology in a Pilot Study*, 3 Nature Nanotech. 423 (2008).

13. *See* Stephan T. Stern & Scott E. McNeil, *Nanotechnology Safety Concerns Revisited*, 101 Toxicological Sci. 4 (2008); Robert A. Yokel & Robert C. MacPhail, *Engineered Nanomaterials: Exposures, Hazards, and Risk Prevention*, 6 J. Occup. Med. Toxicol. Art. 7 (May 2011).

14. *See, e.g.*, The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), The Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies 6 (2006), *available at* http://ec.europa.eu/ health/ph_risk/committees/04_ scenihr/docs/scenihr_o_003b.pdf (last visited Feb. 17, 2013).

15. K. Savolainen *et al*., *Nanotechnologies, Engineered Nanomaterials and Occupational Health and Safety – A Review*, 48 Saf. Sci. 957, 960-61 (2010).

16. Royal Commission on Environmental Pollution, Novel Materials in the Environment: The Case of Nanotechnology 14-15 (Nov. 2008), *available at* http:// www.rcep.org.uk/ reports/27-novel%20materials/27-novelmaterials.htm (last visited Nov. 23, 2012).

This ubiquitous uncertainty about nanotechnology risks is perhaps the top challenge to the regulation of nanotechnology. However, there are other challenges. In addition to the uncertainty about risks, the heterogeneity and diversity of nanomaterials make regulations different, as the balance of risks and benefits, as well as the exposure of scenarios, will differ greatly for the different types and applications of nanomaterials. Even within one category of nanomaterials, there are estimated 50,000 different types of single-walled carbon nanotubes, which may vary greatly in their properties and risks.[17] Any attempt to regulate "nanotechnology" as a single entity therefore, would be both inefficient and ineffective – it will be necessary to distinguish more finely different categories, types or exposure levels of nanomaterials.

The path dependency of national regulatory programs is another obstacle to the regulation of nanotechnology. Most industrial nations have well-developed regulatory frameworks for various types of products including industrial chemicals, pesticides, foods, consumer goods, workplace exposures and medical products. These regulatory frameworks were developed prior to the advent of nanotechnology. Although nano-products falling into these various existing product categories can often be regulated under the existing frameworks, there are some difficulties. Many of the existing regulatory frameworks use the metrics as thresholds that may not be applicable or relevant to the nanomaterials.[18] Moreover, every industrial nation is struggling with the issue of whether nanomaterials, in a particular product category, require greater or *sui generis* regulatory treatment.[19]

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17. J. Clarence Davies, Project on Emerging Nanotechnologies, EPA and Nanotechnology: Oversight for the 21st Century 23 (2007), http://www.nanotechproject.org/file_download/files/Nano&EPA_PEN9.pdf (last visited Dec. 8, 2012).

18. Framing Nano, The Framing Nano Governance Platform: A New Integrated Approach to the Responsible Development of Nanotechnologies: Final Report 45 (Feb. 2010), http://www.framingnano.eu/images/stories/FinalConference/framingnano_ complete_final_report.pdf (last visited Dec. 6, 2012). For example, the U.S. Toxic Substances Control Act and European REACH program both use mass-based thresholds, which may suffice for most chemicals but may not be appropriate for ultra-light nanomaterials.

19. For example, the U.S. Food and Drug Administration (FDA) Task Force on Nanotechnology concluded that "[t]he available information does not suggest that all materials with nanoscale dimensions will be hazardous. Furthermore, if all nanoscale materials are compared to all non-nanoscale materials, whether larger or smaller, it is not apparent that the nanoscale materials as a group would have more inherent hazard." U.S. Food & Drug Admin., Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force 11 (2007), *available at* http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/Nanotechnology/ucm110856.pdf (last visited Nov. 30, 2012).

The rapid pace of nanotechnology development is also an impediment to effective regulation. As national governments struggle to regulate the first generation of relatively simple nanomaterials, companies are already developing and starting to deploy more complex second and third-generation nanotechnology systems. As is the case for many emerging technologies, the pace of technology development is speeding up while the capability of regulatory systems is increasingly overwhelmed, a problem that has been referred to as "the pacing problem."[20] The result is a "governance gap"[21] in which traditional regulation is unable to effectively govern rapidly developing technologies, and any regulations that are adopted become quickly outdated. As David Rejeski predicted almost a decade ago, "[i]f you think that any existing regulatory framework can keep pace with this rate of change, think again."[22]

Moreover, regulation of nanotechnology as a separate category requires a legally-sound and scientifically-credible "bright line" definition of nanotechnology. Most existing definitions use an approximate size range of 1-100 nanometers, often also requiring some type of "special properties." However, such a definition does not meet the requirements of a legally-enforceable definition.[23] For example, every product or object contains some nanoscale particles, so does it become necessary to specify what percentage of particles are 1-100 nanometers? One percent? Ten percent? Fifty percent? One hundred percent?[24] How will such percentages actually be measured? What if different batches of the same product contain different percentages of particles under 100 nanometers? Could companies strategically manipulate their products to squeeze under any threshold percentage? And what are these "special properties," and how are they defined and measured? All of these questions will have to be answered before there is a legally enforceable definition. Further-

20. Gary E. Marchant, *The Growing Gap between Emerging Technologies and the Law*, in The Growing Gap between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem 19, 23–24 (Gary Marchant *et al*. eds., 2011).

21. Ortwin Renn & Mihail C. Roco, *Nanotechnology and the Need for Risk Governance*, 8 J. Nanopart. Res. 153, 162 (2006).

22. David Rejeski, The Next Small Thing, Envtl. F., Mar.–Apr. 2004, at 45, 45.

23. Göran Lövestam *et al*., Joint Research Ctr., *Considerations on a Definition of Nanomaterial for Regulatory Purposes* 12–19 (2010), http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf (last visited Dec. 1, 2012).

24. Gary E. Marchant *et al*., *The Biggest Issues for the Smallest Stuff: Nanotechnology Regulation and Risk Management*, 52(3) Jurimetrics J. 243, 260-61 (2012).

more, these legal problems don't even address the scientific issues – such as, is it really credible to say that a particle with a diameter of 99 nanometers is nanotechnology while a 101 nanometer particle is not? Or to apply the same size threshold to every material, even though their properties are likely to vary over different ranges of sizes?[25]

The only jurisdiction to have adopted a regulatory definition of nanotechnology to date is the European Union, where the European Commission adopted in October 2011 the following definition of a nanomaterial: "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 percent or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm – 100nm [nanometers]."[26] The Commission was ordered to adopt such a legally-enforceable definition by the European Parliament, but the definition suffers from many of the problems discussed above.

Finally, nations are cautious about imposing unduly burdensome regulatory requirements on nanotechnology. In part, national governments do not want to deter developments in the technology, economic competiveness and job growth that can accompany this new revolution of technology. Moreover, nanotechnology has the potential to provide many health and environmental benefits, including more effective targeted cancer treatments, clean energy technologies and environmental remediation technologies.[27] The ROK, for example, has made a major commitment to developing sustainable energy technologies using nanotechnology.[28] Thus, overly precautious regulation of nanotechnology could do more harm than good to the public health.

III. National Regulatory Responses

Nanotechnology may be unique in the history of technology development

25. Andrew D. Maynard, *Don't Define Nanomaterials*, 475 Nature 31, 31 (2011).

26. European Commission Adopts Nanomaterial Definition as Basis for Future Regulation, 35 Chem. Reg. Rep. (BNA) 1018 (Oct. 18, 2011).

27. *See, e.g.*, Korea Researchers Develop Nanotechnology to Kill Cancer Cells, Arirang, Oct. 9, 2012, http://www.arirang.co.kr/News/News_View.asp?nseq=138345&code=Ne6&category=7 (last visited Nov. 24, 2012).

28. Dae Sup So *et al*., *Nanotechnology Policy in Korea for Sustainable Growth*, 14 J.. Nanopart. Res. 854, 859-62 (2012).

in that every industrialized nation is simultaneously developing the technology while struggling to find an appropriate regulatory balance, with no nation or region clearly leading in the technological or regulatory domain. Rather, each nation or region is blazing its own trail, but with a careful eye on the rest of the world to learn from and coordinate with each other as much as possible. Before discussing this potential for coordination in more detail in Part IV, the national regulatory activities of three international leaders in nanotechnology – the United States, the European Union, and the ROK – are briefly summarized, emphasizing their similarities and differences in their approach.

A. United States

The United States has historically been the clear leader of many previous technology revolutions, but, in an increasingly globalized world, it shares the lead in nanotechnology. The governmental vehicle for promoting nanotechnology is the National Nanotechnology Initiative (NNI), a coordinating body of some 25 U.S. federal agencies with an interest in nanotechnology which was created in 1990. The NNI was given a statutory foundation with the passage by Congress of the 21st Century Nanotechnology Research and Development Act of 2003 (P.L. 108-153). The NNI's primary focus is the advancement and promotion of nanotechnology research and commercialization in the United States, and since the creation of the NNI, the U.S. Congress has appropriated approximately $15.6 billion for nanotechnology R&D, including approximately $1.7 billion in the 2012 fiscal year.[29] While the NNI provides some coordination for the U.S. regulatory efforts, the U.S. is proceeding with a relatively decentralized approach to the regulation of nanotechnology, with each of several existing agencies (e.g., the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, and the Occupational Safety and Health Administration) asserting primary responsibilities for nanotechnology applications that fall into the product categories they traditionally have regulated (e.g., chemicals, drugs, consumer products, worker exposures). These agencies have undertaken the

29. John F. Sargent Jr., Cong. Research Serv., RL34511, *Nanotechnology: a Policy Primer* (2012), *available at* http://www.fas.org/sgp/crs/misc/RL34511.pdf (last visited Dec. 24, 2012).

initial "gap assessment" exercises to determine whether existing statutory authorities are sufficient to oversee nanotechnology, and have generally concluded that no new statutes are required at this time to regulate nanotechnology, although some regulatory fine-tuning may be required to address some of the unique issues and risks that nanomaterials may present now or in the future.

The EPA's first official foray into the regulatory consideration of nanotechnology was the publication of the White Paper on nanotechnology in 2007 that discussed the environmental benefits and risks of nanotechnology, and the challenges and steps that the agency planned to take in order to assess the risks and thus begin the regulatory consideration of nanotechnology products.[30] The following year, in 2008, the EPA launched a voluntary program known as the Nanoscale Materials Stewardship Program which invited companies to voluntarily report data on their nanotechnology products, but which generated only modest industry participation and was generally perceived as a failure.[31]

In the past few years, corresponding with the 2008 election of President Barack Obama, the EPA began to take a somewhat more active approach to nanotechnology regulation. Under section 5 of the Toxic Substances Control Act (TSCA), manufacturers of all new chemical substances or those who intend to make new significant uses of existing substances, must submit a premanufacturing notice (PMN) to EPA.[32] For PMN notices filed for over 100 nanomaterials, such as carbon nanotubes, EPA has entered a consent decree with the manufacturer as a condition for the market access requiring subchronic inhalation safety studies and implementations of worker respiratory protection programs.[33] EPA has also developed drafts of proposed rules re-

30. U.S. Environmental Protection Agency, Nanotechnology White Paper (Feb. 2007), http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf (last visited Dec. 24, 2012).

31. U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Nanoscale Materials Stewardship Program: Interim Report (2009), *available at* http://epa.gov/oppt/ nano/nmsp-interim-report-final.pdf (last visited Dec. 24, 2012). (only 29 companies submitted data on 123 nanomaterials in the basic data reporting program, and only 4 companies volunteered to participate in the more in-depth program).

32. 15 U.S.C. § 2604.

33. Philip Sayre *et al.*, *Nanomaterial Risk Assessment and Management Experiences Related to Worker Health Under the Toxic Substances Control Act*, 53 J. Occup. Envtl. Mgmt. S98, S98–S101 (2011).

quiring the testing of nanomaterials under section 4 of TSCA and requiring the reporting of data about nanomaterials by companies under section 8(a) of TSCA.[34] EPA has also recently proposed to require the manufacturers to report information on all nanomaterials used as active or passive ingredients in pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[35]

The other U.S. federal regulatory agency that has been the most active with respect to nanotechnology is the FDA, which is responsible for the regulation of many nanotechnology-based products including prescription drugs, over-the-counter drugs (which in the U.S. includes sunscreens), medical devices, cosmetics and foods. In 2007, the FDA published a report from an internal task force that concluded that the agency's statutory authority is adequate to deal with nanotechnology, but that it planned to issue additional guidance documents to enhance regulatory oversight, especially for products (e.g., cosmetics, foods, dietary supplements) for which there is no pre-market approval process in the United States.[36] The FDA also rejected labeling of nanotechnology products because "the current science does not support a finding that classes of products with nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials."[37]

The FDA has started issuing a series of drafts of the guidance document in 2011 and 2012 to strengthen its oversight of nanotechnology products. In June 2011, the FDA published a guidance draft for the industry on the criteria for identifying products containing nanotechnology, although, without offering any official definition of nanotechnology.[38] In April 2012, the FDA issued two additional draft guidance documents, which like all FDA guidances, are advisory only and are not legally enforceable. One was on the

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34. Irene A. Hantman, *Regulatory Policy: Nanotechnology*, 26 Toxics L. Rep. (BNA) 1126 (Sept. 22, 2011).

35. U.S. Environmental Protection Agency, Pesticides; Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment, 76 Fed. Reg. 35, 383 (June 17, 2011).

36. FDA *supra* note 19, at 32-35.

37. *Id.* at 35.

38. U.S. Food and Drug Administration, Draft Guidance: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology (June 2011), *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm (last visited Dec. 18, 2012).

nanotechnology in food, which stated that "FDA does not categorically judge all products containing nanomaterials or otherwise involving application of nanotechnology as intrinsically benign or harmful."[39] The guidance goes on to state that the use of nanotechnology in food or food-contact products may "warrant additional or different evaluations during a safety assessment of a food substance,"[40] and then cautions "[a]t this time, we are not aware of any food ingredient or FCS [food contact substance] intentionally engineered on the nanometer scale for which there are generally available safety data sufficient to serve as the foundation for a determination that the use of a food ingredient or FCS is GRAS [Generally Recognized As Safe]."[41] The second draft guidance document issued in April 2012 was for cosmetics, and recommended that the industry conduct additional safety testing and evaluation of nanotechnology cosmetics where necessary.[42]

Thus, both the EPA's and FDA's regulatory trajectories have been similar. Both agencies initially found little reason to treat nanomaterials differently from other materials within the same product categories. Over time, however, both agencies have indicated a growing need to address unique risks that may be presented by nanotechnology, and have begun the process of developing nanotechnology-specific regulatory documents that impose requirements over and above what is required for non-nano materials in the same product categories.

Whereas EPA and FDA have started to ramp up their nanotechnology regulatory activities, OSHA has not taken any action on nanotechnology other than creating a web page on nanotechnology, even though worker exposures, which are under the responsibility of OSHA, likely present the highest ex-

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39. Food and Drug Administration, Ctr. for Food Safety & Applied Nutrition, Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, including Food Ingredients that are Color Additives 13 (April 2012), *available at* http://www.fda.gov/downloads/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/UCM300927.pdf (last visited Dec. 18, 2012).

40. *Id*.

41. *Id*. at 14.

42. Food and Drug Administration, Ctr. for Food Safety & Applied Nutrition, Draft Guidance for Industry: Safety of Nanomaterials in Cosmetic Products (April 2012), *available at* http://www.fda.gov/downloads/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/UCM300932.pdf (last visited Dec. 18, 2012).

posure risks.[43] The OSHA nanotechnology webpage lists a number of existing programs and standards that may apply to nanotechnology, including its hazard communication standard, personal protective equipment standard, laboratory standard and the general duty clause.[44] In contrast, the National Institute of Occupational Safety and Health (NIOSH), which is not a regulatory agency, but a research body, has been very proactive in addressing nanotechnology risks in the workplace, including the production of guidance for employers and employees on the safe handling of nanomaterials and the non-binding recommended exposure limits (RELs) for some nanomaterials.[45]

While most nanotechnology regulation has occurred at the national level in the United States, there has been some activity by state and local governments, particularly in California. The City of Berkeley, California adopted a local ordinance requiring entities that handle nanomaterials within the city to report data about those materials on an annual basis.[46] The State of California has also taken action by issuing data "call-ins" for several nanomaterials, such as carbon nanotubes, which require manufacturers and processors of the listed materials to report specified data to the State.[47]

In sum, the United States has taken a fairly decentralized regulatory approach to nanotechnology, with several different agencies at the federal level asserting regulatory authority for the product categories within their traditional jurisdiction, and some states and local governments also taking relevant actions. Most regulatory requirements enacted or proposed to date have been data reporting obligations as opposed to risk management, exposure or emission standards. The U.S. government has also relied significantly on voluntary measures, such as the EPA Nanoscale Materials Stewardship Program, the non-regulatory NIOSH guidance and RELs, and the non-binding draft

43. Yokel & MacPhail, *supra* note 13, at 5.

44. Occupational Safety & Health Administration, Nanotechnology-Applications, *available at* http://www. osha.gov/dsg/nanotechnology/nanotech_applications.html (last visited Dec. 4, 2012).

45. *See* National Institute of Occupational Safety and Health, Nanotechnology (Jan. 21, 2012), *available at* http://www.cdc.gov/ niosh/topics/nanotech/ (last visited Dec. 7, 2012).

46. John C. Monica *et al*., *The Perils of Preemptive Regulation*, 2 Nature Nanotech 68, 68 (2007).

47. Cal. Dep't of Toxic Substances Control, Chemical Information Call-In Program: Nanomaterials, Facts Sheet (Nov. 2009), *available at* http://www.dtsc.ca.gov/TechnologyDevelopment/Nano technology/upload/Nanomaterials_AB289_Factsheet_english.pdf (last visited Nov. 28, 2012).

FDA guidance documents.

B. European Union

Unlike the experience with genetically modified foods, where the regulatory approaches of the European Union (EU) and United States diverged quickly and sharply, the EU's regulatory approach to nanotechnology has been similar to that of the U.S., although very recently, it shows some signs of divergence. Like the United States, the EU initially determined that its existing regulatory authorities were generally sufficient to handle most nanotechnology risks.[48]

In its 2004 document proposing a *European Strategy for Nanotechnology* that concluded no new regulatory authorities were needed, the European Commission nevertheless did propose to develop an international code of conduct that would function as a "global agreement on base principles for the responsible development of nanotechnology."[49] That effort came to fruition in 2008 with the publication of the EU Code of Conduct for Responsible Nanosciences and Nanotechnologies Research.[50] The Code was intended as an instrument that EU Member States could adopt and use to ensure that researchers in universities, research institutes and companies within their jurisdictions were adhering to the principles for the safe development and use of nanotechnologies. The Code of Conduct consists of seven general principles including sustainability, precaution, inclusiveness and accountability. The response of EU Member States to the EU Code has been "tepid" to date, with only the Netherlands initially implementing the Code.[51]

However, the EU regulators are now being pushed towards a more strin-

48. Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory Aspects of Nanomaterials, June 17, 2008, COM (2008) 366 final, at 3. ("Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework.")

49. European Commission, Communication: Towards a European Strategy for Nanotechnology, COM (2004) 338, at 23.

50. European Commission, Commission Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, COM (2008) 424.

51. Observatory NANO, Developments in Nanotechnologies Regulation & Standards - 2012, No.4, at 15-16 (April 2012), *available at* http://www.observatorynano.eu (last visited Dec. 2, 2012).

gent regulatory approach by the European Parliament, which is advocating a precautionary "No data, no market" policy towards nanotechnology.[52] The EU Parliament led the enactment of strict new rules for cosmetics containing nanomaterials during recent proceedings to adopt a new EU cosmetics regulation, which requires labeling and other special notification and safety requirements for nanomaterials in cosmetics.[53] A second initiative of the Parliament to impose similar restrictions on nano foods as part of the Novel Foods rulemaking failed after the proposed regulatory regime collapsed due to a dispute over the treatment of cloned animals.[54]

Perhaps the most important European regulatory program affecting nanotechnology in the long run will be the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program adopted by the EU in 2006, which puts the burden of proof on the manufacturer to demonstrate the safety of both new and existing chemical substances.[55] REACH was not drafted with nanotechnology in mind, and there are some complexities in adapting REACH to nanomaterials, such as the use of mass-based thresholds which might not be appropriate for nanomaterials, and uncertainty whether and when a nanomaterial that has the same chemical structure as a chemical already approved under REACH, will require a new REACH application.[56] Nevertheless, as REACH is adapted to nanomaterials, it likely will represent the most comprehensive and stringent regulation of nanomaterials in the world.

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52. *MEPs Back Tougher Rules for Nanotechnology*, EurActive.com (Apr. 28, 2009), http://www.euractiv.com/science/meps-back-tougher-rules-nanotechnology/article-181695 (last visited Jan. 3, 2013).; *"No Data, No Market" for Nanotechnologies, MEPs Say*, EurActive.com (Apr. 2, 2009), http://www.euractiv.com/science/data-market-nanotechnologies-meps/article-180893 (last visited Jan. 2, 2013).

53. *See* Diana M. Bowman *et al*., *Letter to the Editor, Nanomaterials and Regulation of Cosmetics*, 5 Nature Nanotech 92, 92 (2010).

54. *Novel Foods Talks Collapse on Council Refusal to Label Clone-Derived Products*, Eur. Parliament News (Mar. 29, 2011), *available at* http://www.europarl.europa.eu/en/press-room/ content/20110328IPR16525/html/Novel-Foods-talks-collapse-on-Council-refusal-to-label-clone-derived-products (last visited Nov. 28, 2012).

55. Commission Regulation 1907/2006, Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), 2007 O.J. (L 396) (EC).

56. EU, REACH-Nano Consultation, Specific Advice on Fulfilling Information Requirements for Nanomaterials under REACH (RIP-oN 2): Final Project Report (2011), *available at* http:// ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon2.pdf (last visited Dec. 22, 2012).

As it was the same case in the United States, the EU regulation of nanotechnology at the community-wide level is supplemented by individual actions of Member States. For example, France has recently adopted an annual reporting requirement for nanoproducts that goes beyond any EU requirement.[57] These subsidiary regulatory programs are a double-edged sword – on one hand, they can permit reconciliation with local preferences and contexts, but on the other hand, they can also interfere with developing harmonized regulatory requirements at the national and international levels.

One of the inherent tensions in the EU's regulation of nanotechnology is the appropriate level of precaution that should be used to regulate nanotechnology. The EU is the world's most prominent proponent of the precautionary principle.[58] The EU uses the precautionary principle to severely restrict genetically modified foods, even though its own scientific advisors, and those of other countries, have concluded that such foods likely present no greater risks than non-GMO foods.[59] In contrast, the EU has applied a much more lenient version of the precautionary principle to nanotechnology to date. For example, in its 2004 white paper on a European nanotechnology strategy, the "Precautionary Principle, as used up to now, could be applied in the event that realistic and serious risks are identified."[60] The limitation of the precautionary principle to "realistic and serious risks" that have been "identified" is a significant narrowing of the precautionary principle, relative to how the EU has regulated other uncertain risks, such as genetically modified foods. However, recent actions of the European Parliament discussed above support a more stringent application of the precautionary principle with its "no data, no market" approach.

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57. Rick Mitchell, *France Publishes Nanomaterial Reporting Requirements That Take Effect in 2013*, 35 Int'l Env't Rep. (BNA) 808 (Aug. 15, 2012).

58. Commission of the European Communities, Communication from the Commission on the Precautionary Principle, Feb. 2, 2000, COM (2000) 1, at 23.

59. European Commission, *A Decade of EU-Funded GMO Research (2001-2010)* (2010), *available at* ftp://ftp.cordis.europa.eu/pub/fp7/kbbe/docs/a-decade-of-eu-funded-gmo-research_en.pdf (last visited Feb. 17, 2013).

60. Commission of the European Communities, Communication from the Commission: Towards a European Strategy for Nanotechnology, Brussels, Dec. 5, 2004, COM (2004) 338 final.

C. Republic of Korea

The ROK was an early leader in the government support for nanotechnology, and remains a vibrant leader in nanotechnology within the world today.[61] In July 2001, shortly after the United States launched its National Nanotechnology Initiative, the Korean government issued its Nanotechnology Development Plan (NDP) to coordinate the active development of nanotechnology in the ROK.[62] The NDP has been revised every five years, with the Second Phase NDP in 2005 and the Third Phase NDP in 2011. The vision of the Third Phase NDP was "building the world's leading nanotechnology nation."[63] This central strategy document has been supplemented by a series of subsidiary government policies issued by various ministries, including the 2007 Roadmap for Nanotechnology Standard (Ministry of Knowledge Economy), the 2008 Strategy for Nanotechnology Convergence (Ministry of Education, Science, and Technology), the 2009 Mid- and Long-Term Plan (2010-2014) for the Nanomaterials Safety, and the 2011 government-wide Safety Control in Nanotechnology program.[64]

The Korean government has invested almost $2 billion in nanotechnology since the release of the initial NDP in 2001, which has propelled the ROK into one of the top nations in the world in nanotechnology funding.[65] This investment has resulted in many important advances in nanotechnology-enabled products in fields such as electronics, material science and energy, as well as the rapid increase in the number of scientific publications and patent applications by Korean researchers.[66] The Third and most recent Phase of the NDP released in April 2011 confirmed the ROK Government's strong commitment to nanotechnology, emphasizing the creation of a new industries, companies and products utilizing nanotechnology, and ensuring that nanotechnology

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61. *See* Asian Technology Information Program, ATIP08.018: National Nanotechnology R&D Plan in Korea (Aug. 20, 2008), http://www.atip.org/atip-publications/atip-reports/2008/5273-atip08-018-national-nanotechnology-rd-plan-in-korea.html.

62. *See* Dae Sup So *et al.*, *Nanotechnology Policy in Korea for Sustainable Growth*, 14 J. Nanopart. Res. 854, 854 (2012).

63. Establishing "The Phase-3 Action Plan for National Nanotechnology Development", 12 Asia Nano Forum Society Newsletter, at 10 (Jan. 2011).

64. So, *supra* note 62, at 855.

65. *Id*. at 856.

66. ATIP, *supra* note 61, at 12-13; So *et al*., *supra* note 62, at 856-57.

proceeds in an ethically and socially responsible pathway. The government has shifted its focus in the Third Phase NDP from fundamental science and technology advances to more specific commercial applications. The Third Phase NDP selected 30 future technologies in five different categories (nano devices, nano bio, nano energy/environment, nanomaterials and nano manufacturing/measuring devices), and committed $720 million during the period from 2011-2020 to developing these new nanotechnology applications.[67]

To accompany the new focus on commercialization of specific nanotechnology applications, the Third Phase NDP also provides an increased priority for research and the development of methods for toxicological testing of nanotechnology with respects to human health and the environment.[68] The legal and regulatory infrastructure for ensuring nanotechnology safety had been developing slowly under previous phases of the NDP. The Nanotechnology Promotion Act of 2002, passed by the Korean National Assembly on November 12, 2003, and legislated into law 6812 on December 26, 2002, provided in Article 19 for an assessment of the economic, social, cultural, ethical and environmental impacts of nanotechnology.[69] This resulted in the creation of the Nanotechnology Social Impact Research program, which is a government-wide program to evaluate the industrial and social impacts of nanotechnology, including research and evaluating safety impacts of nanotechnology.[70]

However, the Third Phase NDP represents a major step-up in the attention and resources given to the environmental, health and safety aspects of nanotechnology.[71] Among the specific efforts envisioned in the Third Phase NDP, the following issues were to be addressed: (i) the development of a training program for nano safety specialists; (ii) the introduction of impact assessment and measurement systems for nanomaterial spills; (iii) the establishment of a self-regulating control and report system for manufacturers; (iv) the establishment of a program for ensuring a safe working environment for workers;

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67. So *et al*., *supra* note 62, at 856.

68. *Id*. at 857.

69. So Young, *Nanotechnology Promotion Act of 2002 (South Korea), in Encyclopedia of Nanoscience and Society* (David H. Guston ed., 2010), *available at* http://knowledge.sagepub.com/view/nanoscience/n314.xml (last visited Jan. 4, 2013).

70. ATIP, *supra* note 61, at 9.

71. Korea's *Nanotechnology Roadmap for the Next Ten Years*, TWA Netwerk, March 30, 2011, *available at* http://www.agentschapnl.nl/sites/default/files/bijlagen/Nano%20roadmap%20Korea%202011.pdf (last visited Jan. 2, 2013).

and (v) the establishment of nano safety governance.[72] In addition to these initiatives and the increased safety testing program described above, the NDP also provides for the fostering of international cooperation to ensure the safe development of nanotechnology.[73]

The government's activities to promote the safety of nanomaterials has been coordinated by an inter-agency Nano-safety Policy Council consisting of the Ministry of Education, Safety and Technology (MEST), Ministry of Knowledge Economy (MKE), Ministry of Environment (MOE), Korean Food and Drug Administration (KFDA) and the Ministry of Employment and Labor.[74] In late 2010, these agencies released a master plan on nano-safety that will consist of three phases.[75] Phase 1 (2011-2013) involves creating a list of nanomaterials and focusing on the 13 representative nanomaterials selected by the OECD for safety testing.[76] Phase 2 (2014-2017) will make it mandatory for manufacturers and importers of nanoproducts to register their products. Phase 3 (2018-2020) will institute a Product Certification System based upon the Quality Management and Safety Control of Industrial Products Act.[77]

Several Korean agencies have recently undertaken environmental, health and safety initiatives pursuant to the National Nano-safety Master Plan. For example, the MKE has prepared a guide on the safety management of nanotechnology-based products, adopted as the Korean Standard on May 12, 2011 and which sets forth good safety practices for manufacturers to follow.[78] The MOE has developed a guide on occupational safety management for nanomaterials and has initiated a voluntary survey from companies on the production, use, import and export of the manufactured nanomaterials.[79] The KFDA

72. *Id*. at 7.

73. *Id*.

74. Korea Inter-agency Meeting on Nano-safety (KISTI), 12 Asia Nano Forum Society Newsletter, at 10 (Jan. 2011).

75. Korea Ministry of Knowledge Economy (MKE), Preparing for a Master Plan on Nano-safety, 12 Asia Nano Forum Society Newsletter, at 10-11(Jan. 2011); OECD Environment Directorate, Current Developments on the Safety of Manufactured nanomaterials – Toru de Table, Series on the Safety of Manufactured Nanomaterials No. 34, at 47 (Sept. 4, 2012).

76. MKE, *supra* note 75, at 11.

77. *Id*.

78. OECD Environment Directorate, *supra* note 75, at 47.

79. *Id*.

has been operating its nanotoxicology project since 2007 that seeks to generate toxicology and safety data for foods, drugs, medical devices and cosmetics using nanotechnology, which can then be used for developing guidelines for assessing the risks of such products.[80]

D. Common Trends

From this brief overview of the nanotechnology policies of the three different leading jurisdictions in the field of nanotechnology, some common themes emerge. The United States, European Union and the ROK are all actively promoting nanotechnology with substantial government funding based on their expectation that nanotechnology will be a fundamental foundation of future industrial and commercial economies, where also, the height of their future international competitiveness would depend on becoming a technology leader in the field of nanotechnology. All three jurisdictions recognize not only the economic and commercial benefits of nanotechnology, but also the important role of nanotechnology in providing for a healthier and sustainable future through applications in health care, clean energy and environmental protection. All three governments recognize that nanotechnology will only be successful in the long-term if it is developed in a safe and responsible manner, and although the governments could be criticized for lagging initially in supporting health and safety studies of nanotechnology, they are now actively pursuing such knowledge based on their understanding of the central importance of managing nanotechnology risks.

All three jurisdictions are primarily relying on existing regulatory frameworks to regulate nanotechnology, at least initially,[81] with an increasing amount of fine tuning in terms of governmental guidance documents, recommendations and supplementary regulatory enactments on process and product safety. All three governments are relying heavily on scientific and technical advice from scientists and engineers in adapting their regulatory oversight given the novelty and complexity that nanotechnology represents. Moreover, all three jurisdictions are employing a mixture of traditional regulatory ap-

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80. *Id*. at 49.

81. *See also* Karinne Ludlow, *Nanoregulation –Filtering out the Small Stuff*, 2 Nanoethics 183, 184-190 (2008) (critiquing tendency of jurisdictions such as United States and Australia to rely on existing regulatory frameworks to oversee nanotechnology).

proaches combined with various collaborative and voluntary measures, sometimes referred to as "soft law,"[82] in order to provide oversight that is both effective and adaptive to rapid changes in technology. Given the common approaches to date of these three leading jurisdictions, the potential benefits and importance in maintaining and strengthening international coordination in nanotechnology are important issues, and are addressed next.

IV. International Coordination

This part sets forth the case for, and status of international coordination of, nanotechnology oversight. Subpart A summarizes the key arguments for international coordination. Subpart B describes the precedent of genetically modified (GM) foods, where failure to coordinate international regulation has resulted in substantial economic and political conflicts, which proponents of nanotechnology seek to avoid repeating. Finally, Subpart C describes the key initiatives that have been undertaken with nanotechnology in order to coordinate the national policies and head off the types of international conflicts that have impeded GM foods.

A. Arguments for International Coordination

The United States, European Union and Republic of Korea, along with dozens of other industrial nations, are all simultaneously seeking to promote the development and commercialization of nanotechnology, while also designing regulatory frameworks that will ensure that the technology is developed safely and responsibly. In so doing, these nations are encountering many of the same challenges and complexities. There are powerful reasons why it would be beneficial for nations to resolve these issues in a consistent manner.

First, international coordination of regulatory requirements would provide efficiencies for companies involved in manufacturing or distributing nanotechnology products in international commerce. For example, consistent environmental and occupational safety and health requirements of different countries would enable multinational corporations that manufacture or pro-

82. Kenneth Abbott *et al*., *Soft Law Oversight Mechanisms for Nanotechnology*, 52 Jurimetrics, J. L., Sc. & Tech.. 279 (2012).

cess nanotechnology products to implement uniform environmental, health and safety programs, including internal company compliance, product stewardship, worker training and reporting programs. In addition, consistent regulatory requirements would provide efficiency and consistency throughout the entire product life cycle, from product design and labeling requirements to product testing protocols and regulatory submission dossiers.

Second, consistent regulatory requirements will minimize trade disruptions that can result from divergent national regulations. As the precedent from trade disputes involving genetically modified foods that have resulted from inconsistent national regulations has demonstrated (see subpart B below), such trade controversies can cause both enormous economic losses and political tensions.[83] Consistent regulatory standards for nanotechnology could help avoid such disruptive and damaging trade disputes for this technology.

Third, coordination may help ensure consistent levels of safety protection for workers and consumers, both with respect to products produced domestically and to those sold in international trade. Equivalent protections might also prevent a "race to the bottom" or "risk havens" – where jurisdictions seek to attract industrial development and the accompanying tax revenues and jobs by sacrificing health and safety protections.[84]

Fourth, regulatory coordination would provide an "economy of scale" for both regulators and regulated parties.[85] Rather than each nation separately developing and assessing scientific evidence of risks, costs and compliance models, and criteria and test methods, the regulators could share the expertise, resources and costs that are needed to develop these necessary regulatory support materials. The industry and other regulated parties would likewise only need to participate in that global standard-setting process, rather than separate regulatory proceedings in dozens of different countries. Coordination would not only be more efficient, but would also produce better quality regulations, since the world's best scientists and other experts can focus

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83. Gary E. Marchant, *et al*., *International Harmonization of Nanotechnology Oversight, in The Nanotechnology Challenge: Creating Law and Legal Institutions for Uncertain Risk*s 179-202 (David A. Dana ed., 2012).

84. Gareth Porter, *Trade Competition and Pollution Standards: "Race to the Bottom" or "Stuck at the Bottom"*, 8 J. Env't & Dev. 133 (1999).

85. Kenneth W. Abbott *et al*., *Transnational Regulation: Reality or Romanticism? in International Handbook on Regulating Nanotechnologies* 525, 528 (Graeme Hodge, Diana Bowman & Andrew Maynard eds., 2011).

their efforts on developing one set of regulations based on the best evidence, rather than dissipating their expertise over separate national regulatory efforts in sixty or more individual countries.[86]

For these reasons, many scholars and governments have recognized the benefits of international coordination of nanotechnology regulation.[87] As the International Risk Governance Council has advised, "[h]armonization between nations is … essential as nanotechnology and its applications are already global phenomenon."[88] International coordination or harmonization could occur at several different levels of formality.[89] The strongest form of international coordination would be in the form of binding international law, such as an international treaty. Such a treaty is unlikely in the foreseeable future, given the challenges of negotiating international treaties, the complexity of the subject matter, and other priorities at the international level. The next level of coordination would be harmonization, whereby individual nations would adopt identical or near-identical laws and regulations, perhaps based on model rules produced by some type of international body. Again, given the absence of any such international coordinating body at this time, and the different regulatory frameworks, agencies and approaches that exist in each country upon which nanotechnology governance would be super-imposed, the probability of such a strongly harmonized approach to nanotechnology

86. Kenneth W. Abbott, *An International Framework Agreement on Scientific and Technological Innovation and Regulation, in The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem* 127, 130-32 (Gary E. Marchant *et al*. ed., 2011).

87. Marchant *et al*., supra note 83; Abbott *et al*., *supra* note 86; Gary E. Marchant *et al*., *International Harmonization of Regulation of Nanomedicine*, 3(3) Studies in Ethics, L. & Tech. (2009); Robert Falkner & Nico Jaspers, *Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap*, 12 Global Envtl. Pol. 30 (2012); Linda Breggin, *et al*., *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation*, Envtl. Law Inst. & London School of Economics (Sept. 2009), *available at* http://www.chathamhouse.org.uk/files/14692_r0909_nanotechnologies.pdf (last visited Dec. 29, 2012); Vladimir Murashov & John Howard, *The US Must Help Set International Standards for Nanotechnology*, 3 Nature Nanotech 635 (2008); Diana M. Bowman & Graeme A. Hodege, *A Small Matter of Regulation: An International Review of Nanotechnology Regulation*, 8 Columbia Sci. Tech. L. Rev. 1 (2007).

88. International Risk Governance Council, *Nanotechnology Risk Governance* 20 (2007), *available at* http://irgc.org/wp-content/uploads/2012/04/PB_nanoFINAL2_2_.pdf (last viewed Dec. 18, 2012).

89. *See* Breggin *et al*., *supra* note 87, at 6.

regulation anytime soon is probably remote.

Instead, what is more feasible and what is already being attempted in an unstructured and ad hoc manner are a series of informal coordination efforts between regulatory officials in different countries. Some of these international coordination efforts are summarized below in Subpart C after first exploring in more depth the failed example of international harmonization for genetically modified foods.

B. Avoiding the Biotechnology Debacle

The production of GM plants by modern biotechnology provides an important lesson about the long-term economic and political harms that can result from inconsistent national regulation of an emerging technology. It is a precedent that nanotechnology must avoid. The regulation of GM foods was developed by a traditional model, where individual nations adopted their own national regulations of GM foods and then would discuss bringing those national regulations into harmony. Francis Fukuyama, for example, advocated this traditional two-step approach to biotechnology regulation:

> It is true that regulation cannot work in a globalized world unless it is global in scope. Nonetheless, national-level regulation must come first. Effective regulation almost never starts at an international level: Nation-states have to develop rules for their own societies before they can even begin to think about creating an international regulatory system.[90]

The lesson learned from GM foods is that this two-step process, of focusing on the national regulations first and the international harmonization second, does not work. The United States, European Union, and other nations have adopted inconsistent national regulations based on a series of various factors, including social and economic differences, more weight given to the precautionary principle and public opinion. As the national regulations began to diverge, these differences became more and more entrenched both politically and legally, creating a path dependency that was almost impossible

90. Francis Fukuyama, *Gene* Regime, Foreign Policy, March/April 2002, at 57, 59.

to reverse.[91] These regulatory differences resulted in restrictions on trade in products approved in one country but not in the other, recalls and embargoes of foods shopped from one country to another without compatible regulations, disincentives for food exporting nations to grow beneficial GM crops because of the potential repercussions for trade, and the growing economic, legal and political tensions between countries that were once allies.[92]

The dispute between the United States, Canada and Argentina versus the EU in a recent World Trade Organization (WTO) proceeding was perhaps the most bitter example of an international tension created by inconsistent national standards. The WTO case was filed in 2003, with the US, Canada and Argentina alleging that the EU and six of its member states were unduly delaying approval of GM foods and crops in violation of the WTO rules. The complainants argued that the EU restrictions would "harm worldwide agricultural exports, impede the development of advanced agricultural biotechnology, and increase negative public perceptions of GM foods."[93] For example, the US contended that the EU regulatory delays were costing US corn producers approximately $300 million per year.[94] After a long process and the lengthiest WTO panel decision in history, the WTO held in favor of the complainants, ruling that the EU had failed to provide a timely process for regulatory approvals.[95] However, this WTO decision did not end the dispute, which still lingers today, causing continuing tensions between the U.S. and the EU:

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91. Hannes R. Stephan, *Revisiting the Transatlantic Divergence over GMOs: Toward a Cultural-Political Analysis*, 12 Global Envtl. Pol. 104, 108 (2012).

92. *See, e.g.*, Mark Mansour *et al*., *From Farm to Fork: The Impact on Global Commerce of the New European Union Biotechnology Regulatory Scheme*, 38 Int'l Lawyer 55 (2004); Rick Weiss, *Food War Claims Its Casualties: High-Tech Crop Fight Victimizes Farmers*, Wash. Post, Sept. 12, 1999, at A1.

93. Debra M. Strauss *et al*., *Globalization and National Sovereignty: Controlling the International Food Supply in the Age of Biotechnology*, 15 J. Legal Studies Bus. 75, 80 (2009).

94. Charles E. Hanrahan, Cong. Research Serv., RS21556, *Agricultural Biotechnology: The US-EU Dispute* 1 (March 10, 2006).

95. World Trade Organization [WTO], *European Communities: Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R, 2006, *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm (last visited Feb. 17, 2013).

> The transatlantic GMO dispute has brought into conflict two long-time allies, economically interdependent democracies with a long record of bilateral and multilateral cooperation in both economics and security. Yet the dispute has developed into one of the most bitter and intractable transatlantic and global conflicts, resisting efforts at resolution in bilateral networks and multilateral regimes alike, and resulting in a bitterly contested legal battle before the WTO.[96]

Since the issuance of the WTO decision, international differences in GM food regulations continue to play havoc with the international trade in food and relations between nations. For example, the EU imposed costly testing and certification requirements for all Chinese rice products after finding a form of GM rice (known as Bt 63) in certain rice shipments from China.[97] The EU, Japan and Brazil severely restricted imports of Canadian flax in 2009-10, after certain shipments were found to contain trace amounts of a GM variety which was not approved in those jurisdictions.[98]

C. Existing International Coordination Initiatives for Nanotechnology

The lesson from biotechnology is that nations cannot wait for national regulations to be established before exploring the international coordination possibilities. Rather, international coordination mechanisms should be established first before substantive regulatory requirements are adopted at either the national or international level. These mechanisms and processes can be used to establish relationships between regulators in different countries, share information and concerns about regulatory proposals early in the promulgation process, and begin creating an ethos of coordination and harmonization. These are exactly what have transpired with nanotechnology to date. National

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96. Mark A. Pollack & Gregory C. Shaffer, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* 2 (2009).

97. European Union, *Commission Decision 2008/289/EC of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism 'Bt 63' in rice products*, *available at* http://gmo-crl.jrc.ec.europa.eu/doc/Bt63_2008_289_EC.pdf (last visited Feb. 16, 2013).

98. *Canadian Flax Output to Drop as GM Issue Continues*, TMCnews, Jan. 5, 2010, *available at* http://www.tmcnet.com/usubmit/2010/01/05/4558777.htm (last visited Apr. 4, 2010).

governments, in some cases in partnerships with other stakeholders such as industry groups and non-governmental organizations, have engaged in a series of informal international coordination efforts for nanotechnology. Some key examples are summarized below.

1. OECD Working Groups

The Organization for Economic Cooperation and Development (OECD) is an inter-governmental organization of 34 industrial nation members, including the United States, most European countries and the ROK, in which governments work together to share experiences and seek solutions to common problems.[99] The OECD has become an important focus for international coordination in the nanotechnology policy, and two working groups have been established, made up of government representatives from member nations. The Working Party on Manufactured Nanomaterials (WPMN) was established in 2006 by the Environment Directorate to coordinate testing and assessment methods for promoting international cooperation in ensuring the environmental-safety and health-safety of nanotechnologies.[100] In 2007, the Directorate for Science, Technology and Industry created its own Working Party on Nanotechnology (WPN) to advise on policy issues in science, technology and innovation, related to the responsible development and use of nanotechnology.[101] Both Working Parties have undertaken a number of projects to coordinate national nanotechnology policies.[102] For example, the WPMN is coordinating a "Sponsorship Programme for the Testing of Manufactured Nanomaterials" in which member countries have pooled their expertise and resources to fund the safety testing of 13 specific manufactured

99. Organization for Economic Cooperation and Development [OECD], Members and Partners (undated), *available at* http://www.oecd.org/about/membersandpartners/ (last visited Feb. 15, 2013).

100. OECD, Safety of Manufactured Nanomaterials, *available at* http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_1,00.html (last visited Nov. 29, 2012).

101. OECD, Working Party on Nanotechnology, *available at* http://www.oecd.org/document/36/0,3343,en_2649_34269_38829732_1_1_1_1,00.html (last visited Nov. 29, 2012).

102. OECD, Six Years Of OECD Work On The Safety Of Manufactured Nanomaterials: Achievements and Future Opportunities (2012), *available at* http://www.oecd.org/env/chemicalsafetyandbiosafety/safetyofmanufacturednanomaterials/Nano%20Brochure%20Sept%202012%20for%20Website%20%20(2).pdf (last visited Dec. 22, 2012).

nanomaterials.[103] The WPMN also collects and publishes a compendium of regulatory and policy activities of each OECD nation, which provides useful resources for governmental officials and stakeholders to track regulatory activities in other nations.[104]

2. International Dialogue on Responsible Research and Development of Nanotechnology

Representatives from governments around the world have met three times at a gathering called the International Dialogue on Responsible Research and Development of Nanotechnology. The first meeting was convened by the Meridian Institute in the United States in 2004, the second by the government of Japan in Tokyo in 2006 and the third by the EU in Brussels in 2008.[105] Officials from 25 nations attended the first two meetings, which increased to 49 nations represented at the Third dialogue. The goal of the dialogue was to facilitate informal discussions and sharing of information between officials from different governments, and to encourage a globally coordinated approach to nanotechnology governance. The process of the international dialogue was discontinued after the third meeting in 2008, likely because the OECD process was providing a more institutional format for such discussions.

3. Strategic Approach to International Chemicals Management

The Strategic Approach to International Chemicals Management (SAICM) is an international policy framework for the sound management of chemicals, launched in 2006 by the International Conference on Chemicals Management

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103. OECD, Sponsorship Programme for the Testing of Manufactured Nanomaterials (undated), *available at* http://www.oecd.org/env/chemicalsafetyandbiosafety/safetyofmanufacturednanomaterials/sponsorshipprogrammeforthetestingofmanufacturednanomaterials.htm (last visited Dec. 24, 2012).

104. OECD, Current Developments on the Safety of Manufactured Nanomaterials, *available at* http://www.oecd.org/env/chemicalsafetyandbiosafety/safetyofmanufacturednanomaterials/currentdevelopmentsonthesafetyofmanufacturednanomaterials.htm (last visited Jan. 4, 2013).

105. *See* Report, Third International Dialogue on Responsible Research and Development of Nanotechnology, Brussels, March 11-12, 2008, *available at* ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/report_3006.pdf (last visited Jan. 4, 2013).

(ICCM).[106] Governments, industries and non-governmental organizations all actively participate in SAICM. The goal of SAICM is to ensure that chemicals are produced and used in ways that will minimize significant adverse impacts on human health and the environment by 2020.[107] The SAICM recently added nanotechnology to its Plan of Action.[108] As part of that Action plan, the Second International Conference on Chemicals Management (ICCM-2) held in Geneva in May, 2009, passed a resolution that "…encourages Governments and other stakeholders to assist developing countries and countries with economies in transition to enhance their capacity to use and manage nanotechnologies and manufactured nanomaterials responsibly, to maximize potential benefits and to minimize potential risks."[109] The resolution also called for national governments and other stakeholders to share information on nanotechnology risks, benefits and regulatory actions, and to coordinate their activities in these areas to the extent possible.[110] To help nations prepare to address the oversight of nanotechnology as part of this SAICM process, several Awareness-Raising Workshops on Nanotechnology/ Manufactured Nanomaterials were held during 2009-2011.[111] The workshops informed the participants of the potential applications and risks of nanotechnologies and the manufactured nanomaterials, and identified opportunities for raising awareness of the relevant activities to be undertaken in those countries.

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106. Strategic Approach to International Chemicals Management [SAICM], *available at* http://www.saicm.org/index.php?ql=h&content=home (last visited Dec. 1, 2012).

107. SAICM Information Bulletin No. 1 (2008), *available at* http://www.saicm.org/documents/Publications/SAICM%20Information%20Bulletin%20No%201%20Jan%202008.pdf (last visited Dec. 1, 2012).

108. Lynn L. Bergeson, *SAICM Will Publish Comments on Adding Nanotechnology Activities to Global Plan of Action* (May 11, 2012), *available at* http://www.nanotech-now.com/columns/?article=659 (last visited Jan. 02, 2013).

109. SAICM, Report of the International Conference on Chemicals Management on The Work of its Second Session, at 37, SAICM/ICCM.2/15, May 27, 2009), *available at* http://www.saicm.org/images/saicm_documents/iccm/ICCM2/ICCM2%20Report/ICCM2%2015%20FINAL%20REPORT%20E.pdf (last visited Dec. 27, 2012).

110. *Id*. at 37-38.

111. United Nations Institute for Training and Research (UNITAR), Nanotechnology and Manufactured Nanomaterials: Overview, *available at* http://www.unitar.org/cwm/nano (last visited Dec. 27, 2012).

4. International Conference on Harmonization

The International Conference on Harmonization of Technical Regulations for Registration of Pharmaceuticals for Human Use (ICH) brings together the pharmaceutical regulatory agencies of the United States, E.U. and Japan, along with the pharmaceutical industry trade associations from the same three jurisdictions to develop common guidelines for the regulation of pharmaceuticals.[112] The guidelines agreed to by the ICH consensus process are subsequently adopted into the national laws of the member nations with whatever modifications deemed appropriate during the adoption process of each country. In addition to the three founding jurisdictions, a number of other nations now participate in the ICH process as observers, and also consider adopting the harmonized ICH guidelines into their own national laws. Although the ICH has not actively developed guidelines on nano-pharmaceuticals to date, it has identified nanotechnology as a potential future issue to address.[113]

5. WHO Guidelines on Nanomaterials and Worker's Health

The World Health Organization (WHO) is currently developing international guidelines to protect workers from nanotechnology exposures. WHO's focus on nanotechnology was spurred by the World Health Assembly's adoption of the 2007 Global Plan of Action on Workers Health, which identified nanotechnology in the workplace as a priority action item.[114] In response to this directive, the WHO undertook a two-year process, beginning in 2012, to develop Guidelines on "Protecting Workers from Potential Risks of Manufactured Nanomaterials."[115] The Guidelines are expected to "incorporate elements of risk assessment and risk management and contextual issues," with a particular emphasis on protecting workers handling nanomaterials in low and

112. J.A. Molzon *et al.*, *The Value and Benefits of the International Conference on Harmonization to Drug Regulatory Authorities: Advancing Harmonization for Better Public Health*, 89 Clinical Pharmacol. Therapeutics 503 (2011).

113. *See* Gary E. Marchant *et al.*, *International Harmonization of Regulation of Nanomedicine*, 3(3) Studies in Ethics, L. & Tech., at 10-11 (2009).

114. World Health Organization [WHO], WHO Guidelines on Nanomaterials and Worker's Health, *available at* http://www.who.int/occupational_health/topics/nanotechnologies/en/ (last visited Dec. 1, 2012).

115. *Id.*

middle-income countries.[116]

6. ISO and Other Standard-Setting Organizations

The International Organization for Standardization (ISO) and other international standard-setting bodies have become key players in coordinating nanotechnology risk management practices globally. The ISO, composed of the most representative or official standard-setting body from each member country, established a Technical Committee (TC 229) in 2005 to develop global standards for nanotechnology. As of December 2012, TC 229 had published 30 nanotechnology standards, many of which focused on technical specifications for nanomaterial definitions, characterizations and methodologies.[117] However, other ISO standards are more akin to quasi-regulatory standards, such as the standard governing environmental, health and safety (EHS) management in occupational settings.[118] This standard sets forth detailed specifications for managing occupational and environmental risks in the production, handling, use and disposal of nanomaterials. According to one analysis, "[t]he work of ISO might be viewed as an 'advance guard,' assembling the collective knowledge of experts from around the world and making it available for immediate application while regulators are still attempting to determine what, if any, unique legal requirements are necessary."[119] Other international standard-setting organizations, such as ASTM International, have also published quasi-regulatory EHS management standards for nanomaterials.[120]

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116. *Id.*

117. TC 229 – Nanotechnologies, *available at* http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=381983&published=on&includesc=true (last visited Dec. 1, 2012).

118. ISO, ISO/TR 12885:2008, Nanotechnologies -- Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies (2008), *available at* http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=52093 (last visited Dec. 1, 2012).

119. Chris Bell & Martha Marrapese, *Nanotechnology Standards and International Legal Considerations*, in Nanotechnology Standards 239, 245 (V. Murashov and J. Howard eds., 2011).

120. ASTM E2535 - 07 Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings, *available at* http://www.astm.org/Standards/E2535.htm (last visited Dec. 1, 2012).

7. Bilateral Government Cooperation Agreements

There are numerous examples of bilateral agreements between two nations to cooperate with and coordinate their nanotechnology activities. The ROK has been one of the most active nations in this regard, entering into a series of bilateral relationships on nanotechnology. The ROK and the United States have convened an annual Korea-U.S. Nano Forum since 2003 in which researchers, companies and policymakers from the two nations gather to discuss progress, find new developments and identify opportunities for collaboration.[121] In addition, Korean and U.S. governmental units have co-sponsored a series of more specialized annual conferences in areas such as nanostructured materials, nanoelectroncis and nano-biotechnology.[122] The ROK and China signed a Memorandum of Understanding in July 2005 to jointly establish a Nanotechnology Research Center, which was formally inaugurated in July 2007.[123] The ROK has also signed a Memoranda of Understanding to partner with Thailand on nanotechnology research[124] and with Russia and Singapore to create the Asia Nanotechnology Fund to make investments in nanotechnology-related products.[125]

The U.S. is also participating in some bilateral relationships addressing nanotechnology. In addition to its annual conference with Korea, the U.S. has partnered with Canada to create in 2011 the Canada-US Regulatory Cooperation Council (RCC) to coordinate regulatory approaches in the two nations.[126]

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121. Oh Kyu-wook, *supra* note 2.

122. U.S. Korea JSNT 2012, http://www.utdallas.edu/nsm/jsnt2012/overview.html (last visited Jan. 4, 2013).

123. *China-Korea Nanotechnology Research Center Formally Opens in Beijing*, Nanowerk News, July 7, 2007, *available at* http://www.nanowerk.com/news/newsid=2186.php (last visited January 3, 2013).

124. *Thailand Partners with Korea on Nanotechnology Research*, Asian Scientist Magazine, March 31, 2011, *available at* http://www.asianscientist.com/tech-pharma/thailand-partners-korea-nanotechnology-research/ (last visited Jan.2, 2013).

125. *Russia, Korea and Singapore Announce Launch of the Asia Nanotechnology Fund*, Nanowerk News, June 16, 2011, *available at* http://www.nanowerk.com/news/newsid=21763.php (last visited Jan. 4, 2013).

126. The White House, Joint Statement by President Obama and Prime Minister Harper of Canada on Regulatory Cooperation (Feb. 4, 2011), *available at* http://www.whitehouse.gov/the-press-office/2011/02/04/joint-statement-president-obama-and-prime-minister-harper-canada-regul-0 (last visited Dec. 2, 2012).

Nanotechnology has been identified as one of the primary issues to be addressed by the RCC, as "[e]arly cooperation between both governments on regulatory aspects of nano materials will help ensure maximum alignment."[127] A bilateral Working Group on nanotechnology has been tasked in developing a Nanotechnology Work Plan under the auspices of the RCC.[128] The U.S. and the E.U. are also seeking to better coordinate their nanotechnology policies through the United States-European Union Transatlantic Partnership created in 2004. The goal of the Partnership is to strengthen transatlantic economic integration and cooperation, and nanotechnology has been identified as one of the priority subjects in this initiative, with the countries expressing a commitment to "work to support an international dialogue and cooperative activities for the responsible development and use of the emerging field of nanotechnology."[129]

V. Conclusion: A New Ethos of Coordination

Through these and other mechanisms, national governments are demonstrating an interest and commitment to coordinating their regulatory responses to nanotechnology whenever feasible. To be sure, most efforts in this regard to date are ad hoc and sporadic, and provide no assurance that the international divisions which impacted GM foods will not happen with nanotechnology. Nevertheless, as these initiatives proliferate and expand, they can make a real practical difference in promoting consistent regulatory approaches to nanotechnology in different parts of the world. More importantly, these existing initiatives demonstrate a growing understanding and ethos among national governments about the importance and benefits of international coordination of nanotechnology oversight.

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127. RCC, Joint Action Plan 17 (Dec. 2011), *available at* http://www.whitehouse.gov/sites/default/files/us-canada_rcc_joint_action_plan3.pdf (last visited Dec. 2, 2012).

128. *Regulatory Cooperation Council Holds Stakeholder Webinar on Nanotechnology*, Nano and Other Emerging Technologies Law Blog (Nov. 30, 2012), *available at* http://nanotech.lawbc.com/2012/11/articles/united-states/regulatory-cooperation-council-holds-stakeholder-webinar-on-nanotechnology-initiative/ (last visited Feb. 17, 2013).

129. The European Union and the United States Initiative to Enhance Transatlantic Economic Integration and Growth (2005), *available at* http://trade.ec.europa.eu/doclib/docs/2006/march/tradoc_127675.pdf (last visited Nov. 30, 2012).

The open question, and one that cannot be answered now and perhaps even in the future, is what difference will these various ad hoc, soft law approaches to nanotechnology oversight have? In theory, a stronger and preferable approach to international harmonization would entail an international treaty, or even a framework convention that would formally create some of the international regulatory infrastructure that could gradually be enhanced with substantive requirements as time progresses.[130] However, a formal international harmonization instrument such as a treaty or agreement does not seem politically feasible, at least at this present time. The objective of international harmonization or coordination therefore, must rely on second-best solutions, such as those offered by the various programs described above. At a minimum, such programs may delay or minimize the divergence of national regulatory programs, thus slowing the destructive path dependency on divergent regulatory trajectories.

The various types of soft law international coordination mechanisms in place today for nanotechnology represent an experiment, as few, if any, previous technologies have been the subjects of so many diverse programs of this type. It may be that the process and personal relationships they build may be more important in the long run in creating a shared ethos in and a commitment to internationally coordinated governance than the specific substantive provisions in any or all existing mechanisms; given that, they represent our only hope at the present time for a coordinated and harmonious international governing environment for nanotechnology. These initiatives need to be supported, strengthened and expanded. Only through coordinated regulatory approaches can the almost unlimited benefits of nanotechnology be fully realized for all peoples and nations of the world.

130. Kenneth W. Abbott *et al*., *A Framework Convention for Nanotechnology?*, 36 Envtl. L. Rep. 10931 (2006).

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15 U.S.C. § 2604.

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